

THE BRI INQUIRY INTO PAEDIATRIC CARDIAC SERVICES IN BRISTOL 1984 - 1995

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Background

This statement is submitted in addition to one relating to the Issues B and H. I am a Consultant Anaesthetist appointed in January 1989 with an interest in cardiac anaesthesia. I was the Lead Cardiac Anaesthetist and became Clinical Director of Anaesthesia from January 1993 to December 1995 inclusive. I am currently the Associate Medical Director for Strategic Planning for the Trust.

The statement is detailed from memory and supporting documentation; venues and dates are included when they can be accurately confirmed. The Department of Anaesthesia diaries would have been useful in completing this task but they were destroyed annually as part of the normal course.

ISSUE N. THE EXPRESSION OF CONCERNS**N1 The parents' perceptions, both positive and negative, of the treatment and care received**

1. My contact as an anaesthetist with the patients and parents was for the pre-operative assessment, the anaesthetic and afterwards in the intensive care. Pre-operatively my aims would be to assess the patient, to explain the anaesthetic procedures and its attendant risks, any risks associated with co-morbidities such as diabetes and then to explain the processes of anaesthesia and intensive care. In the ITU setting I would explain the progress of the child and why, if necessary, further interventions were required. No specific concerns were raised regarding the Unit's performance.

N2 The concerns expressed about the quality or adequacy of paediatric cardiac surgical services by Dr Stephen Bolsin

2. Dr Bolsin and I discussed his concerns about the overall quality of the paediatric cardiac surgery (P.C.S.) before he performed his audit. These informal discussions occurred in the theatres, anaesthetic department, at the cardiac anaesthetic meetings and even before

my appointment as a Consultant. At that time my impression was, based on speaking with other anaesthetists from other centres, that the P.C.S. outcome did not compare favourably with other centres listed in the Cardiac Surgical Register. Attending the joint paediatric meetings of cardiologists, cardiac surgeons and anaesthetists, at which the annual mortality figures of the Unit were considered, also helped to form this impression. My opinion was that the outcomes for the unit were acceptable overall but needed to improve and that the appointment of a new surgeon plus the unification of the P.C.S. at the Bristol Children's Hospital steps should happen to achieve the necessary improvement.

3. I became aware of the Steve Bolsin / Andy Black audit (SB/AB) in September 1993 through discussions with Professor Angelini and the perfusionists, Mr Nicholson and Mr Lawrence. From these conversations I believed that SB/AB had prepared an audit that was not the subject of common knowledge and specifically the surgeons. After a number of personal requests, SB brought his data to me in the Department of Anaesthesia, I believe in October 1993. The data was initially presented as a list of paediatric operations, then as a series of associated CHI Square tables to analyse outcome. The initial concern raised was on the outcomes from the switch operation, the closure of VSDs and the treatment of the Tetralogy of Fallot. Over the following months I saw further revisions (3) of the data and I later received a copy from SB having unsuccessfully tried to obtain a copy from Professor Angelini. It was later before the outcome from the AVSD operations was raised as a concern because of the high mortality for the operations performed by JDW.
4. The format of the SB/AB audit by operation and individual surgeon contrasted to the annual figures produced previously by the surgeons, as this data was presented as anatomical diagnoses and unit figures. On receiving a personal copy of the SB/AB audit I found the interpretation difficult, I therefore spoke to AB in his office to clarify the statistical analysis. I believed that it was appropriate for the data to be verified and the interpretation clarified plus, to reverse the clandestine nature of the audit, it had to be presented by SB to the cardiac anaesthetists and the surgeons. I concluded from the audit, assuming the accuracy of the data, that the P.C.S. outcomes required improvement but, in

my opinion, any data errors would have to be gross to nullify all concerns. I urged SB to verify his data and to present it to his colleagues.

N3 The nature, scope and methodology of the confidential audit

5. SB did not discuss the audit methodology used in detail with me. It is my understanding now, following conversations with other colleagues, that using the operation and perfusion records, the relevant patient notes were obtained and the data trawled from these records. I am not aware of the reasons for the choice of epoch, the people involved in data collection, the classification of operations or how the data was verified.

N4 The response to any expression of concern made by Dr Bolsin

N5 Whether such responses was adequate and appropriate

N6 The reason for inadequacy of response

N7 Whether other personnel employed within expressed concerns

6. In considering my response to the four sections N4 - N7 I wish to answer them together. To attempt some clarity my comments will be divided into the following sections: Dr Bolsin; Consultant Anaesthetists; Anaesthetic Board; Mr Wisheart; Mr Dhasmana; Dr Roylance and Professional Colleagues and Managers.

N4 - N7

Dr Bolsin

7. The audit as presented to me (autumn, 1993) suggested that my previously formed impression was correct that the paediatric cardiac outcomes did not compare well to the UK average in some operations. The audit was not verified and could not clarify whether the performance of the Unit needed improvement but was adequate and acceptable, or

whether the performance was unacceptable. My role as Clinical Director of Anaesthesia was to bring together as much relevant data as possible, to act as a facilitator to bring the two sides together and achieve a uniformity of agreed data and to find a solution that enabled an improvement in the P.C.S.

At that time I believed that the following action necessary and acted accordingly.

