

BRISTOL ROYAL INFIRMARY INQUIRY

Synthesis of Statistical Sources: A Note on Expert Consultation on Key Analytical Issues

1. Introduction

1.1 As part of the exploratory phase of the Inquiry's analytical strategy, six key data sources relevant to the Inquiry's remit have been subject to statistical review, analysis, and initial synthesis [INQ 12 / 1-49; INQ 13 / 1-86; INQ 14 / 1-78; INQ 15 / 1-102].

1.2 To allow robust statistical analysis and synthesis of activity and outcomes data by operative procedure, it has proved necessary to secure expert clinical input on key analytical issues. This note clarifies the Inquiry's use of coded clinical data on operative procedures, outlines key analytical issues involved in achieving a synthesis of statistical sources, describes the process of consultation with clinical experts on which key analytical decisions were based, and comments on the subsequent status of statistical analyses by procedure groups.

2. Background

2.1 In March 1999, the Inquiry published - for consultation - a paper outlining its approach to making use of existing data sources relevant to an investigation of the nature and outcomes of children's heart surgery at Bristol. A number of key data sources were identified, together with a phased approach to making effective and appropriate use of these. In July 1999, the Inquiry published a preliminary overview of key data sources relevant to the Inquiry's remit, together with a preliminary assessment of their strengths, weaknesses, and limitations. This provided a backdrop to statistical evidence given to the Inquiry in oral hearing in July.

3. The Inquiry's Use of Coded Clinical Data

3.1 The Inquiry has a public duty to identify, investigate and compare existing key sources of statistical data concerning the nature and outcomes of paediatric cardiac surgical services at Bristol. As robust statistical analysis requires that like is compared with like, ideally this means drawing on clinical information about diagnoses, operations and procedures that is categorised or coded according to strict conventions. Clinical coding of primary data sources, involving the use of established classification systems, provides a means for extracting complex clinical information in a way that is amenable to statistical analysis.

3.2 Of the six key data sources relevant to the Inquiry's remit, two sources are already clinically coded. For the period covered by the Inquiry, the UBHT Patient Administration System [PAS] and national Hospital Episode Statistics [HES] both record diagnoses according to the International Classification of Diseases [Ninth Revision] and operative procedures according to the Office of Population Censuses and Surveys [Fourth Revision] classification system.

3.3 By contrast, the UBHT clinical records of children falling within the Inquiry's terms of reference, and the surgeons' logs, are 'raw' data sources. In order to allow robust statistical analysis of the clinical information contained in them, the Inquiry therefore needed to consider how best to extract relevant clinical data in coded format.¹

3.4 Three clinical coding options were appraised by the Inquiry:

- (i) development of a new clinical coding system specifically designed to meet the Inquiry's needs; or

¹ Coding the clinical records of those children falling within the Inquiry's terms of reference was also necessary in order to generate a representative sample of cases to submit to detailed clinical review.

- (ii) use of the established International Classification of Diseases [ICD] system for diagnoses and Office of Population Censuses and Surveys [OPCS] classification system for operative procedures; or
- (iii) use of the more recently developed 'Read' coding system.

3.5 Statistical advice to the Inquiry made it clear that development of a new clinical coding system specifically for the Inquiry was not a practicable option within the time constraints of the Inquiry, and that use of the newly introduced Read clinical coding system was not a feasible option due to insufficient availability of skilled Read coders.

The established ICD and OPCS classification systems, on the other hand, offered two clear advantages: (i) experienced clinical coders, who could complete the coding process within the time constraints of the Inquiry, were readily available to the Inquiry; and (ii) statistical comparisons would be allowed with the other key data sources already using this classification system.

3.6 On the basis of statistical advice², and to enable comparative analysis and synthesis of key data sources, the Inquiry therefore decided to use the ICD9 and OPCS4 classification systems to code clinical data held in the UBHT clinical records and the surgeons' logs, and thereby to generate two new datasets [the CCR and SL] for the purpose of statistical analysis.

3.7 The remaining key data sources - the UK Cardiac Surgical Register [UKCSR] and the South West Congenital Heart Register [SWCHR] - use quite different categories to record activity, and this necessitated a cross-mapping exercise based on expert clinical advice to ensure comparability.

