

## *Isaacs Report Response*

Response to the Report by  
Her Majesty's Inspector of Anatomy

July 2003



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# Foreword

In 2001 the Chief Medical Officer, Sir Liam Donaldson, set out his advice and recommendations in *The Removal, Retention and Use of Human Organs and Tissue from Post Mortem Examination*<sup>1</sup>. Among other things, this took account of his own investigation and census of organ retention, undertaken during 2000; the Redfern (Alder Hey)<sup>2</sup> inquiry report; and the interim Kennedy (Bristol)<sup>3</sup> report. Sir Liam's advice and recommendations addressed a wide range of issues raised by the unauthorised retention and use of human organs and tissues from adults and children.

The report of H M Inspector of Anatomy, Dr Jeremy Metters, CB, published in May 2003<sup>4</sup>, provides further perspectives on the circumstances in the past where organs and tissue were retained without consent. We are grateful to Dr Metters for the thoroughness of his investigative work. Many of his recommendations are already being addressed, but we have been reviewing our existing programme in the light of the additional insight provided to ensure that this meets the needs identified in the report.

The programme of action undertaken in this area since 2001 has already achieved significant improvements in practice, and in the provision of information to, and support for, patients and their families. Many of the families directly affected have contributed to this process. New guidance from the Department of Health<sup>5</sup>, the Royal College of Pathologists<sup>6</sup>, the Retained Organs Commission<sup>7</sup> and others is already supporting the hard work and commitment of staff to change the culture in this area permanently. Following extensive consultation, the Government will be bringing forward a new Human Tissue Bill as soon as Parliamentary time allows.

Significant reform to the coroner system is also being considered following the publication of the report of the *Fundamental Review of Death Certification and Investigation in England, Wales and Northern Ireland*<sup>8</sup>. As part of this process, the Home Office is seeking to promote a number of interim measures to help improve current arrangements and to support coroners, their officers and their staff, as well as families and others within the system.

The issues considered by the Inspector in his report arise from the particular case of Mr Cyril Isaacs, whose brain was retained without consent after a coroner's post mortem. However, the Inspector found that the retention of the brain was part of a wider research arrangement between Manchester University and the North Manchester coroner's service from 1985 to 1997. The Inspector's insights into other instances of similar practice bear on the use of adult organs and tissue more generally.

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1 *The Removal, Retention and Use of Human Organs and Tissue from Post Mortem Examination; Advice from the Chief Medical Officer* Department of Health, Department for Education and Employment and Home Office (January 2001)

2 *The Royal Liverpool Children's Inquiry Report*. Michael Redfern QC (2001)

3 *The Bristol Royal Infirmary Interim Report*. Sir Ian Kennedy (2001)

4 *The Isaacs Report – The Investigation of Events that followed the death of Cyril Mark Isaacs* (May 2003)

5 See section 1, paragraph 13 below

6 *Guidelines for the retention of tissues and organs at post mortem examination*, March 2000, available at [www.rcpath.org](http://www.rcpath.org)

7 *Guidance from the Retained Organs Commission can be found at:* <http://www.nhs.uk/retainedorgans/guidance.htm>

8 *The Fundamental Review of Death Certification and Investigation*, 4 June 2003, Cmnd 5831

As other, earlier, investigations have found, the *Isaacs Report* identifies systems that were failing to engage with patients and their families, and a culture that was out of step with the expectations of a modern service. Practices that the *Isaacs Report* uncovers were not confined to one location. The lessons are salutary for all coroners' services, university research departments and the NHS Trusts that work with them.

Nevertheless, we should not let the particular findings of this report cast a shadow over the work of others involved in research who have scrupulously ensured that consent and ethical approval have been properly addressed. In this respect, the Inspector has identified examples of good practice. Similarly, in most cases where instances of abuse were brought to coroners' attention, steps were immediately taken to require compliance with the Human Tissue Act 1961.

The use of tissue samples and organs for medical research and education have significant implications for the health of the population in general. Only with an effective research community can we address today's public health challenges such as Parkinson's disease, vCJD, HIV/AIDS and Sars. The development of new drug therapies, the diagnosis of existing conditions and the training of medical professionals all rely heavily on the good will of the public and the donation of tissue and organs. Equally, access to organs and tissue taken in the past can help to identify and respond to new strains of disease that may arise.

Activities such as those described in the *Isaacs Report* have the potential to cause great distress for individuals and to do a disservice to research and researchers more generally. Our aim is to ensure that future arrangements protect the rights and expectations of individuals and families, but also that research into mental health disorders and diseases such as CJD and Parkinson's are safeguarded for the long-term protection of our health.

We are confident that, since the time of the activities described in the *Isaacs Report*, the culture of retaining organs and tissue without consent has changed. However, the improvements made so far will be built on and the planned legislation will secure further improvements and compliance in the future. The Inspector's report will further inform this process.

Department of Health  
Home Office  
Department for Education and Skills

July 2003



# 1. Introduction

**We set out here the background to the investigation and general comments on the findings of the Inspector's report. We outline also action taken by the Government to date on the removal, retention and use of human tissue, as well as preparations made for the publication of the *Isaacs Report*.**

## Background to the Isaacs Investigation

1. Following concerns raised at the Chief Medical Officer's Summit on organ retention in January 2001, including those raised by Mrs Elaine Isaacs, the then Secretary of State for Health appointed Dr Jeremy Metters, CB, HM Inspector of Anatomy, to carry out an independent investigation into the case of Mr Cyril Isaacs, Mrs Isaacs' late husband. Dr Metters was also asked to determine whether similar retention of organs for research had occurred elsewhere in the country.
2. The terms of reference for the investigation were set in October 2001:
  - To investigate and document the procedures and circumstances, which led to the removal and retention of organs of the late Cyril Mark Isaacs during the autopsy, performed at Prestwich Mortuary on 27th February 1987.
  - To investigate what subsequently happened to the organs removed and retained.
  - To review whether similar removals of organs occurred at other public mortuaries after deaths outside hospitals.
  - To examine these events in the light of clinical and ethical policies, relevant legislation, religious beliefs, and the expectations and rights of relatives.
  - To report conclusions and recommendations to the Secretary of State for Health.
3. The extent of organ and tissue retention, in archives across the country, from both adults and children has been public knowledge since the Chief Medical Officer published the findings of his investigation<sup>9</sup> and census<sup>10</sup> of retained organs and tissue early in 2001. Relevant extracts of the census are at **Annex A** of this response. Prior to this, the Kennedy and Redfern reports had indicated that there were widespread problems and had provided particular insights into events leading to unauthorised retention at the Bristol Royal Infirmary and at the Royal Liverpool Children's Hospital (Alder Hey).
4. Since then, the Retained Organs Commission has added to the sum of knowledge through two further investigations at the Central Manchester and Manchester Children's University Hospitals Trust and at the Birmingham Children's Hospital. The Commission has been working with NHS Trusts to ensure that they now have accurate catalogues of organs in their archives and collections.

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<sup>9</sup> *The Removal, Retention and Use of Human Organs and Tissue from Post Mortem Examination; Advice from the Chief Medical Officer* Department of Health, Department for Education and Employment and Home Office (January 2001)

<sup>10</sup> *Report of a Census of Organs and Tissue retained by Pathology Services in England.* Department of Health January 2001

5. The *Isaacs Report* provides additional information, with particular emphasis on:
  - the taking and use of organs and tissue from adults;
  - the role of coroners' post mortems;
  - the roles of NHS and public mortuaries;
  - the handling of deaths in the community;
  - the use of organs and tissues for research; and
  - the relevant religious and cultural considerations.
6. The *Isaacs Report* was published on 12 May 2003. The then Parliamentary Under-Secretary for Health made a Parliamentary Written Statement: see **Annex B**. Among other things, the statement paid tribute to Mrs Elaine Isaacs for bringing the issues surrounding her husband's death to public attention. We are aware of the anguish caused to Mrs Isaacs and her family, as it has been to other families. We hope that the report and this response to it will provide some comfort and reassurance for the future.
7. The report shows, among other things, that relatives were not aware that:
  - organs would be removed as part of a coroner's post mortem examination;
  - organs removed might not be returned to the body after the post mortem examination;
  - organs could be retained legally by the coroner without their permission in connection with establishing the cause of death; and
  - organs might be retained for other purposes, such as research, without their consent and thus without legal authority.
8. Relatives were not given:
  - information about the coroners' post mortem process;
  - information about the options for the ultimate disposal of any organs removed;
  - support, advice or counselling; or
  - suitable consideration of religious or cultural beliefs.
9. The Inspector stresses that, even for those not opposed to organ retention in principle, there was uncertainty. For others, including those for whom such retention runs counter to their religious beliefs, there was the potential for considerable distress.
10. Although the Inspector's report revisits some issues addressed in earlier reports, it has thrown additional light on aspects of organ retention which had not been scrutinised in such depth previously. There are important new insights into the circumstances in the past where there was retention from adults without consent, and a much more complete picture of the roles of coroners, universities and public mortuaries.

