

**Comments on statistical analysis and review of outcomes of paediatric
cardiac surgical services at Bristol and other specialist centres.**

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Comments on statistical analysis and review of outcomes of paediatric cardiac surgical services at Bristol and other specialist centres.

For a surgeon with only a rudimentary knowledge of statistical methods to comment on results of statistical studies is a daunting task. However, I believe that it may be helpful if a clinician reviews findings from such studies and considers them in a clinical context.

I am fully aware that comparing results of paediatric cardiac surgery between departments or between surgeons will always be difficult. Differences in nomenclatures and coding systems, complexity of diagnoses and operations, patients undergoing several procedures during one operation or several operations during the same or during different admissions contribute to these difficulties (1). The small numbers of some procedures performed by individual surgeons is another factor. It is therefore inevitable that compromises have to be made to obtain meaningful information from statistical analyses. For example, patients with different ages, diagnoses or operations are grouped together. However, it has always been stressed to clinicians that estimates of mortality rates should be based on complete and accurate data.

Statistical experts commissioned by the Bristol Royal Infirmary Inquiry to evaluate the results of paediatric cardiac surgery between 1984-1995 at Bristol faced a difficult task (2, 3, 4, 5). The data sets available for statistical analysis from Bristol and from other units have never been validated. After studying the data the statisticians have described them as "poor" (3)- INQ 0014 0002, "having limitations with regards to its quality" and "not ideal for the purpose of the Inquiry" (5) - INQ 0015 0003. I have been a reviewer for a number of Cardiothoracic journals and for many years a member of the Editorial Board of the Annals of Thoracic Surgery. I suspect that studies of mortality rates based on such data would not be considered for publication in any of these journals.

The statistical analysis of results in paediatric cardiac surgery at Bristol and other UK units relied mainly on HES data and the UK Cardiac Surgical Register (UKCSR) data.

HES data

The analysis considered only HES data covering the period between 1991 - 1995. The data collected earlier was described by Aylin et al (2) as not suitable for the analysis and was discounted (INQ 0013 0002).

Patients' records

From Aylin's report (2) I understand that the data used for the analysis was based on records of patients under 16 years of age with the code K* and L* from 1991/92 to 1995/96. (INQ 0013 0023). When I examined the original data set sent to clinical experts by

Dr Chadwick in May 1999, I did not understand why they included so many procedures performed almost exclusively in adults with acquired heart disease (K 40: 72 cases, K 45: 12 cases, K 49: 60 cases, K 572: 268 cases, etc). The only explanation I could envisage was that these procedures were performed on adult patients whose date of birth was coded incorrectly. In view of this, I wondered how many children with CHD had their age coded as being over 16 years and were therefore lost from the analysis?

OPCS 4 codes

Most surgeons are not familiar with OPCS 4 coding, as it is not used in their clinical work. Some of the codes are rather strange and for some procedures specific codes are missing. None of the paediatric cardiac surgery databases with which I am familiar use this coding system (6, 7, 8). The OPCS 4 coding system is not designed to deal with the complexity of congenital heart operations. I agree with the views expressed by Mr Keogh (9) when he discussed problems associated with hospital coding systems in his evidence to the BRI Inquiry. He commented that "the current NHS information technology is not sophisticated enough to deal with the sort of analyses that we need."

An example comparison of data collected at Great Ormond Street Hospital, London in the hospital system (PAS) with the data collected in the surgeons' database showed the discrepancies which are illustrated in Table 1.

TABLE 1

	1997/98		1998/99	
	<u>Open procedures</u>		<u>Closed procedures</u>	
	<u>No</u>	<u>Died</u>	<u>No</u>	<u>Died</u>
Hospital system	526	15	96	2
Surgeons' database	482	22	138	5

At Southampton General Hospital Monro (10) compared the data collected in the hospital system with the data collected in their departmental database for the year 1998/99. He found that 30 % of the diagnoses were entered incorrectly into the hospital system. He commented that the discrepancy was more likely due to be to the inconsistency/inaccuracy of codes rather than a reflection on the work of the hospital coders.

Although the years 1997-99 are outside the period examined by the Inquiry, it seems unlikely that the lack of accuracy of the data collected by PAS would be different during the years 1991-95.

