

The Inquiry into the management  
of care of children receiving  
complex heart surgery at  
The Bristol Royal Infirmary

## Interim Report

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*Removal and retention  
of human material*

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To: Chief Medical Officer for England

May 2000

Dear Professor Donaldson,

- We promised to let you have an Interim Report by the late spring. We hope that it will assist you in your investigation into these matters.
- This Interim Report arises from the BRI Inquiry into paediatric cardiac surgical services. It focuses on parents and their children.
- The Report deals with the removal, retention, use and disposal of human material after post-mortems. We use the term 'human material': 'tissue' and 'organs' are the words usually used but they are unclear and confusing.
- The great majority of post-mortems are Coroners' post-mortems: their purpose is to determine the cause of death.
- Coroners' post-mortems are carried out by pathologists who, in the past, have considered that they were entitled to retain, long-term, human material such as organs (for example hearts) for teaching, research and storage in archives.
- Parents, particularly those of children who have died in hospital, have been shocked. They were almost entirely unaware of this practice by pathologists. In fact, over the past 20 years or so a high proportion of children's hearts have been retained in collections, almost always without the parents' knowledge.
- Human material has also been removed and kept after hospital post-mortems. Parents in the past have often agreed to these post-mortems but without any real understanding of what was involved.
- The law regulating the removal, retention, use and disposal of human material is obscure, uncertain and arcane.
- We identify two ways forward. The first, which we see as essential, is a new Code of Practice backed with appropriate enforcement mechanisms. This does not require passing new law: it simply supplements the existing law. The second option, which is desirable but not essential, involves changes in the law, together with the incorporation into law of the proposed Code of Practice.
- In making any changes we identify two fundamental guiding principles: first and foremost, respect for parents and their dead child; second the value of continued access to human material for the advancement of medical care and treatment.
- We commend this Interim Report to you.

Ian Kennedy (Chairman)  
Rebecca Howard  
Brian Jarman  
Mavis Maclean

A Public Inquiry was established in June 1998 by the then Secretary of State for Health. Its terms of reference are 'To inquire into the management of the care of children receiving complex cardiac surgical services at the Bristol Royal Infirmary between 1984 and 1995 and relevant related issues; to make findings as to the adequacy of the services provided; to establish what action was taken both within and outside the hospital to deal with concerns raised about the surgery and to identify any failure to take appropriate action promptly; to reach conclusions from these events and to make recommendations which could help to secure high quality care across the NHS.'

**Inquiry Panel:** Professor Ian Kennedy (Chairman)  
Mrs Rebecca Howard  
Professor Sir Brian Jarman  
Mrs Mavis Maclean

**Inquiry Secretary:** Ms Una O'Brien

**Inquiry Solicitor:** Mr Peter Whitehurst

**Inquiry Counsel:** Mr Brian Langstaff QC  
Ms Eleanor Grey  
Mr Alan Maclean

The Inquiry Panel gratefully acknowledge the contribution of the Inquiry Solicitors' team, particularly that of Charlotte Martin and Marlo Baragwanath.

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There are two annexes to this report which are published separately. Annex A gives an account of the evidence to the Inquiry and Annex B describes the law and relevant guidelines.



# Explanatory Note on References and Footnotes

Throughout this Report reference is made to source materials referred to during the Inquiry as well as to the transcript of the oral evidence heard by the Inquiry Panel between March and December 1999.

## Source Material

**Documents** submitted to the Inquiry were given an alpha numeric code, for example UBHT 0308 0018. The *letters* indicate the organisation or individual who supplied the document to the Inquiry, in this case, the United Bristol Healthcare NHS Trust.

The *numbers* indicate the page number.

The main alpha codes referred to in this report are as follows:

UBHT	United Bristol Healthcare NHS Trust
RCPATH	Royal College of Pathologists
HOME	Documents from miscellaneous sources

**Witness statements** Those who gave oral evidence to the Inquiry were asked to supply a formal written statement. Many others submitted a formal written statement only. All of these statements are prefixed with the letters WIT followed by a string of numbers indicating the Inquiry witness number, and the page of the witness statement. Thus WIT 0247 0101 refers to page 101 of the statement from witness 247. The name of a witness is given at the relevant point in the text.

**Transcript** The Inquiry heard 95 days of oral evidence. References to the transcript refer first to the day of evidence, and then to the relevant page for that day. Thus T1 p. 02 refers to page 2 of the transcript for day one of the oral hearing.

## Access

The transcript of the Inquiry's oral hearings is available on the Inquiry website [www.bristol-inquiry.org.uk](http://www.bristol-inquiry.org.uk).

**Source material** will not be directly accessible until the conclusion of the Inquiry, but much that is relevant to this report may be viewed by making use of hyper-text links to documents in the daily transcripts. Many relevant witness statements are already on the Inquiry's website.

*Contact point for more information on access to source material, witness statements and the transcript: Becky Jarvis: 0117 938 8716; e-mail: [rjarvis@bri-inq.org.uk](mailto:rjarvis@bri-inq.org.uk).*



# Part I

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## Introduction

- 1 This is an Interim Report. It is published in advance of the Inquiry's Final Report so that it can be taken into account by the Chief Medical Officer for England. He is currently undertaking an investigation into organ and tissue retention in England to consider what the issues are and what needs to be done in the longer term. He will be making a final report to Ministers in September following which comprehensive advice will be issued to the NHS. We commend our views to him.

## Background

- 2 We concentrate on parents<sup>1</sup> and their children, since they are the central concern of our Inquiry. The terms of reference of this Inquiry require us to consider the paediatric cardiac service provided at the Bristol Royal Infirmary<sup>2</sup> from 1984–1995. Where a child died after surgery, the treatment of the child's body after death, and treatment of the child's parents, clearly fall to be considered as part of our examination of that service. Further, it soon became evident to us that this was an issue of great and grave concern.
- 3 The Inquiry took evidence on this issue, both written and oral, from parents of children who had undergone post-mortem examinations following paediatric cardiac surgery at Bristol, from clinicians and other professionals directly involved in that process in Bristol; and from Royal Colleges, the Coroners' Society, the Home Office and the Department of Health in relation to the national framework within which that process took place.<sup>3</sup>
- 4 The issue of concern was that, without the realisation of parents, tissue had, over a long period of time, been systematically taken at or after post-mortems on children who had died following paediatric cardiac surgery at Bristol. The tissue had been removed and retained by the pathologists at the UBH/T<sup>4</sup> and used for a variety of purposes, including audit, medical education or research, or had simply been stored.
- 5 When the practice of tissue retention came to light in Bristol, there was, both in Bristol and elsewhere, an outcry from parents. They sought information about whether tissue had been removed from their children. Once informed, some asked for organs and tissue to be returned for burial. In response, an extensive search was carried out in Bristol to discover what tissue had been removed, and once removed, what had become of it. Parents were notified and, if they wished it, their child's

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<sup>1</sup> Whilst we refer in this Interim Report to 'parents', we do not seek to resolve here wider questions of the exercise of parental responsibility, but refer to the general law

<sup>2</sup> See Appendix for the description of the Bristol Royal Infirmary, UBHT and UBH

<sup>3</sup> A list of witnesses appears in the Appendix

<sup>4</sup> See Glossary in the Appendix

tissue was returned to them. Not surprisingly, given the scale of the exercise and the time period covered, mistakes were made about whether in fact tissue had or had not been removed and retained. Some parents were misinformed, only later to learn the real circumstances.<sup>5</sup> The additional pain and distress is a cause of the greatest concern.

- 6 The press and other media gave considerable publicity to the evidence of Professor Anderson<sup>6</sup> in September 1999 in which he described the various collections of tissue which existed around the country. As a consequence, parents whose children had died in hospital (not necessarily as a consequence of paediatric cardiac surgery), sought information from the hospitals named by Professor Anderson.<sup>7</sup>
- 7 In late 1999, the Secretary of State asked the Chief Medical Officer of England to prepare an inventory of centres where tissue was held and of the tissue retained and to review current practice with a view to making recommendations.

## Problems of language and definitions

### Tissue

- 8 There is no definition of 'organ' or 'tissue' in the relevant statutes. The word 'tissue' has come to be understood by some as a generic term including not only small sections of tissue but whole organs and parts of organs. This is not, however, how the term tissue is understood in everyday language. Indeed, most people would not regard organs as being properly described as tissue. Herein lies one of the many barriers to communication and understanding which are at the root of the problem we are examining.
- 9 *Black's Medical Dictionary* defines tissue as: 'The simple elements from which the various parts and organs are found to be built ... It is customary to divide the tissues into five groups: epithelial tissues, connective tissues, muscular tissues, nervous tissues and wandering corpuscles of the blood and lymph' and defines organ as: 'A collection of different tissues that form a distinct structure in the body with a particular function or functions... [for example] the kidneys, brain and heart.'
- 10 The report of the Nuffield Council on Bioethics, *Human Tissue Ethical and Legal Issues*,<sup>8</sup> took the term tissue to include: 'Organs, parts of organs, cells and tissue, sub-cellular structures and cell products, blood...'

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<sup>5</sup> See Annex A for full details

<sup>6</sup> See Appendix

<sup>7</sup> Professor Anderson, in his evidence, said that major collections were held at Alder Hey Children's Hospital, Royal Brompton Hospital, Great Ormond Street Hospital for Sick Children, Birmingham Children's Hospital, Leeds General Infirmary, and The Freeman Hospital Newcastle, Southampton General Hospital and the Royal Manchester Children's Hospital [Pendlebury]. (see T45 p. 104–106)

<sup>8</sup> April 1995

- 11 To avoid the confusions associated with all other suggested definitions we will adopt in this report our own general term, 'human material', which includes not only tissue in its various forms, organs and parts of organs but extends also to any other material such as amputated limbs. We emphasise that the term 'human material' is not a legal term. (Thus, we do not use it in Annex B, where we discuss the relevant law.)

### Post-mortem examination – the two types

- 12 When a person dies in hospital, the attending doctor completes a medical certificate of cause of death. The certificate is then taken, by parents in the case of a child, to the Registrar so as to register the death.
- 13 As a matter of law, a Registrar is obliged to refer to the Coroner deaths which fall into a number of categories, including those where the cause of death appears to be unknown, or which appear to have occurred during an operation. In practice, in many such cases it is the doctor who contacts the Coroner's office directly. The Coroner may decide to order a post-mortem, or he may consider that there is sufficient information for a death certificate to be issued. The purpose of carrying out a Coroner's post-mortem is limited in law to establishing the cause of death of the deceased. This is considered in full in Annex B.
- 14 There is another kind of post-mortem, known as a hospital or a consent post-mortem. The rationale, authority and legal framework for this type of post-mortem is entirely different from that for a Coroner's post-mortem. A hospital post-mortem arises for a number of reasons, one primary reason being where it would be beneficial to medical care to study the cause of death in greater detail. Such an examination may also be carried out with a view to obtaining human material for the purposes of medical education or research. Although this is often referred to as a post-mortem examination, strictly speaking it is not a post-mortem at all, but a procedure aimed at removing and retaining human material. The legal framework is not the Coroners Act 1988 (the 1988 Act) but the Human Tissue Act 1961 (the 1961 Act).
- 15 It follows that a Coroner's post-mortem should not serve as a vehicle for a number of other medical or scientific purposes, however worthy or beneficial these may be. But, given that when a post-mortem is not requested or directed by the Coroner, the hospital must make enquiries as to whether parents object to a so-called hospital or consent post-mortem, and that such a process is inevitably distressing, it can be understood how hospitals and clinicians might wish to resort to Coroners' post-mortems for purposes which can only properly be authorised through recourse to hospital post-mortems (broadly defined).

- 16 We emphasise again that the focus of this report is parents and their children. In the context of post-mortems, the law is broadly no different as between children and adults. Thus our analysis and recommendations should be applied to all post-mortems, except wherever the law prescribes otherwise.

### Consent and objection

- 17 If a post-mortem is requested or directed by the Coroner, he is not required by law to seek the consent, or respect the objection, of parents. In the case of a hospital post-mortem, however, the central feature of the statutory framework is that it may not be authorised if any relative objects to its taking place. The Human Tissue Act does not require that consent be given; it merely requires that there be no objection. In practice, even before the Human Tissue Act was passed, parents and relatives were commonly asked for their consent.
- 18 In Bristol, as we shall see, when Coroners' post-mortems were carried out on the authority of the Coroner, parents were not advised of, far less asked for their views on, the fact that the pathologist might take or retain human material, nor of the uses to which the human material might be put.<sup>9</sup>
- 19 Equally, in Bristol, when hospital post-mortems were carried out, although asked whether they gave their consent, parents signed forms which were not explicit as to what might be done.

### 'Removal' and 'retention'

- 20 We take the term 'removal' to mean the short-term removal of human material from the body, and subsequent reuniting of that tissue with the body prior to its burial or cremation.
- 21 We take the term 'retention' to mean that tissue is removed from and not immediately thereafter reunited with the body, either being retained in the short term (for further tests to be carried out), or retained in the long term (for example for educational or research purposes).
- 22 Coroners work to a set of rules called the Coroners Rules, made under statute. A Rule of particular relevance to the issue of retention is 'Rule 9'. It states that 'A person making a post-mortem examination shall make provisions, so far as possible, for the preservation of material which in his opinion bears upon the cause of death for such period as the coroner thinks fit.'

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<sup>9</sup> Rule 9, Coroners Rules 1984 (The 1984 Rules), requires a pathologist conducting a coroner's post-mortem to make arrangements for preserving 'material', ie, human material, which in his opinion *bears upon the cause of death*. See Annex B for a full discussion

- 23 As we set out, during the course of the evidence taken by the Inquiry, it became apparent that these terms were not uniformly applied, nor indeed understood, by professionals let alone parents.

## Periods of time during which human material may need to be retained for the purpose of a post-mortem

- 24 Human material may need to be removed for examination. This is important for parents, not least as regards the timing of the burial or cremation of their child. Historically, it has been necessary for a pathologist to keep at least some human material for days or even weeks so as to allow a proper scientific examination. Over time, and particularly over the last decade, the scientific procedures available to pathologists have allowed many of these time periods to be significantly shortened.

## Statistical context

- 25 The Office for National Statistics supplied the following data to the Inquiry in April 2000:

**Table One: Deaths and post-mortems, England and Wales 1984, 1990, 1995 and 1998, all ages**

	Total deaths	Total post-mortems:		Of which hospital deaths <sup>1</sup> Total	Hospital post-mortems:	
		(a) Coroner's	(b) Not at request of Coroner <sup>2</sup>		(a) Coroner's	(b) Not at request of Coroner <sup>2</sup>
1984	566,881	138,071	20,033	343,467	55,746	19,367
1990	564,846	130,443	11,636	357,767	55,860	11,199
1995	569,683	124,231	Not available	309,481	55,977	Not available
1998	555,015	121,584	3,524	304,350	55,929	3,335

### Notes

<sup>1</sup> Hospital deaths for 1984 and 1990 are an aggregate of two institutional categories: NHS (non-psychiatric) and non-NHS (non-psychiatric). For 1995 and 1998 the figures are an aggregate of general hospitals, sanatoria, geriatric hospitals or units, chronic sick hospitals, maternity hospitals, military hospitals and multi-function sites.

<sup>2</sup> A post-mortem not at the request of a Coroner is a post-mortem performed by a certified medical practitioner usually at a hospital but not always. These are the best available data nationally on hospital post-mortems.

Source – ONS: The ONS does not routinely publish all of the data above. It does publish some data relating to death certification by cause of death but not by place of death.

**Table Two: Deaths and post-mortems, England and Wales 1995 and 1998, ages 0–16**

	Total deaths	Total post-mortems:		Of which hospital deaths <sup>1</sup> Total	Hospital post-mortems:	
		(a) Coroner's	(b) Not at request of Coroner <sup>2</sup>		(a) Coroner's	(b) Not at request of Coroner <sup>2</sup>
1995	6,086	1,881	Not available	4,931	1,156	Not available
1998	5,622	1,645	422	4,656	1,122	416

Notes

<sup>1</sup> Figures not available for earlier years in this format.

