

**The UK Cardiac Surgical Register :**  
**Assessment of Data Quality Issues for the Bristol Royal Infirmary**  
**Inquiry**

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## **Executive Summary**

This report describes a study to assess the quality of the data submitted to the Cardiac Surgical Register of the Society of Cardiothoracic Surgeons of Great Britain and Ireland (the Register) by twelve paediatric units during the Inquiry period.

Information was obtained from representative surgeons and other relevant staff from each of the units by means of a semi-structured interview and questionnaire. Interviewees were asked (i) to provide information on the data collection process at their unit, and (ii) to provide their subjective assessment of the quality of their unit's data.

The results show

- i. there has been considerable variability in the ways in which data have been collected in terms of staffing, sources of data and definitions applied;
- ii. the reporting of mortality is unreliable with under-reporting and, less commonly, over-reporting of deaths occurring at different units during the Inquiry period;
- iii. the classification of complex diagnoses, which are not uncommon, has been problematical and subjective, resulting in different surgeons using different categories for the same diagnosis, and in extremely varied use of the category 'miscellaneous – other';
- iv. surgeons have unanimously more confidence in the data they have provided to the Register than in that provided by the hospital administration system (HES), in terms of both procedures and deaths.

These findings lead us to conclude that the quality of the UKCSR data is inappropriate for comparative purposes at the level of diagnostic categories. The systematic differences between centres in the reporting of mortality will introduce substantial bias in comparing units.

## **Abbreviations**

ASD	Atrial septal defect
AVSD	Atrioventricular septal defect
HES	Hospital Episode Statistics
ICU	Intensive Care Unit
ONS	Office for National Statistics
PAS	Patient Administration System
RCSE	Royal College of Surgeons of England
TGA	Transposition of the great arteries
UBHT	United Bristol Healthcare NHS Trust
UKCSR	United Kingdom Cardiac Surgical Register
VSD	Ventricular septal defect

# **1. Introduction**

## **1.1 Background**

1.1.1 In November 1999, the Inquiry published four statistical reports which included analyses of existing data sources relevant to the Inquiry's remit <sup>1</sup>. The UK Cardiac Surgical Register is one of two national data sources which was used to provide comparative analyses of activity and outcomes in paediatric cardiac surgery at Bristol relative to specialist centres elsewhere. In their report on the UKCSR data <sup>2</sup>, Murray et al concluded that the data showed considerable variability and recommended that a study be made of the data collection process at the different specialist centres, in order to assess the primary data quality during the Inquiry period (1984 - 1995).

1.1.2 The report made the point that the primary issues which impinge most on the accuracy of data cannot be deduced from the data themselves, but require a clear understanding of the entire data collection process. Primary data quality issues include the extent to which

- clearly defined procedures are followed
- clear, unambiguous and objective definitions are used
- personnel are suitably competent and motivated to undertake their tasks
- data are validated and reproducible

1.1.3 An assessment of these issues in relation to the UKCSR data would reflect the degree to which data (from different units) are accurate and comparable.

## **1.2 Aims of the study**

1.2.1 The aims of the study were

1. To obtain information from the twelve relevant paediatric cardiac surgery units in England to assess (a) variability within the data collection process, and (b) the data quality of the annual CSR returns during the Inquiry period; and

2. To identify issues relevant to future improvements in recording data on the nature and outcomes of paediatric surgery.

### **1.3 Background to the UKCSR**

1.3.1 In 1977, the Society of Cardiothoracic Surgeons of Great Britain and Ireland (the Society) initiated a process which involved the voluntary submission by cardiac units of their annual figures for cardiac procedures on a standardised form to a central register.

1.3.2 The primary purposes of the Register [statement WIT 0163 0003] are

1. to track the development of the specialty in terms of overall activity;
2. to identify trends in the evolution of different procedures;

and the secondary purpose is to track and benchmark mortality for different purposes.

1.3.3 The Register was intended to cover all NHS cardiothoracic units in England, Wales, Scotland and Northern Ireland.

1.3.4 It includes all cardiothoracic operations, of which paediatric surgery forms only a part.

1.3.5 To encourage submission of data, units remained anonymous in any reported figures and individual surgeons are not identifiable.

1.3.6 Annual reports of the Society are simple totals of procedures and deaths from all contributing centres against which individual centres can compare their own data.

1.3.7 The last three pages of the data collection form deal with congenital heart disease. Data are recorded under diagnostic categories and grouped by age (under / over one year and, more recently, over sixteen years) and by type of procedure (open (on cardiopulmonary bypass) or closed). The number of deaths is also recorded under each diagnostic category.

1.3.8 The Register was not designed to allow comparative analyses of surgical outcome. It does not take into account risks associated with the condition of the patient, the complexity of the surgery or the precise type of operation.

1.3.9 Guidelines on completion of the form have been minimal (Appendix I), and well-defined procedures to standardise data collection and coding were never produced.

1.3.10 The central processing of the forms did not include systematic validation.

1.3.11 One surgeon at each unit was responsible for collating all cardiac surgical activity data for the unit and forwarding the completed form to the Society for processing.

1.3.12 In units where both adult and paediatric cardiac surgery took place, the responsible surgeon could be either an adult or a paediatric surgeon.

## **1.4 Study Methods**

1.4.1 Discussions were held with two senior paediatric cardiac surgeons, appointed clinical Experts to the Inquiry, to confirm areas of variability highlighted in earlier evidence to the Inquiry<sup>3</sup> and to identify potential additional areas of variability within the data collection process. One surgeon, Mr. James Pollock, was not a survey respondent, being from the unit in Glasgow, and therefore could offer an observer's perspective on the survey. The other, Mr. Leslie Hamilton, as a member of the Society's Executive Committee, was able to liaise with the committee on our behalf.

1.4.2 The study proposal was submitted to the Society and accepted prior to approaching the units to arrange interviews.

1.4.3 A detailed schedule was developed to form the basis of a semi-structured interview at each unit, to obtain information on both the current data collection process and the process(es) which applied during the Inquiry period. A face-to-face, semi-structured interview was felt to be the most appropriate approach, providing maximum flexibility in allowing researchers to explore beyond initial responses and to omit questions which were clearly not applicable in certain situations. This was particularly important as respondents were providing information for different periods and, occasionally, different units from the one in which they were interviewed. This approach also allowed respondents to volunteer additional, relevant information, and the fact that the interviews were in-house also allowed them to demonstrate or refer to systems, documentation and other relevant staff.