## Matters relating to the police

11. In the course of his inquiry, the Inspector considered the way that Mrs Isaacs was treated by the police during their investigation of Mr Isaacs' death. The role of the police was outside the terms of reference of the investigation and so the Inspector did not pursue these issues. Some concerns have, however, been drawn to the attention of Greater Manchester Police who have undertaken to consider what lessons

can be learned from the report. The report has similarly been brought to the attention of H M Inspector of Constabulary.

## Government action on human organs and tissue use

12. Since the Chief Medical Officer made his recommendations in 2001, action taken by the Government and others has significantly altered both the practice and culture relating to the removal and retention of organs and tissue from post mortem examinations. In addition to addressing the specific recommendations in the Inspector's report, this response outlines the steps already taken or planned to address the earlier recommendations of the Chief Medical Officer (**Annex C**).
13. The Department of Health published an interim framework (pending legislation) of new guidance and materials on 25 April 2003. This included:
  - an interim statement on the use of human tissue and organs under the current law;
  - a code of practice, *Families and Post Mortems*;
  - post mortem consent forms and information leaflets;
  - a code of practice on the import and export of human body parts.
14. These materials were consulted on and piloted last year. Together they provide a framework for all those involved in post mortem examinations and in the taking and use of organs, including bereaved families, coroners and their officers, staff in the NHS, voluntary and private sectors and medical researchers.
15. The new guidance has been distributed widely in England and Wales and, in particular, has been brought to the attention of all NHS Trusts and Strategic Health Authorities. Coroners, medical schools and university research departments have also been made aware of relevant elements of the package.

The components of the interim framework can be found on the Department of Health website at [www.doh.gov.uk/tissue](http://www.doh.gov.uk/tissue). Further details of all the documents and how to obtain them are also set out at **Annex D**.

16. The Department published at the same time a report of the consultation on legislative change arising from last year's report, *Human Bodies, Human Choices*<sup>11</sup>.
17. A new Human Tissue Bill will build on the interim framework and on the *Human Bodies, Human Choices* consultation. Our objective in bringing forward new legislation will be to construct a comprehensive, modern and sufficiently flexible legal framework, including provisions on consent, regulation and penalties. This will provide clear, unambiguous and transparent provisions enshrining the essential considerations of the wishes of individuals and their families, while, at the same time, underpinning the important work carried out with human organs and tissues in areas such as transplantation, research, training, and public health surveillance.
18. The report of the review of coroner services<sup>12</sup> makes a number of wide-ranging recommendations, including steps to achieve consistent, verifiable standards and practices in the ordering and conduct of coroners' post mortem examinations. We shall be considering the recommendations, and will link these to any relevant proposals from the Shipman Inquiry<sup>13</sup>.

11 *Human Bodies, Human Choices*. The Law on Human Organs and Tissue in England and Wales. A Consultation Report (July 2002)

12 *The Fundamental Review of Death Certification and Investigation*, 4 June 2003, Cmnd 5831

13 The independent public inquiry under Dame Janet Smith into the issues arising from the case of the GP, Harold Shipman

## Preparations for the publication of the *Isaacs Report*

19. Anticipating that the *Isaacs Report* findings would give rise to concern and stimulate enquiries from the public, the Chief Medical Officers of England and Wales asked the Retained Organs Commission to put specific arrangements in place to tackle such enquiries.
20. The Commission provided a national helpline for initial enquiries and advice, and co-ordinated and directed enquiries to NHS Trust hospitals in England and Wales. The Commission also updated and reissued its guidance to NHS Trusts on handling enquiries about retained organs. Strategic Health Authorities were asked to oversee action by NHS Trusts to confirm that they were well placed to provide accurate and comprehensive information to enquirers. The full details of the Commission's arrangements can be found on its website at: [www.nhs.uk/retainedorgans/index.htm](http://www.nhs.uk/retainedorgans/index.htm)
21. The Chief Medical Officer wrote to the Chief Executives of all NHS Trusts and Strategic Health Authorities to ensure that they were aware of these arrangements and prepared to deal with any enquiries effectively. Similar letters were sent to Deans of Post-graduate Medical Schools, to the Medical Research Council and the Wellcome Trust, as these arrangements were expected to generate enquiries for them as well.
22. The Home Office and the Department for Education and Skills wrote respectively to coroners and to all Vice Chancellors of universities in England to notify them of the imminent publication of the report and to alert them to possible enquiries relating to it.

## Enquiries following the publication of the *Isaacs Report*

23. Up to 20 June 2003, a dedicated helpline set up by the Retained Organs Commission had taken over 860 calls, of which some 580 were specific enquiries from families seeking information about organ retention from a deceased relative. The Commission is passing these enquiries to the relevant NHS Trusts for investigation. Since its inception in 2001, the Commission has handled over 8,000 other calls from people concerned about organ retention and there have been around 20,000 other enquiries made directly to NHS Trusts. We are grateful to the Commission and its staff, as well as NHS organ retention teams and others, for their work.

## 2. Responses to H M Inspector's Specific Recommendations

### To prevent unauthorised organ and tissue retention

#### *Review of relevant law relating to unauthorised removal of organs and tissues*

#### *Recommendations 1 a, b and c:*

- a) *The retention of organs and tissues from post mortems, without legally defined and valid consent, should be made an offence;*
- b) *There should be appropriate penalties for unauthorised retention in the Legislation;*
- c) *The term "lack of objection" should be replaced by "with consent of".*

We welcome these recommendations which echo key proposals made by the Chief Medical Officer in his advice *The Removal, Retention and Use of Human Organs and Tissue from Post Mortem Examination*<sup>14</sup>. The Government accepted the Chief Medical Officer's recommendations and set in train a progressive programme of action to implement them. One of the main features of this programme has been the fundamental and broad revision of the law, reflected in the *Human Bodies, Human Choices* consultation report, published in July 2002.

*Human Bodies, Human Choices* considered the current law in England and Wales on the removal, retention and use of human organs and tissue. It provided a comprehensive overview of the circumstances in which organs and tissues may be taken and/or used from adults, children, babies and fetuses, either in life or after death.

*Human Bodies, Human Choices* anticipated that valid consent would form the basis of new legislation, and specifically addressed the issues of oversight, penalties and compliance. Two of five workshops arranged by the Department of Health in Autumn 2002 as part of the consultative process focused on these key issues.

The proposed approach described in *Human Bodies, Human Choices* drew a large degree of consensus. We anticipate the new Human Tissue Bill making provision for consent to be the explicit, underpinning principle in the taking, use and disposal of bodies, body parts, organs and tissue. It would also establish a regulatory framework and provide for penalties where the law is deliberately broken.

This legislation will need to take account of decisions on the findings and recommendations of the review of coroners' service. The report of this review, under Mr Tom Luce, CB, was published on 4 June 2003.

Among other things, the review of coroner services recommends the introduction of a new, professional coroner service with significantly increased medical support which is appointed, trained and supported to modern judicial and public service standards and is responsive to the needs of families.

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<sup>14</sup> *The Removal, Retention and Use of Human Organs and Tissue from Post Mortem Examination; Advice from the Chief Medical Officer* Department of Health, Department for Education and Employment and Home Office (January 2001)

These recommendations are consistent with the changes already made to arrangements for hospital post mortem examinations.

*Until the law can be changed, there are other steps that will deter anyone who might be tempted to retain organs and tissues without proper consent. Therefore, unauthorised organ and tissue retention should become:*

**Recommendations 2 and 3:**

2. A disciplinary offence within the Terms and Conditions of Service for (i) local authority staff working in public mortuaries and (ii) NHS staff working in hospital mortuaries;
3. The General Medical Council should specify in professional guidance to medical practitioners that unauthorised organ and tissue retention will be subject to professional discipline.

Guidance from the Department of Health, the Royal College of Pathologists<sup>15</sup>, the Retained Organs Commission, and other bodies is already supporting transparent new systems founded on valid consent. In March 2000, the Chief Medical Officer and the Royal College of Pathologists both issued guidance to ensure that consent was sought for hospital post mortem examinations and for any retention of organs or tissue.