<sup>2</sup> A post-mortem not at the request of a Coroner is a post-mortem performed by a certified medical practitioner usually at a hospital but not always. These are the best available data nationally on hospital post-mortems.

Source – ONS: The ONS does not routinely publish all of the data above. It does publish some data relating to death certification by cause of death but not by place of death.

The significant points to note from tables are:

- For the population as a whole, many more Coroners' post-mortems are performed than hospital post-mortems following deaths in hospital. In 1998, approximately 18 per cent of hospital deaths were followed by a coroner's post-mortem, and 1 per cent were followed by a hospital post-mortem.
- The number of hospital post-mortems has declined dramatically since the early 1980s for all deaths, as well as for deaths in hospital, whereas the number of Coroners' post-mortems has remained fairly constant. Between 1984 and 1998 the number of hospital post-mortems following a death in hospital fell by 83 per cent.
- While national data on deaths of children aged 16 and under is only available for recent years, the overall patterns apply – that many more Coroners' post-mortems than hospital post-mortems take place.
- It is notable that a high proportion of children who die, do so in hospital, approximately 80 per cent, compared with just over 50 per cent for the population as a whole.

## Part II

### Evidence

#### A. The national scene

- 26 Here we set out the national context and framework against which the conduct of post-mortems and the retention of human material took place.
- 27 A post-mortem may be carried out under the authority of the coroner for one purpose only: to establish the cause of death (and, if necessary, to establish the identity of the deceased). There was, however, a long-standing habit among pathologists of taking and keeping human material, other than that required to establish the cause of death, for other purposes; for example, for research or education. Equally, once the post-mortem was concluded, it was common among pathologists to keep human material, removed for the purposes of establishing cause of death, and similarly, use it for other purposes. For example, Professor Berry<sup>10</sup> cited the following as a benefit of longer-term retention: 'Many of these conditions are rare and no two hearts with a given condition are quite the same. So, by keeping quite a large number, a very large number from the perspective of people who are not pathologists, it is possible to provide somebody who wishes to study a particular anomaly a range of examples that would take them many years to see in their own practice.'<sup>11</sup> For the most part, parents were wholly unaware of these practices. As Mrs Susan Francombe, mother of Rebecca, said: 'I know I felt if another baby could be helped by the retention and, if that was the reason, then we would have said yes; but the fact that they were kept without our knowledge ... came as a very, very big shock.'<sup>12</sup>
- 28 A post-mortem may also be carried out at a hospital at the behest of the relevant clinicians or the parents. It is customarily carried out to assist in understanding the cause of death and what can be learned for future care. This type of post-mortem is variously described as a 'consent' or 'permission' or 'hospital' post-mortem. As a matter of law, consent as such is not required. The hospital may authorise the post-mortem, provided reasonable enquiries have been made to determine whether any relative (in our case the parents) objects. As a matter of practice, it was customary to ask parents to sign a form consenting to such a post-mortem. The form also sought consent to the removal, retention and use of human material for purposes other than to establish the cause of death. To this extent, as has been said, parents were not consenting, strictly speaking, to a post-mortem. Though the forms used referred to 'tissue', they differed from hospital to hospital and did not, however, indicate what the term 'tissue' might mean (that it could include a whole organ, for example) nor what uses such tissue might be put to, except in the most general terms.<sup>13</sup> Furthermore, the forms were signed at a time of the greatest distress and, ordinarily, without advice or guidance.

<sup>10</sup> See Appendix

<sup>11</sup> T55 p. 141

<sup>12</sup> T68 p. 24

<sup>13</sup> The Inquiry notes that some hospitals, such as Guy's, referred specifically to organs as early as the mid-1980s, and that others, such as Great Ormond Street Hospital for Children, introduced a reference to organs in the early 1990s. Yet these appear to have been exceptions

- 29 During the period of the Inquiry's terms of reference and, indeed, for some time after, it was not generally questioned that pathologists or clinicians could take, or at the very least, use human material at a Coroner's post-mortem for purposes other than to establish cause of death. Neither was it seen as necessary to involve parents, except in the general way just mentioned, in the case of hospital post-mortems.
- 30 The benefits to be gained were set out by Professor Anderson in his evidence. He explained: 'We retain the hearts because we examine them for the purposes of our research. We demonstrate them. We make them available for others to study ...I believe it is essential that we keep on adding to these collections so that we have the capability of teaching tomorrow's surgeons and tomorrow's paediatric cardiologists better than we have been doing at the present time.'<sup>14</sup> Dr Eric Silove<sup>15</sup> wrote of the value of 'inspecting' post-mortem hearts in order to get a proper understanding of congenital heart abnormalities: '... it was always impossible to get a proper three dimensional appreciation unless one actually inspected [the heart]'. He continued: 'As a result of looking at numerous hearts with similar or different abnormalities, from numerous different angles, it does become possible to visualise the appearance of an echocardiographic slice through a given plane of the heart and to recognise the abnormality.'<sup>16</sup> These benefits are not specific to paediatric cardiac services. In the Chief Medical Officer's Interim Guidance on post-mortem examination, issued in March 2000, he notes the widely held understanding that appropriate examination of organs and tissue at post-mortem is essential in improving clinical care, maintaining clinical standards, increasing our understanding of disease and in supporting clinical research and training.
- 31 The fact that taking and using human material were important for medical development, research and education was seen by the medical-scientific community as sufficient justification in itself. By and large, during the greater part of the period of the Inquiry's terms of reference and to a degree even later, the medical-scientific community did not appreciate that there might be issues of an ethical and legal nature which needed to be addressed. Equally, Coroners and the Department of Health were largely uninvolved with the issues. They offered little by way of guidance during the period of the terms of reference. Any advice was intermittent: the Royal College of Pathologists relied on Professor Knight's 1985 article *Legal Considerations in the Retention of Post-Mortem Material*<sup>17</sup> to serve as guidance, whereas the Home Office sent a circular to all Coroners in 1989 advising them that no 'tissue' should be 'taken' (two words not free from difficulties) for teaching or research when conducting a Coroner's post-mortem examination.<sup>18</sup>

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<sup>14</sup> T45 p. 109.

<sup>15</sup> A member of the Inquiry's expert group and consultant paediatric cardiologist at the Birmingham Children's Hospital

<sup>16</sup> WIT 0546 0003 – comments from Dr Silove

<sup>17</sup> Knight, Prof. B.H., 'Legal considerations in the retention of post-mortem material', *Bulletin of the Royal College of Pathologists* 1985; 52:3–4; UBHT 0308 0044–47. See Appendix

<sup>18</sup> WIT 0043 0153

- 32 The fact that parents and the public were unaware that human material was routinely taken and used for a variety of purposes and that large collections existed around the country was unacknowledged or ignored. There was, in essence, a professional arrogance, justified when necessary by the recourse to traditional paternalism, that parents, on this view, are best kept from the details but would be thankful if they knew what was being done.
- 33 Fundamentally, there was a social and ethical time bomb waiting to go off. It is no surprise that the explosion of anger, when it came, was huge. The cause lay in two conflicting attitudes. For the parents of a recently deceased child, human material, certainly substantial specimens such as organs and parts of organs and even smaller samples, are still thought of as an integral part of the child's body and, thus, are still the child. For the pathologist and clinician, the material is regarded as a specimen or an object. It is de-humanised.
- 34 It is fair to say that from the latter part of the period of the Inquiry's terms of reference, an awareness was growing among pathologists of the need for greater clarity in, and regard for, the relevant legal and ethical principles. Professor Berry, the pathologist in Bristol since 1983, was one of the leading figures, particularly from 1995 to 1998 in his capacity as Chairman of the Royal College of Pathologists' Specialist Advisory Committee on Paediatric Pathology. Eventually, in 1998–99, the college began to review its guidance and in June 1999 Professor MacSween<sup>19</sup> circulated a consultation paper which culminated in the publication of new guidelines in March 2000.<sup>20</sup>

## B. The Bristol story

- 35 Here we set out the salient points in the account of what happened at Bristol. There is a fuller account in Annex A.

### The paediatric post-mortem practice at Bristol

- 36 Before and during the period of the Inquiry's terms of reference, human material was routinely removed from the bodies of children who had died while undergoing paediatric cardiac surgery:
- as part of a hospital post-mortem;
  - as part of a Coroner's post-mortem to establish the cause of death; and
  - during the course of the Coroner's post-mortem, but not to establish the cause of death.

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<sup>19</sup> See Appendix

<sup>20</sup> Royal College of Pathologists, *Guidelines for the retention of tissues and organs at post-mortem examination*, March 2000

- 37 In all three circumstances, human material, once taken, was frequently retained. On the evidence available thus far to the Inquiry, 265 post-mortems were carried out on children who underwent paediatric cardiac surgery between 1984 and 1995, of which 45 were hospital post-mortems and 220 were coroners' post-mortems.<sup>21</sup> Professor Berry, the paediatric pathologist who performed all the post-mortems on paediatric cardiac surgery patients at the Bristol Royal Hospital for Sick Children (BRHSC)<sup>22</sup> during the Inquiry's terms of reference, until the appointment of Dr Michael Ashworth<sup>23</sup> in 1993, assumed, initially at least, that once the coroner's post-mortem to establish the cause of death was concluded, the retention of human material was not contentious. He regarded it as justified both legally and ethically. In his evidence to the Inquiry, he said that 'it is a generally held view that if tissue has been legally and properly retained during the course of a coroner's post-mortem examination, then it may be further retained for the legitimate processes such as medical audit, clinico-pathological review, and so on'.<sup>24</sup>
- 38 We consider later whether such an assumption was valid (see Annex B). But, as regards the practices set out in the first two points of paragraph 36, Professor Berry grew increasingly concerned. As regards the hospital post-mortem, his concern lay in the quality of the consent given by the parents, although it will be recalled that consent is not required by law. He regarded it as insufficiently informed. He said: 'It has become clear that there is a great range in what parents understand about the post-mortem examination, and this challenges us to increase the public's general knowledge about what post-mortem involves, and the contribution of post-mortem examination to health care.'<sup>25</sup>
- 39 As regards the taking and retaining of human material at a coroner's post-mortem for a purpose other than to establish cause of death, from about 1990–91 Professor Berry viewed this as unauthorised. He said: 'In about 1990–91, I became concerned that legal justification was insufficient for the retention [meaning, it appears, the taking and then keeping] of some tissue. These concerns arose from speaking to parents, and from occasional cases widely publicised in the press. At about this time I wrote a departmental code of practice for the retention of tissue at post-mortem... also at this time I raised this issue with our paediatric cardiologists and cardiac surgeons, and reminded them that hearts could only be retained [meaning, it appears, removed and preserved] for diagnosis under the Coroners Rules, and that I thought they should be telling parents that hearts were generally kept.'<sup>26</sup> However, from 1993, it was Dr Ashworth, not Professor Berry, who performed the vast majority of post-mortems on paediatric cardiac surgery patients. Dr Ashworth

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<sup>21</sup> We note that other post-mortems for other conditions were performed in this period and human material retained from these examinations, but these do not fall within the remit of this Inquiry's terms of reference

<sup>22</sup> See Appendix

<sup>23</sup> See Appendix

<sup>24</sup> T55 p. 75–7

<sup>25</sup> WIT 0204 0050–51

<sup>26</sup> UBHT 0308 0219

appeared less troubled by questions of the legality or otherwise of taking what he referred to as tissue during a Coroner's post-mortem examination for purposes other than to establish cause of death and keeping it afterwards. He thought that this was 'not illegal'.<sup>27</sup>

- 40 Professor Berry expressed his concerns in a letter dated 6 August 1992 which he sent to the Bristol cardiologists and cardiac surgeons. He said, in relation to Coroners' post-mortems: 'In future, we will not be able to retain the heart unless there is a signed statement in the notes from one of the doctors looking after the child that they have satisfied themselves that the parents of the child do not object to the retention of tissue [*sic*] during the course of the Coroner's post-mortem examination.'<sup>28</sup> In particular, he was anxious to point out the limits of what he thought could be done in the course of a Coroner's post-mortem and to urge that more specific consent (presumably for taking and keeping human material for purposes other than establishing cause of death) be obtained from parents. The response of the cardiac surgeons was unenthusiastic. Mr Dhasmana<sup>29</sup> admitted that 'lately there has been some oversight on my part to discuss the matter with parents and relatives and therefore consent was not taken by my junior staff'.<sup>30</sup> Mr Wisheart<sup>31</sup> said he understood that the Coroner, in fact, granted them greater licence than Professor Berry was suggesting.<sup>32</sup> In other words, while he acknowledged the letter, he neither accepted the basis of Professor Berry's position nor agreed to vary his conduct.

## The role of parents at the time of post-mortems

- 41 It was normal practice when a child died after undergoing paediatric cardiac surgery for there to be a Coroner's post-mortem or a hospital post-mortem. Parents would be told that a Coroner's post-mortem was to be carried out or asked to 'consent' to a hospital post-mortem. Parents expressed considerable dissatisfaction as to the timing and manner of the approaches made by medical staff. There was also criticism that the task of approaching the parents was often left to junior staff. After all, it was accepted at the time, perhaps more in the breach than the observance, that the breaking of bad news and consequent discussions should ordinarily be carried out by the consultant in charge of the patient. In 1991, a Joint Working Party of the Royal College of Pathologists, the Royal College of Physicians of London and the Royal College of Surgeons of England stated that 'great care should be taken in obtaining permission for [a hospital post-mortem]. The responsibility lies with the consultant in charge of the case'.<sup>33</sup> In its consultation paper in 1999, the Royal College of Pathologists emphasised this point, stating 'the

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<sup>27</sup> T54 p. 74

<sup>28</sup> UBHT 0308 0018

<sup>29</sup> See Appendix

<sup>30</sup> UBHT 0308 0017

<sup>31</sup> See Appendix

<sup>32</sup> T41 p. 116

<sup>33</sup> WIT 0054 0944. We accept that in certain circumstances the consultant may be unavailable. In such a case we take the view that the task of seeking permission should be undertaken by a senior member of the clinical team, and not left to a junior, a view endorsed by the Royal College of Pathologists in their recent guidelines

most senior doctor who knew the relative best during the patient's last illness should obtain consent to the hospital post-mortem examination'.<sup>34</sup> In their final guidelines, the College refers (para 5.6), in the case of a child, to 'a senior member of the clinical team'. Ordinarily, it is assumed this should be a consultant. In Bristol, there is evidence that the consultant surgeons spoke to the parents about post-mortems but found this difficult. For instance, Mr Dhasmana recalled that 'this used to be a most difficult period... I was always emotional during this meeting and the only way I could really just, you know, express it was just quickly get to the point'.<sup>35</sup> Certainly, none had received any training in bereavement counselling or in breaking bad news as recognised by Mr Dhasmana.<sup>36</sup> But then, neither had the junior doctors received any such training, whether as part of their formal education or at the behest of the consultants. Mr Ross<sup>37</sup> gave evidence that it was common practice throughout the NHS for consent to a hospital post-mortem to be obtained by junior medical staff.<sup>38</sup>

- 42 Parents found themselves asked to discuss the signing of papers at a time, very soon after the death of their child, when many were clearly and understandably unable to comprehend what was being put to them. For example, Mrs Linda Burton, mother of David, recalled that 'we had literally come out of ITU and got back into this family room, I mean a matter of minutes, five minutes at the outside, and there was this junior doctor suggesting that we should agree to a post-mortem. This had never been raised with us.'<sup>39</sup> The fact that it was a post-mortem which was being discussed, with its additional emotional implications, only served to exacerbate the likelihood of this inability to comprehend. As Leading Counsel to the Inquiry said,<sup>40</sup> it is clear on the evidence before the Inquiry that consent to post-mortem, where required, was taken in nearly every case, but parents' recollections of giving 'consent' may be faulty and this 'may suggest that the process was carried out at a time when inevitably concerns and thoughts and feelings were elsewhere, making it difficult to comprehend everything that was happening.'<sup>41</sup>
- 43 A number of parents who gave evidence (written and oral) were adamant that, notwithstanding Professor Berry's evidence that consent was always asked for and given for hospital post-mortems, they had not signed consent forms. It is not surprising that, in the majority of cases, parents cannot recall giving consent, as none was sought or given; 220 of the 265 post-mortems were coroners' post-mortems for which consent and, hence, a signed consent form is not required. In relation to the 45 hospital post-mortems, the Inquiry has verified that in all but three cases parents' written consent was given; there was no suggestion in these

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<sup>34</sup> RCPATH 0001 0072

<sup>35</sup> T87 p. 97–8

<sup>36</sup> WIT 0084 0106

<sup>37</sup> See Appendix

<sup>38</sup> T37 p. 27

<sup>39</sup> T5 p. 43

<sup>40</sup> See Appendix

<sup>41</sup> T55, p. 7

three cases that consent was not obtained. In a further case, whilst the consent form was missing, the parent recalls giving consent.

