



Law and medical ethics in organ transplantation surgery

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ABSTRACT

This article in the series describes how UK law and medical ethics have evolved to accommodate developments in organ transplantation surgery. August committees have formulated definitions of the point of death of the person which are compatible with the lawful procurement of functioning vital organs from cadavers. Some of the complexities of dead donor rules are examined. Live donors are a major source of kidneys and the laws that protect them are considered. Financial inducements and other incentives to donate erode the noble concept of altruism, but should they be unlawful?

KEYWORDS

Organ transplantation surgery – Law – Ethics

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Historical

The *Corneal Transplantation Act 1952* was the first English legislation to address removal of tissue from a deceased donor. Enoch Powell's *Human Tissue Act 1961* was designed to facilitate the collection of other tissues from the deceased, such as pituitary glands. The first cadaveric kidney transplant was performed in Boston, USA, in 1962. British doctors asked for clarification of the law, but Parliament rejected Sir Gerald Nabarro's *Renal Transplantation Bill 1968*. After Christian Barnard's first heart transplants in South Africa, Henry Beecher's Harvard Committee relied on the principle that the diagnosis of death is a matter of accepted medical professional practice and suggested that patients in irreversible coma could be regarded as dead before the cessation of heart beat,¹ so that Norman Shumway and Denton Cooley could proceed with cardiac transplantation in the US.² Donald Ross performed the world's tenth, and the UK's first, heart transplant later in 1968. There has always been a tragic supply and demand gap in organ transplant practice. In 1977, a Working Party of The Royal College of Surgeons of England (RCSE) called upon clinicians managing 'seriously ill, probably dying' patients to take a 'more energetic approach' to discussions of donation to procure more organs.³ They were sure that the 6000 or so annual victims of accidents could provide all the organs the service could require. Organ procurement continued in the near-absence of legal or ethical guidance. Up to the late 1970s, the typical proxy-consented organ

donor would be anaesthetised, and the target organs dissected free of all but their blood supply. On a command, the anaesthetist would disconnect the ventilator, symbolising the point of death, and the final vascular attachments of the organs would be divided. Codes of Practice for the diagnosis of death by brain-stem test criteria followed a 1979 UK consensus statement,⁴ and the first judicial approval of the codes came in a 1992 court case.⁵ In the US, a President's Commission advised on the determination of death in 1981.⁶ In California in 1984, Baby Fae was given the heart of a baboon and lived for 20 days. Hopes were raised that animal organs could be offered to humans (xenotransplantation), but the issue remains controversial. Neurosurgeon Dr Robert White has been advocating whole-body transplant for patients with life-threatening neurological disorders for many years, but the procedure remains hypothetical.⁷ In recent years, transplants of non-vital parts like hands and faces have been pioneered.^{8,9} The *Human Tissue Act 2004* (HT Act) was Parliament's response to public outrage about pathology practices, but it replaced the *Human Tissue Act 1961* and empowers the Human Tissue Authority (HTA) to propound the Codes of Practice which apply in England and Wales today.¹⁰ The HTA regulates living donor transplants in Scotland, but deceased organ transplants are subject to separate Scottish legislation. The annual number of donors in the UK today is approximately 400 heart beating, 200 non-heart beating and 600 living. About 1000 potential recipients die each year, and the size of the waiting list is about 8000.

Dead donor rules

The ideal organ donor is one who cannot be harmed by donation, and so we look first to those who are dead or dying. There is a school of thought that holds the legal distinction between living and dead donors to be unnecessary and problematic.^{11–13} The World Health Organization's Secretariat prefers dead donors, and recommends national co-ordinating organisations with medical and logistic infrastructure backed by the Government.¹⁴ By expanding the definition of death to include death diagnosed by examination of the nervous system, a substantial pool of heart-beating donors (HBDs) has been created in developed countries with intensive care units (ICUs). Variations in national critical care practices cause southern European ICUs to produce more HBDs than Northern European ICUs.¹⁵ Most countries hold to the concept of 'whole brain' death, which may include testing by electroencephalography and/or cerebral blood flow measurement. Japan is one of the countries that has found it difficult to accept the concept of brain death, and many Japanese patients travel abroad for surgery.¹⁶ Israel's Knesset passed a law as recently as 2008 approving the diagnosis of brain death for the purpose of organ donation, but the patient's family may still choose whether or not to accept the diagnosis. The Chief Rabbinate Council controversially recognised brain death in Jewish Law in 2009.¹⁷ The UK is almost unique in adopting the brain-stem death concept which requires only clinical examination to fulfil the diagnostic criteria.¹⁸ A bizarre protocol ('elective ventilation') to increase the number of HBDs was developed in Exeter, and was for a while advocated by the UK Department of Health (DH), but was ruled to be unlawful in 1994.¹⁹ There were no prosecutions.

