

Unrelated living organ donation: ULTRA needs to go

S Choudhry, A S Daar, J Radcliffe Richards, R D Guttman, R Hoffenberg, M Lock, R A Sells, N Tilney

J Med Ethics 2003;29:169–170

The recent review of the Unrelated Live Transplant Regulatory Authority (ULTRA) provides administrative and statistical information regarding living donor kidney transplantation in the United Kingdom.¹ However, it leaves much unsaid. For example, although the report does mention the number of live kidney donations from unrelated donors that ULTRA has approved, (69 in 2002; S Pioli, personal communication, 2001) it fails to mention that the United Kingdom has a low live kidney donation rate compared with other European countries (in 1999, 5.3 kidney donors per million population in the UK; 8.7 in Switzerland, 11.5 in Sweden, 24.6 in Norway).² More importantly, the report does not address the fundamental question of whether the legal framework underlying ULTRA is morally justified. The legal regime in the United Kingdom proceeds on the tacit assumption that genetically unrelated donors are much more vulnerable to coercion than are related donors, and hence are more in need of protective regulation. In this article, we argue that the distinction drawn in the United Kingdom between genetically related and unrelated donors is difficult to justify, that it unnecessarily discourages live organ donation, and that the law should be changed.

BACKGROUND

The Unrelated Live Transplant Regulatory Authority is a creature of the Human Organ Transplant Act (HOTA), which was enacted by parliament in 1989, and which came into force, with regulations, on 1 April 1990.^{3,5} The Human Organ Transplant Act was enacted hastily after the General Medical Council's inquiry into the notorious case of a British physician's involvement in transplants involving Turkish peasants.⁶ Young men were inveigled by an agent to travel to London, ostensibly to take up new jobs. In fact, they were being recruited as living donors of kidneys transplanted into fee paying foreign patients. The consequent debate in the media attracted an emotional outcry at the perceived exploitation of innocent young men and repugnance that rampant commerce in kidneys, decried internationally, had surfaced in London. The inquiry revealed evidence of dishonesty, exploitation, and commercialism and the nephrologist (Dr Crockett) was struck off the register. The media outcry led the government to immediate legislation.

The Human Organ Transplant Act has two key components. First, it creates a series of criminal offences, the combined effect of which is to prohibit commercial dealings in human organs, whether procured from cadavers or from live donors. Thus HOTA makes it an offence for an individual in the United Kingdom to make or receive payments for the supply of, or for an offer to supply, an organ for transplant into another person, whether in the United Kingdom or elsewhere, and also attaches criminal consequences to participating in the chain of distribution—for example, it is an offence to act as a broker who negotiates the sale of an organ. Second, HOTA focuses on live organ donations, and generally makes it an offence either to remove an organ from a living donor or to transplant an organ from a living donor into another person, unless the

recipient and donor are genetically related. The Human Organ Transplant Act provides a list of persons to whom an individual is deemed to be genetically related: biological parents, children, siblings (including half siblings), and nephews and nieces.

But HOTA authorises the secretary of state to create an exception to the ban on unrelated live organ donation through regulations. Such an exception is created by The Human Organ Transplants (Unrelated Persons) Regulations⁴ which lift the prohibition against unrelated living donation under certain conditions. The most important are that (a) no payment has been or will be made, and (b) the donor's consent was not obtained by coercion or the offer of an inducement. The regulation also creates ULTRA, and charges it with the task of ensuring that these conditions have been complied with in each case of unrelated live organ donation. If ULTRA is not satisfied that these conditions have been met, the donation cannot take place.

Finally, HOTA provides that persons shall be treated as not genetically related unless the fact of their relationship has been established. The procedures for making this determination are spelled out by The Human Organ Transplants (Establishment of Relationship) Regulations.⁵ These regulations require that the fact of a genetic relationship must be based on one of a series of tests—for example, HLA (human leukocyte antigen) and DNA typing. Unlike the regulations governing unrelated donors, the related donor regulations do not provide for a determination of whether a payment has been made to relatives, although the general ban on organ sales still applies. More importantly, the related donor regulations neither provide for the determination of whether the consent of the genetically related donor has been freely given, nor create a supervisory authority analogous to ULTRA. In the absence of any explicit statutory provision, the background common law rules on consent to medical treatment apply.

