

A Report on the UK Cardiac Surgical Register and the South West Congenital Heart Register for the Bristol Royal Infirmary Inquiry. A Statistical Analysis and Review of the Key Data Sources Relevant to the Inquiry's Remit.

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Executive Summary

Introduction

The remit for our report was (i) to examine the data quality of two sources available to the Inquiry, namely the national register compiled by the Society of Cardiothoracic Surgeons of Great Britain and Ireland (UKCSR) and the South West Congenital Heart Resister (SWCHR), and (ii) to use the UKCSR data to examine the nature and outcomes of the paediatric cardiac surgical service at Bristol compared with elsewhere.

Data Quality

In assessing data quality we have distinguished between *primary* issues, which relate to the context of data collection, including the scope of written guidelines, the training and motivation of the personnel involved, and the degree of monitoring and feedback to data collectors, and *secondary* issues such as data completeness and consistency. Issues relating to primary quality cannot be assessed by retrospective examination of the data, but are crucial to an overall assessment of data quality.

We have not been able to visit the relevant cardiac units to assess primary data quality directly, and we still maintain this is crucial for any definitive assessment of data quality. From the information which we have gathered, and indeed from data already presented to the Inquiry, it is clear that the primary data quality of the UKCSR is poor, with inadequate written guidelines on data collection, with no training of the staff gathering the data, and with limited checking and feedback of the results. In contrast the stability of the staff involved in running the SWCHR, and their strong sense of 'ownership' of the data, suggest that this source has greater potential to yield reliable data. It is likely that neither source will reliably estimate 30 day mortality rates, as no systematic procedures were in place to ensure complete follow-up after discharge from hospital.

Comparisons between these sources, and between the UKCSR and other available sources, show substantial inconsistencies. The variability from centre to centre in the activity reported via the UKCSR relative to the activity derived from the Hospital Episode Statistics is of

particular concern. The fact that the UKCSR data are essentially based on diagnoses whereas the other data sources are based on operative procedures, makes detailed comparisons difficult.

Outcomes at Bristol

If one takes the UKCSR data at face value, then they provide strong evidence that the death rates following surgery at Bristol were higher than the overall rate at other specialist centres. However, it can not be inferred that the outcomes at Bristol were worse than at all other specialist centres. This could reflect the fact that the surgery and overall clinical care at Bristol was indeed poor, or it could reflect the fact that referrals to Bristol included an unusually high proportion of high risk cases, or it could simply reflect systematic differences between the centres in the rigour with which the UKCSR data returns were compiled.

Conclusion

Further work to assess primary data quality is required, including visits to the relevant cardiac units, before one can assess the weight which should be placed on the results of the comparative statistical analyses. Existing data sources should be linked to national death registries to ensure consistency of follow-up.

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Abbreviations

BRI	Bristol Royal Infirmary
CCR	Clinical Coded Records
DOS	Disk Operating System
HES	Hospital Episode Statistics
OPCS	Office of Population Censuses and Surveys
PAS	Patient Administration System
RCSE	Royal College of Surgeons of England
SL	Surgeons' Log
SWCHR	South West Congenital Heart Register
TGA	Transposition of the Great Arteries
UKCSR	UK Cardiac Surgical Register

1. Introduction

1.1 This report deals with one of four projects commissioned by the Public Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary (the Inquiry) as part of an exercise entitled 'Synthesis of Statistical Sources'.

1.2 A key issue to be investigated by the Inquiry concerns the nature and outcomes of paediatric cardiac surgical services at Bristol relative to other specialist centres. In March 1999, the Inquiry published a consultation document¹ which identified a number of relevant key data sources and proposed a phased approach to analysis and review of these sources². This was followed in July 1999 by publication of a preliminary overview of the strengths and weaknesses of the sources, and by the presentation of expert evidence on statistical sources to the oral hearing³. Three separate groups were then commissioned by the Inquiry to review the data sources and Dr David Spiegelhalter (lead statistical Expert to the Inquiry) was commissioned to draw on the findings of these groups in an initial synthesis exercise.

1.3 This report deals with two of the six key datasets: the United Kingdom Cardiac Surgical Register (UKCSR), a register set up in 1977 to record overall cardiothoracic surgical activity in the UK; and the South West Congenital Heart Register, a computerised information system established and maintained by the cardiologists at the Bristol Royal Infirmary / Bristol Children's Hospital on all patients from the South West region seen by any of the Bristol cardiologists.

1.4 The report aims to inform the work of the Inquiry

- i by examining in detail the quality of the two datasets, both individually and in comparison with the other key datasets,
- ii by assessing the usefulness of the UKCSR in comparing Bristol with other specialist centres, and
- iii by carrying out such a comparative analysis.

2. The Bristol Context

2.1 Along with other NHS hospitals in which cardiothoracic surgery is performed, Bristol submits an annual return to the Society of Cardiothoracic Surgeons of Great Britain and Ireland for inclusion in the UKCSR. The figures submitted are simple totals of activity with associated numbers of deaths. In common with most other units, Bristol has consistently submitted data to the Register since its inception in 1977.

2.2 The Register was set up with the agreement that units would remain anonymous in any reports of the data. Only very limited validation of the data has ever been performed and no analysis has ever been undertaken to look at units over time or to compare units against each other.

2.3 The SWCHR is a local database unique to Bristol, containing records identifying individual patients with various personal and clinical details from the point of referral to the Bristol cardiologists, and potentially up until and including, death. It has been maintained since 1966 by the Bristol cardiologists for the purposes of (i) providing epidemiological information for research and (ii) acting as a back-up system for obtaining basic patient information when hospital casenotes were not available.

3. Description and Statistical Review of the Sources of Data

Introduction : Assessing data quality

3.1 In assessing data quality, we have essentially to try to answer the following questions:

- *How reliable is the information?* (i.e. how accurately do the recorded data reflect actual events?) or, alternatively
- *Could the error or variability inherent in the data be sufficient to invalidate any conclusions that may be drawn by analysing the data at face value?*

3.2 In considering these questions we need to ascertain all the potential sources of variability or error within both the data collection and the data recording processes.

3.3 Errors will increase with the number of personnel and processes involved in getting from the real events to the final interpretation of the data which claim to represent those events.

3.4 Any process which allows an individual scope for subjective interpretation, either of a procedure or a definition, will introduce variability in addition to simple human error. (See Figure 1). Such fundamental issues are increasingly being addressed in the field of clinical research by the introduction of stringent guidelines. The pharmaceutical industry has been applying such guidelines for the last decade^{4,5}, while the UK Medical Research Council, in consultation with the NHS Research and Development Programme, produced its own, similar guidelines in 1998.⁶ According to these guidelines, all studies must be described in a detailed protocol and all study procedures, including the collection and recording of data, must be documented. Additionally, all study personnel must be adequately trained to participate in the research, all should be fully aware of the procedures which they must follow, and all should be prepared to co-operate with continuous monitoring of the research and occasional audit by agents of regulatory authorities or the funding body.

3.5 Clinical trials necessarily involve large numbers of staff from various investigational sites, often in different countries, and such guidelines arose from the need to ensure credibility of data in a heterogeneous and potentially litigable environment. The application

of these guidelines in conjunction with good study design should minimise the amount of error and variability.

3.6 In contrast, the collection of clinical data for non-research or administrative purposes is generally not implemented in such a rigorous fashion, even although such data may be used to inform decisions about patient care. In the case of data being reviewed for the Inquiry we are dealing with ongoing, routine collection of data over many years. Moreover, the data collection was done for purposes other than those of the Inquiry.

3.7 Both datasets were initiated over twenty years ago for medical / surgical purposes, by individuals who were full-time specialists in areas other than information management and statistics. Issues of data quality were probably not considered to be particularly important, or else were considered to require input or resources which were not available.

Measuring data quality

3.8 Data quality can be measured in objective terms, and our review is an assessment of how well the two datasets meet specified criteria. This assessment does not consider whether the datasets served (or continue to serve) the purposes for which they were set up and maintained.

3.9 Assessment criteria can be divided into issues of primary and secondary importance. *Primary issues* of data quality are those which impinge most on the accuracy of the data and which, ironically, cannot readily be deduced from the dataset.

3.10 These include questions such as :

- i. Have personnel been working consistently to clearly defined procedures?
- ii. Have all definitions been clear and unambiguous with no scope for variable interpretation?
- iii. Were personnel implementing the procedures competent and motivated to do so?
- iv. Were all personnel collecting data from the same sources?
- v. What degree of data validation was implemented?

3.11 To illustrate the problems of interpretation, consider the definition of death. This could be defined in a dataset as death within so many days of operation (which operation, if more than one?), or death as a direct result of operation, or death prior to discharge from hospital, or death at any time, depending on the context of the data. Obviously it is important to know which definition has been applied, and this would not be clear from the data if death was simply recorded as 'Yes' or 'No'. Similarly, the procedure followed to obtain information on deaths could vary from centre to centre. While the original intention may have been to record death within thirty days, details of events occurring between discharge from hospital and the thirtieth day may not have been obtainable. It would also be unclear from the data if such information had been actively sought once a patient was discharged from hospital or even transferred from one department to another.