- 44 It is crucial to understand that this gulf between perception and reality may illustrate a number of things which are not mutually exclusive. First, it cannot serve to justify any criticism of the parents. Their beliefs were genuinely held. Second, their anger at what has happened may cause them to paint a picture which is uniformly critical as regards their dealings with the UBHT. Third, the subject matter and the context in which the forms for a hospital post-mortem were signed or a Coroner's post-mortem examination was discussed were such as almost to guarantee that little or nothing would be remembered. Finally, the forms for hospital post-mortems were sufficiently vague and employed such unfamiliar terms that they were not understood or remembered. Indeed, it is extremely doubtful that the language used in the forms made sufficiently clear to parents (i) what a post-mortem entailed; (ii) the circumstances, if any, under which tissue might be removed and retained; (iii) the removing and retaining of it; and (iv) what was meant by 'tissue'.
- 45 To take two examples: while the pathologists and clinicians understood the word 'tissue' to refer to anything from whole organs to slides and frozen sections, the very great majority of parents had no appreciation of this. Second, the word 'retention' was used by Professor Knight in his 1985 article. He stated, in relation to a Coroner's post-mortem, that 'the retention of tissue for teaching and research is not covered by the Coroner's permission and the Coroner cannot grant such permission, as it is not within his remit to do so'. On one reading, this can be said to refer to the keeping or holding back for these purposes of tissue already removed. An alternative meaning is that, when Professor Knight refers to retention, he only means the initial removal and is not referring to any subsequent retention and use, once the tissue has been removed under Rule 9 of the 1984 Rules and the post-mortem is concluded. Professor Berry appeared to interpret the word retention in this latter way.
- 46 Indeed the term 'retention' can have an even greater variety of meanings. Ruth Richardson, a historian of medicine, in her comments on the Royal College of Pathologists' 1999 draft guidelines,<sup>42</sup> identified the following as being encompassed within the term 'retention':
- removal of a part of someone's body for examination at post-mortem;
  - holding on to it for testing in the immediate aftermath of death;
  - storage in the case of criminal/civil proceedings;

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<sup>42</sup> 'Tissue Retention – an outsider's view', *Bulletin of the Royal College of Pathologists* (forthcoming, summer 2000)

- archiving for legal reasons;
- archiving for medical research;
- use long/short term for teaching purposes;
- use for museum exhibition; and
- use for personal research.

### Parents discover the extent of retention

- 47 There was a great deal of shock among parents when they learned first that their children's hearts and, later, other organs and human material had been removed and stored rather than returned to the bodies. It cannot be known whether the degree of anger and outrage was greater than it might otherwise have been because of the surrounding circumstances. After all, most of the parents involved were already convinced that the UBHT was, as they saw it, the author of their misfortune in having been responsible for the deaths of their children. Furthermore, given that the heart has special significance, as well as having been the seat of their children's disease, taking and keeping the hearts was particularly hard to accept. The fact that Bristol was already a 'story' meant that as soon as it was known to the press, the reporting of the removal and retention of human material was inevitably couched in sensational terms. No account was taken of the fact that this was a widespread national practice of longstanding, whatever the shortcomings in information and understanding, and that Bristol was not exceptional.
- 48 The story began with the discovery by Mrs Helen Rickard in April 1996 that her daughter Samantha's heart had been retained at the UBHT, following the post-mortem occasioned by her death after cardiac surgery. In March 1996, after watching a television programme called *Dispatches* about paediatric cardiac surgery in Bristol, Mrs Rickard contacted the hospital and obtained her daughter's medical records. From the records she discovered that her daughter's heart had been retained at post-mortem. Mrs Rickard then obtained the permission of the Coroner to take possession of the heart. Mrs Rickard met Professor Berry and Mr Ian Barrington<sup>43</sup> on 8 May 1996 and took the heart.

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<sup>43</sup> See Appendix

- 49 In due course, the Executive Committee of the Bristol Heart Children Action Group (BHCAG) became aware of the issue.<sup>44</sup> They began discussions with the UBHT, with a view to discovering the scale of retention of human material from those who had died after paediatric cardiac surgery and how they should proceed in terms of appraising their members. The UBHT management had hoped to complete the identification process and then write to parents who had approached the UBHT, via the BHCAG, to appraise them of the situation and ask them what action, if any, they wished UBHT to take. The key feature of this approach was that parents would receive individual letters and would not learn of the issue from the media. Responses were expected to range from a request to return the heart or other human material for disposal, to a desire not to be involved. But the Executive Committee of the BHCAG was made aware that the story, hitherto not public knowledge, was about to appear in the press. Anxious to avoid the very accusation from their members that they, as parents, had levelled against UBHT (namely the withholding of information) they decided to call a press conference in February 1999 to inform the public of the retained hearts. (At that point, it was thought that only hearts had been retained.) Mr Ross, when informed of the BHCAG's press conference, contacted the Bristol Surgeons Support Group (BSSG)<sup>45</sup> 'to give them an opportunity to contact their own members before the news became public'.<sup>46</sup>
- 50 The original letters were not sent: fresh letters were drafted and sent out by the UBHT management to respond to queries from parents who telephoned or approached UBHT through the BHCAG.<sup>47</sup> These letters sought the consent of parents to receiving details about whether organs were retained. Subsequent letters were prepared to confirm that organs had or had not been retained, together with a further letter seeking instructions for the return or disposal of the organs. Parents who thought that they had buried their child and were perhaps coming to terms with their grief, suddenly had to face the agonising question whether they wished to know if their child's heart (and, later, other human material) had been retained; and if they decided to find out and the answer was that it had been, what they would do. Would they want to reclaim it; could they bury or cremate it? These were the painful and unwelcome questions with which they had to deal.
- 51 The scale of the retention of human material in Bristol gradually began to emerge. Professor Berry and Mr Barrington took the lead in establishing the true position. Many weeks were spent tracking down human material and identifying the parents of the children from whom it had been removed. In this period Professor Berry 'took personal responsibility for identifying and collating the data in the Pathology Department in his own department' and later assisted with the data from the BRI Pathology Department. Mr Barrington and his staff were 'asked by the Trust to undertake the role of receiving and responding to parents' enquiries'.<sup>48</sup>

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<sup>44</sup> See Appendix

<sup>45</sup> See Appendix

<sup>46</sup> WIT 0128 0015

<sup>47</sup> WIT 0076 0022-54

<sup>48</sup> WIT 0076 0065-6

- 52 Thereafter, events played themselves out, as parents dealt with the UBHT. The UBHT had 231 enquiries from parents about retained human material, particularly organs. Of these, 219 made follow-up enquiries and in 140 cases organs had been retained. Inevitably, in such a large, labour-intensive, retrospective examination of records, mistakes (albeit few) were made. These caused considerable additional distress to parents. It would be wrong, however, to criticise UBHT or its staff who were clearly doing their best to proceed as quickly and yet as sensitively as possible.
- 53 Some members of BHCAG, through their lawyers, were moved to direct strong criticism at UBHT, specifically Professor Berry, Mr Ross and Mr Barrington. Professor Berry, in particular, was accused of acting unethically and unlawfully. These accusations need to be addressed.

### The ethical propriety of practices at Bristol

- 54 As regards the ethical propriety of what was done at the UBHT, ethics has historically been given more than one meaning. Ethics is seen now as the application of rigorous moral analysis, with a view, for example, to identifying proper standards of conduct in any particular context. Our context is the practice of health care. Until relatively recently, however, ethics was a term more commonly used to describe those standards which, from time to time, a particular professional group judged to be proper. In our case, the professional group involved is the medical profession. The taking and use of human material had attracted little ethical analysis in the first sense until the mid-late 1990s when bodies such as the Nuffield Council on Bioethics and the Working Party of the Royal College of Pathologists looked at issues such as retention, and subsequent use, of human material.<sup>49</sup> Thus, in fairness, in the context of the time, we should here concentrate on professional guidance and practice.
- 55 The practice at Bristol appeared to accord with that adopted generally in England and Wales. It was only over the period of our terms of reference that the general notion of a greater involvement of patients in their medical care along with the principle of informed consent gradually developed. As early as 1992, Professor Berry appears to have recognised that this development had implications for the conduct of post-mortems. He took the view that in respect of a Coroner's post-mortem, consent would need to be sought for the retention of any human material, initially taken to establish the cause of death beyond the conclusion of the examination and once the coroner had discharged his duty. It was for this reason that he wrote to medical staff at the UBHT on 6 August 1992, stating that 'in future we will not be able to retain the heart [after a Coroner's post-mortem] unless there is a signed statement in the notes from one of the doctors looking after the child that

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<sup>49</sup> See Annex B

they have satisfied themselves that the parents of the child do not object to the retention of tissue [*sic*] during the course of the Coroner's post-mortem.'<sup>50</sup> The wording of the letter is, however, ambiguous. The 'retention of tissue during the course of the Coroner's post-mortem' could refer to the initial taking and subsequent retention, for purposes other than to establish the cause of death. Alternatively, the words could refer to retention once the Coroner's duty was discharged. We have given the words the latter meaning. It will be evident, however, that this uncertainty of meaning runs through the story as a constant theme.

- 56 It may be argued that Professor Berry did not go far enough, and that his department continued to be involved in the removal and retention of human material without the real awareness of parents. But that is to be guilty of a failing which this Inquiry must always be alert to guard against: commenting on the past from the perspective of the present. By the standards of his profession at the time, whatever view may be taken of those standards, Professor Berry was not behaving improperly. Indeed, Dr Ashworth told us that commentators such as Professor Knight were 'lone voices ... The pathological opinion ... was that it was not an issue.'<sup>51</sup> We may regret that those standards were the product of a small group of professionals talking to themselves. We may agree that they reflected a degree of professional arrogance. We may lament that they displayed a lack of interest in, or paternalism towards, the views and feelings of parents. But that was how things were. That was the culture of the times. We should also recognise that it is no more easy for professionals than parents to have to talk about the death of a child for whom they have been caring. As Mr Wisheart explained: 'It [seeking explicit permission to retain a child's heart] added to the difficulty' of talking to parents when their child had died, 'certainly for the parents, and I guess for myself as well, to be honest ...'<sup>52</sup>
- 57 The task we have is a task for the future. It is to ensure that parents are respected *and* that medical care is developed, not least through the appropriate use of post-mortems. This is no easy task, given the inevitable and understandable breakdown in trust which currently prevails between parents and professionals. It is made no easier by mistaking the language of shame and blame for the language of accountability. Of course, blame has a proper role where there is personal misconduct. But where, as here, it was a system which was responsible, and a system which needs to be changed, blaming any individual is not only unfair and unhelpful; it is positively counter-productive.

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<sup>50</sup> UBHT 0308 0018

<sup>51</sup> T54 p. 11

<sup>52</sup> T41 p. 116

## The lawfulness of practices at Bristol

- 58 As regards the lawfulness of the practices adopted in Bristol, the overall impression from the evidence before the Inquiry is that, while the law was recognised as having some relevance, it was not clearly understood. This is hardly surprising. Pathologists are not lawyers and there was a distinct lack of authoritative legal expertise. As regards the specific issues which concern us, there was and remains little by way of guidance. It is no wonder that a kind of professional folklore developed which served the role of the real law. Again, we may regret this state of affairs. We may express amazement that in an area as sensitive as this, the importance of the place of law was not immediately recognised and the law changed or clarified, if found to be wanting. But, at the time, the prevailing practice suited the interests of those within the system. Those who might have complained did not do so for the simplest of reasons: they did not know what was going on.
- 59 There are a variety of possible explanations for this state of affairs. The law *is* complex *and* obscure. Practice had developed over decades which suited the interests and needs of those involved: the medical professionals. Coroners, in effect, operate fiefdoms. They exercise considerable discretion and display little uniformity of practice as regards, for example, the proper disposal of human material removed for the purposes of a coroner's post-mortem, once the cause of death has been established. Pathologists and clinicians largely held the view, if they ever gave their mind to it, that the law was something remote, far removed from the realities of their daily practice.
- 60 There was nothing to suggest that the practice of those at Bristol was different from that of other centres. Thus, any claim that they acted unlawfully, is, in effect, a claim that the general practice relating to certain aspects of the taking and use of human material was unlawful. That said, the legal maxim *communis error non facit legem* (a practice may be common but still unlawful) means that those at Bristol cannot rely on the behaviour of others. What they can, perhaps, legitimately say to those who may claim that they behaved unlawfully, is that it is harsh in retrospect to judge them in this way, when they did no more than follow accepted practice.

- 61 This, of course, assumes that those in Bristol did behave unlawfully and such a conclusion is by no means straightforward. To repeat, the law is obscure. Moreover, there have been few attempts to state or clarify the law in legal writings, and no rulings from the courts on a number of the central issues of contention. We need look no further than to notice that two well-researched submissions, one commissioned from our experts, the other put in by the legal team representing BHCAG, take opposing positions on an issue of central importance: the status of human material in the possession of the pathologist after the conclusion of a Coroner's post-mortem. On one view, it is open to the pathologist to use the tissue for such purposes as research or education. On another view, the human material must be returned to the parents.<sup>53</sup>
- 62 We set out later in Part III, with some hesitation, what we regard as the true state of the law. We believe that our description of the law is accurate (although we are not the final arbiters). We also believe that, given its uncertainty and complexity, failure in the past to follow what we set out as the law should not, on that basis alone, attract criticism now.

## Conclusion

- 63 We conclude our account of the evidence from Bristol with an eye to the future. We have seen that many benefits to healthcare can accrue to patients and, in our case, sick children from post-mortems and subsequent access to human material when, sadly, a child has died. Yet for these benefits to be sustained in the future, it is crucial that parents must not be excluded. They must be respected, at this time of all times, and their permission sought to a hospital post-mortem and to the retention of human material subsequent to a hospital post-mortem and Coroner's post-mortem. The information they are given should be clear and comprehensible. Furthermore, the means of informing them and seeking their views must be sensitive and supportive. We feel certain that if an atmosphere of trust can be rekindled, many parents will want to contribute. We can also hope that, despite the current anger and anguish felt by parents, ways may be found whereby existing archives of human material, which could hold the prospect of help for future children, can remain in existence.