THE REAL PROBLEM

The provisions of HOTA and the accompanying regulations suggest that there are two principal goals underlying the regulation of live organ donations in the United Kingdom. First, live organ donations must not be paid for beyond allowable expenses. Second, live organ donations should be uncoerced. Here we focus on the second objective which, we fully agree, is not only appropriate, but should be a central goal of any system of live organ donation. Our concern, however, is with the way that HOTA and the accompanying regulations seek to achieve this goal. The Human Organ Transplant Act could have achieved this goal by imposing a ban on all living donation in cases where consent is coerced, and by making some competent entity—for example, a hospital ethics committee, responsible for determining whether there had been coercion. Instead, HOTA draws a categorical distinction between genetically related and unrelated donors, and provides for the determination of whether there has been coercion for the latter, but not for the former. Coercion is in effect presumed for genetically unrelated donors, because

ULTRA must be convinced that there has been no coercion, putting the burden of proof against genetically unrelated donation.

Since the purpose of HOTA is to ensure that organ donation is not coerced, the fact that it subjects unrelated donors to more rigorous procedures than related donors presupposes that the former are more likely to be coerced and more in need of protective regulation than the latter. Defenders of HOTA have not, however, offered any evidence for this assumption. Moreover, we believe it extremely unlikely that such evidence could be given, for two reasons:

First, HOTA proceeds on the assumption that different kinds of pressures apply in different kinds of relationships and in particular that the relevant distinction to be drawn is that between genetically related and unrelated persons. It seems wrong, however, to make genetic—as opposed to emotional—relatedness the relevant distinction. For example, the line drawn by HOTA has the odd result of grouping spouses and friends of live organ donors with other genetically unrelated donors. But if the point of the distinction is to treat differently complete strangers and those persons in a close relationship with the recipient, spouses and family members should be grouped with the latter, not the former.

Second, even if HOTA drew the line in the right place, it would still be flawed, because there is more scope for coercion within close relationships than there is for coercion by strangers, which is the reverse of what HOTA assumes. Outright force and threats are unlikely to be used by outsiders, and if they were, they would be quickly identified by any competent transplant team. By contrast, there is endless scope for subtle pressure within families and among friends, as is recognised by the transplant teams who try to assess the willingness of related donors. Although the family is idealised as an intimate sphere where relatives act willingly and selflessly to promote each other's interests, it may be characterised by relationships of power and subordination that can be abused, making consent more apparent than real. In addition, even in the absence of unequal power relationships, affective bonds between family members are open to manipulation or exploitation, creating the potential for pressures to consent to organ donation.^{7,8}

It may be said that donation is more likely between related than unrelated individuals and that the distinction between genetically related and unrelated donors drawn by HOTA is an indirect means of prohibiting organ sales. But this objective is already dealt with by the prohibitions on commercial dealings in human organs. The distinction between genetically related and unrelated donors is therefore neither necessary nor sufficient to achieve this end.

In short, the distinction in HOTA between genetically related and unrelated donors is manifestly unjustifiable because it is a totally inadequate proxy for the underlying and ethically justifiable distinction between free and coerced donors.

