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

Interim Report

Annex A and Annex B

The Bristol Royal Infirmary Inquiry

Annex B

Law and Guidelines

Introduction

The meaning of 'post-mortem'

1 *Black's Medical Dictionary*[1] defines a post-mortem examination[2] as 'an examination of a body to determine the causes of death …' There is no statutory definition of what constitutes a post-mortem examination.[3]

The 'removal' and 'retention' of tissue – an overview

2 Several statutes regulate different aspects of the removal and retention of tissue. The key Acts are the Human Tissue Act 1961 [the '1961 Act'], the Anatomy Act 1984 [the '1984 Act'], the Coroners Act 1988[4] as amended [the '1988 Act'] and The Human Organ Transplants Act 1989 [the '1989 Act']. The relevant aspects of these statutes are considered below.

'Organ' and 'tissue'

3 The 1961 Act, the 1984 Act and the Regulations made under the 1984 Act, all refer to 'bodies' or 'parts of bodies' but do not define either organs or tissue. The 1989 Act defines organ[5] as 'any part of a human body consisting of a structured arrangement of tissues which, if wholly removed, cannot be replicated by the body'. The 1988 Act does not refer to parts of a body, but Rule 9 of the 1984 Coroners Rules ('the 1984 Rules') which provides for the retention of parts of the body at a Coroner's post-mortem examination refers to the 'preservation of material' which may bear upon the cause of death.

4 *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.'

5 The report of the Nuffield Council on Bioethics, *'Human Tissue Ethical and Legal Issues'* [the *'Nuffield Council report'*][6] took the term tissue to comprise: 'Organs, parts of organs, cells and tissue, sub-cellular structures and cell products, blood, gametes [sperms and ova], embryos and fetal tissue.'

6 In this Report, we use a more general term, 'human material', which is intended to avoid confusion between tissue in the sense of samples, blocks and specimens, on the one hand, and organs, or parts of organs or material such as amputated limbs. In this Annex, however, because the various Acts refer to tissue or organs, we use the word tissue, in its wide sense (i.e. including organs), so as to examine the law.

[1] 39th Edition
[2] Or 'autopsy'
3 Although Rule 10(1) and Schedule 2, Coroners Rules 1984 prescribe a form for the pathologist to report the results of a post-mortem to the coroner, see WIT 43 60–61
[4] This Act consolidated the Coroners Act 1887 and the Coroners (Amendment) Act 1926
[5] Section 7(2)
[6] April 1995

Short-term and long-term retention of tissue

7 It is important, at the outset, to distinguish tissue which, once removed, is subsequently reunited with the body for burial or cremation from that which, once removed, is:

- retained for a short period after burial or cremation of the body and disposed of separately;
- retained long term.

8 The Inquiry heard evidence on standard practice in relation to post-mortem examinations and why, in certain circumstances, it was not thought possible to carry out the necessary investigations into the cause of death and return tissue to the body in time for burial or cremation.[7]

Removal and short-term retention

9 Professor Green[8] advised that the view of the Royal College of Pathologists was that no post-mortem examination was complete without microscopic examination of a representative small piece of tissue from every major organ.[9] There were many circumstances when it was difficult, impossible or unsatisfactory to examine an organ immediately it had been removed from the body. In relation to the examination of the heart of a neonate 'It is often necessary … to inject the blood vessels of the heart … to cut serial sections, as many as 300, through the so-called "conducting bundle" and this can only be done on fixed tissues. To fix a heart in formalin takes 10 days.'[10]

10 In relation to the practice of examining tissue in addition to the heart, Professor Green continued, 'a goodly percentage of congenital heart disease is in fact not confined to the heart. There are associated abnormalities of the vessels which run between the heart and the lungs and also the aorta, the main blood vessel … it was desperately important to take the thoracic organs en bloc, fix them, recolour them and then look at them with the aid of magnifying spectacles, television camera, dissected against a clean and bloodless background, and … it takes 10 days to do it properly and you would delay the funeral for 10 days if you returned the organs to the body.'[11]

[7] See Report
[8] Michael Alan Green, Emeritus Professor of Forensic Pathology, University of Sheffield, Consultant Pathologist to the Home Office, WIT 54, T 42
[9] See also RCPath 1/74
[10] WIT 54 T42
[11] T42 p. 47–55

11 Professor Berry[12] advised: 'Examination of hearts after surgery for congenital heart disease often involves some of the most difficult dissection pathologists encounter. It was often our practice to perfuse the heart with preservative under pressure for several hours to restore its contours in life, and to carry out much of this dissection after the post-mortem examination of the body itself. Lung tissue was sometimes retained, either to maintain the relationship between the heart and lungs where there were congenital abnormalities of the connections of important vessels, or because they might show microscopic evidence of pulmonary hypertension (raised blood pressure in the lungs) contributing to death. Other tissues were sampled for microscopy to document any other disease process according to good practice.'[13]

Longer-term retention

12 As to longer-term retention, the Inquiry heard evidence from Professor Robert Anderson[14] regarding the benefits of retention of hearts for study and teaching purposes. He considered that one of the many reasons for improvements in mortality in centres of excellence for cardiac surgery was the knowledge that had accrued from the study of retained hearts.[15] He gave evidence as to the scale of the retention of congenitally malformed hearts in this country.[16] He estimated that the largest collection was at Alder Hey Children's Hospital with approximately 2,500 hearts; he had built up a collection at the Royal Brompton Hospital of some 2,000; and there were collections at Great Ormond Street of 2,000, at Birmingham Children's Hospital of about 1,500 and other, smaller collections, in Leeds, Bristol, Southampton, Newcastle and Manchester.

13 Professor Anderson explained that in the case of a congenitally malformed heart it was necessary to retain the whole organ in order to study and demonstrate it.'[17] 'In the case of a heart, no two organs are ever identical, and for proper study, it is essential to retain the entire organ.'[18]

[12] (Peter) Jem Berry, Professor of Paediatric Pathology at the University of Bristol, and Consultant Paediatric Pathologist at the Bristol Royal Hospital for Sick Children, WIT 204/5 para 12
[13] WIT 204/8 and 9, para 26
[14] Robert H Anderson, Joseph Levy Foundation Professor of Paediatric Cardiac Morphology, University College London, President elect of the British Paediatric Cardiac Association, T45
[15] His letter to the Inquiry of 25 January 2000, WIT 546/1–2
[16] T45 p. 104–106
[17] T45 p. 108.
[18] WIT 546/2.

Part I

The Coroner and the Coroner's post-mortem examination

Reporting and registering a death

14 Any death in England and Wales must be reported to the Registrar of Births Marriages and Deaths [the 'Registrar'] for the sub-district in which the death occurred, for entry in the register [section 15, Births and Deaths Registration Act 1953 [the '1953 Act'] and Regulation 41 of the Registration of Births and Deaths Regulations 1987 [the '1987 Regulations'].[19] Before a death can be registered and the body disposed of, there must either be a medical certificate of cause of death from a doctor, or a certificate from a Coroner after his investigations are completed.

15 Under sections 16 and 17 of the 1953 Act it is the duty of a 'qualified informant' to give relevant details to the Registrar concerning a death. Failure to do so is a criminal offence. The Inquiry heard from Mr Clifford[20] that the expression 'qualified informant' applied to a senior member of hospital administration staff in relation to a death in hospital. It also applies to a relative of the deceased who has knowledge of any of the particulars required to be registered concerning the death.[21]

Involvement of the Coroner

16 The Registrar is the only person with a statutory duty to report a death to the Coroner. Regulation 41(1) of the 1987 Regulations provides:

'Where the relevant Registrar is informed of the death of any person he shall, subject to paragraph (2), report the death to the Coroner on an approved form if the death is one:

a) where the deceased was not attended during his last illness by a registered medical practitioner;

b) in respect of which the Registrar has been unable to obtain a duly completed certificate of cause of death or has received a certificate from which it appears that the deceased was not seen by the certifying medical practitioner after death or within 14 days before death;

c) the cause of which appears to be unknown;

[19] SI 1987/2088
[20] Mr Robert Clifford, Head of the Coroners Section of the Animals, Byelaws and Coroners Unit of the Home Office
[21] Section 17(2), 1953 Act

d) which the Registrar has reason to believe to have been unnatural or to have been caused by violence or neglect or abortion or to have been attended by suspicious circumstances;

e) which appears to the Registrar to have occurred during an operation or before recovery from the effect of an anaesthetic;

f) which appears to the Registrar from the contents of any medical certificate of cause of death to have been due to an industrial disease or industrial poisoning.'

17 Regulation 41(1)(e) is interpreted in *Jervis on Coroners,* para 5–27,[22] as applying to deaths which occur during an operation or within 24 hours of the operation or full recovery from the anaesthetic, or to a death where there is reasonable cause to believe that it was related to the operation or anaesthesia. In practice, when deciding whether to report to the coroner under Regulation 41(1)(e) *Jervis,* para 5–32*,* suggests various questions to assist Registrars and medical practitioners:

'(i) Was the death due to disease or injury for which the surgery was being performed, and would death have occurred at the time it did without surgical intervention?

(ii) Was there any other disease process in the patient which pre-disposed to a fatal outcome of surgical intervention, and was this disease process taken into account by the doctors before surgery was begun?

(iii) Was death caused by a disease process unrelated to that for which surgery was performed and was this considered by the doctors before the operation?

(iv) Was the surgical intervention urgent, life-saving or merely elective for the purpose of improving the quality of the patient's life? Was the condition of the patient for surgery and anaesthetic assessed in relation to these motives for performing the operation? and

(v) Was there any evidence of accidental error or negligent technique in the surgical or anaesthetic procedure?'

18 There is no specific statutory requirement for members of the public to inform the Coroner of deaths.

[22] Sweet & Maxwell, 11th Edition

19 There is a common law duty on every person who is at the place of death or nearby at the time it takes place, to give immediate notice to the Coroner or to his officer or to the appropriate officer of police of circumstances which may lead to the holding of an inquest.[23]

20 The only statutory duty, in this context, imposed on a doctor is pursuant to section 22 of the 1953 Act, which requires a certificate of the cause of death to be sent to the Registrar by the doctor attending the person in his last illness.[24]

21 Notwithstanding the position under statute, the Inquiry heard from Mr Clifford that, in practice, deaths are commonly reported to the Coroner by a doctor or other member of hospital staff where they have reason to believe that an inquest is likely to be necessary.

22 In 1996, and therefore outside the period being considered by the Inquiry, in *R v HM Coroner for Wiltshire ex parte Clegg*[25] the High Court criticised the lack of guidance given to NHS staff as to providing information to coroners. The Chief Medical Officer's *Update 20/98* subsequently issued to all doctors advised:

'The Select Committee on Public Administration earlier this year stressed the need for clinicians to disclose all relevant information to the Coroner to ensure a fully informed decision on cause of death. Whilst there is no specific duty on clinicians to do this, all those who have information which could help Coroners' inquiries should disclose it voluntarily and not only when requested. The GMC [General Medical Council] has updated, and the UKCC [United Kingdom Central Council for Nursing, Midwifery and Health Visiting] will shortly be publishing, amended professional guidance emphasising the need to inform the Coroner.'

The Coroner

23 The Coroner is an independent judicial officer. Only a barrister, solicitor or legally qualified medical practitioner of not less than five years' standing in his profession may be appointed [section 2(1), 1988 Act]. He is required to appoint a deputy and may appoint an assistant deputy [section 6(1)]. These officers are not employees or officers of local government and are independent of local government, although the 'relevant council' appoints them, remunerates them and provides their premises. Their appointment and powers are regulated by the 1988 Act and the 1984 Rules.