In April 2003, following extensive consultation, the Department issued a comprehensive package of new materials<sup>16</sup> (see **Annex D** for fuller details). These documents emphasise that organs and tissues must not be retained following post mortem examination without consent or other lawful authorisation. In addition, as our response to recommendation 1 above makes clear, we plan to introduce specific provision for penalties for unauthorised retention in the legislation that is being prepared.

The Health Act 1999<sup>17</sup> imposed a duty of partnership on the NHS and local government. New flexibilities established by the Act facilitate operational co-ordination. The Act also underpins the Government's clinical governance policy which requires all NHS organisations to have in place systems and processes to support the delivery of safe and high quality care, within a patient-centred, multi-disciplinary reporting and learning culture. Guidance on clinical governance (Health Service Circular 1999/065) sets out the relevant roles, responsibilities and processes required.

NHS Trusts and local authorities are responsible for the terms and conditions under which their staff are employed. Most NHS Trusts have disciplinary procedures that have been locally negotiated, usually in line with good practice guidance from the Advisory, Conciliation and Arbitration Service. Most Trusts also have a code which sets out the minimum standards of conduct and behaviour expected of employees. These codes identify the employer's expectations and are intended to give employees illustrations of the types of behaviour that could result in disciplinary action or dismissal.

For doctors, the General Medical Council (GMC) states in its guidance, *Good Medical Practice*<sup>18</sup>, that registration carries both privileges and responsibilities for all medical practitioners. Patients must be able to trust doctors and, to justify that trust, doctors must comply with 14 key principles, referred to as the *duties of a doctor*.

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15 *Guidelines for the retention of tissues and organs at post mortem examination*, March 2000, available at [www.rcpath.org](http://www.rcpath.org)

16 Department of Health materials comprise: an *Interim Statement* on tissue and organ use under the current law, *Families and Post Mortems* code of practice, *Post mortem consent forms* for hospital post mortems and retention of tissue and organs, *Information leaflets* which explain post mortems and relative's rights, Code of practice on the Import/Export of human body parts

17 The Health Act 1999 (came into force April 2000)

18 General Medical Council – May 2001

Following the events at Alder Hey and elsewhere, the medical profession is clearly alert to the issues raised by unauthorised organ and tissue retention and the need to apply certain key principles. The *Isaacs Report*, with its particular focus on retention from adults, has re-emphasised these. These include in particular:

- maintaining good communication with patients/patients' representatives;
- conducting research in an honest and ethical manner; and
- obtaining valid consent.

*Seeking patients' consent: the ethical considerations*<sup>19</sup> enlarges on the general principles of good practice that all registered doctors are expected to follow when seeking patients' consent to investigations, treatment, screening or research.

GMC guidance booklets make clear that serious or persistent failures to meet these standards may put a doctor's registration at risk.

## Coroners Rules 9 and 12

### Retention of "material" under Coroners Rules 9 and 12

These sections of the Coroners Rules have caused confusion to coroners, pathologists and researchers.

#### Recommendation 4:

- *To resolve this confusion, the Rules need to be revised or clear guidance provided to clarify the legality of organ and tissue retention in the following circumstances:*
  - (a) *when criminal legal action will or is likely to follow completion of the coroner's action;*
  - (b) *when civil legal action may follow after the coroner's action has ended;*
  - (c) *In the absence of instructions from the coroner, for how long the pathologist may hold the retained material before it is disposed of in accordance with the instructions of relatives.*

We fully accept the need for clarification of the respective obligations on coroners and pathologists where human organs and tissue need to be retained in connection with the investigation of a death. In advance of any changes to the Coroners Rules, and the introduction of new legislation affecting the regulation of human organs and tissue, the Home Office proposes to draw up and pilot a robust code of practice to regulate how long, and on what authority, human tissue may be retained following coroners' post mortem examinations.

It is envisaged that the Home Office code of practice will require the period of retention, where authorised, to be explicit, and that subsequent disposal will be properly documented, with details available on enquiry by the family of the deceased person where they have not themselves made the arrangements.

In the meantime, the Department of Health code of practice, *Families and Post Mortems*, already explains that consent must be sought separately for any subsequent retention of tissue and organs for medical purposes, once the coroner's duties are complete. The model consent forms, issued by the Department of



Health and circulated to coroners by the Home Office, provide for explicit, separate consent for the donation of any post mortem organs and tissue for uses such as medical education, audit or research.

We are grateful to the Coroners' Society and the Coroner's Officers Association for their advice on developing and implementing aspects of the interim guidance and, in particular, the standards for discussing post mortem procedures with bereaved families and others. This has been at a time of uncertainty for their members, whilst awaiting the outcome of the review of coroner services and the Shipman Inquiry. Both organisations have expressed their support for the code of practice, *Families and Post Mortems*, and wish to work progressively towards the models of practice contained in it. However, until reform of the coroner's system can be effected, many coroners will continue to use, or to adapt, their own forms for recording discussion with bereaved families about post mortem examination and the retention of tissue and organs, in line with standards set out in the code.

Coroners have been asked to take account of recommended practice within the NHS, and to note that NHS Trusts are being encouraged to discuss and agree compatible procedures with local coroners. A number of NHS Trusts and local coroners have already been engaging very actively to review practice. Successful joint training and discussion events between NHS staff and coroner's officers have been held, both locally and nationally, and more are planned. There are also some well established joint working arrangements already in existence, such as those in Nottingham. The Department of Health intends to support further joint training and development initiatives which will continue to extend good practice and help equip staff with the necessary skills to meet families' needs most effectively. This includes working with some individual coroners and their officers to monitor and review implementation of the new model forms and information leaflets. All this work will complement Home Office initiatives to promote incremental change and modernisation of the coroner service.

## To ensure that consent for retention is properly obtained

### *Consent forms and retention of organs and tissues: disposal*

#### *Recommendations 5 and 9:*

5. *The relatives should be routinely asked for their wishes for disposal of any organs or tissues retained from a coroner's post mortem and systems put in place to ensure that these wishes are carried out.*
9. *Relatives should be given the opportunity to indicate whether eventual disposal of retained tissues should be (a) a delayed cremation or funeral to allow the tissues to be returned to the body; (b) returned to them after disposal of the body; (c) undertaken by the hospital; (d) donated for medical research.*

The code of practice, *Families and Post Mortems*, focuses on communication with bereaved families about post mortem examination. The Inspector's recommendations reflect the standards set by the code and the model consent forms and information leaflets issued at the same time.

The code relates both to hospital and coroner's post mortems, and there are separate forms and leaflets for hospital and coroner's post mortems, which ask in detail about relatives' wishes for disposal. Questions about disposal should be asked routinely and, provided that legal and health and safety requirements are met, the disposal of any retained organs or tissue should be in accordance with the expressed wishes of the individual or of those close to him or her.



The advice issued by the Retained Organs Commission in April 2001 set out the need for options to be offered to families where organs had to be retained beyond the time of the funeral for diagnostic purposes.

The four options (9 a, b, c and d above) suggested by the Inspector are set out explicitly on the model consent forms and are explained in the information leaflets. None of these should therefore be problematic and we would usually expect NHS Trusts to offer them to families.

All coroners have been sent copies of the code of practice, *Families and Post Mortems*, although most coroners are understood to have already arrangements in place to advise relatives of their options and to ascertain their wishes. The Home Office proposes to update information on the specific scheme operating in each coroner's district and will provide good practice advice in its own code of practice (see response to recommendation 4).

### **Consent forms and retention of organs and tissues: Information, records and freedom to decide**

#### **Recommendations 6, 7, 8, 10 and 11:**

6. *Organ and tissue retention forms, similar to those already in use in many districts, should be introduced everywhere.*
7. *All post mortem reports should include full and accurate details of all organs, tissues and other tissue samples retained.*
8. *Relatives, unless they decline, should be informed about what samples have been retained.*
10. *Post mortem consent forms should have separate sections seeking (a) consent to the examination and (b) additional consent for organ and tissue retention. Relatives must know that they can refuse consent to the examination and they can separately consent to the post mortem but not to retention, if that is their wish.*
11. *Relatives must never be pressured to agree to a hospital post mortem under the threat that if they do not agree the death will be reported to the coroner.*

As already noted, the following documents produced by the Department of Health aim to ensure that valid consent for organ and tissue retention is obtained:

- a code of practice, *Families and Post Mortems* which sets out standards of communication with families (and others) for all post mortem examinations;
- standardised forms for consent to hospital post mortems and to the retention of tissue and organs following a hospital or a coroner's post mortem; and
- information leaflets which explain the reasons for a post mortem examination, what happens when one takes place, and the family's role and rights in the decision-making process.

These documents form part of a wide-ranging framework for the removal, retention and use of human organs and tissue and the standards to be followed in discussions with families.

