An initial synthesis of statistical sources concerning the nature and outcomes of paediatric cardiac surgical services at Bristol relative to other specialist centres from 1984 to 1995.

David J Spiegelhalter MRC Biostatistics Unit Institute of Public Health Robinson Way Cambridge CB2 2SR

October 1999

© Crown Copyright 1999

The research on which this report is based was funded by the Bristol Royal Infirmary Inquiry. All views expressed in the report are the responsibility of the author alone, and do not necessarily represent the views of the Bristol Royal Infirmary Inquiry.

Executive summary

- Introduction. This synthesis is part of the exploratory investigation of available data sources on activity and outcomes of paediatric cardiac surgery in Bristol from 1984 to March 1995. It aims to review critically available sources of data, and examine what they tell us about Bristol's performance compared with that of other centres in England. However it deals only with early post-operative mortality derived from data which falls short of the ideal, and can only adjust for risk factors to a very limited extent. Detailed investigation of the data sources is contained in separate reports.
- 2. Comparing Care is required when assessing whether a centre is 'divergent' from the institutions. Care is required when assessing whether a centre is 'divergent' from the overall national pattern: the influence of unmeasured patient risk factors is inseparable from institutional 'quality' factors. We have chosen to estimate in specific subgroups the number of excess deaths over that expected in a 'typical' centre, allowing for the inevitable variation between centres. The analysis also assesses the uncertainty associated with the estimate.
- 3 *Bristol context.* It has been necessary to develop common definitions of activity, consensus procedure groups and outcomes for all the data sources. These have been chosen for pragmatic reasons and should not be regarded as definitive.
- *Review of data* Six sources of data on Bristol's activity and outcomes are available. Two are derived from administrative systems: the Patient Administration System (PAS) and national Hospital Episode Statistics (HES). HES draws its information from patient administration systems. Four sources of data are derived from records kept by clinicians: coded clinical records (CCR), surgeons' logs (SL), the South West Congenital Heart Register (SWCHR), and the UK Cardiac Surgical Register (CSR). HES and CSR provide national data, although the former is an administration system while the latter is a voluntary register using data provided by surgeons. HES data before 1991 was considered of insufficient quality to be of value. Each has

limitations with regard to its quality, and none is ideal for the purpose of the Inquiry. In particular, none has systematic follow-up of patients.

- 5 *Data sources* Despite their shortcomings, the six data sources produce a fairly similar for Bristol. picture of activity and outcomes in Bristol when compared across common time periods and clearly identified procedures. There is reasonable agreement between the clinical and administrative systems. The Patient Administration System (PAS) data which appear to be of good quality, which in turn supports the use of national Hospital Episode Statistics (HES) for Bristol. However, the apparently good quality of Bristol data may not be characteristic of other centres.
- 6 HES and CSR There is a broad picture of more activity and deaths being reported to the data for all CSR (which also covers surgery in over 15's) as compared to HES, but similar mortality rates. Centres show a reasonably consistent pattern in their level of agreement between CSR and HES, with Bristol being typical. The agreement with individual consensus procedure groups is not consistently good, but this may be expected as each source records activity and procedures in different ways.
- 7. The mortality estimates obtained from HES and CSR show a fairly strong *Comparison of* Bristol with degree of consistency, except where there are known coding and grouping national problems. Bristol shows no consistent evidence of excess mortality in performance. closed operations. However, there is strong and consistent evidence of excess mortality in open operations over the period 1988 to March 1995, in which the decline in mortality experienced elsewhere was not apparently matched in Bristol. HES data show an excess mortality between 1991 and March 1995 which is estimated to be around half of all deaths following open-heart surgery, while the data submitted to CSR indicate around one third of deaths between 1988 and March 1995 were in excess to that expected. The Table below provides further details.

		HES data	: 1991	- Mar 1995	CSR data	a:1988	- Mar 1995
	Primary	Mortality in	Mortality	Estimated	Mortality in	Mortalit	y Estimated
	procedures	11 other	in	excess deaths	11 other	in	excess deaths
		centres	Bristol	in Bristol	centres	Bristol	in Bristol
				(age-adjusted)			(age-adjusted)
G1	Fallot type	5%	11%	2.7	6%	13%	7.8
G2	Inter-atrial TGA	10%	17%	1.8	18%	0%	-1.5
G3	TGAs (~switch)	10%	58%	9.0 *	13%	19%	4.0
G4	TAPVD	12%	36%	3.2 *	12%	38%	7.8 *
G5	AVSD	8%	35%	9.1 *	13%	31%	9.8 *
G6	ASD	1%	6%	4.2 *	1%	2%	2.1
G7	VSD	5%	1%	-2.4	3%	4%	0.3
G8	Truncus	31%	60%	1.6	36%	40%	0.1
G9	Fontan type	11%	13%	1.0	12%	26%	7.0
G10	Aortic, pulm	5%	10%	3.4 *	8%	3%	-2.7
G11	Mitral valve	11%	13%	1.1	13%	8%	-0.6
	Total			34.7 *			34.1 *
				out of 58 deaths			out of 95 deaths
G88	All open ops	7%	14%	34.3 *	9%	14%	47.3 *
				out of 62 deaths			out of 139 deaths

* indicates greater than 95% confidence that the excess mortality is not due to chance alone.

Excess mortality can be identified with consistency and confidence in only some specific procedure and age groups. Open procedures on children aged less than 1 that can be identified with reasonable consistency as having excess mortality include 'switches', operations for total anomalous pulmonary venous drainage (TAPVD), atrial-ventricular septal defect (AVSD) and, although rare in this age group, atrial septal defect (ASD). Mortality was high for truncus operations, but this could be due to chance alone. In over 1's, there is some evidence for excess mortality in Fallot-type and AVSD operations. Even allowing for the imperfect data sources, the magnitude of these divergences suggests areas in which Bristol was distinctly atypical.

- 8. *Performance* There is consistent evidence from both HES and CSR that one other centre of other apparently had excess mortality similar to that of Bristol's for open operations in children over 1 year over the period 1984 to 1995.
- 9 Recommendations. This synthesis has identified possible areas where Bristol's performance diverges from that of other centres, although we emphasise that no causal reason can be ascribed at this stage. The activity and outcomes in these areas might be confirmed by further cross-relating data sources in Bristol, and there could be investigation of data sources in other centres in order to confirm that the observed performance elsewhere is not a consequence of different ways of recording information. In principle, reasons for any confirmed divergence might be sought by comparing risk factors and the process of care in Bristol and elsewhere.

However, the strong consistency of the Bristol data sources in the areas of maximum concern suggests that the divergent behaviour would not be explained by obtaining better quality data for Bristol. Furthermore, it appears unlikely that such a substantial divergence would be explained by standard patient-specific risk factors. Any further statistical investigation needs to be in complemented by strong clinical insights.

List of contents.

Glossary		8
Technical Terms		9
1. Ir	ntroduction.	
1.1	Background	10
1.2	Aims and objectives of this statistical synthesis.	10
1.3	Limitations and caveats of the synthesis	11
	Reports on specific datasets.	12
2. 0	General issues in comparing the performance of institutions.	
	Performance indicators.	12
2.2	Sources of variability in observed performance.	13
	A statistical strategy.	13
	Is a complex analysis necessary?	14
3. '	The Bristol context.	
	Background.	15
	Definitions.	15
4. 0	Critical review of six sources of data on Bristol.	
	Introduction.	18
	Bristol Patient Administration System (PAS).	18
	Bristol Coded Clinical Records (CCR).	18
	Bristol Surgeons' Logs (SL).	10
	South West Congenital Heart Register (SWCHR).	19
	National Hospital Episode Statistics (HES).	19
	UK Cardiac Surgical Register (CSR).	20
4.8	Interpretation and conclusions	21
	Comparison of sources of data on Bristol.	
	Introduction.	21
	Comparison.	22
5.3	Interpretation and conclusions.	22
	Comparison of HES and UKCSR data on all centres.	
6.1	Introduction.	22
6.2	Comparison.	23
6.3	Interpretation and conclusions.	24
	Comparison of Bristol with national performance	
7.1	Analyses being presented.	24
	Summary results for open and closed operations across all four epochs.	25
	Detailed results for HES.	26
	Detailed results for CSR.	26
7.5	Combined results for CSR and HES for each procedure group.	26

7.6	Other outcomes.	29
7.7	In what ways might Bristol differ from other centres?	30
8 (Comparative performance of other individual centres.	
	Comparative tables.	31
	Results for HES	31
	Results for CSR	32
	Interpretation and conclusions.	32
9.	Summary and conclusions	
	The available data sources.	33
9.2	Summary of findings concerning Bristol, assuming data of impeccable quality.	33
9.3	Does this indicate Bristol has divergent performance, when allowing for the quality of the data sources?	33
10.	Suggestions for next stages in statistical strategy.	
10.1	The strategy.	34
10.2	2 Confirmatory stage.	34
10.3	B Explanatory stage.	34
Ack	nowledgements	35
Ref	erences	35
Tec	hnical appendix.	
A.1	Primary statistical issues.	37
A.2	Specific modelling assumptions made.	39
A.3	BUGS code.	42

Tables

Figures

Glossary.

Abbreviations.

ASD	Atrial Septal Defect.
AVSD	Atrial Ventricular Septal Defect.
BRI	Bristol Royal Infirmary.
CCR	Coded Clinical Records.
CSR or UKCSR	UK Cardiac Surgical Register.
CV	Coefficient of variation: the standard deviation divided by the mean.
HES	Hospital Episode Statistics.
OPCS	Office of Population Censuses and Surveys.
OPCS4	OPCS Classification of Operation and Procedures, Fourth Revision.
PAS	Patient Administration System.
RR	Relative risk.
SL	Surgeons' Logs.
SWCHR	South West Congenital Heart Register.
TAPVD	Total Anomalous Pulmonary Venous Drainage.
TGA	Transposition of Great Arteries.
UBHT	United Bristol Healthcare Trust.
UKCSR	UK Cardiac Surgical Register.
VSD	Ventricular Septal Defect.

