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The *Human Tissue Bill*

Bill 9 of 2003-04

Public attention to the issue of organ retention was heightened when it became widely known that human organs were routinely kept in hospitals after bodies had been returned to families. The biggest concern was the lack of consent from and failure of doctors to communicate with families.

The Government consulted on what should be done with regard to regulating the removal, use and disposal of human tissue. The consultation extended beyond the immediate concerns resulting from the Alder Hey Inquiry, considering also issues such as non-consensual DNA analysis, fetal tissue, stem cells and cell lines.

The Human Tissue Bill was introduced to the House of Commons on 3 December 2003 and is scheduled to have a Second Reading debate on 15 January 2004. The Bill seeks to establish a Human Tissue Authority supported by two Inspectorates. It sets out the main principles of consent with regard to human tissue and creates offences for non-consensual removal and use.

The Bill extends mainly to England and Wales but has some provisions for both Scotland and Northern Ireland.

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Summary of main points

The retention of human organs was first brought to public attention during an inquiry into practices at Bristol Royal Infirmary where children's hearts were retained after surgery without parental consent. During that Inquiry a heart specialist, Professor Robert H. Anderson, indicated the Alder Hey also had such a collection. This led to a second inquiry, this time into Alder Hey (the Redfern Inquiry)[1] where it transpired that it was not only hearts but other organs that were routinely retained after surgery and post mortems without any systematic seeking of consent from families.

At the same time as the Redfern Inquiry the Chief Medical Officer conducted a census of organs and tissues retained by pathology services in England[2] and produced a report, *The Removal, Retention and use of Human Organs and Tissue from Post-mortem Examination*,[3] that outlined the current issues and made recommendation on where changes might be required.

Public concern over the retention of human organs was further heightened by revelations within the Isaacs Inquiry,[4] conducted by the HM Inspector of Anatomy, Dr Jeremy Metters. The Inquiry was begun when it was discovered that the brain of a man who committed suicide was retained after post mortem and no consent had been obtained from the widow.

The Government published its consultation document, *Human Bodies, Human Choices*,[5] in July 2002. The consultation sought opinions on a wide range of issues regarding human tissue and what balance might be struck between the needs of research and teaching on one hand and the concerns of families on the other. In the meantime the Government produced interim guidance on the use and retention of organs and requirements with regard to obtaining consent.

The result of these inquiries and the consultation has been the current Human Tissue Bill. The Government believes that the Bill will:

- **Ensure that no human bodies, body parts, organs or tissue will be taken without the consent of relatives or patients.** Once Coroner's enquiries have

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1 The Redfern Inquiry into the Royal Liverpool Children's NHS Trust - Alder Hey http://www.rlcinquiry.org.uk/download/index.htm

2 Chief Medical Officer, *Report of a Census of Organs and Tissues Retained by Pathology Services in England*, January 2001 http://www.doh.gov.uk/organcensus/index.htm

3 Chief Medical Officer, *The Removal, Retention and use of Human Organs and Tissue from Post-mortem Examination*, January 2001 http://www.doh.gov.uk/orgretentionadvice/index.htm

4 HM Inspector of Anatomy, *The Investigation of events that followed the death of Cyril Mark Isaacs*, May 2003 http://www.doh.gov.uk/cmo/isaacsreport/

5 http://www.doh.gov.uk/tissue/humanbodieschoices.pdf

concluded then organs and tissue taken will come under the authority of the bill;

- **prevent a recurrence** of the distress caused by retention of tissue and organs without proper consent by providing safeguards and penalties;
- **help improve public confidence** so that people will be more willing to agree to valuable uses of tissue and organs like research and transplantation;
- **improve professional confidence** so that properly authorised supplies of tissue for research, education and transplantation can be maintained and improved;
- **allow national museums to repatriate human remains** in response to claims from the descendants of indigenous people whose remains are held in museums.[6]

[6] http://www.doh.gov.uk/cmo/progress/organretention/developments.htm

CONTENTS

I Anatomy

The workings of the human body have been a source of fascination for thousands of years; from the early days of experimentation and discovery, the scientific study of anatomy has now become one of the lynchpins of modern medicine. The fundamental information derived from this field of study has aided in the treatment of many diseases and given insight to the potential relief of many conditions and defects in the human body.

A. What is Anatomy?

Anatomy can be concisely described as the science of the structure and organisation of the human body and its exploration.

Gray's Anatomy, essentially a compilation of knowledge on human anatomy, is one of the cornerstone publications for medical students in the United Kingdom. The introduction to the 37th edition considered the definition of anatomy:

> Assessing the structure (form or morphology) of the parts, or whole, of the human body is the province of anatomy. […] Anatomy is no longer merely descriptive and anecdotal but a central science that is numerate (involving measurement, data storage, statistical analysis, mathematical modelling) and, whenever possible, experimental. Rote repetition of 'acceptable' answers to specific questions, although engrained in many vocational examinations, is an actual impediment to progress. Uncertainty, in the face of insufficient soundly based data, should be stated and will only lessen as these accumulate.[7]

Thus, even a modern anatomical textbook anticipates the development of new information on the subject of anatomy. One of the principles of evolution is that of variation within a species. Many variations are not readily apparent and while of no obvious advantage to the possessor are usually of no obvious disadvantage either. Structural non-conformity means that patients will not possess identical anatomies, though the general shape and placement of organs will be roughly similar in most cases.

Awareness of the limits of variation is useful in identifying whether an organ with colouration, shape or size outside the normal range is diseased or simply abnormal. This awareness must extend beyond the gross structural properties of tissues, however, and into the structure of the tissues of which the organs are constructed. Anatomical science can provide guidelines to aid in this kind of determination.

The analysis of organs and tissues is, by necessity, a continuing process. The physiology of the human population has been changing as the conditions in which the population

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[7] *Gray's Anatomy*, Churchill Livingstone, 37th Edition 1989

lives have changed. For example, people in Western civilisations are becoming more obese as their lifestyle choices include diets that are more calorie rich, increasingly sedentary occupations and a less frequent desire to exercise. It is likely that, as the lifestyle of a population changes, the fundamentals of their anatomy will tend to change as well. This is probably best observed over time and over as wide a representation of the population as possible to detect general trends.

Human anatomical science could be considered the ongoing analysis of human tissues and organs to provide an ever changing snapshot of what might be considered normal for defined human populations. In this context, there may be justification for human tissues to be harvested and analysed and retained for comparison purposes. Anatomists will need to continue their analysis to maintain a current perspective on the structure and function of the human body.

B. How did the science of anatomy develop?

There are limits to what can be determined from the outside of the body. Simple observation of biological processes leads to links being made between form and function. For example, if death follows from the mouth and nose being blocked, it is possible to infer that there is something in the air that is necessary for the continued survival of the person. The five senses mainly depend on external organs and dictate how a person interprets the world around them. When an organ is damaged, a burst eardrum for example, it is possible to begin making theories on how those organs work. Inquiring minds have been drawn to see what is inside the human body, under the skin, and how those things make the human body work.

A Greek physician, Herophilus, performed public autopsies in Alexandria over two thousand years ago. He made public dissections, comparing human and animal morphology, studied the structure of the brain and the spinal cord and distinguished between motor and sensory nerves. He also investigated the eye, the alimentary canal, the reproductive organs, and the arteries and veins. This was not simply an exercise in recording. Herophilus is noted as believing the brain to be not only the central point of the nervous system but also the site of intelligence, thus demonstrating some element of linking form with function.

Although the original works of Herophilus were lost he was extensively quoted by another Greek physician, Galen, in the second century AD. Galen was also interested in what might be learned through the investigation of the body through surgery and performed vivisections of numerous animals to study the function of the kidneys and the spinal cord. He was the author of a seventeen volume piece of work entitled *On the Usefulness of the Parts of the Human Body*.

These early pioneers in anatomy provided a foundation of knowledge that was not significantly advanced until centuries later. Galen's anatomical treatises were lost in the West but retained in Byzantium and the Islamic world where Islamic scholars translated them into Arabic. They were eventually recovered by the West and translated into Latin

as interest in anatomy once again began to grow. In 1235 the first European medical school was founded at Salerno, Italy where human bodies were publicly dissected. In 1316, Mondino de'Liuzzi wrote Anatomia, the first major anatomical publication since Galen, and in 1543 Galen's theories were challenged by Andreas Vesalius in his own book, *De Humani Corporis Fabrica* (On the Workings of the Human Body).

The development of anatomy as a science was enhanced by the development of movable type and the possibility of publishing illustrated documents. Leonardo Da Vinci also conducted human dissections and produced illustrations of his observations.

William Harvey is known as one of the founders of modern physiology and was a prominent English physician during the reign of King James I of England. His major contribution to anatomical science was establishing how blood circulates in the body and the role of the heart in driving the blood through the body's system of arteries and veins. His title as a founder of modern physiology is most likely based on the fact that his theories were based on observation and experiment, a feature of evidence based science, rather than on simple speculation. Harvey proposed the existence of tiny vessels connecting the networks of veins and arteries beyond the capabilities of his techniques to observe. These proposals were confirmed by Marcello Malpighi, an Italian anatomist, when microscopes became available and established conclusively the existence of a single circulatory system with the heart at the centre of it. Harvey's findings were published in 1628 in his book, *Exercitatio Anatomica de Motu Cordis et Sanguinis in Animalibus* (Anatomical Essay on the Motion of the Heart and Blood in Animals).

The availability of microscopes meant that tissues could be studied much more closely than ever before – even the structure of the tissues became open to the gaze of scientists and physicians. Marcello Malpighi was one of the major contributors to the advance of this early work and is often titled the father of histology.[8]

As technology has advanced it has become possible to make ever more detailed observations of the organs and tissues of the human body and to analyse the functions of these tissues within its normal working.

C. Modern medicine and training doctors

The development of modern medicine has relied on the availability of human bodies for students to practise upon. When a doctor is treating a patient it is invaluable for that doctor to have a working knowledge of the physiological functions of the body and how those functions are achieved.

