Chapter 19 – Statistics Relating to the Clinical Performance of Paediatric Cardiac Surgical Services in Bristol Compared with Other Specialist Centres during the Period 1984 to 1995

Introduction: purpose and scope of the chapter

This chapter sets out the evidence received by the Inquiry on statistics relating to the clinical performance of paediatric cardiac surgical services in Bristol relative to other specialist centres.

In this chapter, the term 'clinical performance' means the activity (the type and volume of operations or procedures carried out) and outcomes (in terms of post-operative mortality and morbidity) of paediatric cardiac surgical services in Bristol. Bristol's particular clinical performance may be assessed by examining its own results over a period of years and by comparing them with the contemporaneous performance of other centres.

'Statistics', for the purpose of this chapter, means figures of any kind relating to clinical performance.

The statistics fall into two main categories:

- statistics relating to clinical performance that were available to clinicians in Bristol during the period 1984 to 1995 (the clinicians' *contemporaneous* statistics);
- statistics relating to clinical performance presented to the Inquiry as expert evidence (the Inquiry's *retrospective* statistical evidence).

As regards the clinicians' contemporaneous statistics, the main sources of statistics relating to clinical performance available to clinicians in Bristol during the period 1984 to 1995 were:

- the clinicians' own clinical logs and computerised information systems;
- external sources, including the Society of Cardiothoracic Surgeons' UK Cardiac Surgical Register ('UKCSR'); the reports of national working parties on neonatal and infant cardiac surgery; ad hoc external audit reports; and professional meetings, contacts and journals.

As regards the Inquiry's retrospective statistical evidence,[1] Experts were commissioned to review, analyse and synthesise the six principal sources of data that existed at the relevant time. These were: the national Hospital Episode Statistics (HES); the UKCSR; the UBH/T's Patient Administration System (PAS); the clinical records of children whose treatment fell within the Inquiry's Terms of Reference; the surgeons' logs; and the South West Congenital Heart Register.[2]

1 The Experts' statistical reports appear in full in Annex B

2 The log kept by the perfusionists in Bristol and the mortality records of the Office for National Statistics were also used by the Experts, for the purpose of testing the accuracy of the data derived from the main sources

The statistical investigations described in this chapter make comparisons with other centres. They do not seek to draw conclusions as to the reason(s) for any difference which may be found to exist between Bristol and other centres providing similar treatment. Rather, they seek to establish, on a statistical basis, whether there is such a difference, and how significant that difference is. The experts in their investigations examined a number of suggested causes of such differences as are identified, and expressed their view that some of these proposed causes may be eliminated or discounted. They did not advance any reason for the differences which they identified.

The statistical evidence received by the Inquiry must be distinguished from the Clinical Case Note Review (CCNR), reproduced in Annex B. The CCNR was a clinical audit by experts which focused on the quality of care delivered in a sample of cases in Bristol, as judged by reference to the case notes. The CCNR examined a representative sample of case notes, with a view to generalising from the conclusions drawn from the sample to the whole. The conclusions are derived from what the notes show about the care provided at the different stages of a child's treatment. The experts' views as to what might have been expected elsewhere informed their conclusions, but formal comparison of Bristol with other centres formed no part of the CCNR exercise.

The chapter is divided into two main parts. The first part sets out evidence received by the Inquiry concerning the nature of the statistics relating to clinical performance available to clinicians in Bristol during the period 1984 to 1995, and the views of the Inquiry's experts on the interpretation of these statistics. The second part sets out the principal conclusions of the retrospective statistical evidence received from the Inquiry's experts relating to the activity and outcomes of paediatric cardiac surgical services at Bristol relative to other specialist centres, and the views of the Bristol surgeons and of the experts on the reliability and validity of this statistical evidence.

Section one: statistics relating to clinical performance available to clinicians in Bristol during the period 1984 to 1995

Statistics relating to clinical performance produced by the clinicians in Bristol

1 The sources of statistical data available to the clinicians in Bristol included the clinicians' own logs (handwritten, typed and computerised logs compiled contemporaneously by surgeons, cardiologists, anaesthetists and perfusionists).[3] From these, data were derived for annual statistical summaries, Annual Reports on paediatric cardiology and cardiac surgery from 1987[4] onwards, ad hoc sheets of figures produced for audit[5] and other professional meetings,[6] and Bristol's returns to the UKCSR and to the Supra Regional Services Advisory Group (SRSAG) surveys.

Logs

2 As regards the surgeons, Mr Wisheart stated in his written evidence to the Inquiry that he kept a log of his open-heart operations from 1975 until the end of his consultant career.[7] The log contained information about each patient and in particular about the outcome of the procedure(s) carried out. Mr Wisheart told the Inquiry that he used his log for the purpose of carrying out his own personal audit[8] and stated specifically:

> 'The log was an immediately accessible source of information about the patients on whom I had operated, and was used for such purposes as:
>
> 'a) the preparation of the annual statistical summary;
>
> 'b) the preparation of my contribution to the Department's returns to the UKCSR from 1977 onwards;
>
> 'c) the preparation of any other report of work done, which was requested from time to time;

3 Further sources of data that were kept by clinical staff included the Theatre Register (see WIT 0341 0039 – 0040 Dr Pryn), Helen Stratton's register of the cases that she dealt with (see WIT 0341 0040 Dr Pryn), and the Nurses' Ward Admission Books
4 T90 p. 13 Dr Joffe; 'The 1987 report [UBHT 0055 0009] was the first one'
5 See Chapter 18
6 Such as the meeting on the evening of 11 January 1995 before the operation on Joshua Loveday; see Chapter 30
7 WIT 0120 0255 Mr Wisheart
8 T41 p. 66–7 Mr Wisheart

'd) the purposes of formal or informal audit, or review, of any group or sub-group of patients.'[9]

3 Mr Wisheart confirmed that he would use his log book to monitor his own performance.[10] He stated :

'It [the surgeon's log] had the advantages of being within my possession, (i.e. in my hospital office), accessible, highly reliable and because of the way that it was set up it was both functional and effective.'[11]

'I believed that the log was [as] complete and accurate as possible. … I believe that the quality of the data in the log is high but I would never claim that it is perfect. … I would regard entries concerning death and autopsies as extremely reliable. … In summary – although the log is not perfect I believe it has been a very high quality resource for the purposes identified earlier [set out in para 2 above].'[12]

'For me it [the log] has proved to be an excellent system, which provided accessible and reliable information …'[13]

4 Mr Dhasmana described his surgeon's log in his written evidence to the Inquiry:

'The main purpose of the Logbook was to provide a quick reference for the personal audit of the open-heart operations carried out by me in the Hospital, as an ongoing process. This helped in recognition of problems at an early stage. The Logbook provided figures, which helped with preparation of various audits [*sic*] reports including compilation of data in the U.K. Cardiac Surgical Register. These figures also helped to prepare for various committee meetings concerning [*sic*] with the development of facilities at the unit and also with the development at the Children [*sic*] Hospital.'[14]

5 Mr Dhasmana stated:

'I never treated my Surgeon's Log as a complete record. As mentioned before, this was intentionally made simple and brief for the ease of filing. For me it served as a quick reference book for the purposes mentioned [set out in para 4 above] …'[15]

6 Mr Dhasmana went on:

'I was also maintaining a folder (YearBook) of my surgical activity at the hospital. This would contain a copy of operation notes, discharge summary and autopsy

9 WIT 0120 0256 Mr Wisheart
10 T41 p. 62 Mr Wisheart
11 WIT 0120 0255 Mr Wisheart
12 WIT 0120 0259 – 0260 Mr Wisheart
13 WIT 0120 0262 Mr Wisheart
14 WIT 0084 0001 – 0002 Mr Dhasmana
15 WIT 0084 0004 Mr Dhasmana

report where relevant, of individual patient, adults and children, operated during that year in an alphabetical order. This yearbook usually provided more detailed information on the individual patient and was used for validation of entries in the Surgeon's Log. Individual case notes were also checked from time to time for the same purpose.'[16]

7 As regards the anaesthetists, Professor Prys-Roberts told the Inquiry that he regarded the keeping of an anaesthetist's log as: 'proper medical practice'.[17]

8 Referring to the log which she kept, Dr Susan Underwood stated:

'The purpose for which data was logged in my diaries was as a personal record of the cases I had undertaken. …

'… Some of the data recorded by me is incomplete and it is quite possible that I have failed to record some cases altogether. In any instance where death occurred it was recorded in my log if it occurred in the hospital and I was aware of it. …'[18]

9 Dr Sally Masey stated:

'The purpose for which the data were logged in my diaries were [*sic*] for personal interest, to have a record of cases performed. …

'… The data are, as far as I am aware, complete for my practice, except for 1988. … The record of in-hospital deaths may not be complete, as some deaths may have occurred about which I was unaware.'[19]

10 As regards the perfusionists, Mr Richard Downes, Clinical Perfusionist at the BRI from 1992[20] and Chief Clinical Perfusionist from 1994 (still in post in June 1999),[21] stated that:

'The function of the Perfusionist's Log was to provide a record in the form of lists, of the type and number of open heart surgery cases the perfusionists had carried out over the years. That information was limited to the cumulative number of patients operated on, surgeon's initials, patient name, age, operation type and date of operation …'[22]

16 WIT 0084 0003 Mr Dhasmana
17 T94 p. 5 Professor Prys-Roberts
18 WIT 0318 0001 Dr Underwood
19 WIT 0270 0001 Dr Masey
20 WIT 0169 0002 Mr Downes
21 WIT 0169 0004 Mr Downes
22 WIT 0169 0015 Mr Downes

Accessibility, availability and use of logs

11 Mr Wisheart stated:

> '[My] log was not disseminated in any routine way nor was it disseminated unprocessed. It was however, known to exist amongst my colleagues, i.e. my surgical, anaesthetic and cardiological colleagues, both junior and senior, and a significant number of them used it as a resource. … Information derived from it was disseminated, usually within the paediatric cardiological and cardiac surgical group, but also to other groups as well.'[23]

12 He stated further that he regarded his log as being:

> 'At the time in Bristol … a unique source of information.'[24]

13 Mr Dhasmana stated:

> 'The Surgeon's Log and Year Books were always kept in the department's office with secretaries. They were easily available to members of the department. Similarly other clinicians could also have an access to these books through our secretaries. Junior doctors were often using it for a quick reference before starting on any clinical research and also during their preparation for presentation of figures to the monthly mortality and morbidity (audit) meeting in the department. However this function ceased once the computers became more established in the department in the early 90s.'[25]

14 Dr Underwood stated:

> 'There was not any arrangement for the dissemination of the data I recorded. …
>
> 'In my opinion my diaries provided only an individual record for myself. I did not consider that consultants were obliged to keep a log and I therefore consider that there is no recognised system in place and no standard against which to compare.'[26]

23 WIT 0120 0260 Mr Wisheart
24 WIT 0120 0260 Mr Wisheart
25 WIT 0084 0004 Mr Dhasmana
26 WIT 0318 0001 – 0002 Dr Underwood

15 Referring to her log, Dr Sally Masey stated:

> 'There was no dissemination of data.
>
> '… No practical applications or uses were made of the data. …
>
> '… There is no system for the keeping of anaesthetic logs by consultants. My record was personal. Therefore I cannot comment on any system as none is specifically in place for consultants.'[27]

16 Referring to the uses made of the perfusionist's log, Mr Richard Downes stated:

> 'Apart from the despatch of information to the UK Heart Valve Registry I do not believe there were arrangements for routine data analysis until after 1995 or for its dissemination. Aside from its use as a record of work undertaken, appropriately indexed by operation type, and for stock records there were no other practical applications or use made of the data in the Perfusionist's Log.'[28]

17 In respect of the perfusionists' log, Mr Donald Caddy stated:

> 'I note Mr Downes' comments about the information in the perfusionists' log being of limited use on its own and would remind the Inquiry, as set out in my first statement, that the detailed records for each individual patient made by the perfusionists at each operation were kept in my department during the period when I was Chief Perfusionist. I understand that those records are now kept with each patient's individual medical records instead. However, the point is that during my day, whatever the perceived deficiencies of the logbook, we always had available the full details of every patient who had been perfused in the department as these were contained in the patient's perfusion records kept in my office. Therefore, the perfusionists' logbook was of less relevance at that time, save as a record of the numbers and types of procedures we had carried out.
>
> 'Indeed, when the detailed audit was undertaken by Dr Stephen Bolsin it was to the individual patient's perfusion records, rather than to the logbook, that he turned for the detailed information that he was looking for.'[29]

27 WIT 0270 0001 – 0002 Dr Masey
28 WIT 0169 0018 – 0019 Mr Downes
29 WIT 0143 0041 Mr Caddy

Annual statistical summaries

18 The numbers of operations carried out and of deaths, of both adult and child patients, were compiled in respect of each cardiac surgeon in Bristol into an annual statistical summary.[30] Mr Wisheart explained:

> 'A. … This did not happen right at the beginning, but it began early on and evolved to the point where each year I published an annual – what I have called a "statistical summary". So in the preparation of that, I would have reviewed the cards[31] in the Children's Hospital and used that information.
>
> 'Q. Was that a statistical summary for yourself, or for the service?
>
> 'A. It was for the service, so my colleagues, or colleague, whatever was the situation at the time, provided their information to me, and I collated it.
>
> 'Q. Do I understand that the information was, with odd exceptions … aggregated rather than broken down by surgeon?
>
> 'A. The summaries that I am referring to were aggregated and I continued to produce those up until, I think, 1992.'[32]

19 In most of the categories of operations detailed in Chapter 3 there were a very small number of patients in each year. Mr Wisheart stated in his written evidence to the Inquiry that:

> 'Attempts were made to overcome this in two ways. First, for patients over one year an attempt was made to aggregate operations into groups under the heads of simple, moderate and complex. This aggregation was essentially arbitrary and has not proved to be particularly helpful. The second step which was taken was to include in the report the results for each operative category, not only for the year in question, but also for the previous four or five years. This in principle was a much more satisfactory step and was much more helpful.'[33]

20 A copy of the data was sent to individual consultant cardiac surgeons working in the cardiac unit.[34] These figures also appeared in the Annual Reports of the paediatric cardiology and cardiac surgery services for the years 1987, 1988 and 1989 (discussed below). For the years 1993 to 1994 and 1994 to 1995, copies of the annual data were also submitted to the audit co-ordinator for the particular year.[35]

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30 WIT 0084 0024 Mr Dhasmana
31 Handwritten cards (known as the Cardiologists' Card Index System), recording basic information on all patients seen by the paediatric cardiologists at Bristol, were kept by the secretaries in the Cardiology Department at the Children's Hospital throughout the period of the Inquiry's Terms of Reference
32 T41 p. 63 Mr Wisheart
33 WIT 0120 0394 Mr Wisheart
34 WIT 0081 0019 Mr Bryan
35 WIT 0084 0024 Mr Dhasmana

21 Mr Wisheart stated that the statistics relating to clinical performance in Bristol which were available consisted of:

> '… total numbers of paediatric cardiac surgical procedures. These numbers may most easily be obtained from the annual statistical summaries which are available for each year from 1984-92 inclusive and for the years 1992-93 and 1994-95. My own files do not appear to have a summary for 1993-94, but those figures are contained within the following summaries:
>
> '1. Tabulated summary for all procedures for the years 1990-95 drawn up by Mr Dhasmana (within which the 1993 figures may be identified).
>
> '2. The UBHT published results for all cardiac procedures from 1990-95 (January 1996).
>
> '3. The figures submitted to Dr Hunter and Mr de Leval by Mr Dhasmana and myself on the 10th February 1995.'[36]

The Annual Reports on paediatric cardiology and cardiac surgery

22 During the period of the Inquiry's Terms of Reference, the clinicians in Bristol produced a series of three Annual Reports on paediatric cardiology and cardiac surgery in Bristol:

> (i) Annual Report on Paediatric Cardiology and Cardiac Surgery at Bristol Royal Hospital for Sick Children and Bristol Royal Infirmary, 1987;[37]
>
> (ii) Annual Report on Paediatric Cardiology and Paediatric Cardiac Surgery at Bristol Royal Hospital for Sick Children and Bristol Royal Infirmary, 1988;[38]
>
> (iii) Annual Report on Paediatric Cardiology and Paediatric Cardiac Surgery at Bristol Royal Hospital for Sick Children and Bristol Royal Infirmary, 1989/1990.[39]

23 The Reports contained tables of the results of open and closed surgery for congenital heart disease in patients under 1 year of age and those aged over 1 year, and showed the numbers of deaths, and the rate of mortality. Leading Counsel to the Inquiry asked Dr Joffe about the distribution of the Annual Reports in the following exchange:

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36 WIT 0120 0285 Mr Wisheart

37 UBHT 0166 0001 – 0014; *'Paediatric Cardiology and Cardiac Surgery – Bristol Royal Hospital for Sick Children and Bristol Royal Infirmary – Annual Report 1987'*

38 HAA 0138 0003 – 0012; *'Paediatric Cardiology and Cardiac Surgery – Bristol Royal Hospital for Sick Children and Bristol Royal Infirmary – Annual Report 1988'*

39 UBHT 0133 0073 – 0086; *'Paediatric Cardiology and Cardiac Surgery – Bristol Royal Hospital for Sick Children and Bristol Royal Infirmary – Annual Report 1989/1990'*

'Q. … The [1988] annual report[40] was obviously produced for someone; who got it?

'A. The idea was to send the reports to the then District Health Authority, both the local one and peripheral centres, particularly to the paediatric paediatricians [*sic*] around the region with whom we were related, so to say, by virtue of the peripheral clinics that we held at these various centres and we wanted them to have a view of what we were doing and of our figures and our enterprises.

'Q. It would follow, I suppose, that they, if they had kept the reports from one year to the next, would have seen the same comparison figures as you might if you had done that exercise, or others within the unit might?

'A. Yes, I believe so.

'Q. Within the unit, what circulation did the report have?

'A. It was freely available to the members of the cardiology team. I think on the first page of each of those annual reports there is a list of the people who make up the totality of the cardiac unit … Those[41] are the individuals who would have received copies and, indeed, others who requested copies who might not be on the list would have received them too. There was no sense of restricting access to this report, it was meant to be open.

'Q. … Did anyone who was occupying a management role in the Health Authority at this time receive a copy, the District General Manager —

'A. Yes, certainly.

'Q. You say the idea was to send the reports to the then District Health Authority, both the local ones and the peripheral centres. That was what you described as the idea; was it also the reality or not?

'A. Yes, we sent them out.

'Q. Do you know whether they went to individual paediatricians who might refer cases to Bristol?

'A. I believe so. I really cannot recall exactly how the mechanism worked, but I believe my secretary or a secretary within the cardiology department would have been asked to send these reports to these people plus the referring paediatricians.'[42,43]

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40 UBHT 0055 0022; *'Paediatric Cardiology and Cardiac Surgery – Bristol Royal Hospital for Sick Children and Bristol Royal Infirmary – Annual Report 1988'*

41 Listed at UBHT 0055 0023 for 1988

42 T90 p. 16–17 Dr Joffe

43 Referring clinicians were specifically asked by the Inquiry to address whether they had seen or requested a copy of the Annual Reports. Their written evidence is set out in Chapter 11

24 Dr Jordan told the Inquiry of his recollection of the distribution of the Annual Report after 1987 in the following exchange:

> 'Q. … It is right, is it not, that the cardiac unit at Bristol produced an annual report from the late 1980s onwards?
>
> 'A. My recollection of this has been helped by the fact that I have found a copy of what I think was the first annual report we produced, which was for 1987. I think that was stimulated by the fact that of course that was the first year that we had a catheter laboratory at the Children's Hospital and really had anything physically, if you like, that could be called a paediatric cardiac unit. We did try and produce an annual report – not actually quite of the same size as that one – subsequently.
>
> 'Q. For whose consumption was the report produced?
>
> 'A. The consumption was basically internal and it went I think to the management of the Children's Hospital and to the various people concerned; that is a fairly wide number of people, not just the cardiologists, the cardiac surgeons, it would include people like Sister Wakeley, I think the secretaries had a copy, that sort of thing.
>
> 'Q. It was not disseminated externally? It was not sent, for example, to referring paediatricians?
>
> 'A. I think we did actually send the one in 1987 out much more widely. I think we just wanted to do a bit of advertising then, but my recollection is that we did not send subsequent ones out.'[44]

The Inquiry contacted a number of paediatricians who referred children to Bristol. Sixty-five clinicians replied, of these 64 said, with varying degrees of certainty, that they had not seen the Annual Reports. Some were sure that they had not seen copies, but a number made the point that they were now relying on their memories of events up to 13 years ago.[45]

Statistics produced for audit and other meetings

25 Apart from the basic statistics relating to clinical performance produced by the clinicians in Bristol for the purpose of Annual Reports, figures were also produced on an ad hoc basis for presentation at audit and other meetings. For example, referring to the audit meeting of 19 March 1990,[46] Mr Dhasmana stated:

> 'In order to explain the rise in mortality there was a detailed breakdown of operations and analysis of risk factors.'[47]

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44 T79 p. 140–1 Dr Jordan
45 See Chapter 11
46 UBHT 0061 0126; minutes of audit meeting, 19 March 1990
47 SUB 0010 0009 – 0010 Mr Dhasmana

26 As a further example, Mr Dhasmana stated[48] that he presented the results of a detailed audit of the results of his Switch operations carried out on older children, at a meeting open to all clinicians involved in paediatric cardiology, held on 3 June 1992.[49] He further stated that results of open-heart operations carried out between January 1992 and January 1995 were submitted to the external review of paediatric cardiac services in Bristol conducted by Mr (later Professor) de Leval and Dr Hunter in 1995.[50]

27 Mr Wisheart stated that from time to time reviews of results in particular areas were carried out:

> 'On occasions we believed that the results of the work in a particular area might not be as good as had been hoped for. We examined that area in order to try to find out what were the reasons for the disappointing results and then took whatever steps were necessary to improve our practice. Such reviews were carried out for the Fontan operation, for VSDs in the late 80s, for the complications of pulmonary hypertensive problems in the post-operative period, for the results of the Fallots operation in 1990-91, for TAPVD and for the results of the arterial switch operation. Some of these reviews took place within the format of the multi-disciplinary evening meeting, some within the paediatric cardiological audit programme and others at ad hoc meetings.
>
> 'Reviews of a series of patients were carried out with the intention of communicating the findings to scientific meetings or publishing them in peer review journals. Such reviews were carried out for the Mustard and Senning operations, for the Fontan operation, for the results of our work in Pulmonary Atresia with Intact Ventricular Septum and on a range of topics relating to surgery for Coarctation of the Aorta during the period of the Inquiry's review. These might be regarded as being outside the audit process, but of course the findings were usually also presented at an audit or educational meeting within the Department.'[51]

28 A report[52] entitled *'Analysis of Paediatric Cardiac Mortality Data from UBHT 1990 –92'* was produced which contained the results of statistical analyses of data relating to mortality following paediatric cardiac surgery (omitting the Arterial Switch operation) in Bristol for 1990 to 1992, and comparisons with the rest of the UK for the 'National Average Year' of 1991. It showed that, for certain operations, mortality in Bristol was significantly worse than the rest of the UK. The availability of these statistics to clinicians in Bristol during the period 1990 to 1995 is set out in detail in Chapter 20 to Chapter 30.

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48 SUB 0010 0012 Mr Dhasmana

49 UBHT 0061 0165; *'Hospital Medical Committee – Audit Committee Medical Audit Meeting Report – Paediatric Cardiology'*, 3 June 1992. Further details of this meeting and its content appear in Chapter 18

50 INQ 0045 0118 Mr Dhasmana

51 WIT 0120 0397 Mr Wisheart; see Chapter 3 for an explanation of these terms

52 UBHT 0061 0080 – 0102; *'Analysis of Paediatric Cardiac Mortality Data from UBHT 1990 –92'* (also referred to as 'the Bolsin/Black audit')

29 Further statistical information on mortality following paediatric cardiac surgery at the BRI was produced within the Department of Anaesthesia at the BRI. Dr Pryn stated that he compiled figures from a variety of sources on paediatric cardiac outcome data for the chronological year ending 31 December 1993.[53] The figures were discussed at the audit meeting on 20 January 1994. This meeting is described in further detail in Chapter 29.

