

BRISTOL ROYAL INFIRMARY INQUIRY

PRELIMINARY OVERVIEW OF EXISTING DATA SOURCES

RELEVANT TO THE INQUIRY'S REMIT

A Consultation Paper on Work in Progress

1. Introduction

Background

1.1 A key issue to be investigated by the Inquiry concerns the nature and outcomes of paediatric cardiac surgical services at Bristol – referred to as Issue C in the Issues List published by the Inquiry in March 1999. Also in March 1999, the Inquiry published - for the purpose of consultation - a paper outlining the Inquiry's approach to making use of existing data sources relevant to an investigation of the nature and outcomes of children's heart surgery. A number of key data sources were identified, together with a phased approach to making effective and appropriate use of them.

Purpose

1.2 This paper is intended to provide an outline of the Inquiry's progress to date in identifying and assessing existing data sources relevant to an investigation of Issue C, and to provide a backdrop and context against which subsequent data analyses should be set. The paper also aims to provide, for the purpose of early consultation, a preliminary overview of the strengths, weaknesses and limitations of key data sources relevant to the Inquiry's terms of reference.

1.3 The Inquiry's task of identifying, acquiring and assessing relevant data sources is a considerable one and still in progress. For this reason, this paper necessarily provides a provisional - rather than definitive - overview of key data sources with a view to promoting open discussion and a better understanding of their potential value to the Inquiry. The Inquiry intends to publish at a later date more substantive material providing a high quality review of data sources. A selective list of references to relevant background publications is also provided, to facilitate a wider understanding of some of the complexities involved in making effective and appropriate use of relevant data sources.

1.4 The paper is being published in advance of an oral hearing session on key data sources planned for July 1999, to allow an opportunity for early comment on any gaps and shortcomings in identified data sources; on the priority that should attach to analysis of key data sources; and on the implications of any shortcomings in existing data sources for reaching conclusions about the nature and outcomes of the children's heart surgery service at Bristol compared with elsewhere. Comments on this paper should be sent to: Una O'Brien, Secretary BRI Inquiry, 2-10 Temple Way, BRISTOL, BS2 0BY. Email: inquiry@doh.gov.uk

Sources

1.5 The main sources for this preliminary overview paper are externally commissioned analysis and research, formal and informal contacts with ‘owners’ of key data sources, expert advice and formal written statements to the Inquiry. References to formal written statements received so far are given in the text; these will be published in July, as soon as possible after oral hearings on 13 and 14 July. The Inquiry’s knowledge and understanding of existing data sources is rapidly accumulating but is far from complete, particularly as a considerable number of formal written statements are still expected at the time of publication, and commissioned data analyses are still in progress.

Target audiences

1.6 Target audiences for the paper include parents, families and present and former United Bristol Healthcare Trust [UBHT] staff, their legal representatives, health service professionals and their representative bodies, members of the scientific community and the wider public.

Outline structure

1.7 The paper is divided into three main sections as follows: (1) introduction, (2) a preliminary overview of six key data sources, and (3) summary and emerging implications. A list of additional data sources of potential relevance to the Inquiry’s remit, and selected references, are attached as annexes to the paper.

2. Existing Data Sources of Key Relevance to the Inquiry's Remit

2.1 Information available to the Inquiry to date suggests that six existing data sources are of key relevance to the Inquiry's remit. Listed from national to local level, these are as follows:

- (i) *UK Cardiac Surgical Register*: a voluntary reporting system established and maintained by the Society of Cardiothoracic Surgeons of the United Kingdom and Ireland, which reports activity and outcomes data for all types of cardiac surgery including congenital heart surgery.
- (ii) *Hospital Episode Statistics*: a national reporting system designed to record information about in-patient activity in all NHS hospitals in England; [a similar system, known as the Patient Episode Database for Wales, or PEDW, exists in Wales].

Both the UK Cardiac Surgical Register and Hospital Episode Statistics data could allow for comparisons on the nature and outcomes of children's heart surgery between Bristol and other specialist centres in the country.

- (iii) *United Bristol Healthcare Trust Patient Administration System*: the Trust's patient-based computerised administrative information system designed to record and track all of the Trust's patient activity, including paediatric cardiac surgical services.
- (iv) *South West Congenital Heart Register*: a local computerised information system established and maintained by cardiologists at the BRI/Bristol Children's Hospital to record summary information on children receiving paediatric cardiac surgical services at Bristol, for the purposes of patient tracking, local audit and research.
- (v) *Clinical Records*: the paper-based clinical records of all children falling within the Inquiry's terms of reference, as identified by UBHT through a formal discovery process.
- (vi) *Surgeons' Logs*: the personal surgical logs kept by Bristol heart surgeons for the purpose of local audit and research.