3.12 To summarise, the primary issues in determining comparability and accuracy relate to procedures for data collection and cannot be assessed by looking at the data alone. In the absence of a 'gold standard' against which to compare data, datasets compiled *independently* from different data sources can provide a useful indication of accuracy. If such cross-validation of the data were to yield similar results, then this would increase confidence in the credibility of the data, and conversely, a lack of similarity would cast doubt on accuracy. *Secondary issues* of data quality are issues which can be deduced directly from the dataset, requiring no knowledge of the data collection procedures. They are generally resolvable or at least easily quantified. They include issues such as coverage (the proportion of total relevant activity recorded by the data), completeness (what proportion of cases have each data item recorded), internal consistency (how well related data items match) and, to some extent, data entry errors (such as extreme outlying values).

3.13 We can only really assess primary issues of importance if we have a clear picture of the entire data collection and reporting process from start to finish. In the absence of any detailed procedural documentation or publications, this would necessarily involve detailed observation of the actual data collection process in a sample of units. Unfortunately, the time allocated for the production of this report has not allowed such detailed checking to take place, and we have instead had to rely on information provided by the Inquiry in witness statements and hearing transcripts and in personal communication with relevant individuals.

Format of the Data Sources Reviewed

3.14 The UKCSR was provided as boxes of copied returns (a total of 816 forms) from which we had to create a database. The forms contained cardiac surgical data from all 50 units who have ever supplied data to the Society, most of whom were not units specialising in paediatric cardiac surgery. While this enabled us to check the actual contents of the forms in terms of legibility and completeness, and to control the quality of the data entry process, it also meant that the figures which we subsequently produced were not always identical to those published annually by the Society. This exercise highlights the difficulty of producing consistent data from forms in the absence of any detailed procedures for handling data.

3.15 Our data handling and entry procedures are described in Appendix I.

3.16 The SWCHR was presented as a database consisting of several files on a set of floppy disks, having been archived using BACKUP under DOS 5, an obsolete PC operating system. The files were restored on a PC running the appropriate version of DOS, and transferred to a more modern system for analysis. The database had been built using Paradox 3.5, and comprised a main database with 7445 records, and numerous 'look up' tables giving the coding for the different fields. It appeared as if the look up fields were not linked to the main database, but this might have been a feature which was lost when the database was archived.

3.17 We had no access to the original forms from which the data were entered, so data entry error could not be quantified. However, we encountered various problems which indicated that minimal validation checks had been run on the database. Examples include inconsistent date formats, inconsistent use of codes and multiple records. A substantial amount of data 'cleaning' had therefore to be performed to create a database which could be used for our analyses.

Description and Critical Review of the UKCSR

Background Information

3.18 Since 1977, cardiac surgery units in the United Kingdom have been collecting information on cardiac procedures and deaths to input to the Cardiac Surgical Register of the Society of Cardiothoracic Surgeons of Great Britain and Ireland.

3.19 The stated uses of the register⁷ are :

- 1) to inform members of the growth of the specialty;
- 2) to provide aggregated activity and mortality data for a variety of procedures; and
- 3) to facilitate analysis of the intervention rate by disease category for the population.

3.20 In order to encourage submission of data, surgeons were assured that centres would remain anonymous in any reported figures. Individual surgeons are not identifiable.

3.21 Annual reports of the Society are simple totals of procedures and deaths from all contributing centres against which individual centres can compare their own data. Individual patients are not identifiable, nor can multiple diagnoses be linked to a single patient. Data are grouped by age (over / under one year) and type of procedure (open / closed).

Register collation process

3.22 Each cardiac unit is sent a standard form for completion annually, to be returned to the Secretary of the Society. On receipt of the completed forms, the secretary removes the front page, which identifies the unit by name, and assigns a coded identifier to the form. Forms are then passed on to a third party (the Society's agent) for data entry and reporting. The same third party has performed these tasks since 1977. If the Society's agent has noticed any strange values on a return, he has queried this with the secretary, who would have passed it on to the relevant unit for resolution. Other than this, no validation of the data has been performed, and trends within and across centres over the years have never been examined.

History of the data forms

3.23 We are only concerned with the last three pages of the form, which deal with congenital heart surgery. There are three different versions of the Society returns (*see Appendix II*). The first version was in use between 1977 and 1988 ; the second between 1989 and 1993 ; and the third has been in use since 1994. While the first two forms are very similar, the third has a completely different layout, with three separate age groupings (under one year, one to fifteen years, sixteen years or older), where the previous two versions simply had two age groups (under one year and over one year). Up to and including 1992, the UKCSR returns covered calendar years, but from 1993 onwards the data were for financial years. The majority of our analyses include UKCSR data up to and including financial year 1994/5. The data for 1995/6 are reported separately for comparative purposes, but they extend beyond December 1995, the end of the Inquiry period.

Primary issues of data quality

Data collection procedures

3.24 Guidance on completion of the returns consists of ten points listed on a single page (*See Appendix III*). The guidelines instructed that returns should be made from individual units, that information on repeat cardiac operations was not required, that each operation should be entered only once (taking the major one, if multiple procedures) and for palliative procedures only open ones should be specified. Definitions of mortality and open operation are provided as “death at or within 30 days of operation” and “any operation during which cardiopulmonary bypass is used at some stage of the procedure” respectively. The only change ever made to this page, as far as we can see, was to update the Secretary’s details when a new Secretary took office. As far as we are aware, no other documentation was made available to surgeons to guide the data collection process, to confirm definitions, or to discuss any areas which may have given rise to subjective interpretation.

3.25 One surgeon at each unit was made responsible for collating all the surgical activity data for that unit and completing the return. However, the actual collection of the data would often have been delegated to a junior surgeon or a secretary, sometimes at short notice.³ Data on unit activity could have been obtained from various sources, such as the operating

theatre log book, the perfusion log book and the Intensive Therapy Unit admissions book. Data on deaths would have been more difficult to obtain consistently, involving active follow-up of patients beyond the immediate post-operative period. Deaths occurring outwith the department, for example, in another department or at home may have been missed.³

3.26 It is possible that there was a lack of consistency as to how death was defined, with some units only including death as a consequence of operation rather than death due to any cause in the 30 days post-operation (personal communication). On the other hand, there is also the possibility that there has been some multiple recording of deaths. For example, where a child may have had multiple defects repaired and then died, each procedure may have been individually recorded on the return as fatal (personal communication).

3.27 The extent to which the data collection varied can only be determined by detailed study of the process in a representative group of units. This could not be undertaken in the time allowed for this review. However, we have been able to identify several discrepancies which would certainly introduce sufficient variability to cast doubt on the comparability of data from different units.

Secondary Issues of Data Quality

Quality of the returns

Legibility

3.28 Forms were either typed or handwritten, and this varied according to centre and year. In general, the forms were legible, but in many cases figures had been scored out and replaced, sometimes by the centre, sometimes by the Society's agent, and it was not always clear which figure should be entered. Any clearly edited figures were entered on our database, and a 'best guess' was made where there was any doubt.

Centre number problems

3.28 Centre numbers were missing from eleven forms, but it was possible to deduce the number from the other forms. In some cases, combinations of centre numbers were written on the forms, for example '1 and 2', '9 and 10', but this was not done consistently.

Duplicates and multiple returns

3.29 There were several duplicate returns for 1991, but most were attributable to a photocopying problem and so these records were ignored. There were other multiple returns for the same unit and year, some of which had to be combined (according to written notes on the returns), some of which appeared to be subsets of each other, for example where the first form had incomplete data and the second provided the missing information. Anecdotally, one centre submitted two separate, different returns because 'the surgeons do not speak to each other' (handwritten on form). However, these represented a very small minority of the forms, the majority being generally legible and with a centre number clearly marked on .

Arithmetical errors

3.30 In several cases, the totals recorded at the end of the forms did not match the total calculated by summing the procedures recorded on the three pages of the form. In most cases, however, the figures did not differ by more than one or two.

Blanks and zeros

3.31 Where figures were generally provided on a form, blanks were assumed to be zero, although in a few cases it was likely that the data were missing. In a few cases, a death was recorded but the number of procedures was blank, but more commonly the number of deaths alone was blank.

Summary

3.32 Returns were available and sufficiently legible and complete to enable us to construct a database of returns for the Inquiry period and beyond. Assumptions had to be made, however, in certain cases, as to exactly what should be entered on the database, and so some figures will not have coincided with those entered by the Society's agent at the time of

reporting. Various additional problems, which had not been immediately obvious from the forms themselves, were identified from the database.

Identifier issues and anonymity

3.33 There were problems with centre numbers when centres merged or closed, for example, but both submitted returns, duplicating the data. (See Table 1) We were not given comprehensive details of which centres merged and when. Our information regarding which centres merged was deduced from comments made by Mr Keogh³ and from two lists of centre identifiers (for years 1985-1989 and 1998/9), which were not particularly clear. We will inevitably have failed to identify all such problems.

3.34 There was a lack of consistency within centres, with several instances of huge swings in numbers in consecutive years, in some cases. (See Table 2) Many examples of inconsistent trends within centres occurred going from 1984 to 1985, and the evidence within the database suggested strongly that there had been a major change in the anonymity codes used by the Society. The Secretary for that period was not able to confirm such changes, but the Society's agent did confirm that a renumbering took place in the mid-1980's. Neither the Society nor the Society's agent have been able to provide details of the coding used up to and including 1984, and so unfortunately our only option was to discard all data from 1977 to 1984. This means we have been unable to include any UKCSR data for 1984, the first year of the Inquiry period.