The returns made to the UKCSR

30 Bristol submitted returns to the UKCSR annually from 1977 onwards. They were compiled from the surgeons' logs, and submitted by Mr Wisheart's secretary. The figures submitted in the returns related to acquired heart disease (adults) and congenital heart disease (children). For congenital heart disease, the number of open and closed operations and number of deaths, for patients under the age of 1 year and those aged over 1 year, were presented in different categories.The categories related to diagnosis rather than the type of operation carried out.

31 The data provided a point of comparison within the Bristol service, year by year, by reference to the figures produced by the clinicians in Bristol for the preceding year and years. It was also possible for Bristol to compare its data with the aggregated data from other specialist centres in the UK, albeit that by the time the UKCSR aggregated data was published it was 18 months to 2 years old.

32 Mr Alan Bryan stated:

> 'It has always been accepted in cardiac surgery that there was a professional commitment to supply accurate data to the UK cardiac surgical register throughout the period in question.'[54]

33 Mr Dhasmana told the Inquiry about the circulation within the Bristol service of the figures submitted to the UKCSR in the following exchange:

> 'Q. If anyone within the department had said, "Janardan, what are the figures?" would you have given them a copy of the returns to the register?
>
> 'A. Copies were always sent to my surgical colleagues, so they all had a copy.
>
> 'Q. What about cardiological colleagues?
>
> 'A. Paediatric cardiologists would have had a copy, but it would not have gone to adult cardiologists and I do not think, you know, we were sending copies to anaesthetists in a way, but if somebody would have come and asked, yes, they would have got a copy.

53 WIT 0341 0039 – 0041 Dr Pryn
54 WIT 0081 0017 Mr Bryan

'Q. Why were paediatric cardiologists given the figures but not anaesthetists?

'A. Because we were closely working together; we were discussing problems, and we had audit meetings called in paediatric and Children's Hospital and anaesthetists were called. If they were not coming to the audit meetings, how would I know they were so much interested about the figures, unless they kept bringing their presence into the meeting? They never did that.'[55]

34 Mr Dhasmana was asked by Leading Counsel to the Inquiry about whether the figures, if presented at audit meetings, were circulated to all those entitled to attend the meetings, in the following exchange:

'A. … I do not think any of these papers you saw, except for the minutes or the summary, the figures itself, I do not think they were circulated, no.

'Q. Why not?

'A. I do not know. You ask Dr Martin [who ran the audit meetings].

'Q. For your part, you did not circulate the results because you thought the anaesthetists might not have been interested?

'A. No, I did not circulate because it was not my job, but at the same time, anaesthetists, if they were conspicuous by their absence, I do not think they could really complain that they were not getting minutes. They never attended any of those audit meetings.'[56]

35 Dr Joffe discussed the distribution of the UKCSR figures within the Bristol service in the following exchange:

'Q. You tell us in your statements that there were figures which were available year on year from, certainly from 1986 onwards but relating to the period 1984 through to 1995. Did you yourself see the figures produced by the unit in terms of mortality rates in the different categories, the under 1s, the over 1s, open and closed for each year as each year fell?

'A. They were certainly available year on year. … the figures were made available to all the cardiologists. Access to those figures is by the surgeons only, that is the UK national register, so that we could only respond to those figures as they were shown to us by the surgeons.

55 T86 p. 146–7 Mr Dhasmana
56 T86 p. 148 Mr Dhasmana

'Q. You got the figures for the unit which were collective figures?

'A. Yes. …'[57]

The South West Congenital Heart Register

36 The cardiologists also developed a system[58] for keeping records of all children seen by them with a congenital heart defect. Dr Jordan stated[59] that the system had a long history, as records had moved from books containing notes onto various early computer systems (from 1973 onwards), until the Bristol and South West Children's Heart Circle purchased a computer which was capable of holding a database of information. Dr Jordan engaged his son to write a software application to make the system more 'user-friendly'. A small research grant from the South West Regional Health Authority (SWRHA) paid for a part-time secretary to input the data. Any patient from the South West seen by the cardiologists who was considered to have organic heart disease, had details of the clinical diagnosis entered on the computer. Some 96 items were recorded for each patient. The uses of the database permitted identification of all patients by multiple parameters; for example, all patients with Down's syndrome or AVSD,[60] the first operation under 1 year of age, and the particular surgeon.

37 Dr Jordan explained:

'In general, while the system probably sounds to be amateurish and was by no means perfect, it was better than most units had in place. Clearly it would have been better if we had had more clerical and computer staff, but we had no finances to pay for this. … Even with the system as it was, I could have made much more use of it if I had had more time.'[61]

The METASA System and the Patient Analysis and Tracing System

38 Mr Jonathan Hutter described in his written evidence to the Inquiry the efforts made to introduce computerised data collection in the Department of Cardiac Surgery.[62] He stated that in 1990 Mr Wisheart:

'… was negotiating to buy hardware and software from the METASA company for the purpose of developing a database of patients having cardiac surgery in order to facilitate research and audit. … This was purchased from Mr Wisheart's fund, which had been donated by patients who wished to express their gratitude by making a monetary donation to the fund run for this purpose by Mr Wisheart.'[63]

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57 T90 p. 9–10 Dr Joffe
58 This is distinct from the 'Cardiologists' Card Index System', referred to earlier, which was kept by the cardiologists' secretaries at the Children's Hospital
59 WIT 0099 0001 Dr Jordan
60 See Chapter 3 for an explanation of this term
61 WIT 0099 0003 – 0004 Dr Jordan
62 WIT 0096 0002 Mr Hutter
63 WIT 0096 0002 Mr Hutter

39 Mr Hutter explained that Mr Wisheart correctly anticipated that computerised audit would become essential and was keen to be at the forefront of its development. Mr Wisheart's fund provided the finance for the purchase of both the METASA system and, later, the Patient Analysis and Tracing System (PATS).

40 Mr Hutter stated that he developed a data set of questions designed to assist audit, or 'retrospective research projects on analysis of results (the old name for audit)'.[64] The intention was to develop two data sets, one for adults and one for children. However, as someone who operated on adults, he stated that he decided to concentrate on developing the adult system first: '… with the intention of assisting in the development of the paediatric data set once the adult system was up and running satisfactorily'.[65]

41 Mr Hutter stated that problems were experienced, such that the PATS system never produced data complete enough to be useful, and never functioned effectively during the period of the Inquiry's Terms of Reference.[66]

Statistics relating to clinical performance at other specialist centres (for the purpose of comparison) available from external sources

42 During the period of the Inquiry's Terms of Reference, statistics relating to the clinical performance of other specialist centres, as well as the Bristol service, could be derived from three main external sources:

- the data from the UKSCR, made available to the cardiac surgeons in Bristol by the Society of Cardiothoracic Surgeons;
- the Department of Health's and Royal Colleges' national working parties on supra regional units for neonatal and infant cardiac surgery in England and Wales;[67],[68]
- externally produced ad hoc reports on the clinical performance of the paediatric cardiac service (PCS) in Bristol relative to other specialist centres (such as the report by Jo Weston and Mr Martin Elliott,[69] and the report by Mr (later Professor)

64 WIT 0096 0007 Mr Hutter
65 WIT 0096 0002 Mr Hutter
66 WIT 0096 0008 Mr Hutter
67 For example, the report commissioned by the DHSS from the Society of Cardiothoracic Surgeons of Great Britain and Ireland: UBHT 0061 0205; *'Interim Report of the Working Party on Neonatal and Infant Supra Regional Cardiac Surgical Units in England and Wales'*, July 1989. Graphs of figures are at UBHT 0061 0212 – 0217. See also Chapter 6
68 For example, DOH 0002 0112; *'Report from the Working Party Set Up by the Royal College of Surgeons of England on Neonatal and Infant Cardiac Surgery: Supra Regional Funding and Designation'*, June 1992. Tables of figures are at DOH 0002 0116 – 0124. See also Chapter 6
69 JDW 0004 0930; *'Comparative Analysis of Paediatric Cardiac Surgery Outcome Data from Bristol'*, April 1995

Marc de Leval following his visit to the UBHT with Dr Stewart Hunter on 10 February 1995 [70]).

The United Kingdom Cardiac Surgical Register (UKCSR)

43 Mr Dhasmana stated in his written evidence to the Inquiry:

> 'The [UKCSR] provided annual figures in the form of averages compiled from the returns to the Society of Thoracic and Cardiovascular Surgeons of Great Britain and Ireland (S.T.C.V.S-UK). All cardiac centres in the U.K., including supra regional centres, would be providing data for the register. The register has mentioned a number of defaulters on a few occasions. Bristol has always contributed to the register. These figures were taken as comparators with known limitations. … The U.K.C.S.R was circulated to each member of the society. … The U.K.C.S.R annual figures were the only known comparator during this time.'[71]

44 Dr Joffe discussed the distribution of the comparative figures from the UKCSR in the following exchange:

> 'Q. There would be a comparison which you would be told of by the surgeons because they had access to the comparison figures for the UK generally?
>
> 'A. Yes.
>
> 'Q. And you say that they were made available; what do you mean by that?
>
> 'A. I believe that they were sent around or copies of the results were sent around to the cardiologists for perusal …'[72]

45 Mr Wisheart discussed the value of the UKCSR figures for making comparisons in the following exchange:

> 'In terms of comparing [my performance] with people outside Bristol, the only comparator available to us was in the most recent annual report of the register [the UKCSR] that was available to us. So, for example, say we were compiling the report for 1988 some time in the early months of 1989. The probability is that we would have available to us the report for 1987 but not for 1988. … The value of the register figures … is that, if we just assume their accuracy for the moment, they then reflected the work in the whole country. That is quite different from information that is available to us in the literature for any particular operation or group of operations, because mostly work in the literature is the work of a particular unit. Obviously, that unit may or may not be representative of the work in a country.

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70 UBHT 0061 0471; *'Bristol Paediatric Cardiac Surgery 1990–1995'*, an independent commentary by Mr Marc de Leval with tables of comparative data, and an introduction by Mr Hugh Ross, Chief Executive of UBHT, January 1996. See also Chapter 30

71 WIT 0084 0051 Mr Dhasmana

72 T90 p. 10 Dr Joffe

'So it had that value and it has to be distinguished, therefore, from other sources of information that we would tap into.'[73]

46 Mr Dhasmana, in his written evidence to the Inquiry, gave an example of how he used data for comparison:

'Using U.K.C.S.R as a comparator, I knew that my figures (as shown in Annex-A[74]) had improved overall in almost all categories in the period 1990-5. … In A.V canal the mortality rate was down from 27.7% at the end of 1989 to 17.5% during the second period, and approaching the U.K figure of 11%, in 1995.'[75]

47 Leading Counsel to the Inquiry asked Mr Wisheart how he interpreted differences between figures in the UKCSR and his results in the following exchange:

'Q. This is the paragraph I want to focus on:[76] "Simply looking at the figures suggests that my mortality of 29 per cent was nearly double the 16 per cent reported in the UKCSR. However, if the higher risk, which is appropriate on account of the additional abnormalities, is assigned to my patients, then the actual expected mortality in this small group must be much greater than 16 per cent. Thus, if there is a discrepancy between my observed 29 per cent and the actual expected mortalities, it is much smaller than the raw figures of 29 and 16 per cent would suggest." What you are doing in these paragraphs is this, is it: taking the raw figures, as you call them, for your series and for the UKCSR and seeking an explanation as to why, despite the appearance of the raw figures, your figures are in truth little different from those which the surgical register reflects; is that the process?

'A. I am not sure whether or not I got to the point of "little different", but I think the process was that I had information in front of me about my patients which I sought to use in relation to the UKCSR. I mean I was not seeking to achieve an end, which is I think what your remarks suggested, I was seeking to understand the facts that were available to me and that understanding could have been one thing or it could have been another. So I was seeking to understand those facts, all of those facts.'[77]

Working Party reports

48 Dr Joffe was asked by Leading Counsel to the Inquiry whether he had seen the Interim Report of the Society of Cardiothoracic Surgeons (the appendices to which contained figures allowing comparison between Bristol and the other, named supra regional centres for neonatal and infant cardiac surgery) and the amendments made to it in handwriting:[78]

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73 T41 p. 67–8 Mr Wisheart
74 WIT 0084 0055 Mr Dhasmana
75 WIT 0084 0052 Mr Dhasmana
76 Referring to Mr Wisheart's evidence at WIT 0010 0029
77 T92 p. 104–5 Mr Wisheart

'Q. In July 1989 … we have the interim report of the Working Party on neonatal and infant supra regional cardiac surgical units in England and Wales. This is a report to the Supra Regional Services Advisory Group. Did you ever see it?

'A. … I am not sure I have.

'Q. What you might remember, and I will take you straight to it, is … the table at the back. The original writing at the top is "Figures for 1988 by centre (alphabetical)". The rest of the writing is added later by someone's hand?

'A. Yes. I have not seen this before.

'Q. You have not?

'A. No.

'Q. It is, as it happens, the second column from the right in each of these particular classes. The first is "open under 1 year" and the next is "open over 1 year". Perhaps we can just take a long view of the sheet. That is Bristol and the other bars are those other centres which were designated at the time.

'A. Yes. I am sorry, I really do not know what is being represented, whether it is operations or —

'Q. These are numbers of operations.

'A. Yes. Under 1?

'Q. The top is under 1, the second is over 1, and then closed operations at the bottom.

'A. Yes, I beg your pardon, you said Bristol was second from the right. I was looking under Newcastle.

'Q. Second from the left.

'A. Yes.

'Q. If we bear in mind the top figure, the 29, and just go to WIT 74/1092, turn it sideways, these represent point estimates of mortality in 1988 and confidence intervals around them demonstrated by the bars. It shows, limited to 1988, the relative performance in terms of mortality of the different units. For that year, we have seen the figure 37.5%?

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78 WIT 0074 1083 Dr Baker; *'Interim Report of the Working Party on Neonatal and Infant Supra Regional Cardiac Surgical Units in England and Wales'*, July 1989

'A. Yes.

'Q. And we can see the second from the left, as it happens, is again Bristol.

'A. Yes.

'Q. It appears to represent that the better units tend to be those doing a larger number?

'A. Yes.

'Q. And that was not surprising, I suspect, or would not be surprising?

'A. Yes, that is correct.

'Q. You did not see this at the time.

'A. No.

'Q. Did you have any idea at the time how other individual units were actually performing?

'A. No, not at all.

'Q. If you had seen information such as that in order to put the information you got each year from the annual report into some sort of context, you would have been able to compare Bristol year by year, depending on what the other years looked like with the performance of other units?

'A. Yes.

'Q. If that showed that Bristol as a unit was consistently either the worst or one of the worst, what reaction do you think you would have had to that?

'A. I would have been very disappointed, naturally, but I would need to see this on a year by year basis before making a confirmed response. But of course, it would be one of disappointment, but again, it would be a case of, as you pointed out, fewer turnover of patients, and again, as I have mentioned, we would have reviewed this looking at the particulars of the cases in detail, as indeed we did.

'Q. Let me give you a hypothesis. If this pattern, or something rather like it, were repeated over most years, to what reason do you think would you ascribe the relative low performance of Bristol? For what particular reasons?

'A. I do not think I can add to those we have discussed. We talked about the split site, et cetera.

'Q. So the split site; the absence of a dedicated paediatric cardiac surgeon?

'A. Yes.'[79]

49 Mr Wisheart was also asked by Leading Counsel to the Inquiry about Working Party Reports (the July 1989 Interim Report of the Society of Cardiothoracic Surgeons,[80] and the June 1992 Report of the Royal College of Surgeons of England[81]) in the following exchange:

'Q. Did you know about the comments that had been made to the Supra Regional Services Advisory Group in the report of the working parties?

'A. I have more difficulty with my recollections there because I certainly saw some reports but I have since seen other documents, through this Inquiry chiefly, which I had never seen before. I think the summary of my position on this would be that I knew that they knew about the split site and they never indicated in any way to us that the split site was either a particular problem in their minds or that it was something that really meant we should not be a designated centre. I mean, they never came to us with anything on that particular front. Indeed, when we sought capital monies from them that would have helped us to deal with it, it was not forthcoming, either in 1987 or in the early 1990s. So I can only assume that they did not regard it as unacceptable.'[82]

50 Mr Dhasmana in his written evidence stated:

'… Mr Wisheart was regularly sending our figures for neonates and infants to the Department of Health in connection with a report on the supra regional service. But I did not receive any regular feed back regarding other centres. I attended the B.P.C.A.[83] meeting in 1992/3 in London, where the Supra Regional Advisory/ Assessment Board's Report was being discussed. This Report showed Bristol amongst the bottom two or three, but the numbers were small. The recommendation was to increase the volume of work, as results were good in centres with a larger volume of cases.'[84]

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79 T90 p. 54–7 Dr Joffe

80 The report commissioned by the DHSS from the Society of Cardiothoracic Surgeons of Great Britain and Ireland: UBHT 0061 0204; *'Interim Report of the Working Party on Neonatal and Infant Supra Regional Cardiac Surgical Units in England and Wales'*, July 1989

81 DOH 0002 0112; *'Report from the Working Party Set Up by the Royal College of Surgeons of England on Neonatal and Infant Cardiac Surgery: Supra Regional Funding and Designation'*, June 1992

82 T94 p. 85 Mr Wisheart. See also Chapter 22

83 British Paediatric Cardiac Association

84 WIT 0084 0051 Mr Dhasmana

Statistics relating to clinical outcomes available from professional meetings, contacts and journals as a means of comparison

51 Mr Wisheart referred in his written evidence to the Inquiry to the sharing of data with other centres:

> 'This took place through communication and publication of data within the context of peer reviewed scientific meetings and journals, including the informal meetings of paediatric cardiac surgeons in Great Britain from 1990. In addition to attendance at meetings … both Mr Dhasmana and I regularly read the journals related to Paediatric Cardiac Surgery.'[85]

Professional meetings, other professional contacts and professional journals

52 Mr Dhasmana in his written evidence to the Inquiry stated:

> '… there was some scepticism attached to information received in conversations with colleagues from other centres, as people did not normally like to talk about problems faced during operations. … Mr de Leval is probably the only surgeon to have published his problems in continuing with the Arterial Switch Programme at the G.O.S. [Great Ormond Street] in 1993/4.'[86]

53 Mr Wisheart stated:

> 'Both Mr Dhasmana and I regularly attended National and International Conferences, in the field of paediatric cardiac surgery, as well as various courses and seminars, which were held from time to time. There were informal conversations with colleagues at other centres, of which there will be no record. I visited other centres for periods of up to one week …'[87]

54 Mr Dhasmana stated:

> 'I attended the "Surgery for Congenital Heart Disease" course run by G.O.S London every other year from 1986 to 1994, and the "Paediatric Cardiac Surgical" course in Paris in 1993. I also attended paediatric cardiac surgical symposiums and meetings run at the annual meetings of S.T.C.V.S-U.K, the European Association, the British Cardiac Association, British Paediatric Cardiac Association (B.P.C.A) and the American Association for Thoracic Surgery (A.A.T.S) frequently. Therefore I had knowledge of advances being made and procedures adopted to keep pace with developments in paediatric cardiac surgery. The information available on these courses and at the various seminars, conferences and meetings were in regard to certain groups of operations performed at known centres of excellence … However, discussions with colleagues at these events were useful in helping to make further improvements. It was as a result of discussions at a B.P.C.A meeting in

85 WIT 0120 0292 Mr Wisheart
86 WIT 0084 0052 Mr Dhasmana
87 WIT 0120 0292 Mr Wisheart

Birmingham, in November 1992, that I approached Mr Brawn for further help with the Arterial Switch Programme at Bristol.'[88]

55 Mr Dhasmana went on:

'I am not aware of any published mortality data on paediatric cardiac surgical operations from a particular centre. However, I have attended meetings where excellent results in one particular operation from a centre were presented, i.e. Arterial Switches and A.V. Canal from meetings held at Birmingham, Bristol and COBE[89] respectively. Arterial Switch results for complex T.G.A. and other conditions from Dublin. I have also seen published results of Arterial Switches in T.G.A with V.S.D. from the Brompton Hospital in 1988 or 89. These were isolated publications of good results in a particular group. We ourselves presented some good results at some of these meetings (List attached – Annex B),[90] and published our good results in Senning operation (British Heart Journal. 69.5, 436–441, 1993) …'[91]

Other statistics relating to clinical performance

56 Apart from the statistics produced by the surgeons, cardiologists, and anaesthetists in Bristol, sources of data were kept by administrative staff in the UBH/T and by the Department of Health.

Patient Administration System

57 The principal source of data kept by administrative staff was the Patient Administration System (PAS). PAS was a computerised system for storing, analysing and recording information that was introduced within UBH/T in 1988. Mr Andrew Hooper, formerly UBH/T PAS Manager, in his written evidence to the Inquiry stated:

'PAS is an administrative system only. It was implemented to replace the manual administrative systems, which had been supported by locally developed computer systems in the Health Authority, prior to 1988. PAS does not replace clinical data. It is solely administrative. For example, it provides an index of all patients who have attended the Trust, whether on an in-patient or out-patient basis. It is able to provide information concerning waiting lists and also to print documents, for example, labels and letters, so saving administrative time. … PAS feeds PAD [Patient Administration Database] with patient based information that is used for statistical information and contract purposes. … the in-patient module is an

88 WIT 0084 0052 Mr Dhasmana. Mr Dhasmana's visit to Birmingham is referred to in more detail in Chapter 27
89 'COBE' refers to COBE Cardiovascular Inc., which ran meetings for paediatric cardiac surgeons in the early 1990s
90 WIT 0084 0061 Mr Dhasmana. See Chapter 3 for an explanation of these clinical terms
91 WIT 0084 0051 Mr Dhasmana

administrative tool to enable staff to record the date of admission, the fact and date of transfer to wards, the date of discharge, any change of consultant, whether the patient is being or has been treated at another hospital within the Trust, and referral to another hospital if within the Trust. Most of this information is recorded in "real time", in other words it is recorded as the event occurs.'[92]

58 PAS contained information on patients' diagnoses and procedures. Mr Hooper was asked by Leading Counsel to the Inquiry about how the diagnostic information got onto the PAS:

'Q. So how did the diagnostic information get on there?