2.2 This consultation paper outlines, for each key data source, its purpose and description and, where applicable, provides a preliminary, and therefore provisional, assessment of data quality in respect of coverage, completeness and accuracy. (In this context, coverage is taken to refer to the proportion of total activity recorded by a system, completeness refers to the proportion of records that have an entry in any specific field, and accuracy refers to how far completed records reflect the true nature of the particular field.) Where available, summary information is also presented on arrangements for analysis, dissemination and reporting.

UK Cardiac Surgical Register

2.3 The UK Cardiac Surgical Register was formally established in 1977 following a pilot project in 1976. The purposes at that time were seen to be: (i) to provide information on the volume, type and distribution of

work performed; (ii) to promote the rational use and future planning of cardiothoracic services; and (iii) to improve the overall quality of the cardiac services delivered by enabling individual surgeons to compare themselves against national data. The Society of Cardiothoracic Surgeons [statement WIT 163] has recently confirmed the primary purposes of the Register as: (i) to track the development of the specialty in terms of overall activity; (ii) to identify trends in the evolution of different procedures; and the secondary purpose as: (iii) to track and benchmark mortality for different procedures.

2.4 The Register was set up and is 'owned' by the Society of Cardiothoracic Surgeons. However individual surgeons, as members of the Society, agreed to the introduction of the Register. The Register was intended to cover all NHS cardiothoracic units in England, Wales, Scotland and Northern Ireland. The Register includes all cardiothoracic operations, of which paediatric surgery forms only a part.

2.5 The Register contains a standard aggregated return from each NHS unit performing cardiothoracic surgical procedures. For paediatric cardiac surgery this comprises details of the surgical procedures, deaths and death rates, categorised by diagnosis and type of procedure. A breakdown of age (under 1, over 1) is also included.

2.6 The broad arrangements for gathering data appear to be that a single surgeon in each unit collates the surgical activity of the whole unit by completing a proforma supplied by the Honorary Secretary of the Society of Cardiothoracic Surgeons. Submission is voluntary. The data are submitted in manuscript or in typed form. Each unit is responsible for the accuracy of the data. There is no validation of individual returns by the Society. In order to preserve confidentiality, on receipt, the Society removes the covering sheet and each unit is given a code number. The data are analysed by a separate organisation, which is not able to identify individual units.

2.7 The intention was for all units to be included. However, the UK summaries appear to indicate two years where data are missing, i.e. for 1988 and 1994/95, and the Society's formal statement to the Inquiry indicates that returns are not available for certain units and for a number of years. In addition there is inconsistency in the time period covered for each year. Up to 1992, data were collected by calendar year; for the first three months of 1993 no data were collected, and thereafter, (from 1993/94), data relate to financial years.

2.8 The content of the return has remained largely constant over time. This is helpful in promoting accuracy, in enabling short-term local and national comparisons, and in allowing for trend analysis. However, an aggregated return inevitably constrains possible analysis and interpretation. For example, where procedures within the return become outdated (due to rapid technological development) or a particular breakdown becomes irrelevant, this will affect quality and completion of returns. As the Society recognises, the return does not take into account the following factors:

- (i) risks associated with the condition of the patient, i.e. the risk factors associated with pre-operative morbidity;
- (ii) the complexity of the surgery;
- (iii) the precise type of operation, e.g. arterial switch;

(iv) whether procedures have been planned in advance or are done in an emergency.

2.9 The strengths of the data collection arrangements are that the Register has the support of the Society's members, the Society ensures information is fed back to units, and a designated surgeon in each unit is responsible for collection - ensuring some oversight of the process locally.

2.10 However, no central validation is carried out (other than attempts to correct internal inconsistencies) and the Society is unaware of any validation carried out locally. This means that there is no certainty that each return records accurately a unit's true activity and mortality. The Society acknowledges that this is a serious weakness, and it limits the possible uses of the data set.

2.11 Until 1992, the annual report - i.e. the UK summary only - was sent to the contributing person from each unit. Since 1992, the annual report has been circulated to all active members of the Society, with additional copies sent to the Department of Health's Senior Medical Officer for Cardiac Services. Until 1991, a short presentation of the annual report on the Register was given at the Society's Annual General Meeting. Since 1991, about one hour has been allowed in the scientific section of the AGM for presentation of the various Registers (i.e. the Cardiac Surgical Register, the Thoracic Surgical Register, the Heart Valve Register, and, since 1993, the Intrathoracic Register).

2.12 The timetable for feeding back information to units has improved significantly; whereas 1980 data were not available until 1982, 1993/4 data (financial year) were circulated in first half 1995.

2.13 Analysis and reporting arrangements have been limited and do not appear to have met all the original purposes of the Register. This seems to have arisen largely because of the original agreement relating to confidentiality considerations. The agreement that only national data would be produced does not allow useful regional comparisons to be made; the anonymity of the returns does not allow comparisons at unit level; and the aggregation of returns at unit level does not allow comparisons between individual surgeons to be made.

