

PROPOSALS FOR NEW LEGISLATION ON HUMAN ORGANS AND TISSUE

Why we need new laws

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The need for new legislation on human organs and tissue was recognised initially because of concerns which came to light during 1999-2000. The public inquiries into events at the Bristol Royal Infirmary and Royal Liverpool Children's Hospital (Alder Hey) established that organs and tissue from children who had died had often been removed, stored or used without proper consent.

In June 2002 the report of the Human Organs Inquiry, chaired by John O'Hara QC, confirmed that similar practices had occurred in Northern Ireland and recommended the repeal of the Human Tissue Act (Northern Ireland) 1962. It is clear that the current law in this area is neither as comprehensive nor as clear and consistent as it might be. New legislation must address public expectations about what constitutes valid consent and what are appropriate arrangements for regulation and accountability. To do this properly we also need to consider the Anatomy (Northern Ireland) Order 1992, the Human Organ Transplants (Northern Ireland) Order 1989 and the Corneal Tissue (Northern Ireland) Order 1988.

Contents

Why we need new laws	1
Scope of the proposals	2
Consent	3
The Human Tissue Authority	5
Offences and penalties	6
Existing holdings	7
Further information	7

In 2001/02 England and Wales undertook a fundamental and broad review of the law on human organs and tissues taken from adults or children (including fetuses and stillborn children), either during surgery or after death. A public consultation document, *Human Bodies, Human Choices*, was launched in July 2002 and copied to key stakeholders in Northern Ireland.

Human Bodies, Human Choices examined issues that went beyond organ retention, including the many positive uses of organs and tissue to save lives, to treat patients more effectively and to enhance medical and scientific knowledge and understanding.

This work not only achieved broad consensus on the way forward but also demonstrated that the system of regulation being proposed could apply equally to Northern Ireland as to England and Wales, in very much the same way as the Human Fertilisation and Embryology Authority operates at present.

Interim Arrangements

In May 2003 I issued an Interim Statement on the Use of Human Organs and Tissue [HSS(MD22/03)]. This gave guidance to the healthcare and research communities pending new legislation. The Department will also be consulting on a range of new documents, including consent forms, under the title "Post Mortem Examinations: Good Practice in Consent and Care of the Bereaved".

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SCOPE OF PROPOSALS

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 (Northern Ireland) 1959 and the Coroners' (Practice and

Procedure) Rules (Northern Ireland) 1963, under which a coroner may order a post mortem examination 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 what authority, human tissue may be retained following a coroner's post mortem examination.

- 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.

CONSENT IS THE KEY TO NEW LEGISLATION

Consent is expected to be the foundation for the lawful taking, storage and use of all tissue, including whole or part organs. This is based on the principle that, in general, a person should be able to determine what happens to his/her body or to any of its parts.

Established conditions for obtaining valid consent from a person would be implicit. These conditions include providing sufficient information in a form the person can understand, and consent to be given voluntarily, not under duress nor undue influence from health or other professionals, family or friends.

A statutory code of practice would set out best practice in obtaining consent for a hospital post mortem, as well as communications more generally relating to post mortems, including coroners' ones, and any removal or retention of tissue and organs.

We do not anticipate new legislation on tissues and organs changing the law whereby post mortem examinations, together with removal and the storage of human material, are carried out at the direction of the coroner without consent in order to determine the cause of death. The Home Office is considering whether new legislation on the coroners' system is required.

When would consent be required?

Consent would be required before organs, tissue or cells could be taken from living patients or from deceased persons, and subsequently stored and used for specified purposes. Blocks and slides made from tissue samples for microscopic examination would be subject to the same rules as any other tissue.

The following would be specified purposes:

- anatomical examination covered at present by the Anatomy (Northern Ireland) Order 1992;
- health-related research;
- education and training;
- post mortem examination to investigate the treatment of a deceased person, or to obtain information relevant to the health of someone living;
- public display;
- transplantation.

Removal, storage or use of tissue for these purposes without the required consent would become a criminal offence.

The legislation would allow the specified purposes to be amended in case new activities needed regulation. This would help to keep legislation up-to-date with beneficial scientific and clinical developments.

Consent relating to adults

The legislation would not affect the existing common law position (law developed by the courts rather than through legislation) whereby a competent adult must consent to a medical intervention – which may include removal of tissue – before it can go ahead.