'A. The way that it works is obviously a patient comes into hospital, they have their care, are discharged from the hospital, and then the notes one would normally expect to go back to the consultant's secretary to have a summary dictated. That summary should be dictated as quickly as possible after the discharge, although some clinicians are better than others at doing discharge summaries, so the discharge summary would normally be a side of A4, the top half would have the demographic information, the middle portion would probably have the diagnostic information written down, into a main and secondary diagnosis. If they had an operation, there would be a section for the operation details. At the bottom you would have the text the medical staff dictated about the patient's stay. A copy of that discharge summary would obviously go to the GP and any other interested parties. A copy would be retained in the medical records. As soon as that discharge summary has been dictated and typed, those notes would then go off to the clinical coders for that episode of care to be coded. That would be done as quickly as the discharge summary was dictated. Most of the coding clerks would code directly, all the coders would code from the diagnostic and operational information that had been put on to that discharge sheet.'[93]

59 In his written comment on the preliminary overview of data sources published by the Inquiry, Mr Hooper stated:

'… it is not correct to describe it [the PAS] as a "case-based information system". It is an administrative system. The distinction lies in that of the 5,000 plus users of the system in UBHT 99% of those people using it are only interested in the accuracy of the demographic information and episodal administrative information (i.e. dates of admission and discharge) contained in it. PAS then feeds the statistical information through to PAD [Patient Administration Database]. It has the ability to produce standard reports and utilise an enquiry package. … it was an administrative system which fed information systems.'[94]

92 WIT 0211 0002 – 0003 Mr Hooper
93 T39 p. 12–13 Mr Hooper
94 INQ 0001 0024

60 Referring to PAS systems in general, Ms Ann Harding, then Acting Director of the NHS Information Authority, told the Inquiry:

> '… I think this is one of the problems that we have, the data is collected for the purposes which clinicians believe is managerial, and therefore not relevant to them, and I have a great deal of sympathy for that, because the level of detail at which a clinician would want the information for the purposes of audit is not readily encompassed within the levels of diagnosis and operative coding that we currently have.
>
> 'I also think that we have been quite lax in not feeding back to clinicians the information that is being submitted to the central returns about what it is they are doing. When we did give information back to clinicians, they said "I do not do that operation, I do not have that many patients with that diagnosis", and I think therefore one of the things we must do is to find ways of ensuring that the information does go back to them so they in some ways validate it before it is used for other purposes.'[95]

61 Mr Hooper was asked by Mrs Howard, a Member of the Panel, to comment on the setting up of stand-alone systems within the UBHT to support the clinical staff in the information that they wished to collect, in the following exchange:

> 'Q. You made it clear that this was very much an administrative system, and we have also heard about what I would phrase the "lack of ownership" from clinical staff with regards to that. Do you have any comment about subsequent setting up of stand-alone systems within the Trust to support the clinical staff in the information that they wished to collect? That would be the first part of the question. I would like to explore that after your answer.
>
> 'A. Certainly, as far as I am concerned, I have only ever been involved in implementing the corporate systems. I think probably the Trust … philosophy has always been, where possible, we would like to use those corporate systems, but that is not to say that if a clinician or a group of clinicians wanted to go and purchase perhaps an audit system — they should be able to do that. I think the problem with doing that is, if you are inputting the data into two separate systems, it is always going to be difficult reconciling the information on the two systems.'[96]

62 The data in the PAS was used in ad hoc audit reports, and in making returns to external organisations. Referring to his use of data in the PAS, in his written statement to the Inquiry, Dr Pryn stated:

> '… This was a system used by the ward clerks and enabled me to check whether or not the children had been discharged home and seen in outpatient clinics

95 T39 p. 26 Miss Harding
96 T39 p. 51–2 Mr Hooper

following surgery. This was an indicator as to whether or not they were indeed alive at the time of discharge.'[97]

The CHKS Report

63 In the early 1990s,[98] UBH/T began to use the services of CHKS Limited. Mr Gary Tharme, Sales and Marketing Director of CHKS Limited, wrote to the Inquiry:

> 'CHKS were formed out of a joint venture in 1990 between the King's Fund and CASPE Research and have been building a normative database of UK NHS acute clinical activity since 1992. …
>
> 'The National Comparative Database was launched in 1992 and now has over 100 Trusts subscribing from all parts of the UK.
>
> 'Our aim is to continually improve the quality and use of clinical information in the NHS.
>
> 'We compare hospitals'clinical activity with others that are locally relevant. Comparisons can be simple or extremely refined. Typical comparisons can be at Trust, Hospital, Specialty, HRG [Health Resource Group], and procedure or diagnosis level. Target levels of performance can be derived, for instance looking at high performing Trusts. …
>
> 'Trusts regularly send CHKS information about their activity, which we compare with a range of peer group hospitals that they feel, are relevant to them. Standard performance monitoring reports are sent to the client by return.'[99]

64 In a letter to the Inquiry, Mr Rashid Joomun, the UBH/T's Trust Information Manager, stated:

> 'The Trust provided CHKS with data monthly, which they processed and sent back high level reports in the form of comparative tables. They also provided us with a monthly database on which we could do analysis.'[100]

65 CHKS produced a report,[101] dated 1992, which contained figures of diagnoses, lengths of stay and deaths in relation to the Cardiology and Cardiothoracic Surgery specialties in UBH/T and in a group of similar hospitals for comparison. Statistics relating to paediatric cardiology and cardiac surgery in particular, were not separately identified in the report.[102]

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97 WIT 0341 0040 Dr Pryn
98 UBHT 0343 0002 Mr Joomun
99 SEM6 0003 0131 – 0132 Mr Tharme
100 UBHT 0343 0003 Mr Joomun
101 HOME 0011 0001; *'National Comparative Database, United Bristol Healthcare NHS Trust, Reports for Cardiology and Cardiac Surgery'*, CHKS Limited, 1992
102 UBHT 0343 0003 Mr Joomun

66 In a letter to the Inquiry, Mr Joomun further stated:

> 'Action was taken to improve data quality. This was mostly centred around diagnostic coding. General Managers would be informed individually of their directorates' problems and it was expected that they would take the necessary action to remedy these problems. … As far as I know, none of the Directorates had direct access to the routine reports produced by CHKS.'[103]

Hospital Episode Statistics

67 The PAS was used, further, to provide summary data on episodes of care for patients, for the national returns to the NHS known as Hospital Episode Statistics (HES). In his written statement to the Inquiry, Mr Richard Willmer, a Branch Head in the Statistics Division of the DoH, in describing HES, stated:

> 'The HES system collects records for all (both NHS and private) in-patient consultant episodes of care, including day cases but excluding regular day or night attenders, in NHS hospitals in England.'[104]

68 Mr Willmer also stated:

> 'HES was introduced on the recommendation of the NHS/DHSS Steering Group on Health Services Information, which was appointed by the Secretary of State for Social Services in February 1980. The Chairman, Mrs E Körner, published the First Report on the collection and use of information about the clinical activity in the National Health Service in 1982. The report which is commonly known as the "Körner"report, states at section 8.4;
>
> ' "The DHSS needed information about bed use for:
>
> ' "a. Policy development. Detailed statistical analysis may be required when pursuing issues arising from a preliminary analysis of simple tabulations.
>
> ' "b. Resource procurement and allocation. To prepare and argue the case for adequate funding for the NHS, the DHSS requires ready access to detailed information about the pattern of care in hospitals. Information is also needed for the operation of the resource allocation system, for the monitoring of the system's effects and for the development and improvement of the existing system.
>
> ' "c. Accountability. Health authorities are accountable to the Secretary of State and the Secretary of State to Parliament for the setting of policies and priorities for the use of NHS resources, and the use of resources to achieve those objectives.
>
> ' "d. Research and development activities. Both DHSS and OPCS [Office for Population Censuses and Surveys] carry out a range of epidemiological,

[103] UBHT 0343 0006 Mr Joomun
[104] WIT 0189 0009 Mr Willmer

operational research and economic studies, which contribute to policy development and service planning.

'The Hospital Episode Statistics (HES) system, and miscellaneous Körner Aggregate returns resulted from these recommendations, and is largely still based on the principles established in the First Report.

'… The main additional purposes … are: *performance assessment* of the NHS by DoH and the NHS themselves; identifying *inequalities* in health and healthcare and *small area studies* eg effects of local environmental factors. Even now, there are known deficiencies in the data which impose constraints on the uses but with knowledge and care expert users are seeking to exploit the data more fully than in the past."'[105]

69 Mr Willmer further stated:

'HES data were originally collected centrally from the NHS through the Regional Information System (RIS) based in each of the Regional Health Authority (RHA) areas. The regions varied as to what data they held on their own databases (eg whether or not names and addresses were held), how they compiled their HES submission, and how data were shared with NHS colleagues. What did not vary was the subset of data items the RHAs supplied to OPCS for HES.'[106]

70 In his first report to the Inquiry, Professor Stephen Evans, one of the Inquiry's experts on statistics, stated:

'Bristol, in common with other hospitals within the National Health Service (NHS), is required to provide summary data on episodes of care for patients. It does this using the local computer-based Patient Administration System (PAS) for providing national returns to the NHS, known as Hospital Episode Statistics (HES). Most other Health Care Trusts in England and Wales have similar systems for producing these returns. More details on the national picture derived from HES are given in a separate report (Aylin et al. 1999). The Bristol PAS is a fairly comprehensive computer system developed from a long tradition of using computers for patient administration in the Bristol area that was begun in the late 1960's. Neither in Bristol nor elsewhere have patient administration systems generally been used for looking at clinical outcomes in a rigorous way. In most instances the recording of death is limited to those deaths which occur prior to discharge from hospital. The Bristol system has included patient outcome, in terms of death, for at least some patients beyond the period when a patient was actually in hospital. This is unusual and allows for a more comprehensive picture of the vital status of patients than is usually the case for administration-based systems.'[107]

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105 WIT 0189 0004 – 0005 Mr Willmer (emphasis in original)
106 WIT 0189 0006 Mr Willmer
107 INQ 0012 0007 – 0008; *'A report on local data relating to children who received cardiac surgery under the terms of reference of the Bristol Royal Infirmary Inquiry'*, October 1999, Professor SJW Evans

'The purpose of the system is not to store information that a doctor requires to care for the patient, nor is it intended for audit of the quality of care. Any such use must take account of the likelihood that important details may not be recorded.'[108]

'The administrative clerks (known as "coders") who classify diagnoses and operations for the PAS are not medically qualified, and they may misunderstand the medical information in the medical records of patients. The medical records themselves may not be clear in describing the diagnoses or operations for every patient. The ICD [International Classification of Diseases] coding system may also have inadequacies when used in a very specialised area. Individual coders vary in their experience, but there are some highly experienced coders who are very good at carrying out the classification of diagnosis and operation.'[109]

108 INQ 0012 0012; *'A report on local data relating to children who received cardiac surgery under the terms of reference of the Bristol Royal Infirmary Inquiry'*, October 1999, Professor SJW Evans,

109 INQ 0012 0013; *'A report on local data relating to children who received cardiac surgery under the terms of reference of the Bristol Royal Infirmary Inquiry'*, October 1999, Professor SJW Evans,

Section two: the views of the Inquiry's Experts on the interpretation of statistics relating to clinical performance which were available to clinicians in Bristol during the period 1984 to 1995

Statistics relating to clinical performance produced by the clinicians in Bristol

71 Earlier in this chapter, reference was made to a series of three Annual Reports on paediatric cardiology and cardiac surgery in Bristol that were produced by the clinicians in Bristol during the period of the Inquiry's terms of reference.[110],[111],[112]

72 Four members of the Inquiry's Group of Experts[113] were asked to review these Annual Reports, with specific reference to identifying any concerns to which they would or should have given rise at the time.

73 Dr Duncan Macrae observed:

> 'The most striking feature of all three reports to me is the high mortality quoted for open heart surgery performed in children < 1 year of age. The mortality figures of 20% in 1987, 37.9% in 1988 and 37.5% in 1989 are consistently high and over the three year period showed no sign of improvement. There could be a number of explanations for this, including case-mix. I note, in particular, that as a percentage of total activity, proportionately fewer neonates were operated upon in Bristol than at the Brompton Hospital. This may go some way in explaining the high mortality in Bristol if there was a bias towards selecting the sicker patients for operation under one year of age. Also since the numbers operated were small, I presume, from a statistical point of view, the confidence limits were wide. Nevertheless I believe that the failure of the Bristol annual reports to demonstrate an improving

110 UBHT 0166 0001 – 0014; *'Paediatric Cardiology and Cardiac Surgery, Bristol Royal Hospital for Sick Children and Bristol Royal Infirmary, Annual Report 1987'*

111 HAA 0138 0003 – 0012; *'Paediatric Cardiology and Cardiac Surgery, Bristol Royal Hospital for Sick Children and Bristol Royal Infirmary, Annual Report 1988'*

112 UBHT 0133 0073 – 0086; *'Paediatric Cardiology and Cardiac Surgery, Bristol Royal Hospital for Sick Children and Bristol Royal Infirmary, Annual Report 1989/1990'*

113 Dr Kate Bull (Medical Adviser to the Department of Nursing and Family Services and previously Honorary Consultant Paediatric Cardiologist at Great Ormond Street Hospital), Mr Leslie Hamilton (Consultant Cardiothoracic Surgeon at The Freeman Hospital, Newcastle upon Tyne), Dr Alan Houston (Consultant Paediatric Cardiologist at the Royal Hospital for Sick Children in Glasgow), and Dr Duncan Macrae (Director of the Paediatric Intensive Care Unit at the Royal Brompton & Harefield NHS Trust)

mortality should have raised concerns and led to discussions within the unit about the reason for this, and any necessary remedial action, given that in the wider UK context (I note that the UK figures are appended to the 1989 –'90 reports) mortality for open heart surgery under one year of age was approximately half of that reported in Bristol.'[114]

74 Mr Leslie Hamilton observed:

'The first report contains an amalgamation of figures over a four year period and the unit would have been justified in accepting these mortality figures as a baseline. It is difficult to be specific as the small numbers involved mean the absolute mortality figure will have wide confidence intervals. The figures for "closed" surgery in both age groups would seem to be satisfactory. The mortality figure in the "open" category for the over one age group would again be within acceptable limits. The mortality rate for the "open" surgery in the under one age group are [*sic*] high but that for 1984–87 would have been comparable with national results. The mortality rates in 1988 and 1989 (37.5%) are high with a national mortality rate recorded in the Register [UK Cardiac Surgical Register] of approximately 20%. Even allowing for under reporting of deaths in the National Register and the relatively small numbers in Bristol these figures for 1988 and 1989 would have given rise for concern. It might have been argued that if Bristol had a conservative approach to surgery in this age group and undertook palliative surgery for many conditions, then it would mean that they were only carrying our [*sic*] corrective surgery (i.e. "open") on the very sickest children in the under one age group. Thus the individual cases would need close analysis.'[115]

75 Dr Alan Houston observed:

'The main clinical concern … is the mortality in the open procedures < 1 year of age. However, the lower ratio of operations in this group needs to be explained.

'It would be necessary to consider whether some infants were referred to another centre. And if so were they the less severely ill ones — with the worse ones who needed urgent treatment being referred to Bristol as they were too ill to travel to another more distant centre. This might explain the higher Bristol mortality rate.

'If all were referred and some not operated upon and dying, the mortality ratio becomes even higher than 1.7 and would likely be over 2.0. Double the national mortality would be a major concern, even without statistical analysis of the data.'[116]

114 INQ 0043 0001; *'Clinical audit data'*, 14 December 1999, Dr Macrae
115 INQ 0043 0008; *'Key clinical audit data'*, 13 December 1999, Mr Hamilton
116 INQ 0043 0005 – 0006; *'Clinical audit data on outcomes'*, undated, Dr Houston

76 Dr Kate Bull, referring to the high mortality reported for open-heart surgery in the under-1s in Bristol by 1989, observed:

> '… I believe many readers would be left with the raw figures and some hesitancy about whether there "really was" an issue to be raised. However, even with little in the way of quantitative skills, the impression that mortality for open-heart surgery in infancy was "twice the national average" (37.5% v 18.8%) would have been a conclusion that many readers could and should have come to.'[117]

77 Dr Bull concluded:

- 'The annual reports of Paediatric Cardiology and Cardiac Surgery were primarily documents that gave accounts of the "outcome of developments" rather than the "outcome of patients".
- 'However, by the time that the annual report of 1989 was circulated, a problem with mortality for open-heart surgery in infancy in Bristol was discernible.
- 'In that report a table was generated with some care and presented sufficient historical Bristol and contemporary national data to have given readers reason to "commission" a more detailed report.'[118]

78 As regards the information produced within the Department of Anaesthesia at the BRI, in the document *'Analysis of Paediatric Cardiac Mortality Data from UBHT 1990–92'*,[119] Professor Michael Campbell, Professor of Medical Statistics at the University of Sheffield and an Expert to the Inquiry in statistics, observed:

> 'This contains analysis of paediatric cardiac mortality data from UBHT 1990–1992 and compares it to the national average year of 1991. It omits the neonatal arterial switch operation. It shows Bristol to be statistically significantly worse than the rest of the UK on a number of operations. I have checked the chi-squared tests and they seem correct.'[120]

117 INQ 0043 0013; *'Expression of Concern'*, 13 December 1999, Dr Bull
118 INQ 0043 0014; *'Expression of Concern'*, 13 December 1999, Dr Bull
119 UBHT 0061 0080 – 0102, also referred to as the 'Bolsin/Black audit'
120 INQ 0043 0019; *'Commentary on statistical analyses in response to letter from Dr Chadwick 04/10/1999'*, 8 October 1999, Professor Campbell

Statistics relating to clinical performance at other specialist centres (for the purpose of comparison) available from external sources

The UKCSR

79 Mr Leslie Hamilton stated:

> 'Standards for comparison are difficult — only the best results (by definition) are presented at conferences and the figures from the UK Register usually did not appear for at least a year. It must be further stressed that the UK Cardiac Surgical Register was not set up as an audit tool. Recording of data, particularly in the late 80s, was rather crude and there was certainly no validation. Thus no clinician would have used the mortality figure from the UK Register as being an accurate model, recognising that deaths were likely to be under reported.'[121]

80 Dr Eric Silove, Consultant Paediatric Cardiologist at Birmingham Children's Hospital NHS Trust and a member of the Inquiry's Expert Group, stated:

> 'Unfortunately, the UKCSR data was the only pool of information readily available to all clinicians in the UK who wanted to get what they might have considered to be a reasonable estimate of what the expectations were in the UK. It is unlikely that most centres would have aspired to produce results as good as the best in the United States or, for that matter at Great Ormond Street Hospital. It is also unlikely that clinicians at any centre would have taken into account the best results when communicating expected mortality rates to patients and families. It is more likely that they would have relied on the UKCSR data, however flawed it may have been.'[122]

81 In their Overview Report, the Inquiry's Experts in statistics, Dr Spiegelhalter, Professor Evans, Dr Aylin and Professor Murray, considered, from a statistical perspective, what could have been known at the time by Bristol clinicians about Bristol's performance as compared with the performance of other centres, on the basis of simple statistical analyses of the data available from the UKCSR:

> 'It is possible to consider what simple analyses might have been performed using the data and the statistical tools that would have been readily available to the surgeons at the time. The participating centres in the [UK]CSR were supplied with detailed annual reports giving mortality rates split by age and procedure, aggregated over all participating centres. This would have allowed a centre to compare its mortality rates with corresponding national figures.

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121 INQ 0043 0007; *'Key clinical audit data'*, December 1999, Mr Hamilton

122 INQ 0028 0022; Expert clinical commentary from Dr Silove on *'A systematic review of the outcomes of open heart paediatric surgery'*

'Open [heart] surgery performed in children aged under one year is an appropriate subgroup to monitor, since these children are at high risk and include the majority of deaths.[123] In this group the ratio of the overall mortality rates at Bristol to the rates for other centres in England for 1985 through to 1995 were 1.18, 1.21, 1.24, 2.04, 1.93, 0.79, 2.05, 1.19, 3.18, 1.67 and 0.50 respectively. A chi-squared test performed each year would have given a crude indication of whether the local mortality rate differed from the national rate by more than could be explained by chance. Using such a test, the data for 1988, 1989, 1991 and 1993 are statistically significant at the 5% level. If years had been pooled in pairs or triplets to give larger numbers, then the results for 85/86 and 86/87 are non-significant, as are the results for 85/86/87, but the results for 87/88 and 86/87/88 are statistically significant. Thus with any of these approaches, it is not until the data for 1988 were included that the divergence from the national rates became statistically significant, and this was reinforced by the data for 1989. Given that there was a delay of the order of 18 months before the [UK]CSR data were fed back to centres, it would have been 1990 before the data from the [UK]CSR might have given any reason for concern, and the independent reinforcement for the 1989 data, which would become available during 1991, would have heightened this concern. However, the data for 1990 then came back into line with national figures … which might have been taken as reassurance that any problems which might have existed previously had been resolved.

'This final point illustrates the difficulty of interpreting crude data based on small numbers of patients each year. Taking running totals from three year periods the data are statistically significant for 86/87/88, 87/88/89, 88/89/90, 89/90/91, (borderline non-significant for 90/91/92), 91/92/93, 92/93/94 and 93/94/95. Clearly there is a consistent and on-going pattern of poor outcomes, but it is difficult to know what weight should have been put on these data at the time, with there being questions over the data quality and with inadequate statistical tools to adjust for case mix and to analyse accumulating data from many different centres.'[124]

Professional journals

82 Ms Katerina Vardulaki and others[125] were commissioned by the Inquiry to review the contemporary literature to identify the body of knowledge that, in theory, was available to the clinicians in Bristol. Their approach was systematically to review case series[126] which had been published. They concluded:

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123 A comparison of annual admissions, deaths and mortality rates in Bristol derived from local sources of data for open operations on under-1s can be found at INQ 0045 0054; *'Overview of statistical evidence presented to the Bristol Royal Infirmary Inquiry concerning the nature and outcomes of paediatric cardiac surgical services at Bristol relative to other specialist centres from 1984 to 1995'*, Dr Spiegelhalter et al., September 2000

124 INQ 0045 0037; *'Overview of statistical evidence presented to the Bristol Royal Infirmary Inquiry concerning the nature and outcomes of paediatric cardiac surgical services at Bristol relative to other specialist centres from 1984 to 1995'*, Dr Spiegelhalter et al., September 2000

125 INQ 0039 0001 – 0104; *'A systematic review of the outcomes of open heart paediatric surgery'*, April 2000

126 In their report to the Inquiry, Ms Vardulaki et al. defined a case series as: 'A series of clinical cases, usually consisting of consecutive patients, seen in one or more centres between two time points': INQ 0039 0007; *'A systematic review of the outcomes of open heart paediatric surgery'*, April 2000. At INQ 0039 0004 they reported: 'Searches only yielded case-series, i.e. no comparative studies such as randomised trials or cohort studies were found'

> 'Case series on five open-heart operations/congenital anomalies have been reviewed systematically and the data have been synthesised. The pooled 30-day mortality estimates (at a particular point in time) are likely to represent "best achievable performance" rather than the performance to be expected in everyday practice. …
>
> 'The review was commissioned primarily with the aim of understanding better the knowledge base that might reasonably have been expected to be available to the Bristol clinicians during 1984–1995. We have identified and synthesised the knowledge that existed but have pointed out, by analogy with other literature on systematic reviews, that it is probably unrealistic to have expected the Bristol clinicians to be aware of this knowledge. We propose that the paediatric surgical community should judge the relevance of the knowledge presented in the review to everyday practice.'[127]

83 Seven members of the Inquiry's Expert Group[128] were asked to comment on the extent to which the evidence on mortality in the review by Ms Vardulaki's et al. reflected 'common knowledge' among members of the paediatric cardiac community during the period of the Inquiry's Terms of Reference.

