

Ethical Aspects of Organ Donation Activities

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Renal transplant remains the treatment of choice for patients with end-stage renal disease. Human organs can be harvested from 2 main sources: living and deceased donors. Preference should be given to deceased-donor transplants since they represent the only source of organs for several nonrenal solid-organ transplants and the only modality where there is no risk to the donor. Unfortunately, even the most well-developed deceased-donor program (eg, the Spanish program) can barely cover 50% of its waiting list because the demand for deceased-donor organs far exceeds supply. The success of transplant surgery has created a waiting list dilemma. Despite all efforts, deceased-donor donation cannot meet current needs and therefore, living donation demands serious consideration. This is supported by the fact that the risk to live donors is minimal, graft survival is significantly better than that of deceased-donor kidneys regardless of HLA matching, and professional ethical philosophers have fewer difficulties with voluntary living donations than with the removal of an organ from a cadaver. This is especially true in our region. Living-related donation has always been acceptable ethically. It is, however, limited by the number of willing and qualified donors, the high incidence of familial renal diseases, and donor coercion (especially in our area). Living-unrelated donation increases the availability of donors, decreases the chances of coercion, and eliminates the problem of consanguinity. It raises,

however, the ethical issues of commercialism, transplant tourism, and organ trafficking. The arguments for and against living-unrelated donation are innumerable. They have been the subject of several international forums and have raised endless discussions. We have set long ago a series of rules and regulations that are in close agreement with the recent Amsterdam and Kuwait resolutions. We have been continually modifying them over the last 15 years to try to implement our ideal, which is to protect the interest of the living donor and avoid commercialism.

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Transplant is not a myth; it is no longer experimental. In 2007, transplant surgery is a recognized treatment modality. As of the end of 2004, there were 153,245 people living with a functioning transplant in the United States (1); many already have survived for more than 25 years. Although dialysis successfully prolongs the lives of many patients with end-stage renal disease, renal transplant remains their treatment of choice. Renal transplant offers longer patient survival, better quality of life, and it is a more economical option in the long term (2) (although the latter might not be universally true: in some countries, good quality dialysis might turn out to be less expensive than a good quality renal transplant). One cannot conceive of a good quality renal transplant that does not take advantage of state-of-the-art drugs for induction, maintenance, and short- and long-term prevention of complications. Recently developed drugs are not yet amenable to generic formulations and are excessively costly. Despite impressive scientific progress, cloning and xeno-transplant are still experimental. They remain theoretical options (3, 4) that we cannot realistically depend on for the next 2 decades.

In the mean time, kidney transplant surgery must continue. Numerous studies have shown the

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advantages of early transplant, or even better, pre-emptive transplant (5). For the time being, only human kidneys can be used. Human organs can be harvested from 2 main sources: living donors and deceased donors. These 2 main sources can be subdivided further. Living donors can be genetically related or unrelated, and deceased donors can be brain-dead heart-beating donors or non-heart-beating donors (6, 7). The preference should go to deceased-donor donation since the outcome of deceased-donor kidneys is continually improving (with regard to surgical and preservation techniques and immunosuppression); deceased-donor donation is the only modality where there is, obviously, no risk to the donor; and deceased-donor donation is currently the only source of organs for many nonrenal solid-organ transplants such as a heart and a cornea. That is why the National Organization for Organ and Tissue Donation and Transplantation has spared no effort to promote deceased-donor donation in Lebanon. With limited legal and financial backing, the National Organization for Organ and Tissue Donation and Transplantation has been able to conduct several public information and education campaigns, deliver lectures in schools and universities, distribute posters to all intensive care units in the country, edit a pocket manual for organ and tissue donation (Lebanese model), inaugurate a Web site (www.nootdt.org), participate in the Beirut Marathon (2005), collaborate in organ donation and transplant congresses, organize 5 transplant procurement management courses, and conduct a statistical survey on the attitudes of different Lebanese communities toward organ and tissue donation.

Unfortunately, even the most well-developed deceased-donor program (eg, the Spanish program) can barely cover 50% of its waiting list (8). So the therapeutic promise of transplanting organs from deceased donors as envisioned by the pioneers of transplant has never been realized because the demand for deceased-donor organs has far exceeded the supply (9).

The very success of transplant surgery has led to our present problem: organ shortage. It has created a waiting list dilemma that must be solved. The number of people dying on waiting lists is progressively increasing. In 2000, almost 5000 people died on the waiting list in the United States. In July 2003, there was a total of 82 117 patients waiting for a solid organ transplant (10). This number reached 90 000 in 2005 (1).

To solve the problem of a continuously expanding waiting list 2 solutions are proposed: limiting access to the waiting list, and increasing the donor pool.

Limiting access to the transplant list

We have been, so far, very permissive in admitting patients to the waiting list (11). This is because, we, the transplanters, are reluctant to play God and decide who should and who should not receive a transplant. Should we adopt a purely utilitarian attitude? That is, should we ask, Who will benefit most? This debate is open to discussion. But are we not already playing God when we adhere to principles of organ allocation according to points (12) or when we select the recipient who should be attributed an extended criteria kidney (13)? With improved outcomes using organs from non-heart-beating donors (14), this source can now be promoted and will probably be better accepted socially, at least in societies where the concept of brain death is not universally agreed upon. However, we will be forced to acquire the know-how and the proper technical support and restrict it, initially, to younger donors and to well-experienced, structured, and well-established transplant programs, since a "young" program cannot afford failures!

Increasing the donor pool

Despite all our efforts, deceased-donor donation will not meet our needs. At this stage, we can either relax and delegate to others the responsibility of solving the problem while reserving the right to criticize, or try to find the most adequate solutions, make mistakes, be criticized but be modest enough to accept criticism, listen, learn, and attempt to correct our mistakes. After having relentlessly encouraged deceased-donor donation and exhausted our heart-beating and non-heart-beating deceased-donor possibilities, we must seriously consider living donation.

Is there justification for using living donors? Whether the live donor is related or unrelated, the medical risk, though minimal, is present. Our guiding principle should be *primum nihil nocere* (first, do no harm). Live kidney donation has been tolerated because:

A. The risk for the donor is minimal. And the mortality in developed countries is extremely low (0.03%) (15-16). However, every transplant unit is not necessarily as successful. That is why strict control of the results of centers performing live kidney transplants is necessary. We have analyzed our own short-term results (17) and found that they are in agreement with international norms (15-16). Our long-term results (17), too, do not differ from those obtained by international centers (13). We already know that patients are doing well for more than 50 years after unilateral nephrectomy (18).

- B. The graft survival rate for kidneys obtained from living donors is significantly better than that from deceased-donor kidneys regardless of their HLA matching (19). That is why, in many US centers, the number of kidneys transplanted from living donors has surpassed the number obtained from deceased donors (2) (except for the year 2005).
- C. Professional ethical philosophers have fewer difficulties with voluntary living donations than with the removal of an organ from a deceased donor (19). This is especially true for our region.

Living-related donation has always been ethically accepted. It is, however, limited by the number of willing and qualified donors, the high incidence of familial renal diseases (especially in our area) (20), and the fact that coercion is always a latent problem in any living-related donation (17).

So, in practice, it is not that easy to find intrafamilial donors (it is barely 10% of the total). If we want to increase our pool of kidney donors, we must use living-unrelated donors. Using living-unrelated donors increases donor availability, decreases the chances of coercion, and eliminates the problem of consanguinity. Its use, however, raises the ethical issues of commercialism, transplant tourism, and organ trafficking. Among living-unrelated donors, the emotionally related ones have been classified separately and are ethically tolerated (16). We must bear in mind, however, that the ethical problem is not in the act of donation. It is in the motives behind the act.

The question now is: Do we have the right to judge these motives, and can we be accurate and fair in this judgment process? Every time we consider regulating living-unrelated donation, the objection from a Canadian potential recipient comes to our mind: "And who, pray tell me, gave you the right to make the rules by which my life has to be lived? I suppose this is just another example of the arrogance that you doctors show towards those who challenge your control of things" (21). The arguments for and against living-unrelated donors are innumerable. They have been the subject of several international forums and have raised endless discussions.

Under the pressure of organ shortage and scientific progress, even the World Health Organization (WHO) has had to modify its initial recommendations of 1991 (22). In May 2004, a WHO meeting in Geneva showed a clearly more tolerant attitude toward living donation (22). Along with the globalization of medicine, the initial Judeo-Christian moral concepts have been challenged regularly. Some principles, however, seem to have reached a general

consensus. It is this general consensus that we should insist upon. This consensus has formed the basis of the Amsterdam resolutions in 2004 (23, 24) (Table 1), and we adopted it at the MESOT meeting held in Kuwait in 2006 (25) (Table 2). These resolutions underlie the proposals for living-unrelated donation in the Kingdom of Saudi Arabia. In Lebanon, for more than 15 years, we have been accepting living-unrelated donors. Although our conditions ante date the Amsterdam resolutions, they are almost the same. To implement our ideal—protect the interest of the living donor and avoid commercialism—we have set a series of rules and regulations that we continually modify.

Table 1. Amsterdam resolutions, April 2004 (23)

1. Prior to a live kidney donation, the donor must receive a complete medical and psychosocial evaluation.
2. Prior to donor nephrectomy, the potential donor must be informed.
3. The potential donor should be informed of alternative renal replacement therapies available to the potential recipient.
4. The potential donor should be capable of understanding the information presented in the consent process.
5. The decision to donate should be voluntary (with freedom to withdraw from the donation at any time).
6. After kidney donation, the transplant center is responsible for overseeing the care of the donor.
7. Minors should not be used as donors.
8. Donor autonomy does not overrule medical judgment.
9. A donor registry is necessary.

Table 2. Kuwait statement, November 2006

1. Support the development and expansion of organ and tissue donation from deceased donors in all countries of the eastern Mediterranean region.
2. Oppose commercialism and transplant tourism, including brokerage and medical professionals seeking monetary profit as a result of the vendor sale or coerced donation of an organ or tissue; the placing of an arbitrary monetary value on an organ or tissue; the sole motivation by a vendor to undergo organ or tissue retrieval for monetary gain.*
3. Support the identification of the procedural steps to develop organ and tissue donation from deceased donors.
4. Urge all governments to appropriate the necessary legal, administrative, and financial resources to implement these recommendations through a national transplant authority.
5. Call upon the International Society for Nephrology, the Transplantation Society, and the Global Alliance for Transplantation to take note of, and communicate to partners, the principles contained in the Kuwait Statement on Cell Tissue and Organ Donation.

*These factors do not prohibit financial reimbursement for donor's expenses or loss of income and payment of reasonable professional services.

To protect the donor:

1. We make sure that the donor and a responsible member of the donor's family are fully aware of the short- and long-term risks associated with donation. The information is in writing, and the donor is asked to sign the document. The relationship of the responsible person is confirmed by an official family record of the donor.

2. We then insist on a thorough pretransplant donor work-up. We refuse any donor that presents with what some other centers might consider "minor problems" (eg, controlled hypertension or recent-onset diabetes mellitus) (26).
3. We refuse minors (the legal age in Lebanon is 21 years) and physically and mentally challenged persons. We favor middle-aged donors.
4. A judicial record is required.
5. We insist on a detailed psychosocial work-up of the donor.
6. The donor may withdraw at any time.
7. Surgery is restricted to certified transplant centers.

To avoid commercialism:

1. We refuse donor transfers and middlemen.
2. We restrict living donations to nationals (no possibility of transplant tourism).
3. We forbid advertisements in newspapers, on the Internet, or in any public place.
4. We insist that there be no financial remuneration for unrelated donors; however, we have never been able to ascertain fully the complete absence of financial compensation.
5. Donor and recipient are informed that no matter how advanced the transplant process is, if a financial transaction is found, there is an automatic cancelling of the transplant.
6. While the transplant team provides the medical clearance for both surgeries, final approval to all parties is given by an independent, anonymous ethics committee.
7. The recipient pays for only the cost of the donor pretransplant work-up.

What we hope to add to our present regulations include:

1. A limited compensation for the donor as allowed by the WHO and all monotheistic religions. By limited compensation we mean:
 - a. Mandatory life insurance for the donor to cover the first year after transplant (27).
 - b. Medical insurance to cover any medical problem that the donor might face until he or she is 65 years old (27).
 - c. Reimbursement of out-of-pocket expenses to cover 3 to 4 months' wages related to the forced absenteeism for the donor evaluation and nephrectomy (27).
2. An obligatory donor medical follow-up documented in an official donor registry.

In conclusion, organ shortage remains a great challenge in solid organ transplant. We can solve it

by refining our criteria for choosing recipients to have a more accurate estimate of the effective waiting list and by maximizing organ procurement by encouraging deceased-donor donation and utilizing non-heart-beating donation if allowed by culture and religion. The acceptance of living-unrelated donors at present seems inevitable. No effort should be spared, however, to prevent organ vending. We must protect the donor by allowing limited, regulated compensation and creating a donor registry. While some issues are clear with appropriate solutions, many others are complex with no definite answers. Social acceptance is the final arbiter of ethics.

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