Potential value to the Inquiry

2.14 Preliminary assessment suggests that UK Cardiac Surgical Register data on congenital heart surgery are of potential value to the Inquiry as an indicator of broad activity, outcomes and trends, and for broad comparisons of UBHT with other specialist units in the UK.

2.15 Subject to the limitations on completeness and lack of validation, it would seem possible to use the data for trend analysis. Provided it is possible to eliminate inconsistencies in the description and grouping of operations covered by the different datasets (at the moment they use different descriptors) then it should in principle be possible to make comparisons with the local Patient Administration System, the clinical coded records, and the Hospital Episode Statistics.

Hospital Episode Statistics

2.16 The Hospital Episode Statistics [HES] system was set up in 1987 by the Department of Health to collect information about in-patient activity in all NHS hospitals in England. The purpose of HES is to provide

information for policy makers, managers and planners in the Department of Health and the NHS. Since 1991 HES data have been used for contracting and performance management, for epidemiological studies and in the development of performance indicators. A similar system exists in Wales and the Inquiry is currently exploring the feasibility of analysing these data.

2.17 The basic unit of HES data is a period of care under one consultant, known as a finished consultant episode [FCE]. HES records are derived from a sub-set of routinely collected hospital activity data as recorded by Patient Administration Systems and Hospital Information Service System in hospitals throughout the country. HES returns are made by financial year. During the Inquiry's period, HES returns were submitted from local health authorities and after 1991, from Trusts, via Regional Health Authorities to IBM Global Services, the Department of Health's data manager for HES [statement WIT 189].

2.18 Every hospital in England is asked to submit around forty items for each FCE in every patient's stay in that hospital (for *administrative purposes* patients are mostly attributed to one consultant during a single stay in hospital). The main data items included in HES returns are the patient's summary personal information, clinical information, outcome information and administrative information.

2.19 The clinical information for each patient is recorded in the form of codes for diagnosis and procedure. Coding is carried out in the hospitals. Diagnoses are coded according to the World Health Organisation International Classification of Diseases [ICD]. Between 1984 and 1995, the coding series used was the version known as "ICD9". In March 1995 an improved series was introduced known as "ICD10". Procedures are coded using a system designed by the Office of Population Censuses & Surveys (OPCS - now the Office for National Statistics or ONS). The series used in hospitals in England during the period of the Inquiry is the version known "OPCS4". Currently HES data comprise some 11 million records per financial year, collected from over 400 hospitals.

2.20 The HES system aims to capture 100% of all inpatient clinical activity in England. While there is a strong management expectation that they will participate, there is no legal obligation on hospitals to submit data for the system. The NHS Executive encourages Trusts to include responsibility for supplying statistics in the list of objectives of their Chief Executives.

2.21 HES replaced a more limited system of hospital activity data collection, the Hospital Inpatient Enquiry [HIPE - see Annex 1], which ceased in 1985. The changeover between the two systems caused disruption in routine data collection for several years. Data continued to be collected regionally but were not reported nationally between 1986 - 1988 and have been archived. Data quality during this period is considered to be poor, with coverage, completeness and accuracy all adversely affected. HES data quality is widely considered to have improved significantly after 1991, following the NHS reforms, when hospitals had a better incentive to collect good information for finance and contracting purposes. IBM also took steps to verify, clean and validate each submission after this date.

2.22 The Inquiry has commissioned Imperial College School of Medicine to review HES data quality as well as to analyse relevant HES data for the period April 1991 - March 1996. This work, currently in progress, indicates that the vast majority of fields were complete with 100% for gender, age at start of episode, postcode

and admission date. Primary diagnosis fields were 98% to 99% complete. Specific examination of hospital episode data for children below 16 years suggests a similar level of completeness.

2.23 As mentioned above, the changeover from the previous system compromised data quality across the board up to 1990/91 so that the datasets for the years between 1987 and 1991 did not capture all clinical activity in England.

2.24 As a check on accuracy, hospitals are required to submit paper counts of in-patient episodes (called KP70s), which should be collected independently from the HES counts. The purpose of KP70s is to validate the HES returns, that is, to show the extent to which HES fulfils its aim of capturing all FCEs. Although practice is changing in the NHS, during the years of the Inquiry for most hospitals the KP70s were based on a headcount of patients taken nightly at midnight.

2.25 The Department of Health uses the KP70s as the “gold standard” totals against which HES totals are compared. A correcting procedure (called “grossing”) is applied to the published HES tables. KP70 and HES figures are compared by consultant specialty and by patient classification, and grossing is applied selectively to help ensure consistency and comparability across the whole database. The comparability of KP70 and HES data returns has been erratic and, though it appears to have been improving, studies have thrown some doubt on the independence of the mechanism for KP70 collection.