Technical terms.

Coefficient of variation	The standard deviation of a set of numbers, divided by their mean.
Consensus procedure	A set of related operative procedures derived from expert opinion.
group	
Epoch	A period of time within which an operation took place.
Excess deaths	The number of deaths observed, minus the number that would be
	expected were those centre 'typical'.
Relative risk	The ratio of the observed number of deaths to that number expected
	were that centre 'typical'.
Stratum.	A set of patients with a specified operative procedure, age-group and
	epoch of operation.
True mortality rate, true	The value for the mortality rate, rank etc, that would be observed were
rank etc	there no chance fluctuations in outcomes, <i>e.g.</i> if there were a huge
	sample.
'Typical' centre	One whose true performance is not distinguishable from the range of
	performances seen across the other centres in the country.
95% uncertainty interval.	Assuming the correctness of the data and the modelling assumptions,
	we can be 95% certain the true value for the quantity of interest (e.g.
	true mortality rate) lies in this interval. This is analogous to the usual
	use of a 95% confidence interval.

1. Introduction.

1.1 Background

1.1.1. 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 – referred to as Issue C in the Issues List published by the Inquiry in March 1999 (BRI Inquiry, 1999a). Also in March 1999, the Inquiry published a paper outlining its approach to making use of relevant existing data sources, together with a phased approach to making effective and appropriate use of these 1999 (BRI Inquiry, 1999b). In July 1999, the Inquiry published a preliminary overview of key data sources relevant to the Inquiry's remit, with a preliminary assessment of their strengths, weaknesses and limitations (BRI Inquiry, 1999c).

1.1.2. Phase 2 of the published statistical strategy is an **exploratory** investigation of available data sources on activity and outcomes of paediatric cardiac surgery in Bristol covering the period 1984 to March 1995, making comparisons where possible with the performance of other centres. This phase would be followed by a **confirmatory** phase in which any apparent divergences in performance are to be examined in more detail, but still without ascribing any causal explanation. A final **explanatory** phase would attempt to identify reasons for any confirmed divergence. This report concerns the second, exploratory phase.

1.2 Aims and objectives of this statistical synthesis.

The ten sections of this report have the following aims:

- 1. To provide a brief background to this synthesis, emphasising its aims and limitations.
- 2. To discuss briefly general issues concerning the identification of divergent performance of institutions, and to describe and justify the statistical methods selected.
- 3. To relate the general issues to the Bristol context, with special regard to the choice of outcome measures, operative groups, time periods, and age groups.

- 4. To critically review the sources of data, noting that detailed discussion is considered elsewhere.
- 5. To compare the data sources on Bristol's activity and outcomes over the period 1984 to 1995.
- 6. To compare data sources on activity and outcomes of all English centres over the period 1984 to 1995.
- 7. To compare, as much as is feasible, the performance of Bristol with the national picture to see if specific areas of divergence can be identified, and to review the extent to which key data sources tell the same story or otherwise.
- 8. To carry out a parallel analysis for each of the other national centres, and then to compare the manner and degree of Bristol's divergence with that of other centres.
- 9. To summarise the findings and their relevance to the Inquiry.
- 10. To suggest next stages in the statistical strategy in *confirming* and *explaining* the exploratory synthesis results.

1.3 Limitations and caveats of the synthesis

It should be made very clear that the data being analysed were not systematically collected for the purpose of this exercise, and hence that usual standards of data quality are necessarily compromised. In particular, we emphasise that this exercise -

- only examines short-term mortality, and so cannot comment on longer-term mortality, morbidity, or more subtle patient outcomes such as physical and cognitive functioning, dependency, or quality-of-life,
- 2. is limited to certain admittedly imperfect data sources,
- can only carry out risk-stratification in terms of broad age-group, type of operation and epoch of operation, and so does not adjust for variations in the case-mix of underlying severity, comorbidity, ethnicity, social class and so on,
- 4. does not discuss the availability and accessibility of information on outcomes of paediatric cardiac surgery over the period 1984 to 1995, and hence cannot comment on what might reasonably have been known at the time of the operations.

In conclusion, although we have tried to use appropriate methodological rigour in this synthesis, we repeat that this exercise only forms the **exploratory** phase of the statistical investigation. Hence it is neither aiming to yield definitive results for the Inquiry regarding Bristol's comparative performance, nor to ascribe any causal reason for any apparent divergent performance.

1.4 Reports on specific datasets.

This synthesis is based on six sources of activity and mortality data, two of which cover all centres in England. These were analysed by three groups working for the Inquiry, each of whom has provided a report on their investigations.

- Bristol data derived from the Coded Clinical records (CCR), Patient Administration System (PAS) and the Surgeons' Logs (SL) are discussed and analysed in *A Report on Local Data Relating to Children who Received Cardiac Surgery under the terms of reference of the Bristol Royal Infirmary Inquiry* (Evans, 1999).
- 2. Hospital Episode Statistics (HES) data are covered in *Analysis of Hospital Episode Statistics for the Bristol Royal Infirmary Inquiry* (Aylin *et al*, 1999).
- 3. Cardiac Surgical Register (CSR) and South West Congenital Heart Register (SWCHR) data are described in *UK Cardiac Surgical Register and South West Congenital Heart Register: a Statistical Analysis and Review of Key Data Sources Relevant to the Inquiry's Remit* (Murray *et al*, 1999).

Although frequent reference will be made to these detailed investigations, this synthesis cannot cover all of the material described in these reports or in the preliminary overview (BRI Inquiry, 1999c)

2. General issues in comparing the performance of institutions.

2.1 Performance indicators.

In 'A First Class Service: Quality in the new NHS' (Department of Health, 1998), it is stated that the National Health Service aims to "develop and publish sophisticated measures of clinical quality on a specialty by specialty and hospital by hospital basis". Such indicators are not available to the Inquiry, and it should be clear that analysis of mortality alone is an inadequate investigation of performance. However, it may serve as an indicator in an exploratory analysis.

2.2 Sources of variability in observed performance.

There are four main reasons why institutions may differ in observed outcomes (Goldstein and Spiegelhalter, 1996):

- 1. *Measurable risk factors*. These include age, severity of illness, co-morbidity and so on. Such case-mix factors can, in theory, be incorporated into a risk adjustment procedure, which exists for adult cardiac surgery and, to a very limited extent, paediatric cardiac surgery. However, data to carry out risk-adjustment are not available at this stage, and so all patient-specific factors are included in the unmeasured risk factors described below.
- 2. Unmeasured risk factors. Even after adjustment for measured risk factors, there will always be some variability between the long-term performance of centres due to unmeasured differences between patients. In the absence of any systematic differences between centres, this source of between-centre variability will tend to lead to a fairly regular distribution of performance around the national average. Any centre suspected of differing from a national profile should therefore be compared with this distribution, rather than simply compared with overall national performance. Thus it is inappropriate to make a 'naïve' statistical comparison between a mortality rate in one centre and the overall mortality in all other centres combined: larger centres may dominate such a national rate. Essentially, we compare Bristol's performance with that of an 'average' centre, rather than that experienced by an 'average patient'.
- 3. Institutional factors. Remaining factors reflect institutional differences that create systematic divergence from other centres; these may or may not reflect some aspect of 'quality'. Unfortunately there is no means of explicitly separating the influence of unmeasured patient risk factors from that of institutional factors, and we can only look for systematic differences that appear beyond 'usual' between-centre variability.
- 4. *Random variation*. This may be taken into account by providing intervals for estimates of true underlying performance, expressing unavoidable uncertainty due to the play of chance.

2.3 A statistical strategy.

Our primary interest is whether a centre is 'outlying', in the sense that its performance is divergent from the national profile, even having allowed for the inevitable between-centre variability described above. To this aim, the following statistical strategy has been adopted in this synthesis exercise.

- 1. Remove Bristol from the database.
- 2. Present activity and mortality rates as counts and proportions, comparing Bristol with the pooled remaining centres.
- 3. Within each stratum (a set of patients with specified operative procedure, age and year of operation), estimate the typical performance among the remaining centres, and the variability around that performance.
- 4. Obtain an uncertainty interval for the true performance of a 'typical' centre within that stratum, and compare with that of Bristol.
- Estimate, for a typical centre with Bristol's activity, the number of deaths we would expect to occur, with an interval that allows for all the uncertainty concerning what is 'typical' performance.
- 6. Compare this expectation with the observed mortality in Bristol, and so obtain an estimate and uncertainty interval for the excess number of deaths. Calculate the probability that the true excess is greater than zero, taking into account variability between the other centres.
- 7. Rank the performance of Bristol within each stratum. It is quite possible that a centre may appear to have the highest mortality rate by chance alone, but modern statistical techniques (Marshall and Spiegelhalter, 1998) allow one to go further than simply state an observed rank, and provide an uncertainty interval for that rank and a probability that Bristol was truly the unit with the most extreme performance.
- 8. Compare the degree of Bristol's 'divergence' with that of all other centres. Each is removed each in turn from the database and the entire analysis (2-7) repeated as if that centre were the one in question. We were unaware of the identity of the other centres when carrying out this analysis.

The Technical appendix contains a detailed description of the mathematical assumptions made in modelling between-centre variability, and hence how intervals and probabilities for excess mortality were assessed. It also contains the assumptions made in the ranking exercise.

2.4 Is a complex analysis necessary?

We are carrying out a fairly complex analysis in order to allow appropriately for the between-centre variability in performance, and present a substantial volume of tables in order that each procedure group can be examined by epoch and age-group. We shall not directly address the issue of whether

a simple analysis provides an adequate basis for investigation of comparative performance. However, we note that Figure 7.2, Figure 8.2.1 and Figure 8.3.1 provide a very basic summary of some of the available data, for which no sophisticated analysis is required.

