

# Review of the Cardiac Unit at the Royal Liverpool Children's Hospital NHS Trust Alder Hey

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# Glossary

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| <b>Two by Two Tables</b>               | A means of comparing independent observations for two different groups (e.g. Alder Hey/elsewhere) in respect of a single matter of interest - which can only exist in one of two states (e.g. survived/died).  |
| <b>Aorta</b>                           | The major blood vessel which carries blood from the heart to the rest of the body.   |
| <b>Atria</b>                           | Two of the smaller chambers of the heart. The right atrium receives blood from the major veins of the body. The left atrium receives blood from the lungs.   |
| <b>Atrial Septal Defect</b>            | Defect (usually a hole) in the wall which separates the right and left atria.  |
| <b>Bayesian Statistical Tests</b>      | An alternative approach to analysing statistics where explicit account is taken not only of how often an event occurs in the data, but also of how often it may be expected to have occurred from other information. For example, even if none of a heart surgeon's patients died post-operatively, a Bayesian test would not assess their mortality rate as zero – because we already know that any heart surgery carries some mortality risk. Bayesian methods were applied in the studies commissioned for the Bristol Royal Infirmary Inquiry. |
| <b>Bristol Royal Infirmary Inquiry</b> | The public inquiry announced in 1998 into children's heart surgery at the Bristol Royal Infirmary. The proceedings of the inquiry and many detailed research papers are published on the web-page <a href="http://www.bristol-inquiry.org.uk">www.bristol-inquiry.org.uk</a> .   |
| <b>Chi Squared Test</b>                | The standard statistical test for Two by Two tables where the numbers of observations are not too small. A high value in the test indicates a low probability that different frequencies in the matter of interest could have arisen by chance.  |
| <b>Clinical Audit</b>                  | The continual evaluation and measurement by health professionals of the clinical standards they are achieving.   |
| <b>Clinical Governance</b>             | An approach to continuously improving the quality of clinical outcomes by creating an environment in which excellence in clinical care will flourish.  |
| <b>Clinical Outcome</b>                | The effect of a treatment on the health or well being of an individual.  |
| <b>Closed Procedures</b>               | Operations undertaken without the use of the heart lung by pass machine. During the operation the blood is pumped around the body by the patient's own heart.  |
| <b>Coarctation of the Aorta</b>        | Narrowing of the Aorta. The narrowing is often located very near to the place where the aorta emerges from the heart. The narrowing has the effect of obstructing the normal flow of blood from the left side of the heart to the rest of the body.  |

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| <b>Congenital Heart Disease</b>    | Heart disease which becomes apparent either at birth or during pregnancy.  |
| <b>Consultant Code</b>             | The code in the patient episode record identifying the consultant responsible for the patient.   |
| <b>Episode</b>                     | A continuous period of inpatient or day case treatment under the care of a named consultant. There may be several episodes within any one inpatient spell.   |
| <b>Excess Mortality</b>            | Deaths in excess of an average figure chosen for comparison.   |
| <b>Expected Value or Number</b>    | Number or value based on some assumption and used to compare it with the observed value. The observed value is the value or number calculated from data collected for a study. The comparisons between observed and expected values form the basis of statistical tests.   |
| <b>Fisher's Exact Test</b>         | A statistical test for Two by Two tables that can be applied to small numbers. The test calculates directly the likelihood that the distribution of cases occurring in the four cells of the table might have arisen purely by chance.   |
| <b>Heart Valve</b>                 | Structures in the heart, which permit the flow of blood in one direction only. The heart has four valves. For example the heart valve between the large left chamber of the heart (left ventricle) and the small left chamber of the heart (left atrium) is called the mitral valve. This valve permits the flow of blood in one direction only: from left atrium to the left ventricle.   |
| <b>Hospital Death</b>              | An inpatient who dies in hospital.   |
| <b>Hospital Episode Statistics</b> | The standard national data set of patient details recorded for every inpatient and day case episode in the NHS.  |
| <b>Incidence</b>                   | The count of the number of new events (e.g. new cases of a disease) which occur within a defined period of time, within a defined population. It is expressed as a rate, i.e. the number of new events that occur in a population at risk of experiencing those events within the period of interest. Therefore one would calculate the incidence rate by dividing the number of new cases of a disease which occur within a defined period by the numbers of persons in the population at risk. |
| <b>Inpatient Spell</b>             | A continuous period of inpatient care in a hospital. A spell may be initiated by an admission, a transfer from another hospital, or birth; and will be terminated by a discharge, a transfer to another hospital, or death.  |
| <b>Observed Value or Number</b>    | The number or value of a matter of interest (e.g. death rate or success rate of an operation) calculated by a particular study.  |

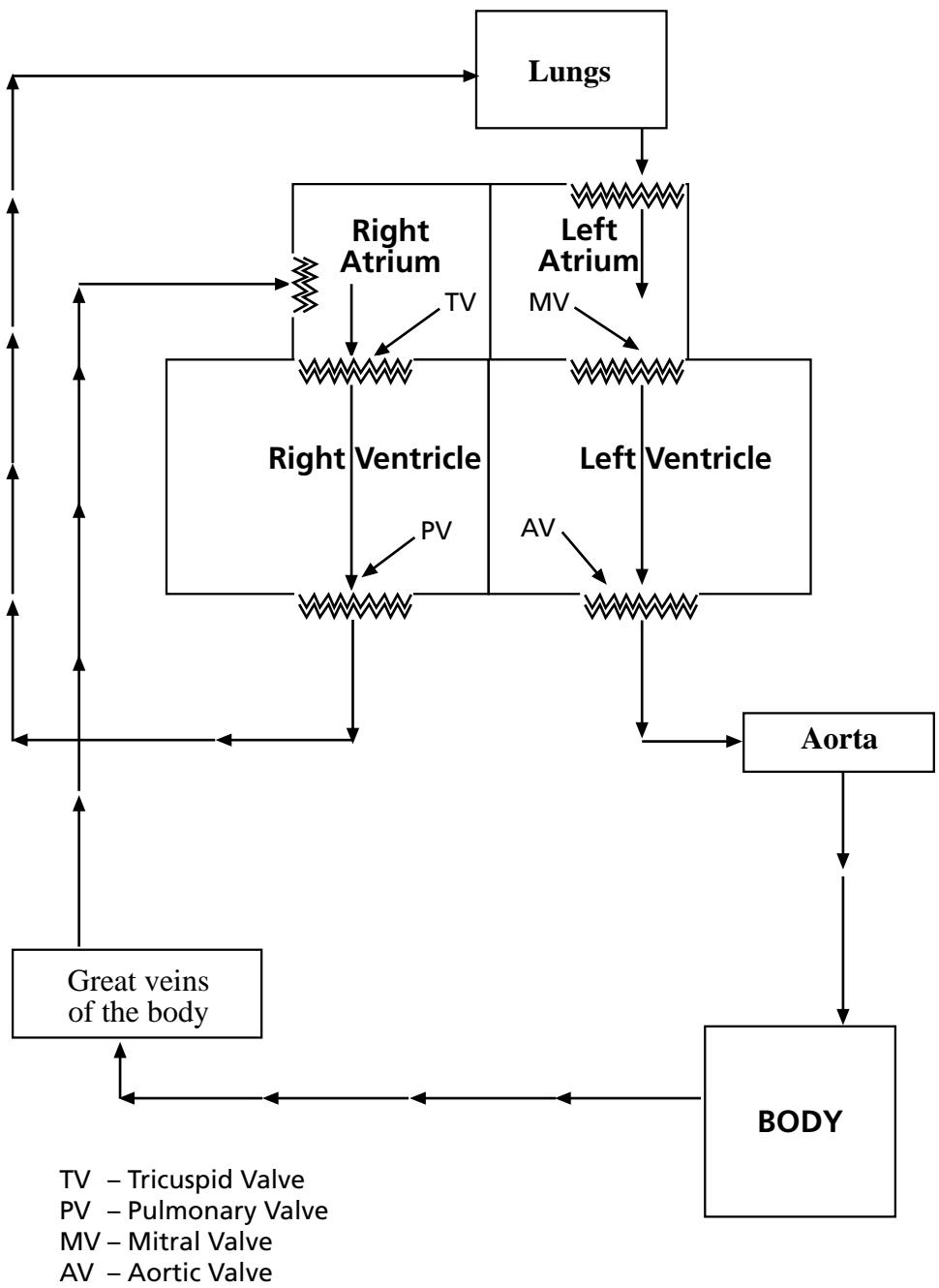
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| <b>Open procedures</b>               | Operations undertaken using the heart lung by pass machine. During the operation the blood is pumped around the body by the heart lung by pass machine.  |
| <b>Operation</b>                     | A continuous session of invasive surgery, throughout which a patient is usually maintained by general anaesthesia.   |
| <b>p (probability) value</b>         | The numerical figure calculated for the value of a statistical test, which states the likelihood of a finding being due to chance. For example, a p value of 0.05 means that the likelihood that a finding of interest uncovered by a study was due to chance is 5%. In other words, one can be 95% certain that the finding in question is due to reasons other than chance.    |
| <b>Paediatric Cardiac Surgeon</b>    | A doctor of consultant status who specialises in performing operations on children's hearts.   |
| <b>Paediatric Cardiologist</b>       | A doctor of consultant status who specialises in the diseases which affect children's hearts but who does not carry out surgical operations.   |
| <b>Persistent Truncus Arteriosus</b> | A congenital abnormality in which there is a failure in the proper development of the Pulmonary Artery and Aorta from two large chambers (right and left ventricle) of the heart.  |
| <b>Post-operative Death</b>          | A patient who is recorded as dying in hospital within 30 days of a surgical procedure having been undertaken – whether in the same inpatient spell or not. (In the data-set available to us procedure dates were not recorded, so we counted a hospital death as a post-operative death if it occurred within 35 days of the hospital admission prior to the primary procedure). |
| <b>Post-operative Death Rate</b>     | For any specific primary procedure, the total of post operative deaths divided by the total of episodes in respect of which this procedure is recorded as the primary procedure.   |
| <b>Prevalence</b>                    | Prevalence provides a measure of the total number of events (e.g. cases of disease both new and old) which exist at the time the measurement is undertaken.  |
| <b>Primary Procedure</b>             | The most complex surgical procedure undertaken in an episode.  |
| <b>Probability</b>                   | The likelihood of something happening.   |
| <b>Procedure</b>                     | A specific surgical intervention. Since many congenital disorders involve a number of inter-linked malformations of the heart and great vessels, it is common for heart surgery operations to consist of a number of different procedures.   |