In the eighteenth and nineteenth centuries medical schools were only allowed to use the bodies of executed criminals for dissection purposes and, with the growing numbers of

[8] The study of tissues and cells under a microscope.

students, it became clear that there were not enough executions to supply the demand. The demand became so acute that there flourished a macabre trade in bodies. Medical schools would pay for bodies that could be supplied without asking questions about their provenance. Thus the practice of bodysnatching arose, one of the more famous examples being that of William Burke and William Hare who practised their trade as body snatchers, or resurrectionists, in Edinburgh in the early nineteenth century. Burke and Hare however did not simply rely on providence to obtain access to bodies; instead they began to guarantee their supply by murdering people.

The scandal that followed the discovery of the practices of Burke and Hare led to the passing of legislation to provide for the supply of bodies for medical purposes, the *Anatomy Act 1832*.

Since that time there have been a number of pieces of legislation dealing with particular issues and currently the two main pieces of legislation governing the removal, retention and use of human organs are the *Human Tissue Act 1961* and the *Anatomy Act 1984*.

This legislation existed to provide a framework within which doctors might be able to more effectively ply their trade and make use of the material they encountered to better understand the workings of the body. The ability to retain human tissue for analysis and comparison has been common practice because of the utility of actually showing the effects of disease or damage upon those tissues to doctors in training. What has not been common practice was informing relatives of the extent of retention or ensuring that the reasons were properly understood.

As a result of evidence given at the public inquiry into children's heart surgery in Bristol, public attention was drawn to the fact that it was "commonplace" for children's hearts and other organs to be retained after post-mortem without the parents' knowledge or consent.[9] As a result, the Department of Health ordered an inquiry (The Redfern Inquiry) into the Royal Liverpool Children's Hospital (Alder Hey) where the practice appeared to be particularly common[10] and, subsequently, the Chief Medical Officer ordered a "census" of all organs and tissues retained by pathology services in England.[11] This census showed that:

> A total of approximately 54,300 organs, body parts, still-births or fetuses were held by pathology services at the end of 1999 which had been retained from post-mortems over the period 1970 to 1999:

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9 Department of Health, *The removal, retention and use of human organs and tissue from post-mortem examination: advice from the Chief Medical Officer*, 2001, p1

10 *The Royal Liverpool Children's Inquiry Report*, HC 12 2000-2001, January 2001 http://www.rlcinquiry.org.uk/

11 Department of Health, *Report of a census of organs and tissues retained by pathology services in England*, 2001

- the holdings of 25 (12%) of the 210 NHS Trusts and medical schools accounted for 88% of the total retentions;
- nearly half the retained organs were brains and a sixth were hearts;
- a total of 2,900 still-births or pre-viable fetuses were being held;
- of those whose organs had been retained, 17,800 were adults and 9,800 were children (aged 1-5 years, infants, still-born babies or fetuses).[12]

These organs/tissues would have been retained either after a post-mortem ordered by a coroner to establish the cause of death (for which no consent is required) or after a "hospital" post-mortem (carried out for a variety of reasons, if the next of kin does not object: for example to confirm a diagnosis where this may have implications for living relatives or to acquire knowledge which may improve treatment for others).

Although "coroners' post-mortems" do *not* require the consent of the next of kin, the *Coroners' Rules 1984*[13] make provision only for "the preservation of material which in his opinion bears upon the cause of death for such period as the coroner thinks fit".[14] The retention of additional organs/tissue is therefore subject to the same rules as the retention of any organ/tissue after a hospital post-mortem.

The relevant statute is currently the *Human Tissue Act 1961*. Section 1 of that Act permits the person "lawfully in possession of the body" (usually taken to be the hospital) to authorise the removal of parts of the body for purposes of medical education or research. Such authorisation requires **either** the deceased person to have expressed such a wish before death **or** if, "having made such reasonable enquiry as may be practicable" it was established that neither the deceased person nor their relatives or spouse would have objected. The current statutory regulation of the retention, for research or education purposes, of organs or tissue after a patient's death is therefore based primarily on lack of objection rather than consent.

The Chief Medical Officer's census results indicated that, since 1970, 95% of NHS pathology services carrying out their own post-mortems have used a signed form of agreement from relatives, with 85% including reference to the retention of organs/tissues. These figures increased to 99% and 95% respectively in 1999, with a further 2% obtaining consent separately to organ retention and post-mortem examination.[15]

The vast majority of NHS organisations would therefore appear to have complied at least with the letter of the law in ensuring that relatives did not object to organs/tissue being

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12 *ibid*, p1

13 http://www.kcl.ac.uk/depsta/law/research/coroners/1984rules.html

14 *Coroner's Rules 1984*, rule 9, SI 1984/552

15 Department of Health, *Report of a census of organs and tissue retained by pathology services in England*, 2001, para 31

retained. It was clear, however, from the public outcry over the events at Alder Hey[16] that "lack of objection" was an insufficient basis for retaining such material and that those (especially parents) who had apparently not objected often had very little idea of quite how much material was being retained. Moreover, it emerged at a "summit" held by the Chief Medical Officer (CMO) in January 2001 that many parents had had no idea at all of what was proposed, even if they had apparently signed a form:

> "We have all learned that our children's organs have been removed and retained at post mortem examination without knowledge and consent. We are led to believe that this practice has been taking place since 1947. We have parents in our group who are revisiting the painful grief of 40, 30, 20 years ago and, indeed, as recently as 1999." – John O'Hare, Committee Member of PITY II Parent's Support Group, speaking at the CMO's Summit on 11 January 2001.[17]

The Chief Medical Officer's report on the retention of organs, published following the summit in January 2001, emphasised the medical importance of the continuation of research on tissues retained after post-mortem. It was, however, scathing about the effect of past practice on parents whose children's organs had been retained without their fully informed consent:

> 15. [The accounts of parents' experiences] show a failure by many doctors, not all, to empathise with parents who have faced the devastating loss of a child and the failure to recognise that a parent feels love and the need to protect a child, even after death. The fact that for many parents the essence of a child is contained in organs such as the heart or the brain, engendered feelings that the child had been violated and that the parent had not been able to protect him or her.
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> 16. This was compounded by the fact that:
>
> - some were explicitly told that the organs had been returned to the body before burial when in fact this was not true;
> - parents were often given inaccurate information about what was and was not being held and some initial information proved misleading;
> - when organs were returned this was often done in an inconsistent or insensitive manner; some parents have had to endure multiple funerals as organs or tissues were returned on several separate occasions;
> - the scale of retention of organs was in many cases disproportionate and unnecessary for the underlying clinical condition or the focus of research activity.

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[16] Documented, for example, in the "summit" held by the Chief Medical Officer on 11 January 2001, the transcripts of which are available at http://www.cmosummit.org.uk/transcripts/Transcrip2t2.pdf

[17] Cited in Department of Health, *The removal, retention and use of human organs and tissue from post-mortem examination: advice from the Chief Medical Officer*, 2001, p24

> 17 It is an insufficient and inadequate explanation for the events to say that the law governing the practices was technically adhered to. In some places, there is clear evidence that custom and practice has departed from the legal framework. Even leaving this aside, parents and relatives are bound to say that within the law there was a better, more humane and more caring way in which those responsible could have operated the system. Improvements have been made, but many will see this as having been driven by crisis and occurring too late in the day to be of comfort to the majority who have suffered.[18]

The Chief Medical Officer made 17 recommendations, including:

- a review of the law to ensure that consent, rather than lack of objection, becomes the statutory basis on which organs/tissue are retained;
- the development of a Code of Practice on how the NHS should communicate with families about post-mortems;
- the development of a standardised consent form for consent to post-mortems and (separately) for consent to the retention of organs/tissue;
- the establishment of an independent Commission to oversee the return of retained organs and tissues to those families who request it;
- all NHS trusts to provide support and advice to families at the time of bereavement, including the development of the role of "bereavement adviser".[19]

Current practice with regard to organ retention is discussed later in the paper but this has been simply an interim measure while waiting for legislation (this Bill) to provide proper regulation. The legislation has taken some time to bring forward due to the difficulties inherent in producing definitions for human tissue that will work in a regulatory environment and distinguishing between the issues concerning organ and tissue retention and organ transplants.

II Organ Retention

The concern over the retention and use of human organs was most recently considered in the House of Commons in a Westminster Hall debate secured by Andrew Lansley, now Shadow Secretary of State for Health, who outlined concerns about the need for legislation on the issue of human tissues and commented on the human issues involved.[20] He believed that there was a need for the legislation to understand the difference between retaining tissue samples and whole organs:

> First, it is vital that the terms "tissues" and "organs" are both used and are clearly distinguished from each other. The past use of "human tissues" as an encompassing term has, I am afraid, failed to make it clear to relatives that whole

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[18] *ibid*, pp24-25
[19] *ibid*, pp38-45
[20] HC Deb 29 April 2003 c269-78

> organs were to be removed or retained. The consent forms published by the Government last week make that distinction, but we need a clear legal basis for whether consent has been given for the removal or retention of whole organs.[21]

There are situations under which a whole organ may be more useful for analysis than a simple tissue sample but given the symbolism that is often attached to organs, particularly the heart and brain, it is understandable that reactions to retention of tissue and retention of organs differ.

Mr Lansley was also concerned that the legislation should address the sometimes contentious issue of next of kin:

> The definition of "next of kin" is also important. Clearly, the wishes of the deceased person should prevail, if known, and that should apply to all those over 16. If those wishes are not known, we need a clear procedure to determine the next of kin that does not involve hospital staff in making arbitrary decisions or prolonged investigation of family and social relationships.[22]

He believed that there should not only be an ability to choose next of kin but also to specifically exclude certain people from that role. The over-riding issue however was that of consent, which should be determined whenever and wherever possible. It was also important that as far as possible that the consent should be well informed.

In response, Hazel Blears, then the Parliamentary Under-Secretary of State for Health, agreed that the existing situation had grown such that institutional considerations had sometimes over-ruled human ones:

> Custom and practice developed within this framework of law, which relied far too heavily on traditional and paternalistic attitudes under which the benefits of pathology for diagnosis, post-mortem examination, teaching and research were understood, but the wishes and feelings of families were not sufficiently recognised.[23]

The following sections provide background on the current requirements for organ retention and on the action taken by the Department of Health to reassure relatives and ensure that, in future, organs are retained only where proper consent has been given.