Groupings

In order to obtain manageable numbers in categories for statistical evaluation, 13 "consensus" groupings of operations were devised. From Figure 2.1 (INQ 0013 0072) I understand that from the total of 41,529 admissions with K* and L* procedure codes, the data from 11,952 admissions (29%) was used for the analysis in these 13 consensus groups. I have discussed these figures with several colleagues and they were able to give me the numbers of all operations for CHD in their respective departments during the same four year time period (1991-1995). Table 2 shows numbers of all operations performed in individual departments and numbers of operations analysed in 13 HES groups. The percentages of operations included in the analysis varied from 69% to 98% between the departments.

TABLE 2

<u>Hospital</u>	<u>Departmental data*</u> <u>all operations</u>	<u>HES data **</u> <u>13 Groups</u>	<u>HES (%)</u> <u>of Dep Total</u>
Liverpool	1703	1460	86%
Southampton	830	639	77%
Newcastle	873	609	70%
Birmingham	2054	1469	71%
Leeds	1092	1068	98%
Great Ormond. St.	2140	1482	69%

*Data obtained between November 1999 and February 2000 from Mr Pozzi (11), Mr Monro (12), Mr Hamilton (13), Mr Brawn (14), Mr Watterson (15).

** From Figure 8.2.1. and Figure 8.2.2. (INQ 0015 0099-0100).

Aylin (2) comments (INQ 0013 0021) that HES data for 1991 - 1995 "is a potential source of useful information, assuming data quality for individual sites is comparable to national quality". The figures in Table 2 suggest that this may not be the case and I wonder what conclusions could be reached if the data quality for individual sites was not comparable.

Selection of operations for 13 consensus groupings

Groups 1 to 11 include "open" heart operations, while groups 12 - 13 include "closed" heart operations. The selection of operations into these groups was difficult as some operations of different complexity and different mortality had to be placed together. The case mix in these groups may vary between centres and makes comparison of mortality rates more difficult. Examples of such groups are groups G 3, G 6, and G 9.

- **G 3:** This group includes arterial switch operations for TGA and may also include Rastelli operations, REV and Damus-Kaye-Stansel operations, which are not arterial switch operations. Furthermore, switch procedures for double outlet right ventricle are almost certainly not included in G 3.

- G 6: Including secundum ASD and partial AVSD in one group is controversial. These two conditions present different clinical pictures, diagnostic problems, operative techniques and results. The differences are mainly related to the mitral valve, which has to be frequently repaired in patients with partial AVSD but not in those with secundum ASD or sinus venosus ASD.
- G 9 (Fontan type operation): This group includes codes K 19.1, K 19.2, and K 19.4, which are Fontan type procedures. It also includes the code L 091 which is described as "anastomose vena cava and pulm art". This operation is called the Glenn operation and is not the Fontan operation; it carries a low risk compared with the risk of the Fontan operation. Thus a centre performing more Glenn operations than the Fontan type operations would record lower mortality than a centre with a high proportion of the Fontan type operations.
- The exclusion of operations from these groupings, such as repair of double outlet right ventricle, some Rastelli operations and others, should also be noted. The overall figures for open and closed heart surgery obtained by the amalgamation of results for 11 "open" groups and two "closed" groups respectively do not equate the overall mortality for paediatric cardiac surgery. The mortality for excluded operations is unknown. The proportion of excluded operations varies between centres from 4% to 31% (Table 2).

UK Cardiac Surgical Register

Quality of data

Murray's (3) critical review of data collection and assessment of data quality in the UKCSR is very detailed and there is little I can add to it. Most paediatric cardiac surgeons I know have been concerned for some time about the quality of the UKCSR data, particularly about under reporting of death.

Perhaps I can describe my personal experience with the preparation of returns to the UKCSR at Great Ormond Street Hospital as this may help to understand some of the reasons for the poor quality of data. The data for the register was compiled from monthly mortality and morbidity reports by departmental secretaries and in later years by junior doctors. As some operations were difficult to place in an appropriate category (operations in the register are recorded under diagnoses, not operations), one of the consultants helped with the finalisation of the report. Operations which did not fit into any of the fields were then listed on separate sheets of paper. Over the years we have become aware that the data sent to the register were not accurate. When members of the department studied various diagnostic or operation groups they usually collected the data from operating books and discharge summaries. We have realised that up to 20% of operations (and deaths) could be missing

from monthly morbidity/mortality reports. As we did not have the means to validate the data submitted to the UKCSR, we had to accept these discrepancies.