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| <b>Procedure Code</b>                              | The code defined in the fourth revision of the list for the classification of surgical procedures produced by the Office of Populations, Censuses and Surveys in 1990. This list is the basis for the identification of the primary procedure undertaken in each episode and is used for statistical analyses.   |
| <b>Procedure Complexity</b>                        | A ranking of procedures undertaken in the course of a study commissioned by the Bristol Royal Infirmary Inquiry. Where a patient has been subject to a number of different procedures in any one episode, the most complex procedure listed is taken as the 'primary' procedure for that episode.  |
| <b>Pulmonary Artery</b>                            | The major blood vessel which carries blood from the right side of the heart to the lungs.  |
| <b>Security and Confidentiality Group Advisory</b> | An advisory panel established to advise the Chief Medical Officer and the National Health Service on uses and applications involving sensitive data-sets of patient information. Proposed uses of such information by the Department of Health and the NHS Executive are submitted to the advisory group for their views before the information can be used.   |
| <b>Senning Procedure</b>                           | An operation undertaken to treat the congenital abnormality of Transposition of the Great Arteries (see glossary below), by effecting a corresponding transposition of the blood flowing into the heart. Once the standard treatment, this procedure has been superseded by the Switch Operation.  |
| <b>Statistical Significance</b>                    | A finding of a study is said to have achieved statistical significance if the p value is either equal to or less than a chosen threshold value. The threshold values chosen in practice are 0.01 or 1% and 0.05 or 5%. In this review the threshold chosen was 0.05. If the calculated p value is either 0.05 or less (if the threshold value chosen is 5%), the implication of a significant test would be that there is 5% chance that the finding of the study is due to chance. In other words there is a 95% chance that finding is due to reasons other than chance.     |
| <b>Statistical Tests</b>                           | Tests conducted on numerical data to estimate the role played by chance in the occurrence of an event or a finding.  |
| <b>Statistics</b>                                  | The science of collecting and analysing numerical data.  |
| <b>Stenosis of a Valve</b>                         | Narrowing of the inlet or outlet of the valve. This narrowing has the effect of obstructing the smooth flow of the blood across the valve. There are four valves in the heart: the aortic valve which controls the blood flow from the left ventricle to the aorta; the mitral valve which controls the flow of blood from the left atrium to the left ventricle; the tricuspid valve which controls the flow of blood from the right atrium to the right ventricle and the pulmonary valve which controls the flow of blood from the right ventricle to the pulmonary artery. |

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| <b>Switch Operation</b>                    | An operation undertaken to correct the congenital abnormality of Transposition of the Great Arteries (see glossary below). During the operation the abnormally placed Great Arteries (the Pulmonary Artery and the Aorta) are repositioned so that they now connect to the correct large chamber of the heart (ventricle).       |
| <b>Tetralogy of Fallot</b>                 | A set of congenital cardiac defects, including a defect (usually a hole) in the wall which separates two large chambers (ventricles), a pulmonary valve narrowing and an abnormally positioned aorta.  |
| <b>Transposition of the Great Arteries</b> | A congenital abnormality in which the aorta connects to the right ventricle (normal connection is to the left ventricle) and the pulmonary artery connects to the left ventricle (normal connection is to the right ventricle).  |
| <b>UK Cardiac Surgery Register</b>         | The self-reported national system for recording cardiac surgical operations and mortality. The Bristol Royal Infirmary Inquiry commissioned a comparative study of the UK Cardiac Surgery Register, and the Hospital Episode Statistics – and found that the latter were generally more complete and more consistently recorded. |
| <b>Ventricles</b>                          | Two of the larger chambers of the heart. The right ventricle receives blood from the right atrium and pumps it to the lungs. The left ventricle receives blood from the left atrium and pumps it via the aorta to the rest of the body.  |
| <b>Ventricular Septal Defect</b>           | Defect in the wall (usually a hole) between the wall which separates the two larger chambers of the heart from each other.   |

Figure 1

Diagram indicating the circulation of the blood within the body



# SECTION 1

## Introduction

1. This is the report of a review of the Cardiac Unit at the Royal Liverpool Children's Hospital NHS Trust (Alder Hey). The review was undertaken to address concerns relating to surgical outcomes in the Cardiac Unit at Alder Hey. The report has been prepared for Ministers at the Department of Health, but is intended to be accessible to the public and to NHS professionals involved with the hospital. In drafting this report, I have been very aware of the need to establish a new tone of openness in relation to the outcomes of clinical practice.
2. This report is divided into two sections. Section 1 provides an overview of the work and presents the key findings and recommendations. Section 2 details the more technical aspects of the review, but is intended to be accessible to a wide readership.
3. In order to assist readers a glossary is provided at the front of the document together with a diagram of the heart and the circulation of blood in the body. Much of the work undertaken was of a technical nature, including complex numerical statistical analyses. The detail of this work is provided in Section 2. It seeks to provide a thorough review of the methods employed and the conclusions that can be drawn from the data. It also discusses the sources from which the data were drawn.
4. An important point of principle, which is observed, is the protection of individual confidentiality. Patient identifiable information is not included. The cardiac surgeons are referred to as A, B and C respectively throughout the report. This report is not about individual children but about the Cardiac Unit and the surgical outcomes of the surgeons who work there.
5. This report contains objective evidence about the outcomes of surgical care in the Cardiac Unit at Alder Hey.

## Purpose

6. In May of this year, an unidentified member of nursing staff in Alder Hey contacted the Royal College of Nursing to report concerns over the treatment of three unnamed children. The Trust provided assistance in trying to identify the specific cases referred to, thereby enabling us to review the standards of care delivered to them individually. More broadly, the review provided an opportunity to look in detail at the organisation and management of the Cardiac Unit, its key internal relationships and its wider external links within the Trust.

7. The introduction of clinical governance by the current Government in the White Paper, *The New NHS: Modern and Dependable (1997)*, has encouraged openness. It has also encouraged health professionals to be more accountable for their clinical practice. This mood is further reinforced by the recent publication of the report of an expert group chaired by the Chief Medical Officer, *An Organisation with a Memory (2000)*. Our review was therefore conducted in the spirit of ensuring that the actions of clinicians in NHS organisations are explained in a way that can be readily understood by lay people as well as professionals. This provides a valuable opportunity for learning and improving professional practice.

## Context

8. Our review draws on two previous studies. The first was carried out in 1992 by external reviewers nominated by the Royal College of Surgeons and the Royal College of Physicians. This is referred to as the West/Ross Review. A second review was undertaken this year by the Professor of Paediatric Surgery from the University of Liverpool and the Alder Hey Medical Director (the Lloyd/Davidson Review). These studies are not public documents, but their findings, which are summarised in Appendix 1, provided a context for this review.

## Background

9. Alder Hey has been at the forefront of public and media interest since September last year. The revelations that emerged concerning retention of organs have caused considerable distress for the families of many deceased children. The Secretary of State for Health ordered an Independent Inquiry, chaired by Michael Redfern QC, to look into the issue of organ removal and retention at Alder Hey.
10. A new management team took over at Alder Hey in March of this year. This has resulted in a renewed effort to address the issues that emerged as a result of the two previous studies.
11. Alder Hey Children's Hospital was founded in 1914, and is probably the largest children's hospital in North West Europe. Modern paediatric anaesthesia was founded at Alder Hey. Neonatal surgery and children's cardiac surgery were pioneered there in the 1940s and 1950s. The Trust is one of the few in England with a University Institute of Child Health. There are some 20 specialist services at Alder Hey as well as supra-regional services including cardiology. The first paediatric intensive care consultant in the UK was appointed to Alder Hey. The Trust prides itself on being a centre of innovation and excellence. The hospital was granted Royal patronage in 1985. Alder Hey enjoys a strong reputation for saving the lives of very sick children, undertaking more than 25,000 treatments a year on children from the North West and beyond.
12. The Cardiac Unit at Alder Hey is the children's heart surgery centre for the North West and North Wales. It is the third largest cardiac surgical unit in the country, the two larger units being Great Ormond Street Hospital in London and Birmingham Children's Hospital.

13. Most children who require heart surgery will be admitted initially under the care of a paediatric cardiologist and then transferred to a children's cardiac surgeon for a surgical procedure.
14. Two consultant paediatric cardiac surgeons provide all the children's heart surgery in the Cardiac Unit at Alder Hey. They are referred to as Surgeon B and Surgeon C throughout this report. Surgeon C joined the unit in 1993, replacing Surgeon A, who left at that time to take up another post.
15. The incidence of serious congenital heart disease in the UK is 0.8% of live births. The congenital heart conditions that may affect babies are given in box 1. Based on the most recent information (1998) Alder Hey would expect to treat around 650 babies a year, the majority of whom will require operations.

**Box 1: Congenital Heart Defects in Live Births in the UK**

|                                 |     |
|---------------------------------|-----|
| Atrial Septal Defect            | 9%  |
| Ventricular Septal Defect       | 30% |
| Coarctation of the Aorta        | 8%  |
| Patent Ductus Arteriosus        | 8%  |
| Aortic Stenosis                 | 6%  |
| Pulmonary Stenosis              | 9%  |
| Fallot's Tetralogy              | 5%  |
| Transposition of Great Arteries | 5%  |
| Remainder                       | 20% |

16. The dividing line indicates those conditions which require surgical correction by simple procedures (those above the line) or complex procedures (those below the line).
17. The terms simple and complex are relative terms. The surgical correction of congenital heart defects always carries a degree of risk, but can improve both the length and quality of life (Stark 2000). Some procedures cannot be undertaken until the child is older. These may require an interim or holding procedure to be undertaken at a younger age, with further corrective surgery being done at a later stage.
18. The split between complex and simple procedures is also reflected in the stage of career at which a cardiac surgeon would perform different procedures. On completion of specialist training, which is carried out under supervision and which is subject to regular assessment, a surgeon will normally be appointed to a consultant post which means that he or she will have full responsibility for the care of individual patients. They are part of a team, which includes junior and intermediate grade doctors and a number of other professionals in the wards and in theatre. There are a large number of people, with a diverse range of skills, involved in the care of very sick children. All have important parts to play in the overall quality of care as members of a team.
19. In the early stages of a cardiac surgical consultant's career the focus normally will be on the simple procedures. Through experience and the development of technical skills a consultant paediatric cardiac surgeon will then progress to more complex work through joint working with more experienced colleagues (Hasan 2000).