8. In discussions over the following weeks with anaesthetic colleagues I understood that they were aware of the audit. At informal meetings and at the cardiac anaesthetic meetings, held at home, the accuracy of the data was criticised. I asked Dr Bolsin to confirm the data and also to present it to his anaesthetic colleagues. Despite my requests this was not done.
9. Over a period of time I was aware that the clandestine nature of the audit caused offence and undermined its credibility through conversations with surgeons, anaesthetists and colleagues across the Trust. To help SB progress his concerns I urged SB on a number of occasions to present the audit to the consultant cardiac anaesthetists, the aim being to make the audit more open. This did not occur even at the meeting (7th Feb '95) arranged at Dr Underwood's home, this was immediately prior to the visit of Mr De Leval and Dr Hunter. The lack of debate regarding the audit and the failure to achieve an agreed stance amongst the cardiac anaesthetists impaired my ability to raise the concerns over the P.C.S. outcomes.
10. Following informal discussions with anaesthetic colleagues, GA and Mr A. Bryan concerning the differences in opinion on the P.C.S. data, I helped to organise a joint meeting of cardiologists, surgeons and anaesthetists in the University Department of Cardiac Surgery (March '94). My objective was for both the surgical data and the SB/AB audit to be presented. At the meeting there was no effective chair, the main data presented was by JDW on a blackboard, plus, from Dr Pryn some of the most recent data available on 1993 operations. The data was collated by Dr Pryn followed my request but was not effective due to differences in classification and not being for the hospital year (April - March). The meeting resolved little as there was not a frank discussion on

outcome, and I believe it did more to consolidate difficulties and differences than start a process to address the problems.

11. In an attempt to depersonalise the continued differences in opinion over the P.C.S. outcomes I spoke individually with JDW, SB, and Professor G. Angelini (GA), I chose these colleagues because it was JDW under criticism, SB had performed the audit and GA supported both SB and the need for change. I spoke with each to explain that the aim was for an informal discussion on the different opinions and that I had arranged a meal at a restaurant (13.4.94) to obtain a non-confrontational atmosphere. Although I directly asked the question whether there were any concerns regarding P.C.S. neither SB nor GA replied. In conversation shortly after with JDW I formed the impression from him that if the concerns were not worthy of discussion at the meal then the concerns could not be major.
12. Dr Bolsin and I discussed our concerns regarding the outcomes of the neonatal switch programme informally in the operating theatres and department. In concert with Drs Pryn and Davies we withdrew our support from the programme in late spring, 1994. At that time I recall that no switch operations had been performed since Aug, '93, I presume that we believed the neonatal programme was to restart. In addition I helped to edit a letter drafted by SB, (June, 94), it was subsequently signed by the six cardiac anaesthetists. This letter expressed our concerns over the arterial switch programme and requested a confidential, formal review. Initially, my signature was included but in a revised version it was deleted and the letter addressed to me. This enabled me to take the letter to the Chief Executive without the appearance of a personal bias, notwithstanding my accord with its content. This letter was subsequently taken to the Chief Executive and is discussed later in my statement.
13. The clandestine method of collection, the restricted release of the data and the failure to present formally the audit to the cardiac anaesthetists or either of the surgeons detracted from the message. Other reservations were expressed by cardiac anaesthetists in informal meetings regarding the small numbers within the audit, the lack of a comparative, accurate national database plus the data previously published by the surgeons conflicted with the numbers within the SB/AB audit. These reservations over the audit made it

difficult to debate the issues and inhibited the process of accepting that action was necessary, and that, within the P.C.S., the numbers of operations and mortality should be more formally discussed. These reservations made any resolutions difficult to achieve and also slowed the implementation of any solution. In my time as the Clinical Director I was able to achieve the appointment of four additional adult cardiac anaesthetists with five sessions for consultant Intensivists in the Adult Cardiac ITU. Additionally I helped achieve the unification of the P.C.S. at the BCH, the appointment of a new surgeon and the appointment of two paediatric cardiac/intensive care anaesthetists.

Cardiac Anaesthetists

14. The concerns raised by the SB/AB audit were discussed amongst the cardiac anaesthetists who already had general concerns over outcome and had looked to improve practice. Meetings were arranged to consider the audit and come to a joint viewpoint, but a presentation by SB did not occur. As documented, a letter from the cardiac anaesthetists requesting a formal review was taken to Dr Roylance. To extend the audit and to try to address any inaccuracies Drs Masey, Pryn and Underwood performed further searches of records; this data was available at the meeting concerning Joshua Loveday.
15. The high mortality of the switch operation concerned all the anaesthetists. I discussed this matter with JDW, I believe in late '92 or early '93, suggesting a visit to Birmingham of a team consisting of Mr Dhasmana, cardiac anaesthetists and paediatric cardiologists. With JDW's support I approached Mr Dhasmana (JD) whom readily accepted the suggestion, particularly because it addressed the whole team and he had already been in contact with Birmingham. He arranged two visits to Birmingham accompanied by Dr Masey and Dr Underwood. The aim of including anaesthetists was to look at all the aspects of care at the Birmingham unit and change our practice as relevant. It is my recollection that three subsequent switch operations were undertaken without problem but JD did not have a visiting surgeon from Birmingham to assist him. The death of the child undergoing the fourth operation led to the suspension of the programme. If there was a meeting to discuss this I did not attend nor am I aware who made the decision to stop.

16. The visit of Dr Masey and Dr Underwood to Birmingham underlined a policy adopted to concentrate the paediatric work on three consultants, the third being Dr Pryn. With the appointment of Mr Pawade these three anaesthetists flew to Melbourne (February '95) to experience the working practices at their Children's Hospital. This enabled the cardiac unit to adapt as necessary and facilitated the start of Mr Pawade's work (May '95). With the same anaesthetic staff, nurses and intensive care organisation, the arrival of Mr Pawade produced a step improvement in P.C.S. outcome.

Anaesthetic Board

17. The Anaesthetic Department has over 50 consultants and junior staff with a responsibility to provide anaesthesia, intensive care and chronic pain therapy on seven different hospital sites. As Clinical Director I received support and advice from an anaesthetic Board consisting of lead clinicians representing each clinical area. Throughout the period considered by the Inquiry I discussed the issue of the P.C.S. performance with these colleagues to gain a perspective from outside the cardiac unit. In particular, a meeting was called at my home to advise how to act following the press exposure of the De Leval/Hunter report. At this meeting, (May 10th 1995), the consensus advice was to: continue to promote the unification of the P.C.S. service at the Bristol Children's Hospital; to provide anaesthesia for paediatric cases considered low risk and to obtain an acceptance by the paediatric surgeons and the senior management of the validity of the concerns raised by the SB/AB audit.