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<sup>53</sup> Refer to Annex B

## Part III

### The background: law and relevant guidelines

#### A. The law

- 64 Our concern is with the carrying out of post-mortems and the removal, retention, use and disposal of tissue during or after post-mortems. We do not see it as helpful here to set out a detailed account of all the relevant law. This can be found in Annex B. Our purpose here is to note the principal salient features of the legal landscape. The hope is that by doing so, the various strands of the law, and the various gaps in the law, can be exposed. In doing this, we have no doubt that the complexity and obscurity of the current law will be manifest to all. Equally, we have no doubt that there will be general agreement that this state of affairs is regrettable, and in need of attention.
- 65 The law as it stands does not distinguish between post-mortems on children and adults and, apart from certain legal issues in relation to parents and parental responsibility, we see no reason for any change in that situation. The arguments and recommendations outlined here refer, therefore, to deceased children and their parents, but unless specifically stated, can be taken to apply across the board.
- 66 In the introduction, we identified the two types of post-mortem, Coroner's and hospital, and identified a number of problems of language and definition. These should be borne in mind when reading what follows.

#### The Coroner's post-mortem

- 67 The large majority of post-mortems carried out in Bristol during the Inquiry's terms of reference were, as we have seen, Coroners' post-mortems.
- 68 The conduct of Coroners' post-mortems is regulated by the 1988 Act and the 1984 Rules. We set out in Annex B the circumstances under which a Coroner's post-mortem may take place, the principal purpose of the Coroner's post-mortem (to establish the cause of death) and who may carry it out. Here we concentrate on those legal issues which are of particular importance regarding the removal, retention, use and disposal of human material.
- 69 The Coroner does not need the consent of the parents before requesting or directing a post-mortem. Indeed, the Coroner has the legal authority to proceed with a post-mortem in circumstances where he considers this will assist him in determining the cause of death, even if the parents object. The justification is one of public interest: to ensure that wherever doubt may exist, the cause of death is established through a

formal judicial process. At the same time, however, there is nothing in the law to prevent the Coroner from receiving, or even seeking out, the views of parents and giving effect to them, to the extent that doing so is compatible with carrying out his duty.<sup>54</sup>

- 70 The Coroner's post-mortem is ordinarily carried out by a pathologist, although the law does not insist on this. (The law requires that the post-mortem be carried out by a 'legally qualified medical practitioner'<sup>55</sup> and requires the Coroner, wherever possible, to instruct a pathologist with suitable qualifications and experience who has access to laboratory facilities.<sup>56</sup>)
- 71 The pathologist, when working under the Coroner's instructions, acts as the Coroner's agent. While conducting the Coroner's post-mortem, the pathologist is an independent agent. Thus, any powers and authority which the pathologist has are derived from and, importantly therefore, no greater than the Coroner's. In practice in the case of hospital deaths, the pathologists who carry out Coroners' post-mortems for the Coroner are mainly hospital pathologists. The Inquiry heard from Mr Burgess<sup>57</sup> that no Coroner has his own mortuary. In many counties, including Surrey for which he is currently the Coroner, the Coroner is entirely reliant on hospitals to provide mortuaries for post-mortems. Indeed, the 1988 Act and 1984 Rules do not prevent the Coroner's post-mortem being performed at the same hospital where the death occurred. Rather, the 1984 Rules<sup>58</sup> require that, if the death occurred in a hospital possessing adequately equipped premises, the post-mortem should be carried out there (provided the hospital authority consents) unless the Coroner decides otherwise.
- 72 The pathologist may carry out whatever procedures on the body he deems necessary to meet the obligation of establishing cause of death. What he, in fact, does is determined by the standards of practice at the time, since he is bound to exercise due skill, and this includes taking account of relevant medical and scientific developments. Thus, the pathologist may remove a wide range of human material, from whole organs to small tissue samples. Once removed, the human material may be investigated and then returned to the body. Alternatively, it may be retained for such a period as allows the pathologist properly to examine it. This is the import of Rule 9 which provides for the preservation of material which bears on the cause of death. There does not appear to be any legal requirement on the Coroner to explain this process to parents, whatever may be ethically desirable.

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<sup>54</sup> See the discussion of the 'Practice Notes for Coroners' in Annex B. Coroners are encouraged to inform families and to give them and others affected by a decision an opportunity to comment on the situation concerned

<sup>55</sup> Sections 19 and 20, 1988 Act; this would appear to mean a registered medical practitioner, and not a medical practitioner with a legal qualification

<sup>56</sup> Rule 6(1)(a)

<sup>57</sup> See Appendix

<sup>58</sup> Rule 11(3)

- 73 Any removal and subsequent keeping of tissue by the pathologist is as the agent of the Coroner and, thus, is legally justified only to the extent that it serves to enable the pathologist to establish cause of death. It follows that the Coroner cannot give authority for the removal and retention of human material for any other purpose, for example research or education, under the 1988 Act. If it is to be lawful, it must be authorised on some other legal basis. That legal basis is the 1961 Act.
- 74 The 1961 Act provides in section 1(2) that the person lawfully in possession of the body can authorise the taking of parts of the body for therapeutic purposes, medical education or research.
- 75 Here we encounter the first of many problems. Who is lawfully in possession of the body? Clearly during the currency of the Coroner's post-mortem, it is the Coroner, but we have seen that his authority extends only as far as establishing the cause of death. So, he cannot give authority under the 1961 Act. We have to look elsewhere for proper authorisation. The 1961 Act can be read as providing that, by virtue of section 1(7), the hospital is in lawful possession of the body. Thus, the hospital is in lawful possession before the body comes under the Coroner's jurisdiction. During the Coroner's post-mortem, the body is in the lawful possession of the Coroner through his agent the pathologist. However, once the Coroner's post-mortem is concluded, we have taken the view, outlined fully in Annex B, that, while the pathologist may have actual and lawful possession, he must cede lawful possession to the parents if requested to do so.<sup>59</sup>
- 76 The importance of this issue lies in the fact that, by section 1(2), the person lawfully in possession of the body can authorise that the body may be used for the purposes set out in section 1(1) of the 1961 Act only if, having made such reasonable enquiry as may be practicable, he has no reason to believe that the deceased had expressed an objection to his body being so dealt with after his death, and had not withdrawn it; or that the surviving spouse or any surviving relative of the deceased objects to the body being so dealt with.
- 77 The effect of our view as set out in the previous paragraph, appears to be that the hospital must have made such reasonable enquiry as may be practicable before surrendering the body to the Coroner. Failure to do so would, on this reasoning, mean that any subsequent use made of the human material, other than for the purposes of the Coroner's post-mortem, would be unauthorised.
- 78 But, this conclusion is not free from difficulty. The position may be reasonably clear that any taking and retaining of human material, during the course of the Coroner's post-mortem, for purposes other than to establish cause of death, is unauthorised.

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<sup>59</sup> We reiterate here that we recognise that there are wider questions as to the exercise of parental responsibility. We do not resolve them here but refer instead to the general law

There is disagreement, however, on other matters. It has been argued that once the Coroner's post-mortem is concluded, human material which has been previously retained for the purpose of establishing cause of death, becomes the property of the pathologist and, thus, the hospital. On this view, it could thereafter be used for any number of purposes, provided they did not offend some sense of public decency.<sup>60</sup> There is some plausible legal argument to support this view, but for it to be right, it depends on whether the human material has been worked on and in consequence has acquired different attributes. We remark in passing that the legal position should not rest on such arcane distinctions. Furthermore, if this is the law, its ignoring of the need to have regard to and respect the views of parents makes it unacceptable. A fuller consideration of this issue is in Annex B.

- 79 Alternatively, it has been argued<sup>61</sup> that, once the Coroner's post-mortem is concluded, all human material reverts to the lawful possession of the parents. On this view, the pathologist has a duty to comply with the parents' request that the human material be returned to them. We tend to agree with this approach but emphasise that this Inquiry is not the arbiter of the law.
- 80 We have seen that the person in lawful possession of the body must at some point have made such reasonable enquiry as may be practicable to determine whether the parents (as 'any relatives') object to human material being used for the purposes specified in the 1961 Act. It is clear that the law does not require the parents' consent, but only an attempt to establish their lack of objection. While this may be thought to be a distinction without a difference, it is of some importance. To ask parents at a time of such emotional strain whether they object may subtly disempower them. The onus is on the parents to object, rather than on the hospital to seek consent. Again, the law seems out of sympathy with the needs and feelings of parents. They may well wish to give consent. Many may hope that something good might come out of their tragedy. But the law is not sensitive to this.
- 81 We turn now to note not so much what the law provides, but what the law is silent on. First, at the conclusion of the Coroner's post-mortem, there does not appear to be any legal requirement placed on the Coroner to indicate what the pathologist should do with human material retained for the purpose of the Coroner's post-mortem. In other words, the law is silent about the transitional point when human material moves from being in the Coroner's lawful possession to ceasing to be so. It is this lacuna which gives rise to the problems we aired earlier. One solution could be to require some positive act of release by the Coroner, but this could only work if it was also stated to whom the human material must be released.<sup>62</sup>

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<sup>60</sup> See, for example, *Doodeward v Spence* [1908] 6 CLR 406, *R v Gibson*, *R v Sylveire* [1990] QB 619 considered further in Annex B

<sup>61</sup> By lawyers for the BHCAG, in their Submission to the Inquiry, SUB 0001 0001

<sup>62</sup> See Recommendations

- 82 A second matter not covered by the law is any obligation on the part of the Coroner and, through him, the pathologist to liaise with parents, both before and after the Coroner's post-mortem.
- 83 The 1984 Rules provide for certain people to be notified of the date and time of a proposed post-mortem<sup>63</sup> (unless it is impracticable to notify them or to do so would cause the examination to be unduly delayed<sup>64</sup>). These people include 'any relative of the deceased who has notified the Coroner of his desire to attend, or be represented at, the post-mortem examination.'<sup>65</sup> It should be noted that the onus is on the relative to notify the Coroner of a desire to attend; there is no duty on the Coroner to indicate that a relative may attend or be represented. The Coroner also has a discretionary power to notify any other person<sup>66</sup>. The Inquiry heard from Mr Clifford<sup>67</sup> that no Home Office guidance had been issued as to how Coroners might or should exercise their judgement under these provisions.
- 84 The Coroners' Society, in their *Practice Notes for Coroners* issued in 1998, advise<sup>68</sup> that 'relatives and family of the deceased person should be given appropriate information' about a proposed post-mortem and, more generally, 'Before making any decision which will affect other people, you [the Coroner] must give all the relevant interested persons an opportunity to comment on the situation concerned.'<sup>69</sup> But this is advice only and, thus, it is a matter of discretion for the particular Coroner.
- 85 There is no statutory requirement for parents to be provided with a copy of the post-mortem report (or notification of the result of an inquest) although the *Practice Notes for Coroners* advise: 'The relatives and family of the deceased person ... should be told the result of the examination as soon as practicable, and in writing, if they request it ... It might be appropriate to offer to forward the result and a copy of the pathologist's report of the examination to their nominated medical attendant so that this can be explained to them.'<sup>70</sup> Again, it may be noted that the onus is placed on the relatives and family to request the result.
- 86 There is a real sense in parents of exclusion, of being caught up in a system in which they play no role and have no say, when it is their child who has just died. This is perhaps exacerbated by the involvement of the Coroner or his officer, as these are people not previously involved with the family and whose role may be unclear to the parents.

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<sup>63</sup> Rule 7, 1984 Rules

<sup>64</sup> By Rule 5, 1984 Rules delay in the holding of a post-mortem is to be avoided

<sup>65</sup> Rule 7(2)(a), 1984 Rules

<sup>66</sup> Rule 7(4), 1984 Rules

<sup>67</sup> See Appendix and WIT 43/8 at para 36

<sup>68</sup> *Practice Notes for Coroners*, Appendix A para 4, WIT 39/14

<sup>69</sup> *Practice Notes for Coroners*, Note 3.2, WIT 39/6

<sup>70</sup> Para 6.1, WIT 39/8

- 87 There can be no real justification for not placing the Coroner under a positive duty to inform the parents about the purpose of the Coroner's post-mortem and what it entails, and about whether an inquest will be held and what it entails.
- 88 Finally, there is no legal obligation on the Coroner or pathologist to discuss the timing of the post-mortem, and to discuss whether human material might need to be retained for a period of time. The length of time for which human material may be retained will be important to parents, not least as they might wish to postpone the burial or cremation of their child's body until the material can be reunited with the body. Currently they depend for this information on the goodwill of the particular Coroner or pathologist.

### The hospital post-mortem

- 89 As we have seen earlier, this form of post-mortem is governed by section 2(2) of the 1961 Act. We have seen and commented on the fact that the consent of parents to the post-mortem is not required, but rather that reasonable enquiry is made to ascertain whether they object. Notwithstanding this, hospital post-mortems are commonly referred to as 'consent' or 'permission' post-mortems.
- 90 In the following paragraphs, we concentrate on areas in which the law is either undeveloped or simply silent. We have seen that the person in lawful possession of the body must, 'having made such reasonable enquiry as may be practicable,' have 'no reason to believe' that '... any surviving relative of the deceased objects' to the body being used for the purposes contemplated by the 1961 Act. The question is: to what extent, in establishing a lack of objection, must the hospital as the 'person in lawful possession of the body' have regard to the evolving law relating to consent?
- 91 In the context of the practice of medicine, the law on consent has developed somewhat since the beginning of the period of our terms of reference. The prevailing law was that, to obtain a properly informed or 'real' consent and thus comply with the legal duty imposed by the law of negligence, the law required the clinician to inform the patient (or parent, in the case of a young child) of those matters which a responsible body of doctors would regard as appropriate: the so called 'Bolam test'.<sup>71</sup> Over time, there began to be a movement away from this paternalistic legal standard which took account only of the views of doctors. We consider this development in further detail in Annex B.
- 92 To answer the question just posed relating to consent, we must proceed in stages. The first matter to be resolved is whether this law relating to consent applies at all. It has developed in the context of exchanges between doctors and patients. At the

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<sup>71</sup> *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582

point at which a post-mortem is being discussed, the child patient has sadly died. Treatment and, thus, consent to treatment, is no longer being discussed. This could lead to the conclusion that the law relating to consent does not apply. Counter-arguments exist. The discussion of the post-mortem is sufficiently closely related in time and context to the care of the child that it could be said that the law remains the same. Additionally, or alternatively, the parents in their grief and distress could, perhaps, be said to have become patients and so the duty is owed to them in their own right. We do not purport to resolve these questions here. Rather, we draw attention to the uncertainty of the law and to the fact that there is no authoritative answer whether in case law or statute. Further, we say nothing about what might be right from an ethical point of view. Our concern here is solely with the law.

- 93 The second question for us is whether the statutory reference to a lack of objection in the 1961 Act, if it engages the law relating to consent at all, imposes on the hospital the same positive duty to impart information as it does if consent to treatment is being sought. Another way of posing the question is whether there is a law of informed refusal or objection which co-exists with the law of consent and which is co-extensive with it. Again, arguments may be mounted, for example, that the reason for establishing a lack of objection is out of respect for the relatives, and that if the relatives are not properly informed, that respect is undermined. There is, however, no definitive answer.
- 94 The third question is, even if the law relating to consent applies and it extends to include a duty to obtain an informed refusal, what, in concrete terms, would be required of the clinician in dealing with the parents? Again, putting aside what might be called for ethically, the answer is that, for the whole of the period covered by the Inquiry's terms of reference, the duty would consist of passing on that information which a responsible body of medical opinion would regard as appropriate. This, in turn, means following the accepted medical practice and if there is more than one practice, following any of them which was not on its face self-evidently unreasonable (and even this gloss of unreasonableness is only relatively recently recognised).<sup>72</sup> It follows that the law is, at most, silent and, at least, uncertain in those very areas about which parents express most concern: their lack of any real understanding of what the hospital post-mortem was for, what it could entail, what 'tissue' could mean, that 'tissue' might be retained, perhaps indefinitely, that 'tissue' could be put to a variety of uses, and, perhaps most important of all, that as a consequence they would be burying or cremating their child's body incomplete. This conclusion only has to be stated to be seen to be indefensible.