[23] R v Clerk (1702) 1 Salk 377: the words used in the case are 'every person who is about the deceased…'
[24] See para 14. Any reference to a 'para' is to a para in this Annex, unless otherwise indicated
[25] (1996) 161 JP 521

24 The Home Office is responsible for the law in relation to Coroners and has a role in setting standards of practice for Coroners by issuing circulars and newsletters, although these have no statutory underpinning. Neither the Home Office nor any other government department has any statutory responsibility for setting educational or training standards for Coroners, although the Home Office has, since 1984, provided study opportunities for them.[26]

25 The Inquiry heard from Mr Burgess[27] as to the role of the Coroners' Society. Most Coroners, deputy and assistant Coroners are members of the Society, which issued guidance in the form of practice notes for Coroners for the first time in 1998, after the period under consideration by the Inquiry.[28]

26 There is no statutory requirement for Coroners to undergo training or achieve particular qualifications other than those required by section 2(1).

The Coroner's power to act

27 The Coroner cannot act unless and until the provisions of section 8(1), 1988 Act are satisfied, namely:

'that he is informed that the body of a person is lying within his district and there is reasonable cause to suspect that the deceased:

a) has died a violent or an unnatural death; or

b) has died a sudden death of which the cause is unknown; or

c) has died in prison or in such a place or in such circumstances as to require an inquest under any other Act.'

The Coroner's post-mortem examination

28 If, after initial consideration, the Coroner concludes that section 8(1) does not apply and that a post-mortem examination and inquest are unnecessary, he will complete Form 100A[29] setting out the cause of death as certified by the deceased's doctor.

29 If the Coroner after initial enquiries considers there is reasonable cause to suspect that the circumstances in section 8(1)(a) or (c) may have occurred, then he must proceed to hold an inquest. He will usually order a post-mortem examination for evidential purposes under section 20, 1988 Act.

[26] See the statement of Mr Clifford WIT 43/2
[27] Mr Michael Burgess, Honorary Secretary of the Coroners Society of England and Wales and HM Coroner for Surrey
[28] See the statement of Mr Burgess WIT 39/2–3
[29] Forms 100A, 100B and 100C, otherwise referred to as Pink Forms A , B and C, are not prescribed by statute, but are provided to Coroners by the Registrar General

30 If, on initial enquiries, the Coroner considers the cause of death to be unknown (section 8(1)(b), 1988 Act), he will direct a post-mortem examination under section 19(1), 1988 Act if he is of the opinion that it may prove an inquest to be unnecessary to establish the cause of death. If, once a post-mortem examination has been carried out under section 19(1), the Coroner is satisfied that an inquest is not necessary, he sends Form 100B[30] to the Registrar stating the cause of death disclosed by the post-mortem report.

31 By section 20, 1988 Act, once Coroners have decided to hold an inquest, they are authorised to request any legally qualified medical practitioner,[31] ordinarily a pathologist, to make a post-mortem examination and report the result in writing to the coroner. By section 20, the Coroner may also direct that a post-mortem be carried out and evidence be given before the Coroner as to how the deceased came by his death.

32 Importantly, the pathologist acts as agent of the Coroner[32] and his remit is limited to the purposes of the Coroner's enquiries.

The Coroner's inquest

33 The purpose of the Coroner's inquest is prescribed by section 11(5), 1988 Act, namely to determine, as far as can be proved, who the deceased was,[33] and how, when and where he came by his death. The written inquisition must set out these particulars.[34] After an inquest has been held, the Coroner must, within five days after the finding of the inquest, send to the Registrar a certificate setting out the information prescribed by section 11(7), 1988 Act.[35]

34 Mr Clifford and Mr Burgess both stressed the limited purpose of the Coroner's inquest as set out in section 11(5), and referred to the Coroners' Society's 'Practice Notes for Coroners 1998' issued after the period with which the Inquiry is directly concerned which state, at paragraph 3.6:

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[30] See footnote 29

[31] Sections 19 and 20, 1988 Act; this would appear to mean a registered medical practitioner, and not a medical practitioner with a legal qualification

[32] See paras 47–54 for a discussion of the role of the pathologist in the Coroner's post-mortem examination

[33] As regards issues of identification, Lord Justice Clarke's Final Report into Thames Safety [Cm 4558] examines at Chapter 12 the treatment of the bodies of 25 of those who died in the collision between the two boats Marchioness and the Bowbelle on the River Thames. Hands were removed for purposes of identification on the authority of the Coroner. The Thames Safety Inquiry heard that the Coroner had determined: 'In circumstances where it was impossible to take adequate fingerprints from the bodies without removing the hands of those bodies to the Fingerprint Laboratory, those hands should be removed' and that the removal was not made known to the relatives for some two years. A non-statutory public inquiry into the identification of victims following major transport accidents was subsequently announced by the Deputy Prime Minister on 17 January 2000, to run in tandem with the statutory Inquiry into the collision

[34] For the form of the Inquisition, see *Jervis* at para A2–93

[35] The form of the Register appears at Schedule 3, 1984 Rules, and requires the following to be recorded: date on which the death is reported to the Coroner, full name and address, age and sex of the deceased, cause of death, whether the case was disposed of by Pink Form A or Pink Form B or whether an inquest was held, and the verdict at inquest if held.

'You will also need to keep in mind the limited purpose of the Coroners inquest, as clearly stated in section 11(5) Coroners Act and Regulations 36 and 42 Coroners Rules.'

35 The 1984 Rules[36] provide:

'36. (1) The proceedings and evidence at an inquest shall be directed solely to ascertain the following matters, namely –

a) who the deceased was;

b) how, when and where the deceased came by his death;

c) the particulars for the time being required by the Registration Acts to be registered concerning the death.

Neither the Coroner nor the jury shall express any opinion on any other matters.'

'42. No verdict shall be framed in such a way as to appear to determine any question of –

a) criminal liability on the part of a named person, or

b) civil liability.'

36 The overall purpose of the inquest was previously considered by the Broderick Committee[37] to be:

a) to determine the medical cause of death;

b) to allay rumours or suspicions;

c) to draw attention to the existence of circumstances which, if unremedied, might lead to further deaths;

d) to advance medical knowledge;

e) to preserve the legal interest of the deceased's family, heirs or other interested parties.

[36] 1984 SI No. 552 (as amended by the *Coroners (Amendment) Rules 1985; 1985 SI No. 1414)*
[37] Report of the Committee on Death Certification and Coroners, September 1971, Cmnd 4810

37 This approach was, some years later and within the period of the Inquiry's terms of reference, noted with approval by Simon Brown LJ in *R v HM Coroner for Western District of East Sussex ex parte Homberg.*[38]

38 Once an inquest is concluded and the verdict returned, it is clear that the Coroner has no further powers in relation to the death and is *functus officio* (without any further lawful authority having discharged the duties of his office). In so far as a pathologist, in conducting a post-mortem examination, does so on behalf of the Coroner, and thus as the Coroner's agent, the pathologist's authority as regards any further dealing with the body (or anything removed from it) will terminate when the Coroner becomes *functus officio.*[39] It is not as clear that the completion of Form A and Form B also has the effect of rendering the Coroner *functus officio*, as the Coroner has not, at the stage of completing either Form, constituted himself into a Coroner's Court, but, as regards the position of the pathologist, in a Form A case there is no post-mortem and in a Form B case, once that form has been completed, the pathologist would not have continued authority *qua* agent of the Coroner to retain or use tissue removed at post-mortem.

39 A number of witnesses expressed a view before the Inquiry as to whether the Coroner's Court is an appropriate forum for audit or identifying local or national trends in mortality. This issue will be addressed in that part of the Inquiry's final report concerned with Audit.

The Coroner's post-mortem examination and inquest: authority and consent

40 There is no statutory requirement for the Coroner or his officers to obtain consent from any natural or legal person before holding an inquest or directing a post-mortem examination or special examination,[40] and these may therefore be conducted notwithstanding lack of consent or even despite objections from relatives.

Information for relatives about the Coroner's post-mortem examination and inquest

41 Although there is no requirement for the Coroner to seek consent from relatives, there are provisions for certain people and bodies to be notified of the date and time of a proposed post-mortem[41] unless it is impracticable to do so or would cause the examination to be unduly delayed.[42] Those to be notified include 'any relative of the deceased who has notified the Coroner of his desire to attend, or be represented at, the post-mortem examination'.[43] The Coroner has a discretionary power to notify any other person whom he is not under a duty to notify.[44]

[38] (1994) 158 JP 357
[39] See this Annex, section on Wrongful removal, retention and use
[40] Sections 8, 19, 20, 1988 Act
[41] Rule 7, 1984 Rules
[42] Rule 7(1). By Rule 5, 1984 Rules, delay in the holding of a post-mortem is to be avoided
[43] Rule 7(2)(a), 1984 Rules
[44] Rule 7(4), 1984 Rules

42 The Inquiry heard from Mr Clifford[45] that no Home Office guidance had been issued as to how Coroners might or should exercise their judgement under these provisions.

43 However, the '*Practice Notes for Coroners'*, issued after the period under inquiry, advise[46] 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 must give all the relevant interested persons an opportunity to comment on the situation concerned.'[47]

44 The report of a Coroner's post-mortem examination or special examination is delivered to the Coroner and may not be disclosed to any other person without his consent.[48] Once received, the Coroner must supply a copy of the post-mortem report (on payment of a fee) to any person who, in the opinion of the Coroner, is a 'properly interested person',[49] but there is no *statutory* requirement for relatives to be provided with a copy of the post-mortem report or notification of the result of the inquest.

45 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.'[50]

46 The Coroner is required (by Rules 19, 20 and 33, 1984 Rules) to notify certain people of the arrangements for any inquest.[51]

The pathologist in the Coroner's post-mortem examination

47 Rule 6(1)(a), 1984 Rules requires the Coroner, wherever possible, to instruct a pathologist with suitable qualifications and experience who has access to laboratory facilities.

48 The *1984 Rules* and 1988 Act do not prevent the Coroner's post-mortem examination being performed at the hospital where the death occurred. Rather, Rule 11(3) requires 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.

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[45] WIT 43/8 at para 36
[46] *Practice Notes for Coroners*, Appendix A para 4 , WIT 39/14
[47] Note 3.2 ,WIT 39/6
[48] Rule 10 and Rule 13, 1984 Rules
[49] Rule 57, 1984 Rules. *Jervis* suggests that the phrase 'properly interested person' should be taken to encompass all those who are entitled to be represented at the Inquest, see para 18–35 and 18–36
[50] Para 6.1, WIT 39/8
[51] They include 'the spouse or a near relative or personal representative of the deceased whose name and address are known to the Coroner' (Rule 19(a)) and 'a parent, child, spouse and any personal representative of the deceased' who has asked the Coroner to notify him and has supplied the Coroner with contact details (Rule 19(b) and Rule 20(2)(a))

49 Under Rule 6(1)(c), Coroners should not direct or request a pathologist on the staff of, or associated with, the hospital to carry out the post-mortem if the pathologist does not wish to; or if the conduct of any member of the hospital staff is likely to be called into question; or if so requested by any relative of the deceased. However, a pathologist at the hospital may still be directed or requested to carry out the post-mortem, notwithstanding the aforementioned considerations, where an examination would be unduly delayed if it were necessary to seek a different pathologist with suitable qualifications and experience.

50 Thus, as regards the pathologist, the 1984 Rules place the onus on him to decline the Coroner's request or direction.

51 The '*Practice Notes for Coroners'*[52] (which, as noted above, were issued after the period under inquiry) provide that:

'The Coroner should recognise that under the provisions of [Rule 6 of the 1984 Rules] the pathologist may wish to excuse himself from such examination. The responsibility lies initially with the pathologist to recognise any conflict of interest although if there seems to the Coroner that there is or may be such a conflict, then he should either instruct an alternate pathologist or seek confirmation from the pathologist as to whether there is any conflict preventing his making the examination.'

52 However, the guidance given in '*The Autopsy and Audit'*[53] is that where the death occurred in a hospital 'Wherever possible, permission should be obtained from the Coroner' to have a post-mortem examination performed in the hospital where the death occurred, so as to provide the consultants concerned in the case, who have the right to attend, with a better opportunity to attend the examination as part of the audit process.