Mapping

To allow comparisons between the UKCSR data and data from other sources such as HES, the UKCSR diagnostic categories were mapped into 12 of the 13 consensus groupings (shunts could not be mapped). Murray commented that "there is substantial variability from centre to centre in the degree of agreement between the UKCSR and HES. With the UKCSR being based on diagnoses rather than surgical procedures, it was not possible to devise a satisfactory mapping of the UKCSR data onto the consensus groups" (INQ 0014 0032). I would like to comment on the mapping of operations for TGA from four diagnostic groups in the UKCSR into G2 (intra-atrial repair) and G3 (other TGA - switch) groupings.

TABLE 3
TGA diagnostic groups used in UKCSR

		Number of operations	
		open	closed
A. TGA with intact vent. septum	palliative		
	corrective		
B. TGA with VSD	palliative		
	corrective		
C. TGA with VSD and PS	palliative		
	corrective		
D. TGA with other significant anomaly	palliative		
	corrective		

Before the introduction of the arterial switch operation, Mustard or Senning operations (intra-atrial repair) were recorded in any of these four categories as open corrective. Furthermore, in category C or D, Rastelli operation, Damus-Kaye-Stansel operation and other operations for TGA could have been entered as open corrective. After its introduction, the switch operation was recorded as open corrective while Mustard or Senning operations were recorded either as open corrective or open palliative. It is not clear how Rastelli and Damus-Kaye-Stansel operations continued to be recorded. A number of patients with TGA and complex additional anomalies were not placed into any of these four categories (A,B,C,D), but were listed on separate sheets of paper. In the absence of clear instructions, there was no consistency in "coding" of all these operations. I therefore believe that the operations recorded in the four diagnostic groups in the UKCSR cannot be mapped into G2 and G3 consensus groupings. The figures presented in TABLE 4. and TABLE 5. support this view.

TABLE 4

Numbers of operations for TGA at Bristol from three data sources (1984 - 1995)

	<u>Surgeons' logs*</u>	<u>SWCHR*</u>	<u>UKCSR**</u>
Group G2	99	111	12
Group G3	24	38	125

* Data from Table 14 (INQ 0014 0051).

** Data from Table 7.4.12 (INQ 0015 0067).

Surgeons' logs data and South West Congenital Heart Register (SWCHR) are described by Evans (INQ 0012 0015 - 17) and Murray (INQ 0014 0019 - 22). The numbers referring to intra-atrial repair (G2) from these two sources are generally considered to be reasonably reliable.

The total number of intra-atrial repairs for TGA (group G 2) recorded in the UKCSR for 11 centres between 1984 - 1995 was 267 (Tab 18 & 19, INQ 0014 0055-6). This figure seemed to be very low. I have asked surgeons from four departments to give me the numbers of intra-atrial repairs performed in their departments during the same period of time. The total number of intra-atrial repairs from these four departments (308) exceeded the number (267) recorded in UKCSR from the 11 centres. I have not therefore tried to obtain the data from the remaining seven departments. The figures from the four departments are shown on Table 5.

TABLE 5

Total number of intra-atrial repairs (Mustard and Senning operations) performed in four centres between 1984-1995 (data available from departmental records*).

Liverpool	124
Leeds	82
Newcastle	39
Great Ormond Street	63
<hr/> Total	<hr/> 308

* Personal communication from Mr Pozzi, Mr Watterson, Mr Hamilton, Dr Bull.

Data from Bristol

UKCSR data from Bristol included 2142 open and closed operations. The operations were analysed in two age categories for four epochs. The fourth epoch (1995-1996) was short and was not considered. Table 6 shows numbers of operations analysed in Bristol in each age category.

TABLE 6

UKCSR	<u>Under 1 year</u>		<u>Over 1 year</u>	
	Open	Closed	Open	Closed
1984-1987	63	154	284	120
1988-1990	108	152	304	127
1991-1995	181*	179	382	88

(From Table 7.5.14. and 7.5.15. - INQ 0015 0081 -2).

HES data in Bristol included 699 operations, which were analysed in 13 groups in three age categories, but only for the third epoch (1991 - 1995).

Table 7 shows numbers of operations analysed in each category.

TABLE 7

HES	<u>Under 90 days</u>		<u>90 day - 1 year</u>		<u>Over 1 year</u>	
	Open	Closed	Open	Closed	Open	Closed
1991-1995	30*	96	113*	57	314	89

(From Table 7.5.14 and 7.5.15 - INQ 0015 0081 -2).