3. The Bristol context.

3.1 Background.

The general issues described in Section 2 need to be pragmatically adapted to the context of the Inquiry and the available data. There is an inevitable conflict between the wish to focus on possibly small strata of patients of interest, and the need to have sufficient numbers in strata in order to draw conclusions with some statistical confidence. The analysis attempts to take into account the interest shown in outcomes associated with higher risk open-heart procedures in neonates and infants such as arterial switches, atrio-ventricular septal defects, and truncuses, while making sure no age group or procedure - open or closed - is excluded from consideration.

3.2 Definitions.

The following 'ideal' definitions have been adopted, and the extent to which the individual data sources can adhere to these definitions is covered in Section 4.

3.2.1 '*Activity*': An event has to be defined that measures activity and hence the denominator in any calculated mortality rate. This is not a straightforward decision, since different data sources are based on different measures of activity. There is a natural hierarchy, in that a **child** may have multiple **admissions** or **spells** recorded in their notes, and at each admission there may be multiple **episodes** of care under different consultants. Each admission may contain multiple **operations**, and at each of these operations there may be multiple **procedures** carried out.

This analysis has attempted to use the number of **admissions/spells** as the basis for comparison, although some of the data sources use operations as their measure of activity. Fortunately, there is normally only one operation per admission and so there is limited difference according to which is chosen; Evans (1999) reports that there were only 5% more operations than admissions recorded in Bristol.

Individual procedures within an admission may be coded according to the OPCS Classification of Operations and Procedures (OPCS4) (Aylin *et al*, 1999). This coding scheme is not claimed to be a gold standard, but it used for PAS and HES data and allows a comparison to be made between all sources.

3.2.2 *Outcome*: A 'death' has been defined as death within 30 days of operation.

3.2.3 *Open/closed groups*. Two broad categories of operations have been defined: 'open' operations refer to those in which the heart is stopped and cardio-pulmonary bypass is required, while 'closed' operations do not require bypass. A scheme for mapping of OPCS4 codes to these two categories was derived, although this was not perfect: Aylin *et al* (1999) (Figure 2.7) report that some 2.5% of observed OPCS4 codes map onto the 13 consensus operations but not onto either of the open or closed group. A better mapping could be established, but would be expected to have little impact on the results of this exercise.

3.2.4 *'Consensus' procedure groups*. Obtaining professional agreement on an appropriate way to aggregate codes into a manageable number of groups is clearly difficult. Consultation with paediatric cardiologists and cardiac surgeons based on procedures carried out at Bristol gave rise to 13 'consensus' groups – no claim is made as to the ideal nature of this grouping, but it provided a means by which the available data sources could be mapped, to an incomplete extent, to a common scheme. Consensus groups 1 to 11 were considered to be open, 12 and 13 closed. Table 3.1 shows the mapping of OPCS4 codes to the 13 groups, including whether mapping to a category of the UK Cardiac Surgical Register (UKCSR) was possible. Since one admission may contain procedures falling in more than one group, the hierarchy shown in Table 3.2 was adopted in order that the admission could be classified into a reasonably appropriate risk group. For data sources where it was impossible to group operations into admissions (CCR and SL), grouping has been by operation.

An example of the problems that arise is provided by a child who may be admitted with coarctation and transposition of the great arteries. There might be an operation to fix the coarctation, followed by a second switch operation for TGA. The HES analysis would classify the entire admission according to a single procedure group, which would be Group 3. However the patient may well provide two entries in the CSR. 3.2.5. Definition of epochs. The following 4 epochs have been adopted:

- 1. January 1984 to December 1987
- 2. January 1988 to December 1990
- 3. January 1991 to March 1995
- 4. April 1995 to December 1995

Not all data sources cover all these epochs. This report primarily deals with Epochs 1 to 3, since Epoch 4 covers the period when the overwhelming majority of paediatric cardiac surgery was conducted by a new surgeon, and therefore is not the main focus of the comparative exercise. Epoch 4 is only considered when considering broad patterns of mortality rates in Section 7.2.

3.2.6 *Definition of Age groups*. The following three age-groups have been adopted:

- 1. up to 90 days
- 2. 90 days to 1 year
- 3. 1 year and above

Age-group 1 extends to 90 days rather than the customary 30-day limit for neonates. Preliminary analysis indicated that mortality rates were not substantially different in the periods 0 - 30 days and 31 - 90 days, and the choice of a longer age-group containing more patients provides a firmer basis for comparisons.

3.2.7 *Selection of centres for comparison*: Comparison has been made only between 12 English centres, including Bristol: these are the 10 designated centres receiving supra-regional funding for paediatric cardiac surgery, plus two centres with considerable volume of activity. Bristol is numbered as Centre 1 in all comparisons. Throughout this synthesis 'elsewhere' refers to the 11 other centres: other reports may include other smaller centres in their definition of 'elsewhere'.

4. Critical review of six sources of data on Bristol.

4.1 Introduction.

Each of the six sources considered in this synthesis is listed below, with brief comments on their purpose, their adherence to the definitions given in Section 3, and the assessments of their quality provided by the individual reports listed in Section 1.4. 'Quality' is defined in terms of:

- *coverage* (how well does the data source feature the activity of interest?),
- completeness (are the individual records complete?) and
- *accuracy* (is the information given in the records correct?).

Table 4.1 summarises the main issues. See the individual reports for full discussion of these data sources, as well as the preliminary description provided by the Inquiry (BRI Inquiry, 1999c).

4.2 Bristol Patient Administration System (PAS)

Evans (1999) reports that the Bristol PAS both provides returns on activity to the Department of Health and supports administration of UBHT. Records are based on episodes (see Section 3.2.1), which need to be linked in order to identify a single admission or spell. Procedures have been allocated to open/closed and one of the 13 procedure groups according to the method described in Sections 3.2.3 and 3.2.4. PAS is not intended for clinical audit, and non-medical coders who vary in their experience carry out coding of diagnoses and procedures using discharge summaries and other sources. However, the Inquiry has heard that the Bristol team has been stable and is considered of good quality. Deaths out of hospital may not be recorded, although such deaths are sometimes added in later and these may not feature in the return made to the Hospital Episode Statistics (HES).

PAS data is only available from 1st Jan 1988, and so cannot inform epoch 1 in this synthesis. 1285 relevant admissions for 1147 children were identified.

4.3 Bristol Coded Clinical Records (CCR)

UBHT has provided to the Inquiry the medical records of all children who underwent cardiac surgery over the period 1984 to 1995, identified through the PAS and Surgeons' Logs (SL). Evans

(1999) describes how records were identified of 1875 children who satisfied the inclusion criteria, from which summary sheets were produced and entered onto a database. Admission dates were not available and so operations have been used as the unit of activity and coded using the OPCS4 scheme by a very experienced team. However, relevant cases may not have been identified, and incompleteness of clinical notes is a problem that may limit the conclusions that can be drawn from this source.

4.4 Bristol Surgeons' Logs (SL).

Hand-written and typed logs of the operations of two surgeons (Mr Dhasmana and Mr Wisheart) have been provided to the Inquiry. These cover the whole period of interest, contain details of the patient and the operation and its outcome, and had been used as a basis for internal audit and submissions to the UK Cardiac Surgical Register (CSR) although with no formal validation. The information was summarised and coded by an experienced but different team from that coding the CCR. Admission dates are unavailable and so analysis is by operation. Only operations at the BRI, which would be expected to be only 'open' operations, are covered. 1318 operations on 1244 children were identified in these logs and coded according to the OPCS4 scheme.

4.5 South West Congenital Heart Register (SWCHR).

This was set up and run by cardiologists rather than surgeons in order to obtain epidemiological information and as a clinical back-up, and has the advantage of having a single record for each individual patient which should avoid 'double-counting'. Its background and potential quality limitations are discussed in detail in BRI Inquiry (1999c) and Murray *et al* (1999): in particular, not necessarily all the included operations were carried out in Bristol. They conclude that although there have been no systematic data-collection procedures, definitions or follow-up, the maintenance of common staff should help consistency. It could form the basis for a comprehensive audit, but substantial work would be required to validate the data.

4.6 National Hospital Episode Statistics (HES).

This national administrative database has been in existence since 1987, and forms the basis for Current performance indicators published by the Department of Health. Aylin *et al* (1999) review the evidence concerning the quality of the coding and the coverage. They conclude that HES could be reasonably reliable at a broad level of procedure groups, but judged that data before 1991 were unreliable. Data is provided by non-medically qualified clinical coders as part of hospital administration, and no clinical data apart from diagnosis and interventional procedures are recorded. As in the Bristol PAS system, which provided data for HES, episodes of care have to be linked into admission/spells for a single patient. A 'primary' procedure is then chosen using the mapping of Table 3.1: 18% of admissions mapped onto multiple consensus groups and required a choice using the ranking of Table 3.2. As already mentioned in Section 3.2.4, procedure codes are also mapped onto open/closed categories. Aylin *et al* (1999) report that a number of procedures have no recorded outcome, with Bristol having an excess of such missing data (19% and 3% for open and closed operations under 90 days, compared with 3% and 1% elsewhere). These incomplete records have been omitted from the analysis in this synthesis, although Aylin *et al* (1999) claim their major findings are insensitive to the true values of these outcomes.

4.7 UK Cardiac Surgical Register (CSR).

This register was established by the Society of Cardiothoracic Surgeons of Great Britain and Ireland in 1977, and collects anonymised data from centres on activity and mortality rates. Ages are categorised into under or over one year, and the latter group includes congenital heart operations on over 15's. Collection followed calendar years until 1993, when it changed to financial years: hence data from January 1993 to March 1993 does not feature in the register. Murray et al (1999) describe the serious quality issues regarding the register, which has had no validation or analysis, and little guidance as to completing the annual form and definitions of terms. There is unknown variability in the identity of seniority of person responsible within each centre for completing the returns, although a general opinion is that the quality of data returned by at least some centres has been low in the past. In particular, there is the possibility of missing deaths and, even though the centres are instructed otherwise, there could have been double counting activity and deaths by entering multiple procedures from the same operation. 1984 data have been excluded due to strong doubts about the consistency of the anonymised centre codes. In addition, Murray et al (1999) report that blank entries for numbers of deaths have led to that procedure being excluded if an open operation, and set to zero if closed. Furthermore, comparison with returns to a 1992 Working Party of the Royal College of Surgeons concerning activity in 1988-1991 showed considerable discrepancies.