Internal consistency of forms

3.35 As already stated, totals often differed from the totals calculated by summing the figures recorded for the individual procedures. (For production of the figures for the annual report, the Society's agent used the component figures, not the totals recorded on the form.) The lack of consistency within centres over time has already been noted. Some of the dramatic changes in figures may have been due to a change in policy / referral pattern, but we have not been able to confirm this. Most are probably due to the change in centre numbering discussed above.

Additional assessment of accuracy

3.36 Accuracy can only be truly determined if 'gold standard' data are available against which to make a comparison, and this is not the case here. Without knowledge of the variability in the way data were collected across the centres it is impossible to determine the accuracy of the figures. We have been able to cross-validate figures for 1988 to 1991 against an apparently independent source. At the very least, this gives an idea of how consistently centres are able to reproduce their own annual totals (intra-centre variability).

Intra-centre variability : comparison with another data source

3.37 We have been able to look at the consistency of the figures within the relevant centres over the period 1988 – 1991 by comparing figures from the society returns with figures produced in the 'Report from the Working Party of the Royal College of Surgeons of England on Neonatal and Infant Cardiac Surgery : Supra Regional Funding and Designation' (RCSE 0002 0165 to 0177).

3.38 This report was produced in June 1992. It contains details of the throughput of twelve centres who were seeking supra regional funding for paediatric cardiac surgery, ten of whom were at that point in receipt of, and two further centres who wished to be considered for, such funding. Based on the data presented in this report, the Working Party recommended which centres should be funded.

3.39 The report states that '...a questionnaire was sent out to the...centres. This requested returns for annual figures and mortality for the years 1988, 1989, 1990 and 1991, for all Neonates and Infants (under one year of age) who underwent open and closed heart surgery, listed separately. The same information for children and adolescents over one year of age (up to eighteen years) was requested...'

3.40 The data requested by the Working Party would already have been recorded on the annual returns made by the centres to the Society of Cardiothoracic Surgeons. Some centres may have used the data from the relevant returns, others may have recalculated the figures without reference to their returns. In either case, the figures should be expected to match. The very fact that the Working Party requested the information independently of the returns

to the Society may well be indicative of a lack of confidence among members of that group in such data.⁸

Data coverage

3.41 Two centres had provided returns to the society for 1988 but there were no corresponding data in the Working Party report. One centre had not provided a return for 1989 but had provided figures (on neonates and infants only) to the Working Party. One centre had not provided a return for 1990 but had provided figures (all categories) to the Working Party.

Comparison with returns

3.42 One of the twelve centres had matching figures for all comparable returns. A further four centres had at least one matching set of returns. Of the forty-two centre returns which could be compared, only ten had completely matching figures on the society returns and in the Working Party report. The figures in the Working Party report for 1988 for one centre matched the return for 1989 – no 1988 return was available. Table 3 gives comparative figures from the report and the returns for the number of open and closed procedures in the under one year group for the twelve units during the period 1988-1991. This age group was selected as it has a defined range, unlike ‘over-one year’, where the upper age limit may vary.

Summary Comments on Comparison

3.43 Comparison of the data from the Society returns with the figures produced in the Working Party report for years 1988 to 1991 indicated considerable discrepancies. Only one centre was consistently biased, with all discrepant figures in the Working Party report higher than the corresponding figures on its annual returns. Assuming units provided figures to the Working Party in the belief that their figures were accurate, and assuming that no transcription error took place in the production of the Working Party report, this raises considerable doubt over the ability of units to reproduce their annual figures. Both sources should have produced identical figures, but this has clearly not happened. Such intra-centre variability suggests a considerable lack of accuracy.

3.44 *UKCSR Data Quality : Summary Points*

- i. No detailed procedures or definitions were set out for the collection of data for the register, and so considerable variability between centres is to be expected.
- ii. The need for anonymity introduced an extra stage and a further source of error in the recording process – centre numbers changed within the recording period but this was not documented, making it virtually impossible to track some centres through time.
- iii. Twelve units were asked in 1992 to submit independent activity figures for 1988-1991 for a Working Party report. Some units clearly referred to their returns to the Society, while others produced very different figures. Considerable discrepancies between the figures suggest a lack of reporting consistency within centres.

3.45 The above points combined illustrate the difficulty in compiling consistent, reliable summaries of surgical activity.

Description and Critical Review of the South West Congenital Heart Register (SWCHR)

Background Information²

3.46 The South West Congenital Heart Register was set up by a consultant paediatric cardiologist at the Bristol Royal Infirmary in 1966 and existed in various computerised formats until his retirement in May 1993. The register contains data on all patients from the South West region seen by any cardiologist from Bristol, including patients seen at peripheral clinics. It was set up to obtain epidemiological information such as incidence of certain conditions and changes over time, and to act as a back-up system with basic patient information in the event of casenotes being unavailable. Each record represents an individual patient and contains demographic and clinical information, including limited follow-up data on outcomes.

Register collation process

3.47 All patients seen by one of the paediatric cardiologists and identified as having any organic heart condition had their basic details entered on a form by a part-time cardiac secretary. Administrative details were recorded by the secretary and the cardiologist concerned added the clinical details in a coded format. The secretary then entered the data from the forms onto the database. The database was updated as the cardiologists became aware of any relevant additional patient information.

Description of the data

3.48 The database contained 7445 patient records, each consisting of ninety-seven data items. Personal details, family history, details of mother's pregnancy, the patient's birth, medical history, diagnosis and type of disease were included along with post mortem information. The patient's status as assessed by the cardiologist was recorded at time of coding and at one, five and ten years, if known. Certain complications were also recorded, but without a corresponding date, so that it is not possible to relate complications to the time of any operation. Appendix IV lists all the data items and Table 4 lists the specific complications which were recorded.

Primary issues of data quality

Data collection procedures

3.49 Data were initially only collected by one cardiologist, and later by a further two, so some consistency of data recording can be assumed. The cardiac surgeons had no input to the process. As with the UKCSR data, follow-up of patients was not a systematic procedure, so that, again, deaths would not have been actively followed up. The database was updated only as information was brought to the attention of the cardiologists, for example when a patient was seen at the hospital.

Secondary Issues of Data Quality

3.50 As we were provided with the database directly, we cannot comment on the quality of the data entry, other than to note any obviously erroneous values.

Duplicate records

3.51 The records were meant to relate to individual children, but it was noted that eleven children were entered more than once on the database. There were twenty-six cases of a hospital number having been assigned to two different patients.

Missing data

3.52 Only six items could be expected to be completed for all patients : name, address, date of birth, diagnosis, year first seen and present status, and these details were complete in the vast majority of records. (See Table 5)

Coding errors

3.53 Comparison of the database entries against the listing of possible codes showed some discrepancies. For example, over four hundred records were assigned a code identifying the referring hospital by a code which did not appear on the coding list of hospitals.

Formatting difficulties

3.54 Many of the fields on the database were dates (e.g. dates of birth, dates of operations, dates of death), but surprisingly these were formatted as text fields and not as date fields. There was no consistency with how dates had been entered, with for example “010188” or “10188” (1st January or 10th January?) or “01JAN88” or “1JAN88” being interchanged freely. This suggests strongly that the database was not used very heavily, and certainly not used for any complex queries. For example, it would have been impossible to provide a tally of the number of children operated per year. This suggests in turn that problems and inconsistencies in the data are unlikely to have been identified or resolved in its day-to-day use.

3.55 A substantial proportion of the dates were re-entered so that all dates were in a consistent format, and hence could be reformatted as date fields. This exercise revealed many partial dates and dates which were obviously invalid (e.g. operations performed in the 1920's or second operations performed before a first operation.)

Internal Consistency

3.56 In general the internal consistency of dates was good, with 18 dates of operation and 11 dates of death being before the corresponding dates of birth. The dates for 10 operations were out of sequence, with, for example, the date of a second operation being recorded as earlier than the date of a first operation.

3.57 *SWCHR Data Quality : Summary Points*

- i. As with the UKCSR, no detailed procedures or definitions were available for the data collection process. However, as the register was maintained by the same people over much of the time of its existence, variability should not have been a major problem.
- ii. The lack of validation of the data has resulted in considerable problems which make extraction of useful data difficult. A substantial amount of work would be required to remedy this situation for any further analyses.

3.58 Although the database contains many errors associated with a lack of detailed checking and due to transfers between computer systems over the years, it potentially provides a comprehensive record of patients referred to the cardiologists at Bristol. Moreover, patients are identifiable by name, date of birth and hospital number, so a detailed comparison could be made against the other sources of data for Bristol.

4. Comparison of UKCSR Data with Other Inquiry Sources

UKCSR Methods

4.1 The UKCSR data are largely based on diagnostic groups with surgery classified as palliative or corrective, rather than based on specific operative procedures. To allow comparisons between the UKCSR data and sources such as HES, which are based on coded operative procedures, a number of groupings based on OPCS4 codes were agreed (Table 6). The UKCSR categories were then mapped onto the consensus groupings as set out in Table 7. Note that it is not possible to identify the group G12 – closed shunts – from the UKCSR returns. These grouping of operative procedures, and the mapping between the UKCSR returns and the consensus groupings, were based on expert advice from paediatric cardiac surgeons and paediatric cardiologists.