The main difference between Bristol and other UK centres was found during the third epoch in open operations under one year. This group included 181 operations in UKCSR or 143 (30 + 113) in HES. Both groups are indicated with an asterisk on Table 6 and Table 7.

Results

Spiegelhalter (5) concludes in his summary that "in general the HES and UKCSR 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 UKCSR, around 25-30% in the mid-1980's and both the UKCSR and HES show that the mortality rates stayed at that level until 1995." (INQ 0015 0025).

The examination of Figures 8.3.1. and 8.3.2. (INQ 0015 0101-2) suggests that during the first two epochs the mortality rates at Bristol for open operations under 1 year were in fact not the worst in the country. Only during 1991-1995 the mortality apparently became much higher than that in other centres. According to figures available for Bristol from HES data, the category open under 90 days (1991-1995) included 37 operations of which 30 were analysed;

19 died. Some groups of operations (ASD, AVSD, VSD, Truncus, Ao/Pulm. valve) included only one or two operations. (Table 2.2. - INQ 0013 0055).

The category open 90 days to 1 year (1991-1995) contained 135 operations of which 113 were analysed; 22 died. Some groups of operations (TAPVD, Truncus, Fontan, and Ao/Pulm. valve) included only two to four operations. (Table 2.3. - INQ 0013 0056).

To try to explain the reasons for increased mortality rates is never easy. Many factors influence the outcome of surgery. Some are well known, others are only suspected. Often these factors are difficult to identify. As a clinician, I would like to understand why the department which seems to follow the national pattern in most categories of operations apparently differs so much in open operations under 1 year in the third epoch.

Perhaps it would help our understandings if these operations could be reviewed in more detail. This should not be too onerous a task, as this group comprises only 143 (HES) or 181 (UKCSR) operations (Table 5 and Table 6). It has been pointed out that in Bristol a smaller number of patients was operated during the first year of life than elsewhere. This could have influenced the case mix in this group.

Comparisons between Bristol and other centres suggest that mortality rates at Bristol were consistently in the bottom quartile of the distribution of centres. However, it is important to acknowledge that some operations at Bristol were carried out with good results which compared favourably with other centres.

The interpretation of the data presented by the statisticians is complex. From a clinicians' point of view to estimate and compare the mortality rates in very small groups of operations is not helpful (Figs. 2.2. and 2.3.-INQ 0013 0073-4). Similarly some figures for excess mortality estimated for individual centres and groups of operations (Tables 8.2.1. to 8.2.12. - INQ 0015 0083 - 98) need clarification. This is a new concept which currently few clinicians are equipped to understand. There is a need for clinicians and statisticians to work out approaches to present such information in a clinically meaningful way.

Other centres

To compare mortality rates of various operations obtained by pooling data from other centres with those published in literature or available from other countries would be an interesting exercise, but not easily undertaken. My impression is that the mortality rates available from UKCSR and HES were rather low. For example the mortality rate for "open under 90 days" for the period 1991-1995 at Toronto Hospital for Sick Children (19) was 26% in a group of 429 patients compared to 16% in a group of 1623 operations analysed from 11 UK centres during the same time period (tab 2.2. INQ 0013 0055). The Hospital for Sick Children in Toronto is a centre with an international reputation and long tradition of reliable

data collection. It is interesting to note that the mortality rate in Toronto was considerably higher than the estimated mortality rate in the 11 UK Centres (1991-95).

Complications

In HES data, central nervous system complications were mentioned in 1.6% admissions in Bristol, four times higher than elsewhere (0.4%) (INQ 0013 0004). The survey by Ferry (16) reported the prevalence of neurological morbidity ranging from 2 to 25 %. Fallon et al (17) reported 31 neurological events (6%) among 523 paediatric cardiac surgical discharges from Great Ormond Street Hospital during 1990-1991. It is clear that complications were not recorded adequately in HES and this data should therefore not be used.

Conclusion

The quality of the data available from HES and the UKCSR for a period 1984 - 1995 is of great concern. This raises serious doubts about the validity of any conclusions based on the analysis of this data. The use of such unreliable data for the assessment of the performance of the paediatric cardiac unit at Bristol may have wider implications. It may set a precedent for the future.

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Comments on statistical analysis and review of outcomes of paediatric cardiac surgical services at Bristol and other specialist centres.

Part 2 (17.5.2000)

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Comments on statistical analysis and review of outcomes of paediatric cardiac surgical services at Bristol and other specialist centres.