Mr Wisheart

18. I spoke concerning the P.C.S. on a number of occasions with James Wisheart over the period of Nov 93 - 1995 inclusive, they occurred usually in his office or in Trust Headquarters. Many factors were inhibiting the resolution of the P.C.S. affair, e.g. the differing opinions on the paediatric performance; the clandestine nature of the SB/AB audit; the format of the cardiac surgical register data and differing mortality figures. My aim was to obtain a constructive dialogue between all the consultants, (surgeons, cardiologists and anaesthetists), involved in the P.C.S. Unit and attempted to achieve this by private conversation and in organising meetings.

19. In these private discussions JDW ('93-'95) agreed on the need for a wide-ranging review and resolution of the differences of opinion and criticisms arising from the SB/AB audit and against the background of concerns. He agreed to produce his own data, discussed the need to improve the P.C.S., the need for a new surgeon and his role as a P.C.S. surgeon. JDW accepted that he would cease to operate on children but not until another surgeon had arrived, otherwise JD would be unsupported in providing the P.C.S. That the data was not produced in a timely manner may be due to the considerable time required to fully audit the paediatric work when his Trust responsibilities were already heavy commitments on his time. We also discussed and both supported the need to centralise the paediatric surgical unit at the Children's Hospital. When the committee was formed (24.3.94) to achieve the move of the P.C.S. to the B.C.H. a core group was formed to perform the majority of the work. The core group was, at the BRI, JDW, Ms J Maher, Mr D Bodill and myself with, at the BCH, Drs Hughes, Joffe and Mr Ian Barrington.
20. During these discussions I did not offer or give JDW a copy of the SB audit. I do not know whether he had a copy, nor did he request one. My reasons for not giving him a copy were, initially, because it required validation and the cardiac anaesthetists were divided upon what action was required. Had the Cardiac Anaesthetists agreed on the audit and formed a joint opinion on an effective way forward then I would have taken the data to JDW. Latterly, I believed the unverified audit would create immense tensions between JDW and me, and also as a consequence, between the other Surgical Directorates and the Directorate of Anaesthesia and also the Directorate of Anaesthesia with the Trust Management. This would stop me being able to further the P.C.S. issues and the problems ascribed to the P.C.S. outcomes would be transferred to a difficulty with the anaesthetists as a group, an anaesthetist producing a clandestine audit and the breaking of a Professional relationship.
21. Regarding the operation on Joshua Loveday I spoke on the 11th Jan '95 with JDW in his office raising my concerns over the outcome. I believed that the unresolved issues surrounding the P.C.S. and the tensions this had produced within the individuals of the P.C.S. team would markedly impair the team's performance and the transfer of the child to another unit was preferable. After a long debate I believed that JDW agreed that it

would be inappropriate to operate on the child and that he would support Mr Dhasmana in deciding not to operate at the meeting scheduled that evening at the BCH. The meeting was attended by the three paediatric cardiologists, the paediatric surgeons and the anaesthetists with responsibilities for paediatric cardiac surgery. I made a personal note of the meeting and this is available to the Inquiry (ref. UBHT 0054001), this is my best recollection of the meeting and I refer you to it.

Mr Dhasmana

22. The criticisms regarding Mr Dhasmana were directed mainly at the switch operation. His other paediatric work being described later in the De Leval/Hunter report as low risk. Although difficult, he and I constructively discussed informally, in his office and elsewhere the issues that encompassed the whole process involved in the P.C.S., i.e. diagnosis, anaesthesia and surgery. JD remained open with his personal data but declined to publish it separately from JDW. On raising the possibility of improving the Unit's performance by visiting Birmingham, he readily accepted the idea and supported the concept of concentrating the paediatric practice upon a limited number of anaesthetists. As I fellow Clinical Director I believe that his role and responsibilities as Clinical Director were impaired because as the surgeon under criticism, he could not be objective.
23. I did not confront him with or offer him a copy of the SB/AB audit during my discussions with him, nor do I think he had a copy. This was for similar reasons as previously outlined (paragraph 25). In addition, to perform surgery, in particular cardiac surgery, the working relationship between the surgeon and the anaesthetist is of great importance; the presentation of the SB/AB audit would have compromised this relationship with him for all the anaesthetists. The resultant loss of teamwork would have impaired concentration, communication and decision making during an operation, thereby risking an increase in mortality or morbidity for operations other than the switch.
24. I had specific concerns over the Joshua Loveday operation. Regarding the operation on Joshua Loveday I spoke with JD in his office, (11th Jan '95), to raise my concerns over the possible outcomes (c.f. paragraph 21). This was after meeting with JDW and preceding the one at the BCH. I spoke with JD at some length to persuade him that he

should not agree to operate. He appeared to accept my viewpoint, but was concerned that he might be persuaded to operate.

John Roylance

25. The managerial style of John Roylance was to empower the clinicians to solve problems arising within the directorates. However, the Clinical Directors had little real power or authority over their fellow consultants. JR believed in personal contact and I found him easy to approach provided he had the opportunity to discuss the problems affecting the Directorate of Anaesthesia, e.g. funding for general ITU, the move of orthopaedic surgery to Southmead or the anaesthetic budgetary overspend. This style of debate, support and decision taking at the Directorate level was helpful in addressing the anaesthetic problems. However, the difficulties experienced in trying to resolve the conflict over the P.C.S. performance were increased by the flat management structure of the Trust.

26. In forwarding the concerns over the P.C.S. I spoke with Dr Roylance on an individual basis (at least on 1.7., 12.7., 21.11., 1994, 11.1.95), and in the company of Professor Angelini (3.3.94), and with Professor J Vann-Jones in the presence of Mr McKinley (22.11.94). I informed JR that there was a problem in the P.C.S. regarding outcomes and that I was unable to solve it as the Clinical Director of Anaesthesia. His response remained unchanging in his assertion that he was the Chief Executive and therefore a manager, that the difficulty lay within clinical practice and therefore it was for the clinicians and clinical directors to solve. He did not accept that the flat management structure of the Trust had failed because it was the Medical Director and the Clinical Director of Cardiac Surgery being criticised. He did not accept the role as a final arbitrator and continued to refer the problem back to the clinicians.