## Interview Topics

1.4.4 Questions were designed to explore potential areas of variability, including those identified in earlier evidence to the Inquiry, under the following general headings:

1.4.5 **Sources of data:** In order to produce the figures required for the Register, manual searching of different sources of data would have been necessary. Sources would vary between units, and would be expected to include some or all of operating theatre log, perfusionist log, ICU admissions book and local computerised record systems.

1.4.6 **Data collection process:** Variations in the type of personnel involved in the data collection and their methods of data collection and validation employed would be expected. Evidence presented to the Inquiry has suggested that, in practice, the actual collection of the data would often have been delegated to a junior surgeon or a secretary, sometimes at short notice<sup>3</sup>.

1.4.7 **Patient population:** The units are known to vary in the numbers of older children and private or overseas patients they treat, and these may or may not have been included in the figures submitted to the Register.

1.4.8 **In-hospital stay and patterns of discharge:** The length of hospital stay, and hence the length of time that patients were actively monitored within the hospital system, may have varied between units depending on the discharge options. For example, hospitals which did not have access to a district general hospital may have kept children in longer than those which did. In an analysis of HES data for the Inquiry, Aylin et al<sup>4</sup> have shown that only 2% of patients at Bristol were discharged within 7 days compared to 27% for the rest of England. Corresponding individual figures for the other units were not examined.

1.4.9 **Unit of data recorded and multiple records:** The guidelines for completion of the form state 'No operation should be entered more than once'. There was the possibility that the unit of measurement may not have been the patient, with multiple procedures / diagnoses being recorded separately.

1.4.10 **Recording of mortality data:** The post-operative time limit within which deaths were recorded for the Register, whether all-cause mortality was recorded and the extent to which

follow-up data were available are all issues which would have a major effect on the mortality figures for any unit.

1.4.11 ***Reproducibility of data:*** An earlier comparison of data submitted to the Register with similar data submitted to the Royal College of Surgeons of England (RCSE) Working Party for the period 1988-1991 showed substantial discrepancies between figures which should have been identical, and cast doubt on the ability of units to accurately reproduce their annual figures<sup>2</sup>. Questions exploring this issue were included in the interview, where relevant.

1.4.12 ***Other data collection systems:*** The existence of other local systems of data collection and the extent to which there were associated skills and resources in this area could potentially indicate a unit which would provide data of reasonable quality.

### **Self-completion Questionnaire**

1.4.13 A self-completion questionnaire was also designed to obtain consultants' subjective assessment of the accuracy of the data which they had submitted to the Register and how their figures compared to the local hospital administration figures (HES / PAS) (Appendix II). This included statements previously made about the Register in evidence to the Inquiry<sup>3</sup> and required responses on a Likert scale (Strongly agree, agree, don't know, disagree, strongly disagree). Respondents were asked to complete the questionnaire for *the unit and period for which they had submitted data to the Register*. It was made clear that the questions did not refer to the Register as a whole

1.4.14 Surgeons were asked at the end of the interview for their assessment of the accuracy and usefulness of the Register as a whole.

### **Interview Methods**

1.4.15 A small team of experienced researchers was recruited, with each individual given responsibility for arranging, conducting and reporting the interviews in a group of units.

1.4.16 The time-scale allowed for the study (four weeks from initial written contact to completion of all interviews) meant that proper piloting of the survey methods was not

possible. Interviews had to be arranged at a time convenient to the surgeons, who all had busy operating schedules, and it was not known in advance how long interviews were likely to take.

1.4.17 Three different interview methods were employed during the first four interviews, and an approach was adopted for the remaining interviews based on a review of these initial results. The methods used were single interviewer, two interviewers and two interviewers using taping equipment.

1.4.18 The consensus view among the researchers was that the two interviewer method (without taping) worked best, as it allowed one researcher to maintain the flow of the questions and the other to take extensive notes, without causing the unnecessary suspicion associated with taping the interview.

1.4.19 It was also decided that the same researcher should attend as many of the remaining scheduled interviews as possible, to maintain consistency of approach.

### **Personnel interviewed**

1.4.20 The units surveyed were the twelve whose data were analysed in the statistical reports to the Inquiry. These are Newcastle (The Freeman Hospital), Leeds, Liverpool (Alder Hey), Oxford (John Radcliffe), Leicester, Birmingham Children's Hospital, Bristol, Harefield, Brompton, Guy's, Great Ormond Street and Southampton.

1.4.21 The consultants currently responsible for submitting data to the UKCSR were identified, contacted and, in all but two cases, interviewed.

1.4.22 The two consultants who did not wish to be interviewed had not been involved in data collection during the Inquiry period, and we were able to interview instead others who could offer relevant information.

1.4.23 In many cases, the current consultant was able to provide information for a large part of the Inquiry period for either the same or a different unit. Where interviews were not possible, additional information was sought in writing from other surgeons.

1.4.24 Over a five-week period, a total of sixteen consultant paediatric cardiac surgeons, three consultant paediatric cardiologists, two data managers and one audit manager, representing all twelve units, provided information to the survey, fifteen of these by interview.

1.4.25 Interviews lasted between forty minutes and two hours.

1.4.26 Staff interviewed at three of the units had contributed to the Register during the whole Inquiry period, and a further six had contributed over a relevant period ranging from four to eight years. Consultants at the remaining three units have only been involved since the Inquiry period, and we were able to obtain information from other consultants for two of these units.

## **1.5 Limitations of the study**

1.5.1 Detailed quantification of the UKCSR data accuracy could only be obtained by detailed audit involving retrospective scrutiny of source data such as hospital records, logs and death records covering several years, at several centres. This was not feasible in the time available for the research.

1.5.2 A retrospective survey of the type we have undertaken is limited by many factors, but mainly by the identification and availability of relevant personnel going back 16 years, and by the extent to which such personnel are able and willing to relate accurately the relevant details of the data collection process, particularly given the sensitive nature of the topic.

