An investigation into the relationship between mortality and volume of cases in surgery for congenital heart disease from 1984 to 1995.

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Executive summary

1.	*Introduction.*	The statistical analysis presented to the BRI Inquiry has raised the issue of whether outcomes are related to the volume of surgery and, if so, to what extent the results observed in Bristol might be attributable to the lower volume of cases. Three past studies in the US have shown that 'high'-volume institutions have lower surgical mortality rates in paediatric cardiac surgery than 'low' volume. However, there are severe methodological weaknesses in all three studies.
2.	*Materials and methods*	Data from both the Cardiac Surgical Register (1984-1995) and Hospital Episode Statistics (1991-1995) were analysed. Methodological characteristics include: analysis of open operations stratified for case-mix, not selecting a single threshold as defining high/low volume, removing Bristol from the analysis, and allowing for correlations between individuals in the same institution.
3	*Results.*	For open operations in under 1s, and for arterial switches and AVSD in particular, there is strong and consistent evidence for an association between mortality rates and volume (not taking into account any data from Bristol), in which higher-volume centres have lower mortality. Stratifying for operation-mix, or including the results from Bristol, strengthens this association.
4	*Conclusions and discussion.*	We estimate that a hospital carrying out 120 open operations a year on patients ages under 1 in 1991-1995 would be expected to have an underlying mortality rate 25 % lower than one carrying out only 40 such operations. If the hospitals had exactly the same age- and operations mix, this reduction is increased to 35 %. These are relative changes - implications in terms of the difference in numbers of deaths depend on the context. However, considerable caution is needed in interpreting these results, and it does not necessarily follow that concentrating resources in fewer centres would reduce mortality rates. Using the association found in other centres, we estimate that only around 12% (HES) or 17% (CSR) of the excess mortality observed in Bristol in open operations in under 1s might be explainable by the lower volume of surgery being carried out in Bristol.

List of contents.

Glossary.

Generalised estimating equations	A statistical technique that adjusts for within-institutional correlations when calculating the precision of estimates.
ICD9	International Classification of Diseases version 9.
Logistic regression	A statistical technique for estimating odds ratios.
Odds on death	Mortality rate / survival rate. For example, a mortality rate of 20% (survival rate 80%) corresponds to an odds on death of 20/80 = .25. For low mortality rates, odds is approximately equal to the risk of death.
Quasi-likelihood adjustment	A statistical technique technique that adjusts for within-institutional correlations when calculating the precision of estimates. An 'over-dispersion' factor is estimated, which measures the extent to which the results of centres vary more than would be expected were there no within-institution correlation. All estimated variances are inflated by the ratio of the residual deviance to the residual degrees of freedom.
p-value	The chance of data as extreme as that observed occurring by chance alone.
Risk	This term has been used interchangeably with 'odds on death'.
r	The percentage change in odds on death (termed 'risk' in this document) associated with a specified change in annual volume of cases.
Stratifying for case-mix in logistic regression.	Estimation of an odds ratio associated with volume, allowing for different underlying risks in procedure groups.
Within-institution correlation	The tendency for patients within an institution to have similar outcomes due to the influence of common factors.

1. Introduction.

1.1 Background

The statistical analysis presented to the BRI Inquiry led to an interest in whether there was an association between volume of cases and outcomes in paediatric cardiac surgery and, if so, to what extent the results observed in Bristol might be attributable to the lower volume of cases. In this report we briefly review the relevant literature, re-analyse the Inquiry data with respect to volume, and present tentative conclusions.

1.2 Potential statistical problems in studies investigating outcome and surgical volume.

A good study should have the following protection against biases:

- *Case-mix*. There should be adjustment for case-mix, to avoid smaller (or larger) centres appearing to have poor performance due to carrying out more complex surgery.
- *Volume definition.* The definitions of 'low' and 'high' volume should be made before the analysis, to avoid post-hoc selection of thresholds to maximise the apparent difference.
- *Influence of single centres*. The conclusions should not be driven by the very good or bad performance of just one or two centres.
- *Within-institution correlations.* It should be recognised that the unit of analysis is really the hospital rather than then individual patient, and hence statistical methods should take into account institutional effects that may induce a correlation between patients within a single hospital. This is related to the need to adjust the analysis in a clinical trial when patients have been randomised in clusters, say by general practice.