The guidance makes clear that:

- the wishes of the person who has died and those close to him or her should be ascertained and respected wherever possible;
- organs and tissue must not be retained following post mortem examination without consent or other lawful authorisation;

- there must be separate consent for the post mortem examination itself and for any organ or tissue retention;
- accurate records must be kept of consents sought, and of any tissue and organs which have been retained;
- records of consent and of any retention must be available to families on request; and
- families should be informed of the findings of post mortem examinations unless they state that they do not wish to know.

We agree that consent should be given voluntarily and freely. This is consistent with the more general legal approach to valid consent, as set out for example, in the Department of Health's *Reference Guide to Consent for Examination or Treatment* (2001)<sup>20</sup> and in *Human Bodies, Human Choices*<sup>21</sup>. The code of practice on *Families and Post Mortems* and leaflets made clear that relatives should never be under duress to consent to a hospital post mortem if they do not wish one to take place.

The Department of Health has funded a short video, *Parents and Post Mortems*, made by a consortium of professionals and families as an aid to the decision-making processes. This is intended to supplement the more direct discussion that needs to take place when decisions may be sought at an often difficult and sensitive time. The video is available free of charge<sup>22</sup>. A video on the procedures for adult post mortem examination is also planned and should be available later this year.

The Department of Health is working closely with the Home Office to support the implementation of the forms and leaflets throughout the NHS and, in advance of the structural changes widely expected to follow the review of coroner services, to further encourage good practice in all coroners' offices across England and Wales<sup>23</sup>.

## To ensure relatives are fully and properly informed when decisions are taken

### *Information and support for relatives following deaths reported to coroners*

#### **Recommendations 12, 13, 14, 15:**

- 12. Information about "what will happen next" during the coroner's investigations should always be explained fully and with sympathy. The relatives should be told of their rights.*
- 13. When there is likely to be a coroner's post mortem, the reasons for the examination should be explained unless the relatives do not wish to be given details.*
- 14. When for the coroner's purposes a formal statement is needed, there should be no pressure on a relative for its urgent completion or duress over the contents. While "in shock", erroneous information may too easily be included.*
- 15. As many relatives do not, at first, take in details of what is explained to them a written summary should be provided.*

20 This guidance can be found at [www.doh.gov.uk/consent/refguide.htm](http://www.doh.gov.uk/consent/refguide.htm)

21 This consultation document can be found at [www.doh.gov.uk/tissue/humanbodieschoices.pdf](http://www.doh.gov.uk/tissue/humanbodieschoices.pdf)

22 Available by telephoning 08701 555 455 and quoting 31007/Parents and Post Mortems (video) 31008/Parents and Post Mortems (CD Rom) or 31235/Parents and Post mortems (DVD)

23 The code, forms and information leaflets are available on the Department of Health website. Details are also at Annex D

The provision of information to enable relatives to make informed decisions about post mortem issues is an underpinning principle of the Department of Health's code of practice, *Families and Post Mortems*. It includes such points as:

- the importance of giving relatives time and space to take in information;
- providing information in writing as well as orally; and
- the need to allow for individuals' differing needs and desires.

By these means, the bereaved family can be helped to determine the amount, type and timing of information they require and to read and absorb at their own pace.

The code also suggests that the information leaflets for families might be offered both directly to the next of kin and indirectly to other friends, relatives, or community members who may be providing support to those who have been bereaved.

The Home Office fully supports the need to provide bereaved relatives with relevant information about the coroner's procedures as soon as possible following the death, and to do so with tact and sympathy. In recent years, coroners have been provided with more accessible public information leaflets to give to relatives for this purpose. This approach was encouraged and endorsed on the introduction of a model coroner's court charter in 1999.

As a local service, however, capacity varies to provide the right kind and level of support to the public when a coroner's post mortem takes place. At present it depends, in part, on the local availability of resources and relevant training. The Chief Medical Officer wrote to NHS Trusts in April 2003 to encourage them to develop joint training and protocols with coroners and their officers where this may be of mutual benefit, as part of reviewing and developing practice to meet the standards set out in *Families and Post Mortems*.

Nevertheless, for as long as the function of the coroner includes the investigation of suspicious and untoward deaths, there will be a need to initiate enquiries at the earliest opportunity, especially where there remains a possibility that an offence has been committed. In these circumstances, the urgent completion of a formal statement by relatives or other witnesses may be unavoidable, and essential if the integrity of the investigation is not to be compromised. It is also essential to ensure that appropriate relatives and family are interviewed. While statements should always be taken with sympathy and understanding, delay may ultimately be neither in the best interests of the family of the deceased, nor in the interests of justice or society as a whole.

The Home Office will be encouraging local authorities, the police and other agencies to help provide the resources, both human and financial, needed locally to maintain acceptable levels of service in all areas.

Longer term changes to the coroner system, following the recently completed review, are likely to address organisational, functional and resource issues.

## Bereavement support

### Recommendation 16:

16. Support from NHS and voluntary sector bereavement services should be made more accessible to relatives of those whose deaths are reported to coroners, particularly after sudden death. The range and availability of such local services should be more widely advertised.

The Department of Health and the Home Office are working together to provide bereavement materials and training to support the local provision of bereavement care. We accept the importance of providing high quality support and advice to families at the time of bereavement and, clearly, a sudden death can add to the distress experienced. We are committed to strengthening bereavement support services, including developing the role of bereavement advisers. A survey completed by the Department of Health<sup>24</sup> showed that by June 2002, almost half (48%) of Trusts had a specific member of staff designated to look after bereavement issues. However, only 15% of Trusts employed a dedicated bereavement officer. Additional funding available this year in general NHS allocations is intended to assist the appointment of suitably trained staff, as well as improvements to accommodation set aside for bereavement work.

As with the Inspector's previous recommendations, the Home Office will encourage local authorities, the police and other agencies to help provide necessary resources. The Home Office will also encourage coroners to ensure that information about bereavement services, both local and, where relevant, national, is readily available.

NHS Trusts were reminded of their responsibilities for bereavement support in May 2001<sup>25</sup> following publication of the Redfern Inquiry report and the Chief Medical Officer's advice. Trusts were referred to earlier Department of Health guidance (1992) to the NHS, *Patients who die in hospital*<sup>26</sup>, which, among other things, advocated the appointment of bereavement officers, written procedures for dealing with relatives of the deceased and training for staff. In 2001, a website, [www.doh.gov.uk/bereavement](http://www.doh.gov.uk/bereavement), was launched to provide further relevant information for NHS Trusts and the public.

In 2001/02, the Department of Health went on to review the quality and availability of bereavement services available in the NHS and consulted a wide range of interested parties, including bereaved families, on their needs. Draft good practice guidance on the provision of bereavement services was issued for consultation in January 2002 and new guidance, based on this, is being prepared for publication later this year. This will address bereavement in general: *NHS interests should not be confined to deaths in hospital*. The new guidance will take specific account of the needs of relatives of those whose deaths are reported to coroners, including those who have died suddenly.

The Department of Health, has been working to support bereavement services in the voluntary sector. For example, it is funding Inquest<sup>27</sup> to produce a series of leaflets to support recently bereaved people who have contact with the coroner. Inquest is also preparing, with Department of Health support, a toolkit for professional staff and others on how to work with bereaved people when an inquest is ordered by the coroner.

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24 The Department of Health Bereavement Services Report can be found at: [www.doh.gov.uk/bereavement/2001bereavementservs-report.pdf](http://www.doh.gov.uk/bereavement/2001bereavementservs-report.pdf)

25 Chief Executives' Bulletin 17 May 2001

26 HSG (92)8 *Patients who die in hospital* (updated by HSG(97)43)

27 Inquest is an organisation campaigning for reform to the inquest system

The Department has funded the Child Bereavement Trust to produce a CD-ROM, *Child Bereavement for Doctors*, and to train NHS Trust bereavement advisers and set up a network for them. The Department of Health will also be funding a number of other initiatives for training bereavement advisers and other professionals, including coroners' officers, who have contact with bereaved families. A successful training event with the Royal College of Pathologists in June 2003 is to be repeated in the autumn. Additional central funding has been made available to Primary Care Trusts as part of their overall allocation in 2003/04 to support the development of bereavement services.

Working closely with the Retained Organs Commission, the Department has commissioned research from Southampton University to look at individuals' and families' responses to organ retention. This is considering the development of effective models of support that particularly meet the needs of families and individuals affected by post mortem organ retention.