1.5.3 One consequence of the events leading to the setting up of the Inquiry has been that the collection of cardiac surgical data has been highlighted. Most centres have now adopted a far more rigorous approach to the subject than was the case in previous years, and consultants are understandably keen to demonstrate the thoroughness of their current data collection systems, rather than to dwell on any possible earlier shortcomings.

1.5.4 A strength of the semi-structured interview method adopted is that respondents generally felt sufficiently at ease to offer important additional, unanticipated information. Where possible, such new issues could then be incorporated in the remaining interviews.

## **2. Survey Findings**

### **2.1 Sources of data**

2.1.1 Sources of data from which the figures for the Register were compiled included: hospital notes (containing correspondence, discharge letters, surgical data, etc.); surgeon's personal logs; operation notes; theatre register; paediatric admission book; ICU book; local computer system; perfusionist logs; anaesthetist logs; UK Valve Register.

2.1.2 None of these sources categorised data in the format set out for the Register and so they all required some degree of transcription and translation to match the Register's diagnostic categories.

### **2.2 Data collection process**

#### **Personnel**

2.2.1 Three units have employed non-medical data collection staff, research assistants and database administrators. At another unit, a clinical audit manager compiles the data, but this started outwith the Inquiry period.

2.2.2 In a further three units, the data have been collected by a single cardiologist or surgeon, while in the remaining units, several surgical staff have contributed to the process.

In some units, the consultants have collected their own data, while in others the task has been allocated to more junior staff, although the extent to which this has been the case over the years was not made clear.

#### **Method**

2.2.3 The method of producing figures for the returns varied considerably.

2.2.4 Although most units now maintain computerised records of patient details, only three have done so for the entire Inquiry period. In these units, data have been computerised routinely for other purposes and this local system provides source data from which the surgeon works to

produce the figures for the Register. In a further two units, surgeons maintain databases of their own patients' information.

2.2.5 Nine of the twelve units have depended on paper systems during the Inquiry period, using combinations of the sources listed above.

2.2.6 The form for providing data for the Register (see Appendix III) asks for totals for various diagnostic categories along with the number of deaths in each category. This is subdivided by age (under / over one year, over sixteen years) and open / closed type of operation. All sources of information used to compile these figures contain information on individual patients and some translation is required to convert it to the format required by the Register and to obtain totals. This is still true when computer systems are used, as patient information does not generally include the categories used by the Register. Totals could be obtained by compiling monthly figures, where provided, or, more usually, by retrospectively going through all records for the previous year.

2.2.7 Transcription methods included:

- i. one surgeon making handwritten notes from the operations book and casenotes and compiling annual totals from these;
- ii. one / each surgeon obtaining computer listings from local systems, translating the information into Register categories and then obtaining totals;
- iii. each consultant compiling figures for their own patients on a photocopy of the form and one consultant collating the information to obtain totals; and
- iv. one surgeon collating monthly reports of totals maintained by a departmental secretary.

### **Validation of figures**

2.2.8 There has been minimal validation of figures, with consultants commonly perceiving data validation to mean simply checking of totals (e.g. figures presented by the registrar or other staff to the responsible consultant). Independent checking of figures against source data has only occurred at the units where data collection staff are involved and where the data are being used for other purposes.

## **2.3 Patient population and patterns of stay**

2.3.1 The proportion of patients with congenital heart defects aged under one year varied substantially, with figures ranging from 12% to 60% being quoted. All units treat patients over the age of sixteen, but one unit does not routinely record older patients in the figures for the Register, and another unit only treats patients under eighteen years of age.

2.3.2 Information obtained on patterns of stay did not suggest any major differences between units in the time patients spent in hospital post-operatively. Patients were usually transferred home after a post-operative stay of up to two weeks, which is consistent with Aylin's HES data findings<sup>4</sup>. However, information was not sufficiently detailed to be able to comment on any differences in lengths of stay of less than a week.

## **2.4 Unit of data / multiple records**

2.4.1 The unit of data recorded on the returns was the operation, and not the patient. Generally, if patients underwent separate operations during separate hospital stays, each would be recorded for the Register, although death would only be attributed to one operation. Hence the reported mortality rate reflects operative, rather than patient mortality. Figures will undoubtedly include many instances of multiple operations on the same patient within the same year.

2.4.2 While there was general agreement on the separate recording of operations during separate hospital stays, there was some confusion in deciding how to record (a) multiple procedures within a single operation, and (b) multiple operations on the same patient if operations occurred within the same hospital stay.

2.4.3 Several consultants commented on the problem of complex diagnoses, with many being of the opinion that the Register lacked appropriate fields for recording them.

2.4.4 Examples quoted included AVSD followed by mitral valve repair followed by valve replacement, tetralogy of Fallot and AVSD, and tetralogy of Fallot with double outlet right ventricle.

2.4.5 Each of these examples involves an element of subjective clinical judgment in classifying them for the Register. Some units would record certain multiple procedures under a

specific category on the form, while others would resort to recording them under the ‘Miscellaneous – other’ category. Two units commented that they used the ‘miscellaneous’ category extensively, regularly including a separate sheet of such diagnoses with the return, while one unit had never used the category. (See section 3.2 below)

2.4.6 Many consultants expressed the view that there are large discrepancies between the units in the categorisation of complex cases, and that such cases are not uncommon.

2.4.7 Multiple procedures resulting in a death posed a problem, with units attributing death to the first, last or ‘major’ procedure.

2.4.8 There was no consensus of opinion regarding the procedure to which death would be attributed if it occurred within thirty days of two or more procedures. This lack of agreement potentially means that where combinations of open and closed procedures result in a fatality, the death could be attributed to either, depending on the surgeon’s preferred classification process.

2.4.9 There was no evidence provided during the interviews to suggest that multiple procedures resulting in death were recorded as multiple deaths, i.e. the double-counting of deaths referred to in the report of Murray et al <sup>2</sup>. However, on the self-completion questionnaire, two consultants recorded that double-counting of deaths had occurred during the time they were involved in submitting figures to the Register (see section 2.8 below).

## **2.5 Recording of mortality data**

### **Method**

2.5.1 With one exception, consultants reported that they were sure that they would be aware of almost all deaths of patients, regardless of when they occurred. However, only five units showed evidence of systems which would reliably capture information on deaths occurring post-discharge, i.e. follow-up information on deaths was fed back into the source from which the Register figures were compiled.