1.3 Published literature.

There is an extensive literature investigating the relationship between clinical outcomes and the volume of cases being treated by an institution or individual. Dudley *et al* (2000) provide a recent review in which they identify 72 articles covering 40 procedures, the majority of which show a significant association between volume and outcome – references are provided to studies in cancer, intensive care, hip replacement, heart transplantation and a wide range of other procedures. Dudley *et al* (2000) select the best quality studies, and estimate the lives that might be saved were patients in California selectively referred to high-volume hospitals.

1.3.1 Adult cardiac surgery.

Dudley *et al* (2000) identifies 11 studies relating outcome with volume of adult cardiac surgery, of which 9 show a statistically significant association. The potential importance of case-mix in such comparisons has been emphasised (see, for example, Sowden *et al* 1995). In a large recent study, Sollano *et al* (1999) consider 97137 cardiac operations in New York State between 1990 and 1995, and after adjusting for clinical risk factors they find there was no significant relationship between volume and outcomes. This is in contrast to an earlier study on New York patients (Hannan *et al*, 1991), and may reflect the increasing concordance between institutions following the intensive quality assurance programme in New York State.

1.3.2 Paediatric Cardiac surgery.

Three papers are summarised below, focussing on the issues raised in Section 1.2. Stark *et al* (2000) find no relationship between surgical volume and mortality, but their analysis is based on very small numbers of events. No claim is made that these papers are the only published examples, but they are the major studies cited in the literature.

Jenkins *et al* (1995)

Patients. 2833 children undergoing cardiac surgery in 37 centres in California in 1988 and Massachusetts in 1989.

Data source. Administrative data-base with ICD9 codes.

Definition of 'volume'. Pre-determined groups : < 10, 10 to 100, 101 – 300, > 301 cases per year. Only two hospitals were in the top group.

Case-mix. Four pre-determined operation complexity categories defined on basis of ICD9 codes.

Statistical methods. Plotting mortality rates by complexity and volume category. Estimated odds ratios for each volume category, adjusting for complexity category. Generalised estimation equations used to allow for within-institution correlations.

Conclusions. No significant difference between three lowest volume categories, but adjusted mortality rate in highest-volume hospitals was significantly lower.

Comments. The conclusions are based entirely on the effect of two large centres of excellence.

Hannan et al (1998)

Patients. 7169 children undergoing cardiac surgery in 16 centres in New York State between 1992 and 1995.

Data source. Clinical data-base with individual risk factors.

Definition of 'volume'. Post-hoc split between 'low' and 'high' volume hospitals defined as 100 patients per year, chosen to maximise statistical significance of difference.

Case-mix. Four complexity categories of operation fed into risk-adjustment index derived from logistic regression.

Statistical methods. Risk-adjusted mortality rates for low and high volume hospitals compared without taking into account within-institution correlations.

Conclusions. Risk-adjusted mortality rate in high-volume hospitals was significantly lower, with the least difference occurring in the highest-risk category.

Comments. The post-hoc definition of a low-high volume threshold, and the lack of allowance for within-institution correlation, invalidate the statistical tests of significance.

Sollano *et al* (1999)

Patients. 7199 children undergoing cardiac surgery in 16 centres in New York State between 1990 and 1995.

Data source. Administrative data-base with ICD9 codes.

Definition of 'volume'. Treated as continuous quantity, separately within each age category (1-30 days, 31 days – 1 year, 1-12 years, 13-17 years).

Case-mix. Four complexity categories of operation as used by Hannan *et al* (1998).

Statistical methods. Logistic regression analysis to estimate mortality odds ratio associated with additional 100 patients over 6 years. Use of generalised estimating equations to take into account within-institution correlations had negligible effect.

Conclusions. A significant relationship between mortality and volume was found for neonates (1-30 days) and 31 days -1 year, with the largest difference occurring in the highest-risk category.

