Statement of evidence by James D Wisheart on:

Issue J

Post-Mortems and Inquests

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INTRODUCTION

This evidence is written from memory and without guidance from the Inquiry on documentation considered to be relevant to the Issue.

The Bristol Royal Hospital for Sick Children shall be referred to either as BRHSC or the Children's Hospital.

J1 – THE NATURE AND EXTENT OF THE RESPONSIBILITIES OF (A) HOSPITAL STAFF; (B) HOSPITAL PATHOLOGISTS; (C) H M CORONER TO REPORT AND INVESTIGATE DEATHS.

A RESPONSIBILITIES OF HOSPITAL STAFF

- In most circumstances when a death occurs its cause is known, the causes are natural and it is possible for the attending doctor to provide a death certificate and in these circumstances the matter does not need to be reported to the Coroner.

- In circumstances where the cause of death is not known, a death certificate cannot be provided and the death must then be referred to the Coroner who will either accept it for investigation or not. In the latter case he may advise the attending doctor to issue a death certificate.

- If a death should occur at or shortly after a surgical operation or general anaesthetic, in principle questions could arise as to whether all the treatment provided was appropriate or not. In these circumstances the death must be referred to the Coroner who in nearly all cases will accept the case for further investigation. Occasionally he may advise the attending clinician to issue a death certificate.

- It was my practice to refer to the Coroner all patients who died after surgery while still in hospital, regardless of the length of the interval between the operation and the death. In nearly all instances he accepted the case for investigation but on a few occasions he advised me to issue a death certificate.

- It is my belief that any member of the hospital staff may report a death to the Coroner if they consider that there was the possibility that the death was not by natural causes or may have occurred for any unlawful reason.

B THE RESPONSIBILITIES OF THE HOSPITAL PATHOLOGIST

- The hospital pathologist may by the nature of his work be in possession of information which may either cast light upon or raise questions about the cause of death in any given patient. It will be his responsibility to report such a question to the Coroner.

C THE RESPONSIBILITY OF THE CORONER

- It is the responsibility of the Coroner to initiate an investigation into a death either if the cause of death is not known or if it is suspected that the death may have occurred for an unlawful reason.

J2 – THE FUNCTIONS OF POST MORTEMS AND INQUESTS IN HELPING TO ESTABLISH THE CAUSE OF DEATH OF A CHILD OR THE ADEQUACY OF THE SURGICAL OR OTHER SERVICES PROVIDED

1 INQUEST

In the event of an inquest taking place the post mortem findings will be part of the evidence put before that hearing. Together with the clinical information the post mortem findings will clearly play a key part in assisting the inquest to reach a view on the cause of death and the adequacy or otherwise of the treatment provided for the child. I have only ever attended one inquest and therefore, it is for others to describe and define the role of the inquest itself in establishing the cause of death and the adequacy of treatment.

2 POST MORTEM

2.1 A complete description of the function of a post mortem should be provided by a pathologist who is the expert in this area.

2.2 To a clinician its role includes the following:

2.2.1. Examination of the structures of the organ of the body by naked eye.

2.2.2. Examination of the structure of the organs of the body using the microscope or the electron microscope.

2.2.3. The bacteriological, biochemical, toxicological, or other forensic investigations of tissues and tissue fluids.

2.2.4. Techniques which shed light on more transient patho physiological changes which do not result in gross structural alterations are at a developmental stage.

2.2.5. A report is provided on all the post mortem findings.

2.2.6. The clinician may be able to attend the post mortem and, therefore, work with the pathologist at that point. However, he may not always be able to do so because of other commitments. A meeting, therefore, may be held at which the pathologist and the clinician can discuss together all the findings relating to the case and the unfortunate death. Such meetings were Clinical Pathological Conferences in our practice, and in more recent years constituted part of our audit activities.

2.3. The range of possible events which can cause or contribute to death is very wide; not all such events and the mechanisms by which they cause death are fully understood. The following are simply examples of some events which can lead to death to illustrate their differing characteristics in relation to findings at post mortems examination.

2.3.1. A grave technical error or omission by the surgeon or anaesthetist which is visible to the naked eye.

2.3.2. A post operative event such as bleeding which may be demonstrated from a combination of clinical and autopsy findings.

2.3.3. An additional abnormality of the heart or other organ which had not been known beforehand and which may cause or contribute to death and which is found at post mortem.

2.3.4. A secondary consequence of the known abnormality of the heart which may be more severe than previously thought. For example pulmonary vascular disease; or altered myocardial structure such as hypertrophy, dilatation or fibrosis.