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<sup>72</sup> To the extent that the written consent forms used in Bristol from 1987 reflected practice generally throughout the country, on this analysis it would be difficult to conclude that there was any breach of legal duty

- 95 We turn now to a number of other areas in which the law is relevant but less than clear. The first relates to the uses to which human material may be put. We assume, for the sake of argument, that an appropriately informed absence of objection to the use of human material has been established. As we have seen, section 1(1) of the 1961 Act specifies certain uses which may be authorised, namely for therapeutic purposes and for the purpose of medical education and research. A number of uses to which human material has been put in the past are not referred to, for example the storage of human material in a bank or archive, or its exploitation for commercial purposes. On one view, such uses are, therefore, unauthorised. Alternatively, it may be argued that they are justified by analogy, in so far as archiving, for example, is sufficiently similar to education as to be within the ambit of the statute. Further, where the argument by analogy breaks down, there is an argument, albeit not strong, that, quite apart from the 1961 Act, the common law permits the uses of human material, except in circumstances where that use would offend public decency. That there is no clear law on this matter demonstrates again the inadequacy of the current law.
- 96 Another area of concern is the length of time for which human material, assuming its retention is lawful, may be retained. Under one statutory system regulating the use of human material, the Anatomy Act 1984 (the 1984 Act), the material may only initially be retained for a limited period of time, and only subsequently either for the purpose of decent disposal or provided that statutory conditions are satisfied (see Annex B). There is no such provision in the 1961 Act.
- 97 Lastly, there is the vexed question of whether human material ‘belongs’ to anyone, and, if so, when and to whom. We set out in Annex B the background to the ‘no property’ rule, that the body, on death, does not become property and cannot, therefore, belong to anyone. We also describe the circumstances in which human material may become property: broadly, when work has been expended on it such that it has acquired different attributes. This has led the few commentators and the even fewer legal cases to reflect on such apparently arbitrary questions on whether, for example, the process of fixing human material, such as a heart in paraffin in order to aid examination by the pathologist, is sufficient to make it property and, therefore, be susceptible to ‘belonging’ to someone.
- 98 It is no hyperbole to describe the law in this particular area as both obscure and arcane. Yet, legal issues, ranging from the status of human material archives to the claim of parents to the return of such material taken from a child, depend for their solution on this law. Thus, while there is no shortage of views, there is no semblance of certainty. It is for this reason that in our recommendations which follow, we offer as one option a scheme of prior consents. By this scheme, modelled

on the Human Fertilisation and Embryology Act 1990, all dealings with human material after death, other than in relation to the Coroner's post-mortem strictly defined, would be the subject of prior agreement by the parents. A default position would come into play at each stage if the circumstances which were contemplated when the consent was given no longer prevail. That default position would indicate what should then happen to the human material. The significance of this approach is that it would obviate the need to determine such vexed questions as whether human material can belong to someone and, if so, when.

## B. Relevant guidelines

- 99 We have already indicated earlier that the reference here to guidelines is intended to refer to the pronouncements of such bodies as the Royal College of Pathologists and government departments. They appear to have at least two aims: to seek to explain or make clear the law, and to seek to urge or prescribe best practice. They culminate in the long-awaited publication by the Royal College of Pathologists of its updated *Guidelines for the retention of tissues and organs at post-mortem examination* in March 2000. We refer to the various guidelines and, in particular, those of the Royal College of Pathologists, at greater length in Annex B and do not attempt any detailed commentary here. Rather, we confine ourselves to some general observations.
- 100 We state at the outset that, in any guidelines, certain ethical principles need to be set out. They must inform the guidance offered, whatever body or organisation may issue them. Equally, they must inform the law and those who interpret the law. We set out later our views on the relevant guiding principles.
- 101 Perhaps the most significant comment about guidance in the past is the low priority which, historically, has been given to the concerns of the family and particularly parents. We are aware that the various guidelines are intended to be of general application and not just concerned with post-mortems on children. But, that said, the particular position of parents who have just lost a child should always have been clear to all as warranting special and sensitive attention. The fact was that, as Professor Anderson put it in evidence, it was only recently that it was realised that the needs of the parents ought to be addressed:<sup>73</sup>

'Q. When you began to study retained hearts and became aware of their retention, do you know what, if any, reference was made to the relatives of the dead person from whom the heart came?

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<sup>73</sup> T45 p. 101–3

A. I think that in many ways this is the one thing that this entire Inquiry has brought to our attention: the fact that we presumed much too much when we made our collections. I mean, I first worked with hearts at Alder Hey Children's Hospital, with the Institute of Child Health there, where they have a wonderful collection of hearts. I do not know how the hearts were collected and I am not exactly sure what questions were asked at that time. When I then came to the Royal Brompton and started to build up my own collection of hearts, because I was not a pathologist – and I am not trying to deflect the decision-making in any way here – but because I was not a pathologist, the pathologist would remove the organs at autopsy, for which we had received consent, so unless it was a Coroner's case and we presumed that the consent given for the autopsy permitted us then to retain the organs, we never asked the question: had the parents been asked if it was appropriate for us to retain the organs? We presumed that appropriate permission had been given. But I think we were wrong in that respect. I do not think we asked the question. I think we should have asked the question... But I do not think that we explained to the parents that we were going to retain the hearts. I think we should have done. I think we were wrong to presume that we had that right...'

102 Professor Green<sup>74</sup> told the Inquiry:<sup>75</sup>

'My generation were, therefore, taught by those who had always themselves been taught that there was no property in a dead body and the general lesson that was drilled into me as a medical student was: be courteous, be polite, explain that you are asking for permission for this autopsy because it will help others, both in learning and in the treatment of disease, but do not go into any more detail; it will upset the relatives and they will be distressed and they might refuse consent... it was felt that if organs were to be retained, relatives should not be further distressed by being presented with a list of organs that might be retained.'

103 The reasons offered are well-meaning: a desire to protect parents from the realities of post-mortem examination; a desire not to intrude further on the parents' grief. But these reasons are also, to a degree, self-serving to the profession. Pathologists and clinicians regarded post-mortems and all that followed to be an important activity, particularly in a teaching hospital. Therefore, the presumption was that they should be carried out and human material retained. Parents need not be involved. They might, after all, say no if they were told 'too much'. And, in any event, they would be pleased to know that research and education were being enhanced, if they ever found out. Their consent should be sought, because this was believed to be a legal requirement, but it need only be consent in form rather than in substance.

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<sup>74</sup> See Appendix

<sup>75</sup> T42, p. 56

- 104 With this historical perspective in mind, we turn to the most recent developments. In March 2000, in advance of his report to Ministers, the Chief Medical Officer for England [the CMO] issued interim Guidance<sup>76</sup> to chief executives of NHS Trusts in the light of new guidance from the Royal College of Pathologists which we consider shortly. He stated that he ‘would be grateful if you [the Chief Executive] would ensure that this is put in place immediately’.
- 105 The interim Guidance goes much wider than post-mortems on children. It does, however, embrace principles which are of particular relevance in the context of our report. The Guidance states at the outset, for example, that standards in the area ‘should improve immediately and become more transparent, particularly communication with the bereaved and obtaining their “consent”’.
- 106 While recognising its interim nature, we welcome this Guidance as an indication of the direction which both principle and practice should follow in the future. We particularly draw attention to the range of information which bereaved parents should be offered, such as what a Coroner’s post-mortem may entail; the relationship (in terms of timing) between a post-mortem and funeral arrangements; whether any human material might be retained and, if so, where and why; and the arrangements for disposal of any human material which have been retained.
- 107 The Guidance goes on to require chief executives of Trusts to ensure that clinicians ‘follow best practice’, and refers in this context to the Royal College of Pathologists’ Guidelines published on the same day. In the light of the reservations we express about these Guidelines, we expect that ‘best practice’ will require further restatement in due course, not least in the light of recommendations we make.
- 108 Then, as we have seen, new guidelines were published by the Royal College of Pathologists. We welcome them as much for their existence as for what they say. They represent a clear recognition by the professional group perhaps most closely concerned with the matters we have been discussing that the future cannot be like the past. They recognise the pre-eminent importance of respect for the parents and family, of the need for agreement except when not required by the current law, and of the need to make that agreement properly informed.
- 109 We recognise that the College saw its brief as being to produce new guidelines. They cannot, of course, make new law. At the same time, they could have proposed that their changes be put into statutory form, on the ground that professional guidelines were not sufficiently binding. After all, previous guidelines have not been conspicuously well-observed. The College chose not to do so. It is a matter of considerable concern whether guidelines, on their own, issued by the very

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<sup>76</sup> ‘*Organ Retention: Interim Guidance on Post-mortem examination*’, Department of Health 23 March 2000

professional body seen by some as having lost trust, will suffice to recapture this trust. We doubt it. For this reason, in our recommendations in Part IV, we argue that, if guidelines were to be used, rather than new law, they would have to come from government, taking account of the views of the public as well as the professionals, and be backed by government.

- 110 We set out in Annex B a detailed description of the Royal College of Pathologists' Guidelines. We confine ourselves here to making a number of general points.
- 111 We welcome the clear recognition in para 1(4) that '... the public and patients no longer wish important decisions to be taken by professional staff on their behalf, but expect a full informed partnership in all such decisions. Relatives therefore need to be given information by people they trust, so that they can understand the implications of decisions and be assured that due account is taken of their wishes.' We also welcome and endorse the recommendation in para 8(1) that 'Medical schools and hospitals must provide training for medical, and other appropriate personnel ... in requesting and obtaining agreement for post-mortem examinations and in dealing with relatives' concerns about tissue and organ retention.'
- 112 On the matter of language, the Guidelines are not entirely satisfactory. Two of the issues we identified at the outset as giving rise to confusion, the meaning of 'tissue' and the difference between consent and objection, remain problematical. As regards 'tissue', there is no definition in the Guidelines, but they refer at different points to 'tissue and organs' and 'tissue, organs and body fluids', and 'organs' are referred to in such a way as to include parts of organs. In Annex A to the Guidelines, which is the Information Leaflet intended for relatives, there is a glossary of terms which includes definitions of 'tissue', organ(s) and body parts. In the model form for recording agreement to a hospital post-mortem, at Annex B to the Guidelines, a whole range of expressions are used at different points without the relationship between them being made clear, including 'tissue samples', 'fluids', 'whole organs', 'organs', 'tissue'. Any distinction between 'tissue' and 'tissue sample' and between 'whole organ' and 'organ' is not specified, and neither parts of organs nor body parts are mentioned. In Annex C to the Guidelines, referring to a model form after a Coroner's post-mortem, 'tissue or [*sic*] organs' are referred to, with tissue immediately translated into 'tissue samples', to be followed in another section of the form with the words, 'tissue, fluids or organs'. No further explanation is offered. The net result is that while all the possible varieties of human material are described at some point in the various documents produced by the College, unless the forms which they propose are read with the leaflet and some explanation given of both, the average relative will still be less than well informed as to what is being agreed to.

- 113 As regards consent and objection, the Guidelines are unsatisfactory. The underlying reason seems to be that the College, while stating at the outset that the Guidelines are not concerned just with the law but with 'the ethical and emotional concerns of bereaved relatives' (para 1.1), feel themselves trapped by the law. For that reason, they decide not to use the word 'consent' (para 1.4, footnote 3), since the Human Tissue Act 1961 does not require consent, only the lack of objection. Instead, they opt for perhaps the worst of all possible worlds by using a third word, 'agreement'. The immediate response is that, if the Guidelines are really concerned with ethics, it is entirely proper for the College to impose a higher duty on pathologists than that required by the law and, thus, use the word 'consent', if that is what they want to say. The language of the 1961 Act is not relevant. Further, the introduction of a third word is unlikely to aid clarity. 'Agreement' is described as being intended 'to infer that a relative does not object' (footnote 3). How this would be translated into the conversation between a distressed relative and a healthcare professional is unclear, but it is likely to be converted into the language of consent, if only to avoid having to establish a negative. If this is so, 'consent' should have been used from the start, since that is really what the College intends to say. But, the confusion does not end there. The Information Leaflet throws in the towel and describes the hospital post-mortem as 'the consented post-mortem', even though it then reverts to the language of 'agreement'. The model forms recommended by the College, however, only use the words 'agreement' and 'agree'. We suggest that it is just this sort of imprecision and vacillation which undermines trust and creates tension. For this reason, we use the word 'consent' throughout our recommendations.
- 114 We turn now to ask what assistance we can find in the Guidelines concerning the crucially important and difficult question of what should be done with human material at the conclusion of a Coroner's post-mortem. Para 3.5 appears to make it clear that to retain 'tissues and organs' for purposes not within the remit of the Coroner's post-mortem, the 'agreement' of the relatives should be obtained. Further, in para 3.5 (b), the Guidelines require coroners to advise relatives of material retained for the purposes of the Coroner's post-mortem, and when and how the material will be released. This would appear to provide a seamless system, such that retained material is to be returned to relatives or dealt with at their direction, unless they agree to its use for other purposes. This position is reinforced by the model form in Annex B to the Guidelines. It specifically details arrangements for the disposal of 'tissue or organs' once the Coroner's post-mortem is concluded, subject to the option of agreeing to the use of the human material for therapeutic purposes or for medical education or research. There is, however, one problem. In para 3.6, the Guidelines contemplate the situation in which the pathologist discovers something, for example a genetic condition, wholly unconnected with the cause of death but warranting further examination in the best interests of the family. In such

circumstances, the guidance given is that the material should be taken and stored, unless reasons for objection, for example on religious grounds, were already known. There should not, however, be any tests carried out until agreement is obtained and, if not given, the material should be returned to the body. While this may be a desirable and defensible proposal in the abstract, it comes at a time of failing trust, when any exception to a rule is seen as swallowing the rule. Also, it appears to be contrary to the law, which provides that material may be preserved only for the purpose of establishing cause of death. If, therefore, it is thought to be a desirable practice, and we see the possible good effects it could bring, it can only be allowed for if consent is gained to do this before the Coroner's post-mortem is begun.

- 115 The apparently seamless system just described is subject to a further problem contained in para 6.3. By this para, the responsibility for 'tissues' is said to revert to the pathologist, once the Coroner's post-mortem is concluded. It is immediately acknowledged, in keeping with what has just been said, that further use or disposal is subject to relatives' wishes. But, it then goes on to state that 'a reasonable compromise is to archive the processed tissue blocks and histological sections, and to retain unprocessed tissue for the same period as biopsy and surgically-resected tissues unless relatives have expressed wishes to the contrary'. It is not clear what, or why, 'compromise' is called for. In addition, 'biopsy and surgically-resected tissues' have not previously been mentioned, nor has any period of time for their retention. This lack of clarity, particularly when the language of 'compromise' is used, is likely to add to rather than reduce trust and is, to that extent, counterproductive.
- 116 We make one final point. The information in the proposed Information Leaflet is helpful not least because it is detailed and specific. But, by being so, we recognise that it will be painful to some parents, already reeling from the loss of their child, while other parents will find it of assistance. We cannot square this particular circle. There is a price to be paid for being informed. We can only seek reassurance in the knowledge that those trained in the area of bereavement understand these difficulties. We observe that the case for their involvement in supporting parents from the start is reinforced.

## European Convention on Human Rights and Biomedicine<sup>77</sup>

- 117 This Convention was produced by the Council of Europe in 1997. It has not yet been ratified by the UK. We notice and endorse the commitment to respect for the dignity and integrity of humans which is the central focus of the Convention. We regard the principle set out in Article 2, that 'the interests and welfare of the human being shall prevail over the sole interest of society or science', as a central ethical

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<sup>77</sup> See further discussion in Annex B

principle which should guide practice in the future, both as regards the issues discussed in this Report and more generally. Equally, while not specifically addressed to the issues of concern to us, we endorse as a guiding principle the central importance given to information and consent. We would wish to see this principle applied as much to the situation of parents asked to consent to the removal and retention of human material from their deceased child for the purpose of medical education and research, as to the care and treatment of the living. We notice and draw attention to the fact that the view we express concerning the proper approach to human material initially removed at post-mortem pursuant to Rule 9 of the 1984 Rules is entirely in keeping with Article 19. This Article sets out a rule consistent with the general principle of consent (in Article 5), that parts of the body which have been removed during an intervention for a specified purpose must not be stored or used for a different purpose unless the general conditions governing information and consent have been observed.

