

decided to hold meetings at BCH specifically for the paediatric cases. This change took place in about 1983 or 1984, well before the catheterisation laboratory opened in BCH in 1987.

a. Throughout the 1980s and early 1990s, the emphasis in our self-organised review process was on the outcome of individual cases. Discussions were mainly about those patients who did not survive or had serious complications, including closed-heart cases at the BCH and open-heart cases at the BRI. The review of these patients took place at the beginning of the regular twice-weekly working meetings at BCH, on Monday mornings at 8.15 am and Wednesdays at 1.00 pm. These discussions focussed mainly on clinical issues. In addition, pathology meetings were held almost on a monthly basis. These provided the opportunity for a comprehensive review of all patients who died, including in many cases a review of the clinical and investigative findings and, in all, a detailed analysis of the pathological findings. As mentioned in Issue B, this meeting was attended by one or sometimes two of the paediatric pathologists, the two paediatric cardiac surgeons, two or three paediatric cardiologists, a paediatric cardiac anaesthetist from time to time, senior nursing and technical staff on occasions, and trainee pathologists, cardiac surgeons and cardiologists, if their duties permitted.

b. Although series of cases were not formally presented and reviewed, the informal strategy meetings held by the paediatric group in the evenings about three or four times a year, often included an assessment of a particular condition that we realised was causing problems. These discussions resulted in changes in policy and management.

M 6 *The use made of national or international information, whether from journals, research findings, registers or investigations such as the Confidential Enquiry into Peri-Operative Deaths (CEPOD)*

The information gleaned from clinical and research papers in *international cardiac journals* is of the utmost importance in maintaining a grasp of advances and trends in paediatric cardiac practice, as in other fields. In terms of the results of operations in series of cases, it is widely recognised that it is the most successful results that are submitted for publication. However, this does set the optimal standard towards which any unit can strive. The task of reviewing the journals was very much left to the individual practitioner. We did discuss the possibility of running a Journal Club, but we could not identify a suitable time for yet another monthly meeting that could be attended by the whole group.

The *UK Cardiac Surgical Register (UKCSR)* was the only national reference data with which any paediatric cardiac unit could compare its results. The data were submitted voluntarily by surgeons, and could only be accessed by surgeons. It is well known that the national data has never been validated. An important drawback throughout the 1980s and early 1990s was that the cases were stratified by diagnostic groupings only and not by the type of operation (see my comments under Issue B). The Bristol figures were collated by our paediatric cardiac surgeons and regularly provided. If we asked for them, they were readily available, eg for the Annual Reports.

M 7 *The individuals to whom, or institutions to which, data or results were circulated as a result of such reviews or audits, and the purpose and regularity of such an information flow.*

These aspects have been covered in my comments on pages 26 to 29 of Issue B 9, (i) to (vii). They include information on communication with paediatricians; the distribution of the Annual Reports from 1987 - 1990 to paediatricians and the DHA, as far as I recall; and the provision of annual surgical results to the UKCSR.

When Bristol commenced as a supra-regional centre in 1984, I was concerned that the data acquisition in the Children's Hospital should be improved. Although Dr Jordan maintained the South West Congenital Heart Register, this was mainly epidemiologic, and I found it difficult to acquire the demographic data and throughput information in the Children's Hospital. The Patient Administration System was simply not sensitive enough to capture data about cardiac catheterisation or closed heart surgery. The MDI system was recommended by the South West Region but, after months of negotiation with the SWRHA Information Technology advisors, it became evident that this system would not fulfil our needs. Therefore, I arranged that my secretary kept a hand-written list of every admission to BCH, including place of origin, whether catheterised or receiving closed-heart surgery, length of stay and outcome (Appendix M I).

Partly in response to the report of the Children's Heart Circle in Wales in June 1987, I decided to collate and write an Annual Report for 1987 (see Appendix B 11). The surgical results were obtained from the paediatric cardiac surgeons. Table 3 in Appendix B 11 presents the figures as total number of closed or open heart operations in patients over and under one year of age between 1984 and

1987, with their percentage mortality rates.