About half a million people die in England and Wales each year. Therefore all clinicians involved in patient care are likely to deal with bereaved relatives from time to time and not only when a post mortem examination is to take place. Consequently, dealing with bereavement is a core communication skill for health professionals. We are currently developing a strategy to ensure common standards and benchmarks across curricula at all levels. Other bodies, such as the medical Royal Colleges, are also addressing these issues. However, in accordance with the principles in *The NHS Plan* (2000), a flexible approach should be adopted which can respond to the individual needs of recently bereaved families in order to agree any necessary action in partnership with them.

The appraisal and revalidation process for doctors explicitly requires evidence of their relations with patients and their families. The considerate handling of bereaved families is an important facet of this and the report of a death to the coroner should not of itself alter the relationship with a deceased patient's family.

The Home Office has been enhancing relevant support arrangements for victims and witnesses of serious crime, including bereaved people, following homicide or road traffic incidents. Measures under way or planned are detailed in *A Better Deal for Victims and Witnesses*<sup>28</sup> and include a National Strategy for Victims and Witnesses and a proposed Victims and Witnesses Bill. The Bill is expected to include provision for a statutory code of practice, a commissioner to champion the rights of victims and witnesses, and an explicit route to the Parliamentary Ombudsman to consider complaints.

A Victims Advisory Panel has already been established, providing an opportunity for victims of serious crime to influence developing policy, such as the first national Strategy for Victims and Witnesses, planned for publication in July 2003. The Strategy will focus not only on how the criminal justice system can be improved to provide better services for victims, but also on how other statutory agencies (for example health, education and social security) can become more sensitive to victims' needs.

## Research and teaching use of retained organs and tissues

### Recommendations 17, 18 and 19:

17. *Consent forms for research or teaching use should be specific to the purpose and investigation for which the organs or tissues have been retained.*
18. *Genetic or other research that could affect other family members must be carefully explained before consent is requested.*
19. *An independent authority should be given the responsibility for deciding whether a hospital post mortem and/or organ retention for research should follow the death in hospital of a person who has no known relatives or next of kin.*

Following extensive consultation, the Department of Health published in April 2003 an interim statement on the use of human organs and tissue under the present law. This covers the areas that have given rise to uncertainty most frequently. The statement aims to clarify those uncertainties where possible and is primarily a guide for clinicians, researchers, research ethics committees and others who wish to use organs and tissue for research, education, training and public health surveillance. However, given that the existing law is neither comprehensive nor, in some instances (notably the Human Tissue Act 1961), adequate for contemporary purposes, the statement may not offer a complete solution in all instances.

The statement advises that specialised guidance, such as that published by the Advisory Committee on Genetic Testing, should be consulted where tissue may be used in genetics research. The Government's recent White Paper on genetics<sup>29</sup> addresses consent issues, including relevant information matters. It emphasises that realising the full benefits of human genetics will require public acceptance and public confidence. The Government is committed to ensuring openness and transparency in genetics policy making.

The model consent forms alongside the code of practice, *Families and Post Mortems*, state that '*no tissue may be taken primarily for use in research without completion of a specific, separate consent form for that purpose*'. The forms also ask about donation of tissue and of organs for use in medical research, education and audit and list a number of options so that the organs to be used or the types of research may be limited.

However, the code and consent forms differentiate between the use of tissue blocks and slides and the use of any other tissue or organs. The documents explain that the making of tissue blocks and slides is an integral part of most post mortem examinations and that medical students, doctors and other health care professionals may witness the examination or a demonstration of the findings for educational purposes, or for maintaining standards of care. This must be explained to the family.

The question of who, if anyone, might represent the views of someone who dies without recording his or her own views on the taking and use of organs and tissue was considered in *Human Bodies, Human Choices* and the Government will be introducing legislation to cover this.

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<sup>29</sup> *Our Inheritance, our future*. Realising the potential of Genetics in the NHS (June 2003) Cm5791-II. Available at [www.doh.gov.uk/genetics/whitepaper.htm](http://www.doh.gov.uk/genetics/whitepaper.htm)

## Coroners' post mortems in NHS mortuaries

### **Recommendation 20:**

*20. The confusion over who is responsible for the conduct of NHS staff during coroners' post mortems in NHS mortuaries should be resolved urgently.*

Employers are responsible for the competence and conduct of staff within their organisation. NHS staff are responsible to the organisation for which they are working at any one time.

The potential for confusion arises for coroners' post mortems in NHS mortuaries as arrangements for these vary from one location to another, and can even change within one location, in accordance with contractual commitments. There are, as a consequence, a number of possible employer/employee relationships reflecting the nature of coroner and local authority arrangements in a particular locality.

An example would be a coroner contracting with an NHS Hospital Trust to undertake post mortem examinations on his/her behalf. In these circumstances, the Trust would remain responsible for the line management of its employees whilst they undertook the work under that contract. However, a Trust may also sub-contract its mortuary facilities to a local authority on behalf of a coroner. In these circumstances, whether or not the Trust were responsible for the line management of staff, such as mortuary technicians, would depend on the arrangements within the individual contract. As such, these responsibilities need to be identified clearly from the outset.

The Department of Health will remind NHS Trusts that they must take responsibility for the conduct and professional standards of all pathologists and mortuary technicians employed by them when carrying out post mortem examinations.

The Department of Health intends to make mortuary technicians subject to statutory regulation as part of the healthcare scientists workforce. Legislation will aim to provide statutory regulation for mortuary technicians (now referred to as "anatomical pathology technicians") from 2005 under the Health Professions Council. This regulation will include standards of proficiency, conduct, performance and ethics.

In the meantime, technicians are developing the basics of a voluntary regulatory system. The Department is working closely with all the healthcare scientist groups that are not regulated currently to assist them in their preparations towards state registration.



## Ethical approval and supervision of research on retained organs and tissues

### Ethics Committees

#### Recommendations 21 and 22:

21. *Ethics Committees should give particular attention to the consent forms that are proposed for any research using retained organs and tissues.*

#### Research funding organisations

22. *Organisations that provide funds for research on retained organs and tissues should include in their procedures steps to check that the ethical approval quoted relates directly to the research that is under consideration.*

The Department of Health and the Department for Education and Skills endorse these recommendations. We refer to the response to recommendation 18 above on guidance to research funding bodies and research ethics committees (RECs) on the use of human organs and tissue, in the form of the interim statement from the Department of Health, Welsh Assembly Government and Central Office for Research Ethics Committees.

This statement, issued to all RECs and to other research organisations in April 2003, describes, among other things, the approaches to consent and ethical review that lie at the heart of any consideration of research using human tissue and organs. The statement makes clear that research proposals should include all relevant information about the source and status of such tissue.

The Department of Health has also published a code of practice on the import and export of human body parts. This is intended to ensure that such tissue has been obtained ethically and with any necessary consents. This code is currently operating on a voluntary basis, overseen by HM Inspector of Anatomy, but may be placed on a statutory basis by new legislation.

The Research Governance Framework<sup>30</sup> for health and social care (RGF), published by the Department of Health in March 2001, sets out the responsibilities of the various stakeholders in research. It brings together standards that apply to all research involving human participants, their organs, tissue or data. This document describes clearly the responsibilities of everyone involved in health and social care research and requires that agreements describing the allocation of responsibilities and rights are reached, documented and enacted.

The responsibilities of the researcher include ensuring that the study follows the agreed protocol. The framework sets out how failures are addressed, including responsibilities for disciplinary action or prosecution in cases of research misconduct or fraud. The framework also defines the responsibilities of the sponsor. One of its standards is that all research involving human participants, their organs, tissue or data, must have a sponsor who has confirmed responsibility for it. This is in the process of being implemented.

The Governance Arrangements for Research Ethics Committees in the NHS were published by the Department of Health in July 2001. These link to the RGF. (The document is to be revised to take account of new draft Regulations for clinical trials of medicines from May 2004.) These arrangements emphasise the role of RECs in checking the consent paperwork and the consent process that has taken place for a research proposal. They also lay down a quality standards framework for RECs. In accordance

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30 Department of Health (March 2001) – [www.doh.gov.uk/research/rd3/nhsrandd/researchgovernance.htm](http://www.doh.gov.uk/research/rd3/nhsrandd/researchgovernance.htm)



with these governance arrangements, RECs should give close attention to the consent forms and protocols for any research proposal using retained organs and tissues. RECs frequently ask for further information and clarification from researchers. The Department's interim statement on the use of organs and tissue contains additional specific guidance for RECs.

The interim statement drew on the Medical Research Council's operational and ethical guidelines on the research use of human tissue and biological samples, published as part of its Ethics Series<sup>31</sup>. The MRC has also reviewed its guidance on the use of tissue derived from the nervous system; its *Interim Guidance on Ethics of Research Involving Human Material Derived from the Nervous System* will be published shortly.