Handling of blank numbers of deaths

4.2 As mentioned previously, when the number of deaths was not filled in it was not possible to be sure that the actual number of deaths was zero. In fact, there were instances with, over 100 open procedures but no reported deaths, where almost certainly blank means not known rather than zero. The following convention was adopted for the analyses:

- Blanks for total numbers of deaths with open procedures were not assumed to be zero. Instead the data on the number of cases was dropped from the analysis. The corresponding data at the level of individual procedures were also dropped from the analyses.
- Blanks for total numbers of deaths with closed procedures were assumed to be zeros. The majority of blanks did correspond to closed procedures, where the mortality rate does tend to be much lower.

4.3 This is undoubtedly somewhat arbitrary, but given the limited time available it appeared to be a reasonable compromise between grossly under-reporting the mortality rates

and discarding a high proportion of the data. There were no such blank numbers of deaths in the Bristol returns, and so this issue only relates to comparisons with HES data

Comparison of UKCSR data with HES data

4.4 References to data quality issues pertaining to the HES data have been made in publications reporting HES data, and these have been summarised in the accompanying report on HES. The Imperial College School of Medicine supplied summary data from HES for the period 1991 to 1995. These were provided separately for each year, although this was by financial year whereas the UKCSR data for 1991 and 1992 are for the calendar years. The HES data for 1995 covered only the nine month period April 1995 to December 1995. The corresponding UKCSR and HES data were linked, dropping Centre 8 from the HES data for 1993/4 and 1994/5, as there were no corresponding UKCSR returns for those years.

4.5 Table 8 shows the comparison of UKCSR with HES broken down by type of surgery (open/closed), age (under/over 1 year), centre, consensus group (Table 6) and year. Overall the UKCSR reports 13% more activity and 19% more deaths. Eight of the twelve centres report at least 20% more activity via the UKCSR than is reflected in their HES data. The UKCSR 'over 1' age category includes adults, but for 1994/5 and 1995/6 the numbers between 1 and 16 years and over 16 years were reported separately. For these years, the numbers over 16 correspond to 20% of the numbers aged 1 to 16. If these years are representative of all years, the inclusion of adults would be sufficient to explain the discrepancies in numbers in the over 1 category. The data by centre show wide variation, with, for example the UKCSR returns for Centre 3 showing only 53% of the HES activity, and the UKCSR returns for Centres 9 and 11 showing a one third excess relative to HES. There is generally poor agreement for the data by consensus group, particularly G2 (interatrial TGA) and G3 (other TGA's (~switch)).

4.6 Table 9 gives equivalent data for Bristol alone, and Table 10 provides a more detailed comparison for Bristol, broken down by surgery, age and year. There is a consistent pattern with less activity being reported in HES for open surgery, and for closed surgery in the under 1's.

Comparison of the UKCSR data with the BRI Patient Administration System, Clinical Coded Records and Surgeons' Logs.

4.7 Quintiles supplied us with summary data from the BRI Patient Administration System (PAS) covering the years 1988 to 1995, Clinical Coded Records (CCR) for 1984 to 1995, and Surgeons' Logs for 1984 to 1995 (SL). The years were defined to coincide exactly with UKCSR, i.e. calendar years for 1988 to 1992 and financial years for 1993/4 to 1995/6. The background to these data sources is described in an accompanying report.

4.8 Appendix V Tables V.1 to V.6 provide a number of comparisons between the UKCSR and PAS, CCR and SL. It is apparent that the SL data essentially exclude closed procedures, and that the CCR data report far fewer closed procedures than the UKCSR data. The data by consensus group again show considerable discrepancies, and in particular, the UKCSR returns report far fewer cases in G2 (interatrial TGA) and far more in G3 (other TGAs (- switch)). This point is explored in more detail later.

Comparison of UKCSR data with SWCHR data

4.9 As described previously, the SWCHR contained a total of 7445 records. From 1984 to 1994, the number of patients having a first referral varied between approximately 400 and 500 per year, with between 150 and 200 per year having a first corrective operation. From 1995 onwards, with the consultant responsible for establishing the database having retired in May 1993, the database does not appear to have been systematically updated. In total there were 1040 deaths recorded on the database, comprising 419 up to 31st December 1983, 1 after 1st January 1996, and 620 during the Inquiry period of 1st January 1984 to 31st December 1995. Of the 620 deaths occurring during the Inquiry period, 216 were within 30 days of a surgical procedure. Of these 216 deaths, 199 took place from 1st January 1985 to 31st December 1992 or from 1st April 1993 to 31st March 1995 (the period covered by our main UKCSR analyses), which compares with 224 reported in the UKCSR for Bristol for the corresponding period.

4.10 As described in paragraph 3.48, the database does contain fields to record complications (see also Table 4). However, there are no date fields associated with the complication fields, and so it is not possible to differentiate between what might be post-operative complications, and complications which merely reflect the patients' clinical condition. It was never intended that these fields should be specific to post-operative complications (personal communication), and so they are of little relevance in any assessment of post-operative morbidity. The one outcome measure in addition to 30 day mortality which could be usefully investigated for the SWCHR would be long-term mortality. However, as there appears to have been no systematic attempt to obtain follow-up data on all patients in the database, such an analysis could be seriously misleading if performed on the SWCHR data as they stand. A meaningful analysis of long-term mortality would require the database to be linked to national mortality registries.

4.11 In total 2010 individuals were recorded as undergoing at least one operative procedure during the Inquiry period (1431 with one operation, 389 with 2, 133 with 3, 45 with 4, 8 with 5 and 4 with 6), and of these 323 died during the Inquiry period. The total of 2010 compares with the corresponding figure of 2142 from the UKCSR data (for 1985 to 1994).

4.12 Given the limited time available for this analysis, the detailed comparison has been restricted to an analysis of corrective operations. Operation categories from the SWCHR database were mapped to the Consensus Groups as described in Table 11. When more than one operation was recorded on the same day, the higher risk category was taken (Table 12). Operations on different days were all included. Table 13 shows the comparison of the UKCSR data with the SWCHR data for 1985-1994/5. Data for 1995/6 are not included since the SWCHR was not being kept up to date during that period. There is good agreement for a number of the consensus groups, but again there are striking discrepancies between consensus groups G2 and G3.

Detailed Comparison of Consensus Groups G2 (Interatrial TGA) and G3 (Other TGAs (- switch))

4.13 In view of the marked discrepancies observed between the UKCSR data and other data sources for Consensus Groups G2 and G3, the data were examined by year for these

procedures. Table 14 compares the UKCSR, SWCHR, HES, PAS, CCR and SL data for Bristol. It can be seen that the UKCSR data are reporting substantial numbers of "switches" from 1985 onwards, whereas the other sources reflect the move from G2 to G3 over time. This clearly reflects the difficulty of mapping the UKCSR categories onto operative procedures. Presumably in the 1980's the Mustard and Senning operations were regarded as being corrective rather than palliative, and so with the UKCSR data they will have been mapped to G3 rather than G2. There is excellent agreement between the UKCSR and SWCSR data for both numbers of cases and deaths if the groups G2 and G3 are combined, but the UKCSR returns cannot differentiate between the earlier Mustard/Senning procedures and the later switches. The CCR and SL data generally report fewer switches and fewer deaths following switches.

Summary

4.14 With the inclusion of adults in the UKCSR data and the low reporting of closed surgery in the CCR and SL databases, the greatest potential for agreement would be for open surgery in children aged under 1 year. These data are summarised for the various sources in Table 15. The SWCHR data are not included since the operative codes have not yet been mapped into open and closed procedures. The data for 1995/6 are not all complete, and also extend beyond the Inquiry period. For the other periods there is a reasonable degree of agreement, especially for the number of deaths, but the agreement is by no means perfect. The HES data tend to report less activity than the other sources.

5. Comparative Analysis of Outcomes based on the UKCSR Data

5.1 Table 16 reports the entire UKCSR activity for all centres for 1985 to 1994/5. The data are presented by Open/Closed procedures, and by Consensus Groups. The mortality rates are remarkably consistent with the ranking by risk which was derived *a priori* on the basis of expert clinical advice (Table 12).

5.2 Table 17 gives a comparison between Bristol and all other centres pooled, broken down by open/closed procedure, age over/under one year, and "epoch" as defined for the Statistical Synthesis. The odds ratios and 95% confidence intervals need to be interpreted with caution, as the confidence intervals take no account of the centre to centre variation outside Bristol. Bearing in mind this caveat, the data do suggest a high mortality rate in Bristol for open surgery in children aged under one year during 1984 to 1987 and 1988 to 1990 relative to the other centres pooled.

5.3 Tables 18 and 19 present similar data by surgery and by consensus group, for children aged under one year and over one year respectively. To give adequate numbers, the data are pooled over 1985 to 1994/5. The confidence intervals for open surgery in both under 1's and over 1's provide strong evidence that the recorded death rates at Bristol are higher than the overall recorded death rates from the other specialist centres. The analyses by consensus group need to be interpreted with caution, and in particular if there are specific groups where on the basis of the UKCSR data the performance at Bristol appears to be poor, one would not necessarily expect similar analyses of the HES data to identify the same areas of concern. Paragraph 4.13 describes this issue in the context of repair of TGA.