84 Dr Duncan Macrae stated:

> 'You asked me to comment on the extent to which the case series presented in the report would have been available to practising clinicians during the enquiry [*sic*] period. I think it is fair to say that the majority of the journals cited were readily available throughout that period in Medical Schools and Departmental Libraries throughout the UK.'[129]

85 Dr Robert Arnold stated:

> 'Clearly the evidence of 30 day mortality derived from so many publications utilising very sophisticated statistical techniques has not previously been available. The individual reports of large series of cases published in the leading journals were accessible and should have been known by any surgeon or cardiologist working with congenital heart patients.'[130]

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127 INQ 0039 0071 – 0072; *'A systematic review of the outcomes of open heart paediatric surgery'*, April 2000

128 Dr Robert Arnold (Consultant Paediatric Cardiologist at Alder Hey Children's Hospital), Dr Kate Bull (Medical Adviser to the Department of Nursing and Family Services and previously Honorary Consultant Paediatric Cardiologist at Great Ormond Street Hospital), Mr Philip Deverall (formerly Director and Head of the Department of Cardiothoracic Surgery at Guy's Hospital), Mr Leslie Hamilton (Consultant Cardiothoracic Surgeon at The Freeman Hospital, Newcastle upon Tyne), Dr Duncan Macrae (Director of the Paediatric Intensive Care Unit at the Royal Brompton & Harefield NHS Trust), Mr Babulal Sethia (Consultant Cardiac Surgeon and Clinical Director of Paediatric Services at the Royal Brompton and Harefield NHS Trust), and Dr Eric Silove (Consultant Paediatric Cardiologist at Birmingham Children's Hospital NHS Trust)

129 INQ 0028 0016; Expert clinical commentary from Dr Macrae on *'A systematic review of the outcomes of open heart paediatric surgery'*, 20 July 2000

130 INQ 0028 0002; Expert clinical commentary from Dr Arnold on *'A systematic review of the outcomes of open heart paediatric surgery'*, 20 July 2000

86 Dr Eric Silove stated:

> 'The case series evidence presented in the report would have been available to practising clinicians during the period covered by the Inquiry (1984 – 1995) but would not have been accessible in the analysed format of the Report. It would have been unrealistic to have expected any clinician to conduct similar analyses. …
>
> 'The evidence about mortality rates in the best centres, presented in the report, probably was commonly known at the time to practising clinicians but it would not have been viewed as immediately achievable in most centres.'[131]

87 Mr Leslie Hamilton stated:

> '... surgeons would have had a feeling of the general principles outlined in the report but would not have had the specific factual evidence on which to base their assumptions.'[132]

88 Dr Kate Bull stated:

> 'Most of the journals used for this review would be fairly readily available to most specialists in the field and most of the material would remain unread by any individual. Scanning the contents of a journal and knowing that he or she cannot absorb it all, a clinician is selective. Thus only a proportion of the material presented would be "actively known".
>
> '… the extent to which the report corresponds to "common knowledge" is hard to say. My own initial reaction to the graphs was that they give an optimistic impression of results in general.'[133]

89 Mr Babulal Sethia, Consultant Cardiac Surgeon and Clinical Director of Paediatric Services at the Royal Brompton and Harefield NHS Trust, observed:

> 'I think that the evidence presented in the report does, in the main, match what was commonly known at the time concerning surgical risks and outcomes of higher risk procedures …
>
> 'Most of the journals quoted … would be perceived by the paediatric cardiac surgical community as sources of seminal or authoritative evidence on surgical risks and outcomes. During the time frame under consideration most of the best publications appeared in the American literature. An important source of evidence on surgical risks and outcomes would have been the Annual meetings of both the

131 INQ 0028 0023; Expert clinical commentary from Dr Eric Silove on *'A systematic review of the outcomes of open heart paediatric surgery'*, 23 July 2000

132 INQ 0028 0015; Expert clinical commentary from Mr Hamilton on *'A systematic review of the outcomes of open heart paediatric surgery'*, 12 July 2000

133 INQ 0028 0008; Expert clinical commentary from Dr Bull on *'A systematic review of the outcomes of open heart paediatric surgery'*, April 2000

British and European Cardiac Surgical Societies at which a steady number of congenital presentations were made on each occasion.'[134]

90 Dr Silove stated further that:

'From the perspective of the practising clinician, it is well-known that centres do not publish if their results are not the best or near the best. It also is self-evident that editors of the more reputable journals will not accept papers unless they have something new to offer their readers. Clearly then, the selection of the publications that were reviewed must have been significantly biased. The reported mortality rates cannot be representative of the expected results in the world as a whole, nor in any one country. We therefore need to view the mortality results as the very best that could be expected in the United States (5 centres), Australia (1 centre), and the United Kingdom (1 centre). This point is made by the authors in their Conclusions (para 110) but is not given enough emphasis in the report as a whole.'[135]

91 Dr Macrae stated:

'I agree that the literature presented in the review does represent fairly the common published literature in the field. As the report points out, it is likely that large ("good") centres are disproportionately represented in this series of published papers. Smaller centres are probably not adequately represented, either because they accumulate too few cases to publish contemporary series or because their results are poor and therefore not deemed publishable. If the Bristol results were only compared to published outcomes, then there is a risk that they be judged unduly harshly because of this inherent publication bias towards large high-volume centres.'[136]

92 Mr Philip Deverall stated that:

'I do … accept that publications from centres of excellence represent gold standards. One has to accept and believe the veracity of the data in this type of publication but equally these publications do not tell the whole truth about the results of treatment which are experienced throughout the world. Bad results are not published. Small numbers of results, which would often reflect the practice of a regional unit, would in general not be considered worthy of publication in a major journal. However and despite these reservations the gold standard data of best practice would represent a goal to which all would aspire.'[137]

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134 INQ 0028 0019; Expert clinical commentary from Mr Sethia on *'A systematic review on the outcomes of open heart paediatric surgery'*, July 2000

135 INQ 0028 0021; Expert clinical commentary from Dr Silove on *'A systematic review of the outcomes of open heart paediatric surgery'*, July 2000

136 INQ 0028 0016; Expert clinical commentary from Dr Macrae on *'A systematic review of the outcomes of open heart paediatric surgery'*, July 2000

137 INQ 0028 0012; Expert clinical commentary from Mr Deverall on *'A systematic review of the outcomes of open heart paediatric surgery'*, July 2000

93 Mr Deverall drew attention to the 'inherent time lapse between practice and publication', and referred to there being 'at least a three year period before knowledge would become available to the general reading surgical public'.[138]

94 As regards the relevance of the published literature to discussions between clinicians and parents concerning the risks of, and consent to, surgery, Dr Macrae stated:

> '… the published papers do accurately reflect the known surgical risks and outcomes. In the present era, all of these risks would be discussed by a surgeon seeking consent in detail. I suspect that in the era starting in the mid '80's, risks were bundled together and perhaps a little glossed over at times. I think there may have also been a greater tendency in this period to rely on anecdotal recollections of local or regional practice, when describing results or procedures to parents, rather than quoting risks from published series.'[139]

95 Dr Silove stated:

> 'It is also unlikely that clinicians at any centre would have taken into account the best results when communicating expected mortality rates to patients and families. It is more likely that they would have relied on the UKCSR data, however flawed it may have been.'[140]

96 Dr Bull stated:

> 'To be fair to the clinicians, I believe it [the review of the published research] could have gone further in conveying the breadth of estimates of early mortality that the clinician has to reconcile and point out that there is no robust method for doing this.'[141]

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138 INQ 0028 0012; Expert clinical commentary from Mr Deverall on *'A systematic review of the outcomes of open heart paediatric surgery'*, 17 July 2000

139 INQ 0028 0017; Expert clinical commentary from Dr Macrae on *'A systematic review of the outcomes of open heart paediatric surgery'*, 20 July 2000

140 INQ 0028 0022; Expert clinical commentary from Dr Silove on *'A systematic review of the outcomes of open heart paediatric surgery'*, 23 July 2000

141 INQ 0028 0008; Expert clinical commentary from Dr Bull on *'A systematic review of the outcomes of open heart paediatric surgery'*, April 2000

97 Mr Deverall advised that the surgeons in Bristol:

> '… should have been aware of the trends and whatever reservations they may have had in regard to centres of excellence they should have been aware of the gold standards being set. I have significant doubts as to whether the busy surgeons in Bristol could have found the time and support necessary to take advantage of the means of acquiring knowledge, which I have described. I have a major doubt that even had the surgeons been able to most efficiently acquire experience and knowledge that they could apply this to their patients in an optimal way. The facilities, for example a split site, the equipment, for example echocardiography machines, and the clinical profile of the patients, for example babies presenting late in the evolutionary clinical process, would all introduce conditions making the achievement of an optimal outcome more difficult.'[142]

[142] INQ 0028 0013; Expert clinical commentary from Mr Deverall on *'A systematic review of the outcomes of open heart paediatric surgery'*, 17 July 2000

Section three: the principal conclusions of the Inquiry's Experts on statistics

98 The Inquiry commissioned its Experts on statistics to advise on the following:

- 'the quality and reliability of key statistical sources, both individually and overall; to include comment on whether or not any of the sources approach "gold standard" quality;
- 'the validity of the analytical and statistical assumptions used in analysing and synthesising key statistical sources; to include comment on classification errors, adjustment for surgical risk and case mix, and estimation of excess deaths;
- 'the overall statistical pattern emerging across sources; to include comment on the strength and consistency of statistical signals, and whether, and the extent to which, these are consistent with published research evidence;
- 'the overall reliability, scientific robustness and degree of confidence attaching to statistical evidence to the Inquiry; to include comment on whether, how, and the extent to which, reliable conclusions can be drawn from flawed statistical sources;
- 'valid conclusions relevant to the Inquiry's remit, if any, that can be drawn from the statistical evidence;
- 'any emerging broad lessons for the future.'

The Experts' summary of their principal conclusions

99 In the executive summary[143] to their Overview Report, Dr Spiegelhalter, Professor Evans, Dr Aylin and Professor Murray summarised their conclusions:

1. 'This overview provides a critical review of statistical evidence presented to the Inquiry regarding the nature and outcomes of paediatric cardiac surgery in Bristol between 1984 and 1995, focusing on the strengths and limitations of the available data sources, and the reliability of conclusions that have been drawn. Key published sources and commentaries have been taken into account. Such a

[143] INQ 0045 0002 – 0005; *'Overview of statistical evidence presented to the Bristol Royal Infirmary Inquiry concerning the nature and outcomes of paediatric cardiac surgical services at Bristol relative to other specialist centres from 1984 to 1995'*, September 2000, Dr Spiegelhalter et al. All subsequent references in this section are to this report, unless otherwise stated

comparative exercise raises a number of difficult issues concerning data quality, the need to aggregate over subgroups, risk-adjustment and so on (Section 1).[144]

2. 'The focus of the analysis is on the performance of surgical services that existed in centres, rather than the performance of individual surgeons. It is therefore not appropriate to adjust for pre-operative risk-factors that may be influenced by preceding care (Section 1.3.5). Comparisons of performance were primarily restricted to analyses of 30-day mortality. The main findings were presented in terms of "excess number of deaths"; namely the number of deaths observed in a given stratum at Bristol minus the number which would have been expected had Bristol been similar to other centres in the country. The excess deaths were summed over strata, and the assessed statistical significance of any excess took account of centre to centre variability (Section 1.3.6).

3. 'Case-mix adjustment was based on age at operation, operative grouping and epoch of operation. Coding of diagnoses and operative procedures in paediatric cardiac surgery is inherently complex and controversial: the operative grouping adopted was devised with substantial clinical input (Section 2).

4. 'All data sources were flawed, and no one source could be considered as representing the "truth". Sources used different definitions and variable degrees of quality control: data concerning follow-up of children after discharge from hospital, for example, were erratic. National data were administrative (Hospital Episode Statistics – HES) and professional (UK Cardiac Surgical Register – CSR). HES data have a poor reputation among clinicians, but a linkage exercise with national death registration showed a reasonably accurate correspondence with recorded 30-day in-hospital mortality (Section 3.1.4). There was evidence within CSR of highly variable submissions from some units over the period in question. Although using different definitions and arising from relatively independent sources, HES and CSR data showed reasonable consistency at an aggregated level, although considerably poorer for individual procedure groups (Section 3.3). The crucial issue is not whether HES or CSR precisely measure activity and outcome, but the extent to which feasible data inadequacies could explain any observed divergent performance (Section 3.4).

5. 'None of the five local data sources could be taken as a reliable basis for clinical audit (Section 4). In spite of all these problems, there was a surprising degree of agreement between the diverse sources regarding performance in Bristol, especially when restricted to looking at mortality rates following open surgery. This degree of consistency lends credibility to the conclusions drawn from the data (Section 5).

6. 'When compared with performance elsewhere, the main finding was a substantial and statistically significant number of excess deaths at Bristol (Section 6.2).

[144] The sections referred to are those contained in the main body of the Experts' Overview Report

Adjusting for operative case-mix did not influence this finding. Particular emphasis was placed on the analysis of data from 1991 to 1995, since data were available for that period from both of the national data sources. Depending on the precise approach to the analysis, the number of excess deaths for open surgery during this period was estimated to be of the order of 30 to 35. The excess mortality corresponded roughly to the mortality rate at Bristol being double that observed elsewhere in England for children aged under one year and even greater for children under 30 days. There was a trend observed outside Bristol for overall mortality rates to fall substantially over the Inquiry period, and this trend was not observed in the Bristol data. Further analysis showed that the excess was not restricted solely to switch and atrial-ventricular septal defect (AVSD) operations, and that missing data on outcomes in HES had minimal influence (Section 6.4.1). Evidence for excess mortality was robust to sensitivity analysis to a number of potential data inadequacies (Section 6.4.3).

7. 'Data sources were not of sufficient quality to make any firm conclusion concerning morbidity outcomes (Section 6.3).

8. 'Over the period 1991–1995, both HES and CSR data suggest performance in England (excluding Bristol) was roughly equivalent to published international sources (Section 7).

9. 'There is evidence of an association between lower volume of surgery and increased mortality in open operations on under 1s over the period 1991–1995, even when ignoring the data from Bristol (Section 8.1). However, this association only explains a small proportion of the excess observed in Bristol. Other factors regarding comorbidity and status at admission are not substantially related to the observed mortality pattern in Bristol (Section 8.2).

10. 'Between the years 1990 and 1994, there is a clear pattern of a concentration of operations just prior to the first birthday, particularly for AVSDs, and the operative mortality rate at this age is higher than that observed elsewhere. This pattern does not feature in any other centre, and the relevant operations in Bristol appear to be delayed rather than brought forward. This finding is associated with around 25% of the observed excess mortality in Bristol (Section 8.3).

11. 'The Clinical Case Note Review suggested that around 30% of children received less than adequate care, and that in just over 5% different management would reasonably be expected to have made a difference in outcome. Many aspects of the process of care were criticised, with no particular highlight on surgical performance. However, similar measures for other centres are not available, and so we cannot know whether similar criticisms could be made of procedures carried out elsewhere (Section 8.4).

12. 'In spite of the many flaws in the data, we do not believe that apparent divergent performance of this magnitude and consistency can be explained fully by statistical variability or systematic bias in data recording. Rather we conclude that there is strong evidence of poor performance at Bristol, especially for open surgery in children aged less than one year, over the period 1988 to 1995 (Section 9.2). Simple statistical analysis of available data might have suggested this pattern by around 1990 (Section 9.4), although the 1990 performance then matched the national average and so might have provided temporary reassurance. We must stress that this does not necessarily imply that there was poor performance by individual surgeons during this period. The whole system of care provided for these children, from diagnosis and referral through to post-operative care and discharge needs to be examined to look for an explanation for the observed poor performance (Section 9.5).'

The principal conclusions in greater detail

100 In the main body of their Report, Dr Spiegelhalter et al. set out their principal conclusions in greater detail. As regards the statistical evidence relating to activity[145] and mortality in Bristol derived from the data produced by Bristol, they concluded:

> 'There are clear limitations to all sources, and none is subject to defined procedures for data collection, follow-up and validation. It would be fair to say that none is held in high regard as a source of reliable evidence for clinical audit. However, Evans (1999) concludes that where direct comparison is sensible, the pattern is similar and there are no startling discrepancies. Although there is no gold standard for comparison, the Bristol PAS system appears of reasonable quality, and hence this lends confidence to Bristol returns to the national HES database. Our overall comparison suggests that the different sources agree well on the open operations in general and for many specific procedures.
>
> 'The main findings of interest concern mortality rate [*sic*] for open surgery in under 1s. Overall, sources agree that the mortality rate was around 25–30% during the period under scrutiny, although with considerable variability between different procedures.'[146]

101 As regards the statistical evidence on activity and mortality in Bristol compared with other specialist centres, as derived from UKCSR and HES data, the experts concluded:

> 'Although the [UK]CSR data report statistically significant excess mortality for Bristol in over 1s during 1988–1990, the primary finding from both [UK]CSR and HES is of excess mortality from 1991–1995 in open operations in under 1s, in which the mortality rate in Bristol was around double that in other centres. This

[145] At INQ 0045 0014, Dr Spiegelhalter et al. stated: 'An event has to be identified that measures activity and hence forms the basis for the denominator in any calculated mortality rate. The primary analysis focused on the number of admissions/spells as the basis for comparison, although some of the data sources use operations as their measure of activity. … There is normally only one operation per admission and so there is limited difference according to which is chosen.'

[146] INQ 0045 0024

difference is retained after stratifying for operative group, which is the available determinant for case-mix. There is no evidence for excess mortality in closed operations, or for open operations in over 1s from 1991–1995. Reported mortality for open operations in under 1s fell in other centres from 21% in 1984–1987 to 12% in 1991–1995. Bristol appears not to have followed that pattern of improvement. There is no evidence of excess mortality in Bristol during Epoch 4,[147] although activity in Bristol was too small to draw any firm conclusion.

'We emphasise that the estimated total excess deaths for HES depends on the age-stratification used: the excess risk is greater in younger children: for all open operations in epoch 3[148] the total is 30.1 when dividing only into under and over 1s (Table 6.1) and 34.3 when including a < 90 day category (Aylin et al., 1999).'[149]

'HES identifies excess mortality with 95% confidence for switches (G3), AVSD (G5), ASD (G6)[150], open operations stratified for case-mix, (G1 to G11), and all open operations taken together.'[151]

'The [UK]CSR results show that each year between 1988 and 1994 (with the exception of 1990), Bristol had either the highest or near the highest mortality rate for open surgery in under 1s. This is reinforced by the HES data between 1991 and 1994. It is clear that Bristol's activity was consistently below the median in the country …'[152]

102 Referring to the national sources of data, the Experts concluded:

'The two national sources, HES and the CSR, are admittedly imperfect. Both suffer considerably from lack of agreed operating procedures for ensuring completeness and accuracy of activity, coding and outcome results. Both the OPCS4 coding scheme and the use of non-clinical coders lead HES to be viewed with suspicion by clinicians. There are also strong concerns about variability between centres in the [UK]CSR's coding procedures and recording of mortality. Even if they were meticulously completed, agreement between the two sources could not be expected due to their different criteria. However, HES was found to be surprisingly accurate in its recording of in-hospital mortality and, with certain clear exceptions, the sources described the same broad picture.'[153]

147 April to December 1995
148 1991 to March 1995
149 INQ 0045 0025
150 Group 6 includes more complex procedures such as closure of persistent ostium primum, and sinus venous atrial septal defects, as well as simple atrial septal defects
151 INQ 0045 0026
152 INQ 0045 0026
153 INQ 0045 0035

103 Referring to the local sources of data, they concluded:

> 'The local sources were found to provide good agreement on activity and overall mortality, although comparison at a finer level was sensitive to the coding conventions used. Nevertheless, the six sources on Bristol's activity and outcome agree well for open operations in general and, to a lesser but still reasonable extent, for finer consensus procedure groups of interest. Where there is disagreement, then there are clear reasons, usually resulting in transfer of operations between two groups.'[154]

104 Dr Spiegelhalter et al. set out their detailed conclusions concerning the evidence of divergent performance in Bristol:

> 'There is no evidence of excess mortality in closed operations carried out in Bristol, and limited evidence in open operations on children aged over 1 year. However, there is strong and consistent evidence of excess mortality in open operations in children less than 1 year old at operation. It is estimated from HES data that in the period 1991–1995, 24.1 (95% confidence interval 12 to 34) of 41 recorded deaths are in excess of that expected were Bristol a "typical" centre: finer age-stratification increases the estimated excess mortality. [UK]CSR data suggest the excess mortality dates back at least to 1988. Open procedures on children aged less than 1 that can be identified with reasonable consistency as having excess mortality include "switches", operations for TAPVD, AVSD and, although rare in this age group, ASD.[155] It is to be expected that excess mortality is easier to detect in higher risk groups.
>
> 'The excess mortality was not just restricted to AVSDs and switch operations, and the conclusions are robust to admissions with missing outcomes. National mortality rates were comparable to those in the international literature. One other centre had a consistent pattern of excess mortality in open operations in children over 1 year,[156] but there were no other centres with consistently divergent raised mortality in the younger age group.'[157]

105 The Experts stated, as their overall conclusions:

> 'The single most compelling aspect of the data is the magnitude of the discrepancy between the outcomes observed at Bristol and those observed elsewhere. For children aged under one year undergoing open surgery between 1988 and 1994, the observed mortality rate at Bristol was roughly double that observed elsewhere

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154 INQ 0045 0035

155 Group 6 includes more complex procedures such as closure of persistent ostium primum, and sinus venous atrial septal defects, as well as simple atrial septal defects

156 Leading Counsel to the Inquiry announced in the oral hearing on 3 November 1999 that this centre was Harefield Hospital. In their Overview Report to the Inquiry, Dr Spiegelhalter et al. stated: 'This finding must be treated with caution. Harefield has been an innovative centre for transplant surgery and these operations are included in the CSR (although not in the HES open category), and it also has a reputation for taking difficult cases from abroad.' INQ 0045 0026

157 INQ 0045 0036; see Chapter 3 for an explanation of these clinical terms

in 5 out of 7 years. While the national trend over this period was for mortality rates to fall substantially, no such trend was seen in the Bristol results. In spite of the many flaws in the data sources, we do not believe that statistical variation or any systematic bias in data collection can explain a divergence of this magnitude. We therefore conclude that there is strong evidence of divergent performance at Bristol in the areas identified above, and we believe that the imperfections of the data do not cast serious doubt on these conclusions.'[158]

106 They added:

'Given the many flaws that have been identified in existing data sources, it is clear that only gross divergence could have been identified with any degree of confidence. If, for example, the mortality rate for open operations in under 1s observed at Bristol had been 50% higher than elsewhere rather than 100% higher, it would have been very difficult to exclude the possibility that the difference had arisen through a combination of differences in case mix, in the coding of operative procedures, and in the thoroughness of achieving follow-up data.'[159]

[158] INQ 0045 0038
[159] INQ 0045 0039

Section four: the evidence of the Inquiry's Experts relating to post-operative morbidity

Terminology

107 Dr Kate Bull described, in a paper prepared for the Inquiry, the meaning of the term 'morbidity' in the context of paediatric cardiac surgery:

> 'Doctors use the term "morbidity" to contrast with a complication-free recovery to a normal state. Cardiac surgery has cardiac outcomes with effects on longevity and quality of life that vary from trivial to severe; very few heart operations are "corrective". The long-term non-cardiac complications of open heart surgery in children include a variety of problems under the heading of "brain damage" or "learning difficulties", problems with the mechanics of breathing (diaphragm palsy, tracheal and chest wall problems) and the psychological consequences of the disease and its treatment on child, siblings and parents. There are also many short-term complications, which may increase length of stay in intensive care or in hospital including infection and respiratory problems; often these are not associated with long-term sequelae. As in natural language, the medical use of a term does not necessarily mean that it has been unambiguously defined.'[160]

108 The definition of 'post-operative morbidity' adopted by the Inquiry was set out by Leading Counsel to the Inquiry:

> 'We take the term "post-operative morbidity" to mean problems with a child's health which were not apparently present before the surgery and which manifest themselves as functional impairments or disabilities, and which would not have been present, or present to such an extent, in the absence of surgery.'[161]

Identifying morbidity in the form of brain damage following heart surgery in children

109 Dr Bull explained:

> 'To assess how commonly brain damage occurs and understand the range of severity involved, ideally we need to identify a large cohort of children, unselected as having a particular problem and follow them up for a long time. In the nature of a fast-changing medical environment, by the time long-term studies are complete they may be rendered less relevant by changes in patient population and in surgical procedure. This may go some way to explaining why such studies do not currently exist. From a scientific point of view, assessing a cohort of operated children fairly

[160] INQ 0049 0002; *'Key issues in retrospective evaluation of morbidity outcomes following paediatric cardiac surgery'*, November 2000, Dr Bull
[161] T88 p. 3, Leading Counsel to the Inquiry

early after surgery has the advantage of relevance (e.g. to assessing alternative techniques for cerebral protection during surgery) but the disadvantage that the findings may have limited predictive validity for understanding how the deficits will impact on a child's prospects for future education and independence. There is also an issue of specialism; the preoperative and early postoperative assessment is the domain of paediatric neurologists and neuro-physiologists. Later assessment is also the domain of educational psychologists, physiotherapists and other allied professions. Paediatric cardiologists and surgeons have few of the relevant skills themselves.'[162]

110 Dr Bull went on:

'The incidence and severity of brain damage around the time of surgery is not completely haphazard and not all children with heart disease even approach surgery with good prospects for normal brain function later. Some are very sick during labour and after delivery. For some children, their heart disease is only one manifestation of a bigger problem that may have been genetically programmed (e.g. the situation in Down's syndrome with atrio-ventricular septal defect). When a syndrome is recognised, it is also more difficult confidently to attribute late abnormality to peri-operative events, partly because so many started off with some neurological abnormalities and partly because knowledge of the developmental milestones of children with syndromes is more sketchy.

