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978-0-521-65164-6 - Legal and Ethical Aspects of Organ Transplantation

David Price

Excerpt

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INTRODUCTION

This is a book exploring the legal and ethical dimensions of the modern ‘miracle’ (or to some ‘false promise’¹) of transplantation: a hugely complex field of human endeavour. As an evolving and pioneering field of therapeutic pursuit it can only be described as dynamic, with even more potentiality than realised actuality. Yet, it is no ‘ordinary’ or conventional form of therapy. Youngner describes transplantation as ‘a unique way to affirm and share our humanity’.² Indeed, qualms themselves typically spring from the depths to which the procedure touches, as well as shares, our humanity. Its profundity is highlighted in the attention given to it in popular (science) fiction, historical, anthropological and religious writings, and folklore. To some, the lengths that it appears to take us in thwarting our natural span is deeply disconcerting. As Chadwick states, ‘Technological advances, however, along with the increase in the demand for cryonics, make us confront the question of what it means to live a human life, and the extent to which we should go in trying to prolong it.’³ Indeed, the translocation of body parts seems so largely commonplace today that one can forget its relatively very modern nature and capability, and its psychological and emotional significance for the ‘players’, as well as its ‘incredible’ intrinsic character. It has been reported for example that one domino heart transplant recipient in Britain actually raced against his

¹ Fox and Swazey have long maintained that the history of transplantation bears testimony to an over-aggressive pursuit of the possible without adequate consideration for the implications and societal costs of the widespread employment of such technological capacity: see R. Fox and J. Swazey, *Courage to Fail*, University of Chicago Press, Chicago, 1974 and *Spare Parts: Organ Replacement in American Society*, Oxford University Press, New York, 1992.

² S. Youngner, ‘Psychosocial and Ethical Implications of Organ Retrieval’ (1985) 313 *New England Journal of Medicine* 321 at 323.

³ R. Chadwick, ‘Corpses, Recycling and Therapeutic Purposes’ in R. Lee and D. Morgan (eds.), *Death Rites: Law and Ethics at the End of Life*, Routledge, London, 1994, 54 at 64.

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own heart (donee) in the British Transplant Games! It has been observed though that what is truly distinctive about transplantation is not technology or cost, but ethics, emphasising the unique and (virtually) utter dependence upon the participation of the public for its continued viability as a therapeutic option at all. These two aspects are of course interrelated. The balancing of the interests of the ‘giver’ and ‘receiver’ is the great challenge for those attempting to regulate in this sphere. The ‘technological imperative’ to keep pushing back the barriers can place enormous strains on our legal and ethical institutions and frameworks of analysis. Yet the huge therapeutic potential requires us to embrace and confront these questions. In short, the fundamental nature of transplantation in clinical, physiological and biological terms is entirely matched by its significance in legal, ethical, theological and cultural terms. The general human rights dimensions to many transplant practices are themselves highlighted by the long-standing involvement of organisations such as the Council of Europe⁴ and the World Health Organisation in this field.

‘Transplanting’ (that is relocating) organs from one individual human being to another is a creature of the twentieth century,⁵ which has (extraordinarily) quickly developed from an experimental and unproven strategy to becoming the treatment of choice for very many diseases and conditions today.⁶ In some instances it is the only available life-sustaining therapy, for example for certain types of end-stage cardiac and liver failure. Experimental transplantation (in animals) began to proceed apace in relation to vascularised organs in the early part of the twentieth century,⁷ and there were even very early attempts to transplant animal

⁴ The recent Council of Europe Convention also contains a specific section on transplantation: see Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine) finalised in 1996 and signed (in Orviedo) by twenty-one Member States on 4 April 1997, Article 19(2).

⁵ It is reported that over 5,000 years ago skin was transplanted to replace noses destroyed by syphilis in Egyptian and Hindu societies, and teeth have been transplanted, usually from servants, in former times, for example by John Hunter the ‘father of modern surgery’, in Scotland in the eighteenth century.

