

Report for Dr Ruth Chadwick related to Issue N: expression of concern.

13 December, 1999

I have available:

Annual reports on Paediatric Cardiology and Cardiac Surgery at Bristol Royal Infirmary for 1987, 1988 and 1989/90

Copy of a letter to Dr Joffe from Dr MA Pitman, Specialist in Community Medicine, SW RHA and dated 5 Jan 1989 acknowledging the receipt of the report for 1987 and documenting its 'wide circulation within the RHA'.

Dr Chadwick's questions are in italics (*i*) to (*iv*)

1. Content of the reports:

- Authorship and audience

Neither authorship nor date of 'publication' is explicitly documented in any of the reports. The purpose of the reports is not discussed; the word 'audit' is not used. The audience targeted by the report is not documented either. However, at least the 1987 report was received (in late 1988 or early 1989) by Dr Pitman and distributed within the RHA. We can probably assume that the consultant surgeons and cardiologists received copies of the reports. It is harder to be sure about the other specialties (anaesthetics, pathology, radiology).

- Description

All the reports were generated before the 1989 'Working with Patients' directives. The longest report is that for 1989/90 which consists of 14 sides of A4 paper.

Each report has a standard format including:

A list of current medical senior staff, senior nursing and paramedical staff and secretarial staff. A list of academic publications by members of the cardiology and cardiac surgery departments.

Some narrative about the events of the year. This documents the expansion of all aspects of the service through this era. There is also often specific comment about resource needs (the echo department's needs are a recurrent theme).

An account of workload: admissions (numbers by age group and geographical source), peripheral clinics, echo and catheter investigations and operations performed for the year. The operations tables have a column for % mortality. Most of the material is reported in Tables with corresponding comments in the text.

(i) *what is your overall clinical view of the content and balance of these annual reports?*

The general flavour of the reports reflect 'audit' as information gathering in the context of service planning. The short letter from Dr Pitman (RHA) to Dr Joffe supports this impression: '...it is important as a follow-up to the funding of the regional specialties that we and those involved should be aware of the outcome of the *developments* which were undertaken'. The outcome of the *patients* (mortality) is not the main focus of these reports.

2. Outcome of the Patients

In each report, there is one table that offers information about outcomes of the patients in the form of summary mortality data.

- 1987: Table 3 deals with the numbers of operations performed in Bristol 1984-7 categorised by open/closed and by age under/over 1 year. There is a separate column for % mortality. The corresponding text offers the comment that 'these results are virtually identical to those obtained nationally (as published in the UK Cardiac Surgical Register)'.
- 1988: Table 5 offers a similar breakdown of operation numbers. Numbers of deaths and % mortality are also recorded. Comparison with % mortality for the 1984-87 era is offered but there is no comparison with the CSR in table or text.
- 1989: Table 5 records % mortality for open/closed and <1 year/>1 year in 1989. Table 6 supplements this with comparative data from Bristol 1984-7 and from the UKCSR for 1988 and is the most comprehensive statement of patient outcome issues in the 3 annual reports. There are no comments on this table in the text. There is no mention of whether the UKCSR registry data is presented with or without the 'subtraction' of the Bristol experience from the total. (If the Bristol experience were *not* subtracted, this would make any difference between Bristol and 'the rest' seem less extreme.)

Comments:

Formal outcome data like this is crucial to clinicians monitoring standards. Everyday professional involvement in patient care cannot be expected to keep track of such mortality rates: eg. in 1989, there was an infant death less than once every three weeks 'on average', the patients being divided between many diagnoses. It is possible – even likely – that clinical impressions of outcomes were more optimistic than the hard data: when examined this is a common finding. Also some professional groups will be more aware of the cumulative death rate than others: consultant cardiologists and surgeons will engage mainly with 'their' patients while anaesthetists, intensivists and nurses will not have such a particular focus. Thus some groups may 'believe' the data more readily than others.

We do not know the purpose of the 1989 report and have no reason to believe that it was prepared as background to a discussion meeting. Thus the question (ii) *'which, if any of these clinical audit data on paediatric cardiac surgical outcomes would – or should – have given rise to clinical concerns?'* must be answered from the point of view of a clinician scanning this report and what he or she might be alerted by.

- 1987: There are no very striking figures in table 3 and the uncorroborated comment about comparability with the CSR (presumably written by a surgeon with access to UKCSR tables) could probably be taken at face value.
- 1988: The mortality rates for open heart surgery under 1 year and for 'complex' open heart surgery over 1 year are beginning to look rather high and have both got worse rather than better when 1988 is compared to 1984-7. There is no comment in the text to guide the reader.
- 1989: Table 6 has obviously been prepared expressly to examine the 'current' early postoperative mortality data. I do not think we can presume that provision of comparative UKCSR data was standard practice in all units in presenting their audit information and to this extent the authors (who must have included a surgeon) have been very open.
- However, in other ways the table is not as helpful as it might be. The reader is offered little help in the exercise of extracting either which figures are 'significant' - in the sense of deserving attention or 'significant' - in the formal statistical sense of being unlikely to have emerged by chance if nothing had really changed over time or if Bristol were simply a typical contributor to the UKCSR.
- Several figures in the table look 'significant' in the sense of seeming rather high (in particular the 37.5% mortality for open-heart surgery in infancy). However, I am aware that this reflects some specialist experience of the area; such a figure alone might not attract the attention of a paediatrician or public health specialist. There is also the impression that outcomes were getting worse rather than better with time.