The CSR is primarily based on diagnoses and so mapping into operative procedure groups may be somewhat contrived. Of particular concern is the mapping to the consensus groups G2 and G3. G3 is corrective repair of transposition of the great arteries (TGA), which in the OPCS4 coding scheme used for the other data sources corresponds to the later 'switch' operation. However, in the CSR there appears to have been substantial use of this category for earlier operations such as 'Mustard' and 'Senning', which leads to poor agreement between data sources for these groups in the earlier part of the period covered by the Inquiry.

4.8 Interpretation and conclusions.

There are clear limitations to all sources, and none is subject to defined procedures for data collection, follow-up and validation. It would be fair to say that none is held in high regard as a source of reliable evidence for clinical audit. In particular Murray *et al* (1999) conclude that the CSR is an unlikely source of reliable 30-day mortality data. However, the Bristol PAS system does appear of good quality and hence the returns to HES from Bristol might be expected to be of similar status. The next section examines the extent to which the sources agree on the activity and outcomes in Bristol.

5. Comparison of sources of data on Bristol.

5.1 Introduction.

All six sources of data described above are available for comparison, with the restrictions that PAS is not available in Epoch 1, and HES not for Epoch 1 and 2. Also, CSR groups age categories 1 and 2. The analysis in this Section compares the six sources within Epoch, pooling over age groups. Sources are compared with respect to apparent activity and number of deaths, using both the 13 consensus procedure groups and (except for SWCHR) the open/closed classification. Certain sources do not provide data on all consensus groups, and occasional inappropriate closed operations recorded in Surgeons' Logs are not considered.

5.2 Comparison.

Tables 5.2.1, 5.2.2 and 5.2.3 show the counts for available sources of data within each of the three epochs. The variability between the sources is summarised by the *Coefficient of Variation*. Values of CV that around 20% could be considered as having reasonable agreement, and less than 10% as having good agreement. The set of clinical records in CCR was partly derived from surgeons' logs, so CCR should include all cases in SL. Disagreement on operation dates between different clinical sources can lead to differences between SL, CCR and PAS.

For many of the procedure groups the agreement is reasonable: for example, in Epoch 3 the coefficients of variation for mortality rates are reasonable for Fallot (*14*), TAPVD (21), AVSD (*15*) and the sum over procedure groups 1 to 13 (*13*). For open operations in general the agreement is remarkably good (*5*). There is poor agreement of CSR with other sources for Groups 2 and 3 for reasons discussed earlier but, if CSR is ignored, agreement is fairly good for G3 (switches). Better agreement may be attributable to procedures that can be fairly unambiguously coded. PAS appears to record more admissions.

5.3 Interpretation and conclusions.

Evans (1999) concludes that where direct comparison is sensible, the pattern is similar and there are no startling discrepancies. Although there is no gold standard for comparison, the Bristol PAS system appears of reasonable quality, and hence the returns made to the national HES database may not be too misleading. Our overall comparison suggests that the different sources agree well on the open operations in general and for many specific procedures.

6. Comparison of HES and UKCSR data on all centres.

6.1 Introduction.

The HES and CSR data may be compared across all centres in this analysis, although such a comparison must be limited to Epoch 3 (1991- March 1995). We also note that HES is missing data from Jan – March 1991 in this Epoch, while CSR is missing data from Jan - March 1993.

However, the overall period covered is three years in each case. Murray *et al* (1999) have carried out a detailed analysis which is summarised here, combining age groups 1 and 2 and hence categorising by less than or greater than 1 year.

6.2 Comparison.

Table 6.1, taken from Murray et al (1999), shows the number of cases and number of deaths from both sources, broken down by open/closed procedures, aged under and over 1, by centre, and by consensus procedure group. The ratios should be 1 if there were perfect agreement between HES and CSR.

- *Open/closed.* For open operations there are both more cases and more deaths reported in CSR than HES, leading to reasonably comparable death rates. Fewer deaths from closed operations are reported in CSR than HES.
- Age groups.There are again more cases and deaths reported in CSR than HES for both age groups,
leaving very similar death rates in the under 1's. Agreement is better in under 1's,
which might be expected as the CSR includes over 15's in the over 1 group. Murray *et*
al (1999) suggest up to 20% of cases in the CSR over 1 group may be over 15, which
would account for the discrepancy observed with HES.
- *Centres.* Across the centres there is a broadly consistent pattern of increased reporting of cases and deaths in CSR resulting in similar mortality rates. Bristol (Centre 1) is typical of this pattern. Centre 3 appears to have made very low returns to the CSR as to activity, although the number of deaths matches HES well.

13 consensus Reasonable agreement is seen for Groups 1, 4, 5, 8, 10, 13. Groups 2 and 3 show
 procedure better agreement if combined - see the discussion in Section 5. Group 6 (ASD) show
 groups. substantial more activity in CSR than HES, Group 9 (Fontan) shows less activity in CSR, and Group 7 (VSD) shows fewer deaths in CSR.

6.3 Interpretation and conclusions.

There is a broad picture of more activity and deaths being reported to the CSR, as compared to HES, but similar mortality rates. Centres show a reasonably consistent pattern in the level of agreement between CSR and HES, with Bristol being unremarkable. The agreement with individual procedure groups is not so good, but this may be expected as the mapping to the groups is based on very different criteria in the two sources. In particular, it was shown in Section 3.2.3 how the CSR could accumulate additional activity through coding multiple operations at the same admission, or even multiple procedures at a single operation.

7. Comparison of Bristol with national performance

7.1 Analyses being presented.

The statistical strategy for the analysis has been generally described in Section 2.3 and technical details are given in the Appendix. We shall present rather extensive tables for both CSR and HES, for each combination of procedure group, epoch and age for which information is available. However, we shall concentrate our discussion on the tables in Section 7.4 that show all sources of data for specific procedure groups.

The following headings occur in the tables in this section:

Mortality in 11 other centres	The number of deaths, the number of cases and the mortality
	rate pooled over all 11 centres other than Bristol.
Mortality in Bristol	The number of deaths, the number of cases and the mortality
	rate in Bristol.
Estimated true mortality rates	The estimates (dots) and 95% intervals (lines) for the true
for "Bristol and elsewhere"	mortality rate in a 'typical' centre (derived from the data from
	other centres), and that in Bristol (derived from the data from
	Bristol). Lack of substantial overlap in these intervals points
	to divergent performance.
Expected deaths if 'typical'	The number of deaths that would have been expected in

	Bristol, had it been a 'typical' centre.
Excess deaths (95% int)	The numbers of deaths in Bristol, minus the number expected
	were it 'typical'. We can be 95% certain that the true number
	of excess deaths lies in the interval provided.
Prob(excess >0)	The probability that the true number excess deaths exceeds 0.
	This is 1 minus the probability of observing as many deaths as
	occurred in Bristol, were it really typical, by chance alone.
RR	The 'relative risk', defined as the observed number of deaths
	divided by the expected. Thus a RR of 1.4 corresponds to a
	40% excess mortality.
Rank (95% int) out of all	The rank of Bristol's mortality rate among those centres
centres	contributing data – we can be 95% certain that the true rank
	lies in the interval provided.
Prob Bristol highest	The probability that Bristol truly had higher underlying
	mortality than all the other units in England.

7.2 Summary results for open and closed operations across all four epochs.

Table 7.2 contains the mortality data for HES and CSR with respect to open and closed operations, divided into those aged under 1 and over 1 at operation. In general the HES and CSR data agree well. For closed operations, and to a large extent the open operations in over 1's, Bristol appears to follow the national pattern. There are clear differences, however, in open operations under 1. Over the period covered by the Inquiry, mortality in other centres has been steadily declining from around 20% in the mid-1980's, to around 12% in 1995. In Bristol the mortality rate was, according to data submitted to the CSR, around 25-30% in the mid-1980's, and both CSR and HES show that the mortality rates stayed at that level until 1995, when there was a sudden decline to below national averages. This corresponded to the arrival of a new surgeon, although we emphasise that the pattern of surgery may have changed at this point and so this decline requires further investigation.

Figure 7.2 displays the results for open operations under 1 and over 1, showing both the consistency of HES and CSR data, and the apparent delayed fall in mortality experienced in Bristol.

7.3 Detailed results for HES.

Tables 7.3.1 to 7.3.4 show the HES results for Epoch 3 for each of the age groups and for all ages combined. Aylin *et al* (1999) discuss these results in detail, identifying the following groups as having is markedly higher mortality in Bristol than elsewhere: for children aged less than 90 days, Group 3 ('switches') and for open operations; for children aged 90 days to 1 year, Group 6 (AVSD) and open operations, and for all age groups combined, 6 of the 13 groups and the open class. The results for each procedure group in turn are discussed in Section 7.4.

As an example of how to read the tables, consider the results for the combination of procedure groups 1-13 shown in Table 7.3.1 corresponding to children under 90 days. 9.4 deaths would have been expected in a typical centre, and 24 were observed in Bristol. The excess mortality is estimated to be 14.6, and this has a 95% uncertainty interval of 8 to 21 deaths. There is essential certainty that excess mortality exists, as such a high observed mortality would not have occurred by chance alone. Examining the other tables shows that for combined 13 procedure groups, we can be essentially certain there was excess mortality for Bristol in children under 90 days and for 90 days to 1 year, with an overall total excess over all age groups of 35.6 (95% interval 23 to 49) deaths out of 67 observed.

7.4 Detailed results for CSR.

Tables 7.4.1 to 7.4.12 show the CSR results for each combination of epoch and age group, for the each of the three epochs combining ages, for the two age groups combining epochs, and finally for all the data combined. Murray et al (1999) discuss these results in detail, and they are described for each procedure group in turn in Section 7.4. Here we only consider the combined outcomes of the 13 procedure groups. Tables 7.3.8 and 7.3.9 show that we can be at least 98% certain there was excess mortality in Bristol in both 1988-1990 and 1991-1995 when combining all age groups.