⁶ It has been recently stated that ‘Kidney transplantation is generally accepted as the primary therapy for chronic renal failure in most patients’: see N. Lefrancois and J. Touraine, ‘Living Kidney Donation: Preoperative Evaluation and Preparation for Surgery’ in G. Collins, J. Dubernard, W. Land and G. Persijn (eds.), *Procurement, Preservation and Allocation of Vascularized Organs*, Kluwer, Dordrecht, 1997, 3 at 3. Kidney transplantation is also the most cost-effective therapy when compared with alternatives such as dialysis.

⁷ In 1902, Emerich Ullmann carried out a kidney transplant from a dog to a goat. The kidney

kidneys into humans.⁸ The first human kidney allograft (between humans) was carried out in 1933 in the Ukraine by Voronoy but was unsuccessful.⁹ It was not until 1954 that the first successful transplant of an organ intended as a permanent ‘replacement’ occurred,¹⁰ when on the day prior to Christmas Eve, a kidney was successfully transplanted from one identical twin to another (his brother) by Dr Joseph Murray in Boston. However, limited accumulated physiological knowledge and experience, and the relative inability to control rejection,¹¹ conspired to make progress slow until the development of effective immunosuppressant agents (most notably cyclosporin) facilitated the rapid expansion of cadaveric transplantation in the eighties. The handful of (kidney) transplants performed in the fifties and early sixties has quickly turned into thousands each year at the advent of the new millennium. In the US alone in 1998 21,926 solid organ transplants were performed.

The first thoracic, liver and lung transplants occurred in the sixties, using cadaveric donors.¹² Most notably, the race to perform the very first human heart transplant was won by Christiaan Barnard in Cape Town, South Africa on 3 December 1967.¹³ Of course, the experimental nature of these procedures made them highly contentious and attracted criticism on ethical and legal bases. Other extreme innovations included xenotransplants, such as the transplant of a baboon’s heart into Baby Fae in 1984, and multi-organ transplants, such as Laura Davies’s second transplant in

even passed a little urine for a short while. A number of dog-to-dog transplants were performed at the same time.

⁸ In 1906, Jabouley (xeno)transplanted a kidney from a pig and goat respectively into human recipients and in 1909, Unger transplanted a kidney from an ape into a young girl dying of renal failure.

⁹ He apparently carried out a further five such transplants. All were unsuccessful. See P. Morris, *Kidney Transplantation: Principles and Practice*, 3rd edn, W. B. Saunders Company, Philadelphia, 1988, at 5–6.

¹⁰ The first attempted cornea transplant actually occurred in 1906, although the modern era of cornea transplantation did not begin until the fifties. Today, this is the most frequent form of surgical tissue transplantation performed.

¹¹ Which was why identical twin (syngenesious) transplants with tissue compatibility were attempted so frequently in the very early days.

¹² Thomas Starzl performed the first clinical liver transplant on a human in March 1963, but this was unsuccessful. He performed the world’s first successful procedure in 1967 at the University of Colorado. The first liver transplant in the UK was carried out by (now Sir) Roy Calne in May 1968. The first lung transplant took place in 1963: see J. Hardy, ‘The First Lung Transplant in Man (1963) and the First Heart Transplant in Man (1964)’ (1999) 31 *Transplantation Proceedings* 25.

¹³ In fact, an earlier, unsuccessful, transplant of a chimpanzee heart had been attempted into one Boyd Rush, in 1964 by Hardy.

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Pittsburgh, and they continue to occur today accompanied by the same controversies. At the very end of the millennium, controversy surrounded the first composite tissue allograft, a hand transplant from a cadaveric donor.¹⁴ Today, the range of transplantable body materials is mind-boggling, from hearts to intestines to corneas to brain tissue. The *sources* of such materials are also myriad, from the person's own stock, for example autologous blood or bone marrow extraction or skin patching; to the use of materials from other human beings, for example hearts, livers, kidneys, etc.; to materials of foetal origin, for example neurological tissue, islet (insulin-producing) cells;¹⁵ to organs and tissues from other species – some already occurring, such as the use of porcine heart valves and islet cells in humans, and others likely shortly to come into widespread use, for example transgenic pig organs; to artificial organs or tissues, for example artificial hearts, knee joints, etc. This book principally addresses *organ* transplantation by which is meant *solid* organ transplantation. It is appreciated that no bright dividing line exists between such organs and other human tissues in many of the relevant legal and ethical contexts. Moreover, caution is required in so far as there is no universally accepted definition of an 'organ' and some statutory definitions, for example that in the US National Organ Transplants Act 1984, include tissues such as bone marrow within their scope.¹⁶