2.5.2 Consultants reported that they were sure that very few patients died post-discharge and within thirty days of operation, with the exception of one consultant, who was equally sure that he could not possibly know how many such deaths occurred. (The issue of deaths post-

discharge is explored in detail in Murray's report on the linkage of HES and ONS mortality data<sup>5</sup>.)

## **Definitions**

2.5.3 The following definitions of 30-day mortality were observed to be applied:

- 30 days post-operation, whether in-hospital or discharged elsewhere (this is the definition issued by the Society) (claimed to be used by six units);
- 30 days post-operation, in-hospital only (used by one unit);
- all in-hospital deaths (including those occurring after 30 days) with no systematic follow-up of information post-discharge (used by two units);
- all in-hospital deaths (including those occurring after 30 days), up to 30 days post-operation for patients discharged (within 30 days) (used by three units).

2.5.4 In addition, and very importantly, it was reported anecdotally that, where the collection of data was delegated to registrars, they frequently only recorded deaths in theatre or ICU, without the knowledge of the consultants responsible for the figures. If true, this would result in considerable under-reporting of mortality.

2.5.5 At least one unit has never recorded all-cause mortality, recording only deaths attributable to surgery. The extent to which this would result in under-reporting of deaths for the unit is not known, but one consultant was of the opinion that very few cases would have been excluded on this basis.

2.5.6 The recording of deaths of premature babies (treated for patent ductus arteriosus) was raised towards the end of the series of interviews. It was suggested that where such children are operated on and then transferred to the neonatal unit, they are often not followed up. Of the two units who were asked about this, one recorded all such deaths of premature babies and the other recorded none.

2.5.7 These last three methods of reporting would lead to under-reporting of 30 day mortality, while the recording of all in-hospital deaths may lead to over-reporting.

## **2.6 Reproducibility of data**

2.6.1 Five of the twelve units were confident that they have retained at least some copies of their returns for the Inquiry period.

2.6.2 Reproducibility was addressed in the report of Murray et al by comparing figures from the Register with those provided to a Working Party of the Royal College of Surgeons of England for the period 1988 to 1991 <sup>6</sup>).

2.6.3 The comparison between the two sets of figures, which should have been identical, showed substantial discrepancies, casting considerable doubt on the ability of many units to reproduce their annual figures, and hence on the accuracy of those figures. (See Table 1)

**Table 1 Number of Open and Closed Operations in Under-Ones : Comparison of figures from RCSE Working Party Report (1992) with annual returns to UKCSR 1988 - 1991**

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

**Notes:**

1. Units have been assigned an arbitrary letter identifier.
2. WP : figures in RCSE Working Party report of 1992
3. Return : figures in return to the UK Cardiac Society Register

2.6.4 This survey has confirmed that a questionnaire was sent to a paediatric surgeon from each unit asking for activity and mortality figures, data which would already have been provided to the Register.

2.6.5 When asked, only two consultants could remember this exercise, and no additional informative comment on reproducibility was obtained from the interviews.

## **2.7 Other local data collection systems**

2.7.1 It has already been reported that three units had their own computerised systems in place throughout the Inquiry period. A further two units have recently set up computerised systems. Of the remaining units, three reported that they had tried to implement computer systems during the Inquiry period, but without success, and two reported that they had repeatedly requested computing resources, but were refused by their Trust. The three who had tried and failed to implement local systems cited lack of local database expertise as the reason. At least one of these units had purchased a system using discretionary funds. Only two units had specialist database staff who were funded by the NHS, one as a research assistant and the other on a low clerical grade.

## **2.8 Surgeons' subjective assessment of data**

2.8.1 The self-completion questionnaires were completed by the surgeons at the start of each interview, with a further two being obtained by post.

2.8.2 The questions applied to the unit and period for which the consultant contributed data to the Register.

2.8.3 Statements reflect comments made about the Register in evidence to the Inquiry<sup>3</sup>.

**Table 2 Results of Self-completion Questionnaire from 17 respondents**

No.	Statement	Strongly Agree	Agree	Don't Know	Disagree	Strongly Disagree
1	There is / was very little missing data on number of diagnoses / procedures.	10	4	1	<u>2</u>	<u>0</u>
2	There is / was very little missing data on deaths.	11	3	1	<u>1</u>	<u>1</u>
3	The number of procedures performed is / was broadly accurate.	13	4	0	<u>0</u>	<u>0</u>
4	There is / was under-reporting of deaths.	<u>1</u>	<u>3</u>	2	2	9
5	There is / was double-counting of deaths	<u>0</u>	<u>2</u>	1	3	11
6	The mortality figures are broadly accurate	11	5	0	<u>1</u>	<u>0</u>
7	The Register is more accurate for procedures than HES/PAS	10	3	4	0	0
8	The Register is more accurate for deaths than HES/PAS	6	4	7	0	0

**Summary:**

- 14 out of 17 think there was little missing data (deaths or procedures) from their unit.
- All think the number of procedures recorded was broadly accurate.
- 16 out of 17 think their unit's mortality figures are broadly accurate.  
Of 13 who expressed an opinion, all thought that their register figures were more accurate than HES / PAS for procedures.
- Of 10 who expressed an opinion, all thought that their register figures were more accurate than HES / PAS for deaths.

2.8.4 Responses which suggest that there may be problems with the data are underlined (i.e. there was missing data, there was under-reporting / double-counting of deaths). These responses were from six consultants at five different units.

2.8.5 Surgeons at five units agreed that their mortality data were under-reported, over-reported or inaccurate.

2.8.6 Splitting results into responses from those who contributed figures to the Register in the first half of the Inquiry period (1984 – 1989) and those whose involvement has been in more recent years gives the following breakdown of figures (responses have been condensed into ‘Agree’ and ‘Disagree’ for simplicity, with ‘Don’t know’ omitted):

**Table 3 Responses by consultants’ period of involvement with the CSR**

No.	Statement	1984 – 1989		1990 - 1995	
		Agree	Disagree	Agree	Disagree
1	There is / was very little missing data on number of diagnoses / procedures.	9	<u>2</u>	5	0
2	There is / was very little missing data on deaths.	8	<u>2</u>	6	0
3	The number of procedures performed is / was broadly accurate.	11	0	6	0
4	There is / was under-reporting of deaths.	<u>4</u>	6	0	5
5	There is / was double-counting of deaths	<u>1</u>	9	<u>1</u>	5
6	The mortality figures are broadly accurate	10	<u>1</u>	6	0
7	The Register is more accurate for procedures than HES/PAS	8	0	4	0
8	The Register is more accurate for deaths than HES/PAS	7	0	2	0

2.8.7 With the exception of one consultant in the more recent period agreeing that there was double-counting of deaths, all underlined responses are recorded by consultants who were involved in the earlier period. These ten responses were provided by five consultants at five different units.