#### Research funding organisations

23. *In complex areas of research on retained organs and tissues, research funding organisations should consider establishing their own Ethics Review Committees.*

#### Universities and organisations that host post mortem research

24. *Universities and other institutions should establish their own Ethics Committees which must be notified of all external grant support and Ethics Committee approvals obtained by their staff.*

Under present arrangements, any research which involves retained organs or tissue obtained from *past or present* NHS patients requires approval from an NHS RECs.

The Department of Health and the Department for Education and Skills recognise that it might be useful for a funding organisation, or other sponsor or host organisation, to undertake its own ethical review. The REC governance arrangements make clear that REC approval does not absolve researchers from legal or ethical responsibilities for their own actions.

A review by the funding organisation or other sponsor might secure more information for them about the proposal in question, but where NHS patients or families were involved, it would not obviate the need for review by an NHS REC before the research could commence.

The same principle would apply to host organisations. In this case, while the establishment of its own ethics committees might be a useful device for the University, or other host organisation, to secure full information about the research for which it has an accountability within the RGF, approval of an NHS REC would still be required, irrespective of whether the University had its own ethics committee.

We believe that for sponsors, funders or hosts, there is scope for this quality assurance accountability to be discharged by means other than setting up an REC. Such accountability is, after all, a managerial function and responsibility, whereas RECs are advisory in nature, albeit within that management framework. For example, the RGF includes the need for the researchers to have the appropriate substantive or honorary NHS contracts. These contracts entail clear responsibilities.

The Department of Health expects all proposals for research to undergo scientific quality assessment by independent expert review before they can take place in the NHS. The funder of the research would normally take the lead in arranging this.

Within the university sector, there is now greater clarity on supervisory and related matters following a review led by Professor Sir Brian Follett<sup>32</sup> (previously Vice Chancellor of the University of Warwick).

31 *Human tissue and biological samples for use in research* (Operational and Ethical Guidelines) [www.mrc.ac.uk/pdf-tissue\\_guide\\_fin.pdf](http://www.mrc.ac.uk/pdf-tissue_guide_fin.pdf)

32 A Review of Appraisal, Disciplinary and Reporting Arrangements for Senior NHS and University Staff with Academic and Clinical Duties by Professor Sir Brian Follett and Michael Paulson-Ellis September 2001 (available at <http://www.dfes.gov.uk/follettreview/>)

This work was prompted by the Redfern (Alder Hey) inquiry and considered the appraisal, disciplinary and reporting arrangements for senior NHS and university staff with academic and clinical duties.

The report of the Follett review proposed better arrangements for more co-ordinated and effective oversight of clinical academic posts. Two of the main outcomes of the review to date are:

- The publication in August 2002 of new joint appraisal arrangements for clinical academic staff ensuring that both the health and education sides have an input into that process.<sup>33</sup>
- The agreement at national level of a new Model Statute for university governance which incorporates, for example, new disciplinary procedures for clinical academic staff.

## Staff training

### *Recommendations 25, 26 and 27:*

*25. Staff in coroners' offices, coroners' officers, morticians and other staff involved in coroners' post mortems should be given training better to assist and help the relatives and to explain the reasons for a coroner's post mortem.*

*26. Guidelines should be developed on all aspects of public mortuary practice and for NHS mortuaries where coroners' post mortems are carried out.*

*27. Systems for the audit and quality assurance of coroners' post mortems are required, and similarly for the procedures and practices in public mortuaries.*

*Families and Post Mortems* offers guidance on record-keeping about consent to post mortem examination, the report of the examination itself and about any retained tissue or organs. It also encourages the NHS to work alongside coroners and their officers in developing good practice in communications with bereaved families about the need for post mortem examination.

In addition, as already noted, the Home Secretary recently published the report of the review of coroner services. This makes a number of recommendations for an effective framework for improving the quality of coroners' post mortems, including a more modern approach to appointment for coroners' pathology work, audit and appraisal. The Government will be considering these proposals carefully.

The Home Office will seek to extend training opportunities to relevant staff and encourage staff to be released for this purpose. It is expected that additional staff will be required to ensure that the same level of service can continue to be provided for the public, but this will depend on local agencies. The report of the review of coroner services recommends a significant increase in training as well as improving the medical contribution to that system. It also makes proposals for better links to medical training more generally.

The Home Office intends to build on the outcome of its recent survey of public mortuaries<sup>34</sup> and has opened up a dialogue on the issues with relevant local authorities, the Health and Safety Executive and the Chartered Institute of Public Health.

We accept the need for guidelines covering accountability, good practice, training audit and quality assurance systems for staff working in both public and NHS mortuaries. The Department of Health and the Home Office will work together with relevant interest groups to develop these. In respect of audit

<sup>33</sup> More details can be found at <http://www.doh.gov.uk/nhsexec/consultantappraisal/>

<sup>34</sup> *Report on the Survey of Public Mortuaries in England*, February 2003, available from the Home Office

and quality assurance, the Home Office proposes to explore accreditation of public mortuaries, for example, with Clinical Pathology Accreditation (UK) Ltd (CPA). In addition, the Department of Health is currently seeking to extend registration with CPA to all pathology laboratories by making the present voluntary arrangements compulsory.

## Recognition of the views of those who oppose post mortem examination and organ retention

### *Recommendations 28, 29 and 33:*

- 28. Enquiries should be routinely made about the religion of the deceased, which should be stated in the papers that accompany each body to the mortuary and/or included in the information obtained by the coroner's officer;*
- 29. In the interval between death and burial or cremation, religious ceremonies and rituals that do not interfere with the coroner's investigation should be permitted;*
- 33. As the retention of organs and tissues poses major religious difficulties for some faith communities, these procedures should be avoided if possible.*

We fully endorse the need to recognise and, where possible, to respond effectively to the views of those who have concerns about post mortem examinations and organ retention on religious, cultural or other grounds.

*Families and Post Mortems* offers guidance on respecting the expressed wishes and religious or cultural traditions of families in any communications with them about post mortem examination, and the importance of training staff in these issues. Coroners have been encouraged to take account of the religious beliefs of the bereaved family when deciding to order a post mortem examination. Opportunities for coroners to familiarise themselves with the ritual requirements of the Muslim and Jewish faiths have also been a feature of recent coroner training events.

In addition, the recently published report of the review of coroner services makes a number of recommendations about how the coroners' system might respond better in future to meet the varying needs of families. These recommendations are based on extensive consultation with families and family organisations. We shall consider all these recommendations carefully, alongside the changes that are already being made to improve communications with families about post mortem examinations.

The new model consent forms for post mortem examination ask for any relevant details about the deceased person and/or the next of kin to be noted on the front of the form. This includes information about the religion of the deceased, where the family wishes to provide this. (In response to comments already received on the new forms, we are considering amending the format slightly in future to avoid a possible inference at present that the religion of the next of kin only is being sought.) It also provides the opportunity for the inclusion of any other information that the family may consider relevant. The forms explain that relatives have the right to refuse any retention of organs not required by the coroner.

We shall review the forms in the light of experience of their use, and of the feedback we receive on them. We are aware, however, that Home Office experience in piloting the routine capture of data relating to the ethnic origin or faith of persons whose death has been reported to the coroner has engendered a degree of concern and suspicion in some areas. More work is therefore likely to be required if acceptable ways to identify this information are to be found.

**Recommendations 30, 31 and 32:**

30. A post mortem should not be carried out routinely where the cause of death can be established without one. Also, a limited post mortem procedure will be more acceptable than a full procedure to some faith communities;
31. Alternative methods for establishing the cause of death, such as Magnetic Resonance Imaging, require further evaluation to see if these will provide an alternative to post mortem examinations in a proportion of sudden deaths;
32. Use of toxicology may identify the cause of death in some cases and avoid the need for a post mortem examination;

At present, the full post mortem examination sets a standard against which the efficacy of alternatives should be measured. The Royal College of Pathologist's *Guidelines on Good Autopsy*<sup>35</sup> set out how this should be done. Nevertheless, we recognise the distress that a full post mortem can cause bereaved families and the concerns of particular faith communities.

The Chief Medical Officer recommended that research should be commissioned into less invasive forms of post mortem examination. A scoping study, commissioned by the Department of Health of the available national and international literature and current practice on less-invasive approaches to post mortem examinations has been completed. This considered, among other things, the potential of magnetic resonance imaging scanning for post mortem examination. It made clear that, at present, there is limited research evidence to support the effectiveness, or otherwise, of less invasive techniques. Consequently, the Department of Health will fund further research in this area, following competitive tender. This research will be expected, among other things, to address concerns expressed by some that these techniques may not provide the same level of information as that provided by a full post mortem<sup>36</sup>.