27. The letter addressed to me from the six cardiac anaesthetists requesting a review of the switch programme was originally addressed to JR. After discussion amongst the cardiac anaesthetists my name was removed and the addressee changed to allow me to speak to JR as the Clinical Director of Anaesthesia. I am unable to confirm the date that I spoke with JR in his office. In spite of discussing the letter's content, the reason for requesting an audit and my concerns JR again used the logic that, if there was a problem it was in the

clinical area and it was the clinicians' responsibility to address. He declined to organise a formal audit, did not accept the existence of a problem and refused a copy of the letter as it was addressed to me and did not require his action. I did not subsequently take the letter to JDW but assumed that JR would speak to the Medical Director regarding the content of the letter.

28. When SB came to my office and brought to my attention the monthly operation list that scheduled Joshua Loveday's operation, we discussed the inadvisability of the operation proceeding. I spoke with JR in his office, I believe some days before the clinical meeting (11.01.95), expressing my belief that the operation should not proceed (c.f. paragraph 23 +26). I thought that JR was persuaded of this view but again he indicated it was a clinical responsibility and it would be for the Medical Director to decide, with the Clinicians involved, whether to proceed or not. I subsequently spoke with both JDW and JD.
29. Over the period of time in question my impression of JR's attitude was that the main difficulty was not with the performance of the P.C.S. but that a member of the Anaesthetic Department had performed a clandestine audit, communicated outside of the Trust and had broken a professional relationship. On many occasions following the early press coverage in 1995, it was necessary for me to defend SB. I was told, by JR and JDW, in JR's office that JDW and JD had received legal advice that they should not work with SB on planned paediatric cases. I gained the impression that if this should occur the legal implications would necessitate the cancellation of the case and/or the removal of the anaesthetist concerned. To avoid this conflict between SB and the cardiac surgeons I had to adjust his clinical programme to avoid the threat of suspension, (correspondence April + May'95). At another time, after the press publicity, JR with JDW raised the suggestion of dismissing SB. I argued that this would be an inappropriate action and bore no relation to the problems within the paediatric cardiac service. SB continued to work as a cardiac anaesthetist until he emigrated. In an attempt to underline the effect that the continued publicity was having on his own future I arranged a meeting (25th April '95) to discuss this with him in the presence of Professor Prys-Roberts and Dr Thomas. I asked my two colleagues to attend as they had both supported SB in raising the issue of the P.C.S. At this meeting I attempted to make SB aware of the feelings held in the Trust HQ and of the progress made in achieving changes in the P.C.S.

Professional Colleagues and Managers

30. **Professor Angelini** - Our numerous conversations concerned the topics of paediatric outcome, the need for an internal and then external review, involvement of the Department of Health, the appointment of a new surgeon and the creation of a single site paediatric cardiac unit at the Children's Hospital. Specific meetings to discuss the implications of the SB/AB audit were: The SB/AB audit - Autumn 1993; The outcome of the meeting between JDW, Professor Farndon and GA - January 1994; To speak with JR re P.C.S. - March 1994; The visit of Mr Durie to GA then CRM to discuss P.C.S. - May 1994; Discussion of Peter Doyle's letter regarding an external review - July 1994; CRM to visit Professor Farndon - November 1994.
31. We agreed that there was a problem regarding P.C.S. outcomes and were aware of the need to get the data out into an open forum, formally confirmed and presented. To solve the issues it had to be accepted within the Cardiac Directorate that there was a problem, and if necessary an internal or external inquiry may be necessary. Individually we worked towards those ends so that the Cardiac Directorate could address the issues as a whole.
32. **Professor Farndon** - I spoke with Professor Farndon in his office asking for his input with JDW to effect a review of the paediatric work (November '94). We spoke candidly on the concerns and the data. After the meeting of Professor Farndon and JDW, Professor Farndon informed that they had been quite frank and he was awaiting developments.
33. **Professor J Vann-Jones** - Professor Jones became Clinical Director of Cardiac Services when the surgical and cardiology services were incorporated into a single Directorate. He was aware of the SB/AB audit as together we discussed what was required to promote a constructive solution. Together and individually we spoke with both JR and Mr McKinley.

34. Paediatric Colleagues

In 1994 on the ward 5 ITU there were about 4 to 6 informal conversations with Dr Martin, and Dr Hayes. Dr Hayes and I modified a submission, initially penned by Ms L Salmon (Cardiac Services manager), to the Trust Management for the transfer of the paediatric service to the Children's Hospital. The changes were to include more clinical information to strengthen the arguments for the move and increase its chances of success. I think that this was submitted in February '94.

Management and Clinical Colleagues

35. Mrs Pat Fields and Ms J Maher were respectively the Managers of the Directorates of Anaesthesia and General Surgery. Although neither was managerially responsible for the P.C.S., I spoke to both of them during the normal course of business for the Anaesthetic Department to obtain differing perspectives and advice. Ms J Maher was one of the core group (c.f. paragraph 21) which developed the plans for uniting the paediatric cardiac service at the BCH.

36. In addition to the aforementioned I discussed the general issues of the P.C.S. with many other colleagues, e.g. Professor Prys-Roberts, Dr Sheila Willatts, Dr P Baskett, Dr J Zorab, Dr D Hughes. Outside of Anaesthesia I also spoke with Drs S O'Connor and J Virjee. In order to get managerial advice I also spoke with my Bath Business School Tutors and Ms Thorn.