'There are also cardiac diagnoses (for instance, coarctation, interrupted aortic arch and hypoplastic left heart, Fallon 1995) which are not related to syndromes but which seem particularly prone to postoperative neurological complications. Some of these complications may not be avoidable with current techniques and understanding. In "left heart syndromes", the fetal brain arteries do not develop in a normal pressure and flow environment and later may not accommodate stress well. Also managing surgery when blood flow to the brain and lower body cannot both be optimal at the same time is very challenging. …

'There are no studies associating particular profiles of learning difficulties with previous heart operations. There are no studies explicitly discriminating "avoidable" from "unavoidable" brain damage but the implication of much of the literature is that, even with best practice, there is inevitably some trade-off between repairing a complex heart problem and inflicting some damage on the brain. The children with profound motor and cognitive disabilities are only the tip of an iceberg of children with more minor difficulties.'[163]

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162 INQ 0049 0003; *'Key issues in retrospective evaluation of morbidity outcomes following paediatric cardiac surgery'*, November 2000, Dr Bull

163 INQ 0049 0003 – 0006; *'Key issues in retrospective evaluation of morbidity outcomes following paediatric cardiac surgery'*, November 2000, Dr Bull

111 Dr Bull concluded:

> 'In the face of all this complexity involving pre, intra and postoperative factors, it is clear that seeking out a single cause of a complication is often not realistic. Even when an event like a post-operative cardiac arrest apparently accounts for a complication like brain damage, the arrest itself is only part of a chain of causation which may lead back to a whole set of conditions preceding it.'[164]

The nature and extent of post-operative morbidity in Bristol

112 Evidence relating to the nature and extent of post-operative morbidity in Bristol was drawn from three local sources of data: the Surgeons' Logs [SL], the Coded Clinical Records [CCR], and the Patient Administration System [PAS].[165]

113 Of the SL, Professor Stephen Evans in his review stated:

> 'The surgeons' logs, as might be expected, are not good sources of information on long term complications of paediatric cardiac surgery. The overall level of 3.2% of children with a recorded code, 2.2% with a recorded complication (codes 996–999), and only 0.5% with a neurological complication is very low, and is likely to reflect under-reporting in the original logs.'[166]

114 Mr Wisheart stated:

> 'I would wish to point out that the record of postoperative complications and follow up information was not well maintained, nor relied on.'[167]

115 Of the CCR, Professor Evans stated:

> 'The Clinically Coded Records were coded with a view to include the post-operative complications, but it is possible that the key problems were not obvious from the medical records. However it is clear that the numbers of children with recorded complications who were still alive is very much less than the numbers of children who died.'[168]

116 He went on:

> 'Thus of 1520 children recorded as alive in the CCR there are at most 26 (1.7%) recorded with neurological complications. Some of these children had closed

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164 INQ 0049 0007; *'Key issues in retrospective evaluation of morbidity outcomes following paediatric cardiac surgery'*, November 2000, Dr Bull

165 Further sources of evidence on post-operative morbidity at Bristol were available as written and oral evidence of Bristol parents and clinicians, and experts. Other sources of local data, such as the South West Congenital Heart Register and the Perfusionists' Logs, were examined by the Inquiry's Experts and found to be unsuitable as sources of statistical evidence relating to post-operative morbidity. See INQ 0014 0026

166 INQ 0029 0009; *'Further reports based on local sources of data for the Bristol Royal Infirmary Inquiry'*, 17 May 2000, Professor Evans

167 WIT 0120 0256 Mr Wisheart

168 INQ 0029 0012; *'Further reports based on local sources of data for the Bristol Royal Infirmary Inquiry'*, 17 May 2000, Professor Evans

operations coded so that the rate in children with open operations who were still alive is 26/1388 (1.9%).'[169]

117 Of the PAS, Professor Evans stated:

'Post-operative complications that are immediately obvious may be recorded on the PAS, and with linkage of subsequent admissions there is a possibility that complications only recognised as such at a later stage will be recorded. From the PAS data it is clear that the level of complications recorded in those children who survived was at a low level.'[170]

118 Professor Evans concluded:

'It is clear that there is a level of disagreement in the three sources.'[171]

119 Of the sample of cases examined for the Clinical Case Note Review, 4 out of the 40 children who were still alive 30 days after surgery in Bristol were found to have a moderate level of recorded disability. Professor Evans observed:

'Although 4/40 is 10%, because the CCNR was weighted towards younger, high-risk operations the reweighted estimate is 89/1473 (estimated number with disability in whole sample/estimated number who were alive at 30 days), an overall rate of 6%. However, all the children with recorded disability were aged under one year at the time of operation and had open heart surgery. In this group the rate is estimated to be 89/348 a rate of 20%. This includes all the children, with disability, not just those whose disability may be related to their medical care. Of the four noted in the CCNR to have disability, two had a post-operative complication recorded in the CCR and one had one in the PAS (one of the four was not in the PAS since their operation was before 1988 when the PAS came into use).'[172]

120 Professor Evans concluded:

'In the first report on [HES][173] higher proportions of central nervous system (1.6%) and renal complications (2.6%) were found in Bristol than elsewhere. These results were for all children, including those who died. The overall levels found in the [PAS] were of this order of magnitude, and somewhat higher in the [CCR]. The Clinical Case Note Review (CCNR) report found a level of recorded disability of about 6% (using the estimate for all children) in those who were alive, but half were believed to be unrelated to the medical care received. The absolute numbers in the CCNR were very small.

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169 INQ 0029 0012; *'Further reports based on local sources of data for the Bristol Royal Infirmary Inquiry'*, 17 May 2000, Professor Evans
170 INQ 0029 0013 – 0014; *'Further reports based on local sources of data for the Bristol Royal Infirmary Inquiry'*, 17 May 2000, Professor Evans
171 INQ 0029 0015; *'Further reports based on local sources of data for the Bristol Royal Infirmary Inquiry'*, 17 May 2000, Professor Evans
172 INQ 0029 0016; *'Further reports based on local sources of data for the Bristol Royal Infirmary Inquiry'*, 17 May 2000, Professor Evans
173 INQ 0013 0001 – 0073; *'Analysis of Hospital Episode Statistics for the Bristol Royal Infirmary Inquiry'*, 27 October 1999, Dr Aylin et al.

'Published work where special study of complications has been done suggests much higher rates, in the range 10–30% for neurological injury. The routinely collected data do not detect anything like these rates. They cannot be used to estimate disability rates accurately, partly because of problems of definition. There is therefore uncertainty in whether Bristol had a higher or a lower rate of post-operative complications compared with other UK centres.'[174]

Post-operative morbidity in Bristol compared with other specialist centres

121 Evidence relating to the nature and extent of post-operative morbidity at Bristol compared with other specialist centres was drawn from HES.[175] In their first report to the Inquiry on HES, Dr Paul Aylin et al. stated:

'Complications were recorded in a higher proportion of all admissions in UBHT than elsewhere in England. … Central nervous system complications are mentioned in 1.6% of admissions with an open procedure in UBHT, 4 times more than elsewhere.'[176]

'This may be due to better recording of diagnoses at UBHT.'[177]

'Although there are a higher proportion of complications in UBHT admissions than elsewhere in England, UBHT also records more diagnoses per admission generally than elsewhere in England (4.2 diagnoses per admission compared to 4.0 per admission). We also know that UBHT is less likely to use vague diagnoses such as "Other ill-defined and unknown causes of morbidity and mortality" (ICD9 799). This suggests that diagnostic information in HES records from UBHT is more complete than elsewhere and may explain the higher reporting of complications. It is also not known whether complications were present before or after the procedure in question.'[178]

122 Dr Aylin et al. concluded:

'There is … a suggestion of a higher complication rate in procedures carried out in the UBHT, but this could be explained by their apparent higher quality recording of diagnosis.'[179]

123 In their second report to the Inquiry, Dr Aylin et al. stated:

'Further analysis of our HES data using diagnoses in the ICD-9 range 996-999 (complications of surgical and medical care) shows that within open procedures,

174 INQ 0029 0002; *'Further reports based on local sources of data for the Bristol Royal Infirmary Inquiry'*, 17 May 2000, Professor Evans
175 The UKCSR was examined by the Inquiry's Experts and found to be unsuitable as a source of evidence relating to post-operative morbidity
176 INQ 0013 0028; *'Analysis of Hospital Episode Statistics for the Bristol Royal Infirmary Inquiry'*, 27 October 1999, Dr Aylin et al.
177 INQ 0013 0004; *'Analysis of Hospital Episode Statistics for the Bristol Royal Infirmary Inquiry'*, 27 October 1999, Dr Aylin et al.
178 INQ 0013 0031; *'Analysis of Hospital Episode Statistics for the Bristol Royal Infirmary Inquiry'*, 27 October 1999, Dr Aylin et al.
179 INQ 0013 0033; *'Analysis of Hospital Episode Statistics for the Bristol Royal Infirmary Inquiry'*, 27 October 1999, Dr Aylin et al.

26.3% (95%CI 22.5-30.4%) of spells in UBHT have complications recorded compared with 11.6% (95%CI 10.9-12.3%) elsewhere. … More information on the consistency with which secondary diagnoses are coded in the UK is required before using them here. … As there was no specific new hypothesis as to what conditions to investigate, we felt that any further analysis of secondary diagnoses would result in comparisons of data quality between trusts rather than actual differences in co-morbidity.'[180]

124 Professor Stephen Evans concluded:

'In the first HES report where complications are discussed [INQ 0013, pp. 0028, 0031 and 0058], the proportions with neurological (central nervous system) complications with open procedures was 1.6% and 2.6% for renal (urinary) complications. These have not distinguished those who were alive and those who died. The overall level of complications found in the PAS and CCR are of this order of magnitude. The CCR has recorded more of the complications than the PAS, but it is possible that diagnoses that are a result of surgery may not be recorded in the PAS if they are not noticed immediately.

'It seems likely from published work that there is severe under-recording of complications in HES in centres other than Bristol. Recording there is at a high level when compared with other centres, but probably under estimates the rate of neurological complication.'[181]

'The evidence from local sources suggests that Bristol routine data collection gives a more reasonable estimate of complications following surgery, rather than that it is genuinely at a higher rate there.'[182]

125 In their review of published evidence on outcomes of open-heart paediatric surgery Ms Katerina Vardulaki et al. stated:

'Longer-term outcomes, such as deterioration in functional and neurological status, the need for re-intervention, late deaths attributable to operation-related factors and non-cardiac disorders, were described in some papers. However, the quality and detail of reporting of such outcomes was inconsistent across papers, making it impossible to attribute them to relevant clinical sub-groups or to generate meaningful quantitative estimates of their frequency.'[183]

180 INQ 0030 0007; *'Supplementary Analysis of Hospital Episode Statistics for the Bristol Royal Infirmary Inquiry',* 29 June 2000, Dr Aylin et al.
181 INQ 0029 0016; *'Further reports based on local sources of data for the Bristol Royal Infirmary Inquiry'*, 17 May 2000, Professor Evans
182 INQ 0029 0017; *'Further reports based on local sources of data for the Bristol Royal Infirmary Inquiry'*, 17 May 2000, Professor Evans
183 INQ 0039 0005; *'A Systematic Review of the outcomes of Open Heart paediatric surgery'*, April 2000, Ms Vardulaki et al.

The Experts' overall conclusions

126 In their Overview Report to the Inquiry, Dr David Spiegelhalter, Professor Stephen Evans, Dr Paul Aylin and Professor Gordon Murray reviewed the evidence on post-operative morbidity and concluded:

> 'In response to the findings of Aylin (1999, INQ 0013 0028) of an apparently higher rate of neurological complications in Bristol, Evans (2000, INQ 0029) examined evidence on complication rates in local data sources. The Surgeons' Logs (SL) did not, predictably, contain good information on longer-term outcomes, while both in the coded clinical records (CCR) and PAS the recorded neurological complication rates among survivors of open surgery was very low (1.9% and less than 1% respectively). There was poor agreement between sources and Evans (2000, INQ 0029 0016) concluded that there was under-reporting in all centres, with Bristol possibly being slightly more accurate in its reporting. The Clinical Case Note Review (CCNR) did look in detail at the possibility of disability in those who had not died at 30 days, but with only 40 cases, even though they were preferentially sampled from high risk groups, the number with any disability was very small (4, all "moderate"disability). It is therefore not possible to draw confident conclusions on the true morbidity rate or make comparisons with other centres. …
>
> 'The routine data sources available form an inappropriate basis for any firm conclusions concerning morbidity rates in Bristol.'[184]

[184] INQ 0045 0024; *'Overview of statistical evidence presented to the Bristol Royal Infirmary Inquiry concerning the nature and outcomes of paediatric cardiac surgical services at Bristol relative to other specialist centres from 1984 to 1995'*, September 2000, Dr Spiegelhalter et al.

Section five: views on the interpretation, reliability and validity of the evidence on statistics received by the Inquiry

Comments of the clinicians at Bristol (and others)[185] on the evidence of the Experts on statistics received by the Inquiry, and the Experts' responses

This section sets out the views of the Bristol surgeons (and others) on the interpretation, reliability, and validity of the evidence received by the Inquiry from its experts on statistics. It also sets out the experts' responses to these views.

The interpretation of the statistical evidence relating to clinical performance in Bristol

127 Mr Wisheart stated that:

> 'Children at one centre could differ from the national profile in terms of case mix or risk stratification. Case mix refers to the proportion of patients whose operation is basically high risk, (e.g. [Persistent Truncus Arteriosus] PTA) or low risk (e.g. ASD). I have already referred to the importance of case mix in determining the outcome in our under ones for 1984–87. Risk stratification refers to the presence of additional incremental risk factors in a patient, whether their operation is basically in a low risk or a high-risk category.
>
> 'There is no scientific basis for a risk stratification exercise in paediatric cardiac surgery at the present time, nor is there data available about patients across the country, to enable the comparison to be made.'[186]

128 Mr Dhasmana stated:

> 'I have read Mr Wisheart's response to the Spiegelhalter analysis and would broadly agree and endorse those views. In particular I agree with his comments on

185 These submissions, and the formal responses of the Experts, are reproduced in Annex B
186 WIT 0120 0300 – 0301 Mr Wisheart

aggregation and risk stratification. Unlike in adult cardiac surgery the absence of any agreed risk stratification for children is a major obstacle to comparative analysis.'[187]

129 As regards the practice of grouping procedures together which was adopted by the Inquiry's Experts on Statistics, Mr Jaroslav Stark, formerly consultant cardiac surgeon at Great Ormond Street Hospital for Sick Children, and a member of the Inquiry's Expert Group, stated:

'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 G3 [switch], G6 [ASD] and G9 [Fontan].'[188]

130 Referring to risk stratification, Mr Wisheart stated:

'Risk stratification is likely to be of much greater significance for certain patient groups than for others. For patients with relatively straightforward abnormalities, who have elective surgery at an older age, issues of risk stratification are likely to be relatively modest. On the other hand where patients are very young, have major congenital abnormalities, are often operated either as an emergency or urgently and in whom a whole range of additional risk factors may be present, the importance of risk stratification is likely to be much greater. The apparent divergences identified by the Inquiry's experts are predominantly in the youngest patients; it is amongst these patients that the importance of risk stratification is likely to be greatest.'[189]

131 Dr Geoffrey Burton, consultant anaesthetist at the BRI until 1990, stated:

'The Statistical Evidence presented to the Inquiry, although useful, can only have a very limited significance because it fails to take into consideration the preoperative state of the patients.'[190]

132 Lorna Wiltshire, Bed Manager and trauma and orthopaedic nurse at the BRI in 1990, stated in her written evidence to the Inquiry:

'It was my impression that Mr James Wisheart operated on the technically more difficult cases. My perception was that Mr James Wisheart was prepared to operate to give the child or baby a chance, where perhaps other surgeons might not have been prepared to operate at all. The other comment I can make is that the age

187 WIT 0084 0150 Mr Dhasmana
188 WIT 0567 0004 Mr Stark
189 WIT 0120 0301 Mr Wisheart
190 WIT 0555 0002 Dr Burton

group of the children was very wide and that a number of children were very ill by the time they arrived for surgery.'[191]

133 Mr Wisheart stated:

'I would not suggest that across the whole range of the work, or even the whole range of infant or neonatal work, there was any systematic difference in the children presenting to us compared to children presenting elsewhere. However I do believe, that there may be evidence of a significant difference in at least 3 identifiable sub-groups of patients. These are:

'(1) Patients referred to me for complete repair of AVSD in the years 1990–1994 inclusive. There were 15 such patients and only 4 were free of additional significant abnormalities or risk factors. This is … very unusual, as normally significant additional factors are present in only 20–25%. For example Left Ventricular Outflow Tract Obstruction ["LVOTO"] is normally present in 2% AVSDs; in my series of 15, there were 3 patients with LVOTO.

'(2) In the under one year age group of operations carried out by me, in 1991, there were a significant number of high risk children. The fact that I agreed to operate on them undoubtedly increased my mortality in that year.

'(3) For the years 1984–87 inclusive, our overall mortality in Bristol for the under one year age group was one third higher than nationally. This was however attributable to the *case mix* of the children operated. When we used the UK mortality to calculate the expected mortality for the patients on whom we actually operated, we found that the expected and observed mortalities were virtually identical.'[192]

134 In his closing submission to the Inquiry, Mr Wisheart stated:

'The main findings seem to be of excess deaths in some sub-groups in the under ones, which when aggregated indicate an important number of excess deaths for the under ones as a group in the epoch 1991–1995 and to a lesser extent 1988–1990.

'That there are excess deaths in the neonatal switch operations and C-AVSD operations in 1991–1995 is not in dispute. These seem to be the most important contributors to the total number of excess deaths. In January 1996, Marc de Leval stated that apart from these two sub-groups the results in Bristol, including those under one year of age, matched the rest of the UK for the period 1992–1995. Is this correct? In other words, are the other sub-groups in the under one year of age, within an acceptable range either individually or when aggregated? If they are, then it is still necessary to find an explanation of the high mortality in the neonatal switch operations and in the correction of C-AVSDs by me. Disappointing findings

[191] WIT 0330 0016 – 0017 Ms Wiltshire
[192] WIT 0120 0301 – 0302 Mr Wisheart

for C-AVSDs are to be found in my series of patients, whereas Mr Dhasmana's results for this condition are in line with the national performance. It is clearly and objectively documented that there were significant additional risk factors in eleven of the fifteen patients in whom I operated in this series. It is my belief that consideration of these factors would bring my results of C-AVSDs within an acceptable range.'[193]

135 Mr Wisheart went on:

'However, the reason why robust methods of risk stratification must be included in any assessment of surgical performance is that this is the only way to protect the access of high risk patients to the surgical treatment which they need. Without such robust methods of risk stratification, surgeons will feel themselves under irresistible pressure to find reasons not to operate on high risk patients.'[194]

136 Mr Dhasmana commented on the interpretation of his results for his series of Arterial Switch cases:

'1. There were no comparative figures from any other centres in the U.K. to make any reliable conclusions from. However, independent experts at the G.M.C. [General Medical Council] Inquiry did state that there was a higher incidence of abnormal coronary arterial pattern in my series of Arterial Switches.

'2. It was not proven, but possibly, some of these children's condition may have deteriorated whilst waiting for surgery, especially in conditions like A.V. Canal, T.G.A. with V.S.D.s and T.A.P.V.D. In some of these patients one of the main causes for failure of surgery has been a pulmonary vascular crises [*sic*]. These patients were on varying degrees of the urgent list; some of these could not be operated upon soon after referral because of lack of resources. I believe that in the present set up, in particular consequent on unification at the Children's Hospital, there is no waiting list for such patients.'[195]

137 Referring to the period of time which patients waited for surgery, Dr Stephen Pryn, consultant anaesthetist at the Bristol Royal Infirmary from 1993, stated:

'I was concerned that patients with AV canals were too old when presented for surgery with the consequence that they had developed raised pulmonary vascular resistance which had become only partially reversible. One patient in particular who underwent repair of an AV canal in August 1994 when she was about 9 months old did not survive; she had been seen and diagnosed at three months when her raised pulmonary vascular resistance was still fully reversible.'[196]

193 SUB 0009 0022 – 0023 Mr Wisheart; see Chapter 3 for an explanation of clinical terms
194 SUB 0009 0023 Mr Wisheart
195 WIT 0084 0053 Mr Dhasmana; see Chapter 3 for an explanation of clinical terms
196 WIT 0341 0014 Dr Pryn; see Chapter 3 for an explanation of clinical terms

138 In response to Mr Wisheart's concerns at the absence of risk stratification in the evidence presented to the Inquiry, Dr Spiegelhalter et al. replied:

> 'Risk stratification for surgical risk factors may not be appropriate when evaluating an organisation since it may tend to obscure limitations in pre-operative care.'[197]

139 In their Overview Report, Dr Spiegelhalter et al. stated further:

> 'When comparing whole surgical systems in centres, one should ideally concentrate on case-mix stratification: i.e. factors beyond all influence of the organisation. In contrast, if surgical performance alone were being compared, then a full "operative-risk stratification" exercise may be appropriate, taking into account the precise clinical state and previous history of the patient just prior to their operation. However, this is *not* appropriate methodology when comparing the whole surgical system, since many features at operation may be influenced by early care, timing of operation etc. – it is even arguable that one should not adjust for age at operation since the process of care could influence this factor … Since the objective is a comparison of the systems in centres, results in the analysis have been broken into strata defined by broad procedure groups, epoch of operation and broad age-groups.'[198]

140 In response to Mr Wisheart's submission that 'excess deaths' were restricted to the switch and C-AVSD procedures, Dr Spiegelhalter et al. examined the results when these specific procedures were excluded from the analysis:

> 'The [UK]CSR [data] show a significant 83% increase in mortality over other centres. The HES data show a 44% increase in mortality over centres elsewhere, although this is not statistically significant at conventional levels. However [the tables] show that there can be at least 95% confidence in excess mortality in some subgroups: for example, TAPVD in < 90 days, and Closure of ASD[199] in 90 days to 1 year. The data reported to the [UK]CSR show significant excess mortality, even excluding switches and AVSDs. (It could be argued, because of the known lack of distinction in the [UK]CSR between switch (group 3) and inter-atrial repair (group 2), that group 2 should also be excluded from [the table]. We have repeated the analysis excluding group 2, and it increases the contrast between Bristol and elsewhere.)'[200]

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197 INQ 0034 0002 Dr Spiegelhalter et al.