53 In certain specified circumstances the selection of the pathologist will be subject to further criteria.[54]

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[52] *Practice Notes for Coroners*, Appendix A para 2, WIT 39

[53] Para 3.6, WIT 54/949

[54] Rule 6(1)(b) requires the Coroner to consult the chief officer of police regarding the choice of pathologist if someone may be charged with murder, manslaughter or infanticide of the deceased, and it is very likely that in that instance the Coroner will select a pathologist from the Home Office list of accredited forensic pathologists (see Home office Circular 9/93). There are examples of government departments laying down guidance on the selection of pathologists. In relation to sudden infant death syndrome (SIDS), the Home Office advised in its Newsletter No. 4 (at WIT 43/112) that the then Department of Health & Social Security considered that maximum benefit would be obtained by using one of the17 consultant pathologists with a special interest in perinatal and paediatric pathology to conduct post-mortem examinations in cases of SIDS, and noted that the government's aim was to have one full-time consultant in perinatal pathology in each health region. Coroners were advised to bear in mind the Royal College of Pathologists' list of pathologists to carry out post-mortem examinations in SIDS cases when selecting a pathologist under Rule 6(1)(a) of the *1984 Rules*. Guidance to Coroners contained in Home Office Newsletter No. 22 (December 1996) suggests that in the case of a suspicious death of a young child, the opinion of a paediatric pathologist should be sought

54 In practice, barring the circumstances envisaged by Rule 6(1)(c), the hospital pathologist's role in a Coroner's post-mortem is to investigate the cause of death following surgery or other treatment, and report to the Coroner. The pathologist's powers are dependent on, and subordinate to, those of the Coroner. The position of the pathologist once his principal, the Coroner, has no further proper interest in the death, will be considered below.

Removal of tissue at a Coroner's post-mortem

55 The pathologist conducting a Coroner's post-mortem or special examination is under a duty, so far as possible, to remove from the body, and to make arrangements for preserving, 'material' which in his opinion bears upon the cause of death. Such arrangements for preservation must be kept in place for such period as the Coroner thinks fit.[55] The Coroner has no power to direct or permit the removal and or preservation of any other 'material'. So it follows that his agent, the pathologist, has no power, *qua* agent of the Coroner, to do so either.

56 In 1985 Professor Bernard Knight,[56] in his paper *'Legal Considerations in the Retention of Post-mortem Material'*, expressed the view that the retention of tissue for teaching and research was not covered by the Coroner's authority, and authority for such purposes could not be granted by the Coroner.[57]

57 Likewise the Coroners' Society[58] takes the view that the Coroner can only ever authorise those acting through him to make examinations to further his own enquiry, and cannot authorise removal or retention or use of tissue other than for the limited purpose of the Coroner's enquiry.

58 Home Office guidance was issued in August 1989[59] on the use of tissue retained at the Coroner's post-mortem:

'You will wish to remind your pathologist that Ministers are concerned that tissue and organs should not be taken for teaching or research purposes from Coroners' post-mortem examination cases.'

Retention of tissue removed at the Coroner's post-mortem examination

59 As noted above, material removed during a Coroner's post-mortem pursuant to Rule 9, 1984 Rules must be preserved for such period as the coroner thinks fit. But once the Coroner has become *functus officio*, it is not clear what legal powers and obligations are possessed by the pathologist, who is often in physical possession of the Rule 9 material. This issue is explored more fully below.

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[55] Rules 9 and 12, 1984 Rules

[56] UBHT 308/44–5

[57] As more fully explained elsewhere in this report, some pathologists, including Professor Berry in Bristol, did not understand Professor Knight to be referring to the use of material initially removed from the body for the purposes of establishing cause of death. They understood him to be referring to the initial removal of material for a purpose not related to determining the cause of death

[58] Mr Burgess T43 p. 15–16

[59] Home Office Newsletter No. 11 (August 1989) WIT 43/153

Use of tissue removed at the Coroner's post-mortem examination

60 The Inquiry heard from Professor Green[60] that the prevailing view in his profession was that where material had been removed for the purposes of Rule 9, once that purpose had been exhausted'…the material which is left over…, once the Coroner has discharged his function and he is *functus officio,* that piece of tissue is in effect the property of the pathologist and the department which has processed it. It has had something done to it and therefore it is perfectly licit to use [it] for research purposes; it is perfectly licit to use that organ for teaching purposes, museum purposes.'

61 Guidelines produced by the Royal College of Physicians in 1990[61] advised on the use of 'discarded tissue'. 'The anonymous use for research of tissues genuinely discarded in the course of medical treatment, and of tissues removed at surgery or at autopsy, is a traditional and ethically acceptable practice that does not need consent from patients or relatives… although there may be legal constraints.' This guidance could refer to material removed pursuant to Rule 9 or to material otherwise removed. The legal constraints are not analysed further in the guidelines, although they are more obvious with regard to material removed pursuant to Rule 9. It is not clear whether the Royal College of Physicians intended the word 'tissue' to have the meaning it has been given in this Report, or to have a more limited meaning (for example, tissue 'blocks' kept for slides and histopathological study).

62 The 1996 update of that guidance[62] advised: 'The use for research of anonymous tissues genuinely discarded in the course of medical treatment … and of tissues removed at surgery or at autopsy, is a traditional and ethically acceptable practice, that we suggest does not need consent from patients or relatives…There may be legal constraints and it remains unclear to whom such samples belong in terms of beneficial ownership.' The concept of 'beneficial ownership' is not analysed further in the guidance. The use of the world 'samples' may suggest that the Royal College of Physicians did not have in mind the retention of whole organs.

Disposal of tissue removed or retained at the Coroner's post-mortem examination pursuant to Rule 9

63 As to the disposal of tissue which has been retained pursuant to Rule 9, Mr Clifford told the Inquiry that the Home Office had issued no guidance on the length of time tissue removed in the course of a Coroner's post-mortem should be retained.[63] Clearly the length of time for which it is necessary to retain tissue is related to the purpose of retention, i.e. establishing cause of death, but may be extended for example until police enquiries or criminal proceedings in relation to the death are concluded.

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[60] T42 p. 80
[61] 'Guidelines on the practice of ethics committees in medical research involving human subjects' originally published in 1984, updated in 1990, WIT 54/978–9 para 13.20
[62] WIT 54/980 para 8.28
[63] WIT 43/8

64 Professor MacSween[64] told the Inquiry that there is no clarity about the issue of how long tissue should be kept and what its ultimate disposal should be, and that the practice of individual Coroners varies widely. Professor Green[65] said that, in practice, Coroners do not order a pathologist or a pathology department to dispose of tissue. 'The Coroner's view is, "I no longer have any interest in this case; it is now up to you what to do with it… They can tell you for how long you can keep it, but they tend not to tell you that you must dispose of it, or there is no disposal order. You are ordered to keep it, but disposal is left to the discretion of the pathologist".'

65 Mr Burgess commented that, in cases where a Coroner's post-mortem examination was carried out, there would not normally be a referral back to the Coroner before tissue retained by the pathologist was disposed of. 'The Coroner will expect the pathologist to clear out his laboratory periodically, but on occasions it has come to my knowledge at least that that has not happened.'[66]

66 As is more fully explained at paragraph 152 below, we consider that the better view of the law at present is that, in relation to human material initially lawfully retained under Rule 9, once the Coroner becomes *functus officio*, the pathologist, while being the person in actual (and lawful) possession, may not be the person with the best claim to the human material. The effect of the cessation of the Coroner's power to override the right to possession of the next of kin, is that this right reverts to them, in order for them to perform their duty to dispose of the human material. They thus have a right of possession attendant upon a duty to dispose. If those with the power to call for possession from the pathologist do not exercise this right, then the pathologist, it seems, has the power himself to dispose of the human material. This is what happened in *Dobson.*[67] However, it would not appear that the pathologist has a duty to dispose of the human material.

[64] Professor Roderick MacSween, the then President of the Royal College of Pathologists, WIT 54/29
[65] T42 p. 96
[66] T43 p. 36
[67] [1997] 1WLR 596. This case is dealt with in more detail later

Part II

The hospital post-mortem examination

The purpose of the hospital post-mortem examination

67 Professor MacSween summarised the functions of the hospital post-mortem examination as providing: a check on the accuracy of diagnosis and certification of death, a form of medical audit of medical competence in both hospital and community care, an essential part in the training of medical students and junior doctors, and a deterrent to homicide.

'Many developments in orthopaedic and cardiac surgery, to name but two specialisms, have followed detailed study of post-operative specimens removed in the autopsy room and studied jointly by the pathologists and by the treating clinical team'.[68]

68 Professor Green told the Inquiry of the importance of the hospital post-mortem in the recognition of new diseases; the assessment of the success of surgical techniques; as a source of information for relatives; for the teaching of medical students; and as a source of human tissue and organs for the treatment of the living.

69 The use of the post-mortem examination in clinical audit was stressed in '*The Autopsy and Audit.'*[69]

70 Professor Green referred the Inquiry to The Royal College of Pathologists' consultation paper *'Guidelines for the retention of tissues at post-mortem examination'*[70] noting the continued importance of the post-mortem examination and subsequent review of the outcome as 'the gold standard against which new techniques are assessed'. In his view 'the importance of the clinico-pathological conference cannot be over-emphasised when all the doctors in the team and the pathologist who carried out the autopsy are together.'[71]

71 The Inquiry heard from Professor Berry that as a hospital pathologist he regarded it as one of his duties:

'to assist clinicians investigating deaths, both individually and as part of audit.' He 'contributed to the cardiac surgery clinico-pathological meetings, presenting post-mortem findings to the cardiac surgeons, cardiologists and others'.

[68] WIT 54/31 para 3.2
[69] Report of the Joint Working Party of the Royal College of Pathologists, the Royal College of Physicians of London and the Royal College of Surgeons of England (August 1991) WIT 54/936–960 and RCPath 54/936-960
[70] (June 1999) RCPath 1–87
[71] T42, p. 41–43

The 1961 Act

72 The 1961 Act provides the statutory basis for the hospital post-mortem examination.

73 Section 1, 1961 Act is not concerned with post-mortems but with the removal of parts of bodies for certain specified purposes. It is section 2, 1961 Act which is concerned with post-mortems. Section 2(2) provides:

'…no post-mortem which is not directed or requested by the Coroner or any other competent legal authority shall be carried out without the authority of the person lawfully in possession of the body…'

74 Section 2(2) provides that where a post-mortem is not directed or requested by a Coroner or other competent legal authority, it is the person lawfully in possession of the body who may authorise the post-mortem. The giving of that authority is governed by the same provisions as regulate the removal of parts of bodies under section 1, with any necessary modifications. We set out the material text of section 1 in due course. In essence, authority may only be given if the person lawfully in possession of the body has made 'such reasonable enquiry as may be practicable' and has no reason to believe that the deceased expressed an objection which was not withdrawn prior to death, nor any reason to believe that the surviving spouse or any surviving relative objects (section 1[2]). Authority cannot be given without the Coroner's consent where there is reason to believe that an inquest or post-mortem may be required by the Coroner (section 1[5]).

75 Thus, whenever the expression 'hospital post-mortem' is used to describe a procedure which is concerned, not with a post-mortem examination, but only with removal of human material for purposes of medical education or research (and therefore a procedure governed by section 1, not section 2, 1961 Act), that expression is used loosely and incorrectly.

76 Authority for the use of parts of the body for therapeutic, medical education or research purposes is governed by section 1(2) which provides:

'…the person lawfully in possession of the body of a deceased person may authorise the removal of any part from the body for use for the said purposes [i.e. therapeutic purposes, medical education or research] if, having made such reasonable enquiry as may be practicable, he has no reason to believe –

a) that the deceased had expressed an objection to his body being so dealt with after his death, and had not withdrawn it; or

b) that the surviving spouse or any surviving relative of the deceased objects to the body being so dealt with.'