The 1988 Annual Report was prepared in similar fashion (Appendix B 12). In Table 4, the surgical results were presented as in the 1987 report, with the figures for 1988 compared with those for the period 1984 to 1987.

The 1989-90 Annual Report followed the same format (Appendix B 13). The results for the calendar year 1989 and the period 1984 to 1988 are provided. For the first time, the most recently published UKCSR results (1988) were included for comparison.

Unfortunately, no further Annual Reports were prepared simply because, having taken on the duties of the first Clinical Director of all Children's services, I was unable to devote any time for this purpose. The other clinicians in our group were also too overloaded to compile the report.

However, Dr Martin took on the task of devising a regular monthly programme of audit meetings from about January 1992, specifically for cardiology. These were held at BCH and were entirely open. The format was for each consultant in the group to select a subject to discuss. These included one by Mr Wisheart on 25th March 1992, titled "Paediatric cardiac surgery mortality for 1991 plus a comparison with the previous year". Mr Dhasmana presented "Results of arterial switch operations" on 3rd June 1992. Regular meetings in that format did not continue after 1992.

M 8 *The constraints (if any) placed by confidentiality and/or the assurance of anonymity upon the use of audit data.*

I believe strongly in the primacy of confidentiality between the doctor and his patients and their families. It is a bedrock upon which the relationship between these parties depends. For instance, only by disclosing all relevant information with confidence is the patient likely to have the benefit of appropriate treatment.

In terms of the revelation of results, the UKCSR came into being in the late 1970s only on the basis that, firstly, the units supplying data would not be identifiable. Each unit could measure its own results against the national average, but even the spread of results was not publicised, so that no unit could determine its own position in the scale. Secondly, the overall results of the units were requested and provided: no surgeon was personally identified. I believe these conditions are still in place today, but will inevitably change in the light of current demands. I also believe that knowledge of our position in a league table, with respect to specific conditions, could have promoted a speedier response by the DHA/Trust or Region.

By the same token, our surgeons conveyed their results to the paediatric cardiologists as unit figures, although I believe that we would have had free access to each surgeon's results had we requested them. I believe this approach would have been followed in many paediatric cardiac units in the

country during the period under review.

M 9 *The advantages and disadvantages of the attitudes prevailing, at the time, to the use of audit data.*

Audit processes which are open, based on clearly defined criteria and are rigorously applied, have undoubted benefits, whether national or within units. However, there was a great deal of anxiety among doctors during the period under review because of the difficulty in ensuring that case mix and risk stratification would be sensitive enough to permit valid appraisal and comparison of units. These concerns persist up to the present time, especially in areas like paediatric cardiology, where there are relatively few patients in each diagnostic category, and significant variations even within each category. Indeed, classification into the appropriate diagnostic group could prove very difficult.

M 10 *How well the systems of review and audit were maintained, and how they functioned in practice.*

In connection with individual cases, I believe the review process following a mortality was thorough, deliberate and extremely helpful. The discussions at the regular two-weekly working meetings and, especially, at the monthly clinico-pathological sessions, led to altered strategies of management and changes in surgical technique.

M 11 *Whether (a) the structures set up; and (b) the manner in which they were, in practice, operated and run, met the professional and contractual standards and obligations imposed on the clinicians and upon the BRI, at the relevant time.*

During the period 1984 to 1995, I do not believe there were any standards or obligations imposed on clinicians in paediatric cardiology regarding audit or review, either by the DHA/Trust, the SWRHA, the Royal Colleges or the GMC. The only requirement was to provide the Supra-regional Services Committee with annual workload data between 1984 and 1992.

M 12 *The success or otherwise of the systems of audit and review in place at the time, in:*

- (a) improving the quality of care or services;*
- (b) detecting any areas or respects in which the services provided fell short of that which was acceptable, and devising and implementing solutions.*

(a) The efficacy of the informal strategy meetings and the clinico-pathological discussions in adopting new policies and modifying surgical techniques has been mentioned above.