3.8 The Inquiry is aware of reservations concerning the clinical accuracy of the OPCS classification system expressed by some paediatric cardiac surgeons and cardiologists, and the Inquiry has asked its independent statistical analysts to take these reservations into account in reporting their results.

² Statistical advice was provided by the NHS Centre for Coding and Classification, and Professor Stephen Evans of the Medicines Control Agency.

4. Key Analytical Issues

4.1 To allow robust statistical analysis and synthesis of key data sources relevant to the Inquiry's remit, it proved necessary to carry out the following key analytical tasks:

- (i) to *classify* procedures as either open or closed;
- (ii) to *group* procedures – in a way that is clinically and statistically valid;
- (iii) to *rank* procedure groups by relative risk.

4.2 Due to the complexity of the clinical issues involved, and despite continuing clinical interest and development activity, performance measurement and risk stratification in the field of paediatric cardiac surgery remains underdeveloped. One consequence is the lack of available 'off-the-shelf' products developed with clinical input to facilitate statistical analysis of activity and outcomes data in the field of paediatric cardiac surgery.

4.3 To facilitate statistical analysis of key data sources within the time constraint of the Inquiry's oral hearings process, it was therefore necessary for the Inquiry quickly to secure expert clinical advice on these key analytical issues with the aim of reaching a clinical consensus. [In particular, the clinical coding decisions outlined in section 3 above necessitated expert clinical advice on the grouping of OPCS4 procedure codes mapped towards UKCSR diagnostic categories.] The process of expert consultation used to reach such a clinical consensus on each key analytical issue is described in **Annexes A - C** attached.

5. Status of Statistical Analyses by Procedure Group

5.1 There is evidence to suggest that the statistical analysis of surgical activity and outcomes by procedure group – based on the process of expert consultation described in Annexes A to C – is soundly based. First, despite severe time constraints, the expert consultation process was extensive and systematic, and analytical decisions were based on a range and balance of clinical views. Secondly, the results of the

synthesis show good agreement between data sources and lend credibility to the classification, grouping and ranking assumptions applied. Thirdly, initial peer review by the statistical Experts to the Inquiry of draft statistical reports suggests that the analytic base is sound, and that the statistical work overall appears to be of seminal quality.

6. Wider Evidence on the Nature and Outcomes of Children's Heart Surgery

6.1 Statistical review, analysis and synthesis of key data sources relevant to the Inquiry's remit comprises one source of evidence on the nature and outcomes of children's heart surgery at Bristol, and has exploratory status. Statistical evidence will need to be set alongside evidence to the Inquiry given by families, hospital staff, organisations and experts, and the results of the Inquiry's clinical case note review of adequacy of care.

6.2 In addition, the Inquiry plans to commission a systematic review of available research evidence on the effectiveness and outcomes of paediatric cardiac surgery, and is exploring the feasibility of a comparative evaluation of quality and outcomes of care based on audit of patient records drawn from a range of specialist provider centres.

7. Summary

7.1 In the absence of established systems of risk stratification or activity and outcomes measurement in paediatric cardiac surgery, and to facilitate robust statistical analysis and synthesis of key data sources, it has been necessary for the Inquiry quickly to secure expert clinical advice on key analytical issues relevant to an investigation of the nature and outcomes of children's heart surgery at Bristol. Expert consultation was targetted towards achieving a clinical consensus on key analytical issues relating to statistical analyses by procedure. There is good evidence to suggest that the analytical decisions based on expert consultation are robust and fit for purpose.

Inquiry Secretariat
November 1999

Synthesis of Statistical Sources:

Expert Consultation on Classification of Procedures as Open or Closed

To allow statistical comparisons between open heart procedures (i.e. requiring cardiopulmonary bypass) and closed heart procedures (i.e. not requiring cardiopulmonary bypass), it was necessary to secure expert clinical advice on classification of operations or procedures as open or closed. To this end, the Inquiry set in place a systematic consultation process as follows:

Stage One: for the purpose of drawing a representative sample of children falling within the terms of reference of the Inquiry, the Inquiry submitted a list of OPCS4 K and L procedure codes occurring in the Bristol coded clinical records [CCR] dataset to a national clinical coding specialist for initial advice on classification of individual procedures as open or closed.