There are currently initiatives to procure more organs from non-heart beating organ donors (NHBDs). There are four 'Maastricht categories' of NHBD²⁰ for donation after cardiac death (DCD), and all have reports of success, including heart transplants:²¹

- I Dead on arrival.
- II Unsuccessful attempts at resuscitation.
- III Controlled withdrawal of life support without attempts at resuscitation.
- IV Cardiac arrest after brain death.

A key question about cardiac death is how long after the cessation of cardiac activity may we diagnose death? After 2 min of asystole, the heart will not restart spontaneously (permanent asystole), and this is the basis of recommendations by the Society of Critical Care Medicine in the US. It makes possible heart donation by one whose death has been diagnosed by permanent asystole. Spain is often admired for its high organ donor rate, due in part to very aggressive DCD initiatives. In Madrid, there is a protocol targeting under 50-year-olds who collapse on the street, who can become organ donors if attempts at resuscitation fail.²² Dutch law allows a number of pre-mortem inter-

ventions on registered donors to optimise DCD.²³ There is no national code of practice on DCD in the UK, but a guidance from the Intensive Care Society and UK Transplant requires a full 5 min without cardiac activity,²⁴ which makes cardiac donation impractical.

The DH has provided guidance on the law concerning pre-mortem treatment of potential NHBDs with 'catastrophic brain injury' who are 'likely to be unconscious'. The DH expresses the opinion that organ donor registration does not provide consent to pre-mortem interventions to procure organs, and that any such interventions are only lawful if believed to be in the best interests of the patient.²⁵ Techniques acceptable in the view of the DH include continuation of (but not initiation of) ventilator support, new vascular access and inotrope therapy, and the taking of blood samples. Femoral cannulation for vital organ preservation is mentioned but no opinion offered as to its lawfulness; it would, however, be inconsistent to oppose it as new cannulation for resuscitation therapy is said to be acceptable. Systemic heparinisation or external cardiac massage are thought to be unlawful unless a declaration by the Court of Protection holds otherwise. Compared to the comprehensive literature surrounding pre-donation diagnosis and treatment of 'brain dead' patients, there is no consensus on the pre-donation diagnosis and treatment of patients with 'catastrophic' brain injury. The legal position of potential NHBDs without brain injury is almost entirely unexplored. In spite of many legal uncertainties for clinicians who supervise end-of-life care for NHBDs, there has been a steady increase in the number of such organ procurements in the UK.

Section 43 of the HT Act gives limited exception to the requirement for consent so that the fewest number of steps may be taken after death, using the least invasive techniques, to preserve organs while consent is sought for donation; the suggested techniques are intravascular or intraperitoneal cooling. 'Appropriate' consent must be obtained for removal, storage and use of organs or tissues for transplantation. Consent may have been given by the donor while alive, and voluntary organ donor registration by a competent minor or adult is deemed to constitute informed consent. If the deceased had nominated a representative while he or she was a competent adult, that person can consent to donation. Otherwise, a qualifying relative may be approached to give consent. At the top of the eight-step hierarchy of qualifying relatives is spouse or partner, and at the bottom is a friend of long-standing. A child cannot have a spouse or partner, so parent is his highest qualifying relative. The HT Act accepts that there may be reasons in certain cases and circumstances to vary the hierarchy, and the urgency of finding someone to consent to donation could be such a circumstance. Consent conditional on who will receive a cadaveric donation is not accepted. There is no guidance to organ procurement in cases where consent is unobtainable, and it is important to emphasise that procurement without consent has been made unlawful.

The number of bereaved families who will not consent to organ donation is rising in the UK. Presumed consent may be a flawed concept,²⁶ but one of Gordon Brown's first initiatives on becoming Prime Minister was to ask the Chief Medical Officer to open consultations on presumed consent for organ donation. In 2008, an Organ Donation Taskforce rejected it.²⁷ The Taskforce was influenced by opposition from critical care staff who would have to deal with anger from dissenting families, but offered to reconsider in 5 years if other initiatives had not produced increases in organ procurement. The Scottish Parliament has twice debated and rejected Presumed Consent Bills.²⁸ The Welsh Assembly have yet to debate the matter.

Live donors

The World Health Organization (WHO) reports that the majority of transplanted organs across the world come from live donors. In the UK, the annual number of live donors is similar to the number of dead donors. In most developing countries, almost all kidney transplants are from live donors, and a 'transplant tourism' industry has been created to exploit those willing to sell a kidney.¹⁵ Many countries have legislated against the purchase and sale of organs in accordance with WHO's *Guiding Principles on Human Organ Transplantation 1991*.²⁹

Sections 33 and 34 of the HT Act demand prior approval by the HTA of live donor transplant, and make it an offence to remove any organ or part of an organ from a live donor unless all the requirements of the Act and the Regulations are met. The HTA must be satisfied that: (i) no reward has been or will be given to the donor; (ii) lawful consent to donation has been obtained; and (iii) an independent assessor has interviewed both the recipient and the donor separately, and submitted a report to the HTA.

