How the Human Tissue Authority's codes of practice are relevant to doctors

The Human Tissue Authority supports public confidence in the use of human tissue by licensing and inspecting organizations that remove, store and use human tissue for purposes such as research, post-mortem examination, teaching, and public exhibitions in England, Wales and Northern Ireland and for patient treatment throughout the UK. These organizations include hospitals, mortuaries and medical schools. The Human Tissue Authority is also responsible for approving organ and bone marrow donations from living people.

Central to the Human Tissue Authority's regulation is the need to have appropriate consent for the removal, storage and use of human tissue. The Human Tissue Authority works under two pieces of legislation: the Human Tissue Act 2004 and the EU Tissues and Cells Directive, which has been implemented in UK law via the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The aim is to make sure that there is compliance with the law by setting clear standards.

The Human Tissue Authority's codes of practice lay down the standards expected for each of the areas the Human Tissue Authority regulates. The codes have been revised to support professionals by giving advice and guidance based on real-life experience. The codes were approved by Parliament in July 2009 following a 3-month public consultation.

Consent

Consent is a legal requirement of the Human Tissue Act 2004. Consent must be given for the removal, storage or use of material for particular purposes. It must be given voluntarily and by an appropriately informed person who has the capacity to agree to the activity in question.

The code provides advice on when and how consent should be sought (Human Tissue Authority, 2009a). It addresses communication and consultation with patients and their families, and covers the requirements for consent from both deceased and living people.

For the removal, storage and use of tissue from a deceased person, consent is required from that person while he/she is alive, or from someone nominated by the person to act on his/her behalf. In the absence of either of these, consent must be sought from a person who was in a 'qualifying relationship' with the deceased person immediately before his/her death. Such a person could be the spouse or partner, parent or child, or a sibling of the deceased person.

Consent to treatment and examination is covered by common law and the Mental Capacity Act 2005, but consent is still required from a living person for storing and using tissue for particular purposes.

Disposal

This is the only code that is not statutory (Human Tissue Authority, 2009b). It provides guidance on the disposal of human tissue from a deceased or living person, and the consent required. The revised code has a new section on disposal following pregnancy loss.

Donation of solid organs for transplantation

Consent is required for all living donations. The Human Tissue Authority is responsible for approving living organ donations and also bone marrow and peripheral blood stem cell donations from children and adults who lack capacity to give consent.

Among other changes, the revised code expands the guidance on the treatment of tissue taken for tissue typing and the information provided to the donor about risks to the recipient (Human Tissue Authority, 2009c).

Post-mortem examination

A post-mortem examination and the removal and storage of relevant material to determine the cause of death do not require consent from the relatives if these activities have been authorized by the coroner. However, when the coroner's authority comes to an end, it is unlawful to use the retained material for a scheduled purpose set out in the Human Tissue Act 2004, or to continue to store it with the intention of using it for a scheduled purpose, without appropriate consent.

The revised code provides guidance relevant to the whole post-mortem process (Human Tissue Authority, 2009d), beginning with communication with the relatives and ending with the retention, return or disposal of tissue. It also includes information on who may seek consent for hospital post-mortem examinations, and expands the guidance relating to paediatric post-mortem examinations.

Anatomical examination

The Human Tissue Authority licenses organizations which carry out anatomical examinations and the code sets out the requirements for seeking consent (Human Tissue Authority, 2009e), which can be given only by an individual who chooses to donate his/her body. Consent must be in writing, signed by the donor in the presence of a witness, or signed by a representative at the direction of the donor, with a witness present – this procedure must take place before the donor's death.

Research

If tissue is removed during the course of treatment or investigation, there may be some remaining tissue after the procedure that can be used for research. The Human Tissue Authority helps to ensure that tissue is removed and stored in an appropriate and well-managed way. The new code of practice on research sets out these requirements (Human Tissue Authority, 2009f). The code also includes information on DNA analysis.

Tissue taken from the living and stored in a diagnostic archive can be released for research if the patient has given consent. Tissue from the living can be released

without consent only if it has been anonymised and it comes from a bank which has generic ethical approval from a research ethics committee, or it is to be used for a specific research project approved by a recognized research ethics committee.

Once tissue is released from a diagnostic archive for research, it must be stored on Human Tissue Authority-licensed premises, unless it is for a specific research ethics committee-approved project.

Since 1 September 2006, consent is required for tissue to be used for research after a person's death. If there is no record of the deceased person's wishes, consent for research can be obtained from a nominated representative or, if no one has been nominated, from a person in a 'qualifying relationship'.

Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation

The focus of this code (Human Tissue Authority, 2009g), like the solid organs code, is donation and consent (according to the Human Tissue Act 2004), and the Human Tissue Authority's approval of bone marrow and peripheral blood stem cell donations. However, tissues or cells which may be transplanted into humans – even for clinical research – must be licensed by the Human Tissue Authority under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The use of tissues and cells in human application is a rapidly developing field and the boundaries between research and human application are continually shifting. The revised code includes guidance on the requirements of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and signposting to further guidance.

Conclusions

The Human Tissue Authority's revised codes of practice provide advice and guidance for professionals who work under the legal and regulatory framework for the removal, storage and use of human tissue. Health-care professionals work across a variety of sectors and will be affected by different codes depending on their area of expertise. Reading and using the codes will help health-care professionals to interpret the legislation and to understand how it has an impact on their work. These can be accessed via the Human Tissue Authority's website (www.hta.gov.uk). BJHM

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Human Tissue Authority (2009a) *Code of practice 1 - Consent.* Human Tissue Authority, London
Human Tissue Authority (2009b) *Code of practice 5 - Disposal of human tissue.* Human Tissue Authority, London
Human Tissue Authority (2009c) *Code of practice 2 - Donation of solid organs for transplantation.* Human Tissue Authority, London
Human Tissue Authority (2009d) *Code of practice 3 - Post-mortem examination.* Human Tissue Authority, London
Human Tissue Authority (2009e) *Code of practice 4 - Anatomical examination.* Human Tissue Authority, London
Human Tissue Authority (2009f) *Code of practice 9 – Research.* Human Tissue Authority, London
Human Tissue Authority (2009g) *Code of practice 6 - Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation.* Human Tissue Authority, London

KEY POINTS

- The Human Tissue Authority is an independent regulator that supports public confidence by licensing organizations that store and use human tissue.
- Consent is the fundamental principle underpinning the lawful retention and use of body parts, organs and tissue from the living or the deceased.
- The Human Tissue Authority aims to help people to understand its requirements by providing advice, guidance and support.
- The nine codes of practice span different sectors, provide practical guidance and lay down expected standards.