7.5 Combined results for CSR and HES for each procedure group.

Tables 7.5.1 to 7.5.15 show combined results for the 12 consensus procedure groups with data from both sources, and the open/closed classification. In reading these tables, attention should focus on the consistency of results across sources and across epochs – in particular, we can directly compare the two sources for Epoch 3, 1991 - Mar 1995.

The findings can be summarised as follows:

G 1	Tetralogy of Fallot	Although the CSR data in individual epochs does not confidently
		indicate excess mortality, pooling across epochs shows Bristol
		having a mortality of 14% versus 7% elsewhere, with 11.4
		excess deaths (95% interval 0 to 19) out of the 22 recorded. HES
		shows good agreement with the Epoch 3 CSR data. Although
		Bristol ranked 11 th out of 12 from in the over 1's, there is a wide
		interval around this rank.
G 2	Interatrial TGA	There is no evidence of excess mortality in Bristol.
G 3	Other TGA (switch)	This group is not similarly recorded in CSR and HES, with CSR
		including procedures other than switches. While CSR suggests
		some excess mortality in under 1 years for 1991-1995, HES
		shows a 90% mortality in under 90 days compared with 10%
		elsewhere, so we can be essentially certain of excess mortality
		estimated to be 7.8 out of 9 deaths (95% interval 5 to 9). There
		is a 90% chance Bristol is the lowest ranking centre for switch
		under 90 days.
<i>G4</i>	TAPVD	CSR shows a consistent pattern of excess mortality in the under
		1's, leading to a pooled figure of 9.9 excess deaths out of 17
		recorded (95% interval 2 to 15). HES closely supports the CSR
		data for Epoch 3.
G 5	AVSD	CSR shows a consistent pattern of excess mortality in both age
		groups, leading to an overall mortality of 32% compared with
		14% elsewhere. This leads to an estimated 12.4 excess deaths
		out of 25 recorded (95% interval 3 to 20). HES shows an even

poorer performance than CSR for Epoch 3, with 9.1 excess deaths out of 12 for this period alone.

G 6	Closure of ASD	CSR shows a consistent pattern of excess mortality in the very
		few operations carried out on under 1's, leading to a pooled
		mortality of 50%, although only based on 10 cases, compared
		with mortality elsewhere of 6%. This corresponds in this age
		group to 4.2 excess deaths out of 5 recorded (95% interval 2 to
		5). HES shows an even poorer performance than CSR for Epoch
		3 in the under 1's, with 4.5 excess deaths out of 5.
G 7	Closure of VSD	There is no evidence of excess mortality in Bristol.
G 8	Truncus Arteriosus	This operation has a high mortality of around 50% from 1984-
		1991 although the CSR suggests this dropped in 1991-1995 to
		around 25%. Although both CSR and HES report higher
		mortality than elsewhere, we cannot be confident that this was
		not due to chance alone.
G 9	Fontan type	The CSR provides evidence that there was excess mortality in
	operations	the over 1's over the period 1988-1991, but based only on 11
		cases. HES and CSR do not provide evidence of excess
		mortality in 1991-1995.
G 10	Aortic and pulmonary	CSR shows no evidence of excess mortality in Bristol over the
	valve procedures	period 1984 – 1991. There is substantial disagreement between
		CSR and HES for 1991-1995: HES reports 96% certainty of
		excess mortality with 5 deaths compared with only 1.6 expected,
		while CSR only records 1/34 deaths.
G 11	Mitral valve	CSR shows no evidence of excess mortality in Bristol, and there
	procedures	is substantial disagreement between CSR and HES for 1991-
		1995.
G 12	Closed Shunts	There is no evidence of excess mortality in Bristol.
G 13	Simple Coarctation	There is no evidence of excess mortality in Bristol.
G 88	Open	CSR shows a consistent pattern of excess mortality in both age
		groups, particularly in the under 1's, leading to a mortality in
		this age group of 26% compared with 16% elsewhere. This
		corresponds to an estimated 29.6 excess deaths out of 90

recorded (95% interval 0 to 53). In Epoch 3, CSR estimates an
excess mortality of 24.1 out of 71 deaths, while HES shows an
even poorer performance with 34.3 excess deaths out of 62 for
all ages. In particular, for children under 90 days, HES shows a
mortality of 63% compared with 16% elsewhere. This
corresponds to an estimated 13.9 excess deaths out of 19
recorded (95% interval 8 - 18). Bristol is virtually certain to be
the lowest ranking unit in children under 90 days. We note that
for children over 1, Bristol is unlikely to be the lowest ranking
unit, and this is discussed further in Section 8.G 99 ClosedAlthough some excess mortality is suggested in cases less than 1
year over the period 1984-1991, there is no strong evidence of
excess mortality in Bristol.

7.6 Other outcomes.

Aylin *et al* (1999) examine outcomes other than mortality using the HES data for 1991 to 1995, although they emphasise the limitations of this approach.

Complications	For open operations, Bristol recorded a higher proportion of	
	admissions with central nervous system, cardiac, respiratory and	
	urinary complications, when compared with other centres.	
Length of stay	For both open and closed operations, substantially fewer patients were	
	discharged from Bristol within 7 days compared to elsewhere.	

These findings must be interpreted with caution. Bristol's recording of diagnostic information appears better than other centres, and hence reporting of complications may be more complete. Increases in both complications and length of stay could be a consequence of quality of care, but also could be a consequence of more severely ill patients being treated.

7.7 In what ways might Bristol differ from other centres?

Aylin *et al* (1999) use the HES data for 1991 to 1995 to investigate a number of ways in which Bristol's activity might differ from other centres, and hence might explain some of the observed divergent behaviour. A brief summary of their findings, which are very tentative in the light of the limitations of HES data, is set out below.

Referrals and	Catchment areas can be defined geographically or on the basis of where the		
activity.	majority of patients arise. For open procedures, the ratio of residents going		
	out of Bristol's geographical catchment area to those coming in was high: for		
	children under 1 no residents from other parts of England were operated on in		
	Bristol. Relative to the <i>empirical</i> catchment area, activity appears neither high		
	nor low.		
Age distribution.	There was a much smaller (7%) proportion of children in the under 90 day		
	group than elsewhere in England (22%).		
Primary	Bristol had fewer ill-defined diagnoses than elsewhere, suggesting Bristol had		
diagnoses.	good quality coding.		
Down's	For open operations, there was a slightly larger (10%) proportion of having		
syndrome.	Down's syndrome than elsewhere in England (7%).		
Socio-economic	Bristol had a much smaller (11%) proportion of children living in the most		
deprivation.	deprived areas than elsewhere in England (22%). However, mortality in open		
	procedures does not appear to be related to deprivation.		

The finding of most interest is the lower proportion of very young children having open operations in Bristol. This may mean that they were more severe cases and provide some explanation for higher mortality in that age group. This might suggest focussing on ages under 1 year as a more robust category for comparison.

8. Comparative performance of other individual centres.

8.1 Comparative tables.

The analysis described above has been repeated for each centre in turn, estimating the excess mortality and 95% interval within each stratum for both CSR and HES data. The tables in this section summarise the conclusions for both data sources, within each age and epoch combination and also pooled over age-groups. Estimated excess mortality is given for each centre in each procedure group, highlighting with an asterix when there is greater than 99% probability that there is positive excess mortality: the high value of 99% is chosen due to the large number of comparisons being made.

8.2 Results for HES

Tables 8.2.1 and 8.2.2 show that, in children less than 90 days, only Bristol was over 99% certain to have excess mortality in any procedure groups. In those aged 90 days to 1 year, there was one non-Bristol centre/group combination with 99%-certain excess mortality, and Bristol was the only centre showing evidence of excess mortality in open operations. Table 8.2.3 shows a slightly different picture for ages 1 to 15, in that Centre 10 is now identified as an divergent centre, with an estimated 22.4 excess deaths in open operations out of 35 observed deaths.

Table 8.2.4 pools over all age groups and reveals Bristol and Centre 10 as the only centres with evidence of overall excess mortality the 13 combined procedure groups, and for open and closdd operations. Bristol has an estimated excess mortality of 32.8 out of 69 deaths, while Centre 10 is estimated to have 31.8 excess deaths out of 70 observed. No other centre remotely approaches these apparently divergent performances.

These results are illustrated by Figures 8.2.1 and 8.2.2, which show the data for open and closed operations from HES for all centres in the period 1991-1995. Figure 8.2.1 shows that Bristol's mortality rate of 63% in children under 90 days is not approached by other centres, its rate of 19% in 90 days to 1 year is also divergent, and that for children ages 1 to 15 Centre 10 has an outlying mortality. For closed operations, the only feature of note is the outlying mortality of Centre 10 in ages 1 to 15 years.

8.3 Results for CSR

Tables 8.3.1 to 8.3.12 reveal a variety of sporadic instances of 99%-certain excess mortality. It is perhaps best to focus on any consistent behaviour on the major open/closed classification. Three main patterns emerge.

- In Table 8.3.10 Centre 5 shows excess mortality for closed operations under 1 year for the combined period 1984 to 1995: examination of Tables 8.3.7 and 8.3.8 reveals that this excess only occurred in 1984-1990.
- In Table 8.3.11 Centre 10 displays excess mortality for open operations, for children over 1 year, over the combined period 1984-1995. Tables 8.3.2, 8.3.4 and 8.3.6 show that this pattern was consistent across the entire period.
- Bristol (Centre1) has excess mortality in a number of separate categories, particularly in aggregated consensus groups in under 1 year for both 1988-1990 and 1991-1995.

These results are illustrated by Figures 8.3.1 and 8.3.2, which shows the data for open and closed operations from CSR for all centres in the period 1984-1995. The only consistent patterns for open operations are the high mortality of Centre 10 in all groups and high mortality in Bristol in under 1 years after 1988. For closed operations Figure 8.3.2 shows that Centre 5 has reported to the CSR apparently divergent performance in children under 1 year between 1984 to 1990.