77 Where the body of the deceased is lying in a hospital (or nursing home or other institution), the necessary authority for post-mortem (under section 2) or removal of parts for therapeutic, medical education or research purposes (under section 1) may be given, on behalf of the person having the control and management of the institution, by any officer or person designated for the purpose by that person.[72]

78 Section 1(7) implies, as the note in Halsbury's Statutes volume 28 indicates, that in the case of a death in a hospital, the manager thereof is in lawful possession. However, the phrase 'person lawfully in possession' is not defined in the 1961 Act.

79 The person who may give the authority must make reasonable enquiries to discover whether there is any *objection* from the surviving spouse or any surviving relative (or from the deceased himself prior to death) to removal under section 1(2) of any part from the body for the specified purposes (therapeutic, education and research). There is no obligation to obtain *consent*, therefore, before the removal under section 1, 1961 Act can be authorised. Where his reasonable enquiries do not reveal an objection, the person in lawful possession of the body may proceed to authorise a removal without the need to obtain any consent.[73]

80 Notwithstanding that the 1961 Act does not, in terms, require consent, the 'form of consent' for hospital post-mortem appended to *'The Autopsy and Audit'*[74] does employ the language of 'consent' in relation to the hospital post-mortem. It provides:

'I understand that the examination is carried out:

a) to verify the cause of death [section 2(2)] and to study the effects of treatment [section 1(2)], which may involve the retention of tissue for laboratory study;

b) to remove amounts of tissue for the treatment of other patients and for medical education and research [section 1(2)].'

81 The advice accompanying this form[75] is that it should be adhered to, but that it might also be helpful for the person giving the consent to be provided with an explanation couched in simpler language, thus:

[72] Sections 1(7), 2(2). Section 1(7) appears to contemplate a formal process of designation. Evidence of this taking place in practice is lacking
[73] See DHSS Circular HC (77) 28 para 3, WIT 43/119
[74] WIT 54/936–960 at 960
[75] WIT 54/958

'…If you give permission it will allow us to carry out a careful internal examination which may reveal new information and, therefore, benefit future patients…It also allows us to remove tissue for laboratory investigations which are not possible during life…'

82 The amount of information to be provided to parents by clinicians seeking their 'lack of objection' to a hospital post-mortem and/or to the removal and retention of tissue consequent on the post-mortem, is not prescribed by statute, nor has it been considered by the courts.

83 We consider here, by analogy, what level of information is required for consent to treatment of a living patient to be valid, or 'real'. Whether the analogy is appropriate is considered in the main body of our report.

84 The prevailing view following the decision in *Bolam v Friern HMC*[76] in 1957 was that, to obtain a properly informed or 'real' consent, 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, i.e. the so-called 'Bolam test'.

85 The amount of information to be provided to a patient was then considered in 1981 by Bristow J in *Chatterton v Gerson*.[77] He held that 'once the patient is informed in broad terms of the nature of the procedure which is intended…that consent is real'.

86 In 1984 the Court of Appeal in *Sidaway v Bethlem Royal Hospital Governors*[78] approved *Chatterton*. However, the decision in the House of Lords[79] marked the beginnings of a movement away from this paternalistic legal standard which took account only of the views of doctors. Although they confirmed that the duty to inform was governed by the Bolam test, their Lordships applied a gloss to the test. Lord Bridge stated that the doctor's duty must 'primarily be a matter of clinical judgement'[80] thus indicating that there comes a point when the doctor should take into account what the patient may wish, or have a right, to know.

87 However, in 1988 the Court of Appeal in *Gold v Haringey Health Authority*[81] reverted to the Bolam test without gloss.

[76] Bolam v Friern Hospital Management Committee [1957] 1 WLR 582
[77] [1981] QB 432
[78] [1984] QB 493
[79] [1985] AC 871
[80] 900
[81] [1988] QB 481

88 In 1997, the House of Lords in *Bolitho v City and Hackney Health Authority* [82] held that the court, not the doctor, was the final arbiter. The court must be satisfied that exponents of the responsible body of opinion can demonstrate that the opinion has a logical basis. However, this case was concerned with the standard to be applied to the quality of care rather than the duty to inform (as in *Bolam*) and there was some doubt whether this decision affects the duty to disclose.

89 In 1999, in *Pearce v United Bristol Healthcare NHS Trust* [83] the Court of Appeal synthesised the decisions in *Sidaway* and *Bolitho* in determining the standard of disclosure. Lord Woolf MR held 'if there is a significant risk which would affect the judgment of a reasonable patient, then in the normal course it is the responsibility of a doctor to inform the patient of that significant risk, if the information is needed so that the patient can determine for him or herself as to what course he or she should adopt.'

90 The extent of the reasonable enquiries required by the 1961 Act is unclear. The memorandum sent by the Ministry of Health to hospital authorities in advance of the 1961 Act coming into effect advised:

'The nearest relative available should be asked if he objects or if he has reason to believe that any other relative would object … The word 'relatives' is not defined in the Act and the minister considers that it should be interpreted in the widest sense, to include those who claim a quite distant relationship to the deceased.' [84]

91 What enquiries are reasonable or practicable may depend on the circumstances, including perhaps, the urgency with which a body part is needed (the Act has in mind organ transplants), and the nature of the relationship between the deceased and the people who may be considered 'any surviving relative of the deceased'. There is no indication as to whether this definition relates exclusively to blood relatives or includes relatives by marriage, and there is no express limit on proximity of the relation.[85]

92 In relation to the Coroner's inquest, the 1984 Rules are specific in Rule 19 (and 20[2]) in identifying certain classes of relative, and the *Practice Notes for Coroners* give guidance[86] on the exercise of the discretion to notify anyone with a proper interest in the inquest under Rule 20(2)(h), by reference to the principles set out in *R v South London Coroner ex parte Driscoll.*[87] It may extend to the classes of relative beyond those of a parent or child to, for example, siblings of the deceased (but only in the absence of any parent, spouse or child), or even perhaps, but less likely, the partner of the deceased, especially if that partner is acknowledged as the other parent of a child of the deceased.

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[82] [1998] AC 232
[83] [1999] PIQR P53 (C A) at P59
[84] Health Memorandum (61) 98 (21 September 1961) WIT 43/115
[85] For further discussion see Skegg 'Human Tissue Act 1961'(1976) 16 Medicine, Science and Law 193, 197; and Dworkin 'The Law Relating to Organ Transplantation in England' (1970) 33 MLR 353, 364–5
[86] Para 5.1, WIT 39/7
[87] (1993) 159 J.P. 45, D.C.; Independent, November 22, 1993

93 Where lack of objection to a hospital post-mortem examination or to removal under section 1(2) is confirmed, then a hospital post-mortem or, as the case may be, removal under section 1(2), may lawfully be authorised. Such procedures are sometimes referred to as 'consent' post-mortems although, as noted above, procedures which are concerned only with removal of parts pursuant to section 1 and not with establishing the cause of death are strictly not post-mortems at all. The proper ambit of what exactly is 'consented to' and whether this accords with the understanding of the person giving consent must be considered. This we do below.

The pathologist in the hospital post-mortem examination

94 The 1961 Act gives no guidance as to the choice of pathologist in a hospital post-mortem examination, save that by section 2(2) it must be carried out by or in accordance with the instructions of a fully registered medical practitioner.

Removal of tissue pursuant to the 1961 Act

95 Section 1(1) provides for the removal (and use) at the request of the deceased. Provided the deceased's directions were given in writing or orally in the presence of two witnesses during his last illness, then unless he has reason to believe the request was withdrawn, the person lawfully in possession of the body may authorise the removal of body parts in accordance with the request.[88]

96 Section 1(2) provides for the removal and use of body parts, in the absence of any request by the deceased.

97 Thus, removal of tissue for purposes unrelated to establishing the cause of death would require specific authority under section 1, 1961 Act.

98 Section 1, 1961 Act, provides for the removal (and use) of parts of a body for therapeutic purposes or for purposes of medical education or research. Provided that the terms of the Act are complied with, any part of the body may be removed.

The 1984 Act

99 The provisions of the 1984 Act provide an alternative framework for the removal, retention, use and disposal of human tissue in certain circumstances. The long title of the 1984 Act is 'An Act to make provision about the use of bodies of deceased persons, and parts of such bodies, for anatomical examination and about the possession and disposal of bodies of deceased persons, and parts of such bodies, authorised to be used for anatomical examination, and for connected purposes'.

[88] Section 1(1) and 1(3)

100 By section 1(4), 1984 Act, nothing in that Act applies to anything done for the purposes of a post-mortem examination requested or required or directed to be made by a competent legal authority or carried out for the purpose of establishing or confirming the causes of death or of investigating the existence or nature of abnormal conditions. By section 1(5), if a part of a body is authorised under section 1, 1961 Act to be removed for the purposes of medical education or research, then that section of the 1961 Act applies to the removal and use of the part, and not the 1984 Act, but the 1984 Act may apply as regards the body after the removal of the part pursuant to section 1, 1961 Act.

101 The 1984 Act and the Regulations made under it[89] provide for and regulate the use of bodies for anatomical examination.

102 An anatomical examination is defined[90] as 'the examination by dissection of a body for purposes of teaching or studying, or researching into, morphology; and where parts of a body are separated in the course of its anatomical examination, such examination includes the examination by dissection of the parts for those purposes'.

103 Given that examination involves removal of tissue, the 1984 Act therefore makes removal of tissue lawful, for the purposes covered by the 1984 Act.

104 The circumstances under which the examination can be carried out are that if the deceased requested that his body be so used, either in writing at any time or orally in the presence of two or more witnesses during his last illness, and the person lawfully in possession of the body after death has no reason to believe that the request has been withdrawn, then that person may authorise the use of the body for anatomical examination.[91]

105 By section 4(3), of the 1984 Act the person lawfully in possession of the body may authorise it to be used for anatomical examination:

> 'if having made such reasonable inquiry as may be practicable, he has no reason to believe –
>
> that the deceased, either in writing at any time or orally in the presence of two or more witnesses during his last illness, had expressed an objection to his body being so used 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 used.'

[89] Anatomy Regulations 1988 SI 1988/44 and Anatomy (Amendment) Regulations 1988 SI 1988/198
[90] Section 1(1), 1984 Act
[91] Section 4(1) and (2), 1984 Act

106 As with the 1961 Act, authority for an anatomical examination under the 1984 Act cannot be given (except with the coroner's consent) if there is reason to believe that a Coroner's post-mortem or inquest will be held,[92] and in the case of a body lying in a hospital (nursing home or other institution), authority for the examination may be given on behalf of the person having the control or management of the institution by someone designated by him.[93]

107 As with the 1961 Act[94] the extent of the enquiries the person lawfully in possession must make to ascertain any objection before authorising an examination is not specified in the legislation, beyond requiring that the extent of the enquiry be such as is practicable and the nature of it is reasonable.

108 Unlike the 1961 Act, the 1984 Act regulates the period for which authority under the Act subsists,[95] provides for inspection and licensing, and for control of possession of the body or part of the body after examination.[96] Both the person carrying out the examination and the premises on which the examination takes place must be licensed by the Secretary of State (sections 3 and 7), and are subject to inspection by HM Inspectors of Anatomy (sections 9–10).

109 Where a body has been subject to anatomical examination, the person with the licence is under a duty to ensure that the disposal of the body shall, as far as practicable, be in accordance with the wishes of the deceased, and that separated parts of the body (other than those parts which are held in possession by virtue of sections 5 and 6 of the 1984 Act) are, so far as practicable, disposed of with the body.[97]

The 1989 Act

110 The 1989 Act creates a prohibition on commercial dealings in organs removed for the purposes of transplantation and extends to organs removed from the dead.

Common law

111 The authors of the Nuffield Council report[98] considered whether there might be a residual power at common law to remove and retain tissue for uses not covered by statute if the use could be justified as being for the public good.

[92] Section 4(5), 1984 Act
[93] Section 4(9), 1984 Act
[94] See paras 74–76
[95] By section 4(10) the period is three years, beginning with the date of death or such other period as the Secretary of State may specify
[96] Sections 5 and 6, 1984 Act
[97] Regulation 4(1)(e), Anatomy Regulations 1988 SI 1988/44
[98] See para 5

112 The archiving or banking of retained tissue (unless falling within the terms education, teaching or research), or the removal of tissue with the intention of exploiting it commercially through, for example, sale of it or constituent elements of it, uses which arguably do not fall within the wording of the statutes considered above, would be covered by such a common-law power.