2.26 HES data accuracy depends in large part on the process of assigning clinical codes to each FCE. HES data is only as good as the data collected at the hospital level for each hospital’s own patient administration or information system, and commentators have noted that the accuracy of clinical coding, whilst improving throughout the 1990s, had shortcomings in the early years of the HES system. (For example, an audit by the Avon Health Authority in 1993 of clinical coding at the United Bristol Healthcare Trust showed that of 77 records checked, 47 had coding errors.)

2.27 Clinical codes are assigned to a patient’s episode of care after the patient has been discharged. The data items are recorded for entry on to the hospital’s own computerised Patient Administration System or Hospital Information System by trained clinical coders working from either patient notes from the ward trolleys, or discharge summaries. The coders are administrative staff, who are rarely supervised by clinicians. Professional qualifications for coding staff were rare during the years of the Inquiry and are only now being introduced.

2.28 The Department of Health annually publishes HES reports presenting data on FCEs by diagnosis, operation, and specialty. Tables on waiting times for elective operations are also produced. Figures are presented by region and codes are used for diagnoses and procedures. The published reports are widely distributed within the NHS and are publicly available for purchase through The Stationery Office.

2.29 Access to HES data extracts is also available to hospitals, health authorities and academics for research purposes. Applicants for access must apply through the NHS Security and Confidentiality Advisory Group

which is charged with ensuring patient confidentiality and proper use of patient information. HES provides a valuable source of comparative data for specialties across the country.

Potential value to the Inquiry

2.30 Evidence available to the Inquiry to date indicates that HES data quality for the earlier years of the Inquiry period is too poor to be usefully analysed. For 1991/92 to 1995/96, HES data quality is better, and the Inquiry has therefore commissioned statistical analyses of HES data on paediatric cardiac surgery for this period. As a national source of hospital activity data, the primary value of HES is that it will allow, within the limitations of data quality, for comparisons of the nature and outcomes of the children's heart surgery between Bristol and specialist centres elsewhere in England, as well as for comparisons with UK Cardiac Surgical Register data. Due to the complexity of this analytical work, results are not expected before the autumn.

South West Congenital Heart Register

2.31 The South West Congenital Heart Register is a computerised information system established and maintained by consultant cardiologists at the Bristol Royal Infirmary/Bristol Children's Hospital throughout the period of the Inquiry. Limited evidence available to the Inquiry to date suggests that the system was designed to allow the cardiologists ready access to essential summary information on patients when clinical records were unavailable, for audit purposes, and to facilitate presentation of clinical data at meetings. Evidence suggests that all the cardiologists had access to the data, and other clinicians involved in cardiac services potentially had access.

2.32 The Bristol and South West Children's Heart Circle provided funds for the hardware and software. The current version is held on a personal computer using Borland Paradox software. Most of the data were entered by a secretary working for the cardiologists.

2.33 Data were apparently recorded on all patients from the South West region, with any form of organic heart disease, seen by any of the cardiologists from Bristol. This included patients seen at peripheral clinics. Patients from Wales were entered if treated at Bristol. The system provided for 97 data items on each patient, covering personal details, family history, details of the mother's pregnancy, the patient's birth, diagnosis and medical history including post mortem information. Two items pertained to disease and status assessment by the clinician, and other items were drawn from the hospital notes. Statements have been requested from the Bristol cardiologists.

Potential value to the Inquiry

2.34 Early indications suggest this data source is of potential value to the Inquiry.

The Inquiry holds an electronic copy of Register data, and plans are in hand to commission an independent review and statistical analysis of these. A full assessment of Register data quality is likely to involve cross-comparisons with other relevant data sources insofar as this is feasible.

United Bristol Healthcare Trust Patient Administration System

2.35 Computer systems for processing information about patients have existed in the Bristol area since 1964. The current United Bristol Healthcare Trust Patient Administration System [PAS] was established with the purpose of tracking hospital activity and forms the basis for HES returns to the Department of Health. Since

the advent of the NHS internal market in 1991, the PAS has been used as the primary source of information for contracting purposes. The PAS is not designed as a clinical information system, nor as a source of clinical or medical audit data on quality of care.

2.36 The PAS is a case-based information system for all patients in all UBHT hospitals, and the basic unit of PAS data is the FCE. Basic demographic data (including date of birth, age, gender, and address) are recorded, and a record of diagnoses, operative procedures, and dates of admission and discharge is built up during the stay in hospital. Information on clinical outcome is limited to death, including date of death where this is known. Deaths occurring outside hospital are retrospectively recorded in some cases. There is no recorded information on the exact clinical condition of the child, but the main factors – age, diagnoses, and type of operation planned – are recorded.