THE WAY FORWARD

Laws governing transplants in other European countries and America do not obstruct genetically unrelated donations in this way. Indeed, other professional organisations have called for additional protective regulation for unrelated donors. The *Consensus Statement on the Live Organ Donor*, issued by a coalition of organisations in the United States—for example, does not distinguish between related and unrelated donors in the manner that HOTA does.⁹ A result is that genetically unrelated donations constitute a significantly larger proportion of total transplants in many European countries and in North America than in the UK,¹⁰ and apparently without problems. In fact, the recent trend, particularly in North America, has been to accept and encourage live organ donations even by altruistic strangers (so called “good Samaritan donors”¹¹). The Unrelated Live Transplant Regulatory Authority discourages this type of donation

The British Medical Association has also criticised the distinction between genetically related and unrelated donors, but has proposed that the ULTRA regime be extended to genetically related donors as well.¹² We believe this is misguided. Although we share the BMA's concern that live organ donations be free and uncoerced, there are two reasons why it has failed to make a convincing case for extending the regime of protective regulation. First, the argument for a centralised system of review vested in ULTRA is weak. The experience from North America and Europe—for example, is that all living organ donation can be managed effectively by transplant centres alone. Second, the BMA's proposal would effectively entail a legal presumption that even living related donations are coerced. This presumption is unwarranted, and may have the unfortunate consequence of preventing uncoerced and life saving procedures from taking place.

In our view, ULTRA should be abolished, rather than extended to related donors, and HOTA should be amended to remove the distinction between related and unrelated donors. The Human Organ Transplant Act should also be amended to impose a ban on all living organ donation in cases where consent has not been freely given and to give the responsibility for determining that no prospective donors are coerced to a hospital committee specifically charged with this task.

FUNDING

The International Forum for Transplantation Ethics (IFTE) is a multinational, interdisciplinary group that examines social and bioethical issues in transplantation. Funding for IFTE is administered by the Liverpool Kidney Transplant Fund (LKTFF), a registered charity. Donors have included the North West Regional Health Authority, Novartis Pharma, Fujisawa Pharmaceuticals Ltd, Roche Pharma, and Vaccins Pasteur Merieux. The donors have no input into IFTE's discussions or publications, neither does IFTE represent or favour any corporate interest. International Forum for Transplantation Ethics members do not receive remuneration

Authors' affiliations

S Choudhry, A S Daar, J Radcliffe Richards, R D Guttman, R Hoffenberg, M Lock, R A Sells, N Tilney, International Forum for Transplantation Ethics, Royal Liverpool University Hospital, Liverpool, UK

Correspondence to: Professor R A Sells, International Forum for Transplantation Ethics, Royal Liverpool University Hospital, Liverpool, L7 8XP, UK; robert.sells@rlbuh-tr.nwest.nhs.uk

Accepted for publication 12 January 2003

REFERENCES

- 1 Department of Health. *Review of the unrelated live transplant regulatory authority*. London: DoH, 2000.
- 2 Anon. Council of Europe [editorial]. *Fundacion renal*. 2000;5:18–19.
- 3 *The Human Organ Transplant Act 1989*. London: HMSO, 1989.
- 4 *The Human Organ Transplant (Unrelated Persons) Regulations*. London: HMSO, 1989. (No 2480.)
- 5 *The Human Organ Transplant (Establishment of Relationship) Regulations*. London: HMSO, 1989. (No 2107.)
- 6 Radcliffe Richards J. Nepharious goings on: kidney sales and moral arguments. *J Med Philos* 1996;21:375–416.
- 7 Biler-Andorno N, Schauenburg H. It's only love? Some pitfalls in emotionally related organ donation. *J Med Ethics* 2001;27:162–4.
- 8 Simmons R. Family tension in the search for a kidney donor. *JAMA* 1971;215:909–12.
- 9 Live Organ Donor Consensus Group. Consensus statement on the live organ donor. *JAMA* 2000;284:2919–26.
- 10 EUROTOLD. European multicentre study. *Transplantation of organs from living donors*. Brussels: Commission of the European Union, 1997: 59.
- 11 Matas AJ, Garvey CA, Jacobs CL et al. Non-directed donation of kidneys from living donors. *N Engl J Med* 2000;343:433–6.
- 12 British Medical Association. *Organ donation in the 21st century: time for a consolidated approach*. London: BMA, 2000.