Notifying the result of the hospital post-mortem

113 There is no statutory requirement for the results of the hospital post-mortem examination to be given to relatives. Guidance given in '*The Autopsy and Audit'*[99] states that it is important to communicate the result of the post-mortem to relatives, whether this is done by the consultant in charge of the case, or his delegate, or the family's general practitioner, and that a copy of the final post-mortem report should be sent to the general practitioner. The guidance suggests that it is not appropriate for the pathologist to speak directly to relatives without the prior knowledge of the consultant in charge of the case.

[99] Para 3.4, WIT 54/948.

Part III

The right to possession of the body and the duty to dispose

114 The accepted legal principle is that there is no property in a dead body.[100]

115 The law does, however, recognise a possessory right; the right to take, or to take and keep, possession of the body in certain circumstances.

116 If it is necessary for the coroner to take possession of the body for the purposes of his inquiries (this would not be the case where he deals with a case by Pink Form A) he has an absolute right to possession of the body at common law until the inquest is determined.[101]

117 Under the 1984 Act, a person is authorised to have possession of an 'anatomical specimen' (which expression includes a body to be used for anatomical examination)[102] if at the time of possession he is licensed to do so under section 3(2)(b), 1984 Act or if he has permission to have possession from a person who is so licensed. The right to possession is for the time period set out in the Act, or such other period as the Secretary of State may from time to time by order specify. When the authority to possess the body for anatomical examination has expired, or when the anatomical examination has been concluded before the authority to possess has expired, no one has the right to possess the body or a part of it, except as is set out in section 5(3)(4), 1984 Act. Those subsections provide, respectively, that possession of a body or a part is lawful only for the purpose of decent disposal, and that possession of a part of a body, the anatomical examination of which has been concluded, is lawful, provided that the person from whose body the part came cannot be recognised by examination of the part, and provided that the possessor is authorised to have possession and provided possession is lawful pursuant to section 6, 1984 Act.

118 Subject to these rights to possession the personal representatives of the deceased have a right to possession of the body until it is disposed of, derived from their duty to dispose of it.[103] If the deceased has made a will appointing executors, they have a right to possession conferred from the time of death. If no executor has been appointed, then the person first entitled to apply for a Grant of Letters of Administration (i.e. the right to deal with the estate of the deceased) has the right to possession once Letters of Administration are granted.

[100] Doodeward v Spence (1908) 6 CLR 406 Aust HC; Williams v Williams (1882) 20 Ch D 659
[101] R v Bristol Coroner ex parte Kerr [1974] QB 652, Lord Widgery CJ at 659B
[102] Section 1(2)(a), 1984 Act
[103] Williams v Williams (1882) 20ChD659

119 In the case of a child, the duty falls on the parents,[104] and they therefore have a right to possession of the body.

120 Subject to the foregoing, hospital authorities appear to be responsible at common law as the person on whose premises the body lies to arrange for the cremation or burial of deceased patients, although if no arrangements were made by them the duty would fall on the local authority.[105]

The exception to the 'no property' rule, and the right to possession of tissue removed from the body

121 The Supreme Court of California held in *Moore v Regents of the University of California* in 1990 that a person could have no property rights in tissue taken from his body during an operation to which he consented.[106] The Court found that Moore never had any property right in the cells excised from his body. However the Court also stated: 'we do not purport to hold that excised cells can never be property for any purposes whatsoever.'

122 In England and Wales, an exception to the 'no property' rule was confirmed in 1998 by the Court of Appeal in *R v Kelly.*[107] The court found that anatomical specimens which had been preserved, fixed or dissected for exhibition or teaching purposes were the 'property' of the Royal College of Surgeons of England for the purposes of the Theft Act 1968, which has its own particular definition, and were therefore capable of being stolen. *Kelly,* therefore, recognised an exception to the common law rule that a dead body or part of such a body could not be 'property': the exception is said to apply where the body or part acquired different attributes by virtue of the application of skill, for example, dissection or preservation techniques: in effect, that it becomes something more than merely a body or part of a body. How the act of dissection alone might result in tissue acquiring different attributes is, perhaps, a difficult concept. In *Dobson*[108] it was suggested that dissection alone did not have this effect.

123 In *Doodeward v Spence*[109] Griffith CJ held that where a person had 'by the lawful exercise of work or skill so dealt with a corpse in his lawful possession that it had acquired some attributes differentiating it from a mere corpse, that person acquired a right to possession of the corpse or part, *at least as against anyone who was not entitled* to have it delivered up to them for the purposes of burial'. It is noteworthy that, whilst *Kelly* uses the language of 'property', *Doodeward* refers to the more limited right to 'possession' rather than ownership.

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[104] R v Vann (1851) 2 Den 325, CCR; Clark v LGO [1906] 2KB 648, 659 and 10 Hals. Laws (4th ed.) para 1017 (we do not set out here the complex law concerning the exercise of parental responsibility but refer to the general law)
[105] Secretary of State for Scotland v Fife County Council (1953) SLT 214
[106] (1990) 793 P 2d 479
[107] [1999] QB 521
[108] Dobson and Dobson v North Tyneside Health Authority and Newcastle Health Authority [1996] 4 All ER 474, [1997] 8 Med LR 357
[109] [1908] 6 CLR 406, High Court of Australia (our emphasis)

124 Furthermore, although *Doodeward* is cited as authority for the proposition that there can be no property in a dead body, it did not deal with the corpse of a person who had been born alive, but rather with a still-born two-headed foetus, in which there had been no independent life. (Whilst various statutory provisions recognise the foetus as having interests which must be considered,[110] it is generally accepted that a child attains the status of a legal person at birth.[111] If a foetus is not a person[112] then a still-born foetus is not the body of a dead person.[113])

125 The extent of the 'skill' which must be applied in order for a right to possession of (as in *Doodeward*) or property in (as in *Kelly*) tissue to vest in the person applying the skill is unclear. In *Doodeward* the body had simply been placed in spirits, and the dissenting judge stated: 'No skill or labour has been exercised on it; and there has been no change in its character.'

126 It is to be noted that in both *Kelly* and *Doodeward* the skill applied to the specimens had rendered them valuable.[114]

127 In *Dobson,* the deceased underwent a Coroner's post-mortem during the course of which the pathologist removed her brain and preserved it in paraffin for the purposes of Rule 9, 1984 Rules. The rest of the body was returned to the family for burial. The brain was subsequently disposed of by the pathologist. Peter Gibson LJ considered whether the pathologist's act of fixing the brain had transformed it into an item of property to which the next of kin might be entitled. He concluded that it did not. While ruling that the administratrix and next of kin had no claim to the brain on the basis that it was the property of the estate, the court found that there was nothing to suggest that the fixing of the brain 'was on a par with stuffing or embalming a corpse or preserving an anatomical or pathological specimen for a scientific collection or with preserving a human freak such as a double-headed foetus that had some value for exhibition purpose'.[115] It is to be noted that, as the brain had already been disposed of, the administratrix was not asserting the right of possession for burial or cremation purposes. She sued for conversion, and that claim failed on the basis that she did not have an immediate right to possession (or actual possession) at the time of the alleged conversion since letters of administration were not taken out until *after* the brain had been disposed of.[116]

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[110] For example, Congenital Disabilities (Civil Liability) Act 1976

[111] C v S and Another [1988] QB 135

[112] In R v Tait [1990] 1 QB 290 a foetus *in utero* was found not to be 'another person' 'in the ordinary sense', 'distinct from its mother'. See also AG Ref (No. 3 of 1994) [1998] AC 245

[113] It was on this basis that Barton J agreed with Griffith CJ in Doodeward

[114] Professor Andrew Grubb, in a commentary predating *Kelly*, suggests that what matters is not simply what skill is applied, but the purpose for which it is applied. He argues that the key concept is an intention to create a novel item with a use or purpose of its own; 'Property rights and body parts' [1997] 5 Med. LR 110, 114; but is this correct?

[115] [1996] 4 All ER 474 at 601

[116] [1997] 1 WLR 596, 600 B–C, 602 C–E

128 Whether the right to call for possession of a body pursuant to the duty to dispose of it extends to parts of the body is unclear. The duty to bury expressed in *Williams* is a duty to bury *the body*: '*prima facie* the executors are entitled to the possession and are responsible for the burial of a dead body' and 'accordingly the law in this country is clear, that after the death of a man, his executors have a right to the custody and possession of his body (although they have no property in it) until it is properly buried'. This question was not specifically addressed in *Dobson,* although Peter Gibson LJ expressed the view that no right to call for the brain existed.[117]

129 The common law is entirely unclear as to whether each and every part of a body which might be discovered, for example after an accident, or after burial of the rest of the body or every slide and tissue sample in a pathology laboratory following a post-mortem examination, should be regarded as within the definition of 'the body', for the purposes of the duty to dispose.

130 If the duty to bury does not extend this far, then it would follow that neither does the corresponding right to call for possession for the purposes of disposal. Thus, institutions in possession of archives or 'banks' of tissue, need not as a matter of law at least, give up that possession, even if the material has not 'acquired different attributes'. This appears so, even if the initial separation of the body part from the rest of the body was itself unauthorised.

Disposal of tissue through burial and cremation

Burial

131 Subject to public-health concerns, there is no statutory requirement for a body to be buried in a properly authorised place, provided all legal formalities are completed. Nor is there any statutory provision preventing the burial of a part of a body such as tissue.

Cremation

132 Cremation is governed by the Cremation Acts of 1902 and 1952 and the Cremation Regulations 1930 (as amended) and may only occur in an authorised crematorium, (section 1[1] 1952 Act and Regulation 3 of 1930 Regulations).

133 It was not until the Cremation (Amendment) Regulations 2000, came into force on 14 February 2000[118] that legal provision was made for the cremation of parts of a body removed during a post-mortem examination.

[117] [1997] 1 WLR 596, 601H – 602A
[118] SI 2000/58

Part IV

Wrongful removal, retention and use

Liability for wrongful removal, retention and use

134 The 1961 Act does not provide any sanction for non-compliance with its provisions. Section 1(3) provides that removal and use of tissue in accordance with authority given pursuant to that section is lawful. If the removal or retention or use are either outwith the scope of the authority or the authority itself was not properly given, there remains the risk of prosecution for criminal offences but only if criminal liability were to be found to lie notwithstanding the lack of express reference to criminal offences in the 1961 Act.[119]

135 In contrast, the 1984 Act creates a number of offences in section 11, such that it is an offence to carry out an anatomical examination or to possess an anatomical specimen or a body or part of a body in contravention of the provisions of either section 2 or section 5; and it is an offence to breach any condition attached to a licence granted under the 1984 Act.

136 Likewise, contravention of the 1989 Act, section 1 in connection with commercial dealings in human organs for transplantation carries with it criminal liability.

137 Notably neither the 1984 Act nor the 1989 Act state that the tissue is 'owned' by the donor or his next of kin, giving rise to a proprietary claim by them.

138 Papers submitted to the Inquiry by CMS Cameron McKenna[120] and by the Bristol Heart Children Action Group (BHCAG)[121] considered what liability might lie for wrongful removal, retention or use of tissue.[122] It is not the purpose of the Inquiry to reach conclusions as to the liability of any person or body in relation to the past removal, retention or use of tissue and thus the report does not therefore express any concluded view as to the merits of the submissions on criminal or civil liability made in these two papers.

Removal, retention or use of tissue in contravention of a statutory provision or for a purpose not covered by statute

139 The next section will consider whether, and if so when, removal, retention or use ostensibly pursuant to Rule 9, 1984 Rules or section 1(2) 1961 Act may be, or become, wrongful.