Ironically, and unfortunately, transplantation has become a victim of its own success. In the US in 1998 patients had an average survival rate after five years of 80+ per cent for kidneys, 73 per cent for livers and 69 per cent for hearts.¹⁷ These results have in turn stimulated demand to the point where there are typically now (often woefully) insufficient numbers of donor organs for transplantation, compounded by an even wider class

¹⁴ One reason for the controversy was that this was supposedly a procedure performed solely to improve the patient's quality of life, although of course since dialysis was introduced this might also be said about the majority of renal transplants.

¹⁵ Their supposed advantage lies in their capacity for growth and differentiation and ability to establish necessary cellular connections in the new host as well as their lesser ability to induce rejection.

¹⁶ See further B. Dickens, 'Donation and Transplantation of Organs and Tissues' in I. Kennedy and A. Grubb, *Principles of Medical Law*, Oxford University Press, Oxford, 1998, 787 at 789–90.

¹⁷ See UNOS/OPTN Annual Report 1998 at <http://www.unos.org/Data/anrpt98/ar98>. Kidney patient survival rates will necessarily be the best as the failure of the grafted organ does not typically lead to death, due to dialysis, by contrast with most hepatic and thoracic graft failures. In the US, *graft* survival rates for kidneys at five years are 61 per cent for cadaveric kidneys and 76.6 per cent for living donor kidneys: *ibid*.

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of individuals becoming eligible recipients, for example elderly patients, a phenomenon which could be unremittingly repeated in the future. It was recently remarked that ‘a critical shortage of donor organs is the single greatest impediment facing transplant programs around the world’.¹⁸ There are, however, developments being heralded as placing us on the verge of a panacea for the shortage. Most notably, animal-to-human transplants (xenotransplants) may soon become a customary feature of the transplant landscape, supported as they are by extremely substantial business investment.¹⁹ Indeed, the possibility of breeding animals specifically for the purpose creates the prospect of transplanting not only those already waiting for a transplant but also those who are currently not placed on waiting lists for organs due to the shortage.²⁰ However, Fox and McHale have suggested that ‘the legitimate boundaries of such [transplant] technology may now have been reached’.²¹

Two series of xenotransplants were performed in the sixties in the United States. In 1963–4, six patients received kidneys from chimpanzees and a further six from baboons. Patient survival times were extremely limited indeed, apart from one recipient of a chimpanzee kidney who survived for nine months.²² Since these procedures, only a handful of xenotransplants have been performed, most notoriously the transplant of a baboon’s heart into Baby Fae in 1984. Germany and Sweden still have voluntary moratoriums on xenotransplants.²³ The new era of xenotransplantation will witness not only tighter controls over the conduct of these procedures however, but also a more comprehensive regulatory framework to oversee their practice. The precise nature of this regulatory structure will vary from state to state. In the UK a new statutory authority is anticipated, and meanwhile a temporary standing body, the United

¹⁸ C. Wight *et al.*, ‘Donor Action: A Systematic Approach to Organ Donation’ (1998) 30 *Transplantation Proceedings* 2253 at 2253.

¹⁹ The market is estimated to be of the order of \$6 billion per annum, and \$100 million is estimated to have already been invested in research and development in xenotransplantation.

²⁰ Of course, this might raise acute cost considerations, especially as, unlike human organs, animal organs would not be free at the point of delivery.

²¹ M. Fox and J. McHale, ‘Xenotransplantation: The Ethical and Legal Ramifications’ [1998] 6 *Medical Law Review* 42 at 42.

²² See A. Caplan, ‘Ethical Issues raised by Research involving Xenotransplantation’ (1985) 254 *Journal of the American Medical Association* 3339 at 3340.