## **2.9 Surgeons' subjective assessment of the accuracy of the Register overall**

2.9.1 In contrast to the general confidence expressed in their own data, almost all surgeons expressed anecdotal lack of confidence in the accuracy of the Register as a whole. The following comments are representative of the opinions expressed:

“The incompleteness of the data returned to the UK Registry was severely compounded by the difficulty of categorising many complex operations, for which there was no correct or appropriate field in the Society’s register.”

“The CSR is not worth the paper it’s written on.”

“..the data collected by the UKCSR have never been ‘trusted’ by UK paediatric surgeons. I have no ‘proof’ that the data in UKCSR were inaccurate but I remember that on a number of occasions I found that some results presented in UKCSR were highly improbable.”

“The congenital heart disease classification was very difficult to complete for many complex cases. For this reason there was a great opportunity for ‘fudge’. For instance it has been said that all patients dying following correction of Fallot’s Tetralogy could be classified as double outlet right ventricles which would obviously conceal a mortality for Fallot operations.”

“I accept that there are some inaccuracies in it, and it’s not a good form in the first place, but it’s all we have and it’s better than anybody else has.”

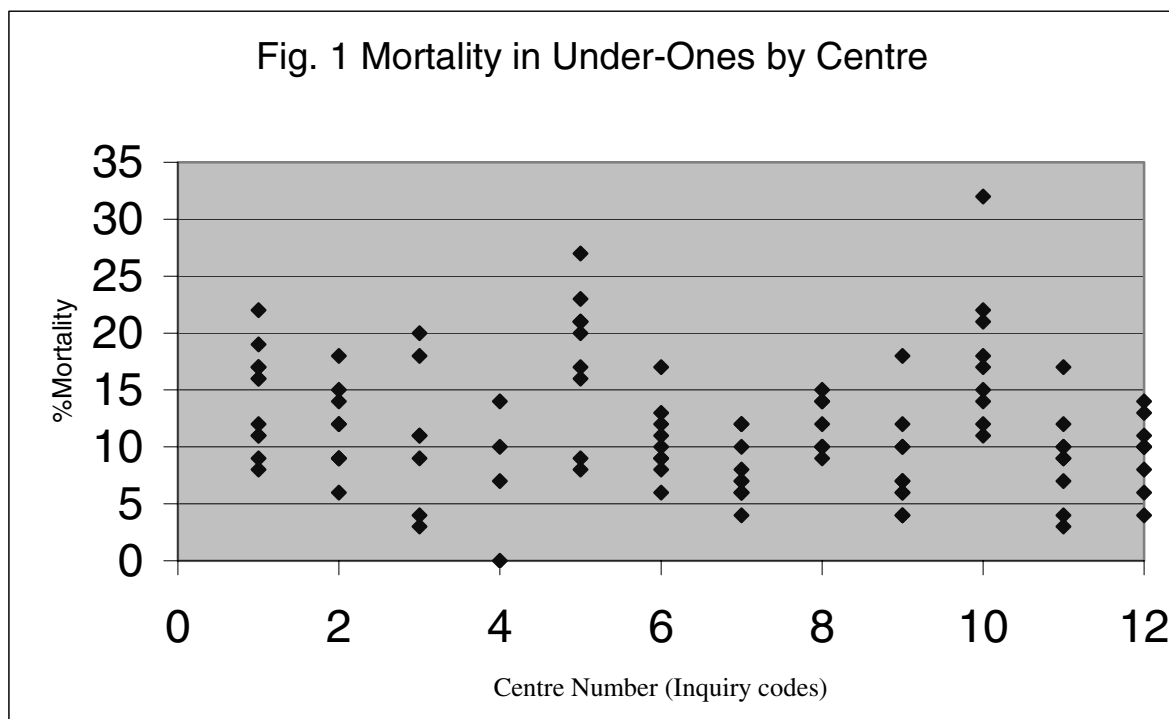
### 3. Consistency of the UKCSR data and the survey findings

3.1.1 We were able to examine the consistency of the survey findings and the Register data. The issues of under-reporting on mortality and the use of the ‘Miscellaneous – other’ diagnostic category were examined in this way.

#### 3.2 Reporting of mortality

3.2.1 In a systematic review of the relevant literature during the Inquiry period<sup>7</sup>, Vardulaki quotes a range of figures for 30 day mortality in various patient groups with the lowest pooled estimates (lower 95% confidence limits) reported being between 8.9% and 16.9%. Given that these figures “are likely to represent ‘best achievable performance’ rather than the performance to be expected in everyday practice”, mortality rates reported to the Register of below five per cent in the under-one age group are either exceptionally good or suspiciously low.

3.2.2 Figure 1 shows annual mortality for open procedures in the under-ones by centre as reported to the Register during the Inquiry period.



Note: Mortality rates involving less than 50 procedures in total have been omitted from the chart.

3.2.3 Six of the twelve centres reported at least one annual mortality rate of below five per cent, with one unit reporting zero mortality in 1994. Details of these figures are provided in Table 4.

**Table 4 Details of reported mortality figures of under 5% in the under-ones**

Centre Number	% Mortality	Year	No. of deaths	No. of procedures
3	3	1986	3	98
3	4	1992	5	114
4	0	1994	0	98
7	4	1985	4	94
9	4	1989	3	67
9	4	1990	3	75
11	3	1993	2	273
11	4	1991	10	239
12	4	1993	3	84

### 3.3 Use of the ‘Miscellaneous – other’ category

3.3.1 Attention had been drawn to the use of the category ‘miscellaneous – other’ during the survey, with representatives from two units commenting that they used it extensively to record complex diagnoses, and another reporting that they had never used it.