But under the proposals for legislation, a person's explicit consent would be needed for storage or use of the removed tissue for the purposes of research, education and training, transplantation or public display. He or she would also be able to give advance consent or refusal to a hospital post mortem examination.

It would also remain lawful to remove tissue or organs from an adult in his/her own best interests if he/she is unable to consent. But the storage and use of tissue removed from an adult unable to consent, for the purposes of research, education and training, transplantation or public display, would remain unlawful where not shown to be in his/her best interests.

In the case of consent to removal, storage and use of tissue and organs after death, the person's wishes while he or she was alive would, where known, take precedence over the views of remaining relatives or next of kin. In the case of storage and use of whole bodies for purposes of anatomical examination or public display, the emerging consensus is that the specific consent of the person concerned, while alive, should be essential.

Nominated representative

The legislation would provide for an individual to be able, while 'competent' (ie prior to a serious illness, loss of consciousness or death), to nominate a representative who would have power to take decisions on whether a hospital post mortem examination should take place, and on the removal, storage and use of tissues and organs.

Next of kin

In the absence of a 'nominated representative', the next of kin would be the person with authority to consent to a hospital post mortem examination. The person closest to the deceased would qualify as next of kin, whether spouse, same sex partner, non married partner, blood relative or a close friend of long standing. This would be compatible with Government plans for recognising civil partnerships.

Consent relating to children

The same principles that apply to obtaining a child's consent to examination and treatment might also apply to the activities regulated by

new legislation. These principles, originally set out in the Gillick case in 1986 (Gillick v West Norfolk and Wisbech AHA[1986]AC112), help to determine whether a child is competent to consent on his or her own behalf. This would mean that children younger than 16 who understood fully what was involved in a procedure would be able to give their own consent to these activities. However, the legislation would not allow the bodies of children to be used for anatomical examination or public display.

If a child is not competent – or competent but chooses not to decide – a person with parental responsibility (as defined in the Children (Northern Ireland) Order 1995) can consent to treatment on behalf of the child. In the absence of a person with parental responsibility, treatment should only be undertaken in the best interests of the child. Under the proposed new legislation, it would be up to the person with parental responsibility to specify lawful use of any removed tissue.

The legislation would provide that a person with parental responsibility could consent to a hospital post mortem examination on a child and to any storage and use of tissues or organs. As in the case of consent to treatment of children, if more than one person had parental responsibility, the consent of one would be sufficient.

Purposes not always requiring consent

The legislation might allow tissue which has been lawfully removed, for example during diagnostic testing or treatment, to be stored and used for clinical audit, certain public health monitoring and quality assurance purposes, without additional consent.

THE HUMAN TISSUE AUTHORITY

The legislation is expected to establish a new statutory body, the Human Tissue Authority (HTA).

The remit of the HTA would extend to the taking, retention, use and disposal of human tissue for specified purposes. It would take on responsibility for approving live transplants and develop policy on new transplant procedures.

Structure of the HTA

The HTA would consist of a lay chair and members appointed by the Secretary of State for Health for limited periods, including a Northern Ireland representative. The membership would comprise people with relevant professional experience, but at least half would be lay members.

The HTA would have two subsidiary bodies, one to look after activities involving human use, and the other to look after activities for other purposes.

Inspectorate of Anatomy and Pathology

This would, broadly speaking, incorporate the functions of Her Majesty's Inspector of Anatomy as currently set out in the Anatomy (Northern Ireland) Order 1992. It would regulate the taking, storage and use for non-therapeutic purposes of human organs and tissue after death, and also regulate the storage and use of human material taken after surgical or other procedures. Its remit would include licensing of all premises carrying out post mortem examinations, tissue banks and medical archives.

Inspectorate of Organs and Tissue for Human Use.

This would incorporate the responsibilities of the existing Unrelated Live Transplant Regulatory Authority (ULTRA), established under the Human Organ Transplants Act 1989, and these would extend to related live transplants. The inspectorate would license tissue banks which store and process tissue for human use; such tissue banks are currently accredited by the Medicines and Healthcare Products Regulatory Authority (MHRA) on a non-statutory basis.

Role of the HTA

The HTA would have specific regulatory powers and responsibilities. These would include licensing activities relating to:

- human tissue banking for therapeutic use;
- the donation, storage and use of human bodies for anatomical examination, research and training;
- the conduct of post mortem examinations (including the removal and retention of tissue and organs);
- the storage of tissue and organs for the purposes of research, teaching, training, quality control, audit, etc; and
- the storage and use of human bodies or parts for public display.