Comments. This study covers essentially the same population as Hannan et al (1998), but using a different data source and statistical methodology. The graphs accompanying the analysis suggest that one large hospital (possibly Columbia-Presbyterian in New York) is having a very substantial influence on the analysis.

1.4 Conclusions.

All three studies have data at individual level and have dealt with case-mix by grouping operations into four risk categories. They adopt a variety of statistical methods when adjusting for case-mix and age, but have all concluded that larger hospitals are associated with better outcomes. However, there are severe methodological weaknesses in all three studies as outlined in the comments above.

2. Materials and methods

2.1 Data sources.

These have been described in detail in Aylin *et al* (1999), Murray *et al* (1999) and Spiegelhalter (1999). The Cardiac Surgical Register (CSR) comprises voluntary returns made by the surgeons to their professional society, while the Hospital Episode Statistics (HES) for 1991-1995 comprise administrative data entered by clinical coders.

2.2 Should Bristol be included in the analysis?

This study has been generated by attention to the results of Bristol, a low-volume centre, and hence it is highly likely that Bristol will be very influential in any analysis. It is also inappropriate to test hypotheses on the same data as that which generated the hypothesis. Thus the primary analysis has been carried out without including Bristol as a centre – this also provides an unbiased assessment of the extent to which any excess mortality in Bristol can be explained away by the lower volume of cases. Results including Bristol are also reported and Bristol is included in plots of raw data.

2.3 Issues in analysis.

The issues raised in Section 1.2 are dealt with in the following way:

- *Case-mix*. Each of the 13 procedure groups has been individually analysed. However, there are acknowledged difficulties in the coding at this level of detail, and so the primary analysis has been based on both pooled open operations and stratified for procedure groups 1 to 11. This stratification estimates a common association within procedure groups, and should be more robust to errors in allocation to procedure groups.
- *Volume definition.* Volume has been defined as the number of cases being treated in the appropriate epoch and age-group. It is a continuous quantity and no threshold between ‘low’ and ‘high’ volume hospitals has been adopted.

- *Influence of single centres*. The plots allow a visual assessment of whether individual centres are having undue influence.
- *Within-institution correlations*. All standard errors and p-values are adjusted for within-institution correlation using a 'quasi-likelihood adjustment' (see Glossary).

2.4 Statistical analysis.

The stages of the statistical analysis are as follows:

- The mortality rate for each centre is plotted against volume for each type of operation, within each age-group and epoch, for both CSR and HES data. The <90 day and 91 day - 1 year age-groups are pooled for the HES data to permit direct comparison with CSR. Prediction limits are superimposed on the plots, assuming constant mortality across centres (Stark *et al*, 2000).
- The relative change in odds on death (expressed as a percentage) per additional unit of volume per year (1 patient or 10 patients) is estimated for each plot, with confidence intervals and p-values allowing for within-institution correlations, and excluding the effect of Bristol. Logistic regression is used to estimate the odds ratio associated with specified change in volume – for example, an odds ratio of .96 per additional patient per year corresponds to a value of r = 100 (1 - .96) = - 4 %. This would mean that for each additional operation of the type carried out, we estimate that the risk (expressed as odds on death) is reduced by 4%, say from a mortality rate of 25% to 24%.
- The estimated relative change in risk is estimated for all *open* operations within age groups, with and without Bristol, and with and without stratification for case-mix, for both data sources for the period 1991-1995. This is repeated for all *closed* operations within age groups, with and without Bristol.

3. Results.

3.1 Relationship between mortality rate and volume for individual procedure groups.

Figures 1.1 to 1.15 show for each of the 13 procedure groups and all open and all closed operations the % mortality rate for each centre (Bristol is indicated by a different symbol), plotted against the volume of cases. See Section 2.4 for details of the statistical analysis – we again emphasise that the association between volume and outcome has been estimated without using the data from Bristol. The results are summarised in Table 1.

