

Organ transplantation

Organ transplantation and the Human Tissue Act

Andy R Weale, Paul A Lear

Changes in the law may have a positive impact on organ donation

On 1 September 2006, the legislation relating to organ donation within the UK changed. The Human Tissue Act 2004 and The Human Tissue (Scotland) Act 2006 established the Human Tissue Authority (HTA) and has altered the way every potential donor is managed, be they deceased or living.

Like the rest of the world, in the UK, the disparity between the number of patients awaiting transplantation of solid organs and the number of organs available continues to increase. In 2005, the number of patients actively waiting on the list had increased by 9% to 6543, and the number of organs transplanted had decreased by around 7% to 2746; (2195 deceased donor and 551 living donor transplants) (www.uktransplant.org.uk/ukt/statistics/statistics.jsp).

In the UK, 80% of all solid organ transplants are from deceased donors (www.uktransplant.org.uk/ukt/statistics/statistics.jsp). The number of such donors continues to decline, with 41% of next of kin approached about potential donation refusing consent.¹ A further 15% of potential donors are not considered for donation, as the next of kin are not approached. The new Act has the potential to make a big impact on deceased donation, as registration with the UK Organ Donor Register (www.uktransplant.org.uk/ukt/RegistrationForm.do) will in itself provide the consent for donation and relatives will no longer have a legal right to over-rule those wishes. The Act also recognises the expansion and successful use of organs from non-heart-beating donors.²⁻³ Last year, 126 of the 715 donors were non-heart beating, an increase of over 40% on the previous year (www.uktransplant.org.uk/ukt/statistics/statistics.jsp). Such donations may be so called "controlled", whereby a patient with irreversible fatal brain injury, who has not undergone formal brain stem death tests, has life-supporting treatment withdrawn in a controlled fashion, usually in the intensive care or high dependency setting. There is usually adequate time to establish whether such patients are on the organ donor register and approach the relatives to

discuss potential donation and obtain consent for donation as appropriate. "Non-controlled" non-heart-beating donation involves the use of organs from patients who are dead on arrival in emergency departments or who have had unsuccessful cardiopulmonary resuscitation within the hospital. Although the main evidence that such organs provide long-term results equivalent to other deceased donor sources comes from kidney transplants,²⁻⁴ other organs including liver⁵ and lung⁶ have been successfully transplanted from uncontrolled donors. In order for the organs to be useable for transplantation, they should be perfused with as little delay as possible after death. This is achieved by using catheters introduced into the femoral vessels via a small groin incision. The new Act allows the "minimum necessary steps to preserve the part for use in transplantation to be taken whilst consent is being sought".⁷ However, the organ procurement team only has the legal right to perfuse organs in situ prior to consent, if authorised by the individual in charge of the institution where death occurs.

The new Act will also affect living donor transplantation schemes. It requires that every living transplant donor and recipient, regardless of whether the donor is related or unrelated, is assessed by a formally trained and HTA-accredited third party. The HTA will then pass judgment on the potential donation. Before the Act only unrelated donor-recipient pairs had to undergo mandatory independent third-party assessment before consideration by the Unrelated Live Transplant Regulatory Authority. At that time, transplants between genetically related individuals did not require mandatory independent, third-party assessment of recipients and donors, although this was seen as good practice.⁸ The process relied on the judgement of the clinicians involved who were adequately informed of both risks and benefits of the procedure and of the fact that there was no coercion or financial inducement involved in the donation. Although the new Act ensures a robust

mechanism for living donation, it also calls for a substantial increase in third party personnel and education. The British Transplantation Society has expressed concern that the HTA may subject many transplants to an administrative delay (<http://www.bts.org.uk/Forms/health%20ministers%20letter.doc>).

The Act does provide legal clarification to two areas of living donation: paired-exchange donation and altruistic non-directed donation. Paired-exchange donation has been successfully used to overcome ABO incompatibility between living donor and directed recipient, particularly in Asia.⁹ In this way, a donor-recipient pair (pair 1) in whom the recipient is blood group B and the donor group A (ABO incompatible) could be linked up with another pair (pair 2) in whom the donor is blood group B and the recipient blood group A. The kidney from the blood group A donor from pair 1 would be transplanted into the group A recipient of pair 2, and vice versa. An alternative exchange programme involves a live donor list exchange. In this way, the donor from the incompatible pair donates the organ to a suitable patient on the waiting list; in return, the incompatible recipient of the live donor pair is prioritised to receive a suitable kidney from the deceased donor pool.¹⁰

Although the logistics of such paired exchange schemes may be challenging, the Act provides a framework by which such transplants can occur both legally and ethically. Current paired donor exchange in the US has involved donation from just 128 living donor couples and 56 live donor list exchanges (living/deceased donor exchange; <http://www.optn.org/latestData/rptData.asp>).

Non-directed donation, also known as altruistic donation, involves individuals who feel compelled to donate an organ, but do not have a recipient in mind. Such cases are rare—in the US only 407 patients have given kidneys by non-directed donation since 1998, <0.8% of all living donor transplants (<http://www.optn.org/latestData/rptData.asp>). Non-directed donation will, however, be made legal by the Act, and any such non-directed donors must be assessed in the same way as all other potential living donors.

The Human Tissue Acts will undoubtedly change the way organ donation and transplantation is carried out at many levels in the UK. It is important that all medical practitioners and the public at large are aware of these changes, so that more potential donors, both living and deceased, are not missed through ignorance of the new legislation.

Postgrad Med J 2007;**83**:141-142.
doi: 10.1136/pgmj.2006.054213

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Competing interests: None declared.

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