N8 The response to any concern expressed by staff employed within the BRI**a) Colleagues**

37. As Clinical Director my responses to the P.C.S. concerns have been documented. Regarding concerns not related to the P.C.S., as Clinical Director, I would speak with the person raising the issue to gain a full understanding. If relevant, to then discuss the matter with my Manager or other involved people before informally speaking with the colleague under criticism. This informal approach was and still is advocated by the Trust, if deemed inadequate I would use a formal procedure that would ultimately involve the Medical Director, the Three Wise Men Committee or the Chief Executive. As Clinical

Director I had to deal with issues of professional under-performance, a breach of confidence and sexual harassment.

b Region or District Health Authorities

38. I did not speak with the Region or District Health Authorities.

c Hospital and Trust Management

39. My response with the Hospital and Trust Management is detailed previously.

d Department of Health

40. The only occasion I contacted the Department of Health was by a telephone conversation with Peter Doyle, 24th June 1995. This phone-call immediately followed a meeting between JR, senior managers and myself in JR's office when the role of the Department of Health arose in conversation. In my opinion, at that time, the attitude of the Trust remained internally focused characterised by a failure to audit the P.C.S. outcomes, discuss formally the problem and deny the advice of Peter Doyle. The aim of my telephone conversation with Peter Doyle was to obtain a relatively unbiased view of how the Department of Health thought the Trust should act and then relay this to JR.

41. My recollection of the views expressed by Dr Doyle is as follows. That the DoH understood the complexities of the problems within the UBHT but found it difficult to accept the Trust activities in the face of their advice to not operate on complex children. The De Laval/Hunter Audit was too hurried to be effective therefore it was preferable for a repeat audit to be performed by an external group. In addition the UBHT needed to rationalise the P.C.S. and that any hangover of the old system could impair the development of the new paediatric service. I spoke to JR in his office with a record of this conversation; I am unaware of any consequence arising from this action.

e Royal Colleges

42. I made no direct response or contact to the Royal Colleges although I spoke informally with College Members.

N9 + N10

Whether such responses were adequate or not and the reasons for these inadequacies

Audit

43. The SB/AB audit raised the questions of performance in the terms of individual surgeons and operations as opposed to the previous data that defined it in terms of the Unit's activity and anatomical abnormalities. In my view the appropriate response would have been for all concerned parties to conduct an accurate audit for a greater period, discuss the findings and decide jointly upon a constructive way forward.

44. That this did not happen may be due to many factors. The implementation of uni-disciplinary and then multi-disciplinary audit was in an early state; audit data was seen as the property of the responsible clinicians; the concept of team responsibility in audit was new and the false criticism of a colleague was in itself a serious action. The GMC regulations at that time were directed more towards poor performance from incapacity rather than the application of clinical skills.

45. The issue of whether the performance of the P.C.S. was poor but acceptable, or, unacceptable and should stop, was not addressed by the SB/AB audit. This is because there was no directly comparative national data; published papers reflect practice in leading centres and no standard had, or has been, determined against which the performance of a Unit can be measured.

Management Structure

46. The creation of Clinical Directorship produced a flat Management structure with a degree of competition between Directorships, a loss of the previous managerial structures e.g.

Divisions and the devolution of responsibility down to the Clinical Directors. This process of change was simultaneous with the concerns over the P.C.S. I believe that this was an important factor in slowing the process of resolution.

Medical Director

47. The Medical Director was the central figure being criticised and simultaneously the holder of a key position of authority within the Trust. Many of the pathways for the Clinical Directors used in dealing with problems of performance led directly to the Medical Director, therefore the process of resolution was impaired.

48. Mr Wisheart did respond to the performance of the P.C.S.: he attempted to create a Chair in Paediatric Cardiac Surgery; advocated that the P.C.S. should be unified (1990); was part of the core group that produced the financial and physical plans for the unification of the P.C.S. and agreed to stop paediatric surgery following the arrival of Mr Pawade.

The De Laval/Hunter Report

49. The appointment of a new Paediatric Cardiac Surgeon to develop further the P.C.S. was an appropriate response. Although Mr Pawade obtained excellent outcomes in the Royal Infirmary the move of the P.C.S. to the BCH was also appropriate. I have no knowledge of the issues that had impeded previous suggestions to amalgamate the open and closed work at the Children's Hospital. Two changes in Purchasing Authority policy allowed 1) paediatric intensive care to contract separately for work and 2) a step increase in adult work towards the national norm. Both helped to create a financial situation where the move of the P.C.S. was affordable. The decision to amalgamate the service represents an acknowledgement by the Trust Board of the necessity to improve the P.C.S. outcomes.

THE TRUST MANAGEMENT

N11 The nature of the concerns about paediatric cardiac surgery at the BRI

a Hospital Audit Committee

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50. I had no contact with the Hospital Audit Committee or know of any activity with regard to P.C.S. outcomes.

b Hospital Medical Committee

51. The issue of Paediatric Cardiac Surgery was not discussed at the Hospital Medical Committee until after the involvement of the Press. I recall that the matter was raised in April 1995, January 1996 and June 1996. When the matter was raised, neither the data from the SB/AB audit or detailed data from the surgeons was presented; therefore discussion was held in the absence of adequate facts. In my opinion the HMC incorrectly believed that the problem lay more with Anaesthetists auditing the P.C.S. performance than the performance itself. Detailed P.C.S. activity data was promised to the HMC but to my knowledge was not presented. The HMC body voted to support the surgeons and the Medical Director in their actions.

c The Trust Management

52. That my concerns were taken to the Chief Executive has already been detailed.

d The Trust Board

53. I did not speak to the Trust Board but I did have conversations with Mr McKinley concerning the P.C.S. outcome (12.11.94). This meeting was in the Chairman's office and attended by JR, Professor Vann-Jones, Mr Nix and myself, if I recall correctly, JDW arrived late. At that meeting Mr McKinley asked whether a problem existed or not, I stated that there was.