Figure 1 and Table 1 show that for all open operations in under 1s, and for switches (Group 3) and AVSDs (Group 5) in particular, there is strong and consistent evidence for an association between mortality rates and volume (not taking into account any data from Bristol). The relationship for open and closed operations generally is examined in more detail in the next sections.

3.2 Association between mortality and volume for open operations.

Figures 2.1 and 2.2 show the estimated relationship between risk and volume for open operations in 1991-1995 for under and over 1s, with 95% confidence intervals for the predicted true mortality rate for each volume. For children under 1, both HES and CSR show a consistent pattern in spite of disagreement in data.

Figures 2.1 and 2.2 use pooled data over all operations, but we can also stratify for operation groups 1 to 11. Results are summarised in Table 2. It can be seen that stratification for case-mix has increased the estimated association between mortality rates and volume – this might be expected if larger centres carried out a greater proportion of more complex operations. Although the HES results for 91 days to 1 year are not statistically significant on their own, the estimates are not statistically significant from those in the neonatal group (1 to 90 days) and it would be inappropriate to claim there was only evidence for an association in neonates.

Table 3 repeats the analysis including the data from Bristol. The associations grow both in their size and statistical significance.

3.3 Association between mortality and volume for closed operations .

Figures 3.1 and 3.2 show the estimated relationship between risk and volume for closed operations in 1991-1995 for under and over 1s, with 95% confidence intervals for the predicted true mortality rate for each volume. The results are summarised in Table 4. Table 4 and Figure 3 do not display a consistent pattern across data sources: the significant association observed for CSR under 1s is not shown by the HES data, and the strongly significant association for HES over 1s is clearly primarily driven by a single centre.

Comparing Tables 4 and 5, we note that the inclusion of Bristol has negligible influence for closed operations.

4. Conclusions and Discussion.

4.1 Conclusions.

A significant association has been found between mortality outcomes and volume of surgery in children less than 1 year old for open operations in the period 1991-1995, even when removing any influence of Bristol. This effect is consistent across both data sources, and becomes more pronounced when stratification for mix of operations is carried out. This finding is not driven by undue influence of just one or two centres.

It is useful to consider the estimated impact of these associations on absolute mortality rates in 1991-1995. Table 6 shows the expected change in mortality rates in open operations in under 1s, comparing a baseline hospital treating 40 patients a year (corresponding to a volume of 160 in Figure 2.1) with a mortality rate of 15 %, compared to hospitals treating 80 and 120 patients a year. Note that these are 'average' hospitals rather than specific institutions. Based on both HES and CSR data shown in Figure 2 and Table 2, *r* may be estimated to be around - 4 % without adjusting for age and operation mix, around - 6% when adjusting for age and operation mix. A value of *r* = - 6 % means that each additional 10 patients per year is expected to change the odds on death by a factor of .94: hence 40 extra patients reduces the odds on death by a factor of .94 x .94 x .94 x .94 = .78 of its current value. This corresponds, for example, to a reduction of a current mortality rate of 15% to 13%.

Thus we estimate that a hospital carrying out 120 open operations a year on patients ages under 1 in 1991-1995 would be expected to have an underlying mortality rate that is 25 % lower (11.3% *vs* 15% mortality rates) relative to one carrying out only 40 such operations. If the hospitals had exactly the same age- and operations mix, this reduction is increased to 35 % (9.7% *vs* 15% mortality rates).

It is useful to examine the extent to which the association with volume might explain the apparent excess mortality in Bristol. Table 7 shows, for both data sources, the mortality rates for open operations in under 1s, between 1991-1995 (***A***). Subtracting the mortality rate elsewhere (***B***) provides a simple estimate of the excess mortality rate (***C***). However, from the fitted line in Figure 2.1 we can estimate the expected mortality rate in Bristol, were it typical of the other centres in the country (***D***). Allowing for the `volume effect' (***E***) reduces the excess mortality in Bristol. Finally, the proportion of the unadjusted excess (***C***) explained by volume can be calculated (***E***).

The data sources are consistent in showing that only a small proportion of the excess mortality observed in Bristol can be attributed to their being a low-volume centre.