Analyses Based on Ranking

5.4 It is important to distinguish between two ways in which the outcomes at a particular centre could be 'outlying'. There might be strong evidence that the outcomes at a centre are worse than average, but the performance could still lie within the natural variability of outcomes from centre to centre. The analyses of the results at Bristol presented above take no account of such variability in performance from centre to centre outside Bristol. This will be fully addressed in the Statistical Synthesis, but to complement that analysis a number of

exploratory analyses were performed looking at the rank of Bristol within the 13 centres under consideration. (Centre 16 is generally not included in this analysis because the numbers were too small for meaningful analysis, bringing the number of centres down to 12).

5.5 Recent advances in statistical theory and practice have provided tools to analyse the variability in rank orders⁵. The underlying mortality rates for each Inquiry centre can be considered to be either independent of each other ("fixed effects" model) or they can be considered as being drawn from some population with similar characteristics ("random effects" model). The latter approach produces estimates of mortality rates that are "shrunk" towards the overall mean, and the effect can be marked for centres where the number of patients is small. The software package WinBUGS was used to fit both types of model to various subsets of the UKCSR data. Running the analysis is time consuming, and attention has been focussed on groups where the overall number of deaths is sufficiently high to allow meaningful results. All analyses were performed initially with a fixed effects model but a number were rerun using a random effects model to investigate the sensitivity of the conclusions to the type of model fitted.

5.6 Table 20 shows the results for the fixed effects models. The table gives the estimated rank of Bristol along with 95% confidence intervals for the rank order. In these analyses a high rank indicates a high mortality rate. In general these results show that the reported performance at Bristol is relatively poor, but in no case does the centre stand out as being clearly worse than all other centres. For open surgery in the under 1's, the 95% confidence interval is Rank 10 to Rank 12, putting Bristol in the bottom quartile of the distribution of reported performance, and in the other analyses the confidence intervals are wider, reflecting largely the smaller number of deaths in the other groupings. For the open surgery in the over 1's, Bristol is ranked 11 out of 12, with the 95% confidence interval for the rank order being 8 to 11. Thus in this category the data provide evidence that Bristol does not have the worst reported performance.

5.7 The analyses pooling 1985 to 1994/5 were repeated using a random effects model, and the results were broadly similar. For under 1's open, the confidence interval was 9 to 12 rather than 10 to 12. For under 1's G5, the point estimate of the rank was 11 rather than 10. For under 1's G8, the point estimate of the rank was 8 rather than 10, and the confidence interval 1 to 12 rather than 3 to 12. For over 1's G1, the confidence interval was 6 to 12 rather than 8 to 12. For over 1's G9 the confidence interval was 5 to 12 rather than 6 to 12. All other results were identical.

6. Summary and Conclusions

6.1 Data Quality – Principles

- i. Neither the UKCSR nor the SWCHR were designed to allow comparative analyses of surgical outcomes.
- ii. Measuring surgical activity is inherently difficult, with potential double counting of multiple procedures during a single operation, or multiple operations within a single admission, or multiple admissions for a single child.
- iii. Measuring death rates following surgery is difficult both in principle (how to define a surgical death) and in practice (without complete and systematic follow-up).
- iv. A system which could provide reliable data in this area would need to be established with far more rigour in terms of well-defined procedures, and more resources to implement and monitor those procedures than was recognised in the mid-1980's.
- v. The SWCHR is the one data source where the records represent individual children, and hence this source has the greatest potential to resolve problems associated with double counting.
- vi. Neither the UKCSR nor the SWCHR had well-defined procedures in place to standardise data collection and coding, and hence *a priori* one would not expect high quality data to be generated.
- vii. The large number of people involved in recording the UKCSR data further reduces the likelihood of obtaining reliable data from this source.
- viii. The stable staffing associated with the SWCHR along with a strong sense of "ownership" potentially compensates for the lack of systematic documented procedures for this database.
- ix. The long time since these systems were initiated has caused many additional problems, such as the missing information on the anonymity codes for the UKCSR, and the awkward formatting of the SWCHR database.

6.2 Data Quality – Comparison of Sources

- x. The UKCSR overall reported 13% more activity and 19% more deaths than HES.
- xi. This is partially explained by the inclusion of adults in the UKCSR.

- xii. There is substantial variability from centre to centre in the degree of agreement between the UKCSR and HES.
- xiii. With the UKCSR being based on diagnoses rather than surgical procedures, it was not possible to devise a satisfactory mapping of the UKCSR data onto the Consensus Groups (Table 6)
- xiv. The CCR under-report closed procedures, and the SL essentially exclude closed procedures.
- xv. (xi) and (xiv) above imply that the greatest potential for agreement between the sources is for open procedures in children aged under one year.
- xvi. Even for the open procedures in children aged under one there is substantial variability from source to source.

6.3 **Comparative Analysis of Surgical Outcomes**

- xvii. None of the available sources allowed a meaningful comparison of morbidity following open surgical procedures.
- xviii. There is strong evidence from the UKCSR that the reported death rate at Bristol is higher than the overall rate reported for the other specialist centres, both for children aged under one year and for children aged over one year.
- xix. It can not be inferred from the UKCSR that the reported outcomes at Bristol are worse than at all other specialist centres. Indeed for open procedures in children aged over one year there is evidence that the reported outcomes for Bristol are not the worst amongst the specialist centres.
- xx. The methodology agreed for the Synthesis Report should provide further insight into the data by exploring difference in outcome according to age, period and surgical procedure.

6.4 **Interpretation**

- xxi. The extent to which the different data sources agree does not necessarily reinforce one's confidence in the accuracy of the data. Excellent agreement could result if several sources drew their data from a single, flawed primary source.

- xxii. The variation from centre to centre in the level of agreement between the UKCSR and HES is likely to reflect wide variation in the rigour with which the UKCSR data were recorded.
- xxiii. The apparent poor performance at Bristol could reflect one or more of :
- the standard of surgery and overall clinical care was indeed poor; or
 - the case mix was such that a large proportion of the referrals to Bristol were high risk cases; or
 - there were systematic differences between the centres in the quality of the data. If, for example, Bristol had been meticulous in gathering follow-up information then this would have increased their reported death rates.

6.5 Recommendations

- xxiv. A detailed survey of the mechanisms used for gathering data at Bristol and other paediatric surgical units should be undertaken, to evaluate the extent to which different secondary sources such as the UKCSR and HES provide *independent* reinforcement of each other.
- xxv. Starting from the SWCHR, it should be possible to merge a number of different Inquiry sources to provide a more accurate assessment of activity at Bristol. This in turn could be linked to existing national systems for recording deaths, to overcome the problem of incomplete follow-up which afflicts all of the Inquiry sources.
- xxvi. There is limited value in performing additional work to further define activity and outcomes at Bristol unless a similar exercise is undertaken at a number of comparator centres.

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Figure 1

The Sources of Error in the Data Collection Process

Sources of Error

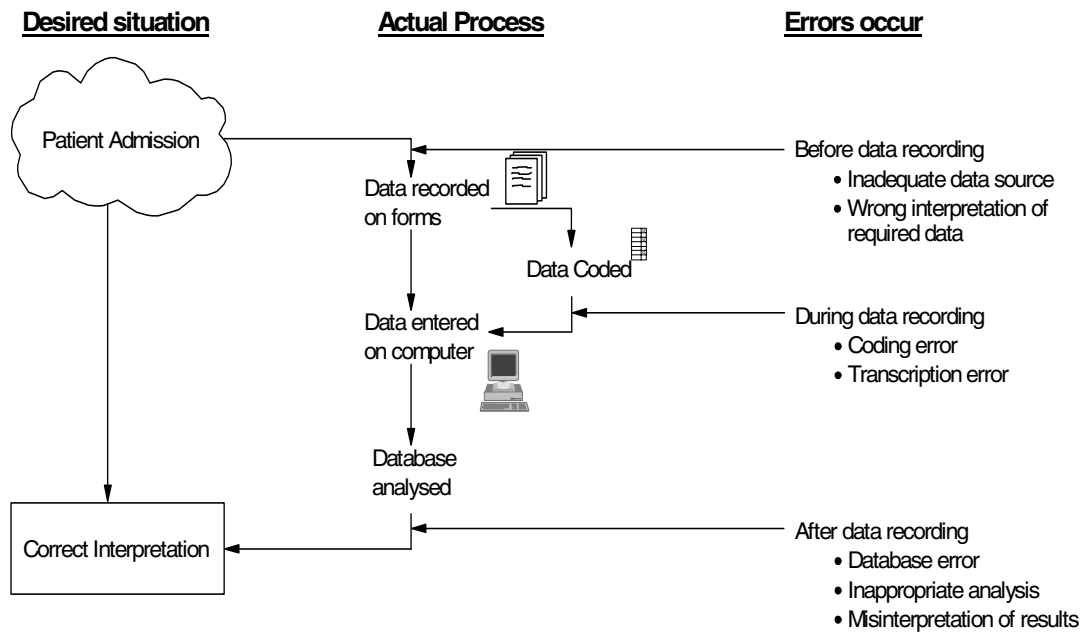


Table 1

UKCSR: Example of returns for 1990 from two units which had merged

Age	Surgery	Unit 'A'	Unit 'B'
Under one	No. of Open procedures	37	37
	Deaths	10	10
Under one	No. of Closed procedures	59	59
	Deaths	5	5
Over one	No. of Open procedures	110	92
	Deaths	5	3
Over one	No. of Close procedures	34	0
	Deaths	32	0

Table 2

UKCSR: Examples of changes in return figures from units in consecutive years

Age	Surgery	Year (X)	Year (X+1)
Under one	open procedures	63	11
Under one	closed procedures	34	5
Over one	open procedures	8	71
		10	126
		136	21
		180	15
		6	99
		3	129
Over one	closed procedures	1	57
		70	177
		3	147
		147	2
		2	61
		55	2

The table illustrates examples of large changes in the number of procedures recorded at a centre in consecutive years.