Table 6 can be redrafted to make messages emerge which in principle could be obvious to anyone. (appendix).

To convert the data in the table 6 has required:

1. calculation of the 'numerator' (number of deaths) from the % mortality and total – a simple arithmetical operation, perhaps with a calculator
2. provision of 95% confidence intervals on the proportions – another relatively easy calculation applying a statistical 'recipe', (albeit with a square-root in it!)
3. noting that the confidence intervals for Bristol and UKCSR do not overlap in the areas of open heart surgery totals or for infants <1 year. On the face of it, this makes Bristol an 'outlier' in these domains.

- (ii) *Which, if any, of these data would or should have given rise to clinical concerns?*
- (iii) *What is the nature of the clinical concerns you would reasonably expect to have been expressed?*

- If this exercise had been done, any reader should have been alerted to the high mortality figures for open-heart surgery in Bristol by 1989. In fact once the 1989 report was published it could have been formally discerned that the mortality for open-heart surgery in infancy in 1988 was excessive in comparison to UKSCR.
- Whether or not they *should* have the skills to go through the process above on the 'back of an envelope', unfortunately many doctors *would* fail somewhere along 1 to 3 due to a lack of arithmetical and statistical confidence. An audit department could be expected to have these skills, but it is unclear if they were involved in the generation of these reports.
- Thus I believe many readers would be left with the raw figures and some hesitancy about whether there 'really was' an issue to be raised. However, even with little in the way of quantitative skills, the impression that mortality for open-heart surgery in infancy was 'twice the national average' (37.5% v 18.8%) would have been a conclusion that many readers could and should have come to.

(iv) *What, if any, course(s) of action would you reasonably expect a clinician at Bristol to have taken in the light of these clinical audit data and statistical analyses?*

With only these data to go on, further exploration of the numbers was necessary internally within the department. The figures needed to be checked and broken down further, perhaps by diagnosis or operation type, maintaining some correspondence with the UKCRS for context. In principle this could happen without anxiety or threat to any individuals or the integrity of the unit. A clinical audit document focusing on outcomes (rather than the annual reports that focused on processes) should have been generated and discussed within the department. There are comments in two of the annual reports along the lines that 'the collaborative approach remains an important feature of our work and during 1989 has led to changes in our practice and the identification of goals for our future development'. Instigation from within and the process of refining the mortality information does not have to have judgmental overtones. I do not know if there was a designated individual or committee either in the department or in the hospital available for this exercise. The exercise would have required the assistance of a consultant surgeon if only to provide UKCSR data.

I believe that no clinical member of the team reading this report should have ignored the mortality summary. Each should have made efforts to call a meeting corporately to allocate responsibility for drawing up a fuller document. On the strength of the data, this should have been done as a 'one off', even if there was no natural mechanism, individual or committee to turn to.

A non-clinician or non-member of the department could also have precipitated such an exercise, perhaps by a non-judgemental letter asking for clarification of the causes underlying the apparently high mortality in particular areas.

3. Summary

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

Dr Kate Bull

Medical Advisor to Department of Nursing and Family Services, Great Ormond St Hospital
(1984 - August 1999 Senior Lecturer and Honorary Consultant Paediatric Cardiologist,
Great Ormond St Hospital)

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Extract of Table 6 from the Annual Report of 1989: As reported and redrafted

	BRISTOL		UK	
	Patients	% deaths	Patients	% deaths
<i>As reported</i>				
>1year				
Simple	36	0	540	0.6
Moderate	60	15.0	860	7.7
Complex	14	28.6	242	18.2
total	110	11.8	1042	6.9
< 1 year	40	37.5	708	18.8
Total open	150	18.7	2350	10.5
<i>Redrafted</i>		% mortality		% mortality
	deaths/total	(95% conf int)	deaths/total	(95% conf int)
>1year				
Simple	0/36	0 (0 - 12)	3/540	0.6 (0.1 - 1.8)
Moderate	9/60	15 (7.5 - 27)	66/860	7.7 (6.0 - 9.7)
Complex	4/14	28.6 (10 - 58)	44/242	18.2 (14 - 24)
total	13/110	11.8 (6.7 - 19.7)	113/1642	6.9 (5.7 - 8.2)
< 1 year	15/40	37.5 (23 - 54)**	133/708	18.8 (16 - 22)
Total open	28/150	18.7 (13 - 26)**	247/2350	10.5 (9 - 12)

** likely to be different from 'national average'