

# Spongiform Encephalopathy Advisory Committee

Agenda Item 8

Date: 11 September 2002

## Title of Paper

PUBLIC CONSULTATION ON:

- A) REMOVAL, RETENTION AND USE OF HUMAN ORGANS AND TISSUES, AND
- B) DEATH CERTIFICATION AND CORONERS' SERVICES

## Issue

Consultation Reports are attached, which

- a) consider the various issues surrounding future arrangements for the removal, retention and use of human organs and tissues and seeks views on what new legislation should contain and
- b) reviews death certification and coroners' services in respect of England, Wales and Northern Ireland.

## Action Required from Committee

To consider the attached paper at 1) in conjunction with documents attached at 3), 4) and 6) and to respond to the questions posed. To agree that the secretariat drafts a response to the Consultation documents, for the Chair to send on the Committee's behalf.

## List of material attached

- 1) [Paper](#) prepared by Secretariat which identifies the key areas of the Consultation Reports that are likely to be of interest to SEAC.
- 2) Cover letter, 10 July 2002, sent out in conjunction with Consultation documents - *Human Bodies, Human Choices*
- 3) *Human Bodies, Human Choices*  
The Law on Human Organs and Tissue in England and Wales  
A Consultation Report. July 2002.
- 4) *Draft Code of Practice on the Import And Export of Human Body Parts*  
Draft for Consultation. July 2002.

5) *Human Bodies, Human Choices*

The Law on Human Organs and Tissue in England and Wales  
A Summary Consultation report. July 2002.

6) Certifying and Investigating Deaths in England and Wales and Northern Ireland  
An Invitation for Views

A Consultation Paper by the Fundamental Review of Death Certification and Coroners' Services  
in England and Wales and Northern Ireland. August 2002.

**PUBLIC CONSULTATIONS ON:  
A) DEATH CERTIFICATION AND CORONERS' SERVICES,  
AND B) REMOVAL, RETENTION AND USE OF HUMAN  
ORGANS AND TISSUES**

## **INTRODUCTION**

Both SEAC and its Epidemiology Sub-Group have previously expressed concern that public health surveillance of CJD is being compromised because of the low numbers of post-mortems that are being conducted in the elderly. This is being further exacerbated by concerns over tissue retention, which has led to reluctance to validate the cause of dementia at post mortem by histology.

At its last meeting, SEAC's attention was drawn to two important linked reviews, one of death certification and coroners' services, and a second on removal, retention and use of human organs and tissues. Both reviews are expected to lead to new legislation in these areas, and both have recently issued public consultation documents. Members are now invited to respond to these consultations.

## **BACKGROUND TO THE CONSULTATIONS**

The Home Office and the Northern Ireland Courts Service have commissioned an [independent review](#) of death certification and coroners' services in respect of England, Wales and Northern Ireland<sup>1</sup>. The main aim of this review is to create new death certification and investigation systems that are "fit for purpose", that is, they "serve the needs of the modern public, are adaptable to change, give bereaved families better rights, and provide professional workers within the systems with better support" (Executive Summary, p4).

The Department of Health and the Welsh Assembly Government have issued a [consultation document](#) on the removal, retention and use of human organs and tissues<sup>2</sup>, which will be taking into account reviews in Scotland and Northern Ireland on retention of organs at post-mortem, and relevant European and other international developments. Whilst recognising that public confidence has been shaken by the events at Alder Hey and elsewhere, the

---

<sup>1</sup> *The Fundamental Review of Death Certification and Coroners' Services.* August 2002

<sup>2</sup> *Human bodies, Human Choices. The Law on Human Organs and Tissues in England and Wales – A Consultation Report.* July 2002.

report emphasises the balance that new legislation will need to strike between the expectations of patients and families, and the broader public health interest in research, training, public health surveillance, etc.

In addition, members will wish to know of two other linked initiatives:

- A consultation by the Retained Organs Commission complementing the Department's review of the law, on the use and disposal of unclaimed organs and tissue and the future regulation of museums and archives. The Commission also intends to consider the status of tissue blocks and slides.
- A working group on human remains, mainly those kept in museums or archives, established by the Secretary of State for Culture, Media and sport.