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21 HC Deb 29 April 2003 c271
22 HC Deb 29 April 2003 c272
23 HC Deb 29 April 2003 c274

A. Action taken by the Department of Health

Following the publication of the Chief Medical Officer's recommendations, all of which were accepted by the Government,[24] Government action has included:

- the establishment of the Retained Organs Commission[25] in April 2001, with a remit of managing the process of returning organs to families who wish to bury or cremate them, providing advocacy for families, proposing a regulatory framework for museums and archives of organs/tissue and advising Ministers;[26]
- the development of new consent forms and information leaflets for next-of-kin when a post-mortem or retention of tissue/organs might be appropriate (published in May 2003);[27]
- the development of a Code of Practice on communication with families after a death (published in April 2003);[28]
- the development of an "interim statement" on good practice in the use of organs and tissue, pending changes in the law (published in April 2003);[29]
- the publication in July 2002 of a consultation document *Human bodies, human choices*, seeking views on possible changes to the current statutory framework, with particular emphasis on the need for informed, voluntary consent before any organs/tissue can be removed, retained or used (the consultation closed on 14 October 2002).[30]

The Retained Organs Commission conducted a consultation on a proposed regulatory framework for the retention and collection of human tissue and organs.[31] The consultation formed the basis of advice provided to the Government on what should be included within such a framework.[32] The Commission concluded that:

> The fundamental principles underpinning retention of human bodies, body parts, organs and tissue after death (elaborated at paragraph 12) must be as follows:
> (i) Respect for the dignity of the human body after death and respect for the wishes of the deceased person (if known) and for the legitimate interests of the deceased person's nearest relatives.

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24 HC Deb 30 January 2001 c177
25 http://www.nhs.uk/retainedorgans
26 http://www.doh.gov.uk/cmo/progress/organretention/orgret6.htm
27 Forms available at http://www.doh.gov.uk/tissue/family.htm
28 http://www.doh.gov.uk/tissue/families&postmortemscode.pdf
29 http://www.doh.gov.uk/tissue/interimstatement.pdf
30 http://www.doh.gov.uk/tissue/review_of_law.htm
31 *Unclaimed and Unidentifiable Organs and Tissue: A Possible Regulatory Framework*, Retained Organs Commission, February 2002 http://www.nhs.uk/retainedorgans/consultationfeb02.pdf
32 *A Proposed Framework for the Regulation of Museums, Archives and Collections of Human Bodies, Body Parts, Organs and Tissue*, Retained Organs Commission, June 2003 http://www.nhs.uk/retainedorgans/regframe.pdf

(ii) The need for retention of human bodies, body parts, organs or tissue to advance public health by way of properly authorised and monitored training and education, research and audit and to enable effective diagnosis of disease and causes of death.[33]

The Commission also advised that 'commercial transactions involving human bodies, body parts, organs and tissue should be prohibited' and that 'retention should be lawful only for purposes consistent with respect for human dignity'.

The Department of Health subsequently published a summary of responses to the *Human Bodies, Human Choices* consultation[34] and the Government indicated that it would introduce a Human Tissue Bill to deal with the issues that had been raised. The broad nature of the legislation was indicated in a document published in September 2003.

> We would expect the following to be incorporated in the legislation:
>
> - Explicit consent to be the fundamental principle underpinning the lawful removal, storage and use of bodies, body parts, organs and tissue.
> - The principle that the human body and its parts should not, as such, give rise to financial gain.
> - A regulatory framework within which an overarching authority would be responsible for licensing and inspecting regulated activities, including public display.
> - Penalties for undertaking certain activities (including DNA testing) without consent or without a licence.
> - Statutory codes of practice issued in relation to matters such as: the conduct of post mortems and anatomical examinations; the import and export of human body parts; communication with families about post mortem examinations; definition of death; and disposal of human tissue.
> - Human organ transplantation to continue to operate broadly under current arrangements, but within the new legislative framework.
>
> The following are unlikely to be affected by new legislation:
>
> - Activities which involve the 'everyday life' taking of tissue such as hair or nail clippings, except in relation to the proposed new offence of 'DNA theft'.
> - The Coroners' Act 1988 and the Coroners' Rules 1984, under which a coroner may order a post mortem and the retention of tissue or organs in order to determine the cause of death. The Home Office is currently considering the recommendations of a fundamental review of the coroners' system, as well as those of the Shipman inquiry, which looked at the coroner's role in investigating death. In advance of any legislative changes, the Home Office is preparing a code of practice to clarify how long, and on

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33 *ibid*, paragraph 3

34 http://www.doh.gov.uk/tissue/summaryofresponsestotheconsultationreport.pdf

what authority, human tissue may be retained following a coroner's post mortem.

- The current legal position that there is no property in a human body or its parts (so they cannot be bought or sold), except where human skill has been applied.
- Collection of blood, and processing and supply of blood and blood products for human use, which are already regulated under an EC directive.
- Matters regulated by the *Human Fertilisation & Embryology Act 1990.*
- Xenotransplantation (animal to human transplants) which is overseen by the United Kingdom Xenotransplantation Interim Regulatory Authority.
- Removal of tissue from patients in the course of diagnosis or treatment for which they have given consent. [35]

B. Current requirements for organ retention

The current *statutory* framework, pending the changes proposed in the consultation paper *Human bodies, human choices*,[36] is still based on "lack of objection" from a deceased person's relatives, rather than positive consent. However, the Government has made very clear that in its view active consent, based on full information, is the only acceptable basis for organ removal, retention or use. The draft interim statement, referred to above, has the following to say:

> 6. In general, human organs and tissue should be used only for purposes for which patients have had the opportunity to give their valid consent. This means
> - that patients must be provided with suitable information in a form that they can understand. For example, they need to know that small pieces of tissue may be placed in blocks or slides for examination under a microscope and possible retention with clinical records;
> - that they have the opportunity to ask questions; and
> - that they are able either to register their objection or to give explicit consent to particular tissue removal, storage or use.
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> 7. It is axiomatic that the human body and its parts are treated with respect in all circumstances.
>
> 8. The principles at paragraph 6 have many similarities with those relating to consent to treatment. However, while organ or tissue removal may be a part of treatment, the consent aspects of treatment and those relating to the removal, retention or use of tissue for other purposes need to be addressed separately. A case in point would be the possible use in education or research of any "surplus" tissue (ie organs or tissue removed as part of ordinary clinical care or investigation).

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35 http://www.doh.gov.uk/tissue/legislationproposals.pdf
36 http://www.doh.gov.uk/tissue/humanbodieschoices.pdf

> 9. Where someone has died without expressing any wishes as regards organ or tissue removal, retention or use, the responsibility for taking any decisions – including whether a hospital post mortem may take place – rests with relatives or those closest to the deceased person. A code of practice on communicating with families about these matters, together with model consent forms for hospital post mortems and the removal, retention and use of organs and tissue, are to be piloted as part of the Department's broader consent initiative. **The Department's view is that only by operating a policy of valid consent by relatives can the requirements of the Human Tissue Act 1961 properly be met**.[37]

In addition, the Department issued interim guidance on post-mortems in March 2000, requiring NHS trusts to:

- ensure all staff who have contact with bereaved relatives have proper understanding of, and respect for, the rights of the dead;
- designate a named individual to provide support and information to families of the deceased where a post-mortem examination may be required;
- provide clear written information about the options for the disposal of organs, body parts and tissues retained at post-mortem, including arrangements for reuniting these with the body;
- ensure professional staff follow best practice; obtain 'consent' to post-mortem on a signed form and provide a copy to the relative who signed it;
- have proper systems in place for recording the details of all post-mortems including: whether consent was obtained; where organs, body parts or tissue were retained; and how retained organs and tissues were archived or disposed of;
- ensure the disposal is in accordance with wishes expressed by the deceased prior to death or by relatives.[38]

C. Existing Guidance

The Royal College of Pathologists issued new guidance[39] in 2000 governing the conduct of post-mortem examinations. This emphasised the need for pathologists to obtain written agreement for the retention of whole organs and for hospitals to provide relatives with an information leaflet explaining the purpose of post-mortem examinations, the medical benefits of tissue and organ retention and their right to grant or withhold consent.

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37 http://www.doh.gov.uk/tissue/interimstatement.pdf

38 Department of Health, *Interim guidance on post-mortem examination*, March 2000, summarised in Department of Health, *The removal, retention and use of human organs and tissue from post-mortem examination*, 2001

39 Royal College of Pathologists, *Guidelines for the retention of tissues and organs at post-mortem examination*, 2000

It also states that if the primary purpose of retention is for research then a research ethics committee must give its approval.

The British Medical Journal has advanced a number of reasons why this guidance is necessary.

> Firstly, discussions with parents about necropsies and the retaining of organs for teaching or research at the time of bereavement are complex, time-consuming, emotionally difficult, and poorly taught in medical training.
>
> Secondly, doctors' decision-making has largely been paternalistic. Only in the past few years has shared decision-making been recognised as more effective, relevant, and appropriate than the traditional physician-directed model.
>
> There are always physicians who believe that they are above institutional norms and regulations, and the language of the Human Tissue Act - in particular, the phrase "has no objections" - clearly was not always construed to imply the need for informed consent.
>
> Finally, and most importantly, without continuing monitoring of physician performance it is always impossible to know whether practice is consistent with standards. [40]

Guidance on establishing the fact that death has occurred, based on a diagnosis of brain stem death, was published by the Department of Health in 1983.[41]

III Organ Transplant

A. Introduction

The issue of organ transplants is not usually as controversial as that of organ retention. It is often easier to explain the value of organ transplants to relatives of a potential donor than it would be to explain the value of retaining the organs for less immediately vital purposes. There are similar issues concerned, however, as well as issues such as whether people should be allowed to sell organs or donate to people with no family or other close connections.

1. The Special Health Authority, UK Transplant

A Special Health Authority, now known as United Kingdom Transplant (formerly called the United Kingdom Transplant Support Service Authority), was set up under section 11 of the *NHS Act 1977*. Its main functions are

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[40] "What have we learnt from the Alder Hey affair?", *British Medical Journal*, 10 February 2001

[41] *Cadaveric Organs for Transplantation: a Code of Practice including the Diagnosis of Brain Death* referred to in Speller's *Law relating to hospitals* 7th edition 1994 page 657

- matching and allocating organs to waiting patients
- maintaining waiting lists and patient data
- monitoring the outcome of all transplants
- maintaining and analysing the National Transplant Database of all donors and recipients
- providing information about transplantation
- maintaining the NHS Organ Donor Register. [42]

It also services three organ transplant users' advisory groups, for kidneys, livers and heart/lung transplantation.