8.4 Interpretation and conclusions.

This comparison reveals consistent evidence from the two sources that one other centre apparently had excess mortality similar to that of Bristol's: Centre 10 for open operations in children over 1 year over the period 1984 to 1995. There is also some evidence that Centre 5 had excess mortality in closed operations in children under 1 year from 1984 to 1990, but this conclusion is based only on uncorroborated data reported to the CSR. We have no means at present of checking the accuracy of the data from these centres, and so these conclusions must remain very tentative. Apart from these findings, the remaining centres appear to show a very consistent pattern with only isolated evidence of high mortality in specific procedure groups.

9. Summary and conclusions.

9.1 The available data sources.

These are admittedly imperfect, and suffer from lack of agreed operating procedures for ensuring completeness and accuracy of data. There is, in particular, strong doubts about the CSR's lack of agreed procedures and the variability in the responsible individual, while both CSR and HES suffers from coding and classification limitations and lack of complete follow-up data. Nevertheless, the six sources on Bristol's activity and outcome agree well in the areas identified by this analysis as being of primary interest: open operations in general, and Fallot, switch, TAPVD, AVSD and ASD in particular.

9.2 Summary of findings concerning Bristol, assuming data of impeccable quality.

The information obtained from HES and CSR show a reasonably strong degree of consistency, except where there are known categorisation problems. Bristol shows no consistent evidence of excess mortality in closed operations, for Inter-atrial TGA (Group 2) and VSD (Group 7). However, there is strong and consistent evidence of excess mortality in open operations, particularly in younger age groups. In children less than 1 year old at operation, HES data estimates that in the period 1991-1995, only 12.7 of 41 recorded deaths would have been expected were Bristol a 'typical' centre (95% interval 4 to 21), while CSR suggests the excess mortality dates back at least to 1988. Open procedures on children aged less than 1 that can be identified with reasonable consistency as having excess mortality include 'switches', operations for TAPVD, AVSD and, although rare in this age group, ASD. Mortality was high for truncus operations, but this could be due to chance alone. In over 1's, there is some evidence for excess mortality in Fallot-type and AVSD operations.

9.3 Does this indicate Bristol has divergent performance, when allowing for the quality of the data sources?

Although having clear quality limitations, the evidence from HES and CSR is broadly consistent across both Bristol and other centres. Thus, although no source can be considered as representing the true state of affairs, their consistency, and the fact that they are derived from very different

sources, suggests that their findings reinforce each other. We therefore conclude that the imperfections of the data do not cast serious doubt on the apparent divergent performance of Bristol in the identified areas.

10. Suggestions for next stages in statistical strategy.

10.1. The strategy.

The purpose of this exploratory stage was to investigate whether there was consistent evidence for divergence of Bristol's performance, and if so to indicate in which areas. This has been achieved. It now seems appropriate to focus on the areas identified in Section 9.2. It must be emphasised, however, that we have neither confirmed the existence of this divergent performance, nor seen whether it can be explained by case-mix or other factors unrelated to quality.

10.2 Confirmatory stage.

Having identified procedure groups of interest, this next stage was intended to verify the findings. This could lead to additional checks on the Bristol data, and investigation of data sources in other centres in order to confirm the performance elsewhere. In doing so, it would be important to record data on important risk factors in order to contribute to any explanation of divergent performance. The Bristol data could also be further subdivided by surgeon, adding to the analysis presented by Evans (1999). However, the strong consistency of the Bristol data sources in the areas of maximum concern suggests that the divergent behaviour would not be explained by obtaining better quality data.

10.3 Explanatory stage.

Ideally a full risk-adjustment scheme would be derived for the areas identified in this synthesis, and the Bristol cases and a stratified random sample of cases from elsewhere compared with regard to

these risk factors. Thus an attempt could be made to identify through case review whether the Bristol patients were systematically different, which inevitably would require the use of information from other centres. There is also a need to relate outcomes to the process of care in Bristol. However, it appears unlikely that such a substantial divergence would be explained by standard patient-specific risk factors, and any explanatory investigation needs to be based on strong clinical insights.

Acknowledgements

The help of the Secretariat to the Inquiry, particularly Ruth Chadwick, is gratefully acknowledged. Paul Aylin, Gordon Murray, Stephen Evans and Nicky Best all contributed both data and ideas to this synthesis, which could not have been done without them. Mr Leslie Hamilton and Dr Kate Bull provided invaluable help on coding. The author, however, takes full responsibility for the opinions expressed in this report.

References

Aylin P, Alves B, Cook A, Bennett J, Bottle A, Best N, Catena B and Elliott P. (1999). *Analysis of Hospital Episode Statistics for the Bristol Royal Infirmary Inquiry*.

BRI Inquiry (1999a) Issues list for Part I of the Inquiry.

BRI Inquiry (1999b) The Inquiry's approach to making use of relevant data sources.

BRI Inquiry (1999c) Preliminary overview of existing data sources relevant to the Inquiry's remit.

Department of Health (1998) A First Class Service: Quality in the new NHS.

Evans SJW (1999). A Report on Local Data Relating to Children who Received Cardiac Surgery under the terms of reference of the Bristol Royal Infirmary Inquiry.

Gelman A., Carlin JB, Stern HS and Rubin D. (1996). *Bayesian Data Analysis*. London: Chapman and Hall.

Goldstein H. (1995) Multilevel Statistical Models 2nd Ed, Edward Arnold, London.

Goldstein H. and Spiegelhalter DJ (1996). League tables and their limitations: Statistical issues in comparisons of institutional performance. *Journal of the Royal Statistical Society, Series A*, **159**, 385-443.

Marshall EC and Spiegelhalter DJ (1998). League tables of *in vitro* fertilisation clinics: how confident can we be about the rankings? *British Medical Journal*, **316**, 1701-4.

Murray G, Lawrence AE and Pollock J (1999). UK Cardiac Surgical Register and South West Congenital Heart Register: a Statistical Analysis and Review of Key Data Sources Relevant to the Inquiry's Remit.

Technical appendix.

A.1 Primary statistical issues.

The main statistical issues and their adopted solutions are summarised as follows: see the technical appendix of Aylin *et al* (1999) for further discussion.

Issue	Solution
Many individual subgroups of patients are of interest	Stratify data by centre (12 categories), operation group (up to 15 categories), epoch (up to 4 categories), age-group (up to 3 categories).
The performance of each centre is to be compared with the national profile.	A symmetric analysis in which each centre is excluded in turn, the remaining baseline centres modelled, and the 'outlyingness' of the excluded centre assessed.
Allow for inevitable between-centre variability.	Use a variance-components (random-effect) model for the 'baseline' centres, in which mortality rates (on a logit scale) are assumed drawn from a normal population distribution.
What should be used as a measure of 'typical' performance?	By adopting a random-effects model, we are implicitly using the performance of an average centre as a basis for comparison, rather than the average mortality rates of all patients treated. To see why these might be different, consider three clinics, one with 110/1000 (11%) mortality rate and two others with $5/100 (5\%)$ and $1/100 (1\%)$ mortality rates. Then of the 1200 patients treated, the mortality rate of an average <i>patient</i> is $116/1200 = 9.6\%$, while the mortality rate of an average <i>clinic</i> could be said to be 5%. Our random effects analysis attempts, in a less naïve way, to estimate the latter quantity.

Measure the extent to which the excluded centre is `divergent'. An excluded centre could be said to be truly `divergent' if its true performance did not even appear to be drawn from the distribution from which the other centres were drawn *- i.e.* its performance is divergent, even allowing both for its internal sampling error and the variability between centres. Some of our plots contrast the estimated interval for the true performance of a centre based on the likelihood arising from its own data, with that predicted from the remaining centres were it 'typical'. A suitable way of summarising the divergence between these intervals is by the estimated excess mortality in each stratum, obtained by obtaining the predictive distribution for the number of deaths in Bristol, subtracted from the observed number of deaths. This can be thought of as an unnormalised unconditional residual in a multilevel model (Goldstein, 1995, pp 41-42).

Pooling over strata.The excess mortalities can be summed over strata, in a similar
manner to the O-E statistics of a Peto/Cochrane meta-analysis
summary. This is essentially an indirect standardisation.

Many of the strata willThis points to the importance of interval estimates based on non-
asymptotic analysis.

Is a Bayesian orA full-probability (Bayesian) model has been adopted using exactfrequentist analysislikelihoods and Markov chain Monte Carlo methods for inference.appropriate?As far as possible, minimally informative prior distributions have
been adopted and sensitivity analysis carried out to alternative prior
assumptions (see Section A.2). The WinBUGS software
(http://www.mrc-bsu.cam.ac.uk) has been used (see Section A.3), but a
similar analysis could have been carried out non-Bayesian software
such as MlwiN (Goldstein, 1995).

Estimation of varianceVariance components in different strata have been assumedcomponents in individual'exchangeable', in the sense that they are assumed drawn from a

strata may be unreliable.	common distribution with unknown parameters. The specific prior
	distributions are justified in Section A.2.
The role of ranking.	The rank of each centre compared to the other centres is an
	attractively simple summary statistic, and modern MCMC techniques
	allow appropriate inferences on the true underlying rank (Marshall
	and Spiegelhalter, 1998), including interval estimates and the
	probability that the centre is truly worst. This analysis does not
	require excluding each centre in turn: see Section A.2 for formal
	details of the prior assumptions made.
Combining across	This has been carried out by summing across excess mortalities.
operation groups.	

A.2 Specific modelling assumptions made.