**This paper presents an overview of the key areas of both the major consultation documents, in which SEAC is likely to have an interest, and tries to set out the main questions for the Committee. The paper does stand alone, but Members may prefer to read it in conjunction with the two consultation documents, which provide more detailed explanation of the issues.**

## **PROPOSED ACTION**

**That, following the Committee's discussion of this paper and the accompanying documents, the secretariat draft responses to the consultation documents for the Chair to send on behalf of the Committee.**

### **A) THE FUNDAMENTAL REVIEW OF DEATH CERTIFICATION AND CORONERS' SERVICES.**

In 2000 SEAC's Epidemiology Sub-Group considered the interim conclusions of a Department of Health-funded research project<sup>3</sup>, the key points of which were:

- If a disease causing dementia is part of the medically-certified cause of death, there is a low probability that a post-mortem examination will be conducted;
- vCJD may not have been detected in the elderly because nobody is looking for it;
- With the decline in numbers of hospital post-mortems, UK surveillance for CJD in the elderly is essentially reliant on the system of coroners' post-mortems. Concern over tissue retention means that the prevailing attitude of coroners in the UK is not to allow pathologists to validate the cause of a dementia at post-mortem.

---

<sup>3</sup> *Prospective Neuropathological Surveillance for Prion Disease in the Elderly Human Population.* DH-funded research project.

Paragraph 47 of the consultation document sets out the purpose of a post-mortem, and describes the process. “A post-mortem examination is an internal examination of a dead body to find the underlying cause of death, and to investigate the processes and events that may have contributed to the death. In a full post-mortem examination, the chest and abdominal cavities and the skull are opened, and the main organs are removed for weighing and dissection to see if abnormalities are present. The organs are then placed back into the body (although not in their original positions) and the body is closed. Tissue samples from these organs are sometimes retained for histological analysis and, in some cases, toxicology”.

- **What, under the current system of coroners’ post-mortems, do the Committee regard as the key issues of concern in relation to public health surveillance of human TSEs?**

Paragraphs 53 – 59 of the consultation document outline the scale and purposes of coroners post-mortems, and provide differing perspectives from wide-ranging views already sought by the review team. In particular, one of the issues raised in paragraph 59 refers to whether it is necessary for a post-mortem to continue after it discloses a likely cause of death. In particular, whether it is necessary, for example, to open the skull and dissect the brain after discovery of abnormalities in the chest or the abdomen sufficient to explain death.

- **Does the Committee wish to comment on the value of a full post-mortem examination in relation to surveillance of TSEs?**

The review document proposes the possible creation of a new Medical Audit Service (paragraphs 26 –29).

“The medical auditor would become responsible for dealing in the first instance with deaths in which there is no ground to suspect criminality, and where the main issue appears to be what natural disease caused the death” and would have “the power to decide the purpose and scope of further medical investigation, including scrutiny of existing case notes and/or ordering post-mortems.”

In addition, there is a proposal to develop a national protocol governing the use and arrangements for post-mortems for coroners and/or medical auditors, allowing full scope for independent professional and judicial judgement, but having legal status and produced by a publicly accountable body after consultation with expert and family interests (paragraph 60, and sub-sections),

- **Does the Committee think the proposals for creation of a medical audit service and a national protocol governing the use and arrangements for post-mortems would address its concerns?**
- **Are there alternative or additional measures that the Committee would like to propose?**

## **B) HUMAN BODIES, HUMAN CHOICES. THE LAW ON HUMAN ORGANS AND TISSUES IN ENGLAND AND WALES – A CONSULTATION REPORT.**

From SEAC's perspective, the key elements of this consultation document relate to public health surveillance (paragraphs 9.23 – 9.25) and research (paragraphs 10.10 -10.14). Members may be aware that there is not always a clear-cut distinction between these two activities. Most, if not all, major public health surveillance systems have research uses, and some surveillance systems began as research projects.

In addition, the Committee may wish to give a view on the relevance of existing stored tissue to work on TSEs (paragraphs 10.22 – 10.23), and the use of tissue for quality assurance purposes (paragraphs 9.21 – 9.22).

The Committee's view is also specifically sought on elements of the Draft Code of Practice on Import and Export of Human Body Parts<sup>4</sup>. The Committee is asked to address the issues in those parts of the consultation document and Code of Practice. A number of additional considerations likely to concern SEAC are also bulleted in the text below.