Following its Quinquennial Review, which was published in 2000, the Authority now has responsibility for setting and monitoring transplant standards and for promoting the procurement of organs for transplantation.[43]

The Government has carried out a modernisation of transplant services, but this leaves the current legal basis of donation untouched. The main focus of the modernisation is twofold: to ensure that donations are never accepted with racist conditions attached (following a well-publicised case in 1999 when organs were donated on the basis that they could only go to a white person)[44] and to streamline the functions of UK Transplant, in an attempt to improve donation rates.[45]

2. The Transplant Partnership

The BMA, in association with 17 other organisations,[46] established The Transplant Partnership with the aim of stimulating wide-ranging debate amongst health professionals, policy makers and the public and "to campaign for a radical review of the organ donation system in the UK". Most of the views set out in a BMA document, *Organ donation in the 21st Century: Time for a consolidated approach*, are shared by the Partnership. In particular:

> In terms of changes to the legislative framework, the Transplant Partnership would like to see the following:
> 1. A single, comprehensive piece of legislation covering all aspects of organ donation – from both live and cadaveric donors.

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42 http://www.uktransplant.org.uk

43 HC Deb 9 January 2001 c528W

44 e.g. "Doctors want organs donated unless patients opt out", *Guardian*, 9 July 1999; "Surgeons ignored donor conditions", *Times*, 9 July 1999; "Dobson pledges to end transplant racism", *Independent*, 8 July 1999; "Legal constraints on donors' wishes", *Times*, 10 July 1999

45 Dept of Health press notice 2000/106, Lord Hunt announces modernisation of transplant services, 22 February 2000 http://www.info.doh.gov.uk/doh/intpress.nsf/page/2000-0106?OpenDocument

46 http://web.bma.org.uk/transplant.nsf

2. Clarification or removal of ambiguous terms and phrases such as "person lawfully in possession of the body" and "such reasonable enquiry as may be practicable".
3. Restricting the range of people it is necessary to make efforts to contact from "any surviving relative". One suggestion is that this should be restricted to any surviving spouse or partner or if there is no partner, any parent or child. (There would be nothing to prevent others being contacted but this would simply limit the legal minimum.)
4. The Act should make specific reference to the NHS Organ Donor Register (but should allow scope for the abolition of the register if, at some stage in the future, it is found to be unhelpful).
5. In order to allay the concerns of some members of the public, a requirement should be added into the legislation that, for heart-beating donors, the most up to date guidelines must be followed in determining death by brain stem tests before organs are removed.
6. Any reference to "brain stem death" should be replaced with "death confirmed by brain stem tests".
7. Specific authorisation should be given to the use of invasive procedures after death in order to clarify the existing legal uncertainty about the use of non-heart beating donors.
8. Removal of the distinction between related and unrelated live altruistic donors. There should be a streamlined system of review applied to all living donations, either by ULTRA or through some other mechanism, to ensure that the potential donor – who is known to the recipient but may or may not be related – is acting voluntarily and free from pressure.[47]

B. Availability of organs

The requirement for donated organs has not diminished over time. UK Transplant has identified an increasing shortfall over the past decade between the number of organs available for donation and the numbers of people waiting for a transplant. The reason is believed to be inertia rather than hostility; too few people carry a donor card or signal their willingness to have organs removed after death. An estimated 1 in 4 families however is resistant to organ donation on principle.[48]

1. Public confidence

In the aftermath of the Alder Hey and Bristol Royal Infirmary Inquiries there may have been some diminution in public confidence leading to still greater reluctance to donate organs. In response to a Question[49] from Lord Faulkner of Worcester about the measures taken to restore confidence in transplant operations following the events at Alder Hey

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47 http://web.bma.org.uk/transplant.nsf/3bff038f4a937bfc802569bc00501f37/e0aed52a953e807f802569c9003dfb1f?OpenDocument

48 "An investigation into Conditional Organ Donation: the Report of the Panel", paragraph 3.20 http://www.doh.gov.uk/pub/docs/doh/organdonation.pdf

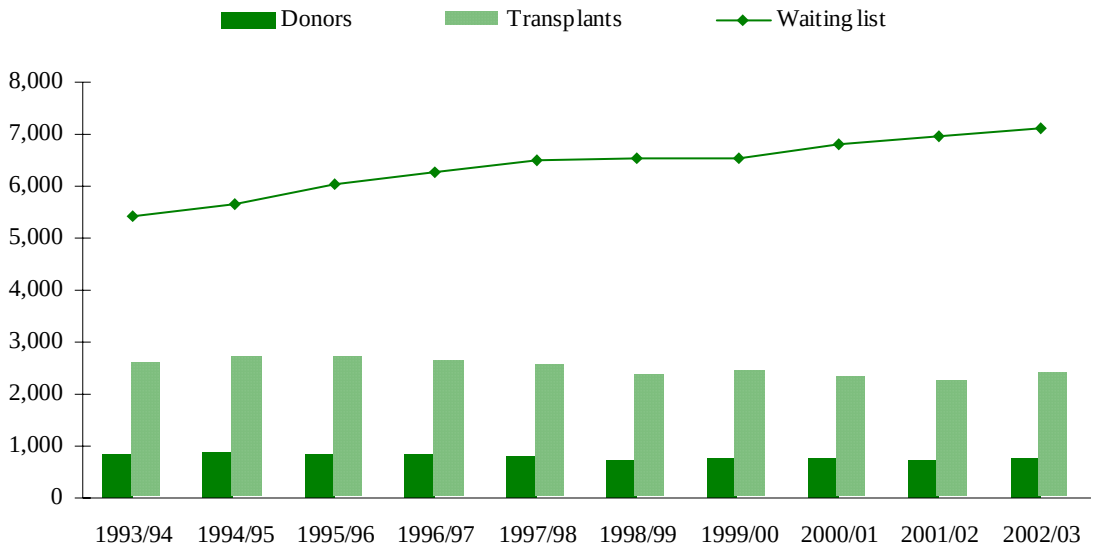
49 HL Deb 7 February 2001 c1153-5

children's hospital, the Minister, Lord Hunt of King's Heath, emphasised the distinction between donation of organs for immediate transplant and keeping organs post mortem and announced that a summit would be held "shortly" to reinforce this distinction and to consider how to boost organ donation rates for transplantation.[50]

2. Availability of organs for transplant

The chart below shows trends in cadaveric (deceased) donors, transplants and the waiting lists for transplants in the UK since 1993/94.

Cadaveric donors and transplants, and patients on the waiting list: UK
Active and suspended waiting lists at 31 March

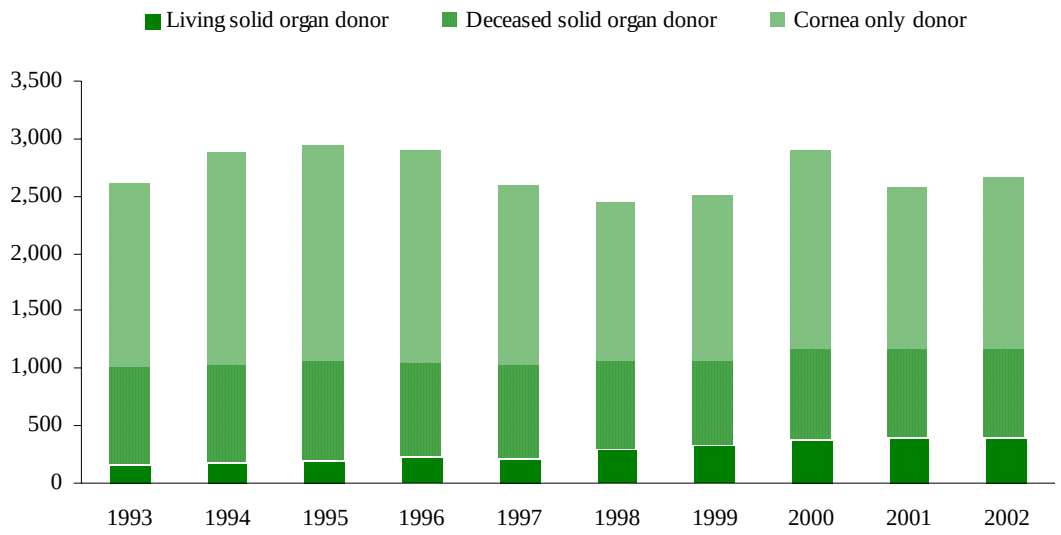


The transplant waiting list has risen by 31 percent since 1993/94 while numbers of both cadaveric donors and transplants have fallen, though less dramatically. Most significantly the shortfall of donors in comparison to the availability of donated organs has steadily increased over this time.