The diverse needs of different faith communities is an issue that some NHS Trusts have already addressed and the Department of Health is supportive of these initiatives. For example, the chaplaincy at St Helier Hospital, Surrey has produced a guide<sup>37</sup> explaining the special requirements of different faith groups within hospitals. This includes information about the care of the dying, attitudes to post mortem examination and burial/cremation needs for the deceased.

Both the Inspector's report and that of the review of the coroners system suggest a need to re-assess the balance between those deaths which are investigated by post mortem examination, and those which might be investigated without. There may be circumstances where, for example, the coroner's purpose might be met by a limited post mortem, or none, but this might also entail losses in information about the causes of a death or health implications for the surviving family. Indeed, recent reports have highlighted problems in this respect and the implications of such an approach would need to be considered by coroners and pathologists and discussed fully with the family. Similarly, recourse to toxicology alone may simply cause delay to the funeral because of the time it can take for analyses to be completed, and it would not be safe to release the body until the results of the tests were known. This delay would not be acceptable to some religious communities, as, for instance, Jewish communities will wish to bury their dead within 24 hours of the death.

The review of coroners services as well as the Shipman Inquiry, have also looked in some detail at ways of improving the quality and targeting of scientific and pathology investigations for the coroner. We shall be considering these issues further.

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35 Royal College of Pathology – September 2002 [www.rcpath.org/index.php?PageID=277](http://www.rcpath.org/index.php?PageID=277)

36 NCEPOD Reports – Functioning as a Team (2002), Changing the Way We Operate (2001); Then and Now (2000); The National Sentinel Clinical Audit of Epilepsy-Related Death (2002)

37 World Faiths in Hospital, 2000 – St Helier Hospital, Carshalton, Surrey

## Return of retained organs to faith communities

### **Recommendation 34:**

*34. In locations where retained organs and tissues from those of the Jewish or Muslim faiths are known to exist and can be identified, these organs should be returned to the religious authorities for burial, even when their return has not been requested by the relatives of the deceased.*

The Retained Organs Commission has been examining this and related issues as part of its recently completed advice to the Department of Health on the disposal and use of unidentifiable and/or unclaimed material (June 2003). The Commission has consulted representatives of a wide range of religious faiths and ethnic groups over the last two years about the range of issues relating to organ retention. This has involved a workshop and the opportunity to respond to two national consultation documents, as well as further contact with religious leaders on specific issues.

A number of issues have arisen which the Commission has reflected in its advice to the Department. These include:

- how the particular needs of individual faith communities can be accommodated in current practice;
- allowing the opportunity for families to express their concerns about post mortem examination; and
- the requirements of particular religions.

The Commission has also considered the disposal of identifiable organs retained in the past about which relatives have made no enquiry. We understand that the views emphasised by religious groups reveal different positions on this question. Some Jewish, Islamic and other communities have expressed a wish to dispose of any unclaimed tissue that could positively be identified as having been taken from members of their community.

We shall be considering the Commission's advice in the broader context of planned legislation and strategic change and will consider the Inspector's recommendation further in discussion with relevant representative organisations.

## 3. Annexes

### ANNEX A

#### Relevant extracts from the Chief Medical Officer's Census

The CMO's Census was undertaken in 2000. At the census point, the end of 1999, a total of 54,300 organs, body parts or fetuses were being held in hospitals or medical schools around the country that had been retained after post-mortem examination carried out some time during the 30-year period 1970–1999 (Table 1).

Medical school collections and archives account for about 30,000 items from this total; some of these may be of surgical origin rather than from post-mortems. A further 50,000 organs, body parts and fetuses from before 1970 were reported as still being retained.

#### Total, organs, body parts and fetuses

Table 1: Total organs, body parts or fetuses dating from 1970 onwards held in pathology collections at the time of the census at the end of 1999.

Time originally removed at post-mortem	Number of organs stored at census point
1970 – 1989	15,700
1990 – 1998	20,600
1999	2,900
Medical School Data post 1970	15,200
Total 1970 – 1999	54,300

Note:

Medical Schools were not asked to provide the more detailed analysis of post-1970 holdings period.

(2) Where medical school returns duplicated previous NHS Trust census returns, the NHS Trust figures with the more detailed time period analysis are shown in the table. In these duplicated returns the medical school holdings cannot be separated from the NHS Trust's own holdings, but it is estimated that up to 15,000 of the 39,000 holdings by NHS Trusts are in fact held in medical school premises.

## Retention of brains

Nearly half the retained organs from 1970 – 1999 were brains, one sixth were hearts and one eighth were lungs. A further tenth were other organs; this category includes kidneys, livers and pancreases (Table 2 refers).

Table 2: Nature of retentions in pathology stores, which had been accumulated since 1970 and were present at census point.

	Number of organs	% of all organs
Brains	23,900	44%
Hearts	9,400	17%
Lungs	6,900	13%
Other organs	6,100	11%
Body parts	3,700	7%
Stillbirths/fetuses	2,900	5%
Not Specified	1,400	3%
Total	54,300	100%

## Retention from adults and children

The retained organs were taken from 27,600 patients. Of these, the majority were adults but a substantial number (9,800) were children, infants or stillborn babies.

Table 3: Age groups of the patients from whom the organs or body parts, accumulated since 1970, had originally been taken.

Age Group	Number of patients
Adults	17,800
Children	2,600
Fetuses and infants	7,200
Total	27,600



## ANNEX B

### Written Ministerial Statement (12 May 2003)

Mr. Cyril Mark Isaacs

**The Parliamentary Under-Secretary of State for Health (Mr David Lammy):**

We are publishing today a report by Her Majesty's Inspector of Anatomy, Dr Jeremy Metters CB, into the case of the late Mr. Cyril Mark Isaacs whose brain was removed following a coroner's post mortem in 1987 without the knowledge or consent of his widow.

The Inspector found that Mr. Isaacs' brain was retained as part of an arrangement whereby the coroners' office in North Manchester would identify brains suitable for a research programme at Manchester University. The Inspector also found evidence that brains were removed from adults in other locations.

The Secretary State for Health asked HM Inspector to undertake this investigation following concerns raised by Mr. Isaacs' widow, Mrs. Elaine Isaacs. I wish to pay tribute to Mrs. Isaacs for bringing this case to public attention and to say how much I regret the distress that has been caused not only to her and her family but to others whose cases are mentioned in the Inspector's report.

The events described in the report relate to unacceptable practices some years ago. Since then, and particularly in the light of other reports, including those into events at Alder Hey and Bristol, we have made considerable steps to improve arrangements relating to any removal, retention and use of human organs and tissue from adults or children. In doing so, we have worked very closely with many statutory, professional, family, voluntary and other bodies. I am grateful to them for helping to change the culture and practice in this area.

The report makes a number of specific recommendations with implications for the National Health Service, coroners, universities and medical researchers. We shall consider these carefully in the light of action already taken in this area and then respond more formally. Following extensive consultation, we have recently published an interim framework of guidance and other materials to reflect transparent new systems founded on consent. Steps have been taken to modernise the practice of pathology and to improve the management of joint NHS and academic posts. My right hon. Friend the Home Secretary is considering the report of the fundamental review of the coroner's system. We have also consulted on changes to the law on human organs and tissue, which is outmoded and inadequate. We shall introduce new legislation as soon as Parliamentary time allows.

I appreciate that some people may be concerned about organ retention in the light of the Inspector's report. We have therefore asked the Retained Organs Commission to put specific arrangements in place for anyone who wishes to make an enquiry. A helpline has been established (0800 838909).

It is important that public confidence in medical research is not adversely affected by the findings in the report. Good quality research is essential if we are to meet today's public health challenges seriously. Our recently published interim statement on the use of human organs and tissue sets out clearly our expectations within the current law. This should help to reassure the public, as well as those who need to use organs and tissue for purposes that serve all our interests.

I am grateful to Dr. Metters for investigating this matter in such detail and for producing such a helpful and comprehensive report. Copies of the report have been placed in the Library.



## ANNEX C

# Chief Medical Officer's Recommendations on Human Organs and Tissue (2001)

Progress is summarised below. There is further material on the CMO's web page [www.doh.gov.uk/cmo/progress](http://www.doh.gov.uk/cmo/progress)

**Recommendation 1:** *As an immediate measure, the Human Tissue Act 1961 should be amended to clarify that consent must be sought from those with parental responsibility for the retention of tissue or organs from post-mortems on children beyond the time necessary to establish the cause of death. A penalty for non-compliance with the provisions of the Human Tissue Act 1961 should be introduced.*

An amending bill was not proceeded with as it would have been difficult to enact satisfactorily in advance of the recently completed review of the law (see rec 6). There remains a commitment to the points of principle.