A.2.1 *Notation*. This section is largely based on the technical appendix of Aylin *et al* (1999). It is helpful to introduce some notation to aid communication of the model:

c indexes centre, with c = 1, ..., 12 and c = 1 denoting BRI.

a indexes age-epoch group, with a = 1, 2, 3 denoting <90 days, 90 days–1yr and >1yr for HES data, and a = 1 to 6 denoting < 1yr and >1yr in epochs 1, 2, 3 for CSR data.

g indexes procedure group or operation class, with g = 1, ..., 13 and 88, 99.

 n_{cag} denotes number of admissions in centre c, age-epoch group a and procedure/class g

- d_{cag} denotes number of deaths in centre c, age-epoch group a and procedure/class g
- d_{cag} / denotes the observed mortality rate in centre *c*, age-epoch group *a* and procedure/class *g*.

n_{cag}

 r_{cag} denotes the 'true' mortality rate in centre c, age-epoch group a and procedure/class g

- m_{ag} denotes the (logit transformed) mean of the underlying distribution of mortality rates across centres 2-11 for age-epoch group *a* and procedure/class *g*
- v_{ag} denotes the variance of the underlying distribution of (logit transformed) mortality rates across centres 2-11 for age-epoch group *a* and procedure/class *g*

A.2.2. *Statistical model*. The observed number of deaths relates to the 'true' mortality rate through the standard Binomial distribution

$$d_{cag} \sim \text{Binomial}(r_{cag}, n_{cag})$$

where '~' means 'is distributed as'. This is the first level in our multilevel model. The second level is to specify the underlying distribution for the true mortality rates r_{cag} . A standard choice is to assume that the logit transformed mortality rate (*i.e.* the log odds of dying) for each centre follows a Normal distribution with unknown mean and variance:

$$\log[r_{cag}/(1 - r_{cag})] \sim \operatorname{Normal}(m_{ag}, v_{ag})$$

A.2.3. *Prior distributions*. We have adopted a Bayesian approach and so the third level of the model involves specifying prior distributions for the mean and variance of the underlying distribution of (logit transformed) mortality rates. We specify a minimally informative prior for the average mortality (on the logit scale), which might correspond to either:

$$m_{ag} \sim \text{Normal}(0, 1000)$$

or

$$m_{ag} \sim \text{Uniform}(-10, 10)$$

These are essentially equivalent to saying that a priori, all values of m_{ag} within a plausible range are equally likely. For the between-centre variances, we assume exchangeability across procedures/classes and age groups. That is, at the third level of the model, we assume that all the variances v_{ag} are drawn from a common prior distribution with an unknown mean:

$$\log(v_{ag}) \sim \text{Normal}(\mu, 1)$$

Choosing an exchangeable prior for v_{ag} allows us to pool information on between-centre variability in mortality rates across procedures/classes and age-epoch groups: independent estimates for the between-centre variance in each stratum *ag* are very unreliable due to their only being 11 centres with generally low numbers of operations. We allow the mean μ of the prior distribution for log(v_{ag}) to be unknown and assign it a minimally informative prior described above; this expresses virtual prior ignorance about the average value of the between-centre variances. We fix the prior variance of log(v_{ag}) to be 1, which corresponds to the belief that there could be at most 7-fold (*i.e.* sqrt($e^{2*1.96*1}$) range in the between-centre standard deviation in mortality rates across 95% of the strata. It would, in theory, be possible to estimate the variance of log(v_{ag}) but we are by this time at the fourth level of a model with rather sparse data, and greater stability is achieved by assuming a plausible value. This is the only stage of the analysis in which an informative prior distribution has been assumed, and sensitivity analysis suggests the precise assumption has little influence beyond inducing stability.

A.2.4 *Sensitivity analysis*. We carried out a range of sensitivity analyses to the various modelling assumptions. These included a comparison between logistic-normal and beta random effects distributions for the centre-specific mortality rates, and between various log-normal and gamma prior distributions for the between-centre variance components v_{ag} . The final inference concerning excess mortality in Bristol was robust to all choices considered.

A.2.5. *Ranking*. In the ranking exercise, the underlying statistical model assumes independent binomial distributions for the observed number of deaths in each centre and procedure/class and age strata, with uniform prior distributions on the 'true' mortality rate in each centre:

 $d_{cag} \sim \text{Binomial}(r_{cag}, n_{cag})$ $r_{cag} \sim \text{Uniform}(0, 1).$

A.2.6. *Calculating excess mortalities*. This is based on a predictive distribution for the number of deaths in a new centre with the same number of cases as in the excluded centre. The BUGS code given below shows this explicitly.

A.3 BUGS code used in the analysis.

This BUGS code follows the formulation given above, assuming centre 1 is to be excluded. This code should run under Classic BUGS or WinBUGS. Extra code is needed for calculating excess mortality on combinations of age-epoch strata, and data and initial value files have to be set up appropriately.

```
model
{
  for(g in 1:G) {
                              # Loop over procedure group
    for(a in 1:A) {
                              # Loop over age/epoch group
      for(c in 2:C) {
                               # Loop all centres except number 1:
         d[a,g,c] \sim dbin(r[a,g,c], n[a,g,c])
         logit(r[a,g,c]) <- b[a,g,c]</pre>
         b[a,g,c] \sim dnorm(m[a,g], v[a,g])
      }
      m[a,g] ~ dunif(-10,10)
                                  # 'vague' prior on stratum mean
      v[a,g] <- exp(logv[a,g])</pre>
      logv[a,g] ~ dnorm(mu, 1)
                                  # exchangeable log(precisions) with variance 1
      # predict mortality rate in a new centre for this stratum
      b.pred[a,g] ~ dnorm(m[a,g], v[a,g])
      logit(p.pred[a,g]) <- b.pred[a,g]</pre>
      d.pred[a,g] ~ dbin(p.pred[a,g], n[a,g,1]) # predicted number of deaths
                                                   # in centre 1
      excess[a,g] <- d[a,g,1] - d.pred[a,g]
                                                  # excess deaths
      p.excess[a,g] <- step(excess[a,g]-0.0001)  # Prob that excess > 0
 }
}
  mu ~ dunif(-10,10); # 'vague' prior for mean of log(precisions)
 }
```

Table 3.1.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	К06	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;	Closure of VSD	Yes
	K11 is superior code to K10)		
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)

Rank	Group	Description
1	G 8	Truncus Arteriosus
2	G 9	Fontan type operations
3	G4	TAPVD
4	G 3	Other TGA
5	G 2	Interatrial TGA
6	G 5	AVSD
7	G 11	Mitral valve procedures
8	G 10	Aortic and pulmonary valve
		procedures
9	G 1	Tetralogy of Fallot
10	G 7	Closure of VSD
11	G 6	Closure of ASD
12	G 12	Closed Shunts
13	G 13	Simple Coarctation

 Table 3.2.
 Synthesis of Statistical Sources: Primary Procedure Ranking

(Note: If any operation features procedures falling into more than one of the consensus groups G1 to G13, the operation is assigned to the highest ranking Group. This table draws on expert clinical advice on the most common combinations of procedures and mortality rates.

	PAS Patient Administration System	CCR Coded Clinical Records	SL Surgeons' Logs	CHR South West Congenital Heart Register	HES Hospital Episode Statistics	CSR UK Cardiac Surgical Register
Purpose	Hospital administration and returns to HES.	Medical records.	Personal record for audit and constructing CSR returns	Epidemiological information and clinical back-up.	National administration system. Now used for DoH performance indicators.	Professional register for comparative anonymous audit.
Completed by:	Coders.	Medical personnel.	Surgeons.	Cardiologists.	Derived from PAS.	Surgical team in Bristol.
'Activity'	Episodes linked to form admissions/spells.	Operations.	Operations.	Operations.	Episodes linked to form admissions/spells.	Diagnostic group subdivided by 'corrective' and palliative' operations.
Grouping for synthesis.	Existing OPCS4 codes.	Coded into OPCS4 by expert team.	Coded into OPCS4 by expert team.	Mapped by expert consensus.	Existing OPCS4 codes.	Mapped by expert consensus in 13 groups. Open/closed provided on report.
Epochs available	2: 1988 - 1990 3: 1991 - Mar 95 4: Apr 95 - Dec 95	1: 1984 - 1987 2: 1988 - 1990 3: 1991 - Mar 95 4: Apr 95 - Dec 95	1: 1984 - 1987 2: 1988 - 1990 3: 1991 - Mar 95 4: Apr 95 - Dec 95	1: 1984 - 1987 2: 1988 - 1990 3: 1991 - Mar 95 4: Apr 95 - Dec 95	3: Mar 1991 - Mar 95 4: Apr 95 - Dec 95	1: 1985 - 1987 2: 1988 - 1990 3: 1991 - Mar 95 (not Jan – Mar 93) 4: Apr 95 – Mar 96
Age groups	1: 0 – 90 days 2: 90 days – 1 year 3: 1 year +	1: 0 – 90 days 2: 90 days – 1 year 3: 1 year +	1: 0 – 90 days 2: 90 days – 1 year 3: 1 year +	1: 0 – 90 days 2: 90 days – 1 year 3: 1 year +	1: 0 – 90 days 2: 90 days – 1 year 3: 1 year +	1+2:0 – 1 year 3:1 year +
Comments.	Considered to be of good quality. Late deaths may be missed.	Usual problems with incomplete medical records. Not all relevant records identified.	Only covers 'open' surgery at BRI.	'Child' is basis for records. Stable team.	Quality depends on local PAS systems. Missing outcomes on some admissions.	Completed by a range of staff . No validation. Missing years for some centres.

Table 4.1 Outline comparison of six available sources of data on Bristol's activity and outcomes.

No sources have validation procedures or systematic follow-up.

Table 5.2.1.