198 INQ 0045 0012 – 0013; *'Overview of statistical evidence presented to the Bristol Royal Infirmary Inquiry concerning the nature and outcomes of paediatric cardiac surgical services at Bristol relative to other specialist centres from 1984 to 1995'*, September 2000, Dr Spiegelhalter et al. (emphasis in original)

199 Group 6 includes more complex procedures such as closure of persistent ostium primum, and sinus venous atrial septal defects, as well as simple atrial septal defects

200 INQ 0034 0004 – 0005; *'A Response to Submissions on behalf of Mr JD Wisheart, Appendix 2, The Inquiry's Statistical Analysis'*, May 2000, Dr Spiegelhalter et al.; see Chapter 3 for an explanation of clinical terms

141 They concluded:

> 'Our estimates of excess mortality are not based solely on Switch and AVSD operations – other procedures make significant contributions.'[201]

And noted:

> 'Excess mortality cannot be explained by identifying additional risk factors for patients with adverse outcomes: the risk profile of the entire series must be considered.'[202]

142 Mr Wisheart also submitted:

> 'The CCNR has underlined emphatically that paediatric cardiac surgery is a team activity, and that its results are determined by the work all of [*sic*] members of the team.'[203]

143 In reply, Dr Spiegelhalter et al. observed:

> 'The acknowledgement of the importance of the team activity serves to downgrade the need for an analysis stratifying for factors present at surgery. Care prior to surgery may affect the presence or knowledge of such factors, and hence "adjusting" for these could tend to obscure important differences between centres in pre-operative care.'[204]

The national sources of statistics used to compare clinical performance

144 Mr Wisheart expressed a variety of concerns about the reliability and validity of the UKCSR as a source for comparing performance between centres:

> 'I now believe that there are substantial limitations upon the reliability and the validity of the UKCSR. Therefore its value to this Inquiry as a comparator must be in doubt.
>
> '… Reservations about the reliability and validity of the Register stem from the possible under-reporting of mortality, the lack of information from some individual centres, other missing data, intra-centre variability and the use of differing definitions. In addition, the absence of information about the range of results obtained by individual centres or surgeons, and the absence of any allowance for risk stratification limit further the value of the available data.'[205]

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201 INQ 0034 0002; *'A Response to Submissions on behalf of Mr JD Wisheart, Appendix 2, The Inquiry's Statistical Analysis'*, May 2000, Dr Spiegelhalter et al.; see Chapter 3 for an explanation of clinical terms

202 INQ 0034 0002; *'A Response to Submissions on behalf of Mr JD Wisheart, Appendix 2, The Inquiry's Statistical Analysis'*, May 2000, Dr Spiegelhalter et al.

203 SUB 0009 0026 Mr Wisheart

204 INQ 0034 0009; *'A Response to Submissions on behalf of Mr JD Wisheart, Appendix 2, The Inquiry's Statistical Analysis'*, May 2000, Dr Spiegelhalter et al.

205 WIT 0120 0294 Mr Wisheart

145 Mr Dhasmana stated:

> 'The reliability of data published in the U.K.C.S.R. has always been questioned, as the figures were never validated. Errors could have been made at the source of entry, as junior members of staff could have been entrusted with form filling, with no arrangements for double checking the figures. The 30-day mortality figures may not represent the true picture, as at some institutions patients are transferred back to referring hospitals after a few days and therefore the follow-up information for this group for the first 30 days may not have been complete. We were also aware that a centre of excellence with a large volume of cases might mask the true mortality figures of smaller centres. The probable deficiencies in data collection and lack of comparison of like with like, meant the resulting average figures given in the Register were not perceived as being statistically accurate, and this limited its value as a tool in providing adequate comparators.'[206]

146 Referring to the UKCSR, Mr Bruce Keogh, Secretary of the Society of Cardiothoracic Surgeons of Great Britain and Ireland, told the Inquiry:

> 'I think it is incumbent upon me to doubt the reliability, otherwise I would not be doing my job properly. I have less reason to doubt the activity data, but I do sometimes feel that operative mortalities that are reported may be a bit low.'[207]

147 Mr Wisheart expressed concern as to the reliability of the categories used in the UKCSR as a means of recording surgical activity. Referring to the reliability of data derived from the UKCSR's diagnostic category 'Transposition of the Great Arteries', he observed:

> 'The handling of Transposition by the Inquiry's experts with regard to the type of operation carried out has not been successful. I do not believe that there is any evidence that paediatric cardiac surgeons have ever consistently classified the Mustard or Senning operation as palliative, in making returns to the UKCSR.'[208]

148 As for the 'over-1' age category in the UKCSR, he stated:

> 'There is a problem in using the UKCSR as a comparator for the Inquiry's children aged 1–15. The UKCSR's category of "over 1" includes older teenagers and adults having open heart surgery for congenital abnormalities; there is no cut-off point in the UKCSR figures at age 15, until the mid-nineties.'[209]

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206 WIT 0084 0052 Mr Dhasmana
207 T38 p. 134 Mr Keogh
208 INQ 0012 0066; *'A review by Mr Wisheart of the evidence offered by Professor Evans, Dr Aylin, Professor Murray, and Dr Spiegelhalter'*
209 INQ 0045 0081; *'Review of data sources and statistical methods, available to the Public Inquiry for discussion'*, 23 September 1999, Mr Wisheart

149 As regards the reliability of the national data as a basis for comparing mortality at Bristol and elsewhere, Mr Wisheart submitted:

> 'Although Dr Spiegelhalter feels it is unlikely that Bristol has produced good quality data whilst other centres have produced unreliable data, serious doubt about the reliability of the data from the other centres has been expressed by a number of experts. The other data is of two types; first, Hospital Episode Statistics (HES) which was collected for administrative purposes and not for the clinical purposes for which it is now being used, and secondly, the United Kingdom Cardiac Surgical Register (UKCSR), the shortcomings of which have been repeatedly rehearsed. The reliability of the UKCSR is most dramatically questioned by the observation that of twelve centres reporting their results for 1988–1991 both to the UKCSR and to a Working Party of the Supra Regional Services Advisory Group of the Department of Health, only one returned the same figures to both – and that one was Bristol. Other questions about the comparator data are:
>
> - 'There is thought to be under-reporting of death.
> - 'There are believed to be variations in the definition of death which have been used by different centres and surgeons.
> - 'Survival status is not known in some HES and some UKCSR data.
>
> 'Unless there is a high degree of confidence in the data both from Bristol and from elsewhere, there cannot be confidence in the comparison.'[210]

150 Mr Wisheart stated further:

> '… the figures [in the Experts' Overview Report] are based upon HES and [UK]CSR which are not high quality, and importantly, do not agree with each other. Indeed the disagreement between HES and [UK]CSR is striking in terms of numbers of deaths, death rates and excess deaths. For example, the number of excess deaths in open operations in children under one, between 1991 and 1995, by case mix stratification, is estimated by [UK]CSR to be 12.9 and by HES to be more than double that figure at 27.2. There is no agreement about the total number of deaths in these databases, therefore I believe that these discrepancies should be examined and resolved. I had hoped that they would have been resolved much earlier but as the end of the Inquiry approaches, there remains uncertainty.'[211]

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210 SUB 0009 0023 – 0024 Mr Wisheart

211 INQ 0045 0100; *'The response of Mr Wisheart to the Overview of statistical evidence concerning the nature and outcomes of paediatric cardiac surgical services at Bristol relative to other specialist centres from 1984 to 1995'*

151 Mr Jaroslav Stark wrote to the Inquiry:

> '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.'[212,213]

152 In their report to the Inquiry, Ms Audrey Lawrence [214] and Professor Gordon Murray advised:

> '… surgeons have unanimously more confidence in the data they have provided to the [UKCSR] than in that provided by the hospital administration system (HES), in terms of both procedures and deaths.'[215]

153 Referring to the data returned by Bristol to HES and UKCSR, Mr Wisheart stated:

> 'I believe that the data available from Bristol is usable, in that both Mr Dhasmana's and my surgeon's logs are reliable sources of information. … The information returned to the UKCSR was based on the data in our two logs.'[216]

154 He stated further:

> 'The data will be very accurate for Bristol, but there is no knowledge of the accuracy from other centres.'[217]

155 Referring to the CCR, Mr Wisheart stated:

> 'The CCR provides a reliable standard against which the local Bristol data can be judged.'[218]

> 'For all the Bristol patients a Coded Clinical Record was created from the case notes and this must be regarded as being of extremely high quality, almost certainly the highest quality database which exists within the Inquiry. Data of comparable quality has not been created for any other centre.'[219]

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212 WIT 0567 0010; *'Comments on statistical analysis and review of outcomes of paediatric cardiac surgical services at Bristol and other specialist centres'*, 7 April 2000, Mr J Stark

213 Professor John Yates, Director of Inter-Authority Comparisons and Consultancy, Health Services Management Centre, University of Birmingham, expressed the view in a submission to the Inquiry that HES data was of value for comparative analysis (see WIT 0568 0027 – 0043), although aspects of his statistical methodology were criticised in peer review reports commissioned by the Inquiry (see for example INQ 0036 0001 – 0013, Professor Stephen Gallivan)

214 Research management consultant, Lawrence Research

215 INQ 0033 0003 Ms Lawrence and Professor Murray

216 WIT 0120 0299 Mr Wisheart

217 INQ 0045 0081; *'Review of data sources and statistical methods available to the Inquiry for discussion'*, 23 September 1999, Mr Wisheart

218 WIT 0120 0471 Mr Wisheart

219 INQ 0045 0092 Mr Wisheart

'If the analysis [advanced by the Experts] was based on the CCR, which is clearly a very high quality database, then it might well be that this argument [the conclusions reached by the statistical Experts] would carry great weight.'[220]

156 In response to these expressions of concern over the reliability of HES and UKCSR as sources of data from which to draw comparisons, Dr Spiegelhalter, Professor Evans, Dr Aylin and Professor Murray stated:

'The Submission [of Mr Wisheart] expresses concern about under-reporting and varying definitions of deaths in other centres. There is always the possibility, although it does not seem especially plausible, that Bristol has produced good-quality data, while the bulk of the rest of the country were systematically under-reporting mortality.'[221]

'Further investigation of the accuracy of the mortality rates derived from the HES data has shown that over 95% of 30-day deaths following open surgery are recorded in HES, and that Bristol's accuracy is typical.'[222]

'When no data source is a gold-standard, corroboration between reasonably independent sources reinforces the conclusions from both.'[223]

157 In their Overview Report to the Inquiry, Dr Spiegelhalter et al. observed:

'The reasonably consistent patterns … lend added weight to the HES evidence, as do the KP70 [224] and linkage exercises carried out to assess the quality of the recorded activity and outcomes in HES. There is no evidence that Bristol was at variance with the national pattern in HES reporting. The [UK]CSR data must be treated with great caution *at the level of individual procedure groups*. The crucial issue is whether the undoubted inaccuracies are sufficient to cast doubt on any observed divergent performance.'[225]

'A possible marker of data quality is the ratio of episodes recorded by HES to those on KP70 (paper returns to the DoH). Aylin et al. (2000, INQ 0030 0017) found that there was excellent agreement both in Bristol and elsewhere for cardiothoracic surgery as a whole, but were unable to compare for paediatric cardiac surgery.'[226]

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220 INQ 0045 0100 Mr Wisheart

221 INQ 0034 0006; *'A Response to Submissions on behalf of Mr JD Wisheart, Appendix 2, The Inquiry's Statistical Analysis'*, May 2000, Dr Spiegelhalter et al. See also WIT 0567 0004 Mr Stark

222 INQ 0034 0002; *'A Response to Submissions on behalf of Mr JD Wisheart, Appendix 2, The Inquiry's Statistical Analysis'*, May 2000, Dr Spiegelhalter et al.

223 INQ 0034 0002; *'A Response to Submissions on behalf of Mr JD Wisheart, Appendix 2, The Inquiry's Statistical Analysis'*, May 2000, Dr Spiegelhalter et al.

224 Mr Richard Willmer, a chief statistician at the Department of Health, describes the nature and purpose of KP70 returns (Körner Patient aggregated return no 70) in his supplementary written statement, WIT 0189 0133 – 0134

225 INQ 0045 0021; *'Overview of statistical evidence presented to the Bristol Royal Infirmary Inquiry concerning the nature and outcomes of paediatric cardiac surgical services at Bristol relative to other specialist centres from 1984 to 1995'*, September 2000, Dr Spiegelhalter et al. (emphasis added)

226 INQ 0045 0018; *'Overview of statistical evidence presented to the Bristol Royal Infirmary Inquiry concerning the nature and outcomes of paediatric cardiac surgical services at Bristol relative to other specialist centres from 1984 to 1995'*, September 2000, Dr Spiegelhalter et al.

'Although using different definitions and arising from relatively independent sources, HES and [UK]CSR data showed reasonable consistency at an aggregated level, although considerably poorer for individual procedure groups … The crucial issue is not whether HES or [UK]CSR precisely measure activity and outcome, but the extent to which feasible data inadequacies could explain any observed divergent performance …'[227]

The statistical methods used by the Experts to analyse the data

158 Mr Wisheart in his submission to the Inquiry challenged the validity of aspects of the statistical methods used by the Experts to analyse the data, in particular referring to the effect of the coding and grouping of data:

'This seems to distort some figures. It is clearly the case for Transposition of the Great Arteries (TGA) but also has had unexpected consequences when the patients in my own Surgeons Log are processed this way.'[228]

159 Mr Stark observed:

'Most surgeons are not familiar with OPCS4 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.'[229]

160 In response to Mr Wisheart's expression of concern about the effect of coding, Dr Spiegelhalter, Professor Evans, Dr Aylin and Professor Murray stated:

'Coding in paediatric cardiac surgery and cardiology is notoriously difficult. Our coding scheme was developed after extensive consultation and was applied in an unbiased and systematic way to all centres … it is important to note that "errors" in coding will tend to make patient groups more homogeneous and hence lead to high-risk groups having lower observed mortality, and low-risk groups having higher mortality. Since there is no dispute about the total number of deaths, it does not seem reasonable only to focus on discrepancies where mortality appears to have been over-stated – if such groups exist, they will be balanced by other groups in which mortality has been under-stated.'[230]

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227 INQ 0045 0003; *'Overview of statistical evidence presented to the Bristol Royal Infirmary Inquiry concerning the nature and outcomes of paediatric cardiac surgical services at Bristol relative to other specialist centres from 1984 to 1995'*, September 2000, Dr Spiegelhalter et al.

228 SUB 0009 0024 Mr Wisheart; see Chapter 3 for an explanation of clinical terms

229 WIT 0567 0003 Mr Stark

230 INQ 0034 0006; *'A Response to Submissions on behalf on Mr JD Wisheart, Appendix 2, The Inquiry's Statistical Analysis'*, May 2000, Dr Spiegelhalter et al.

161 Referring to his concerns about the effect of 'missing outcomes'[231] [shortfalls in the data on deaths, due to failure to link episodes within an admission, or because no outcome was recorded] in HES and UKCSR, Mr Wisheart submitted:

> 'I believe that the arbitrary method of handling this problem may well have contributed to the apparent excess mortality, particularly in the neonates and the children under one in 1991–1995 where the excess mortality seems to be the greatest.'[232]

162 In response, Dr Spiegelhalter et al. stated that they carried out:

> '… a simple analysis to examine what the impact of these missing outcomes might be, taking the most optimistic view that they all were survivors'.[233]

163 They concluded:

> '… even if we assume that all missing outcomes were survivors, there is little effect on the findings. We therefore reject the conclusion that missing outcomes makes the HES analysis unreliable.'[234]
>
> 'Missing outcomes in HES data has negligible effect on the conclusions.'[235]

164 Referring to his concerns about the Experts' use of pooled (unstratified) data for purposes of comparison, Mr Wisheart submitted:

> 'It is clear that in the analyses, some techniques have been reported which involve pooling of data and others have been reported which aggregate differences between relatively homogeneous sub-groups. The validity of using pooled data for comparison raises many questions. To enable a clear understanding to be reached we would ask for analyses which involve pooling of data to be identified.'[236]

165 Dr Spiegelhalter et al. stated:

> 'The distinction between "case-mix" (operative procedures) and "risk-stratification" (clinical risk factors) is very useful. By aggregating over consensus groups we achieve adjustment for case-mix, since excess mortality is only attributed in comparison with mortality elsewhere within the specific stratum defined by

231 SUB 0009 0024 Mr Wisheart
232 SUB 0009 0024 – 0025 Mr Wisheart
233 INQ 0034 0006; *'A Response to Submissions on behalf of Mr JD Wisheart, Appendix 2, The Inquiry's Statistical Analysis'*, May 2000, Dr Spiegelhalter et al.
234 INQ 0034 0006 – 0007; *'A Response to Submissions on behalf of Mr JD Wisheart, Appendix 2, The Inquiry's Statistical Analysis'*, May 2000, Dr Spiegelhalter et al.
235 INQ 0034 0002; *'A Response to Submissions on behalf of Mr Wisheart, Appendix 2, The Inquiry's Statistical Analysis'*, May 2000, Dr Spiegelhalter et al.
236 SUB 0009 0025 Mr Wisheart

operative group, age group and epoch. That is why we present data both for *pooled* open operations, and *aggregated* over operative group. The summary table on INQ 15/0004 shows this makes little difference in the conclusions.'[237]

166 They concluded:

'There is very little disagreement as to whether individual children died or not. This supports the value of overall comparisons of pooled open operations, since these are not so susceptible to coding problems.'[238]

167 In a letter to the Inquiry, Dr Jan Poloniecki, lecturer in statistics at St George's Hospital Medical School, submitted:

'The statistical conclusions that have been drawn first by the GMC and now at the BRI Inquiry are fatally flawed by reason of inadequate allowance for repeated significance testing, and not taking into account the method by which Bristol was selected for scrutiny …

'It [the Inquiry] should consider whether the question of what is an acceptable difference in death rates is capable of a single answer, and that some differences might be acceptable to some surgeons and some patients but not necessarily to all patients or all purchasers.'[239]

168 Dr Aylin, Dr Best, Professor Evans, Professor Murray and Dr Spiegelhalter responded:

'… we believe that examination of the statistical evidence to the BRI Inquiry will show that these valid concerns were, where appropriate, fully taken into account.'[240]

169 Professor Campbell, Professor Curnow, Professor Gallivan, Ms Macfarlane, and Professor McPherson published the following joint statement:

'As members of the Expert Group advising the Bristol Royal Infirmary Inquiry, we have advised on the initial data processing and analysis and heard presentations of the thorough and impressive work of the statisticians contracted by the Inquiry. We have seen their reports submitted to the Inquiry. We are in full agreement with their response on Allstat[241] dated November 26 to the earlier criticisms by Dr Poloniecki.'[242]

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237 INQ 0034 0007 – 0008; *'A Response to Submissions on behalf of Mr JD Wisheart, Appendix 2, The Inquiry's Statistical Analysis'*, May 2000, Dr Spiegelhalter et al. (emphasis in original)

238 INQ 0034 0002; *'A Response to Submissions on behalf of Mr JD Wisheart, Appendix 2, The Inquiry's Statistical Analysis'*, May 2000, Dr Spiegelhalter et al.

239 PHA2 0001 0112; letter from Dr J Poloniecki, 10 November 1999

240 INQ 0015 0133; *'Statistical analysis at BRI Inquiry – Re open letter to Inquiry'*, 26 November 1999, Dr Aylin, Dr Best, Professor Evans, Professor Murray and Dr Spiegelhalter

241 Allstat is a UK-based worldwide e-mail broadcast system for the statistical community

242 INQ 0015 0132; *'Statistical analysis at BRI Inquiry'*, 27 November 1999, Professor Curnow

170 Mr Wisheart concluded his submission:

> 'There seem to be important questions outstanding in relation to the reliability of comparator data, the use of analyses involving pooled data, and some figures given for Bristol which seem to be at odds with the surgeons' own data.
>
> '… If the stages of confirmation and explanation are not achieved, should the Inquiry not acknowledge that the uncertainties inherent in the preliminary data render them unreliable as the basis for any judgement?'[243]

171 Dr Spiegelhalter et al. responded:

> 'We agree that no source of data can be considered as a gold-standard. However, if two reasonably independent sources of evidence corroborate each other and are largely consistent, then this supports both their conclusions. Furthermore, there is no statistical justification for the claim that using pooled data on open operations is in any way "unreliable" – in fact, given the difficulties in obtaining agreed coding categories of diagnoses and operations, such a pooling may be more reliable than a more sophisticated technique.
>
> '… The statistical evidence does not support the claim that "the uncertainties in the preliminary data render them unreliable as the basis for any judgement" – the strength and consistency of the "signal" dominates the indisputable "noise" that exists.'[244]

Differences in the data presented in the evidence of the Inquiry's Experts and the data submitted by the Bristol surgeons

172 Mr Dhasmana stated:

> 'Mr Wisheart has drawn attention to the problems with the raw data and I would endorse those views. The mortality figures for the neonatal arterial switch programme are clearly wrong and I believe that those quoted for ASD and VSD are also incorrect.
>
> 'My own surgical log, which I believe to be the most accurate monitor of my surgical performance, demonstrates that between 1990 and 1995 I operated upon 61 children with ASD's and there were no deaths. Indeed for my entire consultant experience in this group I have only 1 recorded death out of 95 operations.
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> 'Likewise my figures for VSD's are 2 deaths out of a total of 72 operations between 1990 and 1995 (6 deaths out of 117 for my whole experience).'[245]

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243 SUB 0009 0026 Mr Wisheart

244 INQ 0034 0008 – 0009; *'A Response to Submissions on behalf of Mr JD Wisheart, Appendix 2, The Inquiry's Statistical Analysis'*, May 2000, Dr Spiegelhalter et al.

245 WIT 0084 0149 – 0150 Mr Dhasmana

'The conclusions[246] drawn by the statistical team on behalf of the Inquiry are not accepted. It is believed that there are serious flaws with some underlying data. In particular, the results quoted for ASD's and arterial switches are wrong.'[247]

173 Mr Wisheart questioned the accuracy of figures [248] presented in a report to the Inquiry by one of the Inquiry's Experts in statistics. In particular, he raised concerns (by reference to his own and Mr Dhasmana's data) about the number of operations and the number of deaths which the Inquiry's Expert had identified in relation to particular categories of procedure.

174 The report showed 5 deaths in 90 operations for Atrial Septal Defects in 1991–1995. Mr Wisheart stated:

'Mr Dhasmana and I believe there were no deaths out of 102 operations.'[249]

175 The report showed 5 deaths in 50 operations for aortic or pulmonary valve surgery. Mr Wisheart stated:

'Mr Dhasmana and I believe that there was one death out of 35 operations.'[250]

176 The report showed 3 deaths in 23 operations for mitral valve surgery. Mr Wisheart stated:

'Mr Dhasmana and I believe that there was one death out of eleven operations.'[251]

177 In relation to the estimated numbers of excess deaths based on HES data, as shown in the report,[252] Mr Wisheart submitted:

'… [the estimate] is substantially wrong and is likely to be a significant over-estimate of the number of excess deaths … .'[253]

178 Dr Spiegelhalter, Professor Evans, Dr Aylin and Professor Murray responded:

'The point at issue is the classification of operations. There is no evidence that deaths have been recorded when they have not occurred in more than a very few instances overall. The problem is that the classification of operations is difficult. With random misclassification of type of operation, but accurate determination of

246 As set out in the initial statistical reports to the Inquiry, published in November 1999
247 SUB 0010 0019 Mr Dhasmana; see Chapter 3 for an explanation of clinical terms
248 Mr Wisheart refers in his submission to the table presented at INQ 0015 0004; *'An initial synthesis of statistical sources concerning the nature and outcomes of paediatric cardiac surgical services at Bristol relative to other specialist centres from 1984 to 1995'*, October 1999, Dr Spiegelhalter. The number of operations and the number of deaths quoted by Mr Wisheart appear to be extracted from the table presented at INQ 0015 0048
249 SUB 0009 0025 Mr Wisheart
250 SUB 0009 0025 Mr Wisheart
251 SUB 0009 0025 Mr Wisheart
252 The estimated numbers of excess deaths are reported in the table at INQ 0015 0004
253 SUB 0009 0025 Mr Wisheart

death, then [there] will be a tendency for mortality rates in the different groups to be more similar to one another than would be the case if no misclassification occurred. In particular groups there may be a higher rate, but in other groups there will be a lower rate than there should be. *Focusing only on the groups with a higher rate is biased. It is for this reason that examination of all open operations was also done in the statistical analysis.* The other issue is that coders in different centres, who are each familiar with the OPCS4 system, will tend to code operations in a way that reflects that coding system, rather than clinicians' views. The key comparisons are made between centres, and no doubt, individual clinicians in those other centres are also likely to have different ways of classifying their operations. Random misclassification is likely to make the different groups more similar across centres also.