N12 The other sources of information to which these bodies had access

54. I am unaware of other sources of information that the Trust had access to or whether they acted upon them. The Private Eye articles were common knowledge within the Trust,

apart from poorly indicating a problem existed they created a furore concerning the leaking of confidential data to the public arena from within a limited number of clinicians and nurses. The effect of this was to develop a great reluctance for data to be published or even to be discussed in an open forum.

N13 The extent to which these potential sources of information were in fact considered

55. I have no knowledge to the extent that potential sources of information were used.

N14 How (if at all) the bodies described at 11(a) - (d) reacted to any concerns expressed to them

56. I have no knowledge of how these bodies reacted.

N15 Whether such responses (or the lack of them) were appropriate

57. I have no knowledge of whether their responses were appropriate.

N16 The formal or informal managerial, or disciplinary or regulatory structures existing within the BRI

58. As Clinical Director of Anaesthesia I accepted the managerial responsibility for the performance of the Directorate and the individuals within it. With the flat Directorate system I assumed that the other Clinical Directors responsibilities mirrored my own. The Trust's regulatory structure for maintaining professional standards was poorly documented and I believe relied on the GMC's guidance. Regarding professional performance, each individual doctor had their own responsibility to maintain accepted standards, failure to do so being a matter for the Medical Director, Three Wise Men and, ultimately, the General Medical Council.

59. Once aware of a poorly performing anaesthetist the Clinical Director should take a lead role to clarify in writing the available facts. Should it be a nurse or secretary then, in

Anaesthesia, the Directorate Manager would take the lead. If informal action was inadequate or inappropriate then formal steps would be taken and the matter referred to either the Medical Director or the Three Wise Men. The alternative pathway would be to refer the issue via the management pathway to the Chief Executive who was my immediate Line Manager.

60. The weakness of this system was poor documentation; there were few alternative pathways and the focus of the system was on failure due to physical or mental illness or substance abuse, not matters regarding clinical competence and performance. Furthermore I had no contract or job plan to determine the extent of the Clinical Director's responsibilities or to give authority over colleagues to effect change. The delegation of responsibility to the Directorate level did enable many issues to be solved without referral to higher levels of management, this was to the benefit of the Trust and patient care. However, the delegation of responsibility failed when professionals with senior positions within the Trust Management structure were under criticisms because the flat management structure gave few alternative pathways for criticism.

N17 Whether any of these mechanisms or structures were invoked

61. The Three Wise Men are in place to deal with problems of mental or physical illness or substance abuse. The Medical Director is one of the Three Wise Men and using that pathway to respond to criticism was hindered. In addition, the Three Wise Men system at that time was not equipped to deal with problems of clinical performance.

N18 Whether any of these mechanisms or structures should have been invoked

62. I am unaware of other Trust pathways that could have been involved and invoked.

DEPARTMENT OF HEALTH

N18 - N25

63. With regard to the DoH and others I have little direct knowledge of these matters. I am aware from Dr Zorab that he spoke with the Royal College of Surgeons some time after a long conversation, held in Russia, between the two of us discussing the concerns over the P.C.S.

Issue C. The service providers; nature and outcome

64. The Bristol Royal Infirmary data on the number and nature of complex paediatric procedures was presented on an annual basis by the cardiac surgeons to the national Cardiac Surgical Register. It was defined on congenital anatomical abnormalities and comparisons were made to previous years to examine whether any improvement had been made. Individual cases were considered to highlight the deficiencies and possible areas for improvement. The comparative data to understand our P.C.S. in a national context was poorly available but the Cardiac Surgical Register indicated that the performance of the Infirmary's outcomes were ranked as one of the worst within the UK. The ability to compare and contrast the data at meetings was difficult due to arguments over the accuracy of the national data, that different operations were performed for a single anatomical abnormality and that the data had no standard deviations to allow comparison.

65. National meetings specifically concerning paediatric cardiac anaesthesia were uncommon but issues were discussed at meetings of the Association of Cardiothoracic Anaesthesia. These discussions confirmed my impression that our performance could be improved but similar problems existed at other Units.

Issue d. Referrals

66. I have no comments

Issue E. Peri-operative Management of cases

E1 The arrangements and services available to manage the transfer of sick children from referring hospitals to the BRI

67. The arrangement of the transfer of children from the BCH was made between the two Cardiac Units. The choice of an Intensive Care Nurse, Ward Nurse or Anaesthetist to accompany the child during transfer was dependent upon the sickness of the child. It was not uncommon for the Cardiac Anaesthetist to go to the Children's Hospital and transport the child on the previous evening or the morning of the operation, particularly so if the child was intubated and ventilated.

E2 Where children were managed, pre-operatively; and under which clinical speciality

68. The children were managed in one of two ways for admission. If admitted from home for a planned operation they would arrive in the Nursery, Ward 5, BRI and be under the care of the surgeons. Alternatively, the children would be admitted at the Children's Hospital for further investigation or control of symptoms. In this case pre-operative management would be by the cardiologist and anaesthetists at the Children's Hospital. Peri-operatively the children were under the care of the surgeons and the anaesthetists in the Bristol Royal Infirmary. In the Intensive Care the clinical management was by co-operation between the surgeons and the anaesthetists. Occasionally the Paediatric Cardiologist would visit the Unit and give advice.

69. If on the pre-operative visit the anaesthetist believed that the child's condition could be improved by delay or improved therapy then a direct discussion between the anaesthetist and the cardiac surgeon would take place with the decision to delay or cancel taken by the surgeon.

E4 The manner in which decisions to recommend surgery for a child were discussed

70. The decision to recommend surgery was not usually influenced by the anaesthetist. The responsibility for this was a joint one between the cardiologist and the cardiac surgeon. Any specific anaesthetic risk factor or co-morbidity, e.g. renal impairment would be discussed by the anaesthetist and the cardiac surgeon. A plan of appropriate care discussed and decided upon.

E5 Who bore the ultimate responsibility of deciding whether and what surgery was appropriate for a child, who should perform it, and when it should take place.