The chart below summarises recent trends in donor numbers in the UK:

[50] The summit was held on 27 February 2001 Department of Health Press Notice 2001/0104 "New drive to double the number of registered organ donors" 27 February 2001; *Times* and *Independent* 28 February 2001

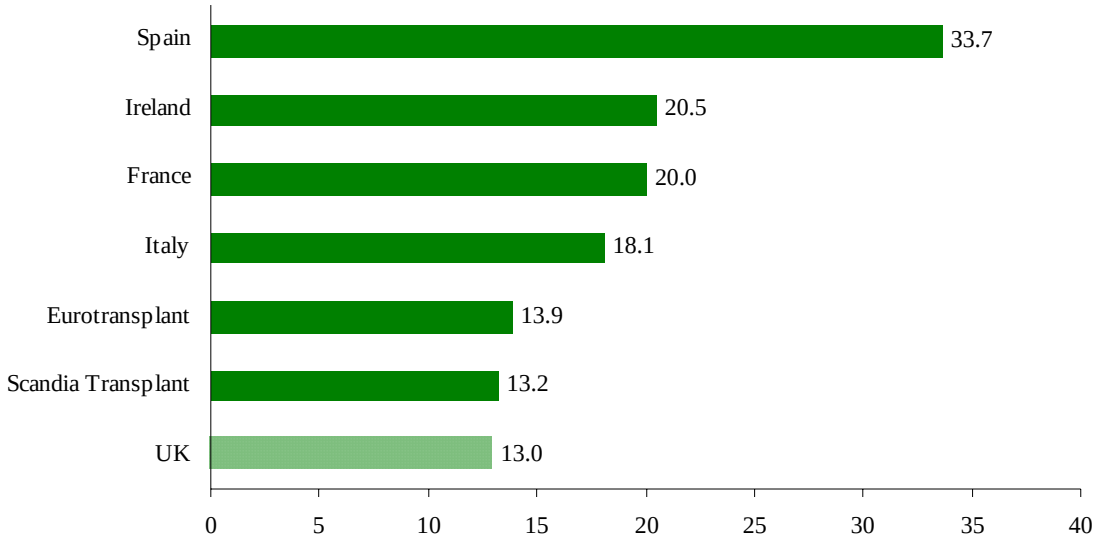
Organ donors in the UK: 1993-2002



There are 384 living solid organ[51] donors in the UK in 2002 compared to 157 in 1993. However, numbers of both deceased solid organ donors and cornea only donors have fallen over the same period.

The chart below compares donor numbers in EU countries in 2002. Eurotransplant incorporates Germany, Austria, Belgium, Luxembourg, the Netherlands and Slovenia. Scandia Transplant includes Sweden, Denmark, Norway and Finland. These figures should be used with caution as differences in definitions may exist between countries.

Cadaveric donors per million population: European countries 2002



The UK has relatively few cadaveric donors per head of population.

[51] As opposed to donors of material such as blood and plasma.

The table below summarises UK transplant activity in 2002:

Transplants performed in the UK, 2002
Numbers

Cadaveric heartbeating kidney	1,201	Cadaveric heart	152
Cadaveric non-heartbeating kidney	85	Domino heart	6
Living donor kidney	371	Heart/lung	16
		Single lung	55
Kidney and heart	1	Double lung	57
Kidney and liver	11	Living lung lobe	0
Kidney and pancreas	52		
Heart and liver	0	Liver heartbeating	596
Liver and heart/lung	0	Liver non-heartbeating	11
		Domino liver	4
Pancreas	8	Liver lobe	88
		Living liver lobe	2
Total kidney transplants	1,721		
Total cardiothoracic transplants	287		
Total liver transplants	712		
Total solid organ transplants	2,716		

Source: UK Transplant, www.uktransplant.org.uk

The table below summarises the latest available data regarding active waiting lists from transplant in the UK:

Persons registered for a transplant: UK, 30 November 2003
Excluding those suspended for health, personal or other reasons

Kidney	5,043
Kidney and pancreas	82
Pancreas	17
Total renal	**5,142**
Heart	103
Heart and lung	63
Lung(s)	267
Total thoracic	**433**
Liver	218
Total waiting	**5,793**

Source: UK Transplant, www.uktransplant.org.uk

Almost 5,800 people were on the active waiting list for a solid organ transplant in the UK at the end of November 2003. Around 1,300 further patients were suspended from the list.[52]

[52] Patients registered for a transplant may be suspended from the list actively waiting for a transplant health, personal or other reasons

Further statistics are available online from UK Transplant.[53]

C. The donation process

Once a potential donor has been identified, two doctors, independent of the transplant team, perform a minimum of two sets of tests to verify brain stem death.[54] At this point an initial approach may be made to the family to raise the subject of donation. Once the clinicians have certified that death has occurred the local transplant co-ordinator is contacted and will determine whether the individual is suitable for donation purposes, and if so, which organs are potentially to be used. Agreement is then sought from the family for organ donation to go ahead.[55]

D. Recent comment

Press coverage of organ transplants is often concerned with 'organ tourism' where the rich travel to developing countries where the poor can be induced to sell organs. A recent Times article, however, demonstrated that this may not be limited to developing nations and that cash might induce even those in the UK to sell an organ for cash.

> A BRITISH woman has offered to sell her kidney for £85,000 to raise money for a new home.
> […]
>
> Websites such as Organ Keeper and Diabetes Daily News play host to a growing number of aspiring sellers from Britain and America.
>
> They include Nicky Ireland, 33, from Paignton, Devon, who last week met an undercover Sunday Times reporter at the Ibis hotel, Heathrow. She was accompanied by her boyfriend John McGowan, a trainee locksmith, who had placed an advert on the Organ Keeper site in his own name, saying simply: "I am interested in selling one of my kidneys. Can anyone suggest possible contacts."[56]

The British Medical Association organised a debate in which the rules concerning allowing payment to donors for organs were considered. The case for allowing the sale of organs was proposed in an article in the British Medical Journal by Professor John Harris arguing that thousands of lives could be saved by the establishment of an ethical market in live organs. He agreed that the ethical market would need regulation.

> One way of attending to this need for prudent regulation would be to establish a monopsony, a situation where only one buyer exists for the products of several

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53 http://www.uktransplant.org.uk

54 *Cadaveric Organs for Transplantation: a Code of Practice including the Diagnosis of Brain Death* referred to in Speller's *Law relating to hospitals* 7th edition 1994 page 657

55 *An investigation into Conditional Organ Donation* op cit paragraphs 3.33-3.36

56 "British woman offers kidney for £85,000 to buy flat", *Sunday Times*, 30 November 2003

> sellers. The one legitimate purchaser in the marketplace would be required to take on responsibility for ensuring equitable distribution of all organs and tissues purchased. This would prevent the rich using their purchasing power to exploit the market at the expense of the poor. The monopsonist would also have other obligations, such as ensuring correct tissue typing to maximise histocompatibility and so minimise graft rejection, and screening for diseased or otherwise hazardous organs and tissues (for example, blood infected with HIV).
>
> In the United Kingdom, the NHS would be ideally suited for this role. [57]

The Guardian reported Professor Alastair Campbell's (his opponent in the debate) rebuttal of the argument:

> The consequence of a market in human organs is inevitably exploitative, as studies of the market in kidneys in India have shown. Far from improving the lot of the poor, it worsens their situation, including their health prospects. The notion of an 'ethical and regulated market' is a myth.
>
> Even in a developed country it will only be the most needy who subject themselves to the risks of surgery for cash. And in any case there is no evidence whatever that such incentives would increase the supply of organs.[58]

Professor Harris accepted that the BMA was unlikely to approve of his scheme:

> Dr Michael Wilks, Chairman of the BMA Ethics Committee, made the following statement:
>
> The BMA is against payment for organs and is not planning to change its policy.
>
> We are holding a conference today where many issues will be debated, one of them is organ donation. There are doctors who support the idea of payment for live donors and we have no problem with the issue being debated. However the BMA has no plans to change its policy on this matter.[59]

The BMA are backing a change in transplant practice to have an opt-out scheme rather than an opt-in scheme. In this scheme it would be assumed that the organs of someone who had died could be used for transplant purposes unless they had specifically indicated that they would rather not donate.

> The BMA has expressed overwhelming support for the introduction of a system of presumed consent. The main factors underpinning this decision were:

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57 http://bmj.bmjjournals.com/cgi/reprint/325/7356/114.pdf

58 "Doctors back cash for organs", *Guardian*, 3 December 2003

59 BMA press release, BMA reaffirms its position on organ donation, 3 December 2003

- Studies show that the majority of people would be willing to donate their organs for transplantation purposes, but only a small number of these are on the NHS Organ Donor Register or carry a donor card.
- Given that the majority of people would be willing to donate, there are good reasons for presuming consent and requiring those who object to donation to register their views.
- A shift to presumed consent would prompt more discussion within families about organ donation.
- It is more efficient and cost-effective to maintain a register of the small number who wish to opt out of donation than of the majority who are willing to be donors.
- With such a shift, organ donation becomes the default position. This represents a more positive view of organ donation, which is to be encouraged.
- Where donation is seen as the norm, rather than the exception and where, in the absence of evidence to the contrary, consent is presumed, grieving relatives are relieved of the burden of making the decision about donation.
- Despite the acknowledged difficulties of obtaining meaningful data about the success of presumed consent in other countries, the BMA believes that, as one part of a broader strategy, a shift to presumed consent is likely to have a positive effect on donation rates.[60]

NACOR would dispute the belief that there is a majority in favour of donation and that presumed consent would be a backward step:

> Public attitudes on this subject are not well understood we believe. The prevailing view among families – in our experience - is that presumed consent would not attract consensus public support.
>
> […]
>
> NACOR supports other more conventional methods, such as extensive public awareness and enhanced professional education, for increasing the supply of available organs and tissues for transplantation. A system of presumed consent for organ donation, in which individuals are presumed to consent to be organ donors after death, unless they indicate their refusal to consent, raises serious ethical concerns we believe.[61]

UK Transplant quote opinion poll studies that suggest around 90% of people are, in principle, in favour of organ donation. A recent study on behalf of the Retained Organ Commission however suggested that this number might be far lower.[62]

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60 http://www.bma.org.uk/ap.nsf/Content/Humantissueorganspresumed

61 Personal communication, 7 January 2003

62 Retained Organ Commission, *Research to Evaluate Topline Public Opinion, Knowledge and Understanding of Retained Organs for Medical Practice, Teaching and Research within England and Wales*, 10 April 2003 http://www.nhs.uk/retainedorgans/roc1604b.pdf

IV Human Tissue

An important part of any statute is to define in law what is and is not covered and what the various terms mean.

A. Considerations on definition and disposal

What would seem to be a simple question becomes much more difficult when applying regulation. The legislation will regulate the removal and retention of human tissue. In a very broad sense this could cover anything that was produced by the human body, including nails and hair. Conversely, concern over organ retention has focused not on human tissue but the retention and removal of whole organs, such as lungs or kidneys, which are more discrete forms of human tissue but would arguably not cover skin, ligaments, muscles etc.