20. The field of paediatric surgery has been a rapidly developing one over the past ten years and children who would have inevitably died at the beginning of this period are now frequently able to benefit from innovations in surgery (Stark 2000). However, at the early stage of such innovations the clinical outcomes have often been poorer than they would become later. It has to be remembered that such initial poorer outcomes must be compared with the consequences of the limited treatments available before these new techniques had been introduced and before surgeons had developed expertise in applying them. During the development phase, there is an onus on clinicians and health care organisations to achieve the improved health outcomes with minimum risk to patients.
21. The situation is further complicated with regard to the switch procedure for Transposition of the Great Arteries, which in the period under review replaced the Senning procedure as the standard treatment. The Senning procedure had a lower post operative death rate but a higher long term death rate. The switch operation offers the possibility of a fuller life but when it was first introduced it had a higher post operative death rate associated with it, as it was then a new procedure (Bull 2000). In other words, when the switch operation was first introduced it was a risky procedure, but over the last few years it has become much safer and with a better outcome than the Senning procedure which it has replaced.
22. Surgeons should only be allowed to do their job if they complete a rigorous training programme and demonstrate that they are keeping up-to-date with professional developments. They are required to participate in clinical audit. This means that the results of surgery and other aspects of care should be compared between colleagues and with other professionals in similar units elsewhere. The aim of the exercise is to identify any variations from expected outcomes to enable these to be investigated. Any cause for concern should be identified early so that action can be taken. However, it is inevitable that some consultants will be better than others; and inherent in developing complex areas such as this will be some variation in clinical outcomes between highly trained surgeons.
23. The statistical analyses that support clinical audit are complex but can provide objective evidence on which decisions can be taken, rather than acting on suspicion or rumour. It is important to note that the numbers of cases being examined will determine the confidence with which results can be interpreted. Small numbers reduce the level of confidence. Larger numbers increase it. It is therefore important to ensure that the results of statistical tests are carefully interpreted, in the full knowledge of the size and type of dataset used. The methods used in this review were the most appropriate tests available to us, but the numbers of procedures meant that the figures available for some of the tests were small and thus our conclusions are qualified on some issues. Detailed statistical tables are included in Appendix 2.
24. Every patient has the right to expect that our NHS surgeons are competent and well trained. The consequences of poorly performed surgery could be as devastating as leaving a critical condition untreated. It is then essential that both senior and trainee surgeons have the opportunity to study detailed relevant anatomy, including donated hearts, for training and reference purposes. For some complex procedures and rare conditions this may be the only means of preparation before operating on patients.

25. Serious heart disease carries with it high death rates and implications for the quality of life of sufferers. Children's heart surgery, whether simple or complex carries risks for the child. These risks must be thoroughly explained to parents or guardians by clinicians. Parents must understand the degree of risk in order to give their consent. This is in accordance with best practice. In recent years there has been an increasing emphasis on ensuring that parents are given all the information they need to be in a position to make fully informed decisions about their children's care. However, the extent to which best practice with regard to consent had been followed at Alder Hey throughout the period under consideration was not within the scope of this report.

## Conduct of the Review

26. I led the review team that undertook the work and which has produced this report. The team comprised Dr Iqbal Sram, Consultant in Public Health Medicine and Mr Tom Hennell, Strategic Analyst, both from the NHS Executive North West. I obtained further expert clinical and statistical advice from Professor Tom Treasure, St George's Hospital, London, Professor Marc de Level, Great Ormond Street Children's Hospital, and Mr Greg Phillpotts, Department of Health.
27. The review was undertaken in two parts. One part involved a series of meetings with a range of staff at Alder Hey, individually and collectively. We spoke to staff in the Cardiac Unit, and to other senior doctors and managers in the Trust. We examined a range of documents including the previous reviews relating to the Cardiac Unit and a number of Trust policy documents.
28. Our review also looked at the data on complaints made by patients, relatives or carers and at legal claims made against the NHS Trust. This was done to provide context. An examination of these issues can provide a useful indication of the quality of care an NHS organisation provides for its patients. The results of this work are reported in Appendix 3.
29. Of the three unnamed cases reported to the Royal College of Nursing, we are reasonably confident that two have been positively identified from the descriptions given. The Trust supplied medical records for three other recent surgical cases where difficulties or complexities had emerged during or after their operations. The then Acting Director of Nursing at Alder Hey provided an initial report on the outcomes for all five cases. I have personally reviewed all five medical records to assess the overall quality of care provided for these children as far as I was able. In addition, I invited any staff with specific concerns to raise them with me in confidence. The member of staff who had contacted the Royal College of Nursing has not chosen to identify him/herself to me. Consequently I am unable to confirm categorically that the five cases that have been reviewed by me include all three of the unnamed cases which were originally reported to the Royal College of Nursing.
30. We contacted the North West Regional Director of the Royal College of Nursing in an attempt to make contact with the complainant. He (Royal College of Nursing Regional Director) felt unable to identify the staff member who had raised the initial concerns, but the Royal College of Nursing did express, in writing, their satisfaction with the way in which we have conducted our Review. They have not suggested additions to the cases we investigated.

31. The second part of our work involved detailed and complex statistical analyses of a range of data obtained from the Trust and from national sources. This was done to provide the basis for a comparison of the Alder Hey Cardiac Unit with other similar units in the country; and for a comparison of the post-operative death rates for individual surgeons within the Cardiac Unit with counterpart figures for patients treated elsewhere. Articles from medical journals provided background information on the most up-to-date findings from research.
32. It must be emphasised here that this review did not look at individual cases (apart from the five referred to above). The analyses were carried out to establish objective evidence of the clinical outcomes of treatment in the Cardiac Unit as a whole, for individual surgeons and for individual procedures. We did not investigate the treatment of individual children, except for the five referred to above in relation to the concerns raised with the Royal College of Nursing. Statistical tests provide the means of establishing whether we can be confident that any variations in death rates indicate real differences, other than those that might have arisen by chance occurrence (as in the results obtained when tossing a coin).
33. An external peer review by two expert referees was undertaken to ensure that:
  - appropriate and robust statistical methods were used in our review;
  - our data sources were reliable and valid;
  - the inferences we drew from the data were correct.

## Findings

34. The evidence obtained during this review indicates that:
  - the overall post-operative death rates for children's heart surgery at Alder Hey were better than the average for units elsewhere in the country.
  - Surgeon A's post-operative death rate did not differ from the national average. The number of operations performed was too small to analyse this surgeon's work by individual procedure.
  - Surgeon B's overall post-operative death rates compare favourably with the national average.
  - Surgeon B had higher post-operative death rates than the national average for the highly complex switch operation, which came into use as a standard procedure from 1992. Surgeon B last performed the switch operation in November 1996. At the beginning of 1997, Surgeon B, following consultation with Surgeon C, decided to undertake no further switches; and the restriction on this surgeon's clinical workload was endorsed as a formal change in clinical policy in 1998. Any delay in formalising this policy had no adverse impact on post operative death rates for the Unit.
  - Surgeon C's overall and individual post-operative death rates compare well with national figures.
  - A number of wider organisational issues emerged. The previous reports we studied identified team working and communications in the Cardiac Unit as long standing problems. Waiting lists are growing as a result of referral patterns and other complex factors. We identified a number of organisational and staffing issues such as the management and organisational processes within theatres, support from other directorates in the Trust, and recruitment

and retention of skilled staff. We did not find evidence to suggest that these had been comprehensively addressed until recently.

- We did not consider that multi-professional audit had been developed to the level that good practice would require.
- We are concerned that staff may not have felt sufficiently free to voice concerns about patient care through the normal hospital channels.

35. The overall post-operative death rates for Surgeon B and Surgeon C are broadly similar for all years up to 1995/96. Both surgeons experienced higher post-operative death rates in 1993/94 than they were to achieve later, although even in that year the death rates for both surgeons compared favourably with the national average (Aylin 1999 p 77). One possible explanation for the higher death rates in 1993/94 may have been the introduction of the 'switch' operation, then a relatively new procedure (Bull 2000). There is a 'learning curve' as surgeons become more skilled in new procedures. It is only after 1995/96 that the difference between the overall post-operative death rates of the two surgeons becomes apparent from the data.
36. The key statistical finding is that Surgeon B's post-operative death rates for the 'switch' operation were higher than the national average for the period 1992-1995. This finding supports the subsequent change in clinical policy that resulted in Surgeon B no longer performing the 'switch' operation. The indications are that the Alder Hey clinicians and management took the necessary action to protect patient safety on the basis of emerging evidence. From the information available to them, it is highly unlikely that they would have been in a position to take this step before they did.
37. The remaining statistical findings of this review indicate that there do not appear to be grounds for believing that, at any time, patients faced a higher risk of dying following cardiac surgery at Alder Hey compared to other cardiac units in the country. The one area of concern was addressed in 1996 when Surgeon B stopped performing the 'switch' operation.
38. The rigorous statistical techniques used for this review indicate that the overall pooled outcomes for cardiac surgery at Alder Hey compare with the best in the country.
39. The individual review of five recent cases did not substantiate the concerns about clinical standards of operative or post-operative care in general in Alder Hey. In four of the five cases, the children made good post-operative recoveries. However, one of the children who had serious and complex medical problems and who was very poorly, had had an operation postponed three times. This raises questions as to whether the management of the overall pathway of clinical care for this child was appropriate. This child, who has sadly died, is the subject of a separate complaint under the normal NHS complaints procedure. There is provision within the complaints procedure for an independent review if this is considered necessary. One of the other four children had a difficult operation that involved protracted surgery. However, this child has gone on to make a good recovery.

## Recommendations

### **In relation to Alder Hey:**

40. The findings of the Lloyd-Davidson Review must be fully implemented by means of the Trust's action plan.
41. An action plan must also be produced in response to our review and it must be implemented by the Trust. The action plan must be communicated to all staff in the Trust, and steps must be taken to ensure that they understand it. The Regional Office of the NHS Executive should evaluate and approve the action plan, and monitor its implementation.
42. Steps must be taken to correct the widely held misconception that clinical performance within the Trust is poor. One way of setting the record straight would be by placing clinical outcome data for the Cardiac Unit in the public domain.
43. Multiprofessional audit must be strengthened in the Cardiac Unit. The Trust's Clinical Governance Subcommittee must ensure that appropriate (as defined by good practice) audit mechanisms are in place.
44. All staff should feel comfortable in making their views and concerns known to senior clinicians and managers. Steps should be taken within the Trust to ensure that there are adequate channels for this to happen, in line with Department of Health policy on whistleblowing.
45. The Trust's Clinical Governance Subcommittee must ensure that systems are in place for the annual appraisal of clinical staff, and that all staff have plans for supporting their personal and professional development.

### **In relation to wider issues:**

46. The datasets and the results of the clinical audit in paediatric cardiac surgery in England should be made more widely accessible and placed in the public domain.
47. The levels of specialist staffing in paediatric cardiac units seem to be an issue. Consideration should be given to the configuration of paediatric cardiac surgery units in England. This will ensure that the highest levels of competence and technical skills are available to all children regardless of where they live. Although this was not within the remit of this review it is the subject of ongoing debate nationally and the findings of this report support the need for action on this issue.
48. In future, reports of reviews of this nature should be produced so to be readily accessible to the public, and easily understood by them. I am placing this report in the public domain.

## Acknowledgements

I am grateful to the review team, the staff at Alder Hey, and the staff at the NHS Executive North West for assisting me in this review.

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September 2000

# SECTION 2

## Introduction

1. The purpose of Section 2 of this report is to expand on the methods employed in undertaking the review and to provide further details in relation to the findings.