Donations can be 'directed' from the donor to a known recipient, or 'non-directed' altruistic. Altruistic donors may not place conditions on who will receive their organ; this rule has been criticised by campaigners for transplants within the Jewish community.³⁰ There is an exception to live donation approval for Domino transplants in which the second (live) donor is primarily a recipient; consent is subject to common law or the *Mental Capacity Act 2005*. Children (for the purposes of the HT Act, under 18 years) and adults who lack capacity to consent may only be live donors with the approval of both the Court of Protection and a Panel of the HTA. To be clear, a Gillick-competent under-16 or a 16 or a 17-year-old may consent to treatment and may consent to cadaveric organ donation, but may not consent to live organ donation. Persons who are empowered to consent to treatment for adults under the *Mental Capacity Act 2005* may not consent to donation.

In 2008, Parliament confirmed that the practice of selecting human embryos which are suitable for organ or tissue donation to a sibling or other family member is lawful under the *Human Fertilisation and Embryology Act 1990*. It was reported in August

2009 that 12 licenses have been granted by the Human Fertilisation and Embryology Authority to create embryos ('saviour siblings') as tissue matches for a sibling.³¹

The market for organs

In 1990, the General Medical Council (GMC) found that Michael Bewick, a member of the 1977 RCSE Working Party on Transplantation, had removed kidneys from paid donors.³² The HT Act Section 32 'Trafficking' now prohibits advertising, buying and selling of organs and tissues, punishable by a fine and up to 3 years imprisonment, but indicates some exceptions. For instance, the National Blood Service may purchase blood products from abroad, and properly licensed commercial tissue banks may function.

For religious and cultural reasons, organ donation rates in Israel are very low. The Ministry of Health made it lawful to buy insurance to cover the cost of life-saving transplants abroad in 1994. Israel has become the first country to incentivise organ donation by giving recipient priority to registered donors.³³ It is argued that an ethical monopsonistic market for tissues and organs could be established within the National Health Service to the benefit of society.³⁴ In the US, economic calculations point to a fair market price of about \$40,000 for a kidney.³⁵ There have been a number of organisations offering vital organs for sale, most notably in China, Pakistan and the Philippines. The WHO carries a list of transplant tourism websites, and quotes prices of US\$14,000–70,000 for a kidney. A liver or heart will cost in excess of US\$100,000.³⁶

Animal to human transplantation

Following a report by the Advisory Group on the Ethics of Xenotransplantation (The Kennedy Report), the UK Xenotransplantation Interim Regulatory Authority was established in 1997, and wound up December 2006.³⁷ There remains only the DH's 'Xenotransplantation Guidance 2006' which requires those contemplating xenotransplantation to adhere to international recommendations and guidance, including the requirement that xenotransplantation should only take place where an adequate regulatory framework exists. The US Food and Drug Administration retains such a framework, and Lord Winston is relocating his company Atazoa to Missouri to continue research on the genetic modification of pig sperm with which to breed animal donors.³⁸ In 2009, Australia's National Health and Medical Research Council lifted a 5-year moratorium on animal to human transplantation research.³⁹

The future

It is both cost-effective and humane to strive to increase the availability of organs for transplantation surgery. The current Harvard Professor of Medical Ethics believes that Henry

Beecher's 1968 brain death concept is too flawed to continue, but too ingrained to abandon now. He believes that: 'A better approach to procuring vital organs while protecting vulnerable patients against abuse would be to emphasize the importance of obtaining valid informed consent for organ donation from patients or surrogates before the withdrawal of life-sustaining treatment in situations of devastating and irreversible neurologic injury'.⁴⁰ Though this would be a radical legal initiative, it could provide substantial benefits for donors and recipients alike. A standard compensation for expenses of at least £10,000 paid to the estate of the deceased after organ donation would probably be a cost-effective way to reduce the high number of refusals to donate. Non-brain injured patients facing a controlled death in ICUs could be enrolled as donors. As public support for physician-assisted suicide strengthens, care protocols which include consented organ donation could be developed. Stem-cell generated tissues and organs are a very long way off, and it may be that animal organs will never be acceptable to the public.

Conclusions

The risk of harm to live donors is falling as surgical techniques and anaesthesia become safer, but dead or dying donors remain the donors of choice. Transplant programmes have relied on consented donations from irreversibly apnoeic coma patients on ICUs, but the numbers of those are falling year on year. The law requires consented, comatose donors who do not fulfil the neurological criteria for diagnosis of death to be subjected to a period of cardiac stand-still and whole-body ischaemia, which varies between jurisdictions, to satisfy the cardiac criteria for diagnosis of death before organs may be removed. If the minimum period of cardiac stand-still is short enough, even heart donation is possible. Where the donor is not comatose or catastrophically-brain injured before death, there is still substantial legal uncertainty surrounding the controlled withdrawal of treatment for the purpose of organ retrieval.

NHS Blood and Transplant provides up-to-date information and statistics on organ donation at <http://www.uktransplant.org.uk/ukt/>.

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