- 118 In the flow charts which follow we describe in diagrammatic form the processes involved in Coroners' post-mortems (Figure 1), hospital post-mortems (Figure 2) and the removal and retention of human material (Figure 3).

Figure 1: The process leading to a Coroner's post-mortem and inquest following a death in hospital

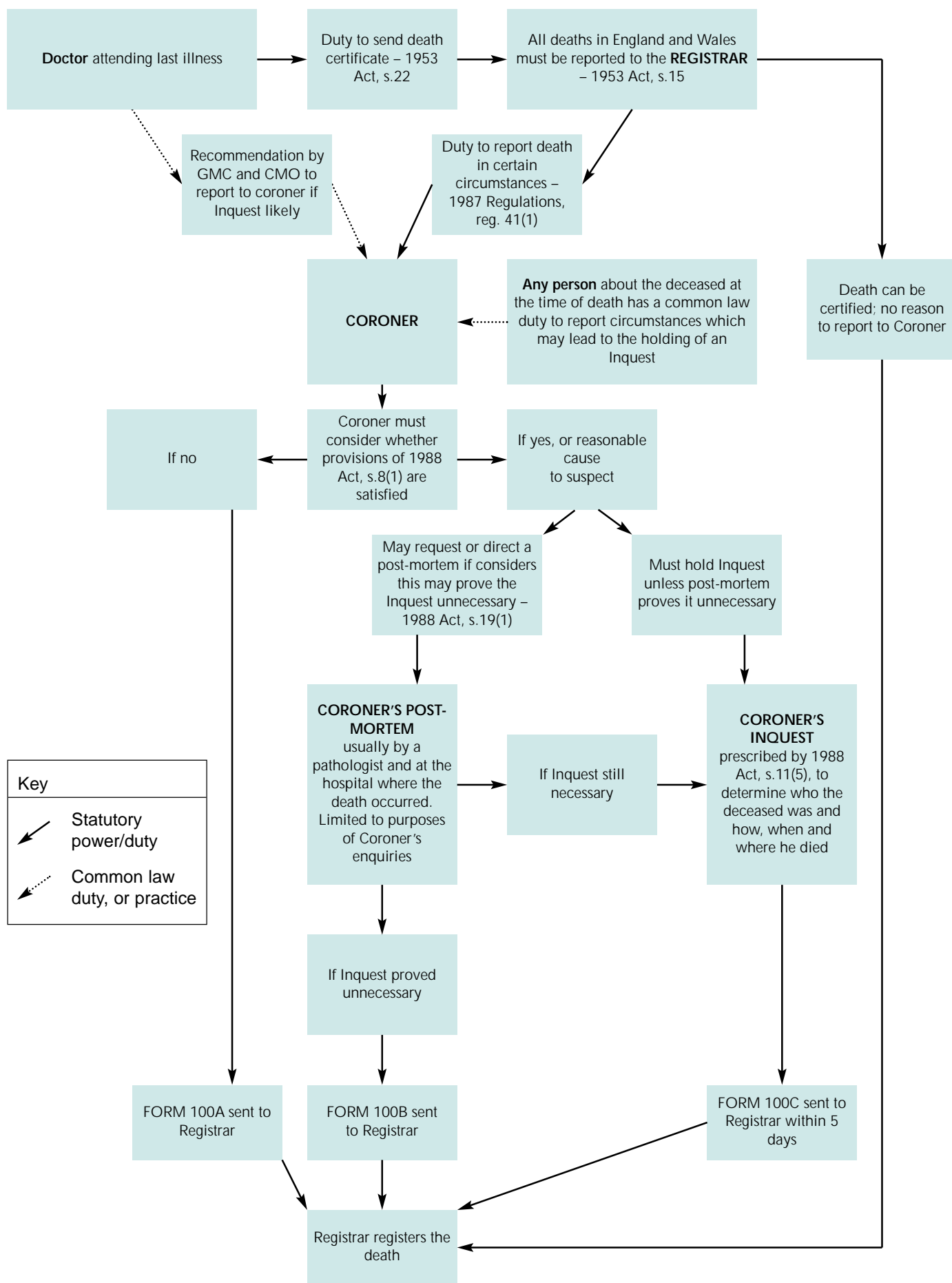


Figure 2: The process typically associated with requesting, authorising and conducting a hospital post-mortem

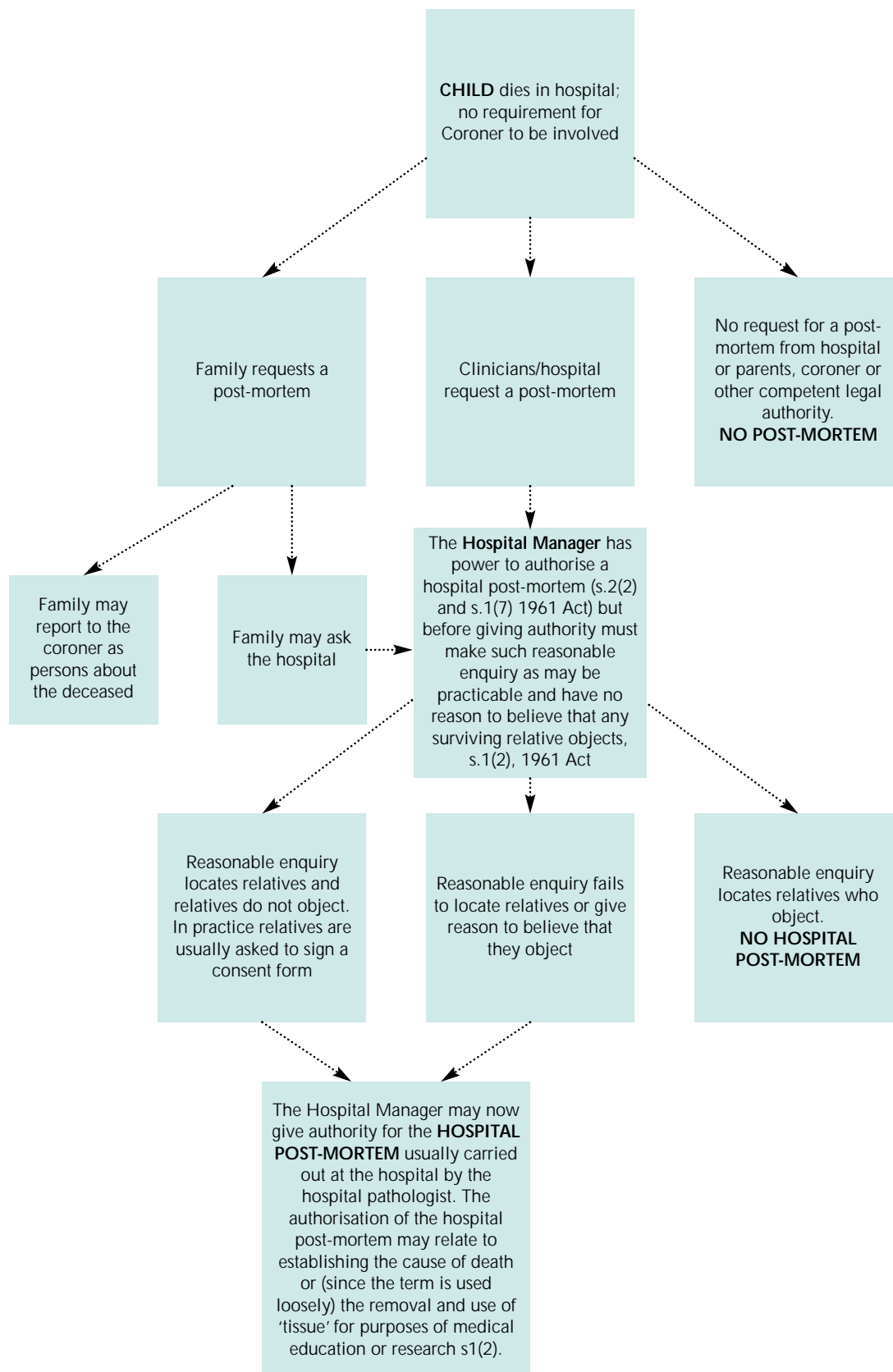
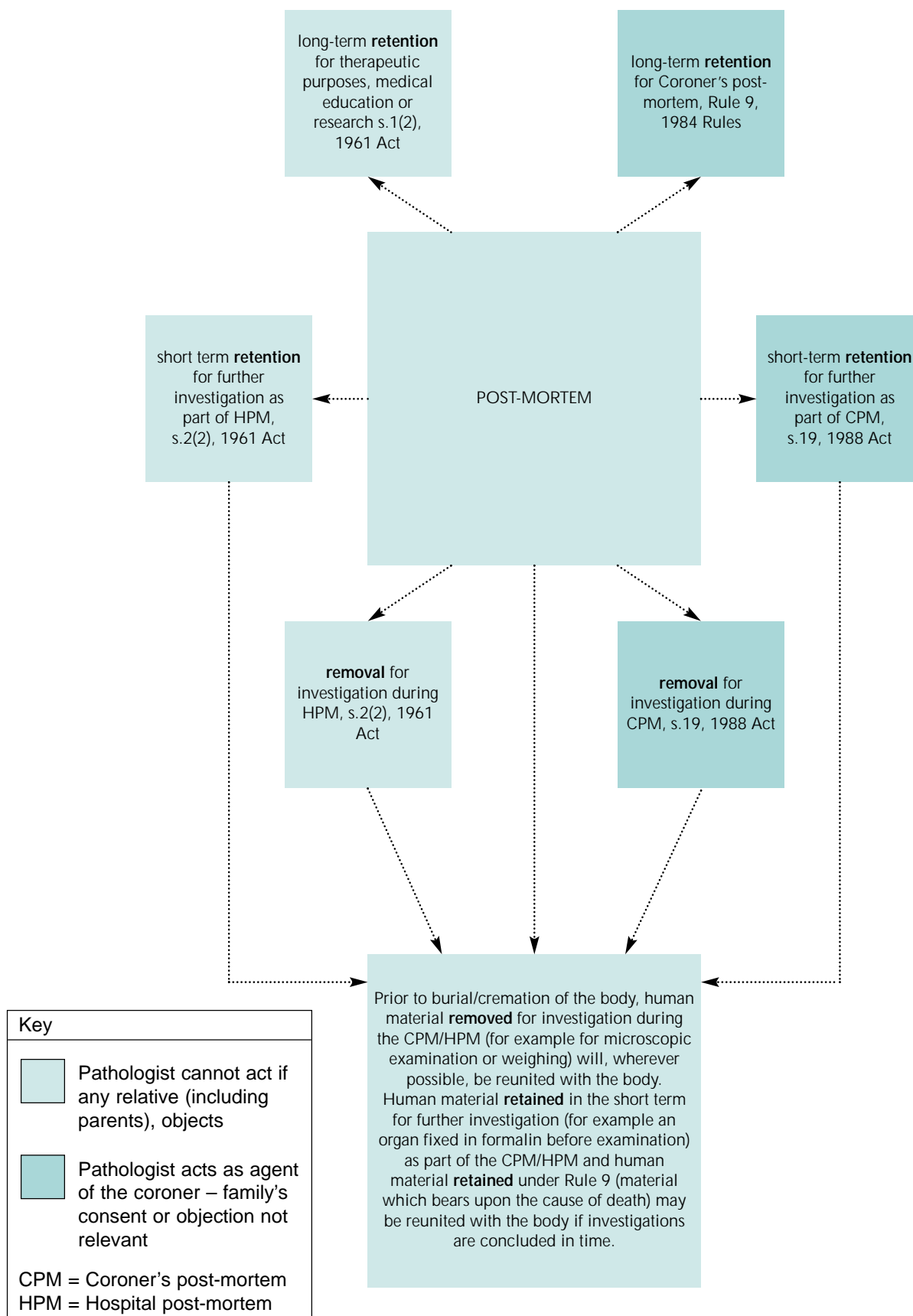


Figure 3: The various procedures by reference to which, currently, human material may be removed, retained used and disposed of



## Part IV

# Recommendations

### Introduction

- 119 As was made clear at the outset, this report has two purposes. It is an interim report of the Inquiry on one of many important issues investigated. It also serves as advice to the CMO. It falls, therefore, into two parts. The first is our account of the events at Bristol, set in the context of time and the national scene. The second is a set of recommendations which arise from what we have learned. It is these latter which constitute our advice to the CMO. It will be for him and others in government to determine the action to be taken in the light of this and other advice.
- 120 We emphasise that our focus is on parents,<sup>78</sup> following the death of a child. There may well be certain recommendations, however, which go beyond this focus. We concentrate on deaths in hospital. Where it is appropriate to do so, however, our recommendations should be applied generally. This applies to both options set out below. Our recommendations constitute what we consider to be the minimum requirements for the future. They are informed by two overarching principles: respect for the families of the child and the benefit to medical knowledge and treatment to be derived from the use of human material.<sup>79</sup> We wish to make it clear again that, although these recommendations have been framed with reference to the conduct of Coroners' post-mortems which follow a death of a child in hospital, the underlying principles hold good for all Coroners' post-mortems. Those responsible for managing the Coroner's post-mortem process, and for liaising with families in the case of non-hospital deaths, should ensure that these recommendations, where applicable, are followed.
- 121 We have approached our task from two different, but overlapping perspectives. Initially, we have made recommendations in the form of a code of practice, working within the fabric of the present law. When we refer to a code of practice, we do not mean something drawn up by, and regarded as belonging to, any professional body or organisation. Rather, we have in mind a code which is produced through the collaboration of all those interested and endorsed by government.
- 122 We recognise the drawbacks of this approach, not least the uncertainty and inadequacy of the current law. We also recognise its benefits, provided always that it is properly observed. Principal among these is the ability to amend the code quickly to take account of developments, for example in our case the science of pathology. Moreover, we would point out that while passing a law may represent a symbolic statement of the importance a subject has in the scheme of things, there is no necessary guarantee that it will be more likely to be followed than a code of

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<sup>78</sup> We repeat here that this is a term which is not free of difficulties. We do not resolve them here, but, instead, refer to the general law on the matter

<sup>79</sup> We should say that, in formulating our views, we were much impressed and assisted by *The Fetal and Infant Post-Mortem: Brief Notes for the Professional*, issued in April 1999 by the Confidential Enquiry into Stillbirths and Deaths in Infancy. We commend it as a source of guidance

practice. Indeed, there is much in public life which is regulated by the latter rather than the former. Finally, to add force to any code, we identify two alternatives. The matters considered in this report may be consolidated with the wider concerns of the CMO, for example, tissue banks and their regulation. If this course were adopted, we recommend that the supervision of the proposed code of practice falls within any more broadly based public body or agency charged with overseeing the whole question of collection, preservation and disposal of human material. (We continue to use the term human material, see para 11). Alternatively, we recommend that government appoint some person or institution to act as a regulator for a fixed period of time to monitor compliance with the code. If after, for example, two years, compliance is unsatisfactory, the legislative option remains open.