Part 2 (15.5.2000)

On 7 4 00 I submitted to the Inquiry "Comments on statistical analysis and review of outcomes of paediatric cardiac surgery services at Bristol and other specialist centres". In these comments I was mainly concerned with quality of data used for the statistical analysis and paid less attention to results presented in four statistical reports. I would now like to add some comments about the results and consider their interpretation.

Data from the UK Cardiac Surgical Register (UKCSR) covered the whole period of the Inquiry (1984-1995) and HES data the period of 1990-1995. As the analysis of these data was very detailed and considered four periods of time (epochs), 13 groupings of procedures (consensus groups), groups of open/closed procedures and three age groups in 12 departments of paediatric cardiac surgery (centres), the reports contain large numbers of results. Their interpretation is complex.

The aim of the Inquiry was to evaluate the performance of paediatric cardiac surgical services in Bristol in relation to the other 11 centres. Mortality rates and numbers of excess deaths were therefore estimated for each centre in several different ways to make this evaluation possible. As I have already explained, I am concerned about the quality of the data used for the analysis and its effect on the results. I have therefore selected some examples which illustrate this point.

Numbers of excess deaths in 12 Centres

Table 1. illustrates that it is difficult to assess the performance of an individual department if different estimates of excess deaths are considered.

Table 1

Estimates of excess mortality for all ages in 12 centres based on the analysis of 12 consensus groupings or open / closed groups from HES and 12 consensus groupings or open / closed groups from UKCSR

(1990-95).

Centre	1	2	3	4	5	6	7	8	9	10	11	12
HES												
12 groups	34	1	-24	9	-10	-19	-15	-14	2	20	-52	-6
HES												
Open/closed	33	-9	-34	1	-3	-18	-21	-20	2	32	-52	-19
UKCSR												
12 groups	15	-5	9	6	1	-14	-4	-11	-3	15	-47	-9
UKCSR												
open/closed	23	-14	10	-0.1	7	-14	-27	-13	-12	37	-75	-13

Figures for table 1 were obtained from Tables 8.2.4. and 8.3.9. (INQ 0015 0086 and 0015 0095)
Group G 12 was excluded from HES data in Table 1. to allow comparison with UKCSR data.

The four estimates of excess mortality in a centre should not differ much, as they all refer to the same operations performed by this centre during the same time period. However, in only one centre (centre 6) the difference between the lowest and the highest estimate of excess mortality was small. In all other centres the differences between the estimates of excess deaths were greater than 8. In centres 3 and 11 the difference reached 44 and 28 excess deaths respectively (confidence intervals were not given).

Excess mortality in Bristol

The figures of excess mortality in Table 2 were obtained from the executive summary of the "Initial synthesis of statistical sources" (0015 0004). Table 2 illustrates that using different estimates of excess mortality is confusing, even if the figures are similar. It shows that there was the same number of excess deaths estimated from consensus groups in HES and UKCSR for two different periods of time. The HES results were obtained for the four year period (1991-95) while the UKCSR results for the seven year period (1988-95). It seems unlikely that the number of excess deaths in Bristol would be the same for a four year and a seven year period.

Table 2

Four estimates of excess mortality for open heart surgery based on HES data and UKCSR data in Bristol

<u>Estimate of excess mortality</u>	<u>(from 0015 0004)</u>	
	<u>HES (1990-95)</u>	<u>UKCSR (1988-95)</u>
from 11 consensus groups	34.7	34.1
from all open group (G 88)	34.3	47.3

Excess mortality in 13 consensus groups (G 1- G 13)

Perhaps the most controversial results concern consensus groups G 2 and G 3, which include operations for TGA

Group G 2 should include all inter-atrial repairs of TGA. As explained in "Comments on statistical analysis" submitted on 7.4.00 the actual number of operations in this group based on UKCSR is very low and manifestly incorrect. Estimates of mortality rates and excess mortality based on these numbers should not therefore be used for evaluation of outcomes of inter-atrial repairs and should be discarded.

Group G 3 is called TGAs (~switch) (90015 0004) although it also includes other operations for TGA. Table 3 demonstrates that it would be misleading to use G 3 for evaluation of arterial switch operations. It shows that none of the 35 operations in group G 3 in UKCSR in the period 1984-87 could be a "switch", because the first switch was performed in Bristol only in February 1988. Of 90 operations in Group G 3 during 1988-1995, only 31 could have been arterial switches.

