

# Ethical and legal issues associated with organ donation and transplantation

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## Abstract

Organ donation and transplantation present many challenges to the medical community and society as a whole that require legal and ethical frameworks. This article sets out the legal framework and key principles of modern bioethics that underpin modern frameworks of organ donation and transplantation practice. In many cases there is no single answer to a problem and the concept is introduced that ethics and implementation of ethical principles to policy is often governed by societal values or represents a best compromise. Organ donation and transplantation will continue to throw up challenging questions for law and medical ethics and it is key that doctors understand the language and principles involved so that they can contribute to the debate.

**Keywords** Conditional donation; consent; directed donation; equity of access; justice; medical ethics

## Introduction

Advances in organ transplantation continue to develop at a rapid pace. Despite these advances, fundamental ethical and moral dilemmas continue to pervade the practice of organ transplantation. This is brought into sharp focus by the ever-increasing gulf between organ supply and demand. Dealing with issues such as who should donate organs, how organs should be allocated and who should receive organs, requires careful and rational evaluation of the moral and ethical concerns, long before the practical aspects can be considered. While the correct path may vary based on the moral code and ideals of the society as well as technological advance, understanding the key ethical principles can assist in formulating a rational approach to these complex issues.

## Principles of bioethics

*Beneficence* or doing good, *Non-Maleficence* or not doing harm, *Respect for autonomy* or the right of the individual and *Justice* or fairness are four trans-cultural principles that are widely accepted as forming the basis of medical ethics.<sup>1</sup> These *prima facie* ideals serve as a basis on which to consider and refine

ethical dilemmas. Understanding these principles in the context of human disease is fundamental to the practice of medicine. These principles are used within frameworks to describe and define arguments and positions in ethics. There are two main frameworks that are used to describe bioethics in the context of transplantation specifically and medicine in the wider sense. The deontological approach focuses on the duties of medical practitioners and the rights of patients. Deontological thinking stresses the importance of patient autonomy and the primacy of the doctor–patient relationship. The utilitarian approach aspires to act in such a way that always leads to the right outcome. In essence, ‘Seek the greatest good of the greatest number’. The need to ration healthcare makes this approach particularly prominent within public health systems such as the National Health Service.

The deontological and utilitarian approaches do not provide opposing views on ethical dilemmas, but rather offer different perspectives on solving a particular problem. At the root of society, moral code and ethical principles lead to rules, regulation and law, reflecting what society deems right and wrong.

## The legal framework for posthumous organ procurement

In the UK the procurement of organs for transplantation is regulated by the Human Tissue Act 2004,<sup>2</sup> in force in England, Northern Ireland and Wales, and the Human Tissue (Scotland) Act 2006, in Scotland. These Acts provide a comprehensive legislative framework for the removal, storage and use of human organs and tissue. Transplantation is one of a range of activities, which include post mortem examinations and medical research, regulated by this legislation. The Human Tissue Act 2004 establishes the Human Tissue Authority (HTA) as the regulatory body for activities involving the removal, storage, use and disposal of human material. The HTA also issues Codes of Practice and directions concerning the proper conduct of the activities within its remit.

The donation of organs in the UK is based upon the fundamental principle that explicit permission is required in law to retrieve organs for transplantation. In the 2004 Act this permission is consent while the 2006 Act uses the term ‘authorization’. Both Acts support an ‘opt-in system’<sup>2</sup> where individuals actively register their willingness to donate organs in the event of their death. Individuals may register online on the organ donor register or as part of driving licence application. These forms of consent are valid consent in law. Oral consent, relayed through third parties, is also valid consent. Individuals may also nominate a representative to consent on their behalf.<sup>2</sup> Where the wishes of the individual are not known, consent may be given by someone who stood in a ‘qualifying relationship’ with the person before death, according to a specified hierarchy.<sup>2</sup>

An alternative framework for donation is the opt-out system where removal of organs is lawful unless the individual registers his or her objection. The onus is therefore on the individual to actively ‘opt-out’. This system is in force in many countries in continental Europe. However, while there is empirical evidence of a positive association between an opt-out system and increased donation rates this conclusion has been approached with caution in the UK.<sup>2</sup> The correlation between the legal framework for donation and donation rates is not straightforward

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as there are many variables to consider when comparing systems in different geographical contexts. The impact of the introduction of the opt-out system in Wales will be scrutinized carefully.

Opt-out systems differ according to how they take into account the views of relatives. In most countries there is a 'soft' opt-out policy and relatives are consulted. The result is that organs will not be removed where they object, blurring the distinction between opt-in or opt-out systems.