²³ In view of the risks from disease transmission, some observers have recommended a worldwide moratorium: see Fritz Bach *et al.*, ‘Uncertainty in Xenotransplantation: Individual Benefit Versus Collective Risk’ (1998) 4(2) *Nature Medicine* 141, and J. Hughes, ‘Xenografting: Ethical Issues’ (1998) 24 *Journal of Medical Ethics* 18.

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Kingdom Xenotransplantation Interim Regulatory Authority, has been established to monitor moves towards initial clinical trials. The British approach to xenotransplantation during the nineties was cautious. The Nuffield²⁴ and Kennedy²⁵ Reports recommended that clinical trials not take place until further research had been conducted, that clinical trials should then take place in selected instances and that even this would not necessarily presuppose a move to a therapeutic programme. It was their view that there was limited evidence relating to transplant function, organ growth and the functioning of the recipient's immune system.²⁶ The UK Government has also announced that no clinical trials may proceed until it is 'fully satisfied' that the risks are acceptable.²⁷ In the US in 1996, the FDA joined the Centers for Disease Control and Prevention and the National Institutes of Health in drawing up a Draft Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation.²⁸ This replaced the more ad hoc approach which previously prevailed, which relied heavily upon approval by local Institutional Review Boards (IRBs).²⁹ There is, however, a concern that some countries with relatively lax controls will be viewed by scientists and companies as attractive 'turf' for experimental xenotransplants. The desirability of minimum universal standards of regulation has prompted the Council of Europe to issue a Draft Recommendation on Xenotransplantation.³⁰ In the UK, legislation has been proposed to regulate this field. This should provide a framework for guidance for clinicians as well as public reassurance. In 1997, an Indian cardiac surgeon performed a transplant using a pig's heart and

²⁴ Nuffield Council on Bioethics Working Party, *Animal-to-Human Transplants*, Nuffield Council on Bioethics, London, 1995, at para. 7.7. This was also the view of the British Medical Association: see 'The Ethics of Xenotransplantation: The BMA's Views', BMA, London, May 1996.

²⁵ A Report of the Advisory Group on the Ethics of Xenotransplantation, *Animal Tissue Into Humans*, Department of Health, 1997, at 4.50.

²⁶ *Animal Tissue Into Humans*, at 4.50.

²⁷ J. Warden, 'Xenotransplantation Moves Ahead in UK' (1998) 317 *British Medical Journal* 365.

²⁸ 61 Fed. Reg. 49,920 (1996). See also J. Kress, 'Xenotransplantation: Ethics and Economics' (1998) 53(2) *Food and Drug Law Journal* 353.

²⁹ See F. Morgan, 'Babe the Magnificent Organ Donor: The Perils and Promises Surrounding Xenotransplantation' (1997) 14 *Journal of Contemporary Health Law and Policy* 127 at 144. In 1995 the FDA and relevant IRB approved a bone marrow transplant of baboon tissue into a patient with AIDS (baboons being resistant to the disease). The bone marrow failed to engraft, but no harm, including infection, apparently resulted from it.

³⁰ Draft Recommendation No. R(97) of the Committee of Ministers to Member States on Xenotransplantation.

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lungs, and was arrested apparently because there was no legislation specifically authorising the procedure.³¹

There are also major initiatives in the fields of tissue engineering and cloning taking place which promise to have a major impact on transplantation in the future and may soon 'overtake' contemporary cutting edge strategies such as xenotransplantation.³² Corneal and skin tissue have been grown in laboratory conditions as has a tissue-engineered bladder,³³ and it has been suggested that in a short time such cell cultures will be able to be used to grow organs for transplantation, although the complexities involved are much greater than with other non-vascularised grafts. Bone, cartilage and ligaments have already been grown, as has a human thumb (around a coral infrastructure), and there are presently attempts being made to grow a human ear.³⁴ Alternatively, cloning may be used to facilitate xenotransplants themselves, with reports being published of the first successful cloning of piglets in March 2000.³⁵ The history of the use of *artificial* organs, primarily hearts, has been chequered to say the least, especially with 'permanent' whole replacement organs. However, research still proceeds. Most success has been obtained with using left ventricular assist devices (LVADs), and with procedures such as the fitting of a temporary 'bridging' device, the Jarvik 2000 artificial heart, into a ten-year-old boy in 1998 in Oxford, which maintained him sufficiently to enable him to receive a human heart transplant five days later.³⁶ Scientists are now working on producing artificial muscles as well as an artificial pancreas, which could be implanted in the patient's abdomen releasing a steady flow of insulin as required and removing the need for daily injections. However, despite their 'promise', whether such procedures will be able to be converted into an everyday clinical reality from experimental