(b) With respect to the surgical outcomes for open-heart surgery, apart from what we discerned from our sporadic visits to the BRI, the paediatric cardiologists depended largely on the reports from the surgeons at the clinico-pathological, informal evening and regular bi-weekly meetings as to the progress of individual patients, serious complications and deaths. The

annual data were presented fully, both for ourselves and the Supra-regional Services Advisory Group, but were not surgeon-specific, in common with practice throughout the country during this period. In addition, the emphasis

in our audit reviews was on the work of the year, and related to conditions which were causing problems at the time. Therefore, the process did not permit the assessment of the individual surgeon's performance, except for the arterial switch operation in neonates, which was performed by one surgeon as a matter of policy. Nor was it readily appreciated what the trends were over a sequence of years for each surgeon. Although it was possible to gain an impression of an individual surgeon's results in a particular condition from all the avenues mentioned above, a specific cardiologist's perception did depend on the number and outcome of patients of a particular diagnostic group that he/she referred to each surgeon.

For instance, with respect to complete AVSDs during 1990 to 1995, the mortality rate for the unit fluctuated year by year. Taking into account the fact that operations for this condition were up to three months apart at times, with a variety of other operations being performed in the interim, it was my perception that the number of deaths per annum for each surgeon was roughly the same. These were the cases that we reviewed comprehensively, but individually. Clearly, the difference in mortality rates between the two surgeons related to the different numbers operated upon by each surgeon, but the patients with successful outcomes were hardly ever mentioned.

Furthermore, my own perception of the outcomes for correction of complete AVSDs was influenced by what transpired with patients that I myself had referred.

In fact, only 1 out of 15 patients succumbed. Also, that case was the only death among the 4 that I referred to Mr Wisheart. Therefore, without a regular, retrospective, surgeon-specific and cumulative review of each diagnostic category, the full picture of our experience cannot be appreciated.

D H S Joffe**ISSUE N. The expression of Concerns****Parents**

- N 1** *The parents' perceptions, both positive and negative, of the treatment and care received by their children, including:*
- a. The nature and form of any concerns that may have been expressed;*
 - b. the persons to whom they were conveyed; and*
 - c. the responses to any such concerns.*

I was not notified of any concerns expressed by parents about paediatric cardiology at the BCH, and I did not receive any myself. Nor was I aware of major complaints from parents about the treatment at BRI, other than that the department could have been more child-friendly, as it was at the Children's Hospital. This includes the responses of families whose children had died. Of course, parents' perceptions changed dramatically after the media publicity of April 1995.

On the other hand, up to 1995, I had frequently heard very complimentary comments about the skill, concern and dedication of both Mr Wisheart and Mr Dhasmana, from the parents of their patients.

Dr Bolsin

- N 2** *The concerns expressed about the quality or adequacy of paediatric cardiac surgical services by Dr Stephen Bolsin; the nature of those concerns; to whom they were expressed, and when.*

Dr Bolsin did not express his concerns about the quality or adequacy of paediatric cardiac surgical services to me personally - either verbally, telephonically or by letter - at any stage during his employment as consultant anaesthetist at UBHT between 1988 and 1996.

I recall that Dr Bolsin attended two or three evening meetings of the cardiac group during these years; I do not know the exact dates.

N 3 *The nature, scope and methodology of the “confidential audit” carried out by Dr Bolsin (with the assistance of others such as Dr Black), eg: the procedures examined; the data used, and the reason why such sources were selected; the dates when the results were compiled, and by whom; the persons who were or were not informed that the data was being collected, and why, to whom, and by what means, and when, the results were made available; and the merits of the methods adopted.*

I have no first hand knowledge of the methodology used by Dr Bolsin in his “confidential audit”, or the sources of his data.

Dr Bolsin did not provide me with any data about patient outcomes following open-heart surgery at the BRI during his period of employment by UBHT, from 1988 to 1996.

I learnt of the existence of Dr Bolsin’s “confidential audit” for the first time after my return from abroad in late February 1995. The results had been presented to Mr M de Leval and Dr S Hunter during their visit to Bristol on 10th February 1995. I heard later that the audit covered the period October 1990 to July 1992.