3.3.2 An example of the CSR form is contained in Appendix III. The congenital section of the CSR return records data under five main headings : Extracardiac lesions, Congenital valve surgery, Defects of partitioning, Right-sided and miscellaneous lesions and Miscellaneous procedures.

3.3.3 The section headed ‘Miscellaneous procedures’ (on page three) lists five specific procedures and has a heading ‘Other (please specify)’.

3.3.4 All entries under the ‘Other’ heading which were recorded by any of the units over the entire Inquiry period are listed in Appendix V. This list includes the following: procedures not recordable elsewhere on the form, multiple procedures, revision operations, and categories which do appear elsewhere on the form and which should have been recorded as such.

3.3.5 As an example of the extent to which the ‘Miscellaneous – Other’ category was used, an excerpt from the Society’s annual report for the period April 1994 to March 1995 is included in Appendix IV.

3.3.6 This shows that, for all congenital cases, the category is the fourth most common category after ASD, corrective VSD and corrective Fallot’s tetralogy. For cases under one year, it is third most common after corrective VSD and corrective TGA with intact septum. The reported mortality associated with it is 14% overall and 19% in the under-ones.

3.3.7 While this category was included in the statistical analyses for the Inquiry of the UKCSR based on open/closed grouping, it was excluded from the analyses using the thirteen procedure groups.

3.3.8 Table 5 shows the variation in the centres’ use of the category over the period 1991 to March 1995, one of the epochs used in the Inquiry’s comparative statistical analyses.

**Table 5 Use of ‘Miscellaneous – Other’ category in period 1991 to March 1995**

Centre No.	Years of data available	Years Misc used	Total procs	Total deaths	Misc procs	Misc deaths	Misc Procs (% of total)	Misc Deaths (% of total)
7	4	4	819	40	66	3	8.1%	7.5%
4	4	2	407	27	23	1	5.6%	4%
11	4	3	1911	93	80	10	4.2%	11%
2	4	3	758	69	27	5	3.6%	7%
1	4	4	830	79	26	8	3.1%	10%
9	4	4	805	49	20	3	2.5%	6%
6	4	3	1538	116	26	10	2.3%	9%
5	4	4	646	61	15	8	2.3%	13%
8	2	2	1187	82	26	2	2.2%	2%
12	4	2	1209	75	24	0	2.0%	0%
3	3	2	555	46	6	3	1%	6%
10	4	0	709	39	0	0	0%	0%

3.3.9 Over this period, the ‘Miscellaneous – other’ category accounts for between 0% and 8.1% of all procedures and between 0% and 13% of all deaths recorded at the twelve units. Use of the category varied within units over the time period, with four using it each year, three using it in three of the four years, four using it in two years and one never using it.

3.3.10 The way in which the ‘Miscellaneous – Other’ category has been used increases the likelihood that some centres may have under-reported mortality, at least within the diagnostic groupings.

## **4. Discussion**

4.1.1 Earlier analysis of the UKCSR data revealed considerable variability in the figures reported both within and between units. This, combined with our limited knowledge of the ways in which data were collected for the Register, suggested that a comparative analysis of units might not actually be comparing like with like.

4.1.2 The main aim of the survey was to assess the variability in the data collection process at each of the twelve units and to examine its potential effect on the data quality.

4.1.3 While the Society's anonymised reporting format means that there is little incentive to falsify figures, there is an equal lack of incentive to put much effort into the data collection process.

4.1.4 The collection of paediatric surgical activity and outcomes data is known to be difficult, requiring meticulous and consistent classification of complex diagnoses and, in common with other outcomes audit, active follow-up and recording of post-operative deaths.

### **4.2 Classification issues**

4.2.1 It is apparent from the survey that surgical input is essential for the correct categorisation of complex cases. We have highlighted the degree of subjectivity present in the classification of cases involving multiple procedures, which means that the same case can be recorded under different register categories by different surgeons, even within the same unit.

4.2.2 This variability is compounded by the design of the form, which lacks appropriate categories for recording certain complex diagnoses and includes categories which are no longer appropriate.

4.2.3 The variability in the use of the 'Miscellaneous – other' category confirms these difficulties.

4.2.4 The reported confidence of many surgeons in the Register's figures for procedures compared to those reported by the hospital information systems reflects their general lack of confidence in the ability of non-surgical staff to correctly classify complex procedures.

### **4.3 Reporting of mortality**

4.3.1 The suspicion that mortality has been under-reported in at least some units has been confirmed by the following findings:

- i. four different definitions of thirty day mortality have been applied over the twelve units,
- ii. some registrars are reported to have used only theatre and ICU books as data sources,
- iii. not all units were recording all-cause mortality, and
- iv. units have not consistently recorded deaths of premature babies.

4.3.2 In addition, three units have recorded all in-hospital deaths, and the extent to which this may have resulted in over-reporting of mortality rates is unknown.

4.3.3 The number of potentially missed deaths after discharge from hospital and within thirty days of operation beyond discharge is similarly unknown.

### **4.4 Staffing and resources**

4.4.1 In units where local staff are specifically assigned to collect data on a routine basis, where an appropriate computer system is maintained, and where the data are used for other purposes (such as the production of reports or discharge letters), the data should be both exhaustive and reproducible.

4.4.2 Alternatively, small units where one surgeon or cardiologist has an interest in collecting the data should be capable of providing accurate, reproducible data, even if the system is paper-based.

4.4.3 When junior surgical staff, who may have various other commitments, are asked to obtain figures on a one-off basis from paper sources, as has been the case in some units over the years, accurate data are unlikely to be produced.

## **5. Conclusions**

5.1 The survey has confirmed that there have been considerable differences between units and within units over time in the rigour with which data have been collected for the UKCSR.

5.2 Important additional sources of variability have been highlighted of which the researchers had previously been unaware, particularly relating to the reporting of mortality.

5.3 This leads us to draw the following conclusions:

- i. Examination of the UKCSR data by diagnostic groups is unreliable. The problems associated with the classification of complex diagnoses, combined with the extremely variable use of the ‘Miscellaneous – other’ category and the lack of guidance in these subjective areas suggest that centres, and indeed surgeons, have varied considerably in the categories under which they have recorded many diagnoses.
- ii. There are likely to be systematic differences between centres in the extent to which 30-day mortality has been captured, with under-reporting having occurred in several centres at some point during the Inquiry period.
- iii. While total numbers of procedures are likely to be more reliable than statistical breakdowns by diagnostic group, the uncertainty surrounding the reported numbers of deaths still precludes reliable estimation of mortality rates from the UKCSR figures.