Stage Two: for sampling and wider analytical purposes, the Inquiry submitted a list of OPCS4 K and L procedure codes - together with the initial advice of the national coding specialist - to a paediatric cardiologist with specialist expertise in this area, for expert clinical advice on classification of individual procedures as open or closed. On the basis of this advice, individual OPCS4 procedures were classed provisionally as open, closed, or excluded. [Excluded procedures are those clinically described as adult, medical, either open or closed, or unspecified.]

Stage Three: further expert clinical advice on this provisional classification was secured from a paediatric cardiac surgeon on the Inquiry's Expert Group; classification of procedures and procedure groups as open or closed was further refined on the basis of this advice and used for analytical purposes.

Stage Four: in view of the apparent complexity of open/closed classification indicated by the clinical advice received, the Inquiry subsequently secured additional clinical advice on aspects of the open/closed dimension from surgeons and cardiologists on the Expert Group; this covered definition of open and closed

procedures, categorisation of procedures as open or closed, potential changes over time in the status of procedures, relative risks of open heart and closed heart surgery, and procedure groups carrying the highest surgical risk. This advice will be used for further validation of the open/closed assumptions applied.

Expert advice was received from:

Stage One:

Mrs Christine Sweeting, Central Clinical Coding Co-Ordinator (London), NHS Information Authority

Stage Two:

Dr Catherine Bull, Consultant Paediatric Cardiologist, Great Ormond Street Hospital

Stage Three:

Mr Leslie Hamilton, Consultant Cardiac Surgeon, The Freeman Hospital

Stage Four:

Mr Leslie Hamilton, Consultant Cardiac Surgeon, The Freeman Hospital

Dr Alan Houston, Consultant Paediatric Cardiologist, Royal Hospital for Sick Children, Glasgow

Mr Christopher Lincoln, Consultant Cardiothoracic Surgeon, The Wellington Hospital

Mr B Sethia, Consultant Cardiac Surgeon, Royal Brompton and Harefield NHS Trust

Dr Eric Silove, Consultant Paediatric Cardiologist, The Birmingham Children's Hospital

Mr Jaroslav Stark, Consultant Cardiothoracic Surgeon, Great Ormond Street Hospital

**Synthesis of Statistical Sources:
Expert Consultation on Grouping of Operative Procedures**

To allow statistical analysis of activity and outcomes data for paediatric cardiac surgical services and comparisons across key data sources, it was necessary to secure expert clinical advice on the grouping of operative procedures. [Time and resource constraints determined that expert consultation must be primarily paper- rather than discussion-based.] To this end, the Inquiry took forward a systematic consultation process as follows:

Stage One: at the Inquiry's request, the NHS Information Authority (Casemix Programme) developed a set of provisional groupings (22 in all) based on the full list of OPCS4 K and L procedure codes;

Stage Two: the Inquiry submitted the provisional procedure groupings to the surgeons and cardiologists on the Expert Group for expert clinical advice; on the basis of this advice, the 22 provisional groupings were reduced to a revised set of 17 procedure groups.

Stage Three: the Inquiry re-submitted the revised set of 17 procedure groups to the surgeons and cardiologists on the Expert Group for further clinical advice; on the basis of this further advice, the groups were further revised and reduced to 12 procedure groups.

Stage Four: the Inquiry submitted the revised set of procedure groupings to the Society of Cardiothoracic Surgeons for advice on mapping onto UK Cardiac Surgical Register diagnostic categories; to this end, the Society nominated one of its members (a paediatric cardiac surgeon) with a specialist interest in the grouping of operative procedures for audit and research purposes, who was also a member of the Inquiry's Expert Group.

Stage Five: the Inquiry convened a meeting between its statistical analysts and the Society's nominated expert, with the aim of achieving consensus groupings of OPCS4 procedure codes that would enable statistical analysis and comparison with UKCSR categories. On the basis of detailed discussion, a final set of 13 procedure groups were agreed, 12 of which map onto UKCSR categories. Subsequent mapping of the agreed procedure groups onto SWCHR procedure categories was achieved on the basis of consultation with a paediatric cardiologist with specialist expertise in this area.