³¹ G. Mudur, 'Indian Surgeon Challenges Ban on Xenotransplantation' (1999) 318 *British Medical Journal* 79. The man died seven days after the procedure, from multiple infections. The doctor was released from arrest and is suing for damages for wrongful arrest.

³² See J. Savelescu, 'Should We Clone Human Beings? Cloning as a Source of Tissue for Transplantation' (1999) 25 *Journal of Medical Ethics* 87.

³³ See J. Tanne, 'Researchers Implant Tissue Engineered Bladders' (1999) 318 *British Medical Journal* 350.

³⁴ See 'The Child who Hopes she can Grow a Second Ear', *The Times*, 15 April 1998. A human ear was attached to the back of a mouse in an infamous televised experiment fairly recently.

³⁵ Five female cloned piglets were born on 5 March 2000 in Virginia, US: see *The Times*, 15 March 2000.

³⁶ See 'Boy First to be saved by New Artificial Heart', *The Times*, 17 June 1998.

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procedures undertaken in the laboratory is yet to be seen, although they remain pleasing visions on the horizon.

Organ transplantation is practised in North America, in virtually all European nations, most South American and Middle Eastern nations, various Asian countries³⁷ and a handful of African nations. Of course, transplantation operates within the broader prevailing cultural and societal milieu in these different jurisdictions, which may lack homogeneity even within a single region. It would seem that an ethical pluralism must exist not only between sovereign states but also within them. In other words ethics are culturally relative rather than universal. Societies still differ to some degree, for instance, as to the appropriate standard for determining that a person is legally dead, with tensions which impact upon organ procurement practices. The major shift towards brain-based standards remains controversial whilst, paradoxically, transplant protocols relying (supposedly) upon traditional (cardiopulmonary) measures of determination have attracted the most criticism of late. Religious perspectives and beliefs have substantially influenced transplant laws and policies in various societies, as have the socio-economic circumstances prevailing: for instance, perceptions as to the legitimacy of commercial practices in organ procurement. The lack of access to transplantation modalities to avoid death or severely decreased quality of life through end-stage organ failure in a specific population will also create effects elsewhere. Transplantation is a *global* pursuit, and a failure to meet critical health needs in one region will drive individuals to seek alternative options elsewhere. 'Transplant tourism' is an increasing phenomenon with vendors from poorer nations in effect subsidising the health care of patients from richer countries, and patients seeking access to waiting lists of other sovereign states.

Views on many aspects of transplantation are influenced by perspectives upon the significance of 'embodiment', the concept of 'self' and how parts of the body relate to the whole (merology). These issues in turn beg questions as to whether a dualist or monist perception of the 'self' and the body is most appropriate. If the body is merely instrumental to our ends,³⁸ as Fletcher and Engelhardt for instance would have it, then

³⁷ A Report of the Asian Transplant Registry recently revealed that seventeen Asian countries have active organ transplantation programmes: see K. Ota, 'Asian Transplant Registry' (1999) 31 *Transplantation Proceedings* 205.