## **6 Implications for the future**

6.1 The survey has subjected the UKCSR data to a level of scrutiny for which it was never intended. The Register was initiated in 1977, in the days preceding computerised data collection in hospitals. It was, and is still perceived to be, the best source of UK cardiac surgical data available.

6.2 The problems which the survey has highlighted only serve to emphasise the difficulties inherent in the collection of good quality data in a routine clinical setting, where complex diagnoses are not uncommon, and where time and resources for activities perceived to be of low priority are scarce.

6.3 It is inevitable that, in the absence of (i) clear and unambiguous guidelines on data collection, (ii) validation of data (either locally or centrally), and (iii) personnel experienced in the routine collection and recording of data, the quality of such complex data will vary considerably from centre to centre.

6.4 The development and implementation of procedures containing clear definitions of the patient population and detailed guidelines on the classification of complex diagnoses and multiple operations would be a useful step towards improving the quality of the data submitted to the Register.

6.5 Some central validation of data and feedback of problems to units would further improve the data quality.

6.6 A more widespread recognition of the role that experienced, local data collection staff can play, *in conjunction with* experienced surgical staff, in pursuing complete and accurate data, could only be of long-term benefit, but would inevitably raise issues of resource allocation within Trusts.

## **7 Acknowledgements**

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Finally, we thank all the surgeons who gave up their time to participate in this survey.

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## **Appendices**

Appendix I Guidance for completion of forms for the UK Cardiac Surgical Register

Appendix II Survey Self-completion Questionnaire : Paediatric Cardiac Surgical Data

Appendix III CSR Form – Congenital Heart Disease Section

Appendix IV Excerpt from the Society’s Annual Report for 1994/5 : Congenital Heart Operations

Appendix V Items recorded under the heading ‘Miscellaneous – other’

## Appendix V

Alphabetical listing of items recorded separately under the heading  
'Miscellaneous – Other'

Item
2 Chamber R V + Absent PV
A V Discordance with VSD
Absent PV Syndrome
Advancement of Lead
Aneurysm of descending aorta-prev coarct repair
Anomalous Origin RPA from Aorta
Anomalous Pulmonary Artery
Anomalous Systemic Venous Connection
AO Valvot + VSD
Aortic Atresia
Aortic Root Replacement
Aortic Root Replacement + VSD
Aorto - Pulmonary Switch for AVD
Aorto R Ventricular Tunnel Closure
Aorto-LV Tunnel & AVR
AO-RV Fistula
Arteriovenous malformation in neck
Asc. Aortic Aneurysm
ASD & TVR (Xenograft)
ASD + Blalock
ASD + CABG
ASD + IMAXI
ASD + MVR
ASD + Partial anom. PVD
ASD + PS
ASD + VSD + Other
ASD/VSD/Dextrocardia. Anomalous. Venous Drainage
Atrial Septectomy & Bilat. PA Banding
Atrial Septectomy & Removal LV Thrombus
Atrial Tumour
AV Canal + MVR (Prosthetic)
AV Canal + TAPVD + Multiple VSDs
AV Canal/LV OT obst/TAPVD/Dextro Cardia
AV Defect + Tetralogy P. Valvotomy + ASD
AV Fistula of vein of Galeen
AV Repair + VSD
B T Shunts
Bacterial Endocarditis
Banding of PA
Blalock - Hanlon
Blalock Shunt following on for TGA
Bottle Closure ASD - Correction PVD
Bronchoscopy
Bypass for Non-Cardiac Case

Item
C AVSD & Other Anomalies - Corrective
C AVSD & Other Anomalies - Palliative
Cardiac Transplant
Cardiac Transplant (Hyponlastic L Heart)
Catheter Injurv - emergency exploration
CAVO - Pulmonary Shunt
Change of Pacing Box
Chest Resuture / Removal Sternal Sutures
Chvlothora Pleural Drainage
Closure ASD & Open Mitral Valvotomy
Closure of hole between ventricle and RA previous Fontan
Closure of Sinus Valsalva
Closure PDO
Complete Heart Block
Complex Congenital Lesions
Conduit and Homograft Replacement
Congenital n. Stenosis
Cong. Heart Block. Pacemaker. Remove PA Band
Coronary Artery Angioplasty for LCA Occl. Post Switch
Corrected Trans + Situs Inversus (Palliative)
Correction
Correction Anomalous Pulmonary Venous Drainage into Coronary
Criss Cross Heart + Pulm stenosis
Critical PS
CROV + Complete AVSD + PS
Cystic Malform Lt Lung - Lobectomy
Dacron graft from ascending aorta to right carotid & subclavian artery
Deband PA on bypass
Debanding
DILV/Transposition/Pulmonary Atresia
DIRV. DORV. PS
DIV
DORV & TAPVD (nan)
DORV + CAV Cannal
DORV + TAPVD
DORV/Complete AVSD/PS/Left Isomerism
Double Aortic Arch
Double Chamber R Ventricle
Double Chamber RV + Mvloma RA
Double Inlet LV
Double Inlet RV
Double Outlet LV
Drain Tamponade
Ebstein Anomaly
ECMO
ECMO Cannulation
Enic. Pacemaker
Excision false an. Prox. Asc. Aorta
Failing RV (prev Mustard)
Fallot + ASVD
Fallot + AV Canal
Fallot + disconnected I.PA + Anomalous Lad + (L.) SVC
Fallot + Multiple VSD'S
Femoral Embolectomy
Fontan

