

13 December 1999

Response of Mr J R L Hamilton, Consultant Paediatric Cardiac Surgeon in response to a request from Dr Ruth Chadwick, Analysis Team Leader, Bristol Royal Infirmary Inquiry

Re: Key clinical audit data

General comments

I have reviewed the annual reports for paediatric cardiology and cardiac surgery from the Bristol Children's Heart Unit for the years 1987, 1988 and 1989/90 as requested. I am not aware of any other unit in the country which produced such a detailed report during these years. In particular I do not think that many, if any, units had a comprehensive database that would have been capable of generating such data.

I do not have information on how audit was carried out in every unit in the UK during these years but I presume the units in which I worked were typical. Audit meetings were held regularly and would have been attended by consultants and junior staff (surgeons, cardiologists and often anaesthetist). Records of children who died or had significant complications after surgery would have been reviewed in detail. Any alternative management which might have made a difference would have been discussed and recorded for use on the next occasion when a child with that condition presented. However the range of cases in congenital heart surgery is wide and each specific diagnostic category is in fact a spectrum so no two children are the same. Thus it is very difficult to "close the audit circle".

Standards for comparison are difficult - only the best results (by definition) are presented at conferences and the figures from the UK Register usually did not appear for at least a year. It must be further stressed that the UK Cardiac Surgical Register was not set up as an audit tool. Recording of data, particularly in the late 80s, was rather crude and there was certainly no validation. Thus no clinician would have used the mortality figure from the UK Register as being an accurate model, recognising that deaths were likely to be under reported.

Specific questions

1. **Clinical view of the content and balance of these reports.**

Each report gives comprehensive detail of the staffing and facilities of the unit and any new developments. They also include publications in the literature authored by the staff. The first report (1987) gives background information from 1980 onwards relating to the admissions, catheterisations and surgical activity of the unit. The subsequent two reports give breakdown of activity by region and purchaser.

Each report details the numbers of procedures and mortality rate for "open" and "closed" heart surgery divided into under and over one year of age (the structure used in the UK Cardiac Surgical Register). The "open" cases in the over one year are broken down into simple, moderate and complex and the increasing mortality reflects this. However there is no definition of these categories and they are not ones that are used in common practice (because of the difficulty of definition).

The surgical activity in the first report (1987) gives the figures for the four-year period 1984-1987. The subsequent two reports give mortality for the individual year. The 1989 report gives a summary table for the preceding period, 1989 and the UK figures from the Cardiac Surgical Register for 1988. These reports are certainly relevant to clinical practice but I suspect were (and probably still are) unique in the UK.

2. Which of these clinical audit data would or should have given rise to clinical concerns?

The first report contains an amalgamation of figures over a four year period and the unit would have been justified in accepting these mortality figures as a baseline. It is difficult to be specific as the small numbers involved mean the absolute mortality figure will have wide confidence intervals. The figures for "closed" surgery in both age groups would seem to be satisfactory. The mortality figure in the "open" category for the over one age group would again be within acceptable limits. The mortality rate for the "open" surgery in the under one age group are high but that for 1984-87 would have been comparable with national results. The mortality rates in 1988 and 1989 (37.5%) are high with a national mortality rate recorded in the Register of approximately 20%. Even allowing for under reporting of deaths in the National Register and the relatively small numbers in Bristol these figures for 1988 and 1989 would have given rise for concern. It might have been argued that if Bristol had a conservative approach to surgery in this age group and undertook palliative surgery for many conditions, then it would mean that they were only carrying out corrective surgery (i.e "open") on the very sickest children in the under one age group. Thus the individual cases would need close analysis.

3. What is the nature of clinical concerns that you would reasonably expect to have been expressed?

This high mortality for "open" surgery in the under one age group would have focused particular attention on these patients although in each year the number of patients is small (29 in 1988 and 40 in 1989) I would not expect clinicians to have focused solely on the absolute mortality rate (wide confidence intervals). However I would expect that the team would look at the management of the patients who died particularly carefully and see if any particular diagnostic group was implicated.

4. What course of action would you reasonably expect a clinician at Bristol to take in the light of these analyses?

If any particular diagnostic group or specific operation was identified as having a high mortality than I would expect a clinician to discuss their approach and technique with doctors in another unit. Ideally an experienced surgeon with good results might come from another unit to guide and assist but most surgeons do not like operating away from "home" - they recognise that outcomes are more than just the surgical technique. The most realistic option is for the surgeon (and other staff) to go and visit another unit to observe practice and hopefully pick up "tips" that can be used to improve practice.

There has been a significant change in philosophy over the last few years and I think in 1999 a unit whose results did not improve with these attempts would stop carrying out that procedure. However in the late 80s I believe the mindset in all units would have been to persevere in making changes in the hope that things would improve. I think this reflects the developments that have happened in the specialty since the pioneering days of the 1950s when if a child survived heart surgery it was a cause for celebration. We have now moved to the other end of the spectrum where it is expected that children will survive heart surgery.



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