### **1. Public Health Surveillance (paragraphs 9.23 – 9.25)**

Public health surveillance of transmissible disease enables disease trends to be tracked, outbreaks or epidemics to be identified, and controlled if appropriate measures exist, and the impact of control measures to be monitored. Systematic disease surveillance of human prion diseases is essential if we are to control these diseases in the population, and to protect public health. Without surveillance and specialist laboratory techniques, it would not have been possible to have identified the first cases of variant CJD (vCJD) in 1996. For these rare diseases, some of which can be difficult to identify at an early stage, and which in older people may possibly be masked by other neurological conditions which give rise to similar symptoms, good surveillance requires not only reporting by clinicians who see patients, but also confirmation by post mortem examination wherever possible, with the agreement of the family concerned.

#### **1a. Surveillance after death**

Agreement to a hospital post mortem is governed by the Human Tissue Act (1961). The purpose of hospital post mortems is "to gain fuller understanding of an illness or cause of death to enhance future clinical care" (paragraph 1.11).

---

<sup>4</sup> *Draft Code of Practice on the Import and export of Human Body Parts.*  
Department of Health. July 2002

- **Does the committee consider that the current explanation of the purpose of hospital post mortems gives sufficient weight to properly approved public health surveillance programmes, where these might be facilitated by data gathered at post mortem?**

### **1b. Surveillance in life**

The following extracts are taken from paragraphs 9.24 and 9.25 of the report:

“In some instances, public health surveillance programmes involve testing, without compromising clinical care, small samples of tissue that are discarded routinely. In the past 10 years, over two million samples have been tested using the unlinked anonymous technique (whereby results can never be traced back to individuals) to help monitor HIV, hepatitis C and infections preventable by vaccination. Such work usually requires research ethics committee approval and, in the case of national surveillance, sometimes Ministerial approval as well.”

“It is important that, where the intention is to test routinely, there are effective means of publicity, and opportunities for patients to obtain more information or ask questions if they wish. Research has shown that publicity for such surveys does, in general, have a positive effect, both in terms of public support for such work and in consistently low levels of “opt-out”. If significant numbers of patients did opt out, it would call into question the validity of such surveys, with possible adverse implications over time for public health itself.”

- **Does the Committee consider that unlinked and anonymised tissue samples, used for properly approved public health surveillance programmes, provide valuable information on the surveillance of human TSEs?**
- **Would the value of such programmes be compromised if patients are allowed to opt out?**

## **2. Research (paragraphs 10.10 - 10.13)**

Our understanding of diseases, such as vCJD, would have been seriously hampered if human tissue had not been available for research. Good research and development is essential for all aspects of health protection. In his recent strategy for combating infectious disease<sup>5</sup>, the Chief Medical Officer identified the following areas where research and development specifically contributes:

---

<sup>5</sup> *Getting Ahead of the Curve. A strategy for combating infectious diseases (including other aspects of health protection)* A report by the Chief Medical Officer. Department of Health, January 2002

- Establishing the causation and pathogenesis of infection, the mode of action of particular micro-organisms and how the body's immune system responds;
- Developing and evaluating effective diagnostic tests;
- Understanding the epidemiology of infectious diseases, anticipating and recognising outbreaks;
- Creating new safe and effective vaccines, and refining existing ones;
- Finding new treatments for infectious diseases;
- Discovering new infectious agents;
- Using existing knowledge to ensure that strategies for infectious disease control and treatment are up to date and evidence-based;
- Supporting front line clinical and public health staff by providing ready access to knowledge.

The Committee may find these points helpful in considering the question asked on page 7, regarding the research principles which they would wish to see taken into account in drafting new legislation.

INTENTIONALLY BLANK

The Department of Health has drawn up a draft interim statement on the use of organs and tissues, based on its understanding of the *current law*. This statement endorses the principles for clinical research, derived in part from guidance issued by the Medical Research Council.

Following consultation on this statement earlier this year, which was largely supportive, the intention is to issue a revised version shortly, although the issues will be considered further in the context of new legislation. Pending such legislation, the Department of Health regards the statement as necessarily limited in scope. The secretariat understands that the statement will be revised to include specific coverage of public health surveillance.