Bristol's activity and outcomes in Epoch 1: 1984 - 1987 - all ages Comparison of six different data sources

		Number of admissions							No of deaths								Mortality rates (%)							
		PAS	CCR	SL	CHR	HES	CSR	CV	PAS	CCR	SL	CHR	HES	CSR	CV	PAS			•	ES CSR	CV			
G1	Fallot type		48	64	54		49	14		9	12	7		7	27		19	19	13	14	19			
G2	Interatrial TGA		31	37	47		5	60		2	0	4		0	128		6	0	9	0	118			
G3	Other TGAs		2	1	2		35	167		0	1	0		3	141		0	100	0	9	180			
G4	TAPVD		15	16	17		17	6		4	4	4		6	22		27	25	24	35	19			
G5	AVSD		22	28			16	27		5	5			6	11		23	18	0	37	79			
G6	ASD		75	62	81		89	15		6	6	8		2	46		8	10	10	2	48			
G7	VSD		57	57	62		39	19		7	4	4		0	77		12	7	6	0	78			
G8	Truncus		4	4			4	0		2	3			3	22		50	75	0	75	71			
G9	Fontan type		7	1	9		4	67		3	1	1		2	55		43	100	11	50	72			
G10	Aortic, pulm		51	44	78		38	33		2	2	5		2	55		4	5	6	5	21			
G11	Mitral valve		12	2	3		5	82		3	1	1		1	67		25	50	33	20	41			
G12	Closed shunts		86							8							9							
G13	Coarctation		76		104		58	29		5		6		1	66		7		6	2	55			
	Total		486	316	457		359	20		56	39	40		33	23		12	12	9	9	17			
G88	Open		337	321			347	4		48	40			40	11		14	12		12	11			
G99	Closed		146				274	43		8				21	63		5			8	24			
	Total		483	321			621	32		56	40			61	21		12	12		10	12			
_																								

PAS: Patient Administration system, CCR: Coded Clinical Records, SL: Surgeons' Logs,

CHR: South West Congenital Heart Register, HES: Hospital Episode Statistics, CSR: UK Cardiac Surgical Register.

Table 5.2.2.

Bristol's activity and outcomes in Epoch 2: 1988 - 1990 - all ages Comparison of six different data sources

				Num	ber of	f adm	ission	S		I	No o	f dea	ths			Mortality rates (%)						
		PAS	CCR	SL	CHR	HES	CSR	CV	PAS	CCR	SL	CHR	HES	CSR	CV	PAS	CCR	SL (CHR HES	S CSR	CV	
G1	Fallot type	47	50	45	53		54	8	8	7	7	5		9	21	17	14	16	9	17	21	
G2	Interatrial TGA	37	28	37	38		3	52	3	2	0	2		0	96	8	7	0	5	0	95	
G3	Other TGAs	11	7	7	11		45	100	4	2	2	5		7	53	36	29	29	45	16	36	
G4	TAPVD	14	8	13	14		13	20	5	4	5	5		6	14	36	50	38	36	46	16	
G5	AVSD	40	14	25			21	44	7	4	6			8	27	17	29	24		38	32	
G6	ASD	46	85	69	84		87	23	3	10	10	6		2	61	7	12	14	7	2	56	
G7	VSD	66	81	76	85		70	10	8	9	8	11		6	22	12	11	11	13	9	15	
G8	Truncus	6	6	6			7	8	3	4	3			4	16	50	67	50		57	14	
G9	Fontan type	24	9	4	14		11	60	3	3	0	4		6	68	12	33	0	29	55	81	
G10	Aortic, pulm	35	32	32	31		35	6	2	5	2	1		1	75	6	16	6	3	3	77	
G11	Mitral valve	13	14	5	9		4	50	4	4	3	5		1	45	31	29	60	56	25	41	
G12	Closed shunts	58	61					4	6	10					35	10	16				32	
G13	Coarctation	79	66		94		62	19	4	5		12		0	95	5	8		13	0	84	
	Total	476	461	325	433		412	14	60	69	48	56		50	15	13	15	15	13	12	10	
G88	Open	337	349	324			412	11	49	58	47			68	17	15	17	15		17	8	
G99	Closed	132	107				279	54	9	11				16	30	7	10			6	31	
	Total	469	456	325			691	31	58	69	47			84	24	12	15	14		12	11	
				•				••						•••								

PAS: Patient Administration system, CCR: Coded Clinical Records, SL: Surgeons' Logs,

CHR: South West Congenital Heart Register, HES: Hospital Episode Statistics, CSR: UK Cardiac Surgical Register.

Table 5.2.3.

Bristol's activity and outcomes in Epoch 3: 1991 - March 1995 - all ages Comparison of six different data sources

		Number of admissions								1	No of	f dea ⁻	ths			Mortality rates (%)						
		PAS	CCR	SL	CHR	HES	CSR	CV	PAS	CCR	SL	CHR	HES	CSR	CV	PAS			-	HES		CV
G1	Fallot type	54	56	63	45	47	58	13	7	6	6	6	5	6	11	13	11	10	13	11	10	14
G2	Interatrial TGA	29	17	26	26	18	4	46	4	0	1	2	3	0	98	14	0	4	8	17	0	101
G3	Other TGAs	29	14	19	25	19	45	44	12	5	8	11	11	10	27	41	36	42	44	58	22	29
G4	TAPVD	20	14	22	21	14	19	19	7	4	5	9	5	6	30	35	29	23	43	36	32	21
G5	AVSD	39	33	44		34	41	12	13	13	13		12	11	7	33	39	30		35	27	15
G6	ASD	92	126	108	92	90	126	16	4	12	9	12	5	2	58	4	10	8	13	6	2	58
G7	VSD	115	108	106	72	93	90	16	4	4	4	3	1	0	66	3	4	4	4	1	0	64
G8	Truncus	9	8	10		5	8	23	4	5	4		3	2	32	44	62	40		60	25	33
G9	Fontan type	43	16	1	30	38	39	58	5	3	0	4	5	7	59	12	19	0	13	13	18	54
G10	Aortic, pulm	57	39	35	42	50	34	21	4	2	1	3	5	1	61	7	5	3	7	10	3	47
G11	Mitral valve	23	24	9	18	23	9	40	3	4	3	2	3	0	55	13	17	33	11	13	0	74
G12	Closed shunts	66	68			65		2	7	13			7		38	11	19			11		36
G13	Coarctation	101	92		80	92	61	18	2	2		3	2	0	61	2	2		4	2	0	66
	Total	677	615	443	451	588	534	17	76	73	54	55	67	45	20	11	12	12	12	11	8	13
G88	Open	501	476	454		457	563	9	65	68	61		62	71	6	13	14	13		14	13	5
G99	Closed	160	136			242	267	31	7	5			7	8	19	4	4			3	3	20
	Total	661	612	454		699	830	21	72	73	61		69	79	9	11	12	13		10	10	14
_										_				-	-			-		-	-	

PAS: Patient Administration system, CCR: Coded Clinical Records, SL: Surgeons' Logs,

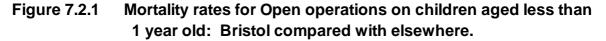
CHR: South West Congenital Heart Register, HES: Hospital Episode Statistics, CSR: UK Cardiac Surgical Register.

Table 6.1Comparison of UKCSR returns with HES data for 1991-1994. For 1991and 1992 the UKCSR data cover calendar years but the HES data cover financialyears. The HES data for 1995 cover only the nine month period April 1995 toDecember 1995. Admissions are grouped by Surgery, Age, Centre, ConsensusGroup and Year. Data for 1995 are only included in the tabulation by year.

	Num	ber of Ca	ases	Numb	er of De	eaths	Ratio of
	UKCSR	HES	Ratio	UKCSR	HES	Ratio	Death Rates
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	2352	2270	1.04	142	144	0.99	0.95
1994	2115	2126 0.99		143	131	1.09	1.10
1995	3509	1982	1.77	195	134	1.46	0.82

Table 7.2Activity and mortality in Bristol and elsewhere in four epochs,
grouped by open/closed and aged under or over 1.Data from both HES and CSR.

				HES			CSR		
		Epoch	Cases		Mortality rate (%)	Cases	Deaths	Mortality rate (%)	
Bristol									
Open	Under 1	1985-1987				63	16	25	
		1988-1990				108	31	29	
		1991-1995	143	41	29	181	43	24	
		1995	24	2	8	50	3	6	
Open	Over 1	1985-1987				284	24	8	
		1988-1990				304	37	12	
		1991-1995	314	21	7	382	28	7	
		1995	87	0	0	136	2	1	
Closed	Under 1	1985-1987				154	18	12	
		1988-1990				152	12	8	
		1991-1995	153	7	5	179	5	3	
		1995	31	0	0	54	0	0	
Closed	Over 1	1985-1987				120	3	3	
		1988-1990				127	4	3	
		1991-1995	89	0	0	88	3	3	
		1995	28	1	4	24	1	4	
Elsewher	9								
Open	Under 1	1985-1987				1308	275	21	
- 1 -		1988-1990				1863	336	18	
		1991-1995	3185	356	11	3161	395	12	
		1995	563	68	12	1049	126	12	
Open	Over 1	1985-1987				2989	242	8	
·		1988-1990				3333	225	7	
		1991-1995	4293	195	5	4508	232	5	
		1995	695	31	4	1305	42	3	
Closed	Under 1	1985-1987				1851	112	6	
		1988-1990				1750	96	5	
		1991-1995	1924	90	5	1839	57	3	
		1995	357	25	7	658	18	3	
Closed	Over 1	1985-1987				1293	21	2	
		1988-1990				1002	21	2	
		1991-1995	1200	21	2	792	21	3	
		1995	111	0	0	233	3	1	



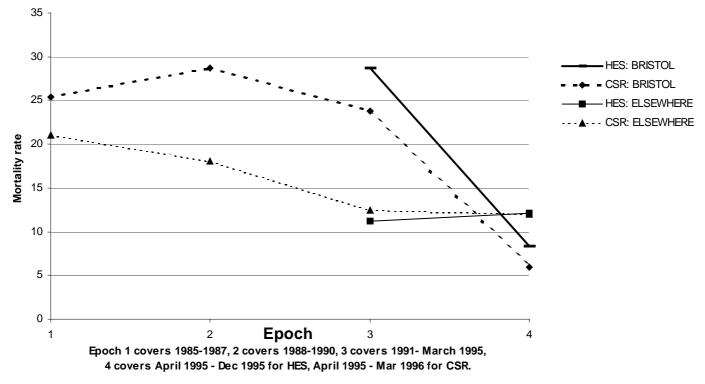


Figure 7.2.2 Mortality rates for Open operations on children aged more than 1 year old: Bristol compared to elsewhere.

