

BRISTOL ROYAL INFIRMARY INQUIRY

A Note on Supplementary Work to Inform the Inquiry's Assessment of the Adequacy of Paediatric Cardiac Surgical Services at Bristol

1. To meet its remit to assess the adequacy of paediatric cardiac surgical services at Bristol during the period 1984 to 1995, the Inquiry has heard a wide range of evidence from many people and organisations – including parents, Bristol clinicians and managers, and independent experts. In addition, the Inquiry commissioned independent analytical work on statistics and on a sample of children's case notes: statistical reports to the Inquiry on the results of review, analysis and synthesis of key statistical sources were published by the Inquiry on 3 November; a preliminary report on the results of the Clinical Case Note Review exercise was published 4th November 1999.

2. The Inquiry has now reviewed priorities for further analytical work to inform and supplement its assessment of the adequacy of paediatric cardiac surgical services at Bristol taking account of comments received and expert advice. This note sets out the Inquiry's plans for further analytical work, and provides an indicative timescale for reporting and publication.

3. The Inquiry has identified the following broad priorities for further analytical work:

- (i) a review of relevant research evidence on the effectiveness and outcomes of paediatric cardiac surgery;
- (ii) consolidation of the Inquiry's statistical review, analysis and synthesis work through further testing of mortality data and some additional analysis of existing data sources;
- (iii) completion of the Clinical Case Note Review exercise.

4. In determining priorities for additional analytical work, the Inquiry Panel have had regard to:

- whether there is other evidence of a scientific nature having to do with statistics or the Clinical Case Note Review which the Inquiry might reasonably have generated and/or taken into account;
- whether key issues before the Inquiry can be further illuminated by data already available to the Inquiry;
- whether any proposals for further work are deliverable in a timescale which would allow for the process of legal review and comment, within the Inquiry's overall reporting timescale.

5. Any evaluation of evidence has to take into account its strengths and weaknesses, and the evidence on adequacy will be no exception to this. In determining the weight and status to be attached to the evidence arising from the statistical and clinical case note reviews, the Panel will take into account all relevant strengths and weaknesses including the reliability or otherwise of the data sources.

6. Further details of work in planning and work in progress are set out at **Annexes A to D** attached. For the purposes of the Inquiry, this will conclude analytical work to deliver the four stages of the Inquiry's published strategy for making effective use of existing data sources. The Inquiry expects to publish reports on the results of this supplementary analytical work in May 2000.

Inquiry Secretariat

March 2000

Selected References

The following documents are available on the Inquiry's website: www.bristol-inquiry.org.uk

Bristol Royal Infirmary Inquiry – Issues List [February 1999]

The Inquiry's Approach to Making Use of Relevant Data Sources [March 1999]

Preliminary Overview of Existing Data Sources Relevant to the Inquiry's Remit [July 1999]

The Inquiry's Approach to the Assessment of the Adequacy of Paediatric Cardiac Surgical Services [July 1999]

Reports to the Inquiry on the Results of Statistical Review, Analysis and Synthesis of Key Statistical Sources [November 1999]

Preliminary Report on the Clinical Case Note Review [November 1999]

Review of research evidence on the effectiveness and outcomes of paediatric cardiac surgery

Work is in progress on a systematic review of published research evidence on the effectiveness and outcomes of paediatric cardiac surgery with specific reference to the period 1984 to 1995. The review is intended to contribute to the Inquiry's understanding of: (i) the knowledge-base that might reasonably be expected to have been available to clinicians during the Inquiry period; (ii) factors that require to be taken into account in the communication of surgical risk; and (iii) wider research evidence on surgical outcomes.

The review is being conducted by a research team at the London School of Hygiene and Tropical Medicine. The report is expected in May 2000 and will be published on the Inquiry's website.

Further consolidation of the Inquiry's review, analysis and synthesis of statistical sources

A range of supplementary analytical work to test further the mortality data available to the Inquiry is underway. This includes:

- a survey of data gathering mechanisms at those specialist centres in England which undertook paediatric surgery and made returns on paediatric cardiac surgery to the UK Cardiac Surgical Register between 1984 and 1995;
- linkage and comparison of Hospital Episode Statistics on paediatric cardiac surgery with Office for National Statistics [ONS] Death Register data;
- comparison of coded data extracted from the Bristol Royal Infirmary perfusionists' logs¹ with other key statistical sources on open heart surgical activity and outcomes at Bristol;
- statistical comparison of personal surgical data on open heart surgical procedures with the Inquiry's coded clinical records [CCR] and surgeons' logs [SL] datasets.

Work is also underway to deliver additional analyses of existing statistical sources, to include further investigation of: (a) post-operative complications; and (b) the effect on surgical outcomes of age distribution; presence of Down's syndrome; other co-morbidities; service volume or throughput; and, inter-hospital transfers.

This further work is being undertaken by the Inquiry's existing expert teams led by Professor Gordon Murray of the University of Edinburgh, Dr Paul Aylin of Imperial College School of Medicine, and Professor Stephen Evans of Quintiles Ltd. Final reports from each of the teams are expected by May 2000 and will be published on the

¹ A perfusionist operates the heart by-pass machine in the operating theatre, working to the anaesthetist.

Inquiry's website - with a final statistical overview, taking account of further analyses, from Dr David Spiegelhalter.

Consolidation of the Inquiry's Clinical Case Note Review exercise

Work is in progress to further consolidate the Clinical Case Note Review [CCNR] exercise. This includes:

- repeat reviews approved by the Panel;
- additional contributions from experts who undertook the review, so as to set out the key clinical considerations the experts had in mind when determining whether a given aspect of care was adequate or less than adequate;
- further analysis of (a) the second reviews forms [CCNR2], and (b) the repeat reviews;²
- new tables to set the sample in the context of the full dataset from which it is drawn;
- expert commentary on the wider issues arising from parents' and from Bristol clinicians' comments on the CCNR forms.

The final report is expected to be completed by April 2000 and will be published on the Inquiry's website shortly thereafter.

² The 15 second reviews conducted in the autumn of 1999, known as CCNR2 reviews, were selected at random as a methodological tool for testing the validity of CCNR results. The repeat reviews, on the other hand, conducted in January and February 2000, were selected on the basis on an application procedure, and not at random. To avoid the possibility of any selection bias in the CCNR report, the results of the second reviews and of the repeat reviews will be dealt with separately from each other and from the main CCNR results, in the final CCNR report.

Inquiry's position on further comparative research to investigate the adequacy of care at Bristol

In outlining its approach to the assessment of adequacy of care [July 1999], the Inquiry indicated that it would examine the potential added value of further comparative research to investigate and explain the differences in activity and outcomes at Bristol relative to paediatric cardiac specialist centres elsewhere in England.

In the light of accumulated evidence now before the Inquiry, and taking into account legal and scientific advice, the Inquiry Panel have concluded that pursuing major new comparative research to inform their assessment of the adequacy of care at Bristol is neither essential nor feasible.

The Inquiry acknowledges the argument for pursuing further research of an explanatory nature. Notwithstanding this, the results of the Inquiry's review, analysis and synthesis of key statistical sources suggest that the poor mortality outcomes at Bristol relative to other specialist centres are unlikely to be explained by surgical risk or casemix factors alone. Furthermore, the Inquiry's experience confirms that a full-scale, comparative case note audit – based on blinding and a controlled design – would not be feasible to deliver within a reasonable timescale.