## Post-operative Death Rates

2. Our review found that the overall post-operative death rate for the Cardiac Unit at Alder Hey for the period 1991-1997 was 4.8%. The average post-operative death rate for children treated in equivalent specialist children's cardiac units elsewhere during the same period was 6.9%.
3. We furthermore took note of a study commissioned by the Bristol Royal Infirmary Inquiry. It compared post-operative death rates for specialist children's heart surgery centres over the period 1991-1995. This Bristol study used the national dataset of hospital treatments (Hospital Episode Statistics). The results of this study have been published on the Bristol Inquiry web-site ([www.bristol-inquiry.org.uk](http://www.bristol-inquiry.org.uk)).
4. The Bristol study demonstrated conclusively that for certain categories of conditions post-operative death rates in Bristol were very much higher than in other specialist children's cardiac units. The study also confirmed that the overall post-operative death rate for the Cardiac Unit at Alder Hey was lower than the average for equivalent cardiac units elsewhere. It found that overall, 16 fewer children died in Alder Hey between 1991 and 1995 than would have been expected had Alder Hey matched the average for the other specialist centres (Aylin 1999, p 62).
5. The Liverpool University Cardiac Surgery Register provided information for our review which indicates that Alder Hey's post-operative death rates for cardiac surgery have continued to reduce since 1997. Post-operative death rates also reduced in the other specialist centres for children's heart surgery during the same period, but Alder Hey has maintained its differential with the national average. In other words, the improvement in Alder Hey since 1997 matched the improvement in children's heart surgery generally and the Alder Hey post-operative death rates are still proportionately lower than the national average. These figures are confirmed by the national dataset of hospital treatments (Hospital Episode Statistics).
6. We therefore conclude that the overall post-operative death rate figures for children's heart surgery in Alder Hey were better (lower) than the average for similar units elsewhere in the country. These better outcomes have been

maintained in comparison to other specialist units, even though post-operative death rates for children's heart surgery are reducing everywhere.

7. It would, however, be premature to conclude that the lower post-operative death rates at Alder Hey are proof of a consistently better underlying performance, as the size of the statistical difference was within the range which might have arisen through chance variation. However, the figures do tell us that overall there should be no cause for concern over the outcomes of heart surgery in Alder Hey.
8. The study commissioned by the Bristol Royal Infirmary Inquiry also analysed the comparative mortality of surgical units in respect of specific operations. For this purpose they classified the most common operations undertaken in Bristol into 13 groups on the basis of the primary procedure codes; i.e. the most complex procedure reported for each case on the episode data-set (Aylin 1999, p55). They also classified all child heart surgery operations undertaken in Bristol (including those 'other' operations not within the 13 groups) into two broad categories – 'open' and 'closed' (Aylin 1999, p83). These categories were based on an assessment as to whether the patient would normally be operated on with the aid of 'open' or 'closed' anaesthesia for the particular procedure. Under the Bristol classification, the term 'open' indicates an operation where heart by-pass techniques would normally be used to maintain anaesthesia, whilst the term 'closed' indicates an operation undertaken without the aid of by-pass techniques. (See glossary of terms)
9. When the Bristol Infirmary Inquiry analysed operations undertaken in Alder Hey using their (Bristol's) definitions of 'open' and 'closed' primary procedures, they found a sub-group of excess post-operative deaths at Alder Hey for cases falling within their category of 'closed' operations. They assessed this excess to be equivalent to an additional 5 deaths in Alder Hey over the period 1991-95, as compared to the average for other specialist units (Aylin 1999, p62). However, the Bristol Study did not find this difference to be statistically significant. Our own initial analysis of hospital episode records, applying the Bristol Inquiry categories, confirmed a higher than average death rate for 'closed' heart operations at Alder Hey during this period.
10. However, when we examined the patient episode records at Alder Hey case-by-case, we found that a particular primary procedure code, which elsewhere in the country would usually be associated with 'closed' operations, had been applied in Alder Hey to describe a high-risk pioneering 'open' procedure for the treatment of newborn babies with hypoplastic left heart syndrome (the Norwood procedure). We therefore conclude that the apparent excess of deaths in this category of 'closed' operations in Alder Hey arises from the coding method used and is not present in the underlying case loads. If these pioneering operations had been classified with the other 'open' operations in Alder Hey, the figures would not have indicated an excess of post-operative deaths for 'closed' procedures in the hospital's cardiac unit.
11. Hypoplastic left heart syndrome is a rare congenital condition in which the left side of the heart and the aorta are undeveloped and incapable of pumping blood round the body. Before birth the circulation of blood in an unborn baby can be adequately maintained by the right side of the heart alone, by means of a connecting blood vessel that links the main arteries. However, in a matter of

days after birth, the connecting blood vessel will close and without the 'Norwood' intervention (see below) the babies will die (O'Kelly 1997).

12. From 1993 onwards, Alder Hey and Birmingham Children's Hospital pioneered the introduction into England of a surgical approach to treating this condition (Ishino 1999). This is termed the 'Norwood' procedure and it consists of a series of three complex open-heart operations spread over the first 4-5 years of life. The first of these operations must be performed within days of birth and it carries a very high risk of mortality. Unfortunately, the first 12 babies to undergo Norwood operations in Alder Hey all died (as also did the first 10 babies operated on in Birmingham Children's Hospital). The programme nevertheless continued, and current survival rates in Alder Hey are reported by the cardiac unit as being similar to those of Birmingham and Guy's Hospital in London – the two other specialist centres now providing this treatment in England. It must be stressed that the first 12 babies who died after undergoing the 'Norwood' procedure in Alder Hey, would have died had they not received the treatment. This 'pioneering' intervention, which was very new at that time, at least gave these babies a chance of life.
13. In assessing the workload of the Alder Hey cardiac unit, we looked separately at the post-operative mortality rates for each heart surgeon – using the procedure groupings defined for the Bristol Royal Infirmary Inquiry. This involved statistically testing each surgeon's workload within 13 procedure categories over six years. It should be noted that individual surgeon workloads are too small for meaningful procedure mortality rates to be calculated for any single year (Stark 2000). It was beyond the scope of this review to analyse clinical outcomes in relation to complexity of individual cases.
14. We found that the overall post-operative mortality rates for Surgeon A, who left the cardiac unit at Alder Hey in 1992, did not differ from the national average. There are not enough cases in the data set to analyse this surgeon's work by individual procedure.
15. We also found that Surgeon B's overall post operative mortality rates did not differ from the national average. However, our analysis of individual procedure codes revealed that for one highly complex procedure, the 'switch' operation for the Transposition of the Great Arteries, 8 out of 27 of Surgeon B's patients died between 1991 and 1997 – giving a mortality rate of 30%. This compares to a national average of 11%. We found that this difference was statistically significant (using Fisher's exact test ( $p=0.018$  – see glossary).
16. We did not find Surgeon B's post-operative mortality figures for other surgical procedures to be statistically significant. We did not find evidence of a problem with this surgeon's work, other than that which was indicated by the statistics for the switch procedure.
17. The type of patients which Surgeon B has operated on was changed in 1997. Since that time this surgeon has ceased to perform a range of complex procedures – including the switch operation.
18. Surgeon C's overall post-operative mortality rates did not differ from the national average, and no statistically significant differences were found for any specific procedure group. The reported post-operative mortality rate for this surgeon, who was appointed in 1993, fell markedly after 1993/94. This fall in

the post operative mortality rate for Surgeon C is most likely to result from Surgeon C becoming more experienced in operating on complex cardiac cases.

19. It has been established that following appointment to their first consultant post, the post-operative mortality rates of paediatric cardiac surgeons tend to improve as they gain greater experience of working without supervision.
20. We found no other instances of statistically significant excess post-operative mortality.
21. We looked at Surgeon B's post-operative death rates for 13 procedures. In 12 of these, both simple and complex, even for complex procedures where the death rates were higher than the national average, they were not statistically significant. However, Surgeon B's post-operative death rates for the switch operation were statistically significant. It could be argued that this was a chance finding because multiple tests were performed on this particular dataset. This statistical finding in itself might not have provided grounds for taking action, as it could be argued that it was due to chance. However, when allied to concerns that had been raised about the surgeon's performance, we reached the conclusion that the Trust management were right to take the action they did in confirming the policy that Surgeon B should no longer perform the switch operation.
22. Only a small number of switch operations were performed between 1992 and 1997. These procedures carried a high risk of mortality at that time as this was a new operation (Bull 2000). Surgeon B's apparently poor record in relation to the switch operation would therefore only have become apparent over a period of years.
23. From a statistical point of view it could be argued that we would have obtained a more reliable picture had we been able to test a sample of cases which were independent of those which drew attention to Surgeon B's performance of the switch operation in the first place. However, because the clinical policy had, quite properly in our view, been changed so that this surgeon ceased to undertake this procedure, such independent data was not available to us.
24. The above point may be illustrated with the example of tossing a coin. Suppose that two persons are successively tossing a coin, and one observes that there have just been 10 'heads' in succession. He demands that the coin be 'tested' for bias – and they therefore perform a test series of 50 tosses – which split roughly evenly between heads and tails. The second person asserts that this proves the coin to be unbiased, but the first objects by stating that the first 10 'heads' already tossed should be counted in. In statistical terms this objection would be wrong although it reflects a common intuitive expectation.
25. We conclude that Surgeon B had higher post-operative mortality rates than the average elsewhere in the country for those babies receiving the 'switch' operation for the Transposition of Great Arteries – and that this difference was significant on a standard test. We note that, during the period under investigation, a formal change of clinical policy was adopted specifically to restrict this surgeon's operations on babies with this condition. Our findings support this change of policy.

## **The Bristol Royal Infirmary Inquiry (BRI) Reports: Adjustments to the Methodology**

26. The Bristol Royal Infirmary Inquiry has published (through its website) a number of technical reports on aspects of its work. In our Review, we made use of two documents: An initial synthesis of statistical sources prepared by Mr David Spiegelhalter of the Medical Research Council's Biostatistics Unit, Cambridge (Spiegelhalter 1999); and Analysis of Hospital Episode Statistics prepared by Dr Paul Aylin at Imperial College School of Medicine (Aylin 1999). Mr Spiegelhalter and Dr Aylin advised us on the methodology we adopted for our Review and on the degree to which their work included specific investigation of the Cardiac Unit at Alder Hey.

### **Application of the Bristol Royal Infirmary Inquiry Methodology**

27. In order to ensure comparability, the Bristol Royal Infirmary Inquiry researchers adopted a methodology for their analytical study of cardiac services in Bristol that was replicated in turn for each of the other specialist cardiac surgery centres in England. Consequently the published reports contain a full analysis of the comparative mortality experience for patients treated at each centre between 1991 and 1995.
28. The Bristol Royal Infirmary Inquiry reports demonstrate that individual Hospital Episode Statistics (HES) records provide a reliable basis for a comparative assessment of post-operative deaths, in specialist centres undertaking paediatric cardiac surgery. (Spiegelhalter 1999 p.22).
29. The inquiry reports identify a classification of Hospital Episode Statistics procedure codes into 13 groups, which correspond to commonly used procedure descriptions (e.g. 'correction of Tetralogy of Fallot' – see glossary). This is shown in the table below. They further publish a general division of procedure codes used in cardiac surgery according to whether they are commonly undertaken into 'open' (i.e. using a heart bypass machine), or 'closed' (i.e. without using a heart bypass machine).
30. It is not unusual for a number of different procedures to be undertaken during the same episode of care. In order to calculate mortality rates, it is therefore necessary to identify the primary procedure. This was done for the Bristol Inquiry by ranking procedures in a hierarchy of complexity (with '1' indicating the highest complexity and 13 the least), so that only the most complex procedure is recorded against each death.
31. The inquiry reports published death rates and procedure counts for each of the 11 paediatric cardiac centres, in addition to Bristol itself. For this Review, we have added these figures to create national totals. The cases at Alder Hey between 1991-1995 were then subtracted from the totals to generate equivalent death rates for England outside Liverpool.