[119] Cases such as R v Horseferry Road Justices ex p IBA [1987] QB 54 indicate that criminal liability will not readily be inferred in such circumstances

[120] 'Removal, retention and use of human tissue following post-mortem examination', CMS Cameron McKenna, November 1999, INQ 23, 23/71 para 1.3

[121] SUB 1/1–40, 19 September 1999

[122] The following were considered: criminal liability for contravention of sections 1(2) and 2(2) 1961 Act; liability for criminal damage under the Criminal Damage Act 1971; tortious liability for breach of statutory duty; tortious liability for conversion; negligently causing nervous shock; outraging public decency; obstructing the coroner; and the common law offence of preventing the lawful and decent disposal of a corpse

The Coroner's post-mortem examination

Possession of the body

140 The Coroner, and the pathologist as his agent, have power to take possession of the body for the purposes of fulfilling his duties under the 1988 Act and, in particular, for carrying out a post-mortem under sections 19–21. This power overrides the right of the next of kin to call for possession for the purposes of disposing of the body.

141 Once the Coroner is *functus officio*, he has no further power or duty over the body. At this point the right of the next of kin (in the case of a deceased child) to possession of the body for the purposes of burial or other disposal is no longer overridden.[123]

Removal, retention and use of tissue

142 Two situations will be considered below: (a) where tissue is taken for purposes other than those of Rule 9 from the outset, and (b) where the tissue is taken for the purposes of Rule 9 and is then kept for other purposes.

143 Dealing first with situation (a), it has been stressed above that the only removal which the Coroner may authorise the pathologist to carry out is that which is consistent with carrying out the preservation of material relevant to establishing the cause of death under Rule 9, 1984 Rules and section 11(5), 1988 Act (situation [b] above).

144 The Coroner has no power to direct or request removal of tissue for any other purpose. The pathologist, as his agent, is likewise restricted, in the absence of any consent or authority obtained pursuant to another statute (such as the 1961 Act, or 1984 Act).

145 The removal of any tissue is not specifically authorised by statute: it is implicitly authorised by the direction or request of the Coroner to carry out the post-mortem under sections 19, 20 and 21 of the 1988 Act. Rule 9 assumes the removal of tissue. Rule 9, however, specifically relates to the *preservation* of material. Thus any removal of tissue, for example, for medical education or research purposes, cannot be authorised by the Coroner. Moreover, the pathologist, since he is only the Coroner's agent, equally cannot remove material for these purposes, unless he has been authorised to do so by some other statutory framework prior to removing the tissue. Thus, it follows that if a pathologist removes tissue at the Coroner's post-mortem other than for the purpose of determining cause of death, such as for educational or research purposes, then that removal is without lawful authority, in

[123] Subject to any powers of the police (if exercised)

the absence of authorisation pursuant to one of the relevant Acts which have been discussed above. It is another question whether, despite the unauthorised removal, the pathologist has any right to retain and use the tissue for these purposes. We consider this shortly.

146 As to situation (b), once the Coroner is *functus officio*, he has no power to require or authorise the pathologist further to retain the tissue, nor to dispose of it. He cannot 'give' long-term possession of the tissue to the pathologist.

147 On one view, any possession the pathologist may have is as agent for the coroner: he does not possess for his own purposes. If this is not accepted, the pathologist would not appear to acquire proprietary rights (beyond actual possession) in tissue removed from the body simply by fixing it for examination.[124]

148 The issues to be considered are whether in these circumstances the pathologist has the *best* claim to the tissue originally removed pursuant to Rule 9 and, if no one has a better claim, whether, by having possession, his rights extend as far as using the tissue for education or research purposes, whether there are circumstances in which he would be under a duty to dispose of the tissue, or whether he can retain it indefinitely.

149 It is suggested that a pathologist in possession of tissue, originally removed for preservation pursuant to Rule 9, ought not to be permitted to use that tissue for education, research or other purposes without the prior obtaining of the necessary consent or authority under one of the other statutes considered above. Whether the law presently prevents any such use, or provides any sanction against such use is not at all clear. As noted above, the view of the Royal College of Physicians has been that the anonymous use for research of tissues discarded in the course of medical treatment, and of tissues removed at surgery or at autopsy, is a traditional and ethically acceptable practice that does not need consent from patients or relatives, 'although [they say] there may be legal constraints'. If the pathologist is not able to use the tissue pursuant to his possessory right then he cannot, it is further suggested, bring himself within the *Doodeward* exception to the 'no property' rule by applying further skill, by for example rendering the tissue suitable for display. This is because *Doodeward* requires the 'lawful exercise of work or skill' and, if use is not permitted, then the pathologist is disabled from being able to put himself in a position to take advantage of the *Doodeward* exception.

150 The difficulty with the argument just advanced is that *Doodeward* precisely dealt with the circumstance in which lawful possession combined with the application of skill conferred the right to retain possession. It needs, perhaps, to be said that the pathologist would still be in lawful possession, even if a better claim to possession

[124] See Dobson, but compare Griffith CJ in Doodeward

could be made by some other.

151 The pathologist would not appear to be under a continuing obligation to preserve tissue[125] but, on the assumption that there may be a duty at common law to bury or otherwise dispose of such tissue, he may be under a duty to dispose of retained material or to deliver it up if claimed by the parents or relevant others.

152 The submissions to the Inquiry from the BHCAG, and from CMS Cameron McKenna[126] addressed the question being considered when they discussed what liability may lie for wrongful removal, retention or use of tissue. In respect of retention by the pathologist after a Coroner's post-mortem, they were divided. The latter suggested that the hospital or pathologist was lawfully in possession and was under no obligation to cede possession to anyone else. The former argued that the pathologist was under a duty to return the tissue to relatives, on the basis that the duty to bury is a duty to bury the body as a whole, where reasonably practicable.

153 We consider that the better view of the law at present is that, in relation to tissue initially lawfully retained under Rule 9, once the Coroner becomes *functus officio*, the pathologist, while being the person in actual and lawful possession, may not be the person with the best claim to the tissue. The effect of the cessation of the Coroner's power to override the right to possession of the next of kin, is that this right reverts to them. They would appear to have the right to possession. Further, this right to possession would not necessarily be defeated by the fact that the pathologist could take advantage of the *Doodeward* exception. Griffith CJ specifically remarked that the person who has exercised skill, '… acquires a right to retain possession of it, *at least as against any person not entitled to have it delivered to him for the purpose of burial'.*[127] To exercise this right, they would have to call for the tissue, at which point, the pathologist would be obliged to surrender it to them. There is, however, an alternative. Because the hospital was in lawful possession (by section 1[7]) prior to the Coroner's taking possession, lawful possession (if it includes tissue as well as the body) would revert to the hospital and, through it, to the pathologist now acting as an employee. Even if this were so, however, the next of kin have a stronger claim for the purposes of burial or cremation and, thus, would be entitled to call for any tissue.

The hospital post-mortem examination

Possession of the body

154 It has been noted above that section 1(7), 1961 Act implies, as the note in Halsbury's Statutes volume 28 indicates, that in the case of a death in a hospital, the manager thereof is in lawful possession of the body. However, the executors or

[125] See Peter Gibson LJ in Dobson [1997] 1 WLR 596, 601H
[126] INQ 23/69–78
[127] See para 114 (our emphasis)
[128] *Clerk and Lindsell on Torts*, Sweet & Maxwell, 17th ed, p. 653, cited in Dobson at p. 600 G. This is subject to the powers of the Coroner or the police (if exercised)

administrators or other persons charged by the law with the duty of disposing of the body have a right to possession of it until it is lawfully buried or cremated.[128]

Removal and use of tissue

155 The hospital is deemed to be capable of giving authority for removal, retention and use of tissue.[129]

156 However, an objection by the deceased before death, or by a relative pursuant to section 1(2), 1961 Act, overrides the hospital's ability to give authority.

157 The relevant provisions of the 1961 Act have been considered above.[130] It is unlikely that the hospital's authority would be considered unlawful unless there were a manifest breach of the requirement to make 'such reasonable enquiry as may be practicable' or having done so, authority was given in the face of a relative's objection.

158 A more difficult question is whether a lack of objection which is expressed by relatives who are not fully informed of what may be involved, may render the authority for removal of tissue unlawful.

159 Where consent to treatment is sought from a live patient, the patient must, at the very least, understand the basic nature and purpose of the procedure for the consent to be valid.[131]

160 Whilst parents who express no objection under sections 1 or 2, 1961 Act, may appreciate the basic nature of the procedures involved, they may well not appreciate that long-term retention of tissue may be intended, or at least retention such that tissue removed will not be returned to the body prior to burial or cremation, unless this is expressly brought to their attention. It is by no means clear that authorisation under these circumstances would be valid. Much depends on the information to which the relatives are entitled.

Retention of removed tissue

161 Where the pathologist removes and retains tissue with valid authority to use the tissue, for example for education or research purposes, and applies the skill necessary to bring him within the exception to the 'no property' rule, property will vest in him (and thus his employer). As mentioned above, the boundaries of the exception to the 'no property' rule, and the degree of skill or work on tissue which is required to come within the *Kelly* exception is by no means clear. The facts of the *Kelly* case have to be borne in mind when seeking to explain the court's decision in

[129] Section 1(7) 1961 Act, see paras 77–8
[130] See para 77
[131] Sidaway v Governors of Bethlem Royal Hospital, [1985] AC 871

that case.

[132] See also para 115

Part V

Other law and guidelines

162 Following *Dobson*, if tissue is removed for examination purposes at the hospital post-mortem examination, and retained thereafter for one of the purposes specified in section 1, 1961 Act, property does not vest in the pathologist or his employer, simply by virtue of the tissue being fixed.

163 Further, where the consent was either not fully informed or the authority invalid, or where the authority does not cover the use to which the tissue is put, the *Doodeward* exception may not apply as *Doodeward* requires 'the lawful exercise of work or skill … in his lawful possession'.[132]

164 The net effect of the above three paragraphs may be as follows. We begin with the assumption previously made that relatives do have a right to call for possession of tissue for the purposes of complying with their duty to bury or cremate it. If retention of the tissue is unauthorised the relatives may, therefore, call for it. If retention is authorised, there is a suggestion in *Doodeward* that, whether or not a property right has vested in the pathologist (and the hospital), this right is subordinate to the relatives' right with a view to burial or cremation. But this would be an odd conclusion. A better view, therefore, may be that compliance with section 1, 1961 Act ousts any further rights of relatives, and, thus, a right to retain possession and, where applicable, property, is vested in the pathologist or his employer.

[133] Section 3
[134] Section 4(2)
[135] Section 2
[136] Section 6(1) and 6(3)(b)
[137] Section 7
[138] INQ 23/86–89
[139] Article 8 – The right to respect for private and family life:
'1- Everyone has the right to respect for his private and family life, his home and his correspondence.
2- There shall be no interference by a public authority of the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others'.
[140] Article 13 – The right to an effective remedy:
'Everyone whose rights and freedoms as set forth in this Convention are violated shall have an effective remedy before a national authority notwithstanding that the violation has been committed by persons acting in an official capacity.'

The Human Rights Act 1998

165 The Human Rights Act 1998 obtained the Royal Assent 9 November 1998 and will come into force on 2 October 2000.

166 It will require that, so far as possible, all legislation, past and future is read and given effect in a way compatible with the European Convention on Human Rights and Fundamental Freedoms [ECHR].[133]

167 The Act will provide for courts to make a declaration of incompatibility where legislation is found to be incompatible with an ECHR right.[134]

168 The Act will require case law of the European Court of Human Rights 'to be taken into account',[135] although strictly it will not have the status of binding precedent.

169 The Act will require that where public authorities such as NHS trusts, or other NHS bodies, do not act compatibly with the ECHR their actions are to be considered 'unlawful'.[136] The 'victim' of such an 'unlawful' act will be able to bring proceedings against the authority.[137]

170 A deceased child would not be a 'victim' acquiring a posthumous cause of action under the Act in relation to matters occurring at his post-mortem examination. Thus the estate or parents will have no cause of action on the child's behalf and would have to show that they themselves were 'victims' of the action of the relevant Health Service organisation in order to bring themselves within the ambit of the Act.

