Ethical guidelines for the evaluation of living organ donors

Linda Wright, MHSc, MSW;* Karen Faith, MEd, MSc;* Robert Richardson, MD;† David Grant, MD‡

Transplantation is an effective, life-prolonging treatment for organ failure. Demand has steadily increased over the past decade, creating a shortage in the supply of organs. In addition, the number of deceased organ donors has reached a plateau.

Living-donor transplantation is increasingly an option, influenced by favourable clinical outcomes and increased waiting times at most transplant centres across North America. Living-donor kidney transplants have exceeded deceased-donor transplant rates at some centres.

Organ donations from living donors have challenged transplant programs to develop a framework for determining donor acceptability. After a multidisciplinary consensus-building process of discussion and debate, the Multi-Organ Transplant Program of the University Health Network in Toronto has developed ethical guidelines for these procedures. These proposed guidelines address ethical concerns related to selection criteria and procedures, voluntariness, informed consent and disclosure of risks and benefits to both donor and recipient.

La transplantation constitue un traitement efficace pour remédier à la déficience d'un organe et prolonge la vie. La demande augmente régulièrement depuis une dizaine d'années, ce qui crée une pénurie d'organes. Le nombre de donneurs d'organe décédés s'est en outre stabilisé.

Les résultats cliniques favorables et l'allongement des périodes d'attente dans la plupart des centres de transplantation en Amérique du Nord poussent à envisager de plus en plus les transplantations d'organes de donneur vivant. Dans certains centres, les transplantations de rein de donneur vivant dépassent les taux de transplantation d'organe de donneur mort.

Les dons d'organe de donneur vivant ont mis les programmes de transplantation au défi de concevoir un cadre de détermination de l'acceptabilité des donneurs. Après un exercice multidisciplinaire de consensualisation fondé sur la discussion et le débat, le programme de transplantation multiorganes du Réseau de santé universitaire de Toronto a créé des lignes directrices sur l'éthique de ces interventions. Ces lignes directrices proposées répondent aux préoccupations éthiques soulevées par les critères de sélection et les interventions, le caractère volontaire du don, le consentement éclairé et la divulgation des risques et des avantages à la fois au donneur et au receveur.

In the fall of 2002, a Toronto newspaper headlined a story of a Canadian man whose housekeeper wanted to donate a kidney to him.[1] According to the report, 4 Canadian hospitals refused to do the transplant on ethical grounds. Patient and donor went to the USA, where the operation was completed. Meanwhile, in the United States, debate continues over the death of a donor of a liver segment in New York, with some people calling for a moratorium on these procedures. What are the ethical boundaries for transplantation from living donors, and how are decisions made regarding donor acceptability? If there are no clear regulations on these procedures, how are individual institutions to approach organ transplantation from living donors?

Background

The worldwide demand for organ transplantation continues to increase

*From the *Joint Centre for Bioethics, †Division of Nephrology, Department of Medicine, and ‡Department of Surgery, University of Toronto, Toronto, Ont.*

This article has been peer-reviewed.

Accepted for publication Apr. 23, 2004

Correspondence to: *Ms. Linda Wright, Toronto General Hospital, 585 University Ave., NCSB11C1270, Toronto ON M5G 2N2; fax 416 978-1911; linda.wright@uhn.on.ca*

 ' 2004 Canadian Medical Association

and is restricted largely by the number of available organs. The rate of Canadian organ donation from deceased donors has been static for the past decade. In 2003, 1804 organ transplants were performed in Canada, and 250 patients died while on transplant waiting lists.[2] For the 3914 people in Canada who were waiting for organ transplants at the end of December 2003,[2] these statistics imply grave consequences. A similar shortfall in organs exists in the USA, where over 87 000 people are currently listed for organ transplants.[3]

Organ donation from living donors has been pursued as an alternative to deceased donation. In 2003, 25 468 organ transplants were performed in the United States, of which 6811 (27%)[4] were from living donors. In Canada in 2003, of the 1053 kidney transplants performed, 403 were from living donors (38%).[2] In Ontario, the rate was even higher: of the 364 kidney transplants performed, 166 were from living donors (45%).[2] In countries such as Japan, where cultural belief systems have not supported the use of organs from deceased donors, living donors are the only source of transplantable organs.[5]

At the University Health Network (UHN), we support all attempts to increase organ donation from deceased donors. However, as there remains a serious shortfall in available organs, resulting in deaths, shorter lifespans and decreased quality of life for many potential recipients, we support the use of willing, consenting, fully informed living organ donors for whom donation poses, from medical and psychosocial standpoints, low levels of risk.

Advantages of organ retrieval from a living donor

First considered for the kidney, living organ donation has now expanded to include the liver, lung, small bowel and pancreas. For kidney donors, risks are minimal. Current research indicates that the survival rates of kidneys transplanted from living donors are better than those from deceased sources.[6] In addition, this form of donation offers the recipient reduced waiting time and an opportunity to schedule the surgery. Furthermore, it invests society with a cost saving. For those who require organs other than kidneys, living donation may be life-saving, and it reduces consequences such as reduced strength, loss of function and increased anxiety during time on a waiting list.

The law and organ donation from living donors

Legal requirements for organ donation from living donors include the wider framework of the Canadian Charter of Rights and Freedoms and the more particular provisions of provincial and territorial legislation which is based on the Uniform Human Tissue Donation Act.[7]

The Canadian Charter of Rights and Freedoms states, "everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice."[8] Furthermore, "every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability."[9] Therefore, if we are to consider anyone as a living organ donor, we must consider all citizens equally, and we must apply our methods of protecting this group of healthy volunteers from harm — by ensuring that living donors are acting voluntarily and that they receive safe, high-quality care.

Canadian provinces and territories have legislation on the exchange of human organs from living donors, encapsulated in various Human Tissue Gift Acts. The law states that living donation is permissible where there is informed consent by a competent adult with no restrictions pertaining to the relationship between the donor and the recipient.[10] Thus, each transplant centre must set its own parameters on who is accepted as a living donor. Such discretionary power raises many challenges. For example, who is responsible for final decisions on candidacy? Should it be the health care community, the involved parties in each case, legislators, or the public at large, whose taxes are used to fund the operation and ensuing or alternative care?

The American law on living donors is similar to Canadian law, focusing on the prohibition of commerce in organs.[11] The 1984 National Organ Transplant Act states, "it will be unlawful for any person to acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation." In the United Kingdom, the situation is more stringently controlled resulting in a lower incidence of living donor transplantation. The Human Organ Transplants Act of 1989 permits transplants from living donors who are genetically related.[12] However, a government agency, the Unrelated Live Transplant Regulatory Authority (ULTRA), oversees transplantation from LURDs — living (genetically) unrelated donors. Permission must be granted from this agency for donation from a LURD to take place. In a North American context this appears to be rather paternalistic: the agency assumes the role of decision-maker, reducing the autonomy of the donor and the transplant team.

Underlying the difference in decision-making for genetically and non–genetically related donors is an assumption that the risks of donation are less justifiable when the donor and recipient are not genetically linked. We disagree with this premise. First, graft and patient survival rates are similar between related and unre-

lated living donors.[6] Second, the quality of the relationship between the donor and recipient is clearly not dependent on a genetic link.

The law recognizes both the need for individual autonomy and the limits of that autonomy when it may encroach on the public good, as it does in policies for inoculation of populations, for example. If autonomy alone were the arbiter of living donation, then the donor and recipient could decide if they are agreeable and ask to proceed. However, members of the health care team are active participants in this process, with an obligation to maintain professional standards of practice. Thus, health care providers act as moral agents with rights to autonomy that must be respected in the decision-making process.[13,14] Specifically, health care providers are not required to become instruments of other people's decisions to undergo a transplant.[13,14] The transplant team maintains a right to veto potential candidates for living donation under certain conditions, for reasons such as professional integrity or the protection of society.

Ethical challenges in organ donation from living donors

To ensure ethical consistency, we believe it is important for each program to develop guidelines for living donation. Advancements in organ donation from a living donor have presented health care teams and society with new ethical challenges, such as recent deaths of liver donors and the emergence of innovative transplant programs. The latter include kidney exchange programs,[15] where medically incompatible donor–recipient pairs register to be matched to exchange organs with others who are unknown to them. Also in this category is nondirected donation[16] by "Good Samaritan" donors, who offer to donate anonymously to a kidney transplant centre. These programs have increased speculation that living donation could lead to commerce in organs.[17]

As there is no legal regulation on how much risk is clinically or ethically acceptable for the donor, transplant centres must set their own standards. Consequently, there is variation in approach and practice.[18–20] The comparatively new procedure involving a liver transplant from a living donor has been unregulated, and the literature indicates that there is considerable debate about the ethical acceptability of using living liver donors.[21] The risk of death in donating a kidney is currently cited as 0.03%.[22] The risk in donating a liver lobe is reported as 0.28%, but as there is no international registry of statistics on living liver donation, this rate is uncertain.[23] Consequently, there is a need for ethical guidelines for the evaluation of living donors of organs.

Guidelines serve as a template for the assessment process of all potential donors, ensuring that all patients are treated equally. By sharing information on guideline development with patients and with other professionals, we encourage debate on any controversial issues. We believe that 2 core standards should be incorporated into the guidelines: (1) Confidentiality of donor information is essential for establishing that donors are acting voluntarily. Just as with recipients, procedures to maintain donor confidentiality and to respect cultural or value differences should be identified as fundamental obligations in caring ethically for a living donor. (2) Consultative options are required to assist consensus-building when there is a lack of agreement or serious reservation about the suitability of a donor.

UHN ethical guidelines for living donation: the creation process

Challenged by the requirement for fairness, transparency and consistency in the process of working up criteria for the acceptability of living organ donors, the UHN Multi-Organ Transplant team decided to develop ethical guidelines for organ transplantation from living donors. In winter 2000, a multidisciplinary task force was established. A literature search was performed. An American initiative titled "Consensus Statement on the Live Organ Donor" was used as the foundation for the first draft of these proposed guidelines.[24] This draft was circulated to all health care professionals involved in the Multi-Organ Transplant Service at UHN, followed by discussion at an open forum. Attendees provided feedback and recommendations that were included in the final draft, which was approved by the UHN Medical Advisory Committee. To complete the process, we decided to submit for publication a review article describing the guidelines, to share our perspectives with the Canadian health-care community and see if the contents reflect national values and standards of practice. A transplant ethics committee with representation from areas of medicine, surgery and ethics along with patient representation has been established to change the guidelines as practice evolves. Highlights of our practice guidelines are provided later in this article; the entire document can be obtained through the UHN Web site (www.uhn.ca).[25]

Donor assessment

Separate health care teams assess potential living donors and recipients. When feasible, each donor and recipient has his or her own physician to act as an advocate. We use separate coordinators, social workers and psychiatry staff whenever possible. These staffing requirements avoid conflicts of interest and permit advocacy for the potential donor while suitability is being determined. Furthermore, separate teams enhance confidentiality as information and record storage is maintained and appropriate information shared by the separate teams. The main barrier to establishing separate teams appears

to be sufficient availability of staff educated in living-donor transplantation issues.

Criteria to measure medical/surgical and psychosocial suitability include low medical/surgical risk, ability to give informed consent, realistic expectations of donation, voluntary motivation (see Box 1) and sufficiency of economic, practical and emotional resources to cope with the donation process. All of these issues are open to interpretation, as they are indefinite. What is accepted as low medical or psychosocial risk, or what constitutes the ability to fully understand risks and benefits and consequently give informed consent may differ from one transplant centre to another, depending on surgical expertise, team judgement and comfort levels. We acknowledge these differences and address them by open discussion among team members on each point, encouraging transparency of process and decisions among staff and patients.

Financial remuneration or exchange of goods for a living organ donation is deemed unethical and is prohibited. Money received by the donor in compensation for out-of-pocket expenses such as travel, loss of income, childcare or accommodation is ethically permissible provided the intention is to reimburse or compensate monetary loss and not to purchase the organ.

Sometimes the donation process is stalled when potential donors do not keep appointments for tests. In these circumstances, the transplant centre may be uncertain if this may indicate a donor's ambivalence around donation. To address such situations, at our centre the test is rebooked twice, after which the donor is sent a letter stating that unless contact is made to reschedule the diagnostic testing, the team will conclude that the donor is not prepared to proceed at this time. In the process of informing the potential recipient of the donor's unsuitability, care is taken to keep information about the donor confidential. This allows the team to proceed with other options for the recipient without pressuring the potential donor, whose non-attendance may express a reluctance to donate.

Potential recipients are told at the outset of the assessment process that they will be informed if a donor is found unsuitable but will not be provided with an explanation. Sometimes potential donors find it difficult to inform recipients or family members that they are unable to donate. If a potential donor is unsuitable for any reason, the transplant team offers to help the potential donor to convey this to significant others. Rather than give reasons that are untrue, the team tells the recipient and/or any third parties that "it was not appropriate to proceed." To preserve confidentiality, specific reasons for our decisions are not provided.

It is desirable for donors to know about recipient outcomes. Permission is sought from the recipient in advance of transplantation on how and when this information can be shared. If a recipient dies, bereavement counselling is offered to the donor and family members.

Informed consent

Informed consent is viewed as a process of confirming capacity to understand and consent, disclosure of information about the proposed procedure, patient understanding and voluntariness.[26] Full disclosure requires a detailed discussion of the risks and benefits, not only to the living donor, but also to the recipient. The potential donor is briefed about alternative treatment options for the recipient as well as the possible impact of donation on the donor's lifestyle, family relationships, finances, future employment and ability to receive life insurance. Donor and recipient are provided with general information and details on program-specific outcomes.

The consent process must be sensitive to the potential donor's language skills and educational level. When a donor appears undecided, counselling is offered by a social worker or psychiatrist to assist the potential donor to solve problems and address psychosocial aspects of this decision such as emotional issues and how to inform others. Family members are generally not used as interpreters, as they may not be impartial toward the information or the decision to donate. Potential donors are informed that they can withdraw from the process of donation at any time, with the full support of the transplantation team.

Protecting donors' right to make their decision free from coercive or manipulative influences is a key part of the assessment process. Sensitivity and awareness about the nature of the donor's circumstances and interpersonal relationships are required to determine how free the donor has

Box 1. Topics addressed in assessing potential donor's voluntarism to donate an organ

1. Motivation to donate
2. Social situation and family constellation
3. Economic situation
4. Relationship with the intended recipient
5. Decision-making around the proposed donation
6. Evidence of solicitation of donation, the people and circumstances involved
7. Comfort level in declining the request to donate
8. Comfort level in presence of family or others involved in proposed donation
9. Evidence or suggestion of a material reward for organ donation

been to make these decisions without influence or urging from others. Elements of coercion and manipulation may be missed by health care providers when they are hidden by societal, familial or personal factors. Nine topics have been identified in assessing how freely a donor's choice to donate is made (Box 1). These include assessing a potential donor's social, financial, interpersonal and behavioural factors.

We strive to provide sufficient time for donors to make their decision about organ donation by including a "cooling-off" period between consent and surgery, when possible.

Occasionally, the need for organ donation from a living donor arises in urgent or emergency situations. Regardless of the urgency of a situation, the assessment team aims to ensure that potential living donors receive sufficient information, support and advocacy to minimize coercive elements in their decision-making.

In making the final decision on the suitability of a living donor, we strive to reach a consensus that is acceptable to the donor, recipient and transplantation team. When there is uncertainty, consultation from other centres is sought, reviewed and discussed. The final decision to perform the living-donor transplant nevertheless rests with the transplant physician, who is not obligated to perform a transplant when he or she believes that the harm to the donor may outweigh the benefits. These benefits include the satisfaction of helping another person via an altruistic act, psychological benefits and any tangible benefits such as increased family income when a recipient returns to work, freedom to travel with the recipient or freedom from caring for a sick relative. In our view, none of these practical benefits necessarily reduces the level of altruism in donation, but altruism must be present.

When donation does not proceed, the donor team ensures that the donor is referred for follow-up of any health issues that were identified during the work-up.

Dispute resolution

Lack of consensus within the transplantation team about the suitability of a potential donor requires a team review of the criteria used to measure suitability and different levels of consultative options. Options for additional input include advice from other professional members of the staff, hospital ethics services, legal counsel, hospital administrative resources or outside hospital consultation. The guidelines provide advice on how to inform the potential donor and recipient about the team's decision and how to respect the donor's wishes when the final decision on donation is shared with the recipient and others.

Monitoring outcomes

Evaluation of donor and recipient experiences and medical, psychosocial and economic outcomes are essential to maintaining standards of care. An annual review is performed to document early and late morbidity, graft function, mortality rates and measures of levels of recipient and donor satisfaction. In the event that a donor requires further care, appropriate care is arranged.

Summary

Donating an organ to another human being always involves real personal sacrifice in the donor. It is a truly heroic act that raises unique ethical concerns for health care providers. Ethical guidelines provide support, guidance and consistency to transplantation teams in their decision making. Centres may not agree on all aspects of organ donation from living donors, but transparency of process and procedures along with reflection on practice may encourage debate on important issues and permit openness and clarity. We believe that these guidelines may be applied to innovative methods of organ donation such as paired kidney exchanges and anonymous donation.

Acknowledgements: The authors thank the staff of the Multi Organ Transplant Program at the University Health Network, Toronto, Ont., who worked on the development of the *Ethical Guidelines for the Care of Living Donors*, and the Joint Centre for Bioethics, University of Toronto.

Competing interests: None declared.

References

1. Priest, L. Boss gets organ from domestic. *Globe and Mail* [Toronto] 2002 Nov 16; Sect A:1.
2. Canadian Organ Replacement Register. Preliminary statistics on organ donation, transplantation and waiting list: 2004 CORR preliminary report [presentation]. Canadian Society of Transplantation annual meeting; 2004 Feb 25–28; Mont Tremblant (QC). Available: http://secure.cihi.ca/cihiweb/en/downloads/sevices_corr_organ_donation_2004_1_e.ppt (accessed 2004 Nov 23).
3. United Network for Organ Sharing Web site. Available: www.unos.org (accessed 2004 Nov 23).
4. United Network for Organ Sharing Organ Procurement and Transplantation Network. Available: www.optn.org/latestData/rptData.asp (accessed 2004 Nov 23).
5. Ota K. Kidney transplantation using kidney donors in Japan: how donors feel. *Clin Transpl* 1994:369-71.
6. Terasaki PI, Cecka M, Gjertson DW, Takemoto S. High survival rates of kidney transplants from spousal and living unrelated donors. *N Engl J Med* 1995;333:333-6.
7. *Uniform Human Tissue Donation Act*. R.S.C. 1990, c. H-12.1 Available: www.ulcc.ca/en/us/index.cfm?sec=1&sub=1h1 (accessed 2004 Nov 23).
8. *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act*, 1982, being Schedule B to the *Canada Act 1982* (UK), c. 7.
9. *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act*, 1982, being Schedule B to the *Canada Act 1982* (UK), c. 15(1).
10. *Human Tissue Gift Act*. R.S.A. 1980, c. H-12.
11. *National Organ Transplant Act (NOTA)*. 42 U.S.C.S. ss. 274e (2004).
12. *Human Organ Transplants Act 1989* (UK), 1989, c. 31, s. 2.
13. Childress JF. *Who should decide? Paternalism in health care*. New York: Oxford University Press; 1982.

14. Ethics of organ transplantation from living donors. *Transplant Proc* 1992;24:2236-7.
15. Park K, Moon JI, Kim SI, Kim YS. Exchange donor program in kidney transplantation. *Transplantation* 1999;67:336-8.
16. Matas A, Garvey C, Jacobs CL, Kahn JP. Nondirected donation of kidneys from living donors. *N Engl J Med* 2000;343: 433-6.
17. Colakoglu M, Yenicesu M, Akpolat T, Vural A, Utas C, Arinsoy T, et al. Nonrelated living-donor kidney transplantation: medical and ethical aspects. *Nephron* 1998;79:447-51.
18. Beasley CL, Hull AR, Rosenthal JT. Living kidney donation: a survey of professional attitudes and practices. *Am J Kidney Dis* 1997;30:549-57.
19. Kasiske BL, Bia MJ: The evaluation and selection of living kidney donors. *Am J Kidney Dis* 1995;26:387-98.
20. Bia MJ, Ramos EL, Danovitch GM, Gaston RS, Harmon WE, Leichtman AB, et al. Evaluation of living renal donors. *Transplantation* 1995;60:322-7.
21. Cronin DC 2nd, Millis JM, Siegler M. Transplantation of liver grafts from living donors into adults — too much, too soon? *N Engl J Med* 2001;44:1633-7.
22. Najarian JS, Chavers BM, McHugh LE, Matas AJ. 20 years or more of follow-up of living kidney donors. *Lancet* 1992;340: 807-10.
23. Trotter JF, Wachs M, Everson GT. Adult-to-adult transplantation of the right hepatic lobe from a living donor. *N Engl J Med* 2002;346(14):1074-82.
24. Abecassis M, Adams M, Adams P, Arnold RM, Atkins CR, Barr ML, et al. Consensus statement on the live organ donor. *JAMA* 2000;284:2919-26.
25. Wright L, MacRae S, Purdy L, Gordon D, Gildner J, Abbey S, et al, on behalf of the Multi-Organ Transplant Program, Toronto General Hospital, University Health Network and University of Toronto. *Ethical guidelines for the care of living donors*. 2003. Available: www.uhn.ca/programs/bioethics/docs/ethical_guidelines_eval_living_donors.pdf (accessed 2004 Nov 23).
26. Beauchamp TL, Childress JF. *Principles of bioethics*. 5th ed. Oxford: Oxford Universit Press; 2001.

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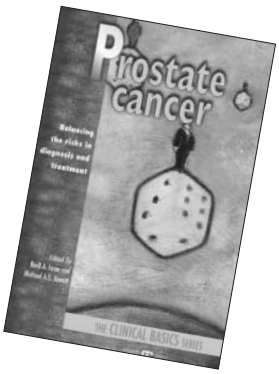

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