The government consultation spent some time on the definition of human tissue. It introduced the current definitions:

> 5.3. "Organs" and "tissue" are difficult to define with precision:
>
> - "Tissue" is not presently defined in law, although "organ" is defined in the Human Organ Transplants Act 1989 [section 7(2)] as "any part of the human body consisting of a structured arrangement of tissues which, if wholly removed, cannot be replicated by the body".
>
> - A dictionary definition of "tissue" is "a part of an organism consisting of a large number of cells having a similar structure and function" (Collins Concise Dictionary, 3rd edition).[63]

The definition will have problems if it is too broad and allows the retention of too much material or too narrow and thus makes the necessary retention of material too difficult to achieve.

There is the question of whether a collective term should be used. Most families would not object to 'samples' being taken from deceased relatives as the implication of sample is of small amounts. However, a sample could encompass the whole of an organ and thus may make relatives feel that the body is therefore incomplete. It may be that the retention of material is not the issue but the scale on which that material is taken.

There is also the consideration of 'discarded material':

> 5.8. The human body continuously and naturally discards tissue or material. Teeth, hair and nails can separate from the body without any form of clinical intervention; so also do the surface layer of the skin and the lining of the womb

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[63] http://www.doh.gov.uk/tissue/choices.pdf

> during monthly periods. The placenta is usually discarded after birth. Some parts, such as the thymus, virtually disappear within the body as a young person matures. There may be a residue of cells on a syringe or spatula after (for example) the taking of a blood sample or a cervical smear. This range of examples suggests that it may be necessary for legal purposes to distinguish between "discarded" human tissue (or material) and other types of tissue.[64]

Legislation may also have to address the issue of what happens to tumours and other diseased tissue that is removed from patients. The consultation paper recognises that tissues removed in surgical operations may be due the respect that would be accorded a complete body. The Bill does consider this issue in Clause 45 dealing with 'surplus tissue' though more detail is probable within Codes of Practice to be produced subsequent to the current legislation. Within the general interpretation of the Bill it is also stated that:

> In this Act, references to decent disposal include, in relation to disposal of material which has come from a human body, disposal as waste.[65]

The Retained Organ Commission suggests in its information leaflet for parents and relatives that respectful disposal of retained tissue may involve a ceremony that recognises the fact that human organs and tissue are being dealt with.

Options presented for respectful disposal were:

- Return to families via a funeral director chosen by the family, or by the hospital, for reuniting with the body, or for burial or cremation
- Release to those providing religious burial services e.g. Muslim or Jewish burial councils
- Return to families via a funeral director for a religious ceremony before being returned to the hospital for research and educational purposes
- Retention by the hospital for burial with another family member at a later date
- Retention by the hospital for respectful disposal at a later date (in cases where retention is a legal requirement, e.g. in criminal cases)
- Donation to the hospital for education or research purposes with the option of future respectful disposal
- Return direct to the family in a sealed casket where there are plans for respectful disposal by the family.[66]

These options were, however, presented only with regard to organs and tissue removed post mortem and not intended to address tissues removed where the donor was alive after

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64 *ibid*

65 *Human Tissue Bill*, Clause 56(5)

66 Retained Organs Commission, *Options for Disposal of Retained Organs and Tissue*, February 2002 http://www.nhs.uk/retainedorgans/disposaloptions.pdf

surgical procedure. Some of the options may still be relevant and applicable under such circumstances.

B. Genetic Material

Medicine is increasingly sophisticated and our ability to manipulate materials increasingly removed from our ability to visualise those materials. For example, it is simple to understand a request to remove and retain a heart. The actions taken and the physical consequences are on a human scale. It is less easy to understand a request to remove and retain genetic material. While such material may be invaluable to medical research related to tissue requests, people are less able to visualise what takes place or to understand what may be done with the material removed and retained.

One problem with genetic material – which may be contained within a single cell - is the ability to copy and replicate it once the sequence is known. It is also possible that particular genetic sequences may be useful in developing medicines and other treatments that companies may wish to license and charge for. The consequences of giving consent may be wide ranging.

The *Human Bodies, Human Choices* consultation asked for opinions on the storage or reproductive tissue outside the scope of the *Human Fertilisation and Embryology Act 1990* (HFEA). This issue is highly relevant to the issue of informed consent. When consent is sought to take such tissue it may be necessary to also seek consent when the tissue is to be used or the original consent could be strictly defined on how it could be used in the future. These issues are often most contentious when the tissue is taken from those that are not able to give consent for themselves.

With the advance of biotechnology the ability to use the information represented in each human cell has advanced. Cells taken from a person may be altered to allow those cells to reproduce indefinitely, rather like a cancerous growth. This is called producing a cell line. Such cell lines can be used to study how human cells react to various chemicals and stimuli and contribute to a variety of basic medical research programmes. It is also possible that such cell lines might provide alternatives to animal experiments for the purposes of testing drugs and the effects of chemicals.

Reproductive tissue is even more important due to the potential for its use in producing gametes[67] and thus contributing to the production of children. Most other cells in the body are ‘switched off’ to a much greater degree. Such so-called ‘stem cell’ lines have far more potential than cell lines created from non-reproductive, or more differentiated or specialised types of cells. It is precisely because of this that stem cells are most likely to be used in, for instance, gene therapy and possibly in major medical advances.

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[67] Reproductive cells such as eggs and spermatozoa.

However, there is an issue that the cell line would carry the genetic information of the individual from whom they were derived. It may not be possible that the uses to which a cell line is put could be envisaged when consent was originally obtained and that the material might actually be used in the production of a commercial product.

A cell line created from stem cells[68] would be even more open to this kind of variation from original consent as those cells have so much more potential than others.

It may be that donors of cells for the production of cell lines and donors of stem cells would be asked to relinquish rights to that tissue in the event that profits might accrue from its use.

Neither human cell lines nor isolated stem cell cultures are subject to statutory control when being used in experimental research. A number of possibilities with regard to potential requirements for consent and/or ethical review on the use of such material were outlined in the *Human Bodies, Human Choices* consultation. One of the major considerations was whether such material could subsequently be traced back to the donor thus raising privacy considerations. Another was that the potential of stem cell therapies might be so wide ranging that having some kind of routine collection of such 'tissue' and the establishment of a bank of these cells should be considered.

V The Bill

The *Human Tissue Bill*, available on the internet[69] with the Government's explanatory notes,[70] is divided into three parts and eight schedules.

Part 1 addresses the removal, storage and use of human organs and other tissue for scheduled purposes. This covers:

- the provision of authorisation for these activities,
- interpretation of appropriate consent (for children and adults),
- the nomination of representatives who might give consent in the event of death,
- prohibition of certain activities when consent is not given,
- makes provision for bodies, anatomical specimens and other existing holdings, and
- exemption from the legislation for activity done for the purposes and functions of a coroner.

Part 2 of the Bill would establish a Human Tissue Authority. This organisation would:

- license activities related to human tissue,
- prepare Codes of Practice,

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68 Stem cells are cells that have the ability to become other kinds of cells such as liver, nerve or brain cells.

69 http://www.publications.parliament.uk/pa/cm200304/cmbills/009/04009.i-v.html

70 http://www.publications.parliament.uk/pa/cm200304/cmbills/009/en/04009x--.htm

- establish Inspectorates on
  - Anatomy and Pathology and
  - Organ and Tissue for Human Use,
- create an offence for the possession of anatomical specimens unless proper conditions can be met, and
- provide for the Human Tissue Authority to regulate transplants from live donors.

This part would also make allowances for the use of human tissue for criminal justice and religious purposes.

Part 3 of the Bill covers a number of miscellaneous purposes. There is provision for:
- maintaining a body so that it might be used for transplantation purposes until it is clear no consent will be given;
- the disposal of tissue that would be surplus to requirements, e.g., that removed during an operation;
- creating an offence of non-consensual analysis of genetic material;
- human remains that are part of a museum collection and
- amendment of the Act by regulation to abide by European Community legislation.

There is also provision in Part 3 for offences under the Bill to be committed by a body corporate rather than simply private individuals.

There are eight schedules to the Bill. These schedules cover
- purposes for which consent is and is not required,
- the establishment of the Human Tissue Authority,
- the licence procedures required by the Bill,
- establishment of the boards for inspectorates under the legislation,
- definition of what constitutes 'qualifying consent' under the legislation,
- an overview of powers of inspection, entry, search and seizure that would be granted,
- consequential amendments and
- repeals and revocations.

A. Issues in the Bill

Possibly the major issue in the Bill is that of consent, fundamental to the concerns of groups formed after the Alder Hey investigation. The Bill does not however provide much detailed information on how and when consent should be obtained, leaving this for the Human Tissue Authority to lay down in Codes of Practice.

The Bill would, unless the Human Tissue Authority believes the issue to be exceptional to the general rule, require Codes of Practice to lay down standards for the obtaining of consent. That consent would have to implement the ranking of qualifying relationships provided in Clause 24(4); consent should come from the highest ranking person. If there is more than one person at the highest ranking then consent is only required from one of

those though it is left undetermined in the Bill what would occur if there was a disagreement among equally ranked persons.

Clauses 2 and 3 of the Bill deal with what is titled "appropriate consent" with regard to children and adults respectively.

A living child (a person under the age of 18 for the purposes of the Bill) may give its own consent. If the child is not competent[71] to provide consent or chooses not to then appropriate consent would be that of a person with parental responsibility.

For a dead child consent may have been given in advance of death, though competency could still be an issue. In this case consent would have to come from someone with parental responsibility. For storage of organs for use in anatomical examination or display, consent would have to be given in writing and validated by a signature and one witness.

For adults the issue of consent is similar. Verbal consent is sufficient unless the purpose involves storage for use in anatomical examination or public display, in which case consent has to be written. Provisions in a will would be sufficient for these purposes and it would also be possible for a person to be nominated within that will to deal with consent issues.

Clause 4 would provide for the appointment of a nominated representative to represent the person after their death. This kind of appointment might be made orally or in writing and could be limited to particular activities and, if more than one representative were appointed, it would not be necessary for them to work jointly unless specifically expressed.

Nominated representatives must be over eighteen years old. Other exemptions could be made by regulations to be made by the Secretary of State.