There were more examples of such changes in the over one age group.

Table 3

Number of Open and Closed Operations in Under-Ones. Comparison of figures from RCSE Working Party Report (1992) with annual returns to UKCSR 1988 – 1991.

Unit	Source	1988		1989		1990		1991	
		Open	Closed	Open	Closed	Open	Closed	Open	Closed
'A'	WP	125	124	114	118	123	109	145	100
	Return	125	124	114	118	123	109	148	110
'B'	WP	101	96	157	93	183	71	200	92
	Return	113	79	146	93	179	71	173	66
'C'	WP	114	118	86	114	102	100	97	94
	Return	115	114	83	108	-	-	97	83
'D'	WP	68	59	60	68	53	21	65	52
	Return	68	59	-	-	53	21	65	52
'E'	WP	30	96	46	87	47	91	71	76
	Return	30	96	46	101	59	77	81	52
'F'	WP	48	41	72	38	65	47	55	43
	Return	47	40	72	35	65	45	55	41
'G'	WP	-	-	28	47	42	44	59	50
	Return	23	55	28	39	28	47	51	43
'H'	WP	46	17	34	16	44	20	36	20
	Return	-	-	46	17	44	20	36	20
'I'	WP	32	65	7	8	43	32	47	17
	Return	32	65	29	42	43	32	48	19
'J'	WP	29	49	40	58	39	45	46	53
	Return	29	49	40	58	39	45	46	53
'K'	WP	-	-	40	32	51	35	43	43
	Return	27	26	40	22	40	36	48	40
'L'	WP	3	15	19	10	37	40	31	36
	Return	5	15	19	10	21	14	13	5

Notes:

1. Units have been assigned an arbitrary letter identifier.
2. WP : figures in RCSE Working Party report of 1992
3. Return : figures in return to the UK Cardiac Society Register
4. Blue figures indicate exact matches (in 42 out of 96 pairs of figures)
Red figures indicate a difference of 10 or more (in 22 out of 96 pairs of figures)

Table 4

SWCHR Database – Complications recorded

Code	Complication
0	No complications
1	Metabolic acidosis
2	Infective endocarditis
3	Respiratory failure
4	Thromboembolism
5	Hypoglycaemia
6	Hypocalcaemia
7	Renal failure
8	D.I.C.
9	Cardiac arrest – resuscitated
10	Septicaemia
11	Cerebral damage
12	Miscellaneous / other
13	N.E.C.

Table 5

SWCHR Database : Data missing for key identifiers (of 7445 records)

Item	No. missing or blank
Name	0
Address	0
Date of birth	4
Hospital code	14
Hospital number	6
Year first seen	4
Disease category	208
Present status	8

Table 6

Paediatric Cardiac Surgical Procedures by Group: OPCS4 Codes mapped by UKCSR Categories

Group	OPCS4 Procedure Code	Description	Map to UKCSR
G1	K04	Tetralogy of Fallot	Yes
G2	K05	Interatrial TGA	Yes
G3	K06	Other TGAs (- switch)	Yes
G4	K07	Repair of TAPVD	Yes
G5	K09 excluding K09.4	Repair of CAVSD (complete not partial)	Yes
G6	K10, K20 and K09.4	Closure of secundum and sinus venosus ASDS	Yes
G7	K11 (only on its own or with K10 or +/- L02; K11 is superior code to K10)	Closure of VSD	Yes
G8	L01.1	Truncus arteriosus	Yes
G9	K19.1, K19.2, K19.4 + L09	Fontan type operations	Yes
G10	K26, K28, K31.2, K31.4, K37	Aortic, pulmonary valve and paravalve procedures	Yes
G11	K25, K31.1, K34.1, K38	Mitral valve procedures	Yes
G12	L05, L06, L07,L08	Closed shunts	No
G13	L23.1, 2 or 3 [- if K code with it, code as K not L]	Coarctation procedures	Yes (simple coarctation)

Table 7

Mapping of UKCSR Categories onto BRI Inquiry Consensus Groupings

UKCSR Question	Consensus Grouping (G1-G13 or 'Other')
<u>Extracardiac Lesions:</u>	
Persistent ductus arteriosus	Other
A-P window	Other
Coarctation of aorta - simple	G13
Coarctation of aorta – complicated (plus other major defect)	Other
Interrupted Aortic Arch	Other
Vascular Ring	Other
<u>Congenital Valve Surgery:</u>	
Aortic (exclude adult calcific disease) – stenosis - valvotomy	G10
- regurgitation – repair	G10
- subvalvular stenosis – repair	G10
- supravalvular stenosis - repair	G10
- replacement (homograph)	G10
- replacement (xenograft)	G10
- replacement (prosthesis)	G10
Pulmonary – stenosis - valvotomy	G10
- regurgitation – repair	G10
- RVOT obstruction - repair	G10
- replacement (homograph)	G10
- replacement (xenograft)	G10
- replacement (prosthesis)	G10
Mitral – stenosis - valvotomy	G11
- regurgitation – repair	G11
- replacement (homograph)	G11
- replacement (xenograft)	G11
- replacement (prosthesis)	G11
<u>Defects of Partitioning:</u>	
Atrial septal defect (Secundum or Sinus Venosus)	G6
Partial A-V Canal (Primum ASD)	G6
Common (single) atrium	G6
Complete A-V Canal - palliative	Other
- corrective	G5
Ventricular septal defect (with or without ASD) – palliative	Other
- corrective	G7
Double outlet RV – palliative	Other
- corrective	Other
Double outlet RV and PS – palliative	Other
- corrective	G1
Truncus arteriosus – palliative	Other
- corrective	G8

Table 7 (continued)

Mapping of UKCSR Categories onto BRI Inquiry Consensus Groupings

UKCSR Question	Consensus Grouping (G1-G13 or 'Other')
TGA with intact ventricular septum – palliative	G2
- corrective	G3
TGA with VSD – palliative	G2
- corrective	G3
TGA with VSD and PS – palliative	Other
- corrective	Other
TGA with other significant anomaly – palliative	G2
- corrective	G3
Corrected TGA and VSD – palliative	Other
- corrective	Other
Corrected TGA and other significant anomaly – palliative	Other
- corrective	Other
Single ventricle – palliative	Other
- septation	Other
- Fontan-type procedure	G9
Tetralogy of Fallot – palliative	Other
- corrective	G1
VSD and PS (Valve or Sub-valve) – palliative	Other
- corrective	Other
Pulmonary atresia with VSD – palliative	Other
- corrective	Other
Pulmonary atresia with intact septum – palliative	Other
- corrective	G10
Tricuspid atresia – palliative	Other
- corrective	G9
Ebstein's anomaly – palliative	Other
- corrective	Other
<u>Miscellaneous:</u>	
Total anomalous pulmonary venous return	G4
Cor Triatriatum	Other
Anomalous origin coronary artery	Other
Coronary artery fistula	Other
Exploration only	Other

Table 8

Comparison of UKCSR returns with HES data for 1991-1994/5. For 1991 and 1992 the UKCSR data cover calendar years but the HES data cover financial years. The HES data for '1995/6' cover only the nine month period April 1995 to December 1995. Admissions are grouped by Surgery, Age, Centre, Consensus Group and Year. Data for 1995/6 are only included in the tabulation by year.

	Number of Cases			Number of Deaths			Ratio of Death Rates
	UKCSR	HES	Ratio	UKCSR	HES	Ratio	
Surgery							
Open	8227	7116	1.16	698	563	1.24	1.07
Closed	2898	2768	1.05	86	98	0.88	0.84
Total	11125	9884	1.13	784	661	1.19	1.05
Age							
Under 1	5360	4896	1.09	500	454	1.10	1.01
Over 1	5765	4988	1.16	284	207	1.37	1.19
Centre							
1	830	691	1.20	79	68	1.16	0.97
2	758	601	1.26	43	37	1.16	0.92
3	556	1049	0.53	50	53	0.94	1.78
4	295	359	0.82	27	27	1.00	1.22
5	664	544	1.22	61	39	1.56	1.28
6	1372	1306	1.05	96	80	1.20	1.14
7	819	633	1.29	40	32	1.25	0.97
8	1187	955	1.24	82	64	1.28	1.03
9	805	603	1.33	49	46	1.07	0.80
10	709	569	1.25	87	70	1.24	1.00
11	1921	1446	1.33	95	85	1.12	0.84
12	1209	1128	1.07	75	60	1.25	1.17
Group							
G1	921	810	1.14	57	46	1.24	1.09
G2	76	152	0.50	15	17	0.88	1.76
G3	685	561	1.22	89	70	1.27	1.04
G4	203	195	1.04	28	26	1.08	1.03
G5	553	758	0.73	65	73	0.89	1.22
G6	1525	1099	1.39	11	18	0.61	0.44
G7	1141	1249	0.91	26	59	0.44	0.48
G8	123	101	1.22	30	32	0.94	0.77
G9	340	616	0.55	42	67	0.63	1.14
G10	827	866	0.95	42	44	0.95	1.00
G11	160	224	0.71	15	22	0.68	0.95
G13	757	618	1.22	12	18	0.67	0.54
Year							
1991	3255	2576	1.26	254	184	1.38	1.09
1992	3403	2912	1.17	245	202	1.21	1.04
1993/4	2352	2270	1.04	142	144	0.99	0.95
1994/5	2115	2126	0.99	143	131	1.09	1.10
1995/6	3509	1982	1.77	195	134	1.46	0.82

Table 9

Comparison of UKCSR returns with HES data for 1991-1994/5 *for Bristol alone*. For 1991 and 1992 the UKCSR data cover calendar years but the HES data cover financial years. The HES data for '1995/6' cover only the nine month period April 1995 to December 1995. Admissions are grouped by Surgery, Age, Consensus Group and Year. Data for 1995/6 are only included in the tabulation by year.