2.37 PAS data on children receiving paediatric cardiac services are not available for the whole of the period covered by the Inquiry, but only from 1 January 1988 to 31 December 1995. The PAS is an information system designed to meet administrative, planning and contracting purposes. It was not used for clinical purposes at the time and the usefulness of PAS data for clinical or medical audit relevant to adequacy or quality of care is therefore limited. Nonetheless, preliminary analysis of PAS data suggests that it has some potential for audit of outcomes.

2.38 All the PAS data, including those on children within the terms of reference of the Inquiry, were generated through coding of clinical records carried out by administrative 'clinical coders' using standard classification and coding systems for diagnoses (mainly ICD-9) and procedures (mainly OPCS-4) - see para 2.19 on HES data. PAS data quality therefore depends to a large extent on the quality of clinical coding and data entry. Shortcomings in the completeness and accuracy of diagnostic and procedural coding can arise where clinical information recorded in the clinical record is unclear, misunderstood by the coder, or not amenable to standard classification or coding. UBHT have formally stated to the Inquiry that the coding of diagnoses and procedures was unreliable prior to the introduction in the early 1990s of the SwiftOp electronic system for recording discharge information. One interesting feature of the Bristol PAS is that it appears to contain information about mortality where death occurred some considerable time after discharge from hospital

Potential value to the Inquiry

2.39 UBHT-PAS data quality appears provisionally to be good. At this stage, it seems that the primary value of PAS data to the Inquiry will be as a source of descriptive information on children receiving heart surgery at Bristol from 1988 onwards, and as a means for cross-validation of other sources of patient information, e.g. the clinical coded records and the surgeons' logs (see below).

Clinical Records

2.40 Clinical records, which record the personal details and treatment of individual children are obviously of prime importance to the Inquiry. The Inquiry requested access to the UBHT clinical records of all children who had received an open or closed cardiac surgical procedure within the terms of reference of the Inquiry. The clinical records discovery process has been detailed in a formal statement to the Inquiry provided by John Gray, Manager of Legal Services at UBHT [statement WIT 137]. The Inquiry is not currently seeking children's

clinical records from GPs or referring hospitals; the terms of reference require an examination of the service provided by the Bristol Royal Infirmary and the Bristol Children's Hospital and not the full care delivered to the children by the NHS generally.

2.41 The Inquiry accepts that the UBHT has made extensive efforts to ensure that the correct records have been submitted to the Inquiry and the Trust is continuing to co-operate in this exercise. Inevitably in such a complex process, discrepancies will arise, such as records being submitted which are outside the terms of reference or the names of children coming to light for whom the Inquiry does not have clinical records. It is important to note that the number of actual sets of clinical records will inevitably be slightly less than the number of procedures performed, as some children had two or more procedures within the Inquiry period. The process of checking and verification against the PAS, Surgeons' logs and other logs will continue in the coming months. Nevertheless, the Inquiry considers it now holds the vast majority of the relevant clinical casenotes, currently of 1808 children who fall within the terms of reference.

2.42 A wide range of information is contained within the clinical records; they consist of letters, records and clinical information compiled by UBHT clinicians and referring clinicians. All the clinical records submitted to the Inquiry have been scanned into a computer system and are available to the Inquiry under conditions of strict confidentiality; the originals have been returned to the UBHT.

2.43 To facilitate analysis, the Inquiry arranged for summary data to be clinically coded afresh and extracted from each set of clinical notes. The result is a *new* database, referred to by the Inquiry as the Clinical Coded Records dataset. The purpose of this exercise was to facilitate a simple descriptive analysis of the children and the care they received, and to enable selection of a fair and representative sample of cases for the purpose of detailed expert review to assess adequacy of services.

2.44 The Clinical Coded Records [CCR] dataset was compiled as follows. Under the supervision of the London Central Clinical Coding Co-ordinator, the Inquiry assembled a team of experienced clinical coders in London in the spring of 1999. The team worked systematically through each set of records submitted to the Inquiry. Where a child had notes from both the Bristol Royal Infirmary and the Bristol Children's Hospital, which was the case for nearly all who had open heart surgery, these were considered together. Information was captured on a standard form designed specifically for this purpose and subsequently entered on to an Inquiry database. Coders recorded demographic information i.e. name, date of birth, gender, hospital record numbers, and clinical information, including diagnoses, operative procedures with dates, and surgeons' names, whether the child is alive or not according to the clinical record, date of death and whether or not a post mortem took place. Diagnoses and operative procedures were clinically coded using the clinical coding classifications applied to the UBHT PAS and to HES i.e. ICD9 for diagnoses and OPCS4 for operations (see paras 2.19 and 2.38 above).