There are no explicit definitions of tissue or organs within the Bill. The need for such definitions may have been avoided through subsuming everything within the general term of 'material from the body' and distinguishing between material removed from the body before and after the point of death.[72] Material created outside the body is not considered as 'from a human body' for the purposes of the Bill.[73] Thus material such as hair and

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71 Statute provision for consent in those under 16 years of age is based under common law and clarity was not gained until the landmark judgement of Gillick v West Norfolk and Wisbech Area Health Authority [1986] AC 112, [1985] 3 All ER 402, (1985) 2 BMLR 11, HL. The initial judgement was disputed until a House of Lords judgement sided with the opinion of the right of children to consent to medical treatment. The Gillick Test is one which judges the understanding of the child about the proposed procedure and its potential consequences.

72 Clause 56(3)

73 Clause 56(7)

nails would be excluded from the provisions of the Bill. There may be an element of uncertainty over whether this would include teeth and skin.

1. Organ Retention

Clause 1 and Schedule 1 of the Bill define what is lawful with regard to the removal, storage and use of human organs. Part 1 of Schedule 1 lists those purposes normally requiring consent and Part 2 those not normally requiring consent. Together these are referred to as *scheduled purposes*.

The wording of the two Parts of Schedule 1 indicate that it may not be restrictive and could be open to interpretation as to whether consent might actually be necessary. There is also the implication that purposes not on the schedule would not be lawful.

The storage of a body for anatomical examination is separated out in the Bill from storage of a body for other lawful uses because the use of the body of a deceased person for anatomical examination requires appropriate consent, a signed death certificate and registration of the death.

The retention of organs without appropriate consent would become an offence through Clause 5 of the Bill. It would be a defence to have reasonably believed that the retention was not contrary to the provisions of the Bill or that appropriate consent had been obtained. Committing such an offence could attract imprisonment for up to twelve months on summary conviction or up to three years on indictment. Financial penalties (a fine not exceeding the statutory maximum in the case of summary conviction) could apply in either case and in addition to the term of imprisonment.

The Bill would make provision for existing holdings in that the storage or use of already retained human tissue would be allowed for purposes listed in Schedule 1 other than anatomical examination. The position regarding existing anatomical specimens is more complex. Those specimens held under the authority provided by the *Anatomy Act 1984* should be considered to have appropriate consent for anatomical examination and, depending on the authority given under the *Anatomy Act 1984*, for storage for the purposes of education and research.

It will become an offence to have possession of anatomical specimens outside properly licensed premises except in particular circumstances:

- the specimen is a cadaver to be used for anatomical examination,
- the person has come into lawful possession of a body immediately after death occurred,
- the specimen is being transported to a properly licensed property, or
- the specimen is to be used in education, training or research.

Purposes of, or under the authority of, a coroner are exempt from these provisions as are the holding of religious relics that may contain human tissue if ‘there is a connection

between' the tissue and the religious activity and the activity occurs at a place of public religious worship.

Regulation of the storage and use of retained organs would come under the Inspectorate of Anatomy and Pathology (IAP) established by Clause 32 of the Bill. The IAP would inspect that the use, storage, import, export and disposal of human materials comply with the legislation.

2. Organ transplantation

Organs for the purposes of transplant may come from donors that are alive rather than dead. If the donor is not alive then the rules for organ retention also cover those for organ donation and transplantation is one of the scheduled purposes within the legislation. Live donors are covered by Clause 30.

This clause would make it an offence for a person to remove, or use, transplantable material from a living donor for the purposes of transplantation unless the Human Tissue Authority was satisfied that no reward was involved in the transplant and that conditions to be outlined in regulations had been met. The regulations, to be made by the Secretary of State, would contain the conditions under which organs might be donated for transplant. The regulations would also provide for reconsideration of decisions made by the Human Tissue Authority with regard to transplanting organs from live donors.

Clause 31 would provide the Secretary of State with the power to make regulations requiring authorities transplanting organs to keep information on those operations. It would be an offence to fail to keep such information or to knowingly or recklessly supply false or misleading information.

Where consent has not been obtained to use organs for transplantation, a body (or relevant part of a body) could be preserved until consent was given. This preservation would have to use the minimum steps possible and must be stopped if consent cannot be acquired.

The Inspectorate of Organ and Tissue for Human Use would supervise the rules with regard to transplantation. Its remit would cover removal, use, storage, import and export and disposal of material removed from a human body for the purposes of transplantation.

3. Organisations to be created under the Bill

Three organisations would be created by the Bill: the Human Tissue Authority and two Inspectorates:

- Inspectorate of Anatomy and Pathology, and
- Inspectorate of Organ and Tissue for Human Use.

The Human Tissue Authority would be the main advisory body for the Government. The Authority would produce a statement of general principles on the removal, use, storage,

import and export and disposal of human tissue (including whole cadavers); and would provide appropriate guidance, supervision and advice to those carrying out procedures and to relevant legislatures.

The detail of the Authority's structure is contained in Schedule 2 of the Bill.

Licences required to carry out activities regulated under Clause 13 of the Bill would be issued by the Authority as detailed in Schedule 3. These activities would include anatomical examinations, post-mortem examinations, organ removal and retention and the storage and display of anatomical specimens. A separate licence would be required for each activity as it would not be possible to obtain a licence to cover multiple activities.

The Authority would be responsible for establishing Codes of Practice to provide practical guidance and establish standards for all aspects of dealing with human tissue. The Codes would be subject to constant review and revision when appropriate. In preparation the Codes would be subject to consultation and should be properly advertised. Different Codes of Practice could be made for England, Wales and Northern Ireland.

The Codes will not be legally binding and so simple non-compliance would not make someone liable to legal proceedings. It is likely however that if the Codes were not followed then that could be material in any case brought against a person for other reasons.

The Secretary of State would have to approve any Code of Practice (consulting the National Assembly for Wales or relevant Northern Ireland department if relevant) before laying it before the relevant legislature. The Code would not require approval by any of those legislatures.

4. Qualifying Museums

The remits of the Human Tissue Authority and Inspectorate of Anatomy and Pathology do not extend to qualifying museums. These museums are also exempt from the offences of trafficking in human remains under Clause 29(1) and licensing requirements for anatomical examination, storage and use of human tissues under Clause 11(2). A museum qualifies if it has a permanent collection that is open to the public and it is, or is maintained by, an institution that:

(a) does not make profits,
(b) is precluded from distributing any profits it makes, or
(c) may distribute any profits it makes only to eligible institutions.

B. Extent of the Bill

While the Bill extends mainly to England, Wales and Northern Ireland some aspects do not affect Northern Ireland and some extend to Scotland, while others extend to Scotland alone.

Provisions relating to non-consensual analysis of DNA (Clause 46 except for 46(4) and Clause 47) and the power to de-accession human remains extend to the whole of the United Kingdom. The ability to bring offences under clause 46 to a body corporate (Clause 51), to make regulations on the de-accession of human remains (Clause 54) and certain interpretations (Clauses 56(3)(a), (6) and (7)) are also extended to Scotland but not Northern Ireland.

Clause 46(4) and Schedule 5 relate to qualifying consent for analysis of DNA. Part 1 of Schedule 5 relates to England Wales and Northern Ireland while Part 2 of Schedule 5 relates only to Scotland.

The varying provisions of the Bill mean that some consequential amendments within Schedule 7 do not extend to Scotland while others do. These variations are listed in Clause 61.

C. Response to the Bill

1. General comment

On publication of the Bill the Conservative and Liberal Democratic Parties were both supportive of the general move towards better regulation of the use of human tissues.[74] Each expressed a desire, however, to ensure that the legislation was not too restrictive and bureaucratic while maintaining proper accountability and respect for bereaved families.

Paul Burstow, opposition spokesman for the Liberal Democrats, said:

> We welcome the Bill as it creates a clear framework for the use of human organs and tissues which reassures the public on their use for research and teaching purposes and transplantation. However, Liberal Democrats will be pressing the Government to introduce a system of presumed consent for the donation of organs for transplantation.[75]

Andrew Lansley, the Shadow Secretary of State for Health, had concerns that the Bill had been introduced directly to Parliament rather than after scrutinising a draft as had been expected:

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[74] Personal communication, 3 December 2003
[75] Personal communication, 6 January 2003

> The Government undertook to publish a draft Bill for pre-legislative scrutiny by the summer of 2003. They failed to do so. The further lack of draft Codes of Practice to accompany the Bill make the process of scrutinising the Bill even less accessible for patient and professional groups.[76]

The British Medical Association (BMA) was supportive of the introduction of the Bill and also disappointed that 'presumed consent' (an opt-out system of organ donation) was not part of it. They would have liked to see a different system of consent for research and teaching to that for transplantation.[77]

The initial response to the publication of the Bill by the National Committee relating to Organ Retention (NACOR)[78] was favourable:

> NACOR is, broadly speaking, delighted with the helpful, proposed legislation, ensuring that families, whose loved one has to undergo a hospital post mortem in the future, can be assured that proper consent - backed with comprehensive information - will allow them choice and the opportunity to donate organs and/or tissues as a 'gift', incorporated within what will be mandatory practice.[79]

NACOR would, however, be entirely opposed to a system of presumed consent as this would almost certainly contradict the central concern of ensuring that informed consent was obtained under all circumstances where tissue or organs were removed and/or retained.