Box 2: Procedure Groups from the Bristol Royal Infirmary Inquiry. (Aylin 1999, p 55)

| Group | Description of Group by the Bristol Royal Infirmary Inquiry          | Procedure complexity ranking | Open/Closed |
|-------|--|------------------------------|-------------|
| G1    | Correction of tetralogy of Fallot                                    | 9                            | Open        |
| G2    | Interatrial correction of transposition of great arteries            | 5                            | Open        |
| G3    | Switch of transposed great arteries                                  | 4                            | Open        |
| G4    | Repair of total anomalous pulmonary venous connection                | 3                            | Open        |
| G5    | Closure of defect of atrioventricular septum                         | 6                            | Open        |
| G6    | Closure of secundum and sinus venosus of the atrioventricular septum | 11                           | Open        |
| G7    | Closure of defect of the interventricular septum                     | 10                           | Open        |
| G8    | Correction of persistent truncus arteriosus                          | 1                            | Open        |
| G9    | Fontan type operations   | 2                            | Open        |
| G10   | Aortic, pulmonary valve and paravalve procedures                     | 8                            | Open        |
| G11   | Mitral valve procedures  | 7                            | Open        |
| G12   | Closed shunts  | 12                           | Closed      |
| G13   | Coarctation procedures   | 13                           | Closed      |

#### **Extensions and Adjustments to the Bristol Royal Infirmary Inquiry Method**

32. In applying the Bristol Inquiry method to the Cardiac Unit at Alder Hey we made a number of extensions and adjustments to the Bristol Inquiry method. These extensions and adjustments and the reasons for making them are specified below.
  
33. The workload of consultants at Alder Hey was analysed separately, on the basis of consultant reference codes on a Regional Office data set of episodes for the period 1991/2 – 1994/5. The counterpart Bristol Royal Infirmary Inquiry examined a national episode extract that did not include consultant codes. Consequently the statistical studies for the Bristol Royal Infirmary Inquiry were confined to assessing specialist units in their entirety. However, it should be noted that some 17% of surgical procedures at Alder Hey are undertaken on patients who continue to be recorded as being under the care of a paediatric cardiologist. Relatively few cases are recorded in this way when patients die, so there was a risk that the apparent death rates for individual surgeons in our study could have been overstated. However, our statistical analysis took this into account and we are confident that our calculated death rates accurately reflect the actual number of post-operative deaths associated with each of the individual surgeons.
  
34. The data for two further years (1995/6 and 1996/7) were also examined. We were not able to look at data from 1997 onwards as access to consultant codes on such data is restricted for reasons of confidentiality. It would have been possible to look at the two paediatric cardiac surgeons at Alder Hey in isolation, but we would not have been able to compare them with surgeons in other units. The information we would have received from the exercise would therefore have been limited.

- 35 Although the statistical techniques we used differed from those used for the Bristol study, the tests we used were appropriate for the data under consideration and in our opinion, the results we are presenting here are reliable. (Bristol used Bayesian techniques. We used Fisher's exact probability test). (Speigelhalter 1999, p 40. Altman 1991 p253 ).
- 36 In the tabulations of consultant workload attached (Tables 1-5) there are two procedure lines for which we have not provided national comparative rates. These are denoted in our table as 'other open' and 'other closed' (operations). The reason for this is that these lines include a range of procedures that were undertaken in Alder Hey, but not in Bristol and which were therefore not included in the Bristol Royal Infirmary Inquiry studies. Consequently, it may be that the death rates that we have calculated for these groups are higher than they would have been had patients with these codes been excluded from our study. This difference will be over and above that due to the higher death rate from cases receiving the pioneer 'Norwood' operation. The effect of this is to overstate rather than to understate death rates at Alder Hey.
- 37 We have defined a post-operative death as one where the patient dies in hospital within 35 days of being admitted for a surgical procedure. This differs from the standard definition of a post operative death, which counts 30 days from the date of the operation; but we were unable to apply this, as our consultant episode data set does not include operation dates. Our method will tend, if anything, towards erring on the side of including more rather than fewer deaths.

# APPENDIX 1

## PREVIOUS STUDIES AT THE ALDER HEY CARDIAC UNIT

### The 1992 Review

This review was commissioned by Alder Hey in 1992, after concerns had been raised by senior consultants in the Cardiac Unit about standards of intensive care for children who had undergone heart surgery. The review was conducted by Sir Keith Ross, nominated by the Royal College of Surgeons and Professor Richard West, nominated by the Royal College of Physicians.

**The key findings were that:**

- some of the working practices in the Cardiac Unit were unsatisfactory;
- there was poor team working between members of the Cardiac Unit, mainly due to the lack of mutual respect and trust between colleagues;
- many members of the staff in the Cardiac Unit stated that they did not enjoy working there;
- some senior medical members of the Cardiac Unit appeared to have restricted their involvement to their specialist work and withdrawn from their wider responsibility;
- there was little structured educational and research activity in the Cardiac Unit;
- most of the problems and shortcomings in the Cardiac Unit could have been overcome by a clear management structure and effective management control;
- the two cardiac surgeons, A and B who worked in the Cardiac Unit at the relevant time were competent surgeons.

It has been noted that some improvements were made following the 1992 review. However it has not been possible to establish if the Trust management of the time had drawn up an action plan, or whether it had been implemented.

In conducting their review of the Cardiac Unit, Sir Keith Ross and Professor Richard West had also examined the performance of the two heart surgeons. This was because of comments that one surgeon had made about the technical skills of the other. An article had also appeared in a local Liverpool newspaper, in relation to these issues, before Sir Keith Ross and Professor Richard West began their inquiry.

As stated above, Sir Keith Ross and Professor Richard West reached the conclusion that both surgeons in the Cardiac Unit were competent.

# Lloyd/Davidson Review 2000

Alder Hey's Chief Executive commissioned a second review of the Cardiac Unit in March, 2000 and this was conducted by Professor David Lloyd, Professor of Paediatric Surgery, University of Liverpool and Dr Campbell Davidson, the Trust's Medical Director.

This review was set up after Surgeon B had raised concerns over the way in which cardiologists in the Trust were allocating work between the surgeons in the Cardiac Unit. It was felt that there was a risk of Surgeon B becoming de-skilled as the more complex cases were being allocated to the other surgeon in the unit.

The cardiologists had changed their system of allocating work between the surgeons in 1997 after an audit indicated that in relation to some complex procedures, the post-operative results of one surgeon were better than those of the other.

Their intention in changing the system for allocating work was to ensure that specific procedures were allocated to the surgeon with the most appropriate skills for handling them.

The terms of reference for the inquiry led by Professor Lloyd and Dr Davidson were to investigate:

- the workings of the existing arrangements for allocation of cases for cardiac surgery;
- team working in the Cardiac Unit;
- the state of inter-departmental communications within the Trust;
- staff perceptions of the effectiveness of the service delivered by the Cardiac Unit as a whole and in particular the post operative mortality outcomes in the Cardiac Unit.

The Lloyd/Davidson review reported on 25 May 2000. The key findings and recommendations were:

- the post operative death rate for the Cardiac Unit at Alder Hey for the years 1996-1999 was 2.5% compared to the national average of 5.2%;
- variations existed in outcomes following cardiac surgery between surgeons in the Unit (the observed variations might require further analysis and explanation);
- working relations between professionals in the Cardiac Unit needed to be more collaborative than in the past;
- team working and communications had been problems for a long time and needed urgent improvement;
- waiting lists for surgical procedures were getting longer. This may have been due to the new system for referring patients to the cardiac surgeons and, if so, urgent measures were needed to reverse the trend;
- theatre scheduling was inefficient with operations starting late and running late on many occasions. This resulted in staffing difficulties as some rosters could not be filled;
- there was frequent difficulty in getting anaesthetists to cover duties other than their scheduled ones. This was a highly undesirable situation in a high risk speciality;
- variations in some pre-operative practices resulted in delays in starting a number of operations on time;
- there were constant pressures on intensive care beds;
- the number of postponed operations was found to be excessive;

- there were difficulties in recruiting and retaining staff with the required range and depth of skills. This particularly applied to nurses possessing experience of neonatal intensive care, anaesthetists with experience in neonatal anaesthetics and Intensive Care Physicians.

The mortality figures used by the Lloyd/Davidson review were derived from the Liverpool University Cardiac Surgery Register. The Regional Office has checked these figures against national hospital treatment records (Hospital Episode Statistics) which confirm that Alder Hey's cardiac post-operative mortality rate for the years 1997/98-1998/99 was 2.7% - well below national levels.

The University of Liverpool has maintained a local register of cardiac surgery for over 30 years. Since 1977, this register has submitted summary reports of cardiac workload to the UK Cardiac Surgical Register, maintained by the Society of Cardiothoracic Surgeons. Surgeons at Alder Hey use these registers to monitor their performance over time and against national standards. We have used this data source to check the extent to which the workload of Surgeon B has, over the years, become concentrated on less complex procedures. We have not, however, applied statistical tests to local or national cardiac register counts. We noted that the Bristol Royal Infirmary Inquiry commissioned a detailed study, comparing procedure counts from cardiac registers with hospital episode records and other formal records of operations (e.g. theatre logs), and found that the cardiac registers nationally tended to inflate the count of 'switch' operations through the incorrect inclusion of patients receiving an older, interatrial, operation (Murray 1999, p 26).

The Alder Hey Senior Management Team has produced an Action Plan to act on the findings of the Lloyd/Davidson review. The NHS Executive's North West Regional Office will monitor the implementation of the Action Plan.

# APPENDIX 2

## DATA SOURCES

### Historic Individual Episode Records, 1991-97

Individual hospital episode records for the period 1991/92–1996/97, archived within the Regional Office in secure files under the supervision of the Regional Director of Public Health, were analysed with the consent of the consultants concerned. The aim was to explore the pattern of post operative mortality in relation to the operative procedures undertaken by each consultant surgeon and distinguishing groups of procedures.

### Extracts from Hospital Episodes Statistics

The Regional Office also holds individual episode records for the years 1997/98 and 1998/99, extracted from the national Hospital Episodes Statistics files. Consultant-specific analysis by procedure could not be performed on these data, as individual consultant codes have been withheld on grounds of confidentiality. Were such an analysis to be required for these years' data (and subsequent years) a case for access to the requisite data on consultants would currently need to be submitted to the Security and Confidentiality Advisory Group of the NHS Executive.

The hospital episode record provides a robust data source for assessment of comparative mortality. This is in line with the conclusion reached by the Bristol Infirmary Inquiry. However, current confidentiality restrictions prevent this being incorporated either into a general monitoring system or being available to clinical governance as part of a menu of immediate responses to perceived crises.