71. The responsibility for deciding whether and what surgery was appropriate for a child was a joint decision between the cardiologist and cardiac surgeons, but ultimately the surgeon.
72. The cardiologist would refer a child to the surgeon whom they wanted to perform the operation and would decide when the operation would take place by timing the referral. For emergency cases it would depend on which surgeon was on call and whether a theatre was available. The joint cardiology, surgical and anaesthetic meetings, held on an occasional basis at a colleague's home, discussed the policies for referral, operation and timing. Therefore, all the involved clinicians worked within the recommendations arising from these meetings.

E6 The organisation and management of theatre lists

73. The organisation and management of the theatre lists was by the surgeons. The routine patients were listed for surgery on a monthly basis and a printed list circulated. Emergencies and urgent cases would result in this list being altered at short notice. The list was structured to ensure the presence of a paediatric anaesthetist for a paediatric case as the anaesthetic work rota was published in advance.
74. The arrangements for emergency cases operated on at weekends and at night were made by direct contact between the surgeon and the anaesthetist. Specific lists and intensive care beds (3 out of 8) were allocated to ensure that the resources for children were protected and that their operations could proceed. However, the shortage of nurses, sick patients occupying intensive care beds and emergency cases could result in either or both paediatric and adult cases being cancelled at short notice. Once listed and admitted a paediatric case would frequently have priority over adult cases provided that the intensive care had an adequate resource, whether the delays in surgery caused by demand exceeding supply had any effect upon the outcome of the operations is uncertain.

E8 - E14

75. No comment.

E15 Liaison of staff with parents; and the participation of parents in the assessment and care of their child

76. The practice of the anaesthetists was to pre-operatively examine the child, take a history from the parents and to assimilate the information in the clinical records. The duty of the anaesthetist was then to discuss any particular risks arising from the conduct of anaesthesia, to explain the process of anaesthesia and the management of the child in the theatre itself. In addition, the intensive care process would be discussed regarding the expected length of stay, the use of support drugs and ventilation. It was common for the parents to accompany the child down to the Anaesthetic Room in theatre, and to remain with the child until the very start of anaesthesia.

77. The use of booklets to inform the patients was not common at that time in the cardiac unit although it is commonplace now and includes the use of videos specifically produced by the Unit.

ISSUE F Management of Surgery

F1 The Qualifications of the Paediatric Cardiac Surgeons

78. No Comment.

F2 The Qualifications of the Paediatric Cardiac Anaesthetists

79. A consultant provided the majority of paediatric anaesthesia. These consultants were qualified in paediatric anaesthesia having trained in one or more institution before appointment to Bristol. All exceeded the minimum standard of the Association of Cardiothoracic Anaesthetists and the Royal College of Anaesthetists (RCA Guidance for Purchasers 1994). As the number of consultants increased it allowed the paediatric

anaesthetic work to be concentrated on three anaesthetists in order to maximise their personal experience and help maintain a high level of skill.

F3 The Qualifications of Other Members of the Surgical Team.

80. The theatre team consisted of nurses and perfusionists, all of whom were trained and skilled in their respective fields. A separate team of nurses usually provided anaesthetic support. Some nurses provide supported either to the surgeon or anaesthetist. At that time the anaesthetic support did not conform to standards set by the Royal College or the Association of Anaesthetists. These standards state that there should be a properly qualified member of staff to assist the anaesthetist in caring for the patient, the staff could either be an O.D.A. or suitable trained nurse. By the end of my time as the Clinical Director the majority of theatres met these standards and the process to create an ODA School in Bristol had been started.

F4 A Co-ordination of the Operating Team.

81. The co-ordination in theatre was determined by the progress of the operation and from an evolved working practice in theatre.

F5 The Factors Effecting Performance in Theatre.

82. The two theatres dedicated to Cardiac Surgery are small by today's standards. There were two adequately sized anaesthetic rooms with routine monitoring, with the exception of capnography. There were not the available funds to upgrade the monitoring equipment either in theatres or anaesthetic rooms.

83. The hours of work were long and through manpower shortages the staff were occasionally challenged by the complexity of the cases. There was no specific system for error management; in cases where patients died or had serious morbidity there were subsequent discussions to highlight deficiencies and areas for improvement. The Department of Anaesthesia had routine critical incident monitoring. Anaesthetic mortality and morbidity meetings highlighted and discussed such incidents from all

theatres across the Trust. The system has now been adopted across the Trust for other areas of clinical activity.

84. There were joint meetings between the pathologists, surgeons and cardiologists to discuss mortality. I was unable to attend these owing to other clinical commitments.

F6 The Existence and Awareness of Any Material Differences in the Manner of Carrying Out Surgery.

85. The commonest material difference discussed was the prolonged operative times which included both cross clamp and bypass times and the ITU morbidity and length of stay.

86. The anaesthetics given in the B.R.I. were similar between anaesthetists, particularly for the use of inotropic drugs, post operative ventilation and sedation. These practices were similar to those used elsewhere in the country and Australia. The cardiac anaesthetists continue to use a process of group discussion and change regarding techniques of anaesthesia. An example of change would be the use of intra-operative inotropic support used in paediatric anaesthesia after the visit of Doctors Masey and Underwood to Birmingham.

Issue G POST OPERATIVE CARE

G1 National Standards or Guidance

87. The Guidance available for the Standards of Paediatric Intensive Care was published in 1992. The combined adult and paediatric unit at the BRI was compromised because the paediatric and adult ICUs were together, the theatres were separated by lift journey and the children were not nursed by the recommended number of nurses with specific paediatric training and qualifications. However, the nurses caring for the children were invariably those with the greatest paediatric experience.

88. Guidelines on the number of intensive care beds and the support facilities for parents were also not achieved due to a lack of space and, I presume, funding. It was an aim of the unit to centralise the paediatric service at the Children's Hospital, until that was achieved everyone worked hard to maintain the highest standards possible.

G3 The Expertise of ICU Staff.