The first time I heard figures from Dr Bolsin’s “confidential audit”, including mortality rates for small groups of children with specific heart conditions, was via television programmes and newspaper articles in April 1995. I had heard of tensions in the cardiac unit at BRI during 1994, mainly between the anaesthetists and surgeons, but had no knowledge of the details.

It appears that his information was not only kept from the surgeons, whose patients and operations were put under scrutiny, but also from the paediatric cardiologists, who were intrinsically involved in referring these patients for surgery. Why did Dr Bolsin not come to us to seek assistance for his audit? He had many formal opportunities to raise these matters with the paediatric cardiology group, ie at the twice-weekly patient review meetings and the monthly clinico-pathological meetings at BCH, as well as the evening strategy meetings mentioned above.

For myself, if Dr Bolsin had raised his concerns and discussed his findings with me, I am sure I would have taken him very seriously indeed. I would have reviewed these issues with my immediate colleagues, and we would have responded openly and positively. In reality, the climate is different today, with more openness and frankness between medical colleagues and between doctors and their patients.

N 4 *The response to any expression of concern made by Dr Bolsin (whether as a result of the audit data collected, or at any other time), from:*

- a. colleagues (whether anaesthetists, cardiologists, cardiac surgeons, nurses or others;***
- b. the hospital or Trust management (or shadow management, prior to April 1995);***
- c. The Department of Health;***
- d. any others made aware of Dr Bolsin's views.***

a. I had no personal knowledge of any such response, since I was not directly appraised of his concerns at any stage.

b, c, and d. I had no personal knowledge of any such responses.

N 5 *Whether such responses (or lack of them) was adequate and appropriate; and, if not, the nature and importance of any inadequacies or deficiencies.*

I was unable to respond, either adequately or inadequately, since I had no knowledge at the time of these concerns.

N 6 *If the response was inadequate or inappropriate, the reasons for these inadequacies or deficiencies.*

Not applicable.

Other hospital staff

N 7 *Whether other personnel employed within, or associated with, the BRI expressed concerns upon the performance of the paediatric cardiac surgery unit; and if so, to whom; as a result of what event or events; in what terms; and when.*

I am unaware of expressions of concern from any other personnel in UBHT, about the performance of the paediatric cardiac surgery unit, except for Professor Angelini. He met me in the corridor of the BRI surgical unit one day, I believe in the Spring of 1993, and invited me into his office for a chat. He mentioned his concern about the arterial switch operation. I believe I replied that the results for *non-neonatal* switches at the time were acceptable; that we were concerned about the *neonatal* switches; but that we expected this situation to improve. I would have indicated that we commenced the neonatal arterial switch programme two or three years later than other units because we were reluctant to stop the Senning operation, for which our results were very good. Since the numbers were very small, we had to regard each patient on a case-specific basis. Professor Angelini suggested that he would consider undertaking some paediatric cardiac surgery himself, since he had worked with Professor Quaegegebur in the past. Our discussion lasted about 20 minutes and was amicable throughout.

- N 8** *The response to any concern expressed by any staff employed within, or associated with, the BRI, from:*
- a.** *colleagues;*
 - b.** *the Regional or District Health Authorities;*
 - c.** *the hospital or Trust management;*
 - d.** *the Department of Health;*
 - e.** *professional or statutory bodies (eg the Royal Colleges); to the extent that any of these bodies were contacted or approached.*

I cannot comment on responses, since I was unaware of concerns being expressed at the time.

- N 9** *Whether such responses (or the lack of them) were adequate and appropriate; and, if not, the nature and importance of any inadequacies or deficiencies.*

I was unaware of such responses.

- N 10** *If the responses were inadequate or inappropriate, the reasons for these inadequacies or faults.*

I was unaware of any responses.

The Trust Management

- N 11** *The nature of the concerns about paediatric cardiac surgery at the BRI (if any) relayed to:*
- a.** *the Hospital Audit Committee;*
 - b.** *the Hospital Medical Committee;*
 - c.** *the Chief Executive of the Trust;*
 - d.** *the Trust Board.*

I was unaware of concerns being relayed to any of these committees or individuals.