# Results of the Analysis of Data from the Hospital Episode Statistics Database

The tables in this appendix present the results of the analysis from the two Hospital Episode Statistics database. The number of procedures undertaken by the consultants is indicated by episode numbers. The relevant episode numbers have been used as the denominator when calculating the 35 day post admission (proxy for date of operation) mortality rate of the related procedure.

## **Key to the Tables**

|              |  |
|--------------|--|
| TGA:         | Transposition of Great Arteries  |
| TAPVD:       | Total Anomalous Pulmonary Venous Connection                                |
| AVSD:        | Atrio-Ventricular Septal Defect  |
| ASDS:        | Atrial Septal Defects  |
| VSD:         | Ventricular Septal Defect  |
| COARCTATION: | Coarctation of the Aorta   |
| ToF:         | Tetralogy of Fallot  |
| Switch:      | Operation to Correct the Defect due to Transposition of the Great Arteries |

Table One

| Consultant code |                              | CARDIOTHORACIC PROCEDURES & MORTALITY – using HES database and the BRI Inquiry methodology |            |            |            |            |            |            | Total | Mortality rate(%)<br>Alder Hey | Mortality rate(%)<br>Elsewhere |
|-----------------|------------------------------|--|------------|------------|------------|------------|------------|------------|-------|--------------------------------|--------------------------------|
| Cardiologists   |                              | FINANCIAL YEAR   |            |            |            |            |            |            |       |                                |                                |
|                 |                              | 1991/92  | 1992/93    | 1993/94    | 1994/95    | 1995/96    | 1996/97    |            |       |                                |                                |
|                 |                              | <b>Nos</b>   | <b>Nos</b> | <b>Nos</b> | <b>Nos</b> | <b>Nos</b> | <b>Nos</b> | <b>Nos</b> |       |                                |                                |
| Primary         | Tetralogy of Fallot          | 3  | 0          | 1          | 0          | 2          | 0          | 6          |       |                                |                                |
| Procedure       | Interatrial TGA              | 2  | 1          | 0          | 1          | 0          | 0          | 4          |       |                                |                                |
| Episode         | TGA (switch)                 | 3  | 0          | 2          | 0          | 1          | 0          | 6          |       |                                |                                |
| <b>Numbers</b>  | Repair of TAPVD              | 0  | 0          | 0          | 0          | 0          | 0          | 0          |       |                                |                                |
|                 | Repair of CAVSD              | 7  | 2          | 3          | 0          | 1          | 1          | 14         |       |                                |                                |
|                 | Closure (ASDS)               | 3  | 3          | 21         | 11         | 12         | 15         | 65         |       |                                |                                |
|                 | Closure (VSD)                | 10   | 0          | 10         | 2          | 0          | 2          | 24         |       |                                |                                |
|                 | Truncus arteriosus           | 0  | 0          | 1          | 0          | 1          | 0          | 2          |       |                                |                                |
|                 | Fontan procedures            | 4  | 1          | 0          | 0          | 1          | 0          | 6          |       |                                |                                |
|                 | Aortic, pulmonary, paravalve | 46   | 4          | 4          | 2          | 5          | 5          | 66         |       |                                |                                |
|                 | Mitral valve                 | 0  | 0          | 1          | 2          | 0          | 0          | 3          |       |                                |                                |
|                 | Closed shunt                 | 8  | 4          | 6          | 2          | 4          | 0          | 24         |       |                                |                                |
|                 | Coarctation                  | 1  | 0          | 2          | 0          | 6          | 2          | 11         |       |                                |                                |
|                 | Other open                   | 20   | 1          | 8          | 8          | 17         | 11         | 65         |       |                                |                                |
|                 | Other closed                 | 28   | 22         | 14         | 15         | 13         | 29         | 121        |       |                                |                                |
|                 | Closed                       | 37   | 26         | 22         | 17         | 23         | 31         | 156        |       |                                |                                |
|                 | Open                         | 98   | 12         | 51         | 26         | 40         | 34         | 261        |       |                                |                                |
|                 | Total                        | 135  | 38         | 73         | 43         | 63         | 65         | 417        |       |                                |                                |
| Death           | Tetralogy of Fallot          |  |            |            |            |            |            |            | 0.0%  | 5.5%                           |                                |
| Episodes        | Interatrial TGA              | 1  |            |            |            |            |            | 1          | 25.0% | 9.4%                           |                                |
| <b>Numbers</b>  | TGA (switch)                 |  |            |            |            |            |            |            | 0.0%  | 11.1%                          |                                |
|                 | Repair of TAPVD              |  |            |            |            |            |            |            |       | 14.8%                          |                                |
|                 | Repair of CAVSD              |  |            |            |            |            |            |            | 0.0%  | 9.9%                           |                                |
|                 | Closure (ASDS)               |  |            | 1          |            |            |            | 1          | 1.5%  | 1.6%                           |                                |
|                 | Closure (VSD)                |  |            |            |            |            |            |            | 0.0%  | 5.1%                           |                                |
|                 | Truncus arteriosus           |  |            |            |            |            |            |            | 0.0%  | 35.1%                          |                                |
|                 | Fontan procedures            |  |            |            |            |            |            |            | 0.0%  | 11.3%                          |                                |
|                 | Aortic, pulmonary, paravalve |  |            |            |            |            |            |            | 0.0%  | 6.1%                           |                                |
|                 | Mitral valve                 |  |            |            |            |            |            |            | 0.0%  | 12.0%                          |                                |
|                 | Closed shunt                 |  |            | 1          | 1          |            |            | 2          | 8.3%  | 8.0%                           |                                |
|                 | Coarctation                  |  |            | 1          |            |            |            | 1          | 9.1%  | 2.6%                           |                                |
|                 | Other open                   | 1  |            |            |            | 1          |            | 2          | 3.1%  |                                |                                |
|                 | Other closed                 |  |            |            |            |            |            |            |       |                                |                                |
|                 | Closed                       | 0  | 0          | 2          | 1          | 0          | 0          | 3          | 1.9%  | 2.8%                           |                                |
|                 | Open                         | 2  | 0          | 1          | 0          | 1          | 0          | 4          | 1.5%  | 8.4%                           |                                |
|                 | Total                        | 2  | 0          | 3          | 1          | 1          | 0          | 7          | 1.7%  | 6.9%                           |                                |
|                 | Annual Mortality             | 1.5%   | 0.0%       | 4.1%       | 2.3%       | 1.6%       | 0.0%       |            |       |                                |                                |

**Note:**

- i) mortality rate is calculated as death in hospital within 35 days of admission – comparative mortality rates elsewhere are from the BRI Inquiry reports, and are the national totals minus those for Alder Hey for the period 1991- 1995.
- ii) operative procedures and post operative deaths in this table have also been used to supplement the analysis of the post operative mortality experience of both Surgeon B and Surgeon C. This has been done to double-check that calculated post operative mortality experience for these surgeons has not been misrepresented, as all the procedures included in the table above are very likely to have been performed by one or another of the consultant surgeons.

Table Two

| Consultant code   |                              | CARDIOTHORACIC PROCEDURES & MORTALITY – using HES database and the BRI Inquiry methodology |         |         |         |         |         | Total | Mortality rate(%) Alder Hey | Mortality rate(%) Elsewhere |
|-------------------|------------------------------|--|---------|---------|---------|---------|---------|-------|-----------------------------|-----------------------------|
| Surgeon A         |                              | FINANCIAL YEAR   |         |         |         |         |         |       |                             |                             |
|                   |                              | 1991/92  | 1992/93 | 1993/94 | 1994/95 | 1995/96 | 1996/97 |       |                             |                             |
|                   |                              | Nos  | Nos     | Nos     | Nos     | Nos     | Nos     |       |                             |                             |
| Primary Procedure | Tetralogy of Fallot          | 39   | 8       |         |         |         |         | 47    |                             |                             |
| Episode           | Interatrial TGA              | 6  | 2       |         |         |         |         | 8     |                             |                             |
| <b>Numbers</b>    | TGA (switch)                 | 0  | 3       |         |         |         |         | 3     |                             |                             |
|                   | Repair of TAPVD              | 4  | 0       |         |         |         |         | 4     |                             |                             |
|                   | Repair of CAVSD              | 14   | 9       |         |         |         |         | 23    |                             |                             |
|                   | Closure (ASDS)               | 18   | 8       |         |         |         |         | 26    |                             |                             |
|                   | Closure (VSD)                | 32   | 7       |         |         |         |         | 39    |                             |                             |
|                   | Truncus arteriosus           | 0  | 0       |         |         |         |         | 0     |                             |                             |
|                   | Fontan procedures            | 25   | 14      |         |         |         |         | 39    |                             |                             |
|                   | Aortic, pulmonary, paravalve | 10   | 11      |         |         |         |         | 21    |                             |                             |
|                   | Mitral valve                 | 3  | 1       |         |         |         |         | 4     |                             |                             |
|                   | Closed shunt                 | 19   | 5       |         |         |         |         | 24    |                             |                             |
|                   | Coarctation                  | 4  | 0       |         |         |         |         | 4     |                             |                             |
|                   | Other open                   | 26   | 13      |         |         |         |         | 39    |                             |                             |
|                   | Other closed                 | 8  | 2       |         |         |         |         | 10    |                             |                             |
|                   | Closed                       | 31   | 7       | 0       | 0       | 0       | 0       | 38    |                             |                             |
|                   | Open                         | 177  | 76      | 0       | 0       | 0       | 0       | 253   |                             |                             |
|                   | Total                        | 208  | 83      | 0       | 0       | 0       | 0       | 291   |                             |                             |
|                   | Death Episodes               | Tetralogy of Fallot  |         |         |         |         |         |       |                             | 0.0%                        |
| <b>Numbers</b>    | Interatrial TGA              | 1  |         |         |         |         |         | 1     | 12.5%                       | 9.4%                        |
|                   | TGA (switch)                 |  |         |         |         |         |         |       | 0.0%                        | 11.1%                       |
|                   | Repair of TAPVD              |  |         |         |         |         |         |       | 0.0%                        | 14.8%                       |
|                   | Repair of CAVSD              | 1  | 1       |         |         |         |         | 2     | 8.7%                        | 9.9%                        |
|                   | Closure (ASDS)               |  | 1       |         |         |         |         | 1     | 3.8%                        | 1.6%                        |
|                   | Closure (VSD)                | 3  |         |         |         |         |         | 3     | 7.7%                        | 5.1%                        |
|                   | Truncus arteriosus           |  |         |         |         |         |         |       |                             | 35.1%                       |
|                   | Fontan procedures            | 4  |         |         |         |         |         | 4     | 10.3%                       | 11.3%                       |
|                   | Aortic, pulmonary, paravalve | 1  |         |         |         |         |         | 1     | 4.8%                        | 6.1%                        |
|                   | Mitral valve                 |  |         |         |         |         |         |       | 0.0%                        | 12.0%                       |
|                   | Closed shunt                 | 2  |         |         |         |         |         | 2     | 8.3%                        | 8.0%                        |
|                   | Coarctation                  |  |         |         |         |         |         | 1     | 0.0%                        | 2.6%                        |
|                   | Other open                   |  | 1       |         |         |         |         | 1     | 2.6%                        |                             |
|                   | Other closed                 | 1  |         |         |         |         |         | 1     | 10.0%                       |                             |
|                   | Closed                       | 3  | 0       |         |         |         |         | 3     | 7.9%                        | 2.8%                        |
|                   | Open                         | 10   | 3       |         |         |         |         | 13    | 5.1%                        | 8.4%                        |
|                   | Total                        | 13   | 3       |         |         |         |         | 16    | 5.5%                        | 6.9%                        |
| Annual Mortality  | 6.3%                         | 3.6%   |         |         |         |         |         |       |                             |                             |

**Note:** mortality rate is calculated as death in hospital within 35 days of admission – comparative death rates elsewhere are from the BRI Inquiry reports, and are the national totals minus those for Alder Hey for the period 1991- 1995.