For closed operations, there is some evidence of an association, but the most significant finding is driven by the results of a single centre and hence cannot be considered reliable.

4.2 Discussion.

Great caution is needed in interpreting these findings and drawing policy conclusions. It would, for example, be tempting to examine the HES data shown in Figure 2.1 and draw a cut-off around 200 operations, corresponding to one operation per week between 1991 and 1995. Total mortality in centres below that volume was 14.7% (not including Bristol) or 16.7% (including Bristol), while total mortality in centres above that volume was 10%. Dudley *et al* (2000) used such data to calculate the number of 'potentially avoidable deaths' were patients at 'low' volume centres treated at 'high' volume centres.

It is certainly feasible that concentrating treatment in fewer centres may lead directly to benefits in outcome through, for example, increased opportunities for surgical learning. However, Posnett (1999) warns that such 'economies of scale' cannot be guaranteed. Volume might be associated with better outcomes without necessarily being a direct cause through, for example, being a 'proxy' for –

- a longer institutional history
- better associated service such as intensive care
- the ability to attract and retain skilled staff
- the ability to attract more patients through reputation

and none of these would necessarily be obtained by, say, merging the caseload of two centres. It is also important not to extrapolate beyond the available data, since further increase in volume of larger centres may even lead to poorer outcomes if communications starts to decline. Finally, it is possible that the concordance between centres may have increased after 1995, as experience with operations such as the arterial switch operations has been gained.

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	Operation type	*Negative association between outcome and volume?*	*Comments on evidence for negative association.*
G1	Fallot type	7 / 8 *	Strongest evidence 1984-1990 in over 1s – increased concordance after 1991.
G2	Inter-atrial TGA	1 / 4	No consistent evidence.
G3	TGAs (~switch)	7 / 7 *	Consistent and strong evidence in all ages between 1984 and 1995
G4	TAPVD	2 / 4	No consistent evidence.
G5	AVSD	8 / 8 *	Consistent and strong evidence in under 1s between 1984 and 1995
G6	Closure of ASD	2 / 6	Just two centres drive significant association in 1988-1990 under 1s.
G7	Closure of VSD	7 / 8	No consistent evidence.
G8	Truncus	4 / 4	No consistent evidence.
G9	Fontan type	6 / 6	Evidence of association between 1988 and 1990 in over 1s.
G10	Aortic, pulm	6 / 8	CSR suggests association between 1991-1995 but only weakly supported by HES
G11	Mitral valves	4 / 7	No consistent evidence.
G12	Closed shunts	1 / 2	No consistent evidence.
G13	Simple coarctation	2 / 4	No consistent evidence.
G14	All open	8 / 8 *	Strong and consistent evidence in under 1s
G15	All closed	4 / 8	Evidence from HES 1991-1995 for over 1s, but driven by one centre,

Table 1. Summary of estimated relationships between volume and outcome within individual procedure groups shown in Figure 1. Each Figure contains up to eight plots with sufficient data to attempt to estimate the association between outcome and volume (at least five deaths) – the fraction of these plots that show a negative association is shown in column 3, with a * indicating strong and consistent evidence of association. (No use has been made of data from Bristol in these analyses).

			Without stratification for operation-mix		*With stratification for operation-mix*	
Data source	*Epoch*	*Age-group*	*Change in risk per 10 extra patients per year (95% interval)*	*P*	*Change in risk per 10 extra patients per year (95% interval)*	*P*
HES	1991-1995	< 90 days	-8.6 % *(-14.5 to –-2.2)*	.0043	-11.2 % *(-17.6 to -4.4)*	.0008
		91 days – 1 year	-6 % *(-15.8 to 4.8)*	0.13	-8.6 % *(-20.6 to 5.2)*	0.11
		1 – 16 years	-2 % *(-8.1 to 4.6)*	0.27	-2.2 % *(-6 to 1.8)*	0.14
CSR	1991-1995	< 1 year	-3.4 % *(-5.6 to -1.2)*	0.0012	-6.1 % *(-9 to -3.1)*	< 0.0001
		> 1 year	-4.5 % *(-12.2 to 3.9)*	0.14	-7.1 % *(-11.7 to -2.3)*	0.0021