Expert advice was received from:

Stage One:

Mr Peter Benton, NHS Information Authority (Casemix Programme)

Stage Two:

Dr David Dickinson, Consultant Paediatric Cardiologist, Leeds General Infirmary

Mr Leslie Hamilton, Consultant Cardiac Surgeon, The Freeman Hospital

Dr Alan Houston, Consultant Paediatric Cardiologist, Royal Hospital for Sick Children, Glasgow

Mr Christopher Lincoln, Consultant Cardiothoracic Surgeon, Royal Brompton and Harefield NHS Trust

Mr B Sethia, Consultant Cardiac Surgeon, The Birmingham Children's Hospital

Dr Eric Silove, Consultant Paediatric Cardiologist, The Birmingham Children's Hospital

Mr Jaroslav Stark, Consultant Cardiothoracic Surgeon, Great Ormond Street Hospital

Stage Three:

Dr David Dickinson, Consultant Paediatric Cardiologist, Leeds General Infirmary

Mr Leslie Hamilton, Consultant Cardiac Surgeon, The Freeman Hospital

Dr Alan Houston, Consultant Paediatric Cardiologist, Royal Hospital for Sick Children, Glasgow

Dr Barry Keeton, Consultant Paediatric Cardiologist, Southampton University Hospitals NHS Trust

Mr Christopher Lincoln, Consultant Cardiothoracic Surgeon, Royal Brompton and Harefield NHS Trust

Dr Eric Silove, Consultant Paediatric Cardiologist, The Birmingham Children's Hospital

Mr Jaroslav Stark, Consultant Cardiothoracic Surgeon, Great Ormond Street Hospital

Stage Four:

Mr Bruce Keogh, Secretary, Society of Cardiothoracic Surgeons of Great Britain and Ireland

Stage Five:

Mr Leslie Hamilton, Consultant Cardiac Surgeon, The Freeman Hospital

Dr Catherine Bull, Consultant Paediatric Cardiologist, Great Ormond Street Hospital

**Synthesis of Statistical Sources:
Expert Consultation on Ranking by Primary Procedure**

To allow statistical analysis by operative procedure taking into account relative risk, and in the absence of an established risk stratification system in the field of paediatric cardiac surgery, it was necessary to secure expert clinical advice on ranking by primary procedure. To this end, the Inquiry co-ordinated a systematic consultation process as follows:

Stage One: provisional procedure code groupings developed by the NHS Information Authority were submitted to the surgeons and cardiologists on the Inquiry's Expert Group for clinical advice on the analytical priority to be attached to specific procedures or procedure groups; on the basis of this advice, a provisional ranking of procedure groups was devised.

Stage Two: clinical advice on the most common combinations of procedures and mortality rates was secured from a paediatric cardiac surgeon on the Expert Group. On the basis of this advice, a ranking system by primary procedure was derived and used for analytical purposes.

Stage Three: in view of the complexities involved in ranking procedures by surgical risk, the Inquiry subsequently secured additional clinical advice from surgeons and cardiologists on the Expert Group on the relative risks of open and closed heart surgery, and on procedure groups carrying the highest surgical risk. This advice will be used for validation of the ranking assumptions applied.

Expert advice was received from:

Stage One:

Dr David Dickinson, Consultant Paediatric Cardiologist, Leeds General Infirmary

Mr Leslie Hamilton, Consultant Cardiac Surgeon, The Freeman Hospital

Dr Alan Houston, Consultant Paediatric Cardiologist, Royal Hospital for Sick Children, Glasgow

Mr Christopher Lincoln, Consultant Cardiothoracic Surgeon, Royal Brompton and Harefield NHS Trust

Mr B Sethia, Consultant Cardiac Surgeon, The Birmingham Children's Hospital

Dr Eric Silove, Consultant Paediatric Cardiologist, The Birmingham Children's Hospital

Mr Jaroslav Stark, Consultant Cardiothoracic Surgeon, Great Ormond Street Hospital

Stage Two:

Mr Leslie Hamilton, Consultant Cardiac Surgeon, The Freeman Hospital

Stage Three:

Mr Leslie Hamilton, Consultant Cardiac Surgeon, The Freeman Hospital

Dr Alan Houston, Consultant Paediatric Cardiologist, Royal Hospital for Sick Children, Glasgow

Mr Christopher Lincoln, Consultant Cardiothoracic Surgeon, The Wellington Hospital

Mr B Sethia, Consultant Cardiac Surgeon, Royal Brompton and Harefield NHS Trust

Dr Eric Silove, Consultant Paediatric Cardiologist, The Birmingham Children's Hospital

Mr Jaroslav Stark, Consultant Cardiothoracic Surgeon, Great Ormond Street Hospital