The Conservative Party was also against presumed consent:

> To include a provision for presumed consent would run counter to the principles of this Bill, which is that consent must be a donation, made with full information. Presumed consent in any case should not override the wishes of next of kin, so the need for securing informed consent to the use of organs for transplant will always rest on the willingness and information of the public generally.[80]

The learned societies that have commented[81] would appear to broadly welcome the intent of the legislation if not its particulars. The Royal College of Pathologists (hereafter referred to as the Royal College) comments:

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76 Personal communication, 7 January 2003
77 BMA, *Second Reading briefing document*, 23 December 2003
78 http://www.organretention.org/
79 NACOR, *Initial comment on the new Human Tissue Bill*, 8 December 2003
80 Personal communication, 7 January 2003
81 Briefing document supplied by those societies and other organisations are available on the *Bill Information Page* generated by the House of Commons Library for the *Human Tissue Bill*: http://hcl1.hclibrary.parliament.uk/parliament/BIPS/0304/HCBill009.asp

> The College is principally concerned about the wording of the Bill. There is no fundamental disagreement with the Bill's intentions other than on some points of detail.[82]

Dr Richard Taylor MP[83] commented that the crux of the Bill appeared to be the guidance on how consent should be taken when there was a desire to remove and/or retain organs. The details of this would not however be present in the Bill itself but within a Code of Practice to be drawn up at a future date by the Human Tissue Authority. The problem of details of implementation to be decided within Codes of Practice was an issue also highlighted by other interested organisations. For example, the Anatomical Society commented that:

> …"the devil is in the detail" and a great deal will depend on the Codes of Practice (2.23 – 36). We believe, therefore, that it is essential that relevant bodies (such as the ASGBI) are given an opportunity to comment on draft codes before they are implemented.[84]

NACOR were concerned that the details of how they would be consulted would not be specified within the legislation. The requirement for informed consent is, in their opinion, an important step forward but the manner in which informed consent would be obtained is just as important and will not be known until the Codes of Practice are published.[85]

The Royal College also had concerns about the difficult wording present in the Bill:

> …the Bill on its own would fail to deal adequately with the problems it intends to address because much of it will be incomprehensible to those whose work it regulates and controls. Some doctors may elect not to request or undertake postmortem examinations or to use surplus tissue from living patients for harmless and beneficial purposes simply because they do not wish to be at risk of imprisonment or fines. The tortuous wording of the Bill may cause much confusion about what is lawful. It fails to provide the clarity in the law that is one of its stated prime objectives.[86]

The major concern is that the legislation will cause those involved in post-mortem examination to do the minimum they think necessary to complete their task and thus potentially reduce the scope, and consequently the value, of such examinations.

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82 Royal College of Pathologists, *Second Reading briefing document*, 22 December 2003
83 Personal communication, 16 December 2003
84 Anatomical Society of Great Britain and Ireland, *Second Reading briefing document*, 22 December 2003
85 Personal communication, 22 December 2003
86 Royal College of Pathologists, *Second Reading briefing document*, 22 December 2003

The Anatomical Society of Great Britain and Ireland (hereafter the Anatomical Society) would have liked clearer indication of the application of the Bill to imported specimens.[87] For example, could specimens be imported from Scotland and thus avoid regulation under the Bill?

The most negative reaction to the Bill was from the Pathological Society of Great Britain and Ireland (hereafter the Pathological Society). The Society was concerned that the Bill:

> (a) will criminalise activity that is part of normal and proper clinical, pathological and research practice and may as a result create a climate of excessive caution
> (b) ignore the practicalities of clinical medicine and pathology, including the management of patients with inherited disorders
> (c) attempt to license, monitor and regulate through a regime that is more detailed and of wider scope than is desirable or necessary for the protection of patients and of the public
> (d) give to the Human Tissue Authority powers to determine legally binding standards without oversight from Parliament
> (e) fails to provide the clarity in the law that is one of its stated prime objectives
> (f) appears at first sight to be unnecessarily complex and convoluted.[88]

Dr Taylor also had some practical concerns about the Bill. Many doctors own a skeleton that was used in learning about anatomy and the application of the Bill towards such human remains was unclear. Would doctors have to obtain a licence for such remains and would they be able to sell or gift their skeletons to student doctors in the future? Would the provisions for the holding of existing anatomical specimens for the purpose of education and training extend to doctors no longer using their skeletons for that purpose?

2. Consent

The issue of consent is high on the list of NACOR's priorities. They would like to ensure that there are no verbal loopholes through which the intent of the Bill might be lost.

> We need black and white, and no chance of grey, so that the words 'never again' as stated by the CMO really do apply.[89]

The mechanisms by which consent would be obtained and from whom was also a concern of Andrew Lansley:

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87 Anatomical Society of Great Britain and Ireland, *Second Reading briefing document*, 22 December 2003
88 Pathological Society of Great Britain and Ireland, *Second Reading briefing document*, 22 December 2003
89 NACOR, personal communication, 22 December 2003

> The Bill clearly requires specific consent for a number of purposes. It is less clear, however, that the consent must equally be specific in distinguishing where retention of major organs is sought and making that consent explicit.
>
> The key principles of the Bill are the requirement for fully informed consent and that consent is in the form of a donation. Both are required and should mean that the subsequent obligations on researchers in terms of informing families should not be made excessive.
>
> Determining next of kin cannot be too mechanistic and must permit individuals both to nominate a representative and exclude people from exercising consent on their behalf. The qualifying relationships should include grandparents.[90]

The BMA welcomed a change made by the Bill in which living individuals are the primary decision makers for what would happen to their tissue after they died:

> The new Bill specifies some uses of human bodies that only individuals themselves can agree to, such as dissection and the use of human material in public display. For other uses, however, living individuals can legally authorise someone they trust to decide for them after the individual's death. The BMA supports this view that the prime decision maker – wherever possible – should be the donor him or herself.[91]

For living people to be able to decide in advance, however, legislation would have to be accompanied with sensitive publicity on how human tissues and organs are vital for teaching and research. There was also a need to educate the public, and health professionals, on the whole issue of consent, where it would be required and where it would not.

> The public needs more information about how data from post-mortems can bring useful scientific knowledge for living people, (including the bereaved family in some cases).
>
> […]
>
> In the case of deceased donors, however, society's need for research and medical training cannot take precedence over the interests and rights of newly bereaved relatives. A balance must be found between the desire to advance medical understanding, the prior wishes of the deceased and the emotional needs of the grieving family. [92]

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90 Personal communication, 7 January 2003

91 British Medical Association, *Second Reading briefing document*, 23 December 2003

92 *ibid*

There have also been some concerns over the estimate of costs associated with obtaining informed consent. The number of tissue banks may be higher than that stated in the Government's explanatory notes:

> The College questions the reliability of the estimate of public sector financial costs (paragraphs 72 to 83 in the Explanatory Notes). In paragraph 81 there is an assertion that "there are about 5 tissue banks for research in England and Wales". This is a gross underestimate. Most teaching hospital NHS Trusts have several tissue banks for research, not all of which are in or managed by the NHS pathology service.[93]

The availability of proper consent to staff in laboratories might also require greater investment than indicated:

> To record the explicit wishes of all patients, in a manner which allows laboratory staff to retrieve rapidly the relevant information on large numbers of patients, will require an investment in information technology which cannot reasonably be funded from existing NHS laboratory or hospital budgets. The cost of the time spent in informing patients, requesting consent and recording consent has not been considered.[94]

The Pathological Society was concerned that no consideration was given to the situation in which nominated representatives disagreed. They also wanted to make clear that they believed that, under the Bill as written, blood used in research would have to be given explicit consent as it did not have the explicit exemption given to blood for transplant. If consent is required then there would have to be some available generic consent to prevent constant reference back to donors. Reference back to donors was also of concern in relation to other tissues:

> Clause 5 subsection 1 indicates that where there is consent to use material for one purpose, then it may not be used for another. Does this apply only to different activities listed in Schedule 1? Will it be possible to use tissue for 'research in connection with disorders or functions of the human body', and use it for 'education or training relating to human health or research' and then to use it 'to obtain scientific or medical information about a living or deceased person which may be relevant to any other person'? In the past, tissues from, say, resection for colorectal carcinoma, could be used for one or all of these purposes. Will generic consent allowed to apply to all these activities?
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> […]

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93 Royal College of Pathologists, *Second Reading briefing document*, 22 December 2003

94 *ibid*

> It is not the acquisition of generic consent which bothers us … but how such consent will be drafted.[95]

Of particular concern were the requirements of consent for analysis of DNA:

> Sections 46 and 47 on the Bill cause especial concern and are very worrying. In Section 46 it is difficult to understand whether or not it will be an offence to analyse any human DNA in the material without qualifying consent. Section 47 states the purposes for which human DNA can be analysed without consent. These include diagnosis, coronial work and the detection of crime, clinical audit, education or training incidental to diagnosis or treatment, and while research is not specifically excluded, there is absolutely no mention of research in this section.[96]

The BMA were more interested in the lack of detailed provision for surplus tissue from mentally incapacitated living donors.

> Surplus tissue and bodily fluid left over from their diagnostic tests could well be useful for research to help other patients suffering from similar conditions but, from the current text of the Bill, it does not seem that any provision is made for proxy decision making for living but mentally impaired adults to donate their surplus tissue.[97]

3. Organ Retention

The Royal College were concerned that the Bill, within its list of Scheduled Purposes, had not separated out those purposes that were acts of retention and those that were uses of retained tissue. Neither was there any compulsion present to ensure that those making clinical decisions to remove tissues would obtain consent for the multitude of purposes that might subsequently be necessary.

> Those who work in NHS pathology services (with few exceptions) are in no position to seek consent for the removal from patients of the many millions of tissue, including blood, samples from living patients that they receive every year. Consent is the responsibility of health care professionals working in other NHS services (e.g. surgical, medical) who make the clinical decision to remove the tissue.
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> […]

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95 Pathological Society of Great Britain and Ireland, *Second Reading briefing document*, 22 December 2003

96 Pathological Society of Great Britain and Ireland, *Second Reading briefing document*, 22 December 2003

97 British Medical Association, *Second Reading briefing document*, 23 December 2003

> Thus, patients who actively wish their surplus tissue to be used for the benefit of all may not be given with the opportunity to grant such consent.[98]

The Anatomical Society was concerned that there would not be separate Inspectorates for Anatomy and Pathology:

> …the Bill arises concerns raised by events at Bristol Royal Infirmary and Alder Hey in 1999-2000. There has been no such concern about material obtained, held and used for anatomical examination. […] Including both Anatomy and Pathology within the same Inspectorate could have adverse effects on public confidence and cadaver donations.
>
> At the very least the Inspectors of Anatomy and Pathology should be different.[99]

They were also concerned that the Bill might actually weaken the accountability inherent in the current *Anatomy Act 1984*. Under the new rules, the Society does not believe it would be necessary for a Licensed Teacher to be present during an anatomical examination as is currently required.

The possession of anatomical specimens away from licensed premises seems unclear to the Anatomical Society. They were concerned whether individual rooms or whole buildings would be licensed. If the Bill was to allow whole buildings to be licensed then they believed that the storage and security of holdings could be made much more difficult.

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98 Royal College of Pathologists, *Second Reading briefing document*, 22 December 2003

99 Anatomical Society of Great Britain and Ireland, *Second Reading briefing document*, 22 December 2003