³⁸ Or as Plato put it, 'a temporary tomb' in which the soul is forced to dwell: see Plato, *Phaedo*

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continued functioning of the body is morally insignificant, so that death may properly be declared despite the continued working of lower brain and various vegetative functions. Moreover, there is no reason why one should not be able to sell body parts, as with most anything else which belongs to us, that is our property. Indeed, not only does the prospect of sale of body organs assume *property*-based conceptions of parts of the human body, but maybe even ‘donating’ body parts implies the same. On the other hand, if the body itself forms part of the self it *is* the individual and not separate from him/her so that its continued functioning is incompatible with a declaration of death or, *prima facie* at least, with selling parts of it. Issues also arise as to the relationship that *others* enjoy with regard to one’s body or parts thereof, especially one’s cadaver. Whilst the corpse has traditionally been viewed as *res nullius*, property rights have sometimes been accorded to third parties in respect thereof. But can we spy some ambivalence here, arguably inherent in the judicially created concept of ‘quasi-property’ rights? Moreover, can individuals and institutions undertaking transplantation properly protect their possession of the cadaver for that purpose or be held to account themselves for improper use without the adoption of some notion of property rights in the human corpus?

Objections to selling body parts for transplantation are most commonly voiced independently of the issue of ‘property rights’, however, and instead insist that the donation of organs should be based on *altruism*. However, this partially depends upon what one means by the term ‘altruism’, and this itself proves to be a source of ambiguity and confusion. Some would argue that some forms of payment connected to organ procurement are not in any event incompatible with altruism. Regardless, is an act of organ transfer any less acceptable for being induced by financial reward than if it were altruistically inspired? There are both deontological and consequentialist objections to organ trading, however, albeit principally emanating from intuitiveness, which require rebutting. In the sixties, Richard Titmuss directly contrasted altruistic and paid blood donation systems on different sides of the Atlantic and stridently declared the virtues of the former model of procurement. Assuming the legitimacy of these findings though, one cannot merely presume that these

(R. Hackforth trans.), 1955, cited in T. Murray, ‘On the Human Body as Property: The Meaning of Embodiment, Markets, and the Meaning of Strangers’ (1987) 20 *Journal of Law Reform* 1055 at 1062 n. 27.

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consequentialist concerns carry over to organ donation. It may also be that the alleged gravamen of commerce is not only relative, but also a function of whether it relates to living providers or cadaveric sources.

Difficulties of other kinds stem from the lack of clarity as to the concept of 'altruism'. Insistence on supposedly 'disinterested' motivations has led to tensions in relation to non-genetically related donors, who have sometimes been rejected on the basis of an assumption that either they were self-interested (that is were being covertly paid) or they were psychologically maladjusted. This has tended to result historically in living donation being confined almost entirely to living genetically *related* donors, a trend which has only fairly recently been broken. But this in turn poses the question whether living related donors always act entirely 'disinterestedly', and even what we mean by 'self-interestedness' in the first place. Contrariwise, objections have been raised to the insistence that 'donation' by incompetent persons (such as minors) be based on their 'best interests', which implies the need for self-interested motivations or effects. But whilst egoism is at odds with altruism, can it properly be said that acts are either altruistic or self-interested, but not both?

The removal of organs for transplantation purposes clearly involves a degree of physical damage and permanent destruction of the human body, which would constitute an 'injury', in ethical terms, if the intended use of the tissue were not ethically acceptable and appropriate. A Nuffield Council Working Party Report considered that the actual transplanting of organs was justified by the intention to avoid greater injury, and that the *removal* of tissue for therapeutic purposes was also ethically legitimate,³⁹ because 'It is clear that there is a close relationship between the lawfulness of the removal and the lawfulness of any subsequent use of the tissue: the propriety of the use largely determines the legality of the removal.'⁴⁰ In fact, the duty not to injure a person in a morally unacceptable way is elevated by the Nuffield Report even above the principle of autonomy, although the latter may also be a necessary feature of a morally acceptable act. But questions are then begged by how one determines the existence of injury in a context such as organ donation, where application of the concepts of non-maleficence and *primum non nocere* is itself a good deal less than obvious or straightforward. It is also left uncertain whether

³⁹ Nuffield Council on Bioethics Working Party, *Human Tissue: Ethical and Legal Issues*, Nuffield Council on Bioethics, London, 1995, at paras. 6.5 and 13.34.

⁴⁰ *Ibid.*, at 65.