Table Three

| Consultant code |                              | CARDIOTHORACIC PROCEDURES & MORTALITY – using HES database and the BRI Inquiry methodology |            |            |            |            |            |            |                             |                             |  |
|-----------------|------------------------------|--|------------|------------|------------|------------|------------|------------|-----------------------------|-----------------------------|--|
| Surgeon B       |                              | FINANCIAL YEAR   |            |            |            |            |            | Total      | Mortality rate(%) Alder Hey | Mortality rate(%) Elsewhere |  |
|                 |                              | 1991/92  | 1992/93    | 1993/94    | 1994/95    | 1995/96    | 1996/97    |            |                             |                             |  |
|                 |                              | <b>Nos</b>   | <b>Nos</b> | <b>Nos</b> | <b>Nos</b> | <b>Nos</b> | <b>Nos</b> | <b>Nos</b> |                             |                             |  |
| Primary         | Tetralogy of Fallot          | 15   | 12         | 10         | 8          | 7          | 8          | 60         |                             |                             |  |
| Procedure       | Interatrial TGA              | 6  | 8          | 1          | 3          | 0          | 0          | 18         |                             |                             |  |
| Episode         | TGA (switch)                 | 5  | 5          | 7          | 5          | 3          | 2          | 27         |                             |                             |  |
| <b>Numbers</b>  | Repair of TAPVD              | 4  | 4          | 4          | 3          | 2          | 4          | 21         |                             |                             |  |
|                 | Repair of CAVSD              | 18   | 19         | 10         | 11         | 11         | 8          | 77         |                             |                             |  |
|                 | Closure (ASDS)               | 29   | 39         | 13         | 13         | 22         | 33         | 149        |                             |                             |  |
|                 | Closure (VSD)                | 29   | 20         | 22         | 20         | 18         | 17         | 126        |                             |                             |  |
|                 | Truncus arteriosus           | 2  | 1          | 1          | 1          | 0          | 0          | 5          |                             |                             |  |
|                 | Fontan procedures            | 1  | 3          | 9          | 12         | 7          | 2          | 34         |                             |                             |  |
|                 | Aortic, pulmonary, paravalve | 8  | 19         | 16         | 13         | 7          | 9          | 72         |                             |                             |  |
|                 | Mitral valve                 | 3  | 9          | 6          | 5          | 5          | 0          | 28         |                             |                             |  |
|                 | Closed shunt                 | 15   | 17         | 14         | 18         | 11         | 11         | 86         |                             |                             |  |
|                 | Coarctation                  | 4  | 11         | 13         | 11         | 14         | 8          | 61         |                             |                             |  |
|                 | Other open                   | 10   | 16         | 16         | 15         | 21         | 20         | 98         |                             |                             |  |
|                 | Other closed                 | 34   | 24         | 19         | 16         | 9          | 20         | 122        |                             |                             |  |
|                 | Closed                       | 53   | 52         | 46         | 45         | 34         | 39         | 269        |                             |                             |  |
|                 | Open                         | 130  | 155        | 115        | 109        | 103        | 103        | 715        |                             |                             |  |
|                 | Total                        | 183  | 207        | 161        | 154        | 137        | 142        | 984        |                             |                             |  |
| Death           | Tetralogy of Fallot          | 1  | 1          | 2          | 1          | 1          | 1          | 7          | 11.7%                       | 5.5%                        |  |
| Episodes        | Interatrial TGA              |  | 1          |            | 1          |            |            | 2          | 11.1%                       | 9.4%                        |  |
| <b>Numbers</b>  | TGA (switch)                 | 1  | 2          | 3          |            | 1          | 1          | 8          | 29.6%                       | 11.1%                       |  |
|                 | Repair of TAPVD              |  |            |            | 1          | 2          | 1          | 4          | 19.0%                       | 14.8%                       |  |
|                 | Repair of CAVSD              | 1  | 1          | 1          |            | 1          |            | 4          | 5.2%                        | 9.9%                        |  |
|                 | Closure (ASDS)               |  | 1          |            |            |            |            |            | 0.0%                        | 1.6%                        |  |
|                 | Closure (VSD)                |  | 1          | 2          |            |            |            | 3          | 2.4%                        | 5.1%                        |  |
|                 | Truncus arteriosus           |  |            | 1          |            |            |            | 1          | 20.0%                       | 35.1%                       |  |
|                 | Fontan procedures            |  | 1          | 1          | 2          | 1          |            | 5          | 14.7%                       | 11.3%                       |  |
|                 | Aortic, pulmonary, paravalve |  |            |            |            | 2          |            | 2          | 2.8%                        | 6.1%                        |  |
|                 | Mitral valve                 |  | 1          | 1          |            | 1          |            | 3          | 10.7%                       | 12.0%                       |  |
|                 | Closed shunt                 | 3  | 2          | 3          | 1          | 4          | 1          | 14         | 16.3%                       | 8.0%                        |  |
|                 | Coarctation                  | 1  |            |            |            |            |            | 1          | 1.6%                        | 2.6%                        |  |
|                 | Other open                   |  | 1          | 2          | 1          | 1          | 2          | 7          | 7.1%                        |                             |  |
|                 | Other closed                 | 2  | 1          | 1          |            |            |            | 4          | 3.3%                        |                             |  |
|                 | Closed                       | 6  | 3          | 4          | 1          | 4          | 1          | 19         | 7.1%                        | 2.8%                        |  |
|                 | Open                         | 3  | 9          | 13         | 6          | 10         | 5          | 46         | 6.4%                        | 8.4%                        |  |
|                 | Total                        | 9  | 12         | 17         | 7          | 14         | 6          | 65         | 6.6%                        | 6.9%                        |  |
|                 | Annual Mortality             | 4.9%   | 5.8%       | 10.6%      | 4.5%       | 10.2%      | 4.2%       |            |                             |                             |  |

**Note:** mortality rate is calculated as death in hospital within 35 days of admission – comparative mortality rates elsewhere are from the BRI Inquiry reports, and are the national totals minus those for Alder Hey for the period 1991- 1995

Table Four

| Consultant code |                              | CARDIOTHORACIC PROCEDURES & MORTALITY – using HES database and the BRI Inquiry methodology |         |         |         |         |         | Total | Mortality rate(%)<br>Alder Hey | Mortality rate(%)<br>Elsewhere |
|-----------------|------------------------------|--|---------|---------|---------|---------|---------|-------|--------------------------------|--------------------------------|
| Surgeon C       |                              | FINANCIAL YEAR   |         |         |         |         |         |       |                                |                                |
|                 |                              | 1991/92  | 1992/93 | 1993/94 | 1994/95 | 1995/96 | 1996/97 |       |                                |                                |
|                 |                              | Nos  | Nos     | Nos     | Nos     | Nos     | Nos     |       |                                |                                |
| Primary         | Tetralogy of Fallot          |  | 4       | 14      | 13      | 20      | 36      | 87    |                                |                                |
| Procedure       | Interatrial TGA              |  | 0       | 1       | 0       | 0       | 1       | 2     |                                |                                |
| Episode         | TGA (switch)                 |  | 1       | 6       | 10      | 9       | 5       | 31    |                                |                                |
| <b>Numbers</b>  | Repair of TAPVD              |  | 0       | 4       | 6       | 3       | 2       | 15    |                                |                                |
|                 | Repair of CAVSD              |  | 5       | 15      | 11      | 15      | 13      | 59    |                                |                                |
|                 | Closure (ASDS)               |  | 33      | 26      | 27      | 21      | 22      | 129   |                                |                                |
|                 | Closure (VSD)                |  | 12      | 21      | 25      | 28      | 25      | 111   |                                |                                |
|                 | Truncus arteriosus           |  | 0       | 5       | 0       | 1       | 1       | 7     |                                |                                |
|                 | Fontan procedures            |  | 0       | 5       | 4       | 4       | 3       | 16    |                                |                                |
|                 | Aortic, pulmonary, paravalve |  | 16      | 12      | 17      | 7       | 22      | 74    |                                |                                |
|                 | Mitral valve                 |  | 0       | 5       | 3       | 2       | 2       | 12    |                                |                                |
|                 | Closed shunt                 |  | 2       | 19      | 22      | 19      | 19      | 81    |                                |                                |
|                 | Coarctation                  |  | 4       | 8       | 11      | 11      | 13      | 47    |                                |                                |
|                 | Other open                   |  | 3       | 18      | 17      | 16      | 28      | 82    |                                |                                |
|                 | Other closed                 |  | 5       | 9       | 13      | 11      | 15      | 53    |                                |                                |
|                 | Closed                       | 0  | 11      | 36      | 46      | 41      | 47      | 181   |                                |                                |
|                 | Open                         | 0  | 74      | 132     | 133     | 126     | 160     | 625   |                                |                                |
|                 | Total                        | 0  | 85      | 168     | 179     | 167     | 207     | 806   |                                |                                |
| Death           | Tetralogy of Fallot          |  | 1       | 2       |         |         |         | 3     | 3.4%                           | 5.5%                           |
| Episodes        | Interatrial TGA              |  |         | 1       |         |         |         | 1     | 50.0%                          | 9.4%                           |
| <b>Numbers</b>  | TGA (switch)                 |  | 1       |         | 1       |         |         | 2     | 6.5%                           | 11.1%                          |
|                 | Repair of TAPVD              |  |         | 1       |         | 1       |         | 2     | 13.3%                          | 14.8%                          |
|                 | Repair of CAVSD              |  | 1       | 1       |         |         | 1       | 3     | 5.1%                           | 9.9%                           |
|                 | Closure (ASDS)               |  |         | 1       |         |         |         | 1     | 0.8%                           | 1.6%                           |
|                 | Closure (VSD)                |  |         |         | 1       |         |         | 1     | 0.9%                           | 5.1%                           |
|                 | Truncus arteriosus           |  |         |         |         |         |         |       | 0.0%                           | 35.1%                          |
|                 | Fontan procedures            |  |         |         |         |         |         |       | 0.0%                           | 11.3%                          |
|                 | Aortic, pulmonary, paravalve |  |         |         |         |         | 1       | 1     | 1.4%                           | 6.1%                           |
|                 | Mitral valve                 |  |         |         |         |         |         |       | 0.0%                           | 12.0%                          |
|                 | Closed shunt                 |  |         | 4       | 2       | 2       | 1       | 9     | 11.1%                          | 8.0%                           |
|                 | Coarctation                  |  | 1       |         |         |         |         | 1     | 2.1%                           | 2.6%                           |
|                 | Other open                   |  |         | 2       | 2       |         |         | 4     | 4.9%                           |                                |
|                 | Other closed                 |  |         | 2       | 1       |         |         | 3     | 5.7%                           |                                |
|                 | Closed                       |  | 1       | 6       | 3       | 2       | 1       | 13    | 7.2%                           | 2.8%                           |
|                 | Open                         |  | 3       | 8       | 4       | 1       | 2       | 18    | 2.9%                           | 8.4%                           |
|                 | Total                        |  | 4       | 14      | 7       | 3       | 3       | 31    | 3.8%                           | 6.9%                           |
|                 | Annual Mortality             |  | 4.7%    | 8.3%    | 3.9%    | 1.8%    | 1.4%    |       |                                |                                |

**Note:** mortality rate is calculated as death in hospital within 35 days of admission – comparative mortality rates elsewhere are from the BRI Inquiry reports, and are the national totals minus those for Alder Hey for the period 1991- 1995.