- 123 We also point to the practical politics of seeking to change the law. First, while the conduct of Coroners' post-mortems falls to be regulated by the Home Office, hospital post-mortems fall within the broad jurisdiction of the Department of Health (DoH). Co-ordination between these departments would be needed. Second, as regards Coroners' post-mortems, the status of the Coroner as an independent judicial officer means that piecemeal legal restraints on the conduct of Coroners' post-mortems may be seen as unravelling the whole system of coronial jurisdiction. While this may have its merits, it should not be as a side wind from changing certain detailed practices. Third, legal changes affecting the conduct of hospital post-mortems will involve a re-examination of the 1961 Act and this may, in turn, require the consideration of a variety of other legal arrangements, touching on such diverse issues as the definition of death and the development of DNA banks. Again, this is not to say that it should not be done. It is merely to remark that once the legislative option is raised, it will be difficult to confine the legal changes to issues surrounding post-mortems.
- 124 We set out now our recommendations. We then consider the option of implementing them by changing the law through legislation.

## General principles

- 125 The ruling principle in the removal, retention, use and disposal of human material must be respect for the dead child and for the concerns and, to the extent allowed by law, the wishes of parents. **(Recommendation 1)**
- 126 There is benefit to be gained, in terms of developing the understanding and treatment of disease, from the use of human material. Such benefit must only be obtained, however, with the informed co-operation of parents. **(Recommendation 2)**

- 127 Hospital Trusts must have in place appropriate management systems to allow them to comply with the code of practice or changes in the law. Responsibility for compliance should rest with the chief executive of each Trust. **(Recommendation 3)**
- 128 In the case of the code of practice, Coroners should bring their practice into line and the 1984 Rules should be amended to the extent necessary to give effect to the code.<sup>80</sup> **(Recommendation 4)**
- 129 Wider questions having to do with, for example, the establishment and maintenance of tissue banks (including whether the meaning of tissue extends to include DNA sequences), the commercialisation of tissue, intellectual property rights, genetic testing, confidentiality and privacy, which fall outside the immediate remit of this report should receive urgent consideration, with a view to establishing an appropriate regulatory system. **(Recommendation 5)**
- 130 While we acknowledge the possible benefits which can flow from the use of human material, we also recognise the emotional concerns which attend such use. Wherever possible, increasing use should, therefore, be made of alternative means of education and research, for example three-dimensional modelling and other technology, rather than of human material. **(Recommendation 6)**

## Option 1 – A Code of Practice

- 131 To command respect, any code of practice must be seen to be enforceable and enforced. We recommend that the duty to comply with the recommendations which follow be incorporated into the employment contract of clinicians<sup>81</sup> (and into the 1984 Rules, as set out in paragraph 122). Breach of them would give rise to possible disciplinary action by both the employer and the regulatory body in the case of clinicians, and judicial review in the case of Coroners.<sup>82</sup> **(Recommendation 7)**

### (a) Coroners' post-mortems

- 132 No matter what the circumstances are which give rise to the need for a Coroner's post-mortem, whether the death to be investigated occurs in hospital or elsewhere, parents should be given information about the Coroner's proposed post-mortem, why it is necessary and what it entails. Even though the law does not require that they consent, parents should nonetheless be told what requests they can make of the Coroner concerning what may be done to the body. **(Recommendation 8)**

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<sup>80</sup> The 1984 Rules are Statutory Instruments and can be changed by laying the proposed change before Parliament, after which it becomes the new Rule after 30 days unless objected to

<sup>81</sup> Consultants and other hospital doctors

<sup>82</sup> Non-compliance could also constitute professional misconduct on the part of the coroner. The Lord Chancellor has powers of removal under section 3(4) of the 1988 Act in the case of 'inability or misbehaviour in the discharge of his duty'

- 133 Currently, consent need not be sought in the case of a Coroner's post-mortem. Where the parents object, having been informed that a Coroner's post-mortem is contemplated, the Coroner should provide them with an explanation as to why he thinks a post-mortem is necessary.<sup>83</sup> **(Recommendation 9)**
- 134 In the case of a death in hospital which gives rise to a Coroner's post-mortem, information about the Coroner's post-mortem should be given to the parents by a designated person within the hospital who has received all necessary and appropriate training.<sup>84</sup> **(Recommendation 10)**
- 135 Meetings concerning the Coroner's post-mortem, including its timing, should be conducted with proper regard for the circumstances of the parents. There should be a designated area with appropriate privacy. The parents should be offered support. If the parents agree, their GP should be contacted with a view to further care and counselling. **(Recommendation 11)**
- 136 Parents should be given information about the Coroner's post-mortem in a permanent form which they can take away. They should also be given the name and telephone number of the hospital's designated person. **(Recommendation 12)**
- 137 As hospitals develop websites, a domain should be created concerned with 'bereavement' in which all the relevant information concerning post-mortems can be set out in an appropriate manner. **(Recommendation 13)**
- 138 Coroners should advise parents about post-mortems and inquests, informing them about such matters as the date, time and place. **(Recommendation 14)**
- 139 The Coroner's post-mortem report should be sent to any consultant who has been involved in the care of the child during his last illness.<sup>85</sup> **(Recommendation 15)**
- 140 The Coroner's post-mortem report should be sent to the patient's GP. This report should indicate whether any human material has been retained and, if so, what. **(Recommendation 16)**

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<sup>83</sup> We would wish to go further and recommend that, in the absence of good evidence justifying the post-mortem, the Coroner should be required to give good reason why a Coroner's post-mortem is called for. We notice in their recent Discussion Paper *Coroners: A Review 1999*, that the New Zealand Law Commission refer to Section 8 of the N.Z. Coroners Act 1988. This section requires that, in deciding whether or not to authorise a post-mortem, the Coroner must consider:

'(e) The desirability of minimising the causing of distress to persons who, by reason of their ethnic origins, social attitudes or customs, or spiritual beliefs, customarily require bodies to be available to family members as soon as is possible after death; and

f) the desirability of minimising the causing of offence to persons who, by reason of their ethnic origins, social attitudes or customs, or spiritual beliefs, find the post-mortem examination of bodies offensive'

We see the value of such a provision. We recognise, however, that any such provision could have wider implications for the conduct of inquests, which take us beyond our remit here. Thus, we confine ourselves here to urging this wider recommendation as part of any broader review of the powers and duties of Coroners

<sup>84</sup> Since consent is not required for the conduct of a Coroner's post-mortem we do not here refer exclusively to the consultant in charge of the child's care, but rather to a designated person whose responsibilities may go wider

<sup>85</sup> We note that a similar recommendation was made by the Allitt Inquiry, para 7.8(1), '*Report of the Independent Inquiry Relating to Deaths and Injuries on the Children's ward at Grantham and Kesteven General Hospital during the period February–April 1991*'

- 141 The pathologist<sup>86</sup> who is to conduct the Coroner's post-mortem should, in consultation with the Coroner, discuss with the parents the timing of burial or cremation so that any human material removed can, wherever possible, be reunited with the body for burial or cremation, if they have not consented to its being used for other purposes. **(Recommendation 17)**
- 142 The Coroner, on requesting or directing a post-mortem, should stipulate that the pathologist carrying out the post-mortem may remove and retain human material from the body only for the purpose of establishing cause of death. Human material may not be removed, or, once removed, retained or used for any other purpose, except with the consent of the parents.<sup>87</sup> **(Recommendation 18)**
- 143 The Coroner should require the pathologist conducting the Coroner's post-mortem to notify him when it has been concluded and to indicate whether, and if so, what human material has been retained separate from the body. **(Recommendation 19)**
- 144 The Coroner's post-mortem should be understood as having been concluded when the pathologist indicates his findings on the cause of death to the Coroner. **(Recommendation 20)**
- 145 On being notified of the conclusion of the post-mortem, if the Coroner decides not to hold an Inquest, he should require the body to be released to the parents for burial or cremation, if this has not already taken place, subject to any prior consent of the parents that human material may be used for other specified purposes, or subject to the needs of public health. Where the Coroner decides to hold an Inquest, the body should be released to the parents as soon as possible and, in any event, not later than the conclusion of the Inquest (save in exceptional circumstances). To avoid any doubt, the Coroner should stipulate to the pathologist that he has no independent right to retain, use or dispose of human material once the Coroner's post-mortem is concluded, except on the authority of the Coroner in, for example, criminal cases, or with the consent of the parents. **(Recommendation 21)**
- 146 Subject again to any prior consent, human material which has been removed should, wherever possible, be reunited with the body before release to the parents, except when the Coroner, having taken the advice of the pathologist, orders that its continued retention is required for the furtherance of legal process. Where it is not possible to reunite the material with the body, the Coroner, unless there is reason to do otherwise, should order that it be disposed of after consultation with the parents. **(Recommendation 22)**

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<sup>86</sup> We note the Allitt Inquiry recommendation 7.8(3) that paediatric pathology services should be engaged in every case in which the death of a child is unexpected or clinically unaccountable

<sup>87</sup> There may, in exceptional cases, be a need to retain tissue, for example, in cases of *Escherichia coli* 0157, meningococcal meningitis and other infectious diseases where it is important for public health reasons to act quickly to identify a pathogen

- 147 Parents should be asked, either at the time that they are informed of the Coroner's post-mortem, or subsequently, whether, on the conclusion of the Coroner's post-mortem, they consent to the retention of human material removed from their child and the use of that human material for certain specified purposes. **(Recommendation 23)**
- 148 In requesting parents' consent, the meaning of human material should be made clear: that it includes organs, parts of organs and tissue in various forms, such as frozen sections and samples fixed in paraffin. **(Recommendation 24)**
- 149 The purposes for which human material is to be kept should be set out and explained; for example, audit, education, research, display<sup>88</sup> or archiving.<sup>89</sup> In the case of use in any programme of research, application to and approval by the relevant Ethics Committee should be required. **(Recommendation 25)**
- 150 Obtaining parents' consent should be seen as a process, and not just the signing of a form. As part of that process, parents should be allowed proper time to reflect and be informed that they may change their minds until such time as they sign a form indicating their consent. **(Recommendation 26)**
- 151 As part of that process, parents should have access to:
- advice (see designated person); and
  - information which is comprehensible, accessible, and in a form which allows it to be taken home if desired. **(Recommendation 27)**
- 152 The information to which the parent is entitled should include:
- what human material it is proposed to retain: there should be an option to refuse consent for the retention of any material and the option of a list allowing the parents to give or withhold consent as regards each type of human material;
  - what may be done to the human material;
  - whether, if the human material was wanted for a limited period of time, the timing of the burial or cremation could be arranged so that the human material was reunited with the body;

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<sup>88</sup> The term 'display' refers to use of human material at a conference or meeting. It does not include any activity which would offend public sensitivity

<sup>89</sup> It is not clear whether parents may consent to uses not otherwise contemplated by the relevant law: the 1961 Act and the 1984 Act. Archiving in a museum collection and display, for example, at a conference, are not specifically referred to in these Acts and audit is covered only to the extent that it could qualify as 'education'. We regard these uses as broadly within the spirit of the law and acceptable, provided that there is consent from the parents and proper respect is shown to the human material

- the uses to which the human material could be put: there would follow a list as above, with the parents having the option of withholding consent to any particular use;
- the length of time for which human material would be retained, with the parents having the option of attaching a time limit;
- the arrangements which the parents could make for the human material after use, where relevant, ie when the human material was not to be placed in an archive or museum (Options include: reuniting the material with the body; disposal by the hospital; or separate burial or cremation.); and
- the arrangements to safeguard confidentiality. **(Recommendation 28)**

153 There should be a formal, open system whereby the pathologist records the consent given, what was consented to, what human material was removed and retained, what was done to it and how it was disposed of. **(Recommendation 29)**

#### (b) Hospital post-mortems<sup>90</sup>

154 Notwithstanding the fact that the law does not require consent for a hospital post-mortem but merely that an attempt is made to ascertain whether there is objection, consent should be sought before undertaking a hospital post-mortem. **(Recommendation 30)**

155 Consent should be sought by the consultant in charge of the care of the deceased or by a senior member of the clinical team.<sup>91</sup> **(Recommendation 31)**

156 A third person, for example a registered nurse, should be present when the consultant seeks consent. **(Recommendation 32)**

157 Consultants should receive training in 'breaking bad news' and in seeking consent for a hospital post-mortem. **(Recommendation 33)**

158 Application to and approval by the hospital's Ethics Committee should be required in all cases in which consent for a hospital post-mortem is sought for the purpose of carrying out a research programme on human material, or when a research programme is contemplated after consent to a hospital post-mortem was given for other purposes. **(Recommendation 34)**

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<sup>90</sup> We use the term hospital post-mortem in its wider sense, to include post-mortem examination and the removal of human material for therapeutic purposes, medical education or research

<sup>91</sup> We notice that the CMO, in his Interim Guidance, suggests that consent be obtained by a designated individual, rather than the consultant in charge. We do not agree; we reiterate our view that it must ordinarily be the consultant who should seek consent from the parents, and in the absence of the consultant, a senior member of the clinical team

- 159 Meetings concerning the hospital post-mortem, including its timing, should be conducted with proper regard for the circumstances of the parents. There should be a designated area and with appropriate privacy. The parents should be offered support. If the parents agree, their GP should be contacted with a view to further care and counselling. **(Recommendation 35)**
- 160 Parents should be given information about the hospital post-mortem in a permanent form which they can take away. They should also be given the name and telephone number of the hospital's designated person. **(Recommendation 36)**
- 161 The hospital post-mortem report should be sent to any consultant who has been involved in the care of the child during his last illness. **(Recommendation 37)**
- 162 The hospital post-mortem report should be sent to the patient's GP. This report should indicate whether any human material has been retained and, if so, what. **(Recommendation 38)**
- 163 The pathologist who is to conduct the hospital post-mortem should discuss with the parents the timing of burial or cremation so that any human material removed can, wherever possible, be reunited with the body for burial or cremation, if they have not consented to its being used for other purposes. **(Recommendation 39)**
- 164 When consent to a hospital post-mortem is requested, parents should be asked whether they consent to the retention of human material removed from their child and the use of that human material for certain specified purposes. **(Recommendation 40)**
- 165 In requesting parents' consent, the meaning of human material should be made clear: that it includes organs, parts of organs and tissue in various forms, such as frozen sections and samples fixed in paraffin. **(Recommendation 41)**
- 166 The purposes for which human material is to be kept should be set out and explained; for example, audit, education, research, display or archiving. In the case of use in any programme of research, application to and approval by the relevant Ethics Committee should be required. **(Recommendation 42)**
- 167 Obtaining parents' consent should be seen as a process, and not just the signing of a form. As part of that process, parents should be allowed proper time to reflect and be informed that they may change their minds until such time as they sign a form indicating their consent. **(Recommendation 43)**

168 As part of that process, parents should have access to:

- advice (see designated person); and
- information which is comprehensible, accessible, and in a form which allows it to be taken home if desired. **(Recommendation 44)**

169 The information to which the parent is entitled should include:

- what human material it is proposed to retain: there should be an option to refuse consent for the retention of any material and the option of a list allowing the parents to give or withhold consent as regards each type of human material;
- what may be done to the human material;
- whether, if the human material was wanted for a limited period of time, the timing of the burial or cremation could be arranged so that the human material was reunited with the body;
- the uses to which the human material could be put: there would follow a list as above, with the parents having the option of withholding consent to any particular use;
- the length of time for which human material would be retained, with the parents having the option of attaching a time limit;
- the arrangements which the parents could make for the human material after use, where relevant, ie when the human material was not to be placed in an archive or museum (Options include: reuniting the material with the body; disposal by the hospital; or separate burial or cremation.); and
- the arrangements to safeguard confidentiality. **(Recommendation 45)**

170 The parents should be told the reason for making the request to carry out a hospital post-mortem. **(Recommendation 46)**

171 The parents should be told that they may refuse consent. **(Recommendation 47)**

172 The parents should be told, if it is intended to do so, that, as part of the hospital post-mortem, human material may be removed from the body. **(Recommendation 48)**