N 12 *The other sources of information to which these bodies had access (eg, audit data, newspaper or magazine articles), that might reasonably have suggested cause for either concern about, or investigation of, paediatric cardiac surgical services.*

I do not know of any of the possible sources of information mentioned that might have suggested cause for concern about paediatric cardiac surgical services.

N 13 *The extent to which these potential sources of information were in fact considered.*

This issue was not raised with me.

N 14 *How (if at all) the bodies described as 11 (a) - (d) reacted to any concerns expressed to them.*

This issue was not raised with me.

N 15 *Whether such responses (or the lack of them) were appropriate.*

Not applicable.

N 16 *The formal or informal managerial, disciplinary, or regulatory structures existing within the BRI, through which issues of the adequacy of paediatric cardiac surgical services, and/or issues of professional inadequacies or incompetence could have been raised or addressed; and the strengths and weaknesses of these systems.*

I was aware of the existence of disciplinary and regulatory structures within the BCH and BRI prior to the change to Trust status in 1992, but I was not aware of the detail since this was not part of my remit.

N 17 *Whether any of these mechanisms or structures were invoked; and, if not, why not.*

Not applicable.

N 18 *Whether any of these mechanisms or structures should have been invoked.*

Not applicable.

The Department of Health and others

N 19 *The concerns about paediatric cardiac surgery at the BRI (if any) relayed to the DOH and the Supra-Regional Services Advisory Group; the nature of those concerns, and the dates at which they were expressed.*

I have no first hand knowledge about concerns relayed to the DOH or Supra-Regional Services Advisory Group (SRSAG).

N 20 *The other sources of information to which these bodies had access (eg contractual performance data, newspaper or magazine articles, DOH statistical data), that might reasonably have suggested cause for either concern about, or investigation of, paediatric cardiac surgical services.*

I have no knowledge as to the sources of information to which the DOH or SRSAG had access.

N 21 *The reaction of the DOH and/or the Supra-Regional Services Advisory Group to any such expression of concern; and whether it was adequate or appropriate.*

I have no first hand information about the reaction of the DOH or SRSAG.

N 22 *The existence of any suggestion, prior to the decision to de-designate all centres in April 1994, that the BRI's neonatal and infant cardiac surgical services should be de-designated because of concerns that the centre no longer met the criteria for designation; and, if so, the grounds for consideration of such de-designation.*

I had no knowledge of the existence of any suggestion that the BRI's neonatal and infant cardiac surgical services should be de-designated.

N 23 *Whether in 1984 - 1995 the district or regional health authorities were, or should have been concerned, about the performance of the paediatric cardiac surgical unit at the BRI, as a result of the information held by such bodies and/or their powers and responsibilities.*

I do not know if the district or regional health authorities were aware of any concerns about the performance of the paediatric cardiac surgical unit at the BRI during 1984 - 1995.

N 24 *Whether in 1984 - 1985, health care professionals in other hospitals or healthcare organisations had expressed concerns about the paediatric cardiac service at the BRI; and, if so, to whom had such concerns been expressed and with what results (if any).*

I do not know if healthcare professionals in other hospitals or healthcare organisations had expressed concerns about the paediatric cardiac services at the BRI during the period 1984 - 1995. Nobody expressed any misgivings to me.

All the consultant paediatricians with whom I came into frequent contact during these years, ie. at Torbay, Exeter, Barnstaple, Bath, Abergavenny, Bridgend, Swansea and Neath, were very supportive and apparently quite satisfied with the services of the paediatric cardiac unit in Bristol.

N 25 *Whether in 1984 - 1995 other professional associations (such as the Royal Colleges) or statutory bodies, were, or should have been concerned, about the performance of the paediatric cardiac surgical unit at the BRI, as a result of the information held by such bodies and/or their powers and responsibilities.*

I did not know whether professional associations or statutory bodies had concerns, or held information, about the performance of the paediatric cardiac surgical unit at the BRI during the period 1984 - 1995.