	Number of Cases			Number of Deaths			Ratio of Death Rates
	UKCSR	HES	Ratio	UKCSR	HES	Ratio	
Surgery							
Open	563	451	1.25	71	61	1.16	0.93
Closed	267	240	1.11	8	7	1.14	1.03
Total	830	691	1.20	79	68	1.16	0.97
Age							
Under 1	360	295	1.22	48	47	1.02	0.84
Over 1	470	396	1.19	31	21	1.48	1.24
Group							
G1	58	47	1.23	6	5	1.20	0.97
G2	4	18	0.22	0	3	0.00	0.00
G3	45	19	2.37	10	11	0.91	0.38
G4	19	14	1.36	6	5	1.20	0.88
G5	41	34	1.21	11	12	0.92	0.76
G6	126	89	1.42	2	5	0.40	0.28
G7	90	93	0.97	0	1	0.00	0.00
G8	8	5	1.60	2	3	0.67	0.42
G9	39	37	1.05	7	5	1.40	1.33
G10	34	48	0.71	1	4	0.25	0.35
G11	9	21	0.43	0	3	0.00	0.00
G13	61	91	0.67	0	2	0.00	0.00
Year							
1991	215	185	1.16	30	22	1.36	1.17
1992	231	176	1.31	12	11	1.09	0.83
1993/4	202	169	1.20	20	18	1.11	0.93
1994/5	182	161	1.13	17	17	1.00	0.88
1995/6	264	170	1.55	6	3	2.00	1.29

Table 10

Comparison of UKCSR returns with HES data for 1991-1995/6 *for Bristol alone*. For 1991 and 1992 the UKCSR data cover calendar years but the HES data cover financial years. The HES data for '1995/6' cover only the 9 month period April 1995 to December 1995. Admissions are grouped by Age, Surgery and Year.

Category	Year	Number of Cases			Number of Deaths			Ratio of Death Rates
		UKCSR	HES	Ratio	UKCSR	HES	Ratio	
Under 1, Open	1991	46	36	1.28	14	10	1.40	1.10
	1992	53	36	1.47	8	9	0.89	0.60
	1993/4	50	37	1.35	14	12	1.17	0.86
	1994/5	32	33	0.97	7	9	0.78	0.80
	1995/6	50	24	2.08	3	2	1.50	0.72
Under 1, Closed	1991	53	42	1.26	2	3	0.67	0.53
	1992	43	38	1.13	0	0		
	1993/4	49	40	1.23	2	2	1.00	0.82
	1994/5	34	33	1.03	1	2	0.50	0.49
	1995/6	54	31	1.74	0	0		
Over 1, Open	1991	93	84	1.11	13	9	1.44	1.30
	1992	94	72	1.31	3	2	1.50	1.15
	1993/4	93	74	1.26	4	4	1.00	0.80
	1994/5	102	79	1.29	8	6	1.33	1.03
	1995/6	136	87	1.56	2	0		
Over 1, Closed	1991	23	23	1.00	1	0		
	1992	41	30	1.37	1	0		
	1993/4	10	18	0.56	0	0		
	1994/5	14	16	0.88	1	0		
	1995/6	24	28	0.86	1	1	1.00	1.17

Table 11

Mapping of operative procedures recorded for the SWCHR onto Consensus Groups

UKCSR	Consensus Group
Fallot repair	G1
Mustard operation	G2
Senning operation	G2
Arterial switch	G3
For TAPVC	G4
ASD	G6
Repair of AV septal defect	G6
Closure of VSD	G7
Fontan procedure	G9
Pulmonary valvotomy	G10
Aortic valvotomy	G10
Aortic valve replacement	G10
Resect sub ao stenosis	G10
Repair supra aortic stenosis	G10
Mitral repair/replacement	G11
Coarctation repair	G13

Table 12

Synthesis of Statistical Sources: Primary Procedure Ranking

Rank	Group	Description
1	G8	Truncus Arteriosus
2	G9	Fontan type operations
3	G4	TAPVD
4	G3	Other TGA
5	G2	Interatrial TGA
6	G5	AVSD
7	G11	Mitral valve procedures
8	G10	Aortic and pulmonary valve procedures
9	G1	Tetralogy of Fallot
10	G7	Closure of VSD
11	G6	Closure of ASD
12	G12	Closed Shunts
13	G13	Simple Coarctation

Note: This table draws on expert clinical advice on the most common combinations of procedures and mortality rates.

Table 13

Comparison of UKCSR data with SWCHR for 1985 to 1994/5

Age	Group	Number of Cases			Number of Deaths			Ratio of Death Rates
		UKCSR	SWCHR	Ratio	UKCSR	SWCHR	Ratio	
Under 1	G1	4	4	1.00	2	1	2.00	2.00
	G2	11	71	0.15	0	5	0.00	0.00
	G3	82	25	3.28	15	12	1.25	0.38
	G4	45	42	1.07	17	17	1.00	0.93
	G6	10	53	0.19	5	16	0.31	1.66
	G7	91	92	0.99	4	8	0.50	0.51
	G9	1	2	0.50	1	1	1.00	2.00
	G10	18	30	0.60	4	5	0.80	1.33
	G11	2	5	0.40	0	2	0.00	0.00
	G13	72	171	0.42	1	19	0.05	0.13
Over 1	G1	157	149	1.05	20	17	1.18	1.12
	G2	1	30	0.03	0	2	0.00	0.00
	G3	43	14	3.07	5	3	1.67	0.54
	G4	4	8	0.50	1	0		
	G6	292	208	1.40	1	9	0.11	0.08
	G7	108	123	0.88	2	9	0.22	0.25
	G9	53	56	0.95	14	7	2.00	2.11
	G10	89	94	0.95	0	0		
	G11	16	26	0.62	2	6	0.33	0.54
	G13	109	98	1.11	0	1	0.00	0.00

Table 14

Comparison of Reporting of Consensus Groups G2 (Intratrial TGA) and G3 (Other TGAs (- switch))

Columns give number of cases (number of deaths)

Year	UKCSR Bristol			SWCHR			HES			PAS			CCR			SL		
	G2	G3		G2	G3		G2	G3		G2	G3		G2	G3		G2	G3	
1984				11 (1)	0 (0)								6 (0)	1 (0)		8 (0)	0 (0)	
1985	2 (0)	11 (1)	11 (1)	11 (1)	0 (0)								7 (1)	0 (0)		8 (0)	0 (0)	
1986	3 (0)	15 (2)	16 (2)	16 (2)	1 (0)								12 (1)	1 (0)		15 (0)	0 (0)	
1987	0 (0)	9 (0)	9 (0)	9 (0)	1 (0)								6 (0)	0 (0)		6 (0)	1 (1)	
1988	1 (0)	12 (2)	10 (0)	10 (0)	4 (2)				11 (0)	5 (2)			10 (1)	2 (1)		12 (0)	3 (1)	
1989	0 (0)	17 (5)	11 (1)	11 (1)	6 (3)				11 (2)	6 (2)			8 (1)	4 (1)		9 (0)	4 (1)	
1990	2 (0)	16 (0)	17 (1)	17 (1)	1 (0)				15 (1)	0 (0)			10 (0)	1 (0)		16 (0)	0 (0)	
1991	2 (0)	11 (1)	11 (2)	11 (2)	4 (1)			3 (2)	12 (2)	2 (2)			8 (0)	1 (0)		10 (1)	3 (1)	
1992	0 (0)	17 (4)	7 (0)	7 (0)	9 (4)			6 (4)	7 (0)	12 (5)			2 (0)	5 (3)		8 (0)	5 (3)	
1993/4	2 (0)	13 (4)	4 (0)	4 (0)	10 (4)			7 (3)	5 (1)	10 (3)			4 (0)	4 (1)		4 (0)	8 (4)	
1994/5	0 (0)	4 (1)	4 (0)	4 (0)	2 (2)			3 (2)	4 (1)	2 (2)			2 (0)	1 (1)		3 (0)	0 (0)	
1995/6	2 (0)	5 (0)	1 (0)	1 (0)	1 (0)			2 (0)	3 (0)	2 (0)			2 (0)	0 (0)		1 (0)	0 (0)	

Table 15

Summary comparison of data from five sources for paediatric surgical activity at Bristol, restricted to open procedures performed on children aged under one year.