- 173 Consent should be recorded and the record retained in the child's medical records. The form used to record consent should include such matters as who obtained consent, the date and the witness. **(Recommendation 49)**
- 174 The pathologist should keep a formal record of who gave consent, what the consent related to, what human material was removed and retained, what was done to the human material and how it was disposed of. **(Recommendation 50)**
- 175 The pathologist and the hospital should periodically take stock of human material retained by them and make the results known in an annual report to the hospital's Trust Board. **(Recommendation 51)**

## Option 2 – New Law

- 176 If it were decided that new law is necessary and if parliamentary time could be found, a twofold approach could be adopted. Specific concerns could be met through amending or clarifying the existing law. In addition, the scheme of consents proposed above as a code of practice could be given statutory form by being incorporated into the new law as a schedule, or by stipulating in the law that the code of practice issued from time to time by the appropriate government department must be observed. It has to be said, however, that the legislative regimes which currently regulate Coroners' post-mortems on the one hand and hospital post-mortems on the other are divided between government departments: Coroners' post-mortems fall within the ambit of the Home Office, while hospital post-mortems are in the Department of Health's jurisdiction. Thus, there would need to be significant co-ordination and agreement between the two if any sensible and credible law reform is to be attempted. (Indeed, any systematic review of Coroners' post-mortems, their procedures and function, would need to be conducted across a number of government departments.) **(Recommendation 52)**
- 177 It would almost be worse than having no change in the law to change one legal regime while leaving the other in its present form. This is particularly true when the focus is largely placed, for example, by the Royal College of Pathologists and the CMO's Interim Guidance, on the 1961 Act, that is, on only one government department's responsibility. We recognise that their approach is not concerned with changing the law. Nonetheless, the relevance of the law as set out in the 1988 Act and the 1984 Rules is insufficiently acknowledged. This is despite the fact that the overwhelming number of post-mortems carried out on those who die in hospital are Coroners' post-mortems rather than hospital post-mortems. **(Recommendation 53)**

178 On the basis of the twofold approach referred to above, we propose first to identify matters which require either clarification or amendment; then we refer back to the consent scheme as reflected in the code of practice. **(Recommendation 54)**

**(a) Coroners' post-mortems**

179 Coroners should be required to give information to parents before a post-mortem on a child, indicating, among other things: the purpose of the post-mortem; what it involves, including any removal and retention of human material; what representations they may make as parents; what will happen to any human material removed and retained; where the human material is retained; whether the timing of the burial or cremation can be co-ordinated with the completion of the Coroner's post-mortem; when the body will be released; and what arrangements may be made for human material retained beyond the date of the burial or cremation.

**(Recommendation 55)**

180 Coroners should be required to provide parents with an explanation, if they object to the proposed Coroner's post-mortem.<sup>92</sup> **(Recommendation 56)**

181 Human material should be defined so as to include organs, parts of organs, tissue in various forms, for example slides and fixed blocks, amputated limbs and other body materials. Attention should be given to the inclusion or otherwise of such material as DNA sequences. **(Recommendation 57)**

182 It should be put beyond doubt that the pathologist, in conducting a Coroner's post-mortem, acts as the agent of the Coroner and thus may neither remove nor retain human material except for the purpose of establishing cause of death.

**(Recommendation 58)**

183 When the Coroner has discharged his legal duty by deciding not to hold an Inquest, or, if there is an Inquest, at the end of the Inquest at the very latest, he should issue a Disposal Order. This would require the pathologist to return the body and any human material not otherwise required for legal process to the parents, unless they have given prior consent for the body or human material to be used for specified purposes. The question of what purposes should be specified, as part of the process of obtaining consent, is addressed below. **(Recommendation 59)**

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<sup>92</sup> We reiterate that we would wish to go further and recommend that, in the absence of good evidence justifying the post-mortem, the Coroner should be required to give good reason why a Coroner's post-mortem is called for. We notice in their recent Discussion Paper *Coroners: A Review 1999*, that the New Zealand Law Commission refer to Section 8 of the N.Z. Coroners Act 1988. This section requires that, in deciding whether or not to authorise a post-mortem, the Coroner must consider:

'e) The desirability of minimising the causing of distress to persons who, by reason of their ethnic origins, social attitudes or customs, or spiritual beliefs, customarily require bodies to be available to family members as soon as is possible after death; and  
f) the desirability of minimising the causing of offence to persons who, by reason of their ethnic origins, social attitudes or customs, or spiritual beliefs, find the post-mortem examination of bodies offensive'

We see the value of such a provision. We recognise, however, that any such provision could have wider implications for the conduct of inquests, which take us beyond our remit here. Thus, we confine ourselves here to urging this wider recommendation as part of any broader review of the powers and duties of Coroners

- 184 It should be established that, in the case of a child, the parents have a right to the possession and control of the body and any human material which has been removed from it, when the post-mortem is concluded and the Coroner has decided not to hold an Inquest. If an Inquest is held, the parents' right to possession and control vests, at the very latest, when the Inquest is concluded, unless the Coroner releases the body and any human material at an earlier time, or there is good reason for its continued retention. This right exists only for the purpose of burial or cremation. It follows that a pathologist has no independent right to use the body or human material from it, unless the parents consent to donate the body or human material for specified purposes. **(Recommendation 60)**
- 185 It should be made clear that, on completion of the Coroner's post-mortem, neither the body, nor any human material from it, may be used for any purpose without the prior consent of the parents. Consent should be obtained according to the proposed amendments to the 1961 Act, which are discussed below in the context of hospital post-mortems, and in compliance with either a statutory code of practice, or guidelines issued by government from time to time and incorporated into the statute by reference. The statutory code of practice or guidelines will be in the form set out earlier under Option 1. **(Recommendation 61)**

#### (b) Hospital post-mortems

- 186 The 1961 Act should be amended to require the explicit consent of parents<sup>93</sup> for the use of their child's body or human material for the purposes set out in the Act. This is a recommendation which is specific to children and is without prejudice to any amendments concerning the range of people who may or should be consulted in the case of adults. **(Recommendation 62)**
- 187 It should be made clear that for the purpose of the amendment in the previous paragraph above, a child is anyone under the age of 16. The 1961 Act should also be amended to provide that any purported donation by the child under section 1(1) of that Act would be invalid. **(Recommendation 63)**
- 188 It should be made clear that, as regards deaths in hospital, a formal process for designating the person lawfully in possession of the body is required under the 1961 Act. **(Recommendation 64)**
- 189 The process of seeking the parents' consent and the information to which they are entitled should be set out in a code of practice, contained in a schedule to the Act (or it should be stipulated in the amended 1961 Act that the guidelines issued by government from time to time must be complied with). **(Recommendation 65)**

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<sup>93</sup> It is suggested that where practicable and reasonable the consent of both parents should be sought, given the matters under discussion. We refer again to wider questions of who may have parental responsibility but do not seek to address them here

- 190 The code of practice should be as set out in Option 1, with any necessary adjustments. **(Recommendation 66)**
- 191 It should be made clear that, if the parents have given consent, the right to possession and control of any human material within the scope of that consent, vests in the pathologist and his employer. The implications of this need detailed elucidation. They touch on such legal issues as title, commerce and intellectual property rights and are beyond the scope of this Interim Report.  
**(Recommendation 67)**
- 192 Parents should have the right to revoke their consent without limit of time and call for the return of the human material. If the pathologist or hospital wishes to dispose of the material, all reasonable efforts should be made to contact the parents so that they may be allowed to decide on the disposal. **(Recommendation 68)**
- 193 The 1961 Act should be amended to provide that breach of its provisions will attract criminal sanction and the possibility of professional disciplinary action.  
**(Recommendation 69)**

# Appendix

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## People and Glossary

## People

\* indicates those who gave oral evidence to the Inquiry on matters referred to in this Report.

<b>NAME</b>	<b>TITLE</b>
<b>Alberti, Professor Sir Kirk George</b>	President of the Royal College of Physicians of London
<b>Anderson, Professor Robert*</b>	President elect of the British Paediatric Cardiac Association and Professor of Morphology at Great Ormond Street. Previously at the Royal Brompton Hospital in a position endowed for him by the British Heart Institute and Joseph Levy Foundation Professor of Paediatric Cardiac Morphology, University College, London. Member of the BRI Inquiry's Expert Group.
<b>Ashworth, Dr Michael*</b>	Consultant paediatric pathologist at the UBHT since 1993
<b>Barrington, Mr Ian*</b>	General Manager since 1991 of the Bristol Royal Hospital for Sick Children (part of the UBHT)
<b>Berry, Professor Peter J (Jem)*</b>	Consultant paediatric pathologist at Bristol since 1983 and Professor of Paediatric Pathology at the University of Bristol since 1990
<b>Burgess, Mr Michael J C*</b>	Honorary Secretary of the Coroners Society of England and Wales and HM Coroner for Surrey
<b>Clifford, Mr Robert*</b>	Head of the Coroners Section of the Animals, Bye-laws and Coroners Unit, Constitutional and Community Policy Directorate, Home Office since August 1995

<b>Creighton, Mr Robert</b>	Chief Executive of the Great Ormond Street Hospital for Children NHS Trust
<b>Dhasmana, Mr Janardan*</b>	Consultant cardiac surgeon at Bristol from 1 January 1986 to 9 September 1998
<b>England, Ms Karen</b>	Director of Operational Services at Alder Hey Children's Hospital, part of Royal Liverpool Children's NHS Trust
<b>Fleming, Professor Peter</b>	Head of the Division of Child Health, Department of Clinical Medicine, University of Bristol from 1982 to the present date
<b>Forrest, Mr Paul*</b>	HM Coroner for the District of Avon since 1992
<b>Gould, Dr Steve J*</b>	Consultant paediatric pathologist, The John Radcliffe Hospital, Oxford. Member of the BRI Inquiry's Expert Group
<b>Green, Professor Michael Alan*</b>	Consultant pathologist to the Home Office and Emeritus Professor of Forensic Pathology, University of Sheffield
<b>Hawkins, Mr Donald</b>	HM Coroner for the District of Avon from 1978 to 1992
<b>Joffe, Dr Hyam S*</b>	Consultant paediatric cardiologist at Bristol from 1980 to the present date
<b>Jordan, Dr Stephen C*</b>	Consultant paediatric cardiologist at Bristol from 1969 until May 1993
<b>Kennington, Mrs Diane*</b>	Patient Affairs Officer at the BRI since 1983
<b>Knight, Professor Bernard</b>	Consultant pathologist to the Home Office since 1965; Professor of Forensic Pathology, University of Wales College of Medicine since 1980

<b>Langstaff QC, Brian</b>	Leading Counsel to the Inquiry
<b>MacSween, Professor Roderick N M</b>	Then President of the Royal College of Pathologists
<b>Martin, Dr Robin P*</b>	Consultant paediatric cardiologist at Bristol from February 1989 to the present date
<b>Moss, Mr David</b>	Chief Executive of the Southampton University Hospitals NHS Trust
<b>Roberts, Dr Clive J C</b>	Clinical Dean and Consultant Senior Lecturer in Clinical Pharmacology and Therapeutics, University of Bristol from 1980 until the present date
<b>Ross, Mr Hugh*</b>	Chief Executive of UBHT from 30 October 1995 until the present date
<b>Shaw, Dr Charles</b>	Director of the Bristol Clinical Audit Unit which was part of the Department of Epidemiology and Public Health Medicine at the University of Bristol
<b>Silove, Dr Eric</b>	Consultant paediatric cardiologist, Birmingham Children's Hospital NHS Trust. Member of the BRI Inquiry's Expert Group
<b>Taylor, Mr Mark</b>	Chief Executive of the Royal Brompton and Harefield NHS Trust
<b>Wisheart, Mr James*</b>	Retired Medical Director and Consultant cardiac surgeon at UBHT 1975–1995

## Glossary

<b>AHA</b>	Avon Health Authority. The AHA came into existence formally on 1 April 1996 following the merger of the former District Health Authority and Family Health Services Authority. It inherited the planning and purchasing roles.
<b>B&amp;WDHA</b>	Bristol and Weston District Health Authority. This was established on 1 April 1982 following the abolition of the Avon Area Health Authority (Teaching), from the old Bristol Health District (Teaching) and the Weston Health District, which had merged in 1978. Continued in existence until the purchaser/provider split took place on 1 October 1991.
<b>BCH</b>	Bristol Children's Hospital. See BRHSC below.
<b>BDHA</b>	Bristol and District Health Authority. This formally came into existence on 1 October 1991 as the purchasing authority for the Bristol area. Remained until 1 April 1996, when it merged with the Avon Family Health Services Authority to become the Avon Health Authority.
<b>BHCAG</b>	Bristol Heart Children Action Group – this group was initially a group of parents who met to provide comfort and support to each other. They called for a public inquiry as early as June 1996. However, the BHCAG was not formally convened until March 1998.
<b>BMH</b>	Bristol Maternity Hospital.
<b>BRHSC</b>	Bristol Royal Hospital for Sick Children (formerly the Bristol Royal Children's Hospital). The only specialist paediatric hospital in the South West of England. BRHSC belongs to the Children's Services Directorate of the UBHT. It is located in central Bristol.
<b>BRI</b>	Bristol Royal Infirmary, part of the UBHT. It is located in central Bristol.
<b>BSSG</b>	Bristol Surgeons' Support Group – a group comprising largely former patients of Mr Wisheart and Mr Dhasmana, but including parents of children on whom the surgeons had performed paediatric cardiac surgery, set up as a result of the General Medical Council hearings in relation to charges against Mr Wisheart, Mr Dhasmana and Dr John Roylance, the former Chief Executive of the UBHT.

<b>DHSS</b>	Department of Health and Social Security. Established on 1 November 1968 when the two separate ministries of Health and Social Security were amalgamated.
<b>DoH</b>	Department of Health. Established in July 1988 following the decision to split the DHSS into two ministries <sup>94</sup> .
<b>NHS</b>	National Health Service established on 5 July 1948 by an Act of Parliament passed on 6 November 1946.
<b>NHS Executive South and West</b>	South and West Regional Office of the NHS Executive. This was created on 1 April 1996 on the abolition of the Regional Health Authorities.
<b>SWRHA</b>	South Western Regional Health Authority. This became operational from 1 April 1974 and continued until it merged with part of the Wessex Regional Health Authority in 1994, to become the South and West Regional Health Authority. It continued in this form until 1 April 1996.
<b>The Trust</b>	The UBHT – see below.
<b>UBH</b>	The United Bristol Hospitals. A group of hospitals <sup>95</sup> servicing Bristol prior to the formation of the UBHT on 1 April 1991.
<b>UBHT</b>	The United Bristol Healthcare (NHS) Trust. A teaching Trust formed on 1 April 1991, comprising nine hospitals <sup>96</sup> and community centres, providing a comprehensive range of healthcare services both in hospitals and the community. The majority of UBHT hospitals are in Central Bristol, whilst community care is provided by staff based in health centres and clinics in Central and South Bristol, and parts of Bath & North East Somerset and North Somerset.
<b>UBH/T</b>	The term used by the Inquiry to refer to the hospitals comprising the UBH and the UBHT, both before and after Trust status.

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<sup>94</sup> Edwards, Brian, – *The National Health Service 1946-1994: A manager's tale* 1995, The Nuffield Provincial Hospitals Trust, page 145.

<sup>95</sup> The Bristol Royal Infirmary, Bristol Royal Hospital for Sick Children, formerly the Bristol Royal Children's Hospital, Bristol Eye Hospital, Bristol Maternity Hospital, Bristol General Hospital, University of Bristol Dental Hospital; between 1960 and 1974 they were joined by Bristol Homeopathic Hospital and Farleigh Hospital (Mental Handicap)

<sup>96</sup> The Bristol Royal Infirmary, Bristol Royal Hospital for Sick Children, Bristol Eye Hospital, Bristol General Hospital, Dental Hospital, Barrow Hospital, Keynsham Hospital, St Michael's Hospital, Bristol Oncology Centre