'… There is very little disagreement between the sources of data in regard to individual children as to whether they died or not. There is disagreement between Mr Wisheart's grouping by diagnosis, and the other sources that are grouped by operative procedure. While it is possible that some groups seem to show a higher rate in the statistical reports provided to the Inquiry than in Mr Wisheart's grouping of the data, there will be other groups where Mr Wisheart's data would seem to have a higher mortality rate than the statistical reports. He has not drawn attention to these, since his own comments apply only to selected groups.'[254]

179 Dr Spiegelhalter et al. further observed:

'It is important to emphasise that the entire analysis of paediatric cardiac surgery at UBHT has been based on operative procedures rather than on diagnosis. This was made very clear in our reports. Two of the major reasons for choosing to use operation were – a) the UKCSR recorded data by numbers of procedures rather than numbers of diagnoses, and b) when comparing different centres, it is likely that agreement about procedures may be greater than agreement on diagnosis. The Submission [by Mr Wisheart] presents its analyses based on diagnosis rather than on operation, and hence considerable discrepancies must be expected between the analysis of the Inquiry's Data (including that of the Surgeons' Logs) and the analysis in the Submission of the Surgeons' Logs.

'… Further analysis based on linkage of HES records with national death certification records has been carried out by Professor Murray … This shows that in open operations HES identifies around 95% of 30-day deaths (in spite of HES only aiming to capture in-hospital deaths). In conclusion, we do not find statistical evidence to support the statement "that the estimate of excess deaths based on HES data is substantially wrong".'[255]

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254 INQ 0034 0015; *'A Response to Submissions on behalf of Mr JD Wisheart, Appendix 2, The Inquiry's Statistical Analysis'*, May 2000, Dr Spiegelhalter et al. (emphasis added)

255 INQ 0034 0008; *'A Response to Submissions on behalf of Mr JD Wisheart, Appendix 2, The Inquiry's Statistical Analysis'*, May 2000, Dr Spiegelhalter et al.

180 Referring to the apparent discrepancies between HES data and hospitals' departmental records, Dr Spiegelhalter et al. in their Overview Report observed:

> 'Stark (2000a, WIT 0567 0004) reports substantially lower counts of activity (sum of operations identified as "open" or "closed") measured by HES and reported in Aylin et al (1999) and Spiegelhalter (1999), compared to the numbers of operations recorded in contemporary departmental records. Some undercount must be expected due to the Inquiry's use of admissions [to hospital] as a measure of activity, rather than operations as used in the departmental records. There will be additional contributions due to miscoding of records in HES, and in particular from admissions excluded from the open/closed groups (see Section 2.4).[256] It is difficult to interpret such discrepancies, as there is unknown variability between departmental record systems in, say, what constitutes an "operation". What is important for the Inquiry's analysis is that the same coding and exclusions (on the basis of OPCS4 codes) have been applied to all centres in a consistent manner. As noted at Section 2.5 above,[257] random errors in coding will tend to reduce differences between groups and hence between centres.'[258]

181 Dr Spiegelhalter et al. reached the conclusion that:

> 'Although we have had some months to reflect on the issues and carry out further examination of the available data, we see no statistical justification to revise to any substantial extent the analyses and opinions stated in written and oral evidence to the Inquiry.'[259]

The Bristol surgeons' formal written comments on the Experts' Overview Report and the Experts' responses

182 The Inquiry's Experts on Statistics presented their Overview Report to the Inquiry in September 2000. In that Report, as has been seen, efforts were made to take account of concerns expressed. In October and November 2000, Mr Wisheart and Mr Dhasmana submitted formal written comments on the Experts' Overview Report, to which the Experts replied.

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256 See INQ 0045 0015; *'Overview of statistical evidence'*, September 2000
257 See INQ 0045 0015; *'Overview of statistical evidence'*, September 2000
258 INQ 0045 0018; *'Overview of statistical evidence'*, September 2000
259 INQ 0034 0002 – 0003; *'A Response to Submissions on behalf of Mr JD Wisheart, Appendix 2, The Inquiry's Statistical Analysis'*, May 2000, Dr Spiegelhalter et al.

183 Mr Dhasmana stated:

> 'I would … like to respond to their conclusion that the high mortality was not restricted to AVSD and switches.
>
> 'I believe that these two groups were the main factors in contributing to the high mortality in this age group [under 1 year of age]. I have stated in my evidence to the GMC and the Public Inquiry that Bristol traditionally lagged behind the rest of the country by about 5 years in keeping up with the pace of development in paediatric cardiac surgery. The arterial switch programme, particularly in neonates, started in earnest in other centres around the late 80's and they were able to overcome their initial high mortality by the early 90's, as shown by the falling trend of mortality in the neonatal age group in this report. On the other hand, in Bristol the neonatal switch programme started in January 1992 and stopped in October 1993. I believe that this contributed to the high mortality figures seen in epoch 3 of this study period. … I always recognised the high mortality of switches in the neonatal period and discussed the mechanisms adopted towards improving the result, which could not be sustained.'[260]

184 In response, Professor Evans and Dr Spiegelhalter observed:

> 'The discussion in the Overview at section 6.4 [INQ 0045 0027], and tables 6.2 [INQ 0045 0056] and 6.4 [INQ 0045 0059] make it clear that, both according to the UKCSR and the HES analysis, the results at Bristol were not as good as those at other centres for other operations. It is clear that the major contribution, as Mr Dhasmana states, is from AVSD and switches. He also notes that there were worse results for other operations, but suggests that the numbers were too small for meaningful comparison. The statistical methods used by the experts in the Overview Report have been able to combine these groups and the overall effect suggests that the worse mortality was not restricted to the highest risk groups.'[261]

185 Mr Dhasmana commented on the Experts' conclusion that Bristol lagged behind the falling trend in mortality elsewhere:

> 'The "Overview Report" … has recognised that there was no excess mortality in this age group[262] during epoch 4 … for the period April 95–December 95. The overview report appears to pay little attention to this improvement by stating that the activity was too small to draw any firm conclusion …
>
> '… I operated on a full range of paediatric cardiac procedures except for the arterial switches during that period. This was in accordance with the recommendation of

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260 INQ 0045 0118; formal written comment from Mr Dhasmana on the *'Overview of statistical evidence'*; see Chapter 3 for an explanation of clinical terms

261 INQ 0045 0136 – 0137; *'Response to Further Submission by Mr Dhasmana in response to Overview of Statistical Evidence'*, December 2000, Professor Evans et al.,

262 The under-1 age group

the de Leval and Hunter committee report (UBHT 0340 0305). I shared the paediatric cardiac work with Mr Pawade, the new appointee from May 1995 till September 95, when the open-heart surgical programme moved to the Children's hospital. The low mortality in this age group [under-1s], recognised by the "Overview Report", demonstrates that I kept pace with the falling trend in mortality in this age group. The absence of neonatal switches during this period supports my statement that the neonatal switches affected the mortality rate under my care during the third epoch and masked the improvement in my clinical work. I have already submitted a complete list of paediatric cardiac operations from 1986 till September 1995 … which demonstrates the improvement in clinical results in all most [*sic*] all groups except for the arterial switches. The de Leval and Hunter committee in their report attributed the cause of high mortality in this group to be multi-factorial (UBHT 0340 0304). I believe that high mortality in this group, coupled with mortality in the TAPVD series under my care, reflects the problem we had of split-site management of neonates and infants undergoing cardiac surgery.'[263]

186 Professor Evans and Dr Spiegelhalter responded:

'There are two problems with the interpretation of data in the period of Epoch 4, April 1995 to December 1995. As Mr Dhasmana notes, the number of arterial switch operations in this period was dramatically reduced. The expected mortality in the remaining groups would then result in a lower overall total mortality. The second is that this is a much shorter time span than the other epochs so that the total numbers of operations and deaths is very much less. In the statistical reports we have not wished to stress the fall in mortality rate in Epoch 4 because, from a statistical point of view, the data are too sparse to over-emphasise the apparent fall in mortality rate. The Overview makes it clear that in this time period there was no evidence at all for any excess mortality in any age group.'[264]

'The overall conclusions of our statistical analysis stand. We agree that the detailed interpretation of group 6 [ASDs] operations based on the original grouping in the local sources was, in some circumstances, subject to error. This has been corrected for the final Overview and did not affect any earlier between centre comparisons. We did not intend that anyone should rely on detailed comparisons based on the local sources, nor that between surgeon comparisons should be a focus of our analyses. The correction of the errors has made the local sources more consistent with one another, strengthening rather than weakening the conclusions.'[265]

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263 INQ 0045 0118 – 0120; formal written comment from Mr Dhasmana on the *'Overview of statistical evidence'*; see Chapter 3 for an explanation of clinical terms

264 INQ 0045 0137; *'Response to Further Submission by Mr Dhasmana in response to Overview of Statistical Evidence'*, December 2000, Professor Evans et al.

265 INQ 0045 0136; *'Response to Further Submission by Mr Dhasmana in response to Overview of Statistical Evidence'*, December 2000, Professor Evans et al.

187 They concluded:

> 'The Overview of the statistical reports does not need to be altered in any way. The data and conclusions are not undermined by what Mr Dhasmana submits. There has been no attempt to distinguish between individual surgeons, since the nationally available data do not permit individual surgeon comparisons.'[266]

188 Mr Wisheart stated:

> '… I have presented a case that the Overview has given insufficient weight to some of the evidence, namely:
>
> - 'that caution should be exercised when dealing with these figures.
> - 'that there are important differences, rather than reasonable agreement, between HES and [UK]CSR data and their analysis.
> - 'That the [UK]CSR data is inappropriate for comparative purposes at the level of diagnostic categories.
> - 'That clinicians (eg Stark and Keogh) have grave lack of regard for HES as a credible basis for evaluation of clinical events.
> - 'that the various sources of inaccuracy in the mortality data, together with the unresolved discrepancies over figures in various consensus groups, lead to uncertainty about the magnitude of the apparent divergence of outcomes in Bristol compared to elsewhere.
> - 'the need for clarification of the difference between pooled and aggregated data, and its significance.
> - 'that some possible reasons for divergence in the Bristol outcomes, compared to elsewhere, have been identified; namely, volume of surgery, timing of surgery and the disproportionately high frequency of additional risk factors in two sub-groups of patients.'[267]

189 Professor Evans, Dr Spiegelhalter, Professor Murray and Dr Aylin responded:

> 'We agree that the quality of the data is a major issue. We disagree that the quality of the data is insufficient to allow conclusions to be drawn about comparative mortality between Bristol and other centres. It is a question of judgement as to when the quality of data is insufficient and the authors of the overview have taken

266 INQ 0045 0137; *'Response to Further Submission by Mr Dhasmana in response to Overview of statistical evidence'*, December 2000, Professor Evans et al.

267 INQ 0045 0112 Mr Wisheart; response to the *'Overview of statistical evidence'*

care to acknowledge the deficiencies but at the same time we feel that the overall conclusions are robust.'[268]

190 Mr Wisheart stated:

'Without apparent regard for the views of Lawrence and Murray, the Overview proceeds to report its findings for excess deaths based on analysis of the [UK]CSR using procedure groups, individually and aggregated, without any obvious caution.'[269]

191 Professor Evans et al. responded:

'It is suggested … that we have not regarded the views of Lawrence and Murray on the analysis of the [UK]CSR. This is incorrect, firstly because Murray is an author of the Overview. Secondly the effect that errors may have on the conclusions are not such as to result in bias against Bristol. The classification into procedure groups of operations for cardiac surgery will always be subject to errors. The key question of importance in epidemiological terms is that such classification error is not different in the different centres. There is no evidence from Lawrence and Murray's study that such differential misclassification has occurred. Our judgement is that in spite of the weaknesses of the different sources of data they all point towards the overall conclusion that there were excess deaths in the younger children in Bristol. There is considerable consistency between the analyses based on pooled data and those based on dividing the data into separate procedure groups. This indicates that there were no major differences between centres in the mix of cases treated in those centres. The absence of major case-mix differences between centres means that argument about details of procedure groups is of limited relevance.'[270]

192 Mr Wisheart stated further:

'The main finding of this Overview, is the number of excess deaths in children under one, operated between 1991 and 1995. The HES estimate of 27.2 is more than twice as high as the [UK]CSR estimate of 12.9 (for aggregated, stratified open cases; Tables 6.1.and 6.2). This seems to be a large difference both in relative terms and in absolute numbers, and to fall well short of "reasonable consistency".'[271]

193 Professor Evans et al. responded:

'… Mr Wisheart emphasises the differences between the HES and [UK]CSR estimates of the number of excess deaths in children aged less than one. Even with extremely good agreement between the sources in the basic data, the different

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268 INQ 0045 0139; *'Response to Further Submission by Mr JD Wisheart in response to Overview of Statistical Evidence'*, December 2000, Professor Evans et al.

269 INQ 0045 0095 Mr Wisheart; response to the *'Overview of statistical evidence'*

270 INQ 0045 0139 – 0140; *'Response to Further Submission by Mr JD Wisheart in response to Overview of Statistical Evidence'*, December 2000, Professor Evans et al.

271 INQ 0045 0096 Mr Wisheart; response to the *'Overview of statistical evidence'*

definitions of activity would lead to different numbers of excess deaths. The key point is that each of these excesses has good evidence that they are more than zero and that although the precise estimates do not agree this is nevertheless reasonably consistent evidence of an increase in Bristol.'[272]

194 Referring to discrepancies between HES and UKCSR data, Mr Wisheart stated:

'If one quarter of the centres and one half of the procedure groupings lie outside an acceptable range of consistency [20%], how can one regard the level of agreement between the two sources of data as "reasonable"?'[273]

195 Professor Evans et al. responded:

'… Mr Wisheart suggests that discrepancies beyond 20 percent are unacceptable. This is not true and it is certainly to be expected that there will be some variation in the ratio of death rates between HES and [UK]CSR.'[274]

196 Mr Wisheart stated:

'The under-reporting of deaths in HES, both quantified and unquantified, could contribute an increment to the estimate of excess deaths in Bristol, in children under one year of age from 1991–1995, but it is unlikely to exceed 5% of the total.'[275]

197 Professor Evans et al. responded:

'There is a misunderstanding regarding the underestimation of death rates in HES. It is important to realise that this underestimation will not only apply to other centres but it applies also to Bristol. The fact that Bristol has about the average underestimation makes it clear that there is no evidence that Bristol has a markedly different rate of underestimation of deaths compared with other centres. Any contribution to the error in the estimate of excess deaths in Bristol will be very small and it is not clear that this would automatically lead to an overestimate of excess deaths in Bristol.'[276]

198 Mr Wisheart stated:

'Table 6.2 continues to include figures for Group 6 (Atrial-Septal Defects) which I believe to be wrong. Please see my Response to a Group of Statistical Papers (2).

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272 INQ 0045 0140; *'Response to Further Submission by Mr JD Wisheart in response to Overview of Statistical Evidence'*, December 2000, Professor Evans et al.
273 INQ 0045 0097 Mr Wisheart; response to the *'Overview of statistical evidence'*
274 INQ 0045 0140; *'Response to Further Submission by Mr JD Wisheart in response to Overview of Statistical Evidence'*, December 2000, Professor Evans et al.
275 INQ 0045 0098 Mr Wisheart; response to the *'Overview of statistical evidence'*
276 INQ 0045 0140; *'Response to Further Submission by Mr JD Wisheart in response to Overview of Statistical Evidence'*, December 2000, Professor Evans et al.

At Para 3.5 I make a detailed presentation based on the belief that the worst possible figures in this group are that there were 3 deaths amongst 5 patients, rather than 5 deaths among 10 patients as is indicated in Table 6.2. If my figures were accepted this would reduce the number of excess deaths by 1.65 to 2.65.'[277]

199 Professor Evans et al. responded:

'Although it is acknowledged that group 6, which includes atrial-septal defects, may have some misclassification, if consequently there is over-recording of deaths in that group then those deaths would be balanced by under-recording of deaths in some of the other groups. Therefore they would not substantially affect the number of excess deaths overall. Similar arguments apply to the other groupings so that picking on those groups where the numbers recorded by the surgeons are lower than those in the Overview is biased. Examination of all groups, where there will be some with higher numbers recorded by the surgeons than in the Overview, should be done. The failure to realise that there should be higher numbers of deaths in the other groups leads to a misunderstanding regarding the estimation of the number of excess deaths. The values presented by Mr Wisheart need to be balanced by those in the opposite direction.'[278]

200 Mr Wisheart stated:

'The Inquiry's statistical experts have not accepted my point about discrepancies over figures, data and coding ... on the grounds that there was said to be agreement by all parties about the number of deaths which occurred in Bristol. This means that if a death is not allocated to one group, it is allocated to another and when the analysis of these groups are aggregated, errors of allocation will not matter. This lack of rigor [*sic*] inevitably undermines the confidence required in such serious work.'[279]

201 In response, Professor Evans et al. stated:

'We would wish to strongly refute the argument … that there has been "lack of rigour" in the overall analysis. Mr Wisheart does not seem to accept that if a given child had died, but the classification of the group was incorrect, then an underestimate of deaths will occur in the group to which they should have been allocated. This is balanced by the overestimation of deaths in the group to which they had actually been allocated. It is also important to realise that this effect will occur in centres other than Bristol, and will apply approximately equally to all centres.'[280]

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277 INQ 0045 0099 Mr Wisheart; response to the *'Overview of statistical evidence'*

278 INQ 0045 0140 – 0141; *'Response to Further Submission by Mr JD Wisheart in response to Overview of Statistical Evidence'*, December 2000, Professor Evans et al.

279 INQ 0045 0100 Mr Wisheart; response to the *'Overview of statistical evidence'*

280 INQ 0045 0141; *'Response to Further Submission by Mr JD Wisheart in response to Overview of Statistical Evidence'*, December 2000, Professor Evans et al.

202 Stating that 'The data are too flawed to allow a conclusion to be reached',[281] Mr Wisheart added:

> 'I wish to repeat the case, which I have made on a number of occasions in my earlier submissions, that taken together the various potential flaws may make a considerable contribution to the estimate of excess deaths.'[282]

203 Professor Evans et al. responded:

> 'We do not agree that the data are "too flawed" to allow conclusions to be reached.'[283]

204 Mr Wisheart stated:

> '… there are four estimates [of excess deaths] in all for open surgery carried out on all age groups between 1991 and 1995. These estimates range from 15.7 to 31.2, with HES estimates consistently greater than [UK]CSR estimates. Bearing in mind the acknowledged flaws in the data and the caution which has been advised in their use elsewhere in this Overview, it seems very strange that the estimate given in the Executive Summary is at and beyond the upper limit of the range of reported estimates.'[284]

205 Professor Evans et al. responded:

> '… it is suggested that the estimate of excess deaths given in the executive summary of the Overview [285] … is greater than that given elsewhere. At paragraph 6.2.1 of the Overview it is made clear that the estimate of the excess depends on the age stratification used. When the age stratification includes a "less than 90 days" group then the excess is 34.3. There is uncertainty in this value and the executive summary reflects this.'[286]

206 Mr Wisheart observed:

> '*Public perception*. If it is stated that there are a certain number of excess deaths in any category, this is seen as meaning that that number of deaths should not have occurred. This is so whether or not the number is statistically significant (statistical significance indicates the probability that the number of excess deaths is truly greater than zero). This concept also fails to take account of the fact that around the

281 INQ 0045 0102 Mr Wisheart; response to the *'Overview of statistical evidence'*
282 INQ 0045 0102 Mr Wisheart; response to the *'Overview of statistical evidence'*
283 INQ 0045 0141; *'Response to Further Submission by Mr JD Wisheart in response to Overview of Statistical Evidence'*, December 2000, Professor Evans et al.
284 INQ 0045 0104 Mr Wisheart; response to the *'Overview of statistical evidence'*
285 The estimated range of excess deaths was identified in the Executive Summary of the *'Overview Report'* in the following terms: 'Depending on the precise approach to the analysis, the number of excess deaths for open surgery during this period was estimated to be of the order 30 to 35.' INQ 0045 0003
286 INQ 0045 0141; *'Response to Further Submission by Mr JD Wisheart in response to Overview of Statistical Evidence'*, December 2000, Professor Evans et al.

mean performance of the centres, there will be a normal variation with a range which must be considered acceptable. Yet any deviation from the mean is described as excess deaths, even if it lies within that acceptable range.'[287]

207 Professor Evans et al. responded:

'… Mr Wisheart questions the public perception of the phrase "excess deaths", and we acknowledge that these words are not the ideal, but there does not seem to be a good alternative way of expressing "observed – expected". We have made it clear exactly how the numbers were obtained.'[288]

208 Mr Wisheart stated:

'… in principle, if a patient comes to surgery with advanced pulmonary vascular disease, one must regard that as something which has been permitted to occur as a result of the total system of care. Ideally, surgery would take place before such a development. On the other hand, the presence of associated additional anatomical abnormalities within the heart, or indeed outside the heart, are patient factors which cannot be influenced by the system of care, other than in the selection or non selection of such a patient for surgery. Therefore they remain as patient related factors which will influence the outcome of care and are legitimate considerations when assessing the system of care.

'… The presence of additional anatomical abnormalities in Mr Dhasmana's series of neo-natal Switch operations is also well documented. These are coarctation of the aorta in 1 patient, and coronary arterial abnormalities in 4 other patients which add to the risk of the operation to a varying extent.

'Within the framework of considering factors outside the control of the system of care which may contribute to adverse outcomes, it seems that one should still consider both the volume of surgery and the presence of significant associated anatomical abnormalities in the patients. Each of these two factors would make a significant contribution to understanding the occurrence of excess deaths in this group of patients.'[289]

209 Professor Evans et al. responded:

'The issues of risk adjustment … are described entirely reasonably, but the presence of, for example, anatomical abnormalities in other centres has not been allowed for.'[290]

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287 INQ 0045 0105 Mr Wisheart; response to the *'Overview of statistical evidence'* (emphasis in original)

288 INQ 0045 0141 – 0142; *'Response to Further Submission by Mr JD Wisheart in response to Overview of Statistical Evidence'*, December 2000, Professor Evans et al.

289 INQ 0045 0108 – 0109 Mr Wisheart; response to the *'Overview of statistical evidence'*

290 INQ 0045 0142; *'Response to Further Submission by Mr JD Wisheart in response to Overview of Statistical Evidence'*, December 2000, Professor Evans et al.

210 Mr Wisheart stated:

> 'The authors of the Overview say that the crucial issue is whether the flaws in the data are *likely* to be great enough to overcome the observed patterns in the data. I suggest that a more prudent view is to ask whether it is *possible* that they might offer an explanation. If account is taken of the flaws in the data, and the potential explanations for divergence which have been put forward, I believe that it is definitely possible that the observed patterns may be overcome.'[291]

211 Professor Evans et al. responded:

> '… it is implied that the standards of proof are those for criminal prosecution. This is not a court so it is not a matter of standards of proof. However, it is always "possible" that an explanation exists for every adverse case. The issue is not one of "possibility", but "plausibility". It remains the case that the Overview takes into account the relevant uncertainty and draws conclusions based on the expert opinion of its authors as statisticians and epidemiologists. We have carefully considered Mr Wisheart's comments, and recognising that our phraseology could be improved in places, we feel no reason to change the substance or conclusions of our overview.'[292]

Assessments of the Experts' Overview Report

212 The Inquiry commissioned two experts in statistics to assess the Overview Report: Professor Stephen Gallivan Director of the Clinical Operational Research Unit at University College London; and Professor Robert Curnow, Emeritus Professor at the University of Reading and former President of the Royal Statistical Society. Professor Gallivan commented:

> 'In order to investigate the robustness of their findings, the authors have carried out an extensive programme of "sensitivity analysis".
>
> '… In all cases, even with the final artificially optimistic scenario, analysis still indicated strong evidence for substantial excess mortality at Bristol.
>
> 'In view of the evidence from this sensitivity analysis, one can only conclude that the analytical approach adopted was indeed statistically robust.'[293]
>
> 'No major errors or ambiguities were detected in the report.'[294]

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291 INQ 0045 0113 Mr Wisheart; response to the *'Overview of statistical evidence'* (emphasis in original)
292 INQ 0045 0142; *'Response to Further Submission by Mr JD Wisheart in response to Overview of Statistical Evidence',* December 2000, Professor Evans et al.
293 INQ 0045 0070 – 0071; *'Peer Review Report – Overview of statistical evidence'*, October 2000, Professor Gallivan
294 INQ 0045 0071; *'Peer Review Report – Overview of statistical evidence'*, October 2000, Professor Gallivan

'… to deny the divergence of outcome, one would need to believe that HES and [UK]CSR both gave grossly inaccurate estimates for many of the 11 mortality rates, or alternatively, that case load and mortality at Bristol has been hugely misrepresented. In the opinion of this reviewer, this is highly improbable.'[295]

'Given such strong evidence that outcomes at Bristol were indeed divergent, analysis has been carried out to examine whether there were intrinsic factors, other than case mix, that could mitigate such findings.