- **The Committee is asked to consider the research elements of this interim statement, which supplement additional principles for consent that are not included here. Does the Committee have any views on what research principles ought to be embedded in proposed new legislation/guidance?**

***Draft Interim Statement – Principles for Clinical Research***

*Research should go ahead only if the potential benefits outweigh any potential risks (which will usually be minimal) to the donors of the samples;*

*Samples of human organs or tissue obtained for use in research should be treated as gifts;*

*The human body and its parts should not, as such, give rise to financial gain (though it is legitimate for suppliers to levy an administrative and/or handling charge for parts that have been acquired and stored in an ethical manner);*

*Patients should be asked whether organs or tissue left over following diagnosis or treatment may be retained and/or used for research;*

*Records of storage and use should be properly maintained and, where necessary, linked to (or unlinked from) relevant patient information systems;*

*All research using samples of human organs or tissue must be approved by a properly constituted research ethics committee;*

*Researchers should treat all personal and clinical information relating to research participants as confidential;*

*Where this is possible, research participants, if they wish, should be able to know individual research results that affect their interests. (This will not be possible where research involves anonymised samples).*

### **3. Existing Stored Tissue (paragraphs 10.22 and 10.23)**

Retrospective unlinked anonymous studies to detect abnormal prion protein in stored tissue have been in progress since 1998, in order to begin to assess the prevalence of this protein in a particular subset of the population. As long as ethics committee approval is obtained, the MRC guidelines make provision for unlinked anonymous testing in such circumstances. The consultation document does not however, specifically discuss the use of the unlinked anonymous technique in the study of existing stored tissue.

- **Does the Committee wish to comment on the value of such studies?**
- **Does the Committee have a view on how long tissue samples might need to be retained for TSE surveillance or research purposes, for both existing and future collections of tissue?**

### **4. Quality Assurance (paragraphs 9.21 and 9.22)**

Quality assurance schemes are an important part of maintaining high quality clinical services generally. The consultation document explains that the current view is that provided patients have consented to a particular intervention, tissue samples may be used for quality control/audit purposes without specific consent being obtained.

In the field of human TSEs, appropriate positive and negative control samples are essential in development and quality control of, for example, diagnostic tests for TSEs.

The consultation document asks whether it is acceptable for tissue samples taken from living patients to be used for quality assurance and audit purposes without seeking specific consent, provided that patients are aware that tissue may be used in this way.

- **Does the Committee have a view on this?**
- **Do members wish to comment on the implications for development/conduct of tests for TSEs, should patients object?**

### **5. Draft Code of Practice on the Import and Export of Human Body Parts<sup>4</sup>**

As part of the Chief Medical Officer's recommendation in January 2001 for a fundamental and broad revision of the law on the taking, storage and use of human tissue from the living and the dead, he recommended that formal controls be introduced on the import and export of body parts. Pending this

---

<sup>4</sup> *Draft Code of Practice on the Import and export of Human Body Parts.*  
Department of Health. July 2002

review of the law, he recommended that a Code of Practice be introduced to require proper records to be kept of imports and exports of all human body parts for teaching, education, research or other non-therapeutic purposes.

“The aim of the Code of Practice is to ensure that body parts have been obtained ethically, that the appropriate consents have been obtained, and that they have been subject to screening to minimise the risk of infection.”

A draft Code of Practice is currently available for consultation, and has been provided to the Committee.

There are some specific points upon which SEAC members may wish to comment.

#### **5a. Is the scope of the Code right? (paragraphs 4 – 6)**

The Code does not currently include small, unfixed tissue samples, for example exchanged between professional colleagues for diagnosis, although this material is potentially hazardous. Would inclusion of such material be unnecessarily onerous? Should this code apply to small, unfixed tissue samples (for research or diagnosis) or body fluids (eg blood, bile or cerebrospinal fluid)? Should dry bones and skeletons be included?

- **What, in the Committee’s view, are the benefits/disbenefits in including such materials within the scope of the Code?**
- **Does the Committee consider that the scope of the Code should be expanded to include such materials?**

#### **5b. What should the Code say with respect to potential risks of CJD transmission? (paragraphs 14 – 18)**

Paragraph 18 of the Code recommends that the importation of brains, brain tissue and spinal cord should be avoided because of the potential risk of CJD infection.

- **Does the Committee agree with this recommendation? What would be its likely effect on international co-operation on public health surveillance and/or research and development?**
- **If the Committee’s view is that import/export of brains or spinal cord should be allowed, should advice be included in the Code on precautions to be taken?**