



The Royal College of Pathologists

Ethical issues in organ and tissue transplantation to humans

August 2005

This position statement was produced by the Ethics Committee in March 2005 and, in accordance with the College's publications policy, was placed on the Fellows' and Members' area of the College website for consultation from 29 March to 29 April 2005. Five detailed comments were received and forwarded to the lead author, Dr Phil Dyer. He and the Ethics Committee considered the feedback and amended the document accordingly. Please email publications@rcpath.org if you wish to see Dr Dyer's annotated responses to the feedback received.

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Introduction

Despite its relatively young age, the field of clinical organ and tissue transplantation has spawned extensive predictable and unpredictable ethical issues. The rate of occurrence of these issues continues to accelerate with the demand for longevity and expansion of clinical innovations such as cloning and stem cell research. Many books have been written on the topic, many people present their views in the media on a regular basis and the popular press seizes every opportunity to journey down the 'Frankenstein' path. However, in reality, many thousands of lives, worldwide, have been saved by effective clinical transplantation. This paper highlights aspects of clinical transplantation that have particular relevance to College members.

The Human Tissue Act 2004 defines relevant material as "consisting of or including human cells". Excluded from the Act are cell lines, hair and nail from living persons, live gametes and embryos (the remit of the Human Fertilisation and Embryology Authority), and blood and derivatives for transfusion. Convention accepts that organs are composed of tissues, but that tissues may have independent biological functions and may also be transplanted for therapeutic purposes. The Human Tissue Act proposed for Scotland simply refers to "body parts".

Contentious issues

The list of contentious ethical issues is long. Topics currently highlighted on the British Transplantation Society's website (www.bts.org.uk) as topical are:

- definition of death
- consent for organ and tissue donation
- living liver donation
- face transplantation

- non-heartbeating organ donation
- waiting list criteria for potential renal transplant recipients
- paired organ exchange
- altruistic (non-directed) living donation
- care of deceased donors in intensive care units
- payment for live organ and tissue donation
- ‘transplant tourism’.

Which issues have significant implication for the clinical practice of College members?

Donation

Members will often find themselves in a situation where they can influence the opportunity for organ and tissue donation. Public opinion surveys show that a substantial majority support donation for transplantation and currently over 12 million people have joined the National Organ Donor Register (see www.uktransplant.org.uk). On this basis, members should be confident to raise the opportunity of donation whenever it is a clinical possibility. Members should be familiar with clinical situations when donation is possible and have ready access to support teams, such as organ and tissue donation coordinators. The views of religious communities should be understood (none of the main faiths veto donation). The Department of Health has published *Policy for Organ and Tissue Donation*, available from www.uktransplant.org.uk

Consent

The Human Tissue Act 2004 establishes the Human Tissue Authority, which will be effective from 2006. Until that time, College guidelines on obtaining consent should be followed. Organ and tissue donation is, by its nature, time limited but this should not impinge on the need to obtain consent. The UK operates an ‘opting in’ system for organ and tissue donation for transplantation, which necessitates consent from the person lawfully in charge of the body. In practice, the consent of the next of kin is overriding.

Allocation

Members will be involved in influencing allocation in many ways and ethical practice is essential. Possible influences vary widely, from prompt reporting of laboratory testing (e.g. HLA typing) to efficient administrative systems that do not delay patient access to timely transplantation (e.g. locating a stem cell donor from a registry).

Human Organ Transplants (HOT) Act 1989 and Regulations

This Act is repealed by the Human Tissues Act 2004. Meanwhile, College members must be aware of the implication of this law for their clinical practice. They must not facilitate illegal practice, such as provision of test results that might allow a transplant to proceed when the terms of the Human Organ Transplants Act have not been met.

Payment

Inducement to donate organs and tissues for transplantation is illegal in the UK under the Human Organ Transplants Act 1989 and remains so under the Human Tissues Act 2004. Members should also be aware that, although some countries have no law specifically forbidding inducement, the Transplantation Society, a worldwide professional body, condemns this practice. Members should be aware in their own practice that provision of training and laboratory tests can facilitate unethical practice elsewhere. Members should consider the term ‘inducement’ in its broadest sense and include both financial and non-financial inducements.

Research

Transplantation of organs and tissues promises much hope for patients with chronic and life-threatening conditions, and often short development times transpire. Current clinical governance may limit radical steps. For example, transplantation of organs and tissues from non-human donors is regulated by the UK

Xenotransplant Interim Regulatory Authority. Any development of therapeutic stem cell transplantation will use embryonic cells and tissue and so the Human Fertilisation and Embryology Authority will play a regulatory role. Ethical practice in research is paramount in this field and referral to a Local Research Ethics Committee is essential.

The role of the pathology team in transplantation

There is an extended role for healthcare professionals such as Coroners and bereavement officers, and particularly for scientists and pathology consultants, in facilitating and ensuring that tissue donation for transplantation is safe and efficacious.

This includes the provision, with family consent, of any post-mortem report, since this is an important part of the deceased donor's medical record and helps assess the risk of transplant transmitted disease.

Enabling entry to post-mortem facilities for the tissue retrieval team (most deceased tissue donations are undertaken in post mortem rooms) is critical and ensures that post-mortem examinations are undertaken, wherever possible, after rather than before therapeutic tissue retrieval, thus reducing the risk of bacterial contamination. Assistance in the retrieval of hearts for subsequent heart-valve dissection using methodology specified by the tissue bank also helps to prevent cross contamination of the tissue.

Ethics Committee

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