Table 3.

Number of operations in Bristol in group G 3 (UKCSR) and number of all switch operations in Bristol for TGA as presented at GMC hearing

Group G 3 TGAs (~switch) in UKCSR			Switch operations for TGA ("GMC hearing")		
	Operations	Deaths		Operations	Deaths
1984-1987	35	3	before 1988	0	0
1988-1995	90	17	Feb.1988 - Jan 1995	31	16
Total	125	20	Total	31	16

The validated list of all children who underwent arterial switch operations for TGA in Bristol, dates of operations, diagnoses and outcomes was available at GMC hearing. The first arterial switch was performed in February 1988, the last in January 1995. The total number of switches was 38, of which 31 were for TGA and seven for DORV. Switches for DORV are not included in Table 3 and Table 4.

(UKCSR figures were obtained from Table 7.5.3. on page 0015 0070).

The numbers of operations and deaths in group G 3 from HES in Bristol are shown in Table 4 together with numbers of switch operations for TGA available from the list presented at the GMC hearing. The mortality rate in G 3.(58%) is higher when estimated from HES data than the mortality rate for switch operation for TGA (44%) for the same time period, as presented at GMC.

Table 4

Results for group G 3 TGAs (~ switch) operations from HES data and results for arterial switch for TGA as presented at GMC hearing (1.4.1991-1995)

	Operated	died
Group G 3 TGAs (~ Switch)	19	11
Switch for TGA ("GMC")	25	11

HES results obtained from Table 7.5.3.(0015 0070)

Groups G 6, G 9 and G 10. Consensus groups G 6 (secundum ASD and partial AVSD), G 9 (Fontan type operation and Glen operation) and G 10 (operations for pulmonary and aortic valve) also contain mixtures of different operations which are known to carry different operative risks. Interpretation of results in these heterogeneous groups is difficult for a clinician.

Excess mortality in groups with small numbers of operations

Sixteen tables (8.2.1.-8.3.12) in the report "Initial synthesis of statistical sources" give estimates of excess mortality for each consensus group of operations and for open/closed groups by various age groups

in 12 centres, using HES and UKCSR data. The number of figures estimating excess mortality exceeds 2700. As a clinician I am not accustomed to handle such large amounts of numbers and find it difficult to understand the meaning of these figures, particularly when excess mortality is estimated in groups with a few operations. Table 5 gives some examples.

Table 5

	Operations	Deaths	Centres operating	Excess mortality in each centre
TAPVD *	39	1	10	-0.1,0.0,-0.1,-0.1,-0.2,-0.1,+1.0,-0.1,-0.3,-0.1
Truncus	24	6	12	0.5,0.8,-0.3,1.6,0.8,-0.6,-0.3,-0.3,-1.2,-0.3,-0.7,-0.6
Mitral valves	11	6	4	1.1 -0.6 -0.6 0.5 -0.2

* 9 departments performed 39 operations for TAPVD without mortality; one centre apparently reported one death. It is indicated that there was 99% certainty that excess mortality occurred in this centre. Data for excess mortality in table 5 were obtained from 0015 0084 and 0015 0083. Numbers of operations and deaths for TAPVD (HES) 90 days-1 year are from 0015 0071, for Truncus 90 days-1 year from 0015 0075, and for mitral valve < 90 days from 0015 0078.

From a clinical point of view to understand the meaning of excess mortality is not much easier, even if the excess mortality is estimated in groups with greater numbers of operations than those shown in Table 5. I believe that the estimation of excess mortality (deaths) is a new method, which as far as I know has not been evaluated yet. I am concerned that this method is now being used for assessment of performance in 12 departments of paediatric cardiac surgery for a period of 11 years.

Conclusion.

To assess performance of individual departments from the results available from the analysis of HES or UKCSR data appears to be a difficult task. I am not criticising the statistical methods; in any case this would be inappropriate for me to do so. I am mainly worried that some of the figures presented in the statistical analyses are undeniably wrong (UKCSR data for G 2), or are probably wrong (estimates of excess mortality in centre 3 - Table 1). Other results cannot be scrutinised, as with one or two exceptions, we do not have reliable data from any of the centres for the period under investigation . The results of the statistical analyses have been published on the BRI Inquiry Webb site. Subsequently some of them have been quoted in various articles and submissions both on the internet and in the public press. They may be used in any future assessment of other departments/surgeons.