Item
Fontan type procedure for complex heart defect with left isomerism
Haemangioma
HAPVD
Hemi truncus
Hypertrophic Cardiomyopathy
Hypoplastic aortic arch and VSD and PDA and ASD (on Ligation
Hypoplastic Arch
Hypoplastic L Heart Banding + Septectomy
Hypoplastic L Heart PAPVD
Hypoplastic Left Heart Syndrome
Hypoplastic Left Ventricle
Hypoplastic R V
Inf. Resection Closure VSD Aortic Valve Repair
Insertion Internal Pacemaker
Intermediate AVSD - Palliative
Interrupted Aortic Arch
Interrupted Arch + VSD + ASD + AS
Isolated Ventricular Inversion + VSD
KONO OP
LAVV Atresia - Palliative
Left AV Valve Repair/Replace
Left Ventricular Tumour
Ligate Ascending Channel between upper lobe vein & innominate
Ligate Lymphatic Duct
Ligate MAPCA (prev P Atresia on)
Ligation Collateral (Scimitar)
Ligation MAPCA'S
LT a v regul. Repair
Lung Biopsy - Diagnosis
Lutembacher Syndrome
LV/PA Conduit
LVOT Obstruction
Mitral Atresia
Mitral atresia + hypoplastic left heart. VSD
Mitral Atresia with Hypoplastic L Ventricle
Mitral Atresia. TAPVD + IAA
Multiple VSDS
Mustard On
Mustard + Fontan
Myectomy LVOT Reconstruction for familiar Hypertrophic
Myectomy LVOT
Norwood
P Atresia - IVS - Corrective
P Atresia - IVS - Palliative
P Atresia VSD - Removal of Stent + Septectomy
P.V Obstruct Relief
P/Maker
PA Band on BP - intended to close VSD but no M Valve
PA Debanding
PA embolectomy
PA reconstruction
PA Stenosis following Switch
PA Stenosis following TA correct
Pacemaker Change
PAPVA

Item
PAPVC
PAPVD
PAPVD (Intact Septum)
Parachute MV
Paraprosthetic leak
Partial Anomalous Pulmonary Venous Connection
Partial anomalous PV drainage
Partial anomalous venous return
Partial PVD
Patch for Pulmonary Artery Stenosis
Patch to prev Blalock
PDA + open proc
Pericardial effusion not as result of surgery
Pericardial Procedure - Drainage
Pericardial Vascular
Pericardial Window
Pericardiectomy
Peripheral PA Stenosis
Permanent Epicardial Pacemaker
Pneumonectomy
Plication of Diaphragm
PTA + Interrupted Arch
Pulmonary Atresia + AVSD
Pulm A-V Fistula
Pulm. Artery Enlargement after Switch
Pulm. Artery Repair
Pulm. Vein Stenosis
Pulmonary Artery Banding
Pulmonary Atresia IVS RV "Overhaul" or Shunt
Pulmonary atresia with IVS
Pulmonary Embolism
Pulmonary Sling
R Vein Stenosis
Rastelli
Re Op Pulm. Venous Obstruction
Reconstruction of RV
Redo Enlargement VSD
Re-do Excision of Clotted Prosthetic Tricuspid Valve Cavo
Redo Mustard
Redo Rastelli Conduit (TGA + VSD + PS)
Re-exploration on Bypass
Reimplantation of RPA to main PA
Relief Ruoto in Previous Truncus
Removal Clot R Atrium
Removal Intra AO Balloon
Removal of Atrial Tumour
Removal of Guide Wire PA
Removal of Infected Blalock Shunt
Removal of Intra-Aortic Pedunculated Mass
Removal of LV Assist Device
Removal of Pacemaker
Removal of Pulmonary Embolus with broken AV Valve
Removal of Secondaries from RA
Removal of Vegetation
Removal right atrial thrombus

Item
Removal Wilms Tumour
Remove Stent from RPA
Reopening of PFO-prev on for Pulm Atresia + IVS
Repair Anastomotic Stenosis. prev IAA
Repair of Aneurysm of membranous Septum
Repair of Ruptured Thoraco-Abdominal Aortic Aneurysm
Repair of Sinus of Valsalva Aneurysm
Replace Homograft - previous correction of Truncas
Replace prev homograft prev Fontan
Replace prev imograft. DOLV
Replacement RV/PA Conduit
Resect Left Ventricular Outflow + VSD
Resection IVC Web
Resection of ascending aorta aneurysm
Resection of Trachea
Residual VSD
Resuscitation after drowning (Hypnoth)
Revise Rastelli - Relieve Sub-AO Sten + Resid VSD
Revision following previous operation
Revision Mustard
Revision of Fontan's Age 16
Revision of previous operation
Right Atrial Laceration
Right Isomerism
Right Isomersion DROV. TAPVD. AV Canal PS
Romano-Ward Syndrome
RPA from AORTA
Ruptured Sinus Valsalva
RV Outflow Tract Obstruct + VSD
RV Outflow Tract Obstruction
RV to PA Conduit
RVOT Aneurysm
RVOT Tumour Excision
RVOTO Relief
RVOTO Repair
RVOTO with PS
RV-PA Conduit Replacement + Repair of False Aneurysm
SBE Pacing Wire
SBE VSD Patch
Scimitar Syndrome
Shunts
Sinus of Valsalva Aneurysm
Sinus of Valsalva Fistula
Small Left Heart
Sternal Re-Wiring
Sternotomy Removal RA Clot
Sub aortic myectomy for HCOM
Sub Valve stenosis in RV following Fallots repair
Subaortic Membrane
Subobstruction
Supravalve Mitral Membrane
SVC/IVC Thrombosis
Switch for TGA
Systemic Abnormal Venous Drainage
Take down of Fontan

Item
TAPVC + AVC
TAPVC + PAI + AVC
TAPVD
Tetralogy F + CAVSD
Tetralogy of Pulmonary Atresia/Complete AVSD
TGA + Incomplete AVSD (Senning Op)
TGA + TA + VSD
TGA. AVSD. TAPVD. RA Isorevision
Thoracic
Thoracic duct ligation
Thrombotic Occlusion of SVC
TOF with Absent PV
Tracheoplasty
Tracheoplasty on Bypass
Tric. Valve Repair
Truncus Arteriosus / Interrupted Aortic Arch
Tumour - Rhabdomyoma
Tumour / Mycetoma
Unifocalisation Pulmonary Blood Supply
Unroofed Coronary Sinus Syndrome
Valved conduit RA-RV for TS
Vargas Operation
Vascular Procedure
VSA + AT
VSA + LVOTO + COA
VSD + A I
VSD + AVR
VSD + Debanding
VSD + MI Stenosis + PDA + (Rev. PA Band)
VSD + RVOFT Obs.
VSD + TVR
W P W (+EBSTEINS)
W P W (+TA)
Weaning from LV Assist Device on BP
Wolfe Parkinson White