89. The evolving guidelines for adult and paediatric intensive care indicated the need for a lead clinician in charge of Intensive Care plus specific sessions for an Intensivist. On my appointment as Clinical Director there was no medical time allocated to the Cardiac Intensive Care. As Clinical Director, I argued against this with the Cardiac Surgeons both informally and at cardiac management meetings. The appointment of Doctors Pryn and Davies created three clinical sessions dedicated to the ITU, subsequently this has been increased to five sessions per week with the appointment of Drs Ryder and Linter. The transfer of the P.C.S. to the BCH led me to appoint Dr Wolf and later Dr Murphy to provide cardiac anaesthesia. The transfer of the cardiac work required the appointment of four paediatric Intensivists, later increased to six, to provide a 24 hour, 7 days a week consultant based service.

G4 The Availability of Staff Through a 24 Hour Day

90. The resident medical staff on the Intensive Care for each 24-hour period was an SHO in Cardiac Surgery. On call there was a surgical team plus the consultant anaesthetist of the day and an anaesthetic registrar. In my time as the Clinical Director the registrar anaesthetist was not resident because of the changes to junior hours of working and the demands of other clinical areas for resident staff. The guidance on working practice reduced the hours available to 56 per week, defined the intensity of work and for an adequate period of rest after an on-call period. To change the cardiac rota to resident required the appointment of more junior staff or the loss of another resident on-call rota already in place.

91. During the day the consultant anaesthetist would have dual responsibility for the theatre and intensive care. Difficulties in managing sick patients in both sites simultaneously

during the day. When requested to the cardiologists would give support and help in treating the children.

G8 The Extent to Which the Demands and Requirements Placed Upon the ICU Nurses and Other Staff Differ from Those imposed in adult cardiac cases.

96. The care of paediatric patients requires specific skills and attention to detail that may not be required in the routine adult cardiac patients. Hence the paediatric workload was concentrated on to specific anaesthetists and nurses so that they gained and maintained a greater expertise in the more complex children. The anaesthetists would discuss with their colleagues a complex case, and would give support in theatre if needed.

97. To ensure the skills of the anaesthetist matched the needs of the P.C.S., the on-call rota was organised to provide the paediatric anaesthetists on specific days. As lead cardiac anaesthetist I would be contacted over the provision of anaesthetic support. Managerially I considered the requirement to be for more anaesthetic theatre input, more Intensivist sessions and the need to develop flexible job plans as the unit changed and expanded. In my time as the Clinical Director four cardiac anaesthetists with five ITU sessions were appointed to the BRI unit.

G9-G12

98. I have no comment to make.

Issue J Training and Retraining.

99. The support and assistance available to the Anaesthetists was the standard for the hospital. This being 10 days study leave per year to attend courses in anaesthesia deemed relevant by the professionals concerned. The clinical support from colleagues on an informal basis was always available, as co-operation between colleagues was good. The surgical procedures were in place when I was appointed, therefore I cannot comment on the mechanisms used to introduce new procedures.

100. As Clinical Director, I spoke to JDW regarding the concerns over the switch programme outcomes. The suggestion for representatives of the P.C.S. team to visit Birmingham was accepted by JDW and JD. Subsequently JD, Dr Masey and Dr Underwood visited to Birmingham and this resulted in changes in the anaesthetic and surgical practice. Unfortunately we were unable to import a surgeon from Birmingham to support JD during the next phase of developing the switch programme.

101. With regard to clinical performance, as Clinical Director I was responsible for the quality of the Anaesthetic Department clinically, professionally and interpersonally. In this role, the Clinical Directors across the Trust did not have job descriptions, contracts or terms of reference to work within. The GMC Regulations regarding team working applied but the guidelines were not clear until the 1995 edition. Member of the P.C.S. aware of differing techniques in other areas would discuss this with the relevant professional, be they fellow anaesthetist, perfusionist or nurse. An example being the visit of a paediatric anaesthetist from Melbourne enabled an outside look at our anaesthetic practice and the suggestions made were incorporated.

K10-18 No specific comment.

Learning Curves.

K19-21

102. The learning curve of any medical process was recognised, but the implications were not as openly discussed or debated as they could be today. There is a relationship between the numbers of patients operated upon and the outcome, this applies within cardiac and other fields of surgery. Specific research that addressed this issue was being published as the P.C.S. issue evolved.

103. The introduction of any new treatment will incorporate the step where the training support is removed and exposes the patient to the "learning curve" of the doctor. The

timing and acceptability of this is a judgement taken at the time and is imprecise. The length of the learning curve will be dependent upon the individual's skill, the effectiveness of the team, previous training, outside support and the infrastructure of the hospital. However, whether the definition of an acceptable mortality rate can be derived prior to starting a new procedure is difficult to make comment on. At that time it will be an innovative technique for the unit plus, published data will reflect expert centre outcome and not that of the peripheral hospitals. The statistical effect of clustering and the small numbers as the experience increases makes the definition of acceptable almost impossible.

104. To ensure the absence of a learning curve during the promulgation of new techniques there would need to be enough recognised centres that could train surgeons to have experienced the majority of complications and variances in the surgical technique. This implies a prolonged training period of many months or years for each surgeon if the operation is uncommon with multiple anatomical nuances. The consequence is that only a few surgeons could be produced annually to start to develop the technique at other centres. Therefore some patients at undeveloped centres must continue to undergo an old fashioned operation and suffer the consequences of this. By shortening the training period, the technique could be more rapidly developed throughout the country, thereby allowing more patients to receive the preferred corrective surgery. However, in doing so, the learning curve dangers are increased such that patients may suffer morbidity of mortality when an event, not previously experienced, occurs. The balance between these two options is beyond my knowledge to comment on.

105. Whether it is possible to explain these macro-health economics to a parent, guardian or child pre-operatively is a moot point. Obviously everybody would prefer to have their operation performed in the best unit wherever that may be located.

This completes the statement of Dr C.R.Monk.