**Recommendation 2:** *The Coroners Rules 1984 should be amended to clarify that the pathologist has no independent right to retain, use or dispose of human material once the Coroner's post-mortem is concluded, except on the authority of the Coroner in, for example, criminal cases, or with the consent of parents.*

The Home Office is considering how to give effect to this change and will introduce a code of practice to regulate how long, and on what authority, human tissue may be retained following coroners' post mortem examinations.

**Recommendation 3:** *A Code of Practice, supported by Directions from the Secretary of State for Health under the National Health Service Act 1977, should be introduced as soon as possible, to set out the required standards of practice in communications with families about both hospital and coroners' post mortems.*

**Recommendation 4:** *A standardised consent form should be provided for use throughout the NHS to obtain consent to hospital post-mortems and, separately, to the retention of tissue and organs following post-mortem.*

(3 & 4) Following extensive consultation and piloting, these materials were published in April 2003. We are considering ways of supporting implementation: for example, through facilitated events and, in the medium term, more specific education and training.

**Recommendation 5:** *An independent Commission should be established to oversee the proper return of retained organs and tissues to families who request it and to address the question of historical and archived collections obtained from post-mortem examinations. The role of HM Inspector of Anatomy should be broadened to assist with these tasks.*

The Retained Organs Commission was established in 2001 and its lifespan has been extended until March 2004.

**Recommendation 6:** *As soon as possible, there should be a more fundamental and broader revision of the law, encompassing the taking, storage and use of human tissue from the living and the dead and introducing an independent system of regulatory control. To be comprehensive this should encompass aspects of coroners' practice. It should shift the emphasis from 'retention' to 'donation' to signal a new relationship with the public and bereaved families.*

Consultation on the Department's report, *Human Bodies, Human Choices* (2002), has taken place. A report on the consultation process was published in April 2003. Legislation will be introduced as soon as Parliamentary time allows.

**Recommendation 7:** *Formal controls should be introduced on the import and export of body parts.*

Following consultation, a code of practice was issued in April 2003. Pending legislation, its operation will be overseen by HM Inspector of Anatomy.

**Recommendation 8:** *The ultimate disposal of retained tissues, organs, body parts, stillbirths and fetuses should be in accordance with any expressed wishes of the individual or his or her family.*

This is being addressed in a number of ways, including through the review of the law and the code of practice on families and post mortems. The Retained Organs Commission has also consulted on disposal issues.

**Recommendation 9:** *Time limits should be specified for the retention of tissue blocks and slides retained after post-mortem.*

The Retained Organs Commission issued a consultation document on blocks and slides for response by February 2003. The Commission's advice will help to inform new legislation (see 6 above).

**Recommendation 10:** *The Coroners' system as it relates to hospital deaths and deaths under the care of a general practitioner should be reviewed and the concept of introducing a 'medical examiner' system should be explored.*

**Recommendation 11:** *The feasibility of establishing a new system of death certification involving a medical examiner should be explored.*

(10 & 11) The report of a review established by the Home Secretary has recently reported and Ministers are considering its recommendations. The Home Secretary expects to consider recommendations from this review together with those in due course from the Shipman Inquiry.

**Recommendation 12:** *All NHS Trusts should provide support and advice to families at the time of bereavement.*

We are drawing up plans for further development of bereavement services. Additional funding for these was included in NHS allocations for 2003/4. This follows a review of existing services and includes revising and extending the scope of existing DH circulars on people who die in hospital (issued in 1992 and 1997).

**Recommendation 13:** *Research using donated tissue and organs taken at post-mortem can provide valuable information on disease, treatments and standards of care. It should be promoted where families have given informed consent to tissue or organs from their deceased relative being used in that way. There should be feedback to families on the research use of donated tissue or organs where requested. For tissue or organs donated for teaching, families should be invited to prepare a 'life book' on the child (or adult) who has died which would be shown to students in conjunction with the use of the tissue or organ for teaching.*

An interim statement on the use of human organs and tissue (consulted on last year) was published in April 2003. This took account of advice by the Retained Organs Commission on the use of unidentifiable (and unclaimed) organs and tissue known to have been taken at post mortem.

**Recommendation 14:** *There should be a programme of public education to ensure that there is general understanding of what is involved in the post-mortem process and its value to maintaining standards of patient care and medical science.*

**Recommendation 15:** *There should be a programme of education and training for all health professionals on the meaning of the law and appropriate standards of practice.*

(14 & 15) A strategy for education and training is being developed. There are both short term and longer term needs. It will be necessary to involve a wide range of stakeholders. A number of individual initiatives (conferences etc) are already in hand.

**Recommendation 16:** *Procedures should be established (after public consultation) to provide for obtaining appropriate consent for research using stored human tissue.*

The considerations here are similar to those at Recommendation 13.

**Recommendation 17:** *Research should be commissioned into less invasive forms of post-mortem examination.*

A scoping study of the available national and international literature and current practice on less-invasive approaches to post mortem examinations has been completed. Further research is planned.

## ANNEX D

### Summary of Guidance Issued on 25 April 2003

On 25 April, the Department of Health published an interim framework of guidance, pending new legislation, to ensure that valid consent for organ and tissue retention is properly obtained. This includes:

- a code of practice *Families and Post Mortems* which sets out standards of communication with families (and others) for all post mortem examinations;
- model forms for consent to hospital post-mortems and to the retention of tissue and organs following a hospital or a Coroner's post-mortem, and
- information leaflets which explain the reasons for a post-mortem examination, what happens when one takes place, and the family's rights in the decision-making process.

In addition, the Department published:

- an Interim Statement on use of human tissue and organs under the current law
- A Code of practice on the Import and Export of human body parts for non-therapeutic uses
- Report of the consultation on *Human Bodies Human Choices*<sup>1</sup>

These documents were distributed widely and, in particular, were brought to the attention of all NHS Trusts, Strategic Health Authorities, Coroners Services, Medical Schools and university research departments.

Together, these documents provide a clear legal framework for all those involved in post-mortem examinations and in the taking and use of organs, including bereaved families, coroners and their officers, NHS staff and medical researchers. The documents can be found on the Department of Health's website at [www.doh.gov.uk/tissue](http://www.doh.gov.uk/tissue).

**How to order copies of the post mortem consent forms, leaflets, codes of practice, interim statement and report of the *Human Bodies, Human Choices* consultation, and the video *Parents and Post Mortems* from the NHS Response line**

Copies of all the documents may be ordered from:

Department of Health Publications  
PO Box 777  
London SE1 6XH

Tel: 08701 555 455

Fax: 01623 724 524

E-mail: [doh@prolog.uk.com](mailto:doh@prolog.uk.com)

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<sup>1</sup> *Human Bodies, Human Choices. The Law on Human Organs and Tissue in England and Wales. A consultation Report* (July 2002)

Please quote the relevant number and document name as follows:

### Forms

- 29767/Consent to a hospital post mortem examination of an adult
- 29771/Consent to a hospital post mortem examination of a baby or child
- 29769/Post mortem examination of an adult, ordered by the coroner
- 29773/Post mortem examination of a baby of child, ordered by the coroner

### Leaflets

- 29772/Guide to the post mortem examination procedure
- 29770/Simple guide to the post mortem examination procedure
- 29768/Guide to the post mortem examination procedure involving a baby or child

If NHS trusts wish to arrange to print their own copies locally, a CD Rom containing the “artwork” is also available for the post mortem consent forms and leaflets by quoting:

- 31732/Post mortem consent forms and leaflets

### Video

- 31007/Parents and Post Mortems (video)
- 31008/Parents and Post Mortems (CD Rom)
- 31235/Parents and Post mortems (DVD)

### Guidance and other relevant documents

- 31518/The import and export of human body parts and tissue for non-therapeutic uses – a code of practice
- 31519/Families and post mortems – a code of practice
- 31520/The use of human organs and tissue – an interim statement
- 31521/Human Bodies, Human Choices – a summary of responses to the consultation report

The consultation document *Human Bodies, Human Choices* was published in July 2002 and copies also still available by quoting 28090/Human Bodies, Human Choices

Low resolution ‘pdf’ versions of all the documents (and other information) are available on the Department of Health website [www.doh.gov.uk/tissue](http://www.doh.gov.uk/tissue). These will enable you to print off further copies of the documents but they will not be of sufficiently high resolution for commercial printing.







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