The HTA would have power to delegate licensing decisions to its subsidiary bodies and could itself act as an appeal body against these decisions.

The HTA would also have a general role in informing the public and the Government about

issues within its remit. It would maintain a statement of general principles relating to regulated activities, monitor developments in the field and advise the Government as necessary. The HTA would have power to inspect premises. It could maintain its own inspectorate and/or commission such services from other bodies in the private, public or voluntary sectors.

Licences, inspections and records

The HTA would be given the power to impose licensing requirements, including what records should be maintained and what information about licensed activities should be reported to the authority. Requirements would probably vary depending on the type of activity to be licensed.

Licences would identify:

- the activity authorised;
- the ‘designated individual’ who would be responsible for ensuring the lawful conduct of the licensed activity; and
- the premises in respect of which the licence was granted.

Licences would be issued subject to general conditions and/or to specific conditions. Legislation would cover provisions regarding the granting, variation, revocation and suspension of licences, and for appeals against licensing decisions.

Regular inspections of licensed premises would be carried out, ensuring compliance with the relevant codes of practice, licence conditions and directions. The powers of the HTA inspectorates might include powers of entry and the power to inspect or remove records.

Codes of Practice

The HTA would also have a role in issuing statutory codes of practice giving practical guidance and setting standards relating to activities within its remit, such as:

- conduct of anatomical examinations;
- conduct of post mortem examinations;
- definition of death;
- communication with families at post mortem and arrangements for consent;
- the removal, storage and use of material from living or deceased persons;
- the disposal of organs and tissue; and
- import and export of bodies and body parts.

Compliance with codes of practice could be taken into account in making licensing decisions.

OFFENCES AND PENALTIES

Existing offences under the Anatomy (Northern Ireland) Order 1992 of carrying out an anatomical examination without a licence or on premises which are not licensed would be maintained under new legislation, together with offences under the Human Organ Transplants (Northern Ireland) Order 1989 relating to commercial dealing in organs and advertising for organs. Maximum penalties for these would be increased.

New offences

Some new offences would be created, including:

- taking, retaining or using human tissue or organs without the consent of the relevant person for any of the specified purposes;
- trafficking in human bodies or body parts;
- carrying out licensable activities without holding a licence from the HTA (with corresponding penalties for related offences such as falsifying records or obstructing the authority in exercising its powers or responsibilities);
- having or using human tissue for DNA testing without the consent of the individual concerned, unless during the investigation by public authorities of a suspected crime. This was recommended by the Human Genetics Commission and anticipated in the Government's White Paper on genetics.

Existing Holdings of Tissue

The legislation would need to provide for continuing storage and use of existing holdings of bodies, or tissue from bodies, particularly where there was no consent to use the material for a specified purpose. This issue is still under consideration.

The Retained Organs Commission has recently submitted advice to the Department of Health in London on unclaimed and unidentifiable human organs and tissue. This was copied to HPSS Trusts here with the Chief Medical Officer's 'Interim statement on the Use of Human Organs and Tissue' HSS(MD22/03) in May 2003.

Where Legislation Would Apply

The legislation is expected to extend to England, Wales and Northern Ireland. Provision will be made to take account of Northern Ireland views on specified matters such as the content of codes of practice issued by the HTA. There will be a Northern Ireland member of the HTA.

Scotland is considering separate legislation, however any new position on non-consensual DNA testing is expected to extend to Scotland, as this particular area is reserved to the UK Parliament.

Education and Information

The Report of the Human Organs Inquiry recommended that the Department should develop a public education and information programme about post mortem examinations as well as a multimedia publicity campaign informing relatives that they may reclaim tissue blocks and slides.

A leaflet entitled 'Post Mortem Examinations and the Human Organs Inquiry' has been issued to every household in Northern Ireland and a telephone enquiry line (0808 800 8810) has been open since November 2002.

Tendering is under way for further advertising and public relations work.

Education and information for clinical and nursing staff will be prepared on the meaning and application of new legislation.

WANT TO KNOW MORE?

Information on the use of human organs and tissue and the implementation of the recommendations of the Human Organs Inquiry Report (June 2002) can be found at the DHSSPS website www.dhsspsni.gov.uk/hss/hoi/index.html And the Department of Health website www.doh.gov.uk/tissue.