171 Cameron McKenna's submission[138] considered various possible circumstances in which a Health Authority might be found in breach of Article 8[139] of the ECHR in removing, retaining or using tissue, and the possible impact of Article 13.[140]

[141] Belgian Linguistics (Merits) Series A No 6, 23 July 1968
[142] Department of Health, HMSO, London, 1991, HOME 0001 0001–0013

172 Article 8 has been interpreted as protecting the individual against arbitrary interference by public authorities in his private or family life.[141] The concept of 'family life' has been construed broadly, although the question of whether the removal, retention and use of tissue from a deceased member of a family can be an interference with family life has not yet been determined. Assuming it were, Cameron McKenna suggest that the following may be considered acts incompatible with Article 8:

the 'no property' rule and the apparent lack of effective sanction for 'wrongful' removal of tissue;

a failure properly to comply with the provisions of section 1(2), 1961 Act in seeking lack of objections from relatives;

where tissue lawfully removed, for example for the purposes of Rule 9, 1984 Rules, is subsequently retained by the pathologist for an unauthorised use when relatives are not given the opportunity to object;

the use of retained tissue, which may affect a relative's own health, for example, for genetic research (the use of the tissue will not, of course, affect a relative's health, but the information derived from it could).

173 Article 13 is not incorporated directly into the Act, since the Act itself is intended to establish a scheme whereby effective remedies for breaches of ECHR are provided. To the extent that domestic law does not provide, for example, an effective remedy against unauthorised use of tissue, Article 13 could be relied upon before the Strasbourg court in proceedings against the UK brought by a person who could demonstrate that a Convention right of theirs had been violated.

Patient's Charter rights and standards

174 The Patient's Charter[142] was launched in October 1991 and took effect on 1 April 1992. It identified ten guaranteed National Charter Rights to care in the NHS. It is important to recall that these are not statutory rights recognised by law. Seven of the charter rights were expressed to be already well established, and three were introduced by the Charter. It also introduced nine National Charter Standards for the NHS to achieve in key areas, and required local health authorities to set their own Local Charter Standards from 1 April 1992.

[143] HA(A) 0163 0043-0078

175 '*The Patient's Charter & You',*[143] published by the Department of Health in January 1995, provided a new expanded and updated Charter introducing further standards. This document defined charter rights as 'Rights – which all patients will receive all the time', and expectations as 'standards of service which the NHS is aiming to achieve. Exceptional circumstances may sometimes prevent these standards being met.'

176 Two charter rights identified in the Patient's Charter in 1991 as already being 'well established' were:

'to be given a clear explanation of any treatment proposed, including any risks and any alternatives, before you decide whether you will agree to the treatment',

and

'to choose whether or not you wish to take part in medical research or medical student training'.

177 A National Charter standard of service is:

'Respect for privacy, dignity and religious and cultural beliefs. The Charter standard is that all health services should make provision so that proper personal consideration is shown to you, for example by ensuring that your privacy, dignity and religious and cultural beliefs are respected. Practical arrangements should include meals to suit all dietary requirements, and private rooms for confidential discussions with relatives.'

178 The right to choose whether or not to take part in medical research or medical student training, and the right to the respect of your privacy, dignity and religious and cultural beliefs were reiterated in '*The Patient's Charter & You'*.

179 It may be said to be consistent with the spirit if not the strict letter of the Charter that a parent of a deceased child has a right under the Charter to be given a clear explanation of a proposed hospital post-mortem examination, and to decide whether their child's body or tissue may be used in medical research.

180 Further, the right to respect for religious views can be said to require the person seeking to obtain consent (or, strictly, ascertaining that there is a lack of objection) for the removal, retention and use of organs or tissue, to ascertain whether the parents have any objections or reservations on religious grounds.

144 Nuffield Council report para 13.13
145 Nuffield Council report para 13.15
146 'Consensus Statement of Recommended Policies for Uses of Human Tissue in Research, Education and Quality Control – with notes reflecting UK law and practices', Working Party of the Royal College of Pathologists and the Institute of Biomedical Science, Royal College of Pathologists, 1999, RCPath 1/88–110
147 'Consensus statement' Note A
148 'Consensus statement' Note C
149 'Consensus statement' Note H

Nuffield Council on Bioethics

181 It is to be noted that, in 1995, the authors of the Nuffield Council's report highlighted the lack of clarity in the law in this area, and particularly in relation to any property rights in tissue.

182 They recommended that, as an aid to ensuring that consent to treatment was properly informed, bodies such as NHS Trusts and independent hospitals responsible for consent procedures 'should consider whether any addition to their explanations or forms are needed to make it clear that consent covers acceptable further uses of human tissue removed during treatment'.[144]

183 They also recommended that these bodies review their practices on all handling and disposal of human tissue to ensure that they met 'the requirements both of law and of professional standards and also to ensure that major body parts (for example, limbs and hands), and tissue subject to special public concern or scrutiny (for example, foetal tissue) are handled and disposed of in ways which show respect.' [145]

Consensus statement of recommended policies for uses of human tissue in research education and quality control[146]

184 In the notes reflecting UK law and practice, the working party note that, by 1999, the recommendations of the Nuffield Council's report had not yet been translated into legislation.[147]

185 In relation to 'ownership' of tissue, they adopt the term 'custodian' for the pathologist who holds pathological records and archives. In their view it is for the pathologist to exercise discretion over requests for research access to them.[148]

186 They note the recommendation of the authors of the Nuffield Council's report that general consent forms for the removal of tissue might refer to the possibility that removed tissue may be used for research, teaching or study. They also note the apparently contradictory advice of the Royal College of Physicians that the use of left-over tissue for research is a traditional and ethically acceptable practice that does not need consent from patients or relatives.[149]

[150] 'Consensus statement' Note I
[151] Report of the Working Party of the Royal College of Pathologists and the Institute of Bio-Medical Science, 2nd Edition, 1999, RCPath 1/20–47
[152] RCPath 1/31
[153] RCPath 1/42–43

187 The working party conclude that 'the prevailing legal opinion is that tissue obtained with consent or under [the 1961 or 1984 or 1989 Acts] is obtained free of all claims and the user obtains at least a right to possess and probably a right of ownership'.[150]

188 This conclusion may suggest a degree of confidence bordering on the rash.

Retention and storage of pathological records and archives[151]

189 The Working Party of the Royal College of Pathologists and the Institute of Bio-Medical Science made recommendations in relation to minimum retention times for pathology records, including retained tissue.

190 In relation to retained tissue generally (the paper does not at this stage distinguish between a Coroner's post-mortem and a hospital post-mortem), they note that the mere possibility of tissue constituting material evidence in future litigation is not sufficient ground for the imposition of a duty to store indefinitely (following the decision in *Dobson*).[152]

191 They recommend that 'wet tissue' (whether a representative aliquot or whole tissue or organ) be retained for a minimum of four weeks after the final post-mortem report.

192 In relation to tissue retained under Rule 9, 1984 Rules, they note that this is to be retained until the completion of the inquest and, in deaths subject to criminal inquiry, until both the Coroner's interest has expired and other interests such as those of the Crown Prosecution Service have been fulfilled.

193 The working party notes that the retention of tissue beyond 30 years, 'other than in the case of recognised historical or teaching or research archives already kept in approved places of deposit … requires application to the Lord Chancellor … if there is a need for them to be retained by the Health Authority'. They therefore recommend that pathologists should be prepared to destroy tissue after 30 years.[153] However they do not, in terms, recommend the destruction of tissue on the expiry of minimum retention periods.

194 In relation to the 'ownership' of retained tissue the working party advises that 'Property in pathological materials and records, as in other Health Service (NHS) records and items, vests ultimately with the Secretary of State for Health or in NHS Trusts (Scotland). In private practice it vests in the maker of the records … Property in records, reports and materials relating to procedures within the jurisdiction of [the Coroner] does not vest in the same way.'

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[154] 'Human Tissue and Biological Samples for Use in Research' Interim Operational and Ethical Guidelines, published for consultation by the Medical Research Council (November 1999)
[155] Interim Guidelines, MRC para 2.2
[156] Interim Guidelines, MRC Appendix 1

Human tissue and biological samples for use in research[154]

195 The interim guidelines published by the Medical Research Council (MRC) deal principally with tissue taken from living donors, and defer, in para 1.4 to the then forthcoming guidelines from the Royal College of Pathologists in relation to tissue taken from the deceased. Their recommendations about the ownership of tissue and consent are considered here by way of analogy.

196 In relation to the ownership of tissue they note[155] present uncertainties in the law as to whether tissue may be considered 'property' and suggest that it is 'more practical and more attractive from a moral and ethical standpoint to adopt the position that, if a tissue sample could be property [on the basis of *Kelly*], the original owner was the individual from whom it was taken.'

197 They recommend, in paras 2.1 and 2.2, that tissue samples taken with consent from the living be treated as having been donated (rather than abandoned as recommended by the authors of the Nuffield Council's report), and that the hospital or other institution where the researcher is based should have formal responsibility for the custody of new collections, whilst the researcher has responsibility for the day to day management.

198 They use the term 'custodianship' in preference to 'ownership' and define 'custodianship' as the responsibility for safe keeping of samples and the control of their use in accordance with the terms of consent given by the donor. They state, in para 3.1, that 'Custodianship implies some property rights over the samples, but also some responsibility for safeguarding the interests of the donor'[156] and 'We understand that custodianship brings with it the right to determine what happens to a collection' once the research is concluded.

199 We suggest that this approach would result in the 'custodianship' of the tissue passing on removal rather than on the exercise of whatever skill or work might bring it within the exception to the 'no property' rule.

[157] Not, so far, by the United Kingdom
[158] Authorised for publication by the Committee of Ministers on 17 December 1996. See http://www.coe.fr/oviedo/rapporte.htm

200 In relation to consent, as samples may be stored for long periods and may be of value for future research which could not have been foreseen at the time the tissue was obtained, they recommend that unless the sample is to be used for a single project, consent must be obtained for storage and for future use for other research. A two-part consent process is recommended where the donor is first asked to consent to the research which has been planned, and is then asked to give a broader consent to the storage and future use of the tissue for a specified type of future research. They recommend, in para 2.6, that when seeking consent, the information should be presented in a form easily understood and, where necessary, by way of audio-taped information.

201 However, in relation to collections of tissue already in existence they advise, in para 4.2, that, generally, these can be used for further research, for which consent has not been obtained, provided the tissue has been coded or anonymised and there is no potential harm to the donors.

The European Convention on Human Rights and Biomedicine

Introduction

202 'The European Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine' ('the Convention'), was opened for signature in Oviedo, on 4 April 1997. Since it was opened for signature it has been signed by 24 member states of the Council of Europe.[157]

203 The Convention is designed to protect the dignity and integrity of human beings, and to guarantee respect for their rights and freedoms, with regard to developments in science and medicine. It stipulates that the interests of human beings must prevail over those of science or society. The Convention is the first internationally-binding legal text designed to protect people against the misuse of biological and medical advances. The Convention does not, of course, prevent a State from giving greater protection than that set out in the Convention.

The general philosophy of the Convention

204 The Explanatory Report to the Convention[158] provides that, 'The whole Convention, the aim of which is to protect human rights and dignity, is inspired by the principle of the primacy of the human being, and all its articles must be interpreted in this light'.

205 Article 2 of the Convention provides:

> 'The interests and welfare of the human being shall prevail over the sole interest of society or science.'

206 This general philosophy is reflected by Article 5, which provides:

> 'An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.
>
> This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.
>
> The person concerned may freely withdraw consent at any time.'