2.45 The CCR dataset is more extensive chronologically than the PAS in that it captures information about children for the entire 12 year period of the Inquiry. The information captured on the CCR dataset is similar to that held by the PAS system but the Inquiry's re-coding may result in different clinical codes being assigned to the same case. There is a minor discrepancy between the individual cases covered by the CCR and those

recorded by the PAS for the years 1988-1995. The Inquiry is investigating the reasons; one explanation may be that the PAS data includes information about children who were referred for surgery but did not receive it for whatever reason, whereas the CCR is based on records of those children who actually received surgery.

2.46 According to the Inquiry's clinical coding team, the Bristol notes compare favourably with other acute NHS Trust clinical case notes. Overall, the content of the Bristol clinical case notes is complete and of high quality, with operation details particularly well-documented. Minor weaknesses include occasional incomplete recording of matters such as admissions data, events occurring in the operating theatre, deaths and post-mortems. There are also a number of incomplete UBHT coding sheets for congenital cardiac diagnoses and procedures.

2.47 The Inquiry's clinical records coding exercise was undertaken by experienced clinical coders, working solely on the Bristol children's records over a concentrated period of two months. The clinical coding team coded procedures directly from the operation note whereas it is routine practice in many parts of the NHS to code such information from the abbreviated discharge summary or the discharge letter. These factors lend strength to the CCR as a data source to describe surgical activity. There may be minor errors in subjective coding and data entry but the Inquiry sought to minimise these by validation checks. The quality of the clinical records themselves, although generally good, was variable, and there may be incomplete recording within the clinical record of deaths which occurred after discharge from hospital.

Potential value to the Inquiry

2.48 The clinical records form the most comprehensive source of data available covering the whole period of the Inquiry. Despite some minor shortcomings in data quality, their potential value to the Inquiry is considerable both as a source of summary descriptive information on all children falling within the Inquiry's terms of reference, and as a sampling base from which the Inquiry intends to select a fair and representative sample of cases for in-depth clinical case review to help assess adequacy of cardiac surgical services.

Surgeons' Logs

2.49 Personal surgical logs were kept by BRI surgeons throughout most of the period covered by the Inquiry. The Inquiry currently holds two sets of surgeons' logs. One set of logs, kept throughout the Inquiry period, covers open heart surgery for all age groups and all types of congenital and acquired heart conditions. The second set covers the period from 1 January 1986 to the end of 1995. Both sets of logbooks contain a summary of information recorded in the operation notes held in the patient's medical record. The format provides for entries of the patient's personal details, diagnosis, proposed operation, pre-operative condition, post-operative condition and complications, discharge note, and follow-up or post mortem as appropriate. In the main, logbook entries were dictated to and subsequently typewritten by the surgeons' secretaries, though in some instances they were completed directly by the surgeon.

2.50 In recent written evidence to the Inquiry the logs are described as being intended to meet several purposes: for example, to provide a complete record of all patients on whom the surgeon had performed open heart surgery; to facilitate preparation of the annual statistical summary and annual returns to the UK Cardiac Surgical Register; to facilitate report preparation; to provide data for formal and informal audit of patient

groups; to provide a quick reference for personal audit of open-heart operations; to facilitate recognition of problems at an early stage; and to facilitate identification of priorities for clinical research [statements (1) Mr Dhasmana WIT 84 pages 1-5; (2) Mr Wisheart WIT 120 pages 255-262].

2.51 Preliminary assessment of the surgeons' logs by the Inquiry - based on formal written evidence and initial examination of the logs - suggests that data entry was variable in completeness and quality, and that data validation was not always systematically carried out. This is consistent with what might reasonably be expected of a log system voluntarily kept for personal use by the surgeon and does not necessarily reflect criticism of the way in which the logs were kept.

Potential value to the Inquiry

2.52 Preliminary assessment of the surgeons' logs indicates that they are of potential value to the Inquiry. The Inquiry has therefore undertaken a clinical coding exercise to extract summary information from the surgeons' logs and these clinically coded data will be analysed. The clinical coded data will be used alongside other data sources to help build up – as far as possible within the limitations of the data – a picture of the nature and outcomes of children's heart surgery at Bristol.

3. Summary and Early Implications

3.1 In summary, this paper has outlined - for the purpose of consultation - the purpose and content of six data sources that appear to be of key relevance to the Inquiry's remit, together with a preliminary overview of data quality, and arrangements for analysis, reporting and dissemination, insofar as such information is available. A number of further data sources of potential relevance to the Inquiry's remit have been identified and work is currently in hand to reach a preliminary assessment of the potential added value of these sources. The paper reports on work in progress and therefore is provisional.