Number of Admissions

Period	UKCSR	HES	PAS	CCR	SL
1985-1987	63	-	-	67	78
1988-1990	108	-	103	107	128
1991-1994/5	181	142	167	163	197
1995/6	50	24	22	20	6

Number of Deaths

Period	UKCSR	HES	PAS	CCR	SL
1985-1987	16	-	-	16	15
1988-1990	31	-	25	28	31
1991-1994/5	43	40	45	46	48
1995/6	3	2	3	3	0

Death Rates

Period	UKCSR	HES	PAS	CCR	SL
1985-1987	25.4%	-	-	23.9%	19.2%
1988-1990	28.7%	-	24.3%	26.2%	24.2%
1991-1994/5	23.8%	28.2%	26.9%	28.2%	24.4%
1995/6	6.0%	8.3%	13.6%	15.0%	0.0%

Data from all sources other than HES relate to calendar years from 1985 to 1992 inclusive and financial years from 1993/4 to 1995/6 inclusive. Data from HES relate to financial years throughout, except for '1995/6', when the data cover only the nine month period April 1995 to December 1995. Data from CCR and SL for 1984 have been dropped, so that the reporting period corresponds exactly to the data available from the UKCSR. Similarly the period 1991-1994/5 for PAS, CCR and SL omits the three months January 1993 to March 1993 to correspond with the UKCSR data.

Table 16

Total UKCSR Congenital Activity 1985-1994/5, split by Open/Closed and by Consensus Group, for Under and Over 1's

	Aged Under 1 Year			Aged Over 1 Year		
	Cases	Deaths	Death Rate (%)	Cases	Deaths	Death Rate (%)
Surgery						
Open	6666	1088	16.3	11696	782	6.7
Closed	5878	297	5.1	3333	73	2.2
Total	12544	1385	11.0	15029	855	5.7
Group						
G1	455	45	9.9	1729	110	6.4
G2	199	34	17.1	79	4	5.1
G3	1303	203	15.6	355	31	8.7
G4	452	78	17.3	85	5	5.9
G5	587	103	17.5	427	56	13.1
G6	265	21	7.9	3276	19	0.6
G7	1552	80	5.2	1176	34	2.9
G8	239	101	42.3	32	7	21.9
G9	31	11	35.5	517	80	15.5
G10	538	105	19.5	1375	60	4.4
G11	67	12	17.9	251	33	13.1
G13	1177	30	2.5	814	3	0.4

Table 17

BRI versus All Other Centres Pooled by Period, Age and Surgery (Death rates, Odds ratios, 95% Confidence Intervals)

Surgery	Age	Period	Bristol				Non-Bristol				Odds Ratio	
			Death		Death		Death		Death		Estimate	95% Confide Interval
			Cases	Rate (%)	Cases	Rate (%)	Cases	Rate (%)	Cases	Rate (%)		
n	Under 1	1985-1987	63	16	25.4	1308	275	21.0	1.28	0.67 - 2.34		
n	Under 1	1988-1990	108	31	28.7	1863	336	18.0	1.83	1.14 - 2.86		
n	Under 1	1991-1994/5	181	43	23.8	3161	395	12.5	2.18	1.49 - 3.15		
n	Under 1	1995/6	50	3	6.0	1049	126	12.0	0.47	0.09 - 1.49		
ed	Under 1	1985-1987	154	18	11.7	1851	112	6.1	2.06	1.14 - 3.52		
ed	Under 1	1988-1990	152	12	7.9	1750	96	5.5	1.48	0.72 - 2.79		
ed	Under 1	1991-1994/5	179	5	2.8	1839	57	3.1	0.90	0.28 - 2.26		
ed	Under 1	1995/6	54	0	0.0	658	18	2.7	0.00	0.00 - 2.79		
n	Over 1	1985-1987	284	24	8.5	2989	242	8.1	1.05	0.65 - 1.63		
n	Over 1	1988-1990	304	37	12.2	3333	225	6.8	1.91	1.28 - 2.79		
n	Over 1	1991-1994/5	382	28	7.3	4508	232	5.1	1.46	0.93 - 2.20		
n	Over 1	1995/6	136	2	1.5	1305	42	3.2	0.45	0.05 - 1.76		
ed	Over 1	1985-1987	120	3	2.5	1293	21	1.6	1.55	0.29 - 5.32		
ed	Over 1	1988-1990	127	4	3.1	1002	21	2.1	1.52	0.37 - 4.60		
ed	Over 1	1991-1994/5	88	3	3.4	792	21	2.7	1.30	0.24 - 4.47		
ed	Over 1	1995/6	24	1	4.2	233	3	1.3	3.33	0.06 - 43.17		

Table 18

BRI versus All Other Centres Pooled, 1985-1994/5 (Death rates, Odds ratios, 95% Confidence Intervals) for Under 1's

	Bristol			Non-Bristol			Odds Ratio		
	Cases	Deaths	Death Rate (%)	Cases	Deaths	Death Rate (%)	Estimate	95% Confidence Interval	
Surgery									
Open	352	90	25.6	6332	1006	15.9	1.82	1.40 -	2.34
Closed	485	35	7.2	5440	265	4.9	1.52	1.02 -	2.20
Group									
G1	4	2	50.0	452	44	9.7	9.27	0.65 -	129.5
G2	11	0	0.0	189	34	18.0	0.00	0.00 -	1.92
G3	82	15	18.3	1222	188	15.4	1.23	0.64 -	2.24
G4	45	17	37.8	411	65	15.8	3.23	1.56 -	6.50
G5	49	15	30.6	538	88	16.4	2.26	1.09 -	4.46
G6	10	5	50.0	255	16	6.3	14.94	3.02 -	70.7
G7	91	4	4.4	1462	77	5.3	0.83	0.21 -	2.28
G8	16	9	56.3	223	92	41.3	1.83	0.58 -	5.99
G9	1	1	100.0	30	10	33.3	∞	0.05 -	∞
G10	18	4	22.2	527	102	19.4	1.19	0.28 -	3.90
G11	2	0	0.0	66	12	18.2	0.00	0.00 -	25.5
G13	72	1	1.4	1115	29	2.6	0.53	0.01 -	3.28

Table 19

BRI versus All Other Centres Pooled, 1985-1994/5 (Death rates, Odds ratios, 95% Confidence Intervals) for Over 1's

	Bristol			Non-Bristol			Odds Ratio		
	Cases	Deaths	Rate (%)	Cases	Deaths	Rate (%)	Estimate	95% Confidence Interval	
Surgery									
Open	970	89	9.2	10830	699	6.5	1.46	1.15 -	1.85
Closed	335	10	3.0	3087	63	2.0	1.48	0.67 -	2.94
Group									
G1	157	20	12.7	1575	91	5.8	2.38	1.34 -	4.04
G2	1	0	0.0	78	4	5.1	0.00	0.00 -	731.0
G3	43	5	11.6	315	26	8.3	1.46	0.41 -	4.19
G4	4	1	25.0	82	4	4.9	6.50	0.10 -	102.7
G5	29	10	34.5	399	46	11.5	4.04	1.57 -	9.76
G6	292	1	0.3	3032	18	0.6	0.58	0.01 -	3.67
G7	108	2	1.9	1069	32	3.0	0.61	0.07 -	2.46
G8	3	0	0.0	29	7	24.1	0.00	0.00 -	9.14
G9	53	14	26.4	464	66	14.2	2.16	1.03 -	4.34
G10	89	0	0.0	1305	61	4.7	0.00	0.00 -	0.89
G11	16	2	12.5	237	31	13.1	0.95	0.10 -	4.46
G13	109	0	0.0	731	4	0.5	0.00	0.00 -	10.2

Table 20

Analysis of UKCSR mortality rates, looking at the rank of Bristol relative to centres. A high rank corresponds to a high mortality rate.

Group	Period	Number of Centres	Rank of Bristol		
			Estimate	95% Confidence Interval	
Under 1 open	1985-1994/5	12	12	10	12
	1985-1987	12	8	3	11
	1988-1990	12	10	7	12
	1991-1994/5	12	12	10	12
Over 1 open	1985-1994/5	12	11	8	11
	1985-1987	13	8	4	12
	1988-1990	13	11	8	13
	1991-1994/5	13	9	6	11
Under 1 G3	1985-1994/5	12	8	2	12
	1985-1987	11	2	1	9
	1988-1990	12	4	1	9
	1991-1994/5	12	11	6	12
Under 1 G4	1985-1994/5	12	11	9	12
	1985-1987	11	9	5	11
	1988-1990	12	10	7	12
	1991-1994/5	12	10	6	12
Under 1 G5	1985-1994/5	12	10	6	12
	1985-1987	10	8	4	10
	1988-1990	12	8	3	11
	1991-1994/5	12	11	6	12
Under 1 G8	1985-1994/5	12	10	3	12
	1985-1987	11	10	4	11
	1988-1990	11	7	1	11
	1991-1994/5	12	7	1	12
Over 1 G1	1985-1994/5	12	11	8	12
	1985-1987	11	9	5	11
	1988-1990	12	9	4	12
	1991-1994/5	12	10	5	12
Over 1 G9	1985-1994/5	12	10	6	12
	1985-1987	10	7	1	10
	1988-1990	12	10	7	12
	1991-1994/5	12	9	5	11