Table 2. Relationship between risk and volume in open operations between 1991-1995, *excluding Bristol.*

			Without stratification for operation-mix		*With stratification for operation-mix*	
Data source	*Epoch*	*Age-group*	*Change in risk per 10 extra patients per year (95% interval)*	*P*	*Change in risk per 10 extra patients per year (95% interval)*	*P*
HES	1991-1995	< 90 days	-11.7 % *(-20.4 to -2.1)*	.0.0089	-15.4 % *(-21.9 to -8.3)*	< 0.0001
		91 days – 1 year	-11.4 % *(-25.6 to 5.5)*	0.087	-16 % *(-27.6 to -2.6)*	0.01
		1 – 15 years	-2.4 % *(-8.1 to 3.7)*	0.22	-2.5 % *(-6.1 to 1.3)*	0.096
CSR	1991-1995	< 1 year	-4.2 % *(-6.9 to -1.3)*	0.0023	-6.7 % *(-9.7 to -3.7)*	< 0.0001
		> 1 year	-4.7 % *(-12 to 3.1)*	0.11	-7.4 % *(-11.9 to -2.6)*	0.0013

Table 3. Relationship between risk and volume in open operations between 1991-1995, *including Bristol.*

Data source	*Epoch*	*Age-group*	*Change in risk per 10 extra patients per year (95% interval)*	*P*
HES	1991-1995	< 90 days	-4.6 % *(-25.1 to 21.5)*	0.35
		91 days – 1 year	34.8 % *(-42.4 to 215.7)*	0.75
		1 – 16 years	-90.1 % *(-98.2 to -46.5)*	0.0036
CSR	1991-1995	< 1 year	-14.4 % *(-26.2 to -0.7)*	0.02
		> 1 year	-30.7 % *(-70.8 to 64.3)*	0.2

Table 4. Relationship between risk and volume in closed operations between 1991-1995, *excluding Bristol.*

Data source	*Epoch*	*Age-group*	*Change in risk per 10 extra patients per year (95% interval)*	*P*
HES	1991-1995	< 90 days	-4.9 % *(-23.9 to 18.9)*	0.33
		91 days – 1 year	34.7 % *(-40.1 to 202.9)*	0.76
		1 – 16 years	-91.7 % *(-98.4 to -56.1)*	0.0017
CSR	1991-1995	< 1 year	-14.3 % *(-25.7 to –1.2)*	0.017
		> 1 year	-29.9 % *(-68.7 to 57.0)*	0.19

Table 5. Relationship between risk and volume in closed operations between 1991-1995, *including Bristol.*

r = change in risk per additional 10 patients treated per year	*% Mortality rate in a baseline hospital treating 40 patients per year.*	*% Mortality rate in a hospital treating 80 patients per year.*	*% Mortality rate in a hospital treating 120 patients per year.*
- 4 %	15	13.0	11.3
- 6 %	15	12.1	9.7

Table 6. Illustration of the estimated effect on mortality rates when comparing hospitals with different volumes of cases. For open operations in under 1s, *r* has been estimated to be around 4% without adjusting for age and operation mix in 1991-1995, and around 6% when adjusting for age and operation mix (excluding influence of Bristol).

Data source.	*Mortality rate in Bristol.*	*Mortality rate elsewhere.*	*Excess mortality in Bristol, **not adjusted** for volume.*	*Expected mortality rate in Bristol, adjusted for volume.*	*Excess mortality in Bristol, **adjusted** for volume.*	*Proportion of excess mortality `explained' by effect of volume.*
	A	***B***	***C=A-B***	***D***	***E=A-D***	***1 – E/C***
HES	41/143 = 28.7%	11.2%	17.5%	13.3%	15.4%	.12
CSR	43/181 = 23.7%	12.5%	11.2%	14.4%	9.3%	.17

Table 7. Mortality rates for open operations in under 1s between 1991-1995, showing the extent to which the apparent excess mortality in Bristol can be explained by its volume of surgery.