3.2 Early implications emerging from work undertaken by the Inquiry to date include the following:

- (i) it appears feasible to analyse data from all the key sources outlined;
- (ii) there appear to be significant shortcomings in data quality for most of the key data sources;
- (iii) it is crucial, therefore, that any data analyses should be set in the context of a critical review of the strengths, weaknesses, and limitations of the data source;
- (iv) the potential value of two of the key data sources outlined in contributing to an understanding of the nature and outcomes of the children's heart surgical service at Bristol compared with elsewhere is such that the Inquiry considers further work to analyse the relevant data is fully justified;
- (v) although the comparability of the data sources appears limited, added value is likely to be gained by using these data sources as a means for cross-validating the results derived from each.

3.3 To date, the Inquiry has commissioned independent analysis and research to review data quality critically and to deliver statistical analyses of relevant data extracted from the following sources: Hospital Episode Statistics (1991-96), the UBHT Patient Administration System (1988-95) , and the clinical records (1984-95). Work is currently in hand to commission similar analytical work in relation to the following sources: the UK Cardiac Surgical Register, the South West Congenital Heart Register and the surgeons' logs. Due to the complexity of the analytical work involved, results are not expected before the autumn.

3.4 Work to reach a preliminary assessment of other data sources of potential relevance to the Inquiry's remit will continue. However, early indications suggest that the potential added value of other data sources, if any, will be as a means to further cross-validate data derived from the key sources outlined above.

3.5 Comments on this preliminary overview paper are welcome. In particular, the Inquiry is interested to seek views on:

- (i) any gaps or shortcomings in identified data sources;
- (ii) the priority that should be attached to analysing specific data sources;
- (iii) implications of any shortcomings in data quality for reaching conclusions about the nature and outcomes of children's heart surgery at Bristol.

BRI INQUIRY SECRETARIAT

July 1999

Additional Data Sources of Potential Relevance to the Inquiry's Remit

The Inquiry is aware of a number of additional data sources of potential relevance to the Inquiry's remit. The Inquiry is currently in the early stages of assessing their potential relevance and value but early indications suggest that acquiring and analysing these data is unlikely to add much value to the Inquiry's analytical work already in progress. Where sufficient justification exists, the Inquiry will take steps to acquire and analyse relevant data as a means of further cross-validation of the key data sources outlined earlier.

The additional sources of data include the following:

Cardiologists' Card Index System

A card index system containing brief details of children with heart disease was kept by the cardiologists at the Bristol Children's Hospital throughout the period of the Inquiry. The system was used for quick reference and research purposes. The cards recorded brief personal details, diagnosis and proposed treatment of children seen by the cardiologists at the BCH and at peripheral clinics. They are in alphabetical order by patient and contain details of children who required heart operations. They contain information which is also found in hospital notes. There are eight drawers of cards accessible to the Inquiry .

Operating Theatre Logs

Operating theatre logs in bound books were kept at the BRI throughout the Inquiry period. These are a record of activity in the operating theatres in date order. The patient's hospital number, name, age, date of operation, procedure, the roles and signatures or names of health personnel involved were noted. Operation duration or time under anaesthetic was often recorded and, on occasion, the entry "DOT" (died on table) with a corresponding time appears.

Clinical Perfusionists' Records

Clinical perfusionists manage heart-lung and other machines to ensure an adequate supply of blood to patients during cardiac and other major surgery. The clinical perfusionists at Bristol Royal Infirmary kept a register in bound logbooks of operations in which they took part during the period of the Inquiry. This provides what appears to be a relatively comprehensive and accurate record of operations for adults and children requiring cardiopulmonary bypass. The patient's hospital number, name, age, surgeon, operative procedure and date of operation are noted in early logs. From late October 1991, cases were identified in the log by a computer label which also gave the patient's address and date of birth. This allowed space for comments which give more detail of the operation and note when the lead surgeon was not the consultant. At the end of each volume there is a breakdown of cases by type of procedure.

Anaesthetists' Logs

To date, the Inquiry has acquired copies of the personal logs kept by two anaesthetists at UBHT during the Inquiry's period. One of the logs covers all anaesthetic work carried out by the two clinicians, not just cardiac surgery, the other is incomplete. The logs provide personal details of the patient, American Society of Anesthesiologists' risk grade, operation, method of anaesthesia, the name of the surgeon and comments. The Inquiry is in the process of clinically coding the logs to allow simple descriptive statistical data analysis.

Bristol Cardiac Surgeons' Systems - METASA & PATS

Information available to the Inquiry to date indicates that a computerised register of patient data was kept by Bristol cardiac surgeons on a personal computer using software from a company called "Metasa". This was discontinued in 1992 and the whereabouts of the information is presently unknown. A computerised Patient Analysis and Tracing System (PATS) succeeded the "Metasa" system. [statements (1) Mr Dhasmana WIT 84 pages 6-13, (2) Mr Wisheart WIT 120 page 263]. This was set up so that clinicians could themselves enter information into the computer as the patient's treatment progressed. Evidence available to the Inquiry to date indicates that records for the period 1992-5 were incomplete. Apparently data quality improved when the system was relaunched in 1996 with a paper-based data entry system and full-time clerical and technical support. The Inquiry holds PATS data in electronic format for the period 1992-5.

NHS Regional Data Archives

During the period 1991-5, in the former South Western Region of the NHS, minimum datasets from provider units such as the UBHT were collected and held by a clearing house under the management of the Regional Computing Centre. These were detailed, patient-specific datasets collected for regional management purposes. An extract from these data was supplied to the Department of Health, in an adjusted form, for the national Hospital Episode Statistics. A private contractor, EDS, has taken over the work of the Regional Computer Centre and holds archived regional data covering the period 1991-5.

Hospital In-Patient Enquiry (HIPE)

The Hospital In-Patient Enquiry was the national data system for recording hospital activity that preceded the HES system (see section 2.2 above). It was in operation for only one year of the period covered by the BRI Inquiry, 1984-5. HIPE was based on a random 10% sample of hospital activity data on deaths and discharges collected on a regional basis from all hospitals in England. The system did not have the capacity to pick up re-

admissions for the same patient and the 10% sample means that the data relates to small numbers. Published tables based on HIPE data do not relate to the Inquiry's terms of reference. HIPE data are owned and archived by the Office for National Statistics. Expert information available to the Inquiry to date points to significant shortcomings in data quality and indicates that data retrieval and analysis would be difficult, of little value and costly.

Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI)

The Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) was established in 1992 to improve understanding of how the risks of death in late foetal life and infancy, from 20 weeks of pregnancy to one year after birth, might be reduced. CESDI attempted to identify risks which can be attributed to sub-optimal clinical care. CESDI covered England, Wales and Northern Ireland. CESDI is a voluntary data collection system but for completeness compares well with the compulsory ONS death register: CESDI figures for stillbirths and deaths in infancy were 7.3% fewer than ONS figures in 1993 and 4% fewer in 1995. Mortality rates by region are published annually. Investigations have been conducted into unexpected deaths and stillbirths, focusing on management of the delivery in different circumstances and on resuscitation of the child in emergencies.

National Confidential Enquiry into Perioperative Deaths (NCEPOD)

NCEPOD is an independent body set up in 1988, funded by Health Departments and independent sector hospitals, and supported by all the relevant Royal Colleges. It collects data on deaths occurring in hospital within 30 days of a surgical operation, in order to review clinical practice and to identify remediable factors in the practice of anaesthesia and surgery. It considers the quality of care rather than the cause of death. Reports on overall mortality and detailed analyses of selected priority areas of surgical activity are published annually [statement WIT 68].

Basic details are collected through a system of voluntary local reporting. Each year, for a priority area of surgery, a follow-up questionnaire is sent to relevant consultants for the purpose of more detailed investigation or analysis. Data reported on 30-day deaths is not validated and participation by clinicians is voluntary. Clinicians are aware that data is used only to produce the annual report and is then destroyed. Completeness of consultants' questionnaires has varied between regions and over time.

In 1989, the selected priority area of surgery for detailed investigation related to consultants' paediatric practice, in terms of how many children aged 10 years and under they operated on/anaesthetised per year. In 1989, of the 417 children who were reported to NCEPOD to have died, 266 were under the care of cardiac surgeons.

National Reporting System for Congenital Anomalies

The Office for National Statistics (ONS) runs this system covering England and Wales, which was set up in 1964 for collecting data on congenital anomalies following the Thalidomide disaster. It was implemented to monitor statistically significant changes in congenital anomalies in order to detect other hazards more quickly. Its purpose is not to record the national prevalence of particular anomalies, though it is probably the best available data source on prevalence of anomalies for England and Wales. Until 1990, anomalies apparent in the first seven days of life were notified and from 1990-95 those apparent in the first ten days of life were included (since 1995 there has been no time limit on notifications). There is no statutory obligation to provide data and collection depends on co-operation from local NHS community trusts. ONS takes steps to check completeness and accuracy of information on certain conditions but accuracy of the data overall is unknown. The Inquiry understands from ONS that during the period 1984-95, congenital cardiac anomalies were under-reported.

Register of Deaths

The Register of Deaths maintained by ONS has recorded all deaths in England and Wales since 1838. Information available to the Inquiry to date suggests that Register data may be of potential value in helping to identify deaths occurring following discharge from hospital.

Other data sources

Other data sources of potential relevance to the Inquiry's remit include operation notes, discharge summaries, surgeons' yearbooks, local audit data, performance data from other specialist centres in paediatric cardiac surgery and the NHS Central Register. The Inquiry is currently in the early stages of assessing the potential added value of these data sources.

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