Table Five

| Consultant code   |                              | CARDIOTHORACIC PROCEDURES & MORTALITY – using HES database and the BRI Inquiry methodology |            |            |            |            |            |            | Total rate(%) | Mortality rate(%) Alder Hey | Mortality rate(%) Elsewhere |
|-------------------|------------------------------|--|------------|------------|------------|------------|------------|------------|---------------|-----------------------------|-----------------------------|
| All Alder Hay     |                              | FINANCIAL YEAR   |            |            |            |            |            |            |               |                             |                             |
|                   |                              | 1991/92  | 1992/93    | 1993/94    | 1994/95    | 1995/96    | 1996/97    |            |               |                             |                             |
|                   |                              | <b>Nos</b>   | <b>Nos</b> | <b>Nos</b> | <b>Nos</b> | <b>Nos</b> | <b>Nos</b> | <b>Nos</b> |               |                             |                             |
| Primary Procedure | Tetralogy of Fallot          | 57   | 24         | 25         | 21         | 29         | 44         | 200        |               |                             |                             |
| Episode           | Interatrial TGA              | 14   | 11         | 2          | 4          | 0          | 1          | 32         |               |                             |                             |
| <b>Numbers</b>    | TGA (switch)                 | 8  | 9          | 15         | 15         | 13         | 7          | 67         |               |                             |                             |
|                   | Repair of TAPVD              | 8  | 4          | 8          | 9          | 5          | 6          | 40         |               |                             |                             |
|                   | Repair of CAVSD              | 39   | 35         | 28         | 22         | 27         | 22         | 173        |               |                             |                             |
|                   | Closure (ASDS)               | 50   | 83         | 60         | 51         | 55         | 70         | 369        |               |                             |                             |
|                   | Closure (VSD)                | 71   | 39         | 53         | 47         | 46         | 44         | 300        |               |                             |                             |
|                   | Truncus arteriosus           | 2  | 1          | 7          | 1          | 2          | 1          | 14         |               |                             |                             |
|                   | Fontan procedures            | 30   | 18         | 14         | 16         | 12         | 5          | 95         |               |                             |                             |
|                   | Aortic, pulmonary, paravalve | 64   | 50         | 32         | 32         | 19         | 36         | 233        |               |                             |                             |
|                   | Mitral valve                 | 6  | 10         | 12         | 10         | 7          | 2          | 47         |               |                             |                             |
|                   | Closed shunt                 | 42   | 28         | 39         | 42         | 34         | 30         | 215        |               |                             |                             |
|                   | Coarctation                  | 9  | 15         | 23         | 22         | 31         | 23         | 123        |               |                             |                             |
|                   | Other open                   | 56   | 33         | 42         | 40         | 54         | 59         | 284        |               |                             |                             |
|                   | Other closed                 | 70   | 53         | 42         | 44         | 33         | 64         | 306        |               |                             |                             |
|                   | Closed                       | 121  | 96         | 104        | 108        | 98         | 117        | 644        |               |                             |                             |
|                   | Open                         | 405  | 317        | 298        | 268        | 269        | 297        | 1854       |               |                             |                             |
|                   | Total                        |  | 526        | 413        | 402        | 376        | 367        | 414        | 2498          |                             |                             |
|                   | Death Episodes               | Tetralogy of Fallot  | 1          | 2          | 4          | 1          | 1          | 1          | 10            | 5.0%                        | 5.5%                        |
| <b>Numbers</b>    | Interatrial TGA              | 2  | 1          | 1          | 1          | 0          | 0          | 5          | 15.6%         | 9.4%                        |                             |
|                   | TGA (switch)                 | 1  | 3          | 3          | 1          | 1          | 1          | 10         | 14.9%         | 11.1%                       |                             |
|                   | Repair of TAPVD              | 0  | 0          | 1          | 1          | 3          | 1          | 6          | 15.0%         | 14.8%                       |                             |
|                   | Repair of CAVSD              | 2  | 3          | 2          | 0          | 1          | 1          | 9          | 5.2%          | 9.9%                        |                             |
|                   | Closure (ASDS)               | 0  | 1          | 2          | 0          | 0          | 0          | 3          | 0.8%          | 1.6%                        |                             |
|                   | Closure (VSD)                | 3  | 1          | 2          | 1          | 0          | 0          | 7          | 2.3%          | 5.1%                        |                             |
|                   | Truncus arteriosus           | 0  | 0          | 1          | 0          | 0          | 0          | 1          | 7.1%          | 35.1%                       |                             |
|                   | Fontan procedures            | 4  | 1          | 1          | 2          | 1          | 0          | 9          | 9.5%          | 11.3%                       |                             |
|                   | Aortic, pulmonary, paravalve | 1  | 0          | 0          | 0          | 2          | 1          | 4          | 1.7%          | 6.1%                        |                             |
|                   | Mitral valve                 | 0  | 1          | 1          | 0          | 1          | 0          | 3          | 6.4%          | 12.0%                       |                             |
|                   | Closed shunt                 | 5  | 2          | 8          | 4          | 6          | 2          | 27         | 12.6%         | 8.0%                        |                             |
|                   | Coarctation                  | 1  | 1          | 1          | 0          | 0          | 0          | 3          | 2.4%          | 2.6%                        |                             |
|                   | Other open                   | 1  | 2          | 4          | 3          | 2          | 2          | 14         | 4.9%          |                             |                             |
|                   | Other closed                 | 3  | 1          | 3          | 1          | 0          | 0          | 8          | 2.6%          |                             |                             |
|                   | Closed                       | 9  | 4          | 12         | 5          | 6          | 2          | 38         | 5.9%          | 2.8%                        |                             |
|                   | Open                         | 15   | 15         | 22         | 10         | 12         | 7          | 81         | 4.4%          | 8.4%                        |                             |
|                   | Total                        |  | 24         | 19         | 34         | 15         | 18         | 9          | 119           | 4.8%                        | 6.9%                        |
| Annual Mortality  |                              | 4.6%   | 4.6%       | 8.5%       | 4.0%       | 4.9%       | 2.2%       |            |               |                             |                             |

**Note:** mortality rate is calculated as death in hospital within 35 days of admission – comparative mortality rates elsewhere are from the BRI Inquiry reports, and are the national totals minus those for Alder Hey for the period 1991- 1995.

# APPENDIX 3

## A STUDY OF COMPLAINTS & LEGAL CLAIMS AGAINST ALDER HEY

An examination of the data on complaints and legal claims made by patients and carers can provide an insight into the quality of care provided to patients. The NHS complaints system was set up to provide patients, their carers and relatives with a means of bringing concerns to the attention of NHS organisations. Most complaints are dealt with by the NHS organisations themselves. However, in cases where an NHS body does not meet the concerns of the complainants to their satisfaction, the complaint is investigated by an independent panel.

The register of formal complaints records that Alder Hey received 1195 complaints in the past ten years, of which 47 related to the work of the cardiac unit. To put these complaints in perspective, there were 530,000 episodes of inpatient and outpatient care in Alder Hey during that 10 year period and 630,000 first attendances in the hospital's Accident and Emergency Department. The cardiac unit was responsible for 30,000 episodes of patient care.

Of the 47 complaints relating to the cardiac unit, 17 were about clinical issues (e.g. these were complaints about medical or surgical treatment). The remaining 30 complaints related to non clinical issues, such as waiting times for operations, cancelled operations and poor communication.

All but four of the 47 complaints received by the cardiac unit were resolved locally, without resort to an independent panel. The remaining four complaints became subject to litigation. In three of these cases, the legal action did not relate to the surgery the patients underwent.

In the ten years we looked at, only one 'clinical' complaint had been made against Surgeon B and three had been made against Surgeon C. We have not conducted a comparative study of complaints against other cardiac units during this 10 year period. The present system for collecting data on complaints in the NHS is not standardised and therefore does not permit comparison with other Trusts and with surgeons working in other Trusts. However, the available evidence indicates to us that the number of complaints against the two cardiac surgeons in Alder Hey is small.

We need to add that the complaints register in Liverpool is manually based and we cannot be absolutely certain of its degree of accuracy. This is an issue that will be addressed through the implementation of the Chief Medical Officer's Report, *An Organisation with a Memory*, enabling much better information to be available with regard to these matters in future.

## Legal Claims

In addition to looking at complaints, we undertook a study of the records of legal claims against the Trust. 517 claims were made between 1991 and 31st May 2000, of which 34 related to the Cardiac Unit. 10 of these claims related to operations performed by Surgeon B and 7 claims related to operations performed by Surgeon C. We noted that Surgeon B had worked in the Trust throughout the entire period we reviewed, whilst Surgeon C only commenced work at Alder Hey in 1993.

Of the 17 legal claims involving Surgeon B and Surgeon C, 10 were either dropped or are not currently being pursued. A further 3 claims related to alleged quality assurance issues in the Trust laboratory and the surgical competence of the two surgeons was not an issue in any of these cases. The remaining 4 claims relate specifically to surgical clinical care and these may be pursued further.

As with the data on complaints, the data on legal claims is not at present collected in a standardised form and therefore it is not possible to make comparisons across Trusts and between doctors working in different Trusts. However, from our study of the complaints and legal claims against the NHS Trust, we did not find any trends or patterns that could be regarded as a cause for concern with cardiac surgery at Alder Hey.

Normal professional and ethical rules would demand that the surgeons and other clinical staff should use complaints to assess their clinical practice, even though any errors uncovered may not amount to what the courts would consider to be negligence. The new arrangements for mandatory audit and the recommendations contained in the report, *An Organisation with a Memory* are likely to ensure that standards of clinical practice will rise in the future.

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