207 Article 5 is obviously concerned with consent given by living persons. However, many of the principles elaborated in the Convention and the Explanatory Report are relevant also to the issues considered by the Inquiry in this Interim Report. The Explanatory Report states that Article 5:

> '…makes clear patients' autonomy in their relationship with health care professionals and serves to restrain the paternalist approaches which might ignore the wish of the patient…
>
> The patient's consent is considered to be free and informed if it is given on the basis of objective information from the responsible health care professional as to the nature and the potential consequences of the planned intervention or of its alternatives, in the absence of any pressure from anyone…In order for their consent to be valid the persons in question must have been informed about the relevant facts regarding the intervention being contemplated. This information must include the purpose, nature and consequences of the intervention and the risks involved… Requests for additional information made by patients must be adequately answered.
>
> Moreover, this information must be sufficiently clear and suitably worded for the person who is to undergo the intervention. The patient must be put in a position, through the use of terms he or she can understand, to weigh up the necessity or usefulness of the aim and methods of the intervention against its risks and the discomfort or pain it will cause…'

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159 Article 19
160 Part of Chapter VII, headed 'Prohibition of financial gain and disposal of a part of the human body'
161 Article 29
162 The draft Protocol is not, therefore, concerned with xenotransplantation
163 Article 18. This article is intended to deal with so-called 'domino transplants', for example where the valves of an explanted heart are suitable for transplantation into another recipient, whereby the first recipient (of a heart) becomes a live donor (of valves) for a second recipient.

Removal of human material

208 Chapter VI of the Convention is concerned with the removal of organs and tissue from living donors for transplantation purposes. One of the conditions for a living donor transplant is that there is no suitable human material available from a deceased person.[159]

209 Article 22 of the Convention,[160] goes on to provide that:

> 'When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.'

210 Legal oversight and the promotion of consistency in approach throughout States which are parties to the Convention is provided by the provision for the Steering Committee on Bioethics, or any other committee designated by the Committee of Ministers or the parties to the Convention, to request the European Court of Human Rights in Strasbourg to give advisory opinions on legal questions concerning the interpretation of the Convention.[161]

The draft Protocol to the Convention

211 The Council of Europe draft Protocol to the Convention ('the draft Protocol') was published in February 1999.

212 The draft Protocol amplifies the principles embodied in the Convention, with a view to ensuring protection of people in the specific field of transplantation of organs and tissues of human origin.[162] It contains general principles and specific provisions. The draft Protocol was accompanied by an Explanatory Report. For the most part, the draft Protocol addresses issues beyond the particular concerns of this Report. One provision, however, is worthy of note.

213 Pursuant to Chapter V of the draft Protocol, concerned with the disposal of human material which has been removed, when, in the course of an intervention, an organ or tissue is removed for a purpose other than 'donation for implantation', it may be transplanted only if this is done in conformity with appropriate information and consent procedures.[163] This principle of Chapter V could, perhaps, be given wider application, such that no human material could be used for a purpose other than that for which it was initially removed from the body, without the appropriate

[164] Neither is comprehensively defined
[165] Called 'post-mortem examinations required by law', no doubt because the guidelines apply to Scotland as well as to England and Wales, and in Scotland there is no coroner as such
[166] Called 'post-mortem examinations performed with relatives' agreement'
[167] Para 1.4 of the Guidelines
[168] Para 1.5.

express consents first being obtained.

'Organ' and 'tissue'

214 Finally, we note that the Explanatory Report to the draft Protocol contains an interesting passage on the definitional difficulties of the words 'organ' and 'tissue'. The Report describes how medical advances can give rise to difficulties of definition. The Report says:

> 'There is … difficulty in agreeing on a scientifically precise definition of "organ" and "tissue". Traditionally an "organ" has been described as part of a human body consisting of a structured arrangement of tissues which, if wholly removed, cannot be replicated by the body. In 1994 the Committee of Ministers adopted a definition of tissues as being "All constituent parts of the human body, including surgical residues, but excluding organs, blood, blood products as well as reproductive tissue such as sperm, eggs and embryos. Hair, nails, placentas and body waste products also excluded". These were useful definitions in the early days of transplantation when only a few solid organs were transplanted, for example kidney, heart and liver. However, developments in transplantation have given rise to difficulties of definition. For example, only a part of an adult liver may be removed and transplanted into a child and the residual liver will regrow and the transplant will grow to adult size. This is a liver transplant but is clearly not an "organ" transplant according to the traditional definitions. Conversely, if a whole bone is removed and transplanted, the body cannot replicate the bone, but bone is normally considered to be a tissue not an organ…
>
> For the purposes of this Protocol, the term "organ" is accordingly applied to vital organs or parts of vital organs which require a major surgical procedure for removal and which need to be transplanted rapidly. The term "tissues" covers all other those parts of the body, including cells, not specifically excluded.'

215 We have already drawn attention elsewhere in this Interim Report, to the fact that the terminology of 'organ' and 'tissue' is apt to confuse. It is vital that the terminology employed on consent forms and the like is kept under regular review to ensure that it continues to be appropriate as science develops and medical advances permit new techniques to be performed.

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169 This word itself is not defined, but presumably, in the light of the scope of 'post-mortem', means the keeping of tissue beyond the time needed to perform not just the original dissection of the corpse but also any histological or other laboratory examination of tissues removed from the corpse at post-mortem

170 Para 3.6 (emphasis added)

171 Thus at Para 5.14 'written agreement must be obtained for the retention of whole organs in all cases' is almost certainly a guideline rather than a statement of law: but the world 'must' suggests the latter

172 Para 3.6 and see also Para 6.3

173 Para 3.5

174 Para 5.3

Royal College of Pathologists Guidelines for the retention of tissues and organs

216 The Guidelines published by the Royal College of Pathologists in March 2000 constitute advice to doctors (particularly pathologists) and Coroners. They are not primarily addressed to the public. They consist of the Guidelines themselves and three Annexes, comprising a model information leaflet, a model form for agreement to a post-mortem examination and a model form for a post-mortem required by law.

217 Some overarching points are apparent:

(a) there is no sanction for any breach of the Guidelines;

(b) the legal status is that of advice, and nothing more;

(c) they apply only to the 'retention' of 'tissues and organs'[164] from post mortem examinations, and do not cover the retention of material from biopsies or surgical resections;

(d) although Coroner's post mortems[165] are distinguished from hospital post-mortems[166] in the Introduction[167] to the Guidelines, both are treated indistinguishably. In the Introduction there is said to be a need in some cases to retain one or more whole organs for further examination not only to verify the cause of death but also to study the effect of treatment. Establishing the cause of death is the principal focus of a Coroner's post-mortem: any study of the effects of treatment as a *separate* exercise is not in fact permitted within the scope of a Coroner's post-mortem.

218 There is no separate definition of many of the terms used in the Guidelines. The use of the words 'tissue', 'tissue samples', 'fluids', 'tissues and organs' and 'tissues or organs' is considered in the report to which this is an Annex. Equally, there is no definition of 'post-mortem examination' in the Guidelines although the Glossary which forms part of the Information Leaflet does describe a post-mortem in some detail. The scope of a post-mortem appears to be wider than an examination by dissection of the corpse on one occasion: it is said[168] that the post-mortem examination is not just the external and internal examination of the body, but includes histological or other laboratory examination of retained tissues.

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[175] Para 5.6. Agreement is the word used to describe the absence of objection by a relative after such reasonable enquiries as are practicable have been made pursuant to the 1961 Act
[176] Para 5.7–5.10
[177] Emphasis added
[178] Para 5.14. This statement is followed by the sentence 'Organs must not be retained without relatives' agreement', which appears merely to be an echo of the statement quoted, though the adjective 'whole' is missing. It is difficult to see whether this repetition serves any, and if so what, purpose
[179] Para 5.15
[180] Para 6.1–6.6.

219 The Guidelines take the view that the law requires 'proper authorisation' for the retention[169] of even the smallest amount of tissue. Since a Coroner, pursuant to Rule 9 of the Coroner's Rules 1984, may require the retention and preservation of material which in the opinion of the pathologist bears upon the cause of death, and since the Coroner's powers are otherwise limited to enquiring into the cause of death, the identity of the deceased, and how and when he met his death, it would appear to follow that a Coroner has no power to authorise the retention of tissue for any other purpose. At Paragraph 3.6, however, it is suggested that a pathologist should retain appropriate samples when, during the course of the post-mortem, he discovers a condition '*which has no bearing on the cause of death*',[170] but may have implications for other family members. Even though the Guidelines go on to say that the agreement of relatives should be sought and, if refused, the tissue samples should be reunited with the body, this advice on its face would appear to exceed the Coroner's authority.

220 The distinction between that which is recommendation or guideline, and that which is intended as an exposition of the existing law is not stated as such.[171] Ordinarily, if the Guidelines and recommendations are followed it is likely that the practitioner will be within any permissible interpretation of the present law, save where the Guidelines appear to go beyond what the law provides.[172]

221 Of particular relevance to the terms of reference of this Inquiry, the Guidelines suggest:

a) pathologists should routinely, in the case of a Coroner's post-mortem, preserve samples from major organs for histopathological examination, unless it is known there are objections to that course or that retention has been disallowed by the Coroner,[173] and protocols providing for this should be drawn up between pathologists and Coroners;

b) that where a hospital post-mortem is intended, it must be made clear that the retention of 'tissue samples' is an integral part of the conduct of a post-mortem itself, and that 'the retention of whole organs for verification of the cause of death and investigation of the effects of treatment must also be explicit', and, thus, subject to potential objection;[174]

[181] Para 8.1–8.10

c) that, in the case of children, 'asking parents to agree to the post-mortem examination of a young child is a difficult and challenging task' which 'must be the responsibility of a senior member of the clinical team'.[175] The Guidelines refer to and adopt the well-regarded advice produced by the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI, 1998);

d) that where the primary purpose of retention is to conduct research on retained material, the research protocol must be approved by a Research Ethics Committee.[176] It will be noted that this leaves somewhat unclear the propriety of research on other retained material, an uncertainty not dispelled by para 5.9, which merely provides that 'research on *residual tissue* may not require individual agreement'[177] provided that not too much was initially taken and the identity of the person from whom it was taken is not disclosed. Neither of these conditions is entirely clear;

e) that written agreement must be obtained for the retention of 'whole organs' in all cases;[178]

f) that where it appears unexpectedly to the pathologist that there is either 'necessity for or desirability of' the retention of a whole organ, it should be retained pending immediate steps to obtain written agreement.[179] This appears to contradict the previous guideline which calls for agreement in advance 'in all cases'. The two guidelines cannot readily be reconciled, and the appearance of this latter guideline may be said to undermine the trust essential for the guidelines to succeed, that, in an important development of practice, the pathologist be available directly to the family. Para 5.4 provides that: 'Relatives should be informed that a pathologist can be available to answer any specific questions or concerns'. The Para concludes: 'Pathologists must be willing also to speak to relatives, on request, after the autopsy and this is best done in liaison with the patient's clinician.'

222 There are detailed provisions in respect of the disposal of tissues retained at any post-mortem examination.[180]

[182] Section 1(2)

223 The Guidelines conclude with 10 recommendations,[181] urging

(a) training for medical and other appropriate personnel in the requesting and obtaining of agreement for post-mortem examinations and in dealing with relatives' concerns about tissue and organ retention;

(b) the need for liaison of such a person with the pathologist to determine the necessity of and grounds for retaining tissue;

(c) the advisability of an information leaflet for relatives;

(d) the need for relatives to be given and to keep a copy of the signed form authorising (a) the post-mortem and (b) the retention of tissue;

(e) that post-mortem examination forms should offer a range of options for which agreement may separately be granted or withheld;

(f) that Coroners should provide an information leaflet explaining the legal necessity in certain circumstances to retain tissues or organs, and explaining the relatives' right to material when examination has been completed;

(g) that reports of post-mortem examinations should state what, if any, tissues or organs have been retained;

(h) that there should be standard procedures for the archiving and disposal of tissues retained from post-mortems, with safe and secure storage of any retained material, and a respectful safe and lawful method of disposal;

(i) that where the body has been buried or cremated, any remaining tissue which has been retained should be released for disposal only with authoritative confirmation of the identity of the organs or tissue and of the deceased to funeral directors chosen by and acting on behalf of those who have 'legitimate responsibility' for the disposal of the body; and finally,

(j) a recommendation that such Guidelines be periodically reviewed.