Addressing the organ shortage: presumed consent and xenotransplants Vijay Rajput

The transplantation of organs is a triumph of modern medicine. Kidney transplantation provides a longer life expectancy and better quality of life than maintenance with dialysis does. Successful liver and heart transplantation are life saving. However, there is a wide gap between the need for organs and their supply. In 1999, 6,448 people in the USA died while waiting for an organ transplant; 3088 were for kidneys and 1,767 for livers (1).

The organ shortage is due not to a lack of potential donors, but rather to a failure to turn potential donors into actual donors —"a paradox of shortage in the face of plenty."(2) Our system of organ procurement is clearly inadequate.

Transplantation is physically possible because of an intricate biological inherence, with varying degrees of compatibility, between members of the human species, and given technical advances, between humans and some non-human species. It becomes an ethical option on the basis of conventions, using moral reasoning and grounded in altruism, reconciling the claims of bodily integrity with the claims of others in need, in a non-exploitative manner (3).

The ethics of transplantation can be expressed in certain requirements. The first is medical integrity. Patients and the public must be able to trust their doctors not to sacrifice the interest of one to that of another. Individual may make that sacrifice, but not their doctors. The second requirement is scientific validity: the basic biology and technology must be sufficiently assured to offer a probability of beneficial outcome, case by case. The third is consent, based upon information adequately presented, weighted and understood, and unforced.

The collection and use of human body tissue — from 18th century practices of dissection to 20th century organ transplantation — have evoked various concerns: about the use of body parts without consent; the psychological, social and religious impact of breaking down bodily integrity; and the potential exploitation of individuals who are the sources of organ and tissues. Physicians and scientists have been accused of profiteering, insensitivity to the emotions of patients or family members, and secrecy about unseemly practices as they sought out cadavers and body parts (4).

Presumed consent

The ethical basis of donation is consent. Consent to donation may be explicit or presumed. If not given explicitly by the deceased beforehand, it may be given by proxy under conditions set out by law, regulation and professional practice. Proxy consent will not suffice for a live donation, except — perhaps — bone marrow, from a child. Proxy consent gives the relevant organisations liberty to exact

Dr Vijay Rajput, assistant professor of medicine, UMDNJ-Robert Wood Johnson Medical School, 401 Haddon Avenue, E&R Bldg., Room 242, Camden, NJ, 08103, USA. Email: rajputvk1@home.com material unless the source has expressly refused to donate, in prescribed form, in advance. Explicit consent *may* also permit donation even if it is to our own detriment.

Over 30 years ago, Dukeminier and Sanders said, "The legal rule should favor removal of cadaver organs and preservation of life; the exception should permit objection and decay."(5) The suggestion was opposed with the argument that presumed consent discards the principle of autonomy and voluntary donation and thus would not supported by the public. Furthermore, every member of the public would have to be informed of the proposal in order to have opportunity to object. Despite these objections, today some countries have a system of presumed consent to organ donation. All citizens agree to become organ donors unless they have actively taken steps to indicate that in the relevant circumstances they would not wish to do so. It is felt that this system results in a greater availability of organs for transplantation.

Presumed consent can be criticised because those who are unable, or too slow, to take the necessary steps to opt out may later have their organs used in violation of their wishes. As a result of this argument, a number of countries do not have presumed consent.

Presumed consent is based on the following argument. Doctors and families surely expect patients to permit a transplant if it was in their best interest. Likewise, most persons would accept an organ transplant if their condition required it. If we assume this, why do we not accept — in the absence of positive evidence — that most persons would be prepared to donate their organs on their death? The justification for this asymmetry of inference seems to be that there is no interdependent relation between donor and recipient: the recipient depends on the donor, and not vice versa. However, before any particular person is identified as either a donor or a recipient, all people are interdependent as potential donors or recipients. An opting out system recognises this potential interdependence while ensuring the right to individual exceptions. (6)

However, if a person has not opted out of organ donation, at the time of death, the system must also take into account the wishes of the deceased's relatives, who may refuse removal of the organs. Such wishes are respected — though they may seem weak against the claims of the person in need of a transplant — consistent with WHO recommendations. On the other hand, in Singapore, the Human Organ Transplant Act presumes consent to kidney donation in the absence of written refusal, and family consent is not required.

In such a system, when people refuse consent to organ donation on religious grounds, they become free riders in the system, predisposed to benefit without ever consenting to contribute. In practice, 'free riders' needing organ transplant may be discriminated against in the allocation of organs. Singapore has adopted a controversial set of incentives and disincentives, with those who consent to donation getting priority access to kidneys over those who refuse. This raises questions of coercion and discrimination. The humanitarian and altruistic principles behind organ donation may be undermined by a law which tends to foster spirit of self-interest in some donors. (7)

It is difficult to overcome some of ethical problems associated with presumed consent. Conceivably, it is a violation of the principle of consent to assume an altruistic motive to donate organs. The response has been to presuppose self-interest, combined with the concept of interdependence and obligation. Singapore also held a public awareness campaign before the law was passed, and ensures careful implementation, though it has not been able to respond to the charges that incentives and disincentives are coercive.

Xenotransplantation

Each new announcement of medical progress calls forth a sense of hope, even urgency. What sickness might soon be cured? Whose lives might be saved? What critical knowledge might be gained? The seduction of medical progress can tip the balance of careful public policy consideration.

Xenotransplantation raises a host of complex issues, challenging division between individual and public health, human and animal identity and welfare and scientific progress and public concern about risk.

Despite the immunological hurdles, animal organs appear to offer the best solution to an inadequate supply of donor organs. The pig has been identified as a potential donor, its advantage being its availability in large numbers, ease of breeding and maintenance under gnotobiotic or pathogenfree conditions, and its more likely public acceptance, as it is already an accepted food source (8).

The crucial distinction between pigs and primates is made to rest on the presumption of the latter's greater capacity of suffering. The conclusion is that the harm to pigs is not so unjustifiable as to make their use unacceptable in principle. The ethical acceptability of the use of the pig then becomes a matter of balancing the potential benefits to the human against the harm involved to the pig (9).

The overlapping capacities of humans and other animals is often advanced as an argument against the use of animals in, for example, medical research. Other such as RG Frey have argued that in fact this aspect makes experimentation on animals too valuable to do without. Frey goes so far as to suggest that the use of severely mentally impaired humans as experimental subjects (10). In the area of transplants, this could mean mentally impaired humans should be used for their organs.

The infectious disease risk of xenotransplants poses a problem for the recipients of organ transplants and the public at large if they create an epidemic of a new infectious disease in humans. Two years ago the risk of disease spread by pig to human transplants was so worrisome that the US FDA placed a hold on ongoing clinical trials. Several developments since then suggest that there is no appreciable current evidence of porcine endogenous retroviral infection in human recipients of xenotransplants.(11)

The main ethical issue raised by these risks is that of consent. The US Department of Health's reports recommend that early xenograft be offered only to competent adults who make an informed choice to accept such transplants. The reports recommend that patients who refuse xenografts should remain eligible for human organs on the same basis as before (12).

The issue of reallocating resources is not specific to xenotransplants, but raises the same problem as the introduction of any other new and experimental treatment: predicting future costs and benefits and ensuring effective and equitable use of resources. The question here is whether xenotransplant would be a better or worse use of resources than the available alternatives. Xenotransplants as bridges to allotransplants might improve some patients' survival chances and quality of life. They could also serve as definitive treatment for some groups of patients who are excluded from allotransplant waiting lists.

Conclusion

From a moral standpoint, the social context in which any law — or medical practice — is to operate must be considered when determining policy. A law on presumed consent can follow informed public debate and a demonstration that it would be morally acceptable to most people. Most objection to change would be mitigated by public education.

Presumed consent must be explored before resorting to xenotransplantation. It would avoid, or at least postpone, the risk of transmitting infectious disease from animals to the human population. However, it is not known if such measures would be sufficient to close the organ gap.

References:

1. United Network for Organ Sharing: unpublished data, May 6, 2000

2. Bart KJ, Macon EJ, Whittier FC, et al. cadaveric kidneys for transplantation: a paradox of shortage in the face of plenty. *Transplantation* 1981;31:379-82

3. Dunstan, GR. The ethics of organ donation. *British Medical Bulletin* 1997; 53 (4): 921-939

4. Andrews L, Nelkin D. Whose body is it anyway? Dispute over body tissue in a biotechnology age, *Lancet* 1998; 351:53-57

5. Dukeminier J Jr., Sander D. Organ transplantation: a proposal for routine salvaging of cadaver organs. *N Eng J Med.* 1968; 279: 413-9

6. Eaton S, The subtle politics of organ donation: a proposal. *Journal of Medical Ethics*, 1998; 24: 166-170

7. Bernard Teo. Organ for Transplantation: The Singapore Experience. *Hastings Center Report*, 1991; November-December: 10-13

8. Cooper DKC, Ye Y, Rolf LL, et al: In Cooper DKC, et al (eds.): *Xenotansplantation*. Heidelberg, springer, 1991, p481

9. B. Brophy. 'In the pursuit of a fantasy' in S. Godlovitch and J. Harris (Eds.), *Animals, Men and Morals* (Victor Gallancz) **place of publication and year?** 124-45

10. Frey RG. Medicine, animals experimentation, and the moral problem of unfortunate humans. *Social Philosophy and Policy*. (1996) 4019 55

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11. Patience C. et al. No evidence of pig DNA or retroviral infection in patient with short-term extracorporeal connection to pig kidneys. *Lancet* 1998;352:699-701