'… It can be seen that none of these factors provides mitigation for the level of excess mortality estimated and provides further reassurance that the findings are not a statistical artefact. Again, this suggests that the analysis provides reliable and valid evidence of divergence of the outcomes at Bristol.'[296]

213 Professor Curnow stated:

'In my view, the scrutiny of the various data sources, their comparison and synthesis; the data analyses, and the reporting of the conclusions from the analyses are of the highest professional standard. The analyses have been exhaustive and have been based on appropriate and up-to-date methodology. In their interpretative role, the authors have steered a careful route, balancing the possible misinterpretations of the available data because of biases in the collection and collation stages with the need to derive robust conclusions where this is possible. The authors have studied the sensitivity of their conclusions and recommendations to the inadequacies of the data. This has been done in terms of both possible biases in the data and the representation of the inevitable random variation in the outcome measures. In no place could I identify areas where the authors had been other than cautious in their findings.

'I can therefore confirm that I believe the authors have fulfilled their remit. The analytical approach is statistically robust and fit for purpose. I have found no errors or ambiguities of a statistical nature. I believe the overall conclusions to be reliable and valid.'[297]

295 INQ 0045 0073; *'Peer Review Report – Overview of statistical evidence'*, October 2000, Professor Gallivan (emphasis in original)
296 INQ 0045 0074; *'Peer Review Report – Overview of statistical evidence'*, October 2000, Professor Gallivan
297 INQ 0045 0067 Professor Robert Curnow

Chapter 20 – Concerns: Foreword, 1984 and 1985

Concerns

Foreword

1 The next 11 chapters set out, in chronological order, the development of concerns about the paediatric cardiac surgical services at the United Bristol Hospitals and the UBHT (UBH/T). There is a distinction between a view that the service at the Bristol Royal Infirmary/Bristol Royal Hospital for Sick Children (BRI/BRHSC) was capable of improvement but was nevertheless acceptable, and a view that the service (or aspects of it) at the BRI/BRHSC was unacceptably poor. The expression of the latter view is that which the Inquiry regards as a 'concern'.[1]

2 The following chapters, arranged annually, thus concentrate upon comments from various sources that the service was unacceptably poor. However, there is also evidence which led some individuals to identify what they saw as shortcomings in the Bristol service, and evidence from which it might be argued that others should have done so. This evidence, to an extent, is also reviewed in the chapters that follow. In particular, the Inquiry is conscious that the identification of a number of minor shortcomings might, when taken together, equate to an expression of concern. It is not the function, however, of this account of the evidence put before the Inquiry to pass any judgment upon these matters. It merely lays out the relevant evidence. Furthermore, at the end of each chapter will be found the available data (if any) for the year which the paediatric cardiac surgery Unit produced for its return to the UK Cardiac Surgical Register (UKCSR). Mr Wisheart said that he had maintained records of each and every operation he did (as did Mr Dhasmana), and that one of the purposes of doing so was to allow for a continuing review of performance.

3 It should also be noted that concerns expressed were not only in relation to Neonatal and Infant Cardiac Surgery (NICS). This was only part of the paediatric cardiac surgery work carried out at the BRI.

4 Finally, it should not be assumed that because events set out in the following chapters were simultaneous, or occurred in sequence, that any one individual was aware of that which was occurring, or being said, outside his or her direct personal involvement.

5 In order to provide an overview of the events which happened in any one year, there is a chronology in Chapter 31. Like all chronologies, it aims to assist by simplifying, and should not be taken as a substitute for the evidence, but merely a précis of some of the main features of it.

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[1] In addressing this issue, the Inquiry bears in mind the distinction between expressing the opinion that the service at the BRI/BRHSC was capable of improvement but nevertheless acceptable; and the view that the service at the BRI/BRHSC (or aspects of it) was unacceptably poor. It is the latter which is meant by 'an expression of concern'. See Issue N Inquiry on the Inquiry's Issues List in AnnexB

1984

6 In the context of the designation of Bristol as a Supra Regional Centre (SRC) in 1984, Sir Terence English, past President of the Royal College of Surgeons of England (RCSE), was asked by Counsel to the Inquiry: 'Could it be said of Bristol that in 1983 there had been developed there a special expertise in neo-natal and infant cardiac surgery?' He answered: 'No'.[2]

7 The view of Dr Norman Halliday, Medical Secretary of the Supra Regional Services Advisory Group (SRSAG),[3] was:

> '… Bristol did not actually shine as a star, whereas many of the other units such as Birmingham, Harefield, Brompton, Guy's, GOS [Great Ormond Street], would stand out, so it did not seem to be one of the leading lights in this area.
>
> 'Q. "Shine as a star" in what sense?
>
> 'A. In terms of clinical work that was going on there, in terms of research, in terms of the results that they were getting.'[4]

8 Dr Halliday's view as to the numbers of operations performed was similar:

> 'Q. … Is what you are saying that the track record in terms of numbers of operations done was not really a justification for Bristol becoming a supra-regional centre?
>
> 'A. Well, it certainly did not perform anything like on a par with the other units, no.'[5]

9 A table appended to the Report of the Joint Working Party of the Royal College of Physicians of London and the Royal College of Surgeons of England[6] showed the number of open- and closed-heart operations carried out on children under 1 year old in 1984 in the nine designated SRCs:[7]

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2 T17 p. 68 Sir Terence English
3 See Chapter 7
4 T13 p. 28 Dr Halliday
5 T13 p. 27 Dr Halliday
6 Report of the Joint Working Party of the Royal College of Physicians of London and the Royal College of Surgeons of England *'Supraregional Services: Neonatal and Infant Cardiac Surgery'*, dated 1 September 1986
7 RCSE 0002 0017; figures taken from table 3 to the Report

Supra Regional Centre	open-heart operations	closed-heart operations	total
BRI and BRHSC	11	39	50
The Freeman Hospital, Newcastle	32	40	72
Birmingham Children's Hospital	35	84	119
Brompton Hospital, London	55	94	149
The Royal Liverpool Children's Hospital	63	97	160
Southampton General Hospital	41	53	94
Guy's Hospital, London	19	74	93
Great Ormond Street Hospital for Sick Children	82	152	234
Killingbeck Hospital, Leeds	28	94	122
	366	**727**	**1,093**

The table also provided figures for two other centres which had applied for designation as SRCs:

Centre	open-heart operations	closed-heart operations	total
Harefield Hospital, Middlesex	32	19	51
Groby Road Hospital, Leicester	13	32	45

10 The designation of Bristol as an SRC is considered in Chapter 7. The evidence was that the inclusion of Bristol in the list of centres designated occurred late, and that, in effect, the only claim that Bristol had for such designation was on the basis of geography. There is also evidence, set out in Chapter 7, from Dr Halliday and Sir Terence, to the effect that the Unit at Bristol needed to be developed if it was successfully to fulfil its intended role as a designated centre.

1985

11 This was the first full year after designation of Bristol as an SRC. Evidence as to the need to establish and develop what was thought to be an appropriate caseload is contained in Chapter 7[8] and is not repeated here.

12 Records were maintained of the throughput of paediatric cardiac cases including whether or not the child operated on had survived. In particular the surgeons Mr James Wisheart and Mr Janardan Dhasmana kept logs, and each year Mr Wisheart ensured that his secretary informed the Society of Cardiothoracic Surgeons of Great Britain and Ireland (SCS) of the numbers of operations, and numbers of deaths, recorded in the Bristol Unit.

[8] Evidence as to the views of referring clinicians is contained in Chapter 11

13 In 1985, the return to the Register showed that the Bristol Unit performed 14 open-heart operations on children under 1 year of age, and 85 on children over 1 year of age.[9] There were three deaths in the under-1 group, and two in the over-1s.[10]

14 The table appended to the Joint Working Party Report referred to in para 9 above[11] also gave figures for the number of open- and closed-heart operations carried out on children under 1 year old in 1985:[12]

Supra Regional Centre	open-heart operations	closed-heart operations	total
BRI and BRHSC	14	41	55
The Freeman Hospital, Newcastle	28	47	75
Birmingham Children's Hospital	42	68	110
Brompton Hospital, London	71	85	156
The Royal Liverpool Children's Hospital	82	113	195
Southampton General Hospital	47	53	100
Guy's Hospital, London	12	60	72
Great Ormond Street Hospital for Sick Children	74	142	216
Killingbeck Hospital, Leeds	32	80	112
	402	**689**	**1,091**

Centre	open-heart operations	closed-heart operations	total
Harefield Hospital, Middlesex	38	17	55
Groby Road Hospital, Leicester	16	42	58

9 UBHT 0055 0005; return to the SCS produced by the UBHT
10 UBHT 0055 0154; return to the SCS produced by the UBHT
11 Report of the Joint Working Party of the Royal College of Physicians of London and the Royal College of Surgeons of England *'Supraregional Services: Neonatal and Infant Cardiac Surgery'*, dated 1 September 1986
12 RCSE 0002 0017; figures taken from table 3 to the Report

Chapter 21 – Concerns 1986

Concerns

1 Professor Gareth Crompton, Chief Medical Officer for Wales from 1978 to 1989, stated in his written evidence to the Inquiry that there was:

> '… an evident undercurrent of dissatisfaction with the Bristol Centre. This, at a time when paediatricians from Wales not working in the Cardiff Centre, e.g. Gwent and Carmarthen, were strong in their support of the care their patients were getting in Bristol.'[1]

2 Professor Andrew Henderson, at that time Professor of Cardiology, University of Wales College of Medicine, and some of his colleagues were openly critical of the quality of work at Bristol. At a meeting between the Welsh Office and South Glamorgan Health Authority (SGHA) on 20 October 1986, Professor Henderson distributed a letter that he had co-written with Mr Butchart[2] and Professor I A Hughes.[3] As regards Bristol, the letter stated:

> 'It has been suggested elsewhere that Bristol provide a supra-regional neonatal cardiac surgical service for Wales. The overriding objections to this have been stated. Moreover it is no secret that their surgical service is regarded as being at the bottom of the UK league for quality, and it is difficult to see how this problem could be resolved in the foreseeable future.'[4]

3 Professor George Sutherland, a cardiologist at Southampton General Hospital from 1983 to 1987, indicated that he was personally contacted by Professor Henderson:

> 'During 1986 I was personally contacted by Prof. A Henderson … with regard to paediatric cardiology services in Wales … Prof. Henderson expressed his concerns to me about referring children from Wales to Bristol in view of the poor surgical results in that department. He suggested that it would be appropriate that I offer a service to Cardiff similar to that Dr Keaton [*sic*] and I were offering to Plymouth.'[5]

1 WIT 0070 0004 Professor Crompton
2 Consultant cardiothoracic surgeon, University Hospital of Wales, College of Medicine
3 Cardiologist and Chairman of the Division of Child Health, University of Wales College of Medicine
4 WO 0001 0006; letter dated 20 October 1986 from Professor Henderson and others to South Glamorgan Health Authority
5 REF 0001 0149; letter dated 21 January 2000 from Professor Sutherland to the Inquiry

4 Professor Crompton told the Inquiry that he did take steps to try to find out if there was substance to Professor Henderson's allegations that Bristol was at the bottom of the league for quality. He raised the matter with Professor Sir Donald Acheson, then the Chief Medical Officer (CMO) for England. Professor Crompton told the Inquiry:

> '… I decided to mention to my colleague Professor Sir Donald Acheson, the Chief Medical Officer at the Department of Health, the opinion of Professor Henderson that Bristol were fortunate to have been designated a Supra Regional Centre in 1984 and that the team there had not progressed year on year as maybe the Supra Regional Advisory Group and/or others had expected. We met regularly as CMOs do in various fora to do with the National Health Service and it was in the margins of one of these that I spoke with him about the Bristol Unit. I had no evidence to present as at no time had Professor Henderson supplied me with any, even though I and my Welsh Office medical colleagues asked for any material he had to substantiate his viewpoint. Sir Donald properly asked me to see his Senior Principal Medical Officer with responsibility for the Supra Regional Services Programme, Dr Norman Halliday. That I proceeded to do the very same day. I saw Dr Halliday in his office, the only time I recall visiting with him, although I saw him often at meetings elsewhere in London where we represented our two departments. I raised with him the misgivings that Professor Henderson had raised with me about the Bristol Unit. We had a brief and un-minuted discussion. I received no confirmation that there were problems, other than about waiting lists, which the Department of Health were considering.'[6]

5 Professor Crompton said that he had told Dr Norman Halliday, Medical Secretary to the Supra Regional Services Advisory Group, of:

> '… repeated comments from Professor Henderson about his view that the quality of the service in the Bristol centre was not improving year on year, as might have been expected. That was the essence of what I said. I had no evidence other than that, and that was, I think, a fair summary of what I had heard from Professor Henderson from time to time.'[7]

6 Professor Crompton added:

> 'I would have hoped that he [Dr Halliday] would have been in a position to have assured me that there was no basis to what Professor Henderson was saying to me, or that if there was a problem, that he had been able to share a confidence as to the extent of it, if he knew. But I do not recall any acknowledgement either way in that conversation about that.'[8]

6 WIT 0070 0003 Professor Crompton
7 T21 p. 29 Professor Crompton
8 T21 p. 33 Professor Crompton

7 When Professor Crompton was asked what action he would have expected Dr Halliday to have taken upon receipt of the information that he had given him, he replied:

> 'Well, from Dr Halliday's reaction, it did not seem to have been news, because he focused on the waiting list issues, not the quality and outcomes issues, and as far as I knew maybe similar things were being said in other parts of England about other centres, he might be privy to. I was not. I did not know what was known or not known to Dr Halliday, and he kept any confidences that he had.'[9]

8 When questioned further he stated:

> 'I would have expected from the beginning, when they established the supra-regional centres, that there would have been a system of data capture and analysis and publication from each of the centres, distributed freely to the Department of Health and to Regional Health Authorities who were sending patients there from Wales or wherever and that the Supra Regional Services Advisory Group would have been in full knowledge of all the facts relating to this important initiative. If that was not the case, then I am surprised.'[10]

9 Dr Halliday gave oral evidence on two occasions. On the first of these he was asked whether he was aware of the concerns that Professor Henderson had in 1986. Dr Halliday replied:

> 'It does not ring a bell, no. I mean, throughout all the discussions with the Welsh Office and everyone in that area, there were constant concerns about Bristol, but they were vague concerns and they appeared to be about the problems of referral. We also had a situation of, quite properly, clinicians in Cardiff wishing to establish their own unit and if they were building that empire there, that would threaten Bristol. So one reason for not referring to Bristol may well have been to strengthen their own case. They would constantly send them to London whilst they argued for a service within Cardiff. So one had to balance these arguments very carefully. But no-one raised any concerns about the clinical outcome in Bristol.'[11]

10 Asked about discussions with Professor Crompton about concerns over outcomes at Bristol, Dr Halliday replied:

> 'I had many discussions with Dr Crompton. As I said earlier, I met with the Welsh Office regularly and we regularly discussed Bristol, but I do not remember any discussion with any clinician or official where the performance of Bristol was questioned. "Performance" I am interpreting as meaning clinical outcome.'[12]

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9 T21 p. 72 Professor Crompton
10 T21 p. 72 Professor Crompton
11 T13 p. 50–1 Dr Halliday
12 T13 p. 112 Dr Halliday

11 When Dr Halliday gave evidence for a second time he had had the opportunity to read the oral evidence of Professor Crompton.

12 Dr Halliday explained that he now did recollect the meeting at which Professor Crompton had expressed to him the concerns of Professor Henderson. He explained:

> '… we did not have a formal meeting. Professor Crompton was not coming to me to say "I have a major concern here that I need you to address", because had he done so we would have arranged a formal meeting, we would have had agendas, we would have taken minutes, we would have considered future action. There was nothing like that at all.'[13]

13 Dr Halliday went on to explain that, as there was no evidence to support Professor Henderson's concerns, as relayed by Professor Crompton, he could not take the issue any further. He said:

> 'I am sorry, but you receive information, you do not necessarily take action, but you do not dismiss it; you retain the information and if something else comes along to complement what you have just been told you might well take action. In terms of what Professor Crompton had told me, I had no justification for taking action. What was I expected to do? I could not go to the Royal College and say "A Professor Henderson in Wales is alleging there is something wrong in Bristol". It would be irresponsible of me to ask the College to investigate on that basis. If, however, I was presented with some evidence, some data to suggest there was something wrong then, yes, I could do something.'[14]

14 In the autumn of 1986, the Bristol Unit was visited by health officials from the Welsh Office. Professor Crompton explained that the motivation behind this visit was to:

> '… explore for ourselves whether there was any substantiation of Professor Henderson's critical comments about the Unit'.[15]

In her report of the meeting, Dr Jennifer Lloyd, Senior Medical Officer, Welsh Office, subsequently wrote:

> '… We did however raise the question of outcome with Bristol staff. They put to us the accepted point that outcome is influenced greatly by case mix. They were quite open in quoting outcomes for some of the commoner procedures they undertake. They see a gradual improvement in these as expertise grows and specialist equipment becomes available. For most of the more commonly occurring conditions their figures compare well with other centres. They acknowledge however that surgeons in different centres develop special expertise in rarer

13 T89 p. 123 Dr Halliday
14 T89 p. 125–6 Dr Halliday
15 WIT 0070 0004 Professor Crompton

conditions and that outcomes may therefore vary greatly for these between centres.'[16]

15 As regards Dr Lloyd's reference to case mix, Dr Hyam Joffe, consultant cardiologist, said in evidence that he could see no reason for Bristol's case mix to be any different from that of any other unit in the country,[17] with the exception of Down's syndrome cases, since he claimed that Bristol was more ready to operate on children with Down's syndrome than other centres, particularly in the mid-1980s to early 1990s.[18]

16 As to the phrase in Dr Lloyd's report, 'gradual improvement ... as expertise grows', Mr Wisheart was asked whether it could be seen as an explanation for under-performance. Mr Wisheart replied:

'I think it could equally be a positive statement, that as experience, expertise in the volume of work undertaken grows, then it is likely that results will improve. I do not think it has to be seen as an explanation for something that may or may not be inadequate.'[19]

17 Mr Wisheart was then shown figures[20] that indicated that in 1986 the number of open-heart operations carried out on children under 1 at the BRI was very small (24) and in previous years had been even smaller: 14 in 1985, 11 in 1984 and four in 1983. Mr Wisheart went on to explain that when he had made the suggestion to Dr Lloyd that 'They [the Bristol Unit] see a gradual improvement in these as expertise grows', it was more a reflection of an aspiration rather than a statement of fact. He said:

'I think the historic setting of what we were talking about is very important, because surgery in the under 1s was something that had been at a very low level through the 1970s and was beginning to grow, so, okay, some folks were a year or two ahead of other folks, and quite a number of folks were not doing very much, and in the early to mid-1980s, we were in that latter group, and hoping to develop the work as others were doing.'[21]

18 Mr Wisheart added:

'... those who are behind are seeking to achieve the standards of those who are presently in front of them … That, I think, was everyone's goal at that time.'[22]

16 WO 0001 0260; Report on NICS for Wales, December 1986
17 T90 p. 4 Dr Joffe
18 T90 p. 4 Dr Joffe
19 T92 p. 73–4 Mr Wisheart
20 DOH 0004 0028; Table of surgery 1975–1991 produced by the UBH/T
21 T92 p. 75 Mr Wisheart
22 T92 p. 76 Mr Wisheart

19 Mr Wisheart was asked about the phrase 'They put to us the accepted point that outcome is influenced greatly by case mix'.[23] In his evidence to the Inquiry Mr Wisheart made several points about case mix. First, he pointed out that a unit doing a small number of operations would probably be doing a proportionally smaller number of elective operations and probably a proportionally higher number of emergency cases and that outcome in emergency cases was nearly always worse, simply because of their unplanned emergency nature. The non-urgent and, therefore, often less serious nature of elective operations regularly led, he said, to a better outcome. Mr Wisheart then referred to some figures that he had prepared in 1988.[24] He explained that he had prepared the comparative table as a normal exercise and not as a response to any concern over rates of mortality at Bristol that had been raised with him. The table showed that in some operations – Pulmonary Stenosis, VSD + PS, and TGA in particular – Bristol had results that were better than the national average, which Mr Wisheart had calculated. In other operations the results were broadly comparable to this national average: Aortic Stenosis and TAPVD in particular. In other operations including PTA, TGA + VSD and AVSD, Bristol was below these national norms.[25] Mr Wisheart's evidence was that out of 74 open-heart operations on children under 1 in the period 1984 to 1987, 20 patients died, and that if the national mortality figures for the year 1984 to 1985 were extrapolated to the Bristol case mix in the period 1984 to 1987, then one would have expected to see 19.24 deaths.[26] Exchanges between Counsel to the Inquiry and Mr Wisheart on this point were as follows:

> 'Q. The overall conclusion then that you drew from this was that the difference in overall figures in Bristol compared to the UK was because Bristol was doing a higher number within the period 1984 to 1987 of those cases which carried the higher risk of mortality.
>
> 'A. Yes.
>
> 'Q. And if one allowed for that in the way that you have done here, the results were so close as to be almost indistinguishable?
>
> 'A. Yes. I am not sure that "allow" is the right word because it suggests a concession, and I do not think it is a concession; I think it is a statement of reality, if I may.'[27]

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23 T92 p. 69–73 Mr Wisheart

24 UBHT 0167 0032. (These figures are 1988 figures. Thus, they may have retrospective value. They were not available, nor were other such figures, at the time of the visit by the Welsh Office.)

25 See Chapter 3 for an explanation of these clinical terms

26 T92 p. 82 Mr Wisheart

27 T92 p. 83–4 Mr Wisheart

Report of the performance of the PCS Service in 1986

20 The Unit forwarded to the UK Cardiac Surgical Register (UKCSR) the data that was available from the Unit itself. The Unit's return to the UKCSR for 1986 showed the following data for open-heart surgery:[28]

Operations – Over-1s	Operations – Under-1s
89 (10)	24 (6)

21 Of the under-1s, there was only one child operated on for 'complete a-v canal (corrective procedure)': that child died. Only two were operated on for 'truncus arteriosus (corrective procedure)', both of whom died. There was one operation for 'TGA with VSD (corrective procedure)'; the child died.

22 The outcomes for the UK as a whole, as recorded in the 1986 Annual Report on the UKCSR, showed the following mortality rate for 1985:[29]

Over-1s	Under-1s
7.2%	21.7%

[28] Figures taken from UBHT 0055 0162 – 0164; Unit return to the UK Cardiac Surgical Register; figures in parentheses are for deaths
[29] Figures taken from UBHT 0055 0269; UK Cardiac Surgical Register, 1986