SUBMISSIONS ON BEHALF OF CARDIOLOGISTS

1. Decisions regarding the advice given to parents in relation to treatment of children with congenital heart disease were made on an individual basis considering the benefits and risks of possible procedures, both in relation to the likely natural history of the condition and the merits of particular lines of treatment, and were not driven by any statistical analysis involving comparisons with other units.

2. No reliable statistical information in useful or appropriate format in relation to Bristol or other units was available to influence decision-making.

3. Cases with adverse outcomes were reviewed to consider explanations for the outcome and lessons to be learned.

4. The relevance of previous cases to subsequent cases was whether a lesson had been learned which could lead to a more favourable outcome next time.

5. If the next case did not appear to involve the same or similar features which had caused or contributed to mortality or morbidity then the fact of adverse outcomes in those previous cases was not sufficient by itself to determine the decision on surgery in that case.

6. The surgeons were performing many other operative procedures with very good results such that there was no obvious or glaring reason to question surgical competence or judgment and consider referrals elsewhere. The operations under consideration constituted a small number of the total paediatric cardiological procedures performed by the unit and therefore the results for these operations were generally not considered at Path meetings in isolation separate from the overall operative mortality figures.

7. All cases involving mortality were discussed at Path meetings – however these often occurred many weeks, or months, after the relevant referral for surgery (given the delays in operating) and because the number of operations for specific complex conditions was small (often with gaps of several months) the impact of adverse outcomes was not immediately apparent at the time against the background of the large number of other successful procedures.

8. Information gained from Path meetings led the cardiologists to focus on factors such as pre-operative assessment and post-operative care which may have contributed to the adverse outcome. The identification of, or exclusion of, adverse factors, in the view of the cardiologists, made it possible to advise individual parents more appropriately than from a purely statistical approach based only on patient numbers.

9. Caution should be exercised when performing any retrospective analysis of a statistical nature; the exercise is of necessity artificial in failing both to assess the outcomes against the totality of the work of the unit, and to take account of what was known and what was thought at the time.

10. The analysis of outcomes which the cardiologists were able to obtain was not available to them until some time after the operations for which they had made referrals, and the delay between any referral and operation (often several months) meant that, if advising based on statistical evidence only, the position could have changed by the time the patient actually had his/her operation.

11. It is artificial to select only a random sample as given the variety of congenital abnormalities this can be highly unrepresentative of the total work. It is also artificial to have experts performing a retrospective analysis based only on case notes which may not provide the full picture given that doctors write notes in summary form rather than as a verbatim record of everything said, done or thought. Without comment or explanation from the relevant clinicians a misleading picture can be obtained.

12. Direct comparison with other centres cannot reasonably be made without detailed analysis of their figures and case selection/case mix – for example a number of centres did not accept Down's Syndrome patients and/or classified as inoperable patients which Bristol accepted for operation; it is submitted that those that other units sent home as inoperable should be added to their mortality statistics to give a more fair comparison with Bristol.

13. It is submitted that the correct/proper approach to treatment and surgery requires that decisions are not dictated by statistics. These can be misleading and unrepresentative if the number of cases is small and varied on a case mix and there is any significant number

of difficult presentations. The proper approach requires consideration of adverse outcomes, carefully to determine whether they were unacceptable outcomes and/or if there had been error on the part of a doctor in the team or the Unit which might not be correctable such as to put the next patient at additional risk.

14. Although a cardiologist has a duty to act in the best interests of his patients within the NHS this can only be within the limitations and resources of the service.

15. The role and effectiveness of the cardiologists at Bristol must be considered in the light of the working environment, in particular the split site, the lack of junior staff, and the onerous work loads they were subjected to (ten peripheral clinics).

16. Diagnosis of cardiac conditions, and anatomical abnormalities pre-operatively by cardiologists will depend on a variety of factors, including available resources. Non-diagnosis or non-identification of particular abnormalities may arise in circumstances without error, or failure by the cardiologist. In short, it is not possible to identify all conditions pre-operatively.

17. Whilst of course it may in theory be possible to refer a patient elsewhere for surgery sometimes it may not be practicable or desirable given the patient's own circumstances, the need for follow-up treatment, the need for continuing cardiological input, the waiting lists at other centres, the difficulty of extra-contractual arrangements post Trust status and indeed no guarantee of the other centre accepting the referral.

18. Whilst the relationship between cardiologists and surgeons was important, and maintaining good relations benefited patients, this would not have deterred cardiologists making referrals elsewhere if thought appropriate. However there were no operation specific statistics available for other centres and referrals on the basis only of rumour or supposed reputation without direct knowledge of the surgeon, his individual figures, his case mix and policy on case selection, his waiting list and his willingness to accept a patient from outside the area could have been at the very least inappropriate given the practical difficulties in referrals to centres distant from the patient's home.

19. It is submitted that if looked at contemporaneously and in the context of everything else that was going on within the unit and all the other work being undertaken and requiring the attention of cardiologists and surgeons (rather than with the benefit of hindsight and time-consuming analysis which only scrutinises a minority of the work undertaken in the period) in isolation from explanations of the relevant surgeon and cardiologist, the approach of examining the reason behind each clinical outcome and deciding whether the mortality rate was acceptable cannot be criticised.

20. It is submitted that in advising parents it would have been wrong to quote statistics which may not reflect the true risks for their child or to give statistics for other units when these were not operation specific or surgeon specific and nothing was known of case mix or case selection policies.

21. In any event statistics can be dangerous because 49 per cent, of necessity, are below average and if this causes a refusal to consent to operation, waiting lists will increase and patients will die; the true test must not be the average but whether the surgeon's performance comes within an acceptable range.

22. If parents are to be provided with detailed statistics, arguably 49% of all parents would have to be told that the centre advising them did not come up to the national average. If parents then exercised the right that it is assumed such information gives them, to have their child operated in one of the 49% of centres which statistically were above average in results for the last year, the number of centres carrying out such surgery would halve each year until there was only one centre left. Additionally, statistics being what they are, that centre might not be the one which operated on the most difficult cases or even the one which, prior to the previous year, had had the best statistical results.

23. Care must be taken to ensure that over-reliance on figures does not cause Units to refuse to operate on marginal cases where patients need or could benefit from surgery for fear of damaging their statistics or individual surgeons to be nervous in accepting patients with difficult presentations.

24. Concerns have been expressed as to delays between referral by cardiologists and performance of surgery. Although the cardiologists could advise as to the optimum time for surgery, the practicalities of actual timing were for surgeons alone.

25. The cardiologists did make very effort to visit ward 5 and see the children, both pre and post operatively, but the agreement was that they should not write in the surgical notes unless particularly requested to do so in case this caused confusion to the junior surgical and nursing staff. It follows that the absence of any entry in the surgical notes should not be seen to indicate that the cardiologist concerned did not see the patient at all. Nevertheless, the way that surgeons and anaesthetists visited cardiac surgical patients at different times did make it more difficult for the cardiologists to make their view known and some way of recording this would have been an advantage.

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24 January 2000