### Brain stem death

The traditional definition of death as cardiopulmonary demise has been adapted to include death diagnosed by neurological criteria. The UK has adopted clinical criteria to determine brain stem death based on guidance from the Academy of Medical Royal Colleges.<sup>3</sup> As the diagnosis of death by neurological criteria became established there was a shift in reliance upon donation after brain stem death (DBD), also known as heart beating donation, which became the main procurement strategy for deceased donation. A significant advantage of DBD is that cardiorespiratory support is continued after death allowing donation to occur in almost optimal conditions of organ viability.

The whole system of organ donation in the UK is based on the principle of a living will. We ask people to state in life whether if they were to die in appropriate circumstances they would like their organs to be used for transplantation. This process is based on affording autonomy to the person's wishes in life, which are then carried over into death. If a representative had been nominated by the deceased, while they were competent, then that person can consent to organ donation. In the absence of this a qualifying relative can be used such as a spouse or partner. By their very nature deceased donors meet the requirements of non-maleficence.

### Circulatory death

Donation after circulatory death (DCD), also known as non-heart beating donation, refers to organ donation after death has been confirmed by cardiorespiratory criteria.<sup>3</sup> Cardiopulmonary criteria for the diagnosis of death were the basis for the original model of cadaveric donation programs in the UK and recent years have seen a revived support for DCD programs. This is, in part, a result of falling rates of brain stem death with improvements in neurocritical care. DCD has real potential to increase the number of organs available for transplant with acceptable outcomes for recipients.

Controlled DCD typically takes place in the intensive care unit setting and this allows for the implementation of measures to increase the chances of successful transplantation.

Ante mortem interventions constitute a *prima facie* harm to the individual as they are an invasion of the physical integrity of the patient. In the majority of DCD cases the potential donor is unconscious and lacks the mental capacity to express any wish to donate or object to organ donation.<sup>4</sup> In England and Wales any decision regarding the management of these patients falls under the Mental Capacity Act 2005 (MCA 2005) and must be in their 'best interests'. In Scotland the Adults with Incapacity (Scotland) Act 2000 applies where the term 'benefit' is used.

When deciding in the best interests of the patient, the wishes, values and beliefs of the person are taken into consideration. Interventions that confer no-clinical benefit can be lawful where they further the goal of organ donation, once it is established that organ donation was the wish of the person. This application of 'best interests' goes beyond mere clinical considerations and reflects the common law notion that 'broader ethical, social, moral and welfare considerations' are important. It accords with the position in Scotland, where the concept of benefit captures considerations which go beyond mere medical benefits. In practice, it is for the responsible clinician, generally the ITU consultant, to establish whether intervention will be in the patient's best interests and this involves concern for proportionality when weighing up the risks and benefits to the relevant parties.<sup>1</sup>

### The legal framework for donation from live persons

At an international level, the official stance has generally been to maximize deceased donation programs.<sup>5,6</sup> In practice, however, the shortage of deceased donors has resulted in living donation becoming accepted as the standard treatment for organ failure. The HT Act and the HT Scotland Act establish a presumption of illegality of live donation so that live donation is lawful only where certain requirements are met.<sup>2</sup> These requirements relate to consent to donation and the prohibition of payments or rewards. Consent to donation is subject to the common law doctrine of consent and the consent process is heavily regulated by the HTA.<sup>7</sup> Live donation was at first restricted to genetically related persons and has gradually expanded to include donations to persons who are neither genetically nor emotionally related. A person may make a directed or non-directed donation (often referred to as 'altruistic' donation).

According to World Health Organization data the majority of organs donated across the world come from living donors, although in the UK the annual numbers are similar. With regards to living donors the Human Tissue Act (2004) states that no reward can be given or will be given to the donor, lawful consent to donation must be obtained and an independent assessor must interview both the recipient and donor separately. A report must then be submitted to the Human Tissue Authority. It is an offence to remove any organ or part of an organ from a live donor unless all the requirements of the Act and Regulations are met. The living donor may direct an organ to a known recipient or can donate a non-directed organ. Non-directed, or altruistic organ donors cannot specify who can and cannot receive their organ.

Views of society change over time. Activities that are deemed legal today may be challenged in the future and practices that are currently deemed illegal may be legalized. Single events, campaigns, or technological advances may raise concern, highlight discrimination or demonstrate potential benefits. This can prompt debate and lead to changes in the process and practicalities of organ donation and transplantation. For example the Human Tissue Acts came about in part as a response to public outrage about pathology practices of tissue retention, with relatives successfully suing for legal damages. Changes to the Human Fertilisation and Embryology Act came about due to a combination of technical advance and public pressure. Living donation

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