2.3.5. A post operative abnormal heart rhythm relating to which it is possible that no structural abnormality will be identified either by naked eye or microscope. In such circumstances the post mortem will fail to identify the cause of death.

2.3.6. When postoperative infection occurs its extent and consequences may be demonstrated at post mortem; but the underlying causes of or predisposition to the infection may well not be demonstrable.

2.3.7. Transient biochemical changes (for example altered pH, potassium levelsor blood sugar levels) may lead to death. These altered levels may be obscured at post mortem by the subsequent events which preceded the death so that the actual abnormality may never be identified.

2.3.8. Respiratory complications may be of great importance and in general will be identified as structural changes in the lungs.

2.3.9. A hypoxic event which if it leads rapidly to death (for example by causing a dysrhythmia) may leave few structural clues as to its presence or causation.

2.3.10. A small amount of blood may be found in the pericardium following surgery but whether or not it led to death may be impossible to say.

2.4. These illustrations are intended simply to show that the post mortem may demonstrate a cause of death, a contributing factor to death or neither. Thus it is sometimes, but not always helpful.

2.5. These illustrations also show that a post mortem may demonstrate a surgical error or a diagnostic inadequacy if either is present. The meeting with the pathologists (the clinical pathological conference) is of great educational value in such circumstances and I would like to acknowledge the contributions of Professor P J Berry, Dr M Ashworth and Dr H Porter to these meetings which have undoubtedly added to our knowledge and enabled us to improve the quality and standards of our subsequent work.

2.6. I can only recall one inquest on a child under my care following cardiac surgery during my time at Bristol. The point at issue in that case was the possibility that a packet of plasma given to the child had been infected, leading to overwhelming septicaemia and death.

J3 – THE EXTENT TO WHICH POST MORTEMS AND ANY INQUESTS HELD UPON CHILDREN WHO DIED FOLLOWING COMPLEX CARDIAC SURGERY IN THE BRI PERFORMED SUCH A FUNCTION.

1 INQUESTS

There were so few that for us they did not perform such a function or contribute to our understanding of the causes of death.

2 POST MORTEMS

- I cannot provide a precise quantitative analysis of how frequently post mortems contributed to a better understanding of the cause of death.
- The pathologists are probably in a better position to do this.
- My estimate (and it is no more than that) is that in deaths following surgery for congenital abnormalities the post mortems contributed to our understanding in less than half of such patients.

J4 – WHETHER CONSENT (IF REQUIRED BY LAW) TO: (A) HOSPITAL OR CORONIAL AUTOPSY; AND/OR (B) THE RETENTION OF TISSUE AND/OR ORGANS OF THE BODY WAS PROPERLY AND SENSITIVELY SOUGHT; AND, IF CONSENT WAS NOT REQUIRED, WHETHER PROPER AND ADEQUATE INFORMATION ABOUT THIS MATTER WAS GIVEN TO PARENTS, IN AN APPROPRIATE FASHION.

A HOSPITAL OR CORONIAL AUTOPSIES

1 Hospital Autopsies

It is my understanding that consent was required for a hospital autopsy at all times during the time under review by the Inquiry. In my surgical practice a hospital autopsy was relatively rare. When the need arose I explained to the family that such an autopsy might give us information concerning the cause of death which would help and enlarge our understanding; thereby it would increase our knowledge for the future. I personally always sought consent explicitly on the basis that once I had stated my reasons for requesting permission for a post-mortem the decision of the family would be final without any further discussion of the subject.

2 Coroner's Autopsy

When the Coroner accepted the referral of a patient's death for investigation and decided to do an autopsy my understanding was that consent was not required and that neither the family nor myself could influence the decision of the Coroner.

As far as was humanly possible I personally met with the parents following the death of a child and usually did so with a senior nurse or a counsellor. I did not consider that this duty should be delegated to a junior colleague if I could do it myself. At such a conversation I informed the parents about the events that had led to death and that the death was being referred or reported to the Coroner. I went on to explain that the Coroner would make the decision about a post mortem and it would be his decision alone. (I know of one instance where the family made representations to the Coroner that there should not be a post mortem, which he accepted.) I hope that I undertook this duty in a 'proper and sensitive' manner.

B THE RETENTION OF TISSUES

1 At a Hospital Autopsy

- Whilst it was not clear whether or not consent was needed I did know that there was provision in the BRI's autopsy consent form for obtaining consent for the retention of organs and that this clause was used.

2 Coroner's Autopsy

- Once the patient's death had been reported to the coroner, the matter was out of my hands. The decision to carry out an autopsy, and any consequences of that, was not within my sphere of control.

- To the best of my knowledge the practice of retaining organs following post mortems was widespread, if not universal, in the UK.

- It was not my practice to seek consent for retention of the heart after a coroner's autopsy. I did not feel that it was appropriate to add to the anguish of the parents by asking for permission to keep their child's heart for scientific purposes.

- The beneficial purpose of the practice of organ retention is so that the clinical team, together with the pathologist, can review all the circumstances leading to the death of the patient, and learn from them. The importance of the clinico-pathological conference in our audit programme has been referred to. (see also J2: 2, 2.2.6).

- I have to say that there was very little, if any, guidance on this issue from the legal or ethical authorities.

Signed:

Date: 29th June 1999

STATEMENT BY JDWISHEART, CONCERNING THE SURGEON'S LOG WHICH HE MAINTAINED.

This statement answers the questions set out in Annex A to Mr PFO Whitehurst's letter of May 14th, 1999.

Introduction.

In the centre in the United States, where I spent one year during my training in 1971/72, the computer capability of the day was already established. Records of the operations carried out were stored and were accessible for review and study. It seemed to me that it was right to collect data and to have it available in this way.

When I came to Bristol in 1975 there were no computers, the term 'Audit' had not been used in this context, there was no obligation to keep records and no encouragement to do so within the NHS. However I felt that it was right to keep a record and I did so, for all open heart operations carried out on patients under my care in Bristol. I adopted a simple manual method with the help of my secretary. It had the advantages of being within my possession, (i.e. in my hospital office), accessible, highly reliable and because of the way that it was set up it was both functional and effective. I regarded it as a highly positive part of my practise, long before "audit" was proposed. It has continued to be very useful, although today there are better methods of achieving this objective.

1.The primary purpose for which data was logged

The log was kept so that I would have a record of all the patients on whom I had performed open-heart surgery. This was commenced in 1975 and was continued throughout my consultant career.

2.Additional purposes for which the data was logged

The log was an immediately accessible source of information about the patients on whom I had operated, and was used for purposes such as:

a) the preparation of the annual statistical summary,

b) the preparation of my contribution to the Department's returns to the UKCSR from 1977 onwards.

c) the preparation of any other report of work done, which was requested from time to time.

d) the purposes of formal or informal audit, or review, of any group or sub-group of patients.

3.The process used to log the data

The operation note was dictated following the completion of the operation. At the end of that note I dictated the additional information needed for the secretary to make an entry into my log. If the operation was performed by my senior registrar or registrar, and therefore the note was dictated by him, either he would dictate the additional information or else my secretary would seek it from me subsequently. For logging events subsequent to the operation such as postoperative complications, death, autopsy findings and follow up information, this was dictated by me, to the secretary when such information came to hand. I would wish to point out that the record of postoperative complications and follow up information was not well maintained, nor relied upon.

4.The scope and coverage of the log

Scope.

The log covered all open-heart surgery in all age groups and for all types of acquired and congenital conditions. It did not include closed heart surgery.

Coverage of the log.

The initial intention of the log was quite ambitious and its scope included:

a) demographic data.

b) diagnostic data..

c) details of the operation.

d) details of the preoperative catherisation findings.

e) post operative haemodynamic pressures.

f) post operative complications.

g) drugs on discharge.

h) follow up information.

i) notes of any particularly important events

j) a "shorthand code" was used to simplify the entry some of the data.

With the passage of time however, these goals were not all maintained, so that for the greater part of the period in question the information was confined to the demographic data, the diagnostic data, the operative data, the post operative haemodynamic findings and the condition

on discharge or death. The Autopsy findings were consistently entered.

5.The Content of the data logged, in terms of data items and the definitions. Please identify any changes in data items or definitions over the period.

- Classification was by diagnostic group similar to UKCSR (the beginning of this log pre-dated UKCSR)

- The demographic data was name, age, gender, hospital number, and weight in kgms. The age was given in years, unless the patient was around or below one year in which case it was given in months, and this is indicated by X/12.

- The diagnostic data was given and inevitably abbreviations were used.

- The operative data includes two dates; the earlier date was the date on which the patient's name was put on the waiting list and the later date was the date of the operation. There is then the title or very brief description of the operative procedure.

- Operative technique usually refers to the use of cardio-pulmonary by-pass (CPB), the use of cardio plegia (CP), topical hypothermia (TH), and or circulatory arrest (CA).

- The catheter and angio-graphic data has not been consistently entered during the period in question, but where it is present it consists of listing the pressures within the chambers of the heart, the oxygen saturation within various parts of the heart, and a free text description of the angio-graphic findings.

- Post operative pressures are the pressures in various chambers of the heart which are relevant either to the technical adequacy of the correction or to the adequacy of cardiac function at the end of the procedure.

- Postoperative complications are listed either by full text or by a code which is listed in full in each section of the log.

- If the patient died, there is usually a free text description of the post operative course together with summary of the findings at autopsy, which are based on either attendance at the autopsy, the autopsy report or the clinico-pathological meeting.

- The follow up information was not regularly maintained.

6.The data validation (if any) carried out, and by whom.

There was no formal data validation carried out. I from time to time, in reviewing data, identified errors of omission or commission and dealt with them. The most common error was that the patient was entered under the wrong diagnostic category.

7.The Completeness and quality of data logged. This should include, as far as possible, an overall statement on completeness and quality together with a statement for each year and whether this affects trends.

I believed that the log was complete and accurate as possible. In preparing my own data for this inquiry I have identified the omission of two patients out of a total of approximately 820 operations for congenital abnormalities in the period 1984-1995. I believe that the quality of the data in the log is high but I would never claim that it is perfect. In preparation of my data for this inquiry, I have discovered one early death that had not been noted out of approximately 820 operations. I would not regard the logging of complications as reliable; by this I mean that if it *is* logged I believe it is reliable but its *absence* from the log would not mean that it had not occurred. On the other hand, I would regard entries concerning death and autopsies as extremely reliable. I do not believe any statement about quality on an annual basis for the period 1984-95 would add any substance to what I have said and I do not believe that there are

trends in the quality of data entry.

In summary – although the log is not perfect I believe it has been a very high quality resource for the purposes identified earlier. At the time in Bristol this was a unique source of information.

8.Any arrangements for routine data analysis.

The routine analysis of this data as indicated under 1 and 2 above was for the preparation of annual returns.

9.Any arrangements for dissemination of the data and data analysis.

This log was not disseminated in any routine way nor was it disseminated unprocessed. It was however, known to exist amongst my colleagues, i.e. my surgical, anaesthetic and cardiological colleagues, both junior and senior, and a significant number of them used it as a resource for the purposes indicated above. Information derived from it was disseminated, usually within the paediatric cardiological and cardiac surgical group, but also to other groups as well.

10.Illustrative examples of practical applications and uses made of the data.

Examples of the uses to which the data was put include:

a) preparation of the annual statistical summaries.

b) Preparation of an audit presentation e.g. on patients operated under one year of age over a

given period of time.

c) Review of the Senning operations carried out in the department. This was the subject of work by a number of my senior registrars, as well as the paediatric cardiologists and myself, leading to a number of publications and communications.

d) When requests for information came, such as from the Working Party advising the Supra Regional Services Advisory Group, a Working Party preparing plans for the development of cardiac surgery in Bristol or from any other source, then the information could be extracted from this log book.

11.The estimated costs to BRI/UBHT of data logging and analysis.

If a rigorous view is taken then the costs would include that portion of the secretary's time devoted to making entries, and that portion of my time and the time of my registrars devoted to dictating the information for entry. It would include the paper used in the logbooks and the files in which they were kept.

If the time of the secretaries, the junior doctors and myself is regarded as already being provided, then the marginal cost of the maintenance of these logs was negligible. The time spent in analysis was all for the performance of functions and tasks which were properly within my clinical duties. It is likely that the maintenance of this log represented a saving to the Trust, as otherwise a significant amount of clerical time would have been devoted to extracting the information from other sources within the hospital. This would have been both time consuming, difficult and less reliable. Alternatively, the information would not have been available.

12 Your views on the strengths, weaknesses, and limitations of the surgeon's log system, and any ways in which the log system could have been improved.

The value of this log system must be judged against what was available in 1975 when I began the log, or in 1984 when the period of this Inquiry commences. For me it has proved to be an excellent system, which provided accessible and reliable information, which was not subject to technical failure.

However, as computers became developed and more widely used, in the late 1980s we began our efforts to log data on a computer database. We eventually achieved this to a reasonable degree of completeness and reliability in the early 90s, but it was not until the mid-90s, when the expensive computer equipment was complemented by the appointment of a full time data collector, that it became a fully efficient and reliable system.

In summary, while no surgeon beginning his career in 1999 would consider having a system like this, during the period of my clinical practice it has been extremely useful. Its use could have been enhanced if more detailed data had been entered, and more time devoted to it both in terms of data entry and analysis. Time to do that extra work was not available to me or my colleagues, nor was there a financial resource available to me to do it any other way.

29th June 1999.