A Protocol for Paid Kidney Donation in Israel

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The following are recommendations for the establishment of a paid living kidney donor program in Israel. These were requested by the Director of the National Transplant Center in response to the recognition of the growing numbers of Israeli renal failure patients – estimated to be over 100 annually – who have already traveled abroad to receive such transplants, taking with them an Israeli donor. The present waiting time for a cadaver kidney transplant in Israel is 5 years, and only patients already in dialysis treatment are eligible.

A paid living donor kidney program has the following aims:

- To obviate the need for most patients to seek such transplants outside Israel
- To control the medical standards of such operations by performing them only in licensed medical centers
- To protect the interests of the donors
- To reduce the present excessive cost of such procedures both to the medical insurance and to the patients
- To give poorer patients an equal opportunity to receive unrelated living donor kidney transplants
- To increase the number of kidney donations in Israel.

There have been loud objections to the concept of payment for organ donation. Professional organizations and governments have decreed that such actions are immoral and should not be allowed. The various social, ethical and religious reasons on which these decisions were founded do not appear to have been challenged. However, objective reappraisal of the concept of payment to organ donors has recently been encouraged [1–4]. A resolution adopted at the recent International Congress on Ethics in Organ Transplantation states that "The well established positions of transplantation societies against commerce in organs has not been effective in stopping the rapid growth of such transplants around the world. Individual countries will need to study alternative, locally relevant models, considered ethical in their societies, which would increase the number of transplants, protect and respect the donor, and reduce the likelihood of rampant, unregulated commerce." The present proposal is a logical step in this debate and presents a possible option around which the debate should continue. It proposes that existing laws and directives forbidding procuring and performing such procedures in Israel, outside the protocol as elaborated below, should continue to be enforced. Furthermore, to prevent the temptation of any illegalities, it is proposed that this donation program should be non-recipient directed [Appendix 1].

After a break-even period of 1 or 2 years, kidney transplantation significantly reduces the cost of treating patients with end-stage renal disease years as compared to the cost of chronic dialysis treatment [5]. Furthermore, living donor kidney transplants are considerably more successful – both in short and long-term results – than those from cadaver donors [6]. Thus this program should provide a means not only to save money for the transplant procedure by bypassing the brokers and performing the procedures in Israel, but also, by increasing living donor kidney donations, would reduce the overall costs of treating patients with end-stage renal disease.

Donor assessment

1. This would be initiated by an experienced nurse who will make preliminary assessment including the following:
   - Age
   - Gender
   - Family status
   - Work and social status
   - Nationality or residential status
   - Place of residence
   - Languages (native and others, including fluency and reading ability)
   - Body size (body mass index = body weight in kilograms / height m^2)
   - Motivation
   - Drug abuse
   - Previous illnesses or hospitalizations
   - Medications
   - General impression, including donor response to an explanation of procedure, financing and follow-up [Appendix 2].
2. An experienced transplant team physician to be appointed by the National Transplant Center will review the preliminary donor assessment.

3. Prospective donors considered suitable should sign an agreement [Appendix 3] to cooperate with medical screening as a possible kidney donor. This should include a clause stating that the screening procedures will be free and that the potential donor understands that he or she might be refused on medical or other grounds depending on the results of the tests. The prospective donor may withdraw his/her consent at any time.
4. Prospective donors will then be referred for donor work-up as for related living donors. This should include two urine drug and toxin screens. (Note: The National Transplant Center has a special committee to screen living donors who are not first-degree relatives. This includes a thorough psychological assessment). It is recommended, as for all living donors, that the committee ensure that the donor fully understands the procedure.
5. Donors considered non-suitable at any stage of assessment should receive written documentation of the refusal (with a 'thank you' note) and, where possible, a reason for the refusal.

Donor consent

This consent is to be signed by the donor before hospitalization, and should include:

- Consent for the surgical procedure, financing and annual follow-up (see donor follow-up below) [Appendix 4]
- Acknowledgment that a full explanation of the procedure has been given. The initial explanation given by a nurse should be repeated by a physician in the transplant team [Appendix 2]
- Financial compensation of an agreed amount will be given in full before hospital discharge
- Acknowledgment to forego the right to know the identity of the recipient and to claims against the recipient
- Life-long free medical follow-up will be provided but only for medical matters connected to the donation of a kidney
- Agreement to notify the National Transplant Center annually of the donor follow-up status
- This consent form should be signed by the donor, by a physician in the surgical team performing the nephrectomy, and by the National Transplant Center.

Donor operation

This should be fully explained to the patient by the surgical team – as in Donor Consent [Appendix 2]. The method of nephrectomy is at the discretion of the surgical team. The operation requires completion of the following documents with appropriate signatures:

- Living Donor Kidney Transplant Permission from the National Transplant Center
- Non-related Living Kidney Donor Consent Form [Appendix 5] – also to be signed by the National Transplant Center
- Hospital surgical consent form.

Recipient

The choice of recipient will be made by the National Transplant Center according to the current computerized recipient selection criteria for cadaver kidney allocation. This does *not* allow the donor or his/her family to choose a recipient. A single waiting list for all patients would be maintained, as at present.

There are possible corollaries to this:

- In special rare cases application to the Kidney Committee of the National Transplant Center can be made for special preference for individual recipients to receive such a kidney. Such applications, in writing, should be made by the chief transplant surgeon where the recipient is registered. The only reason for such a request would appear to be requirement for complicated immunologic matching techniques and/or the necessity for pre-transplant immune modulation treatment of the recipient.
- All patients with end-stage renal failure (creatinine clearance less than 12 ml/min) should be eligible. This is in line with the current trend to have a preemptive kidney transplant before requiring dialysis treatment, and is justified since dialysis decreases the long-term success of kidney transplantation [7]. In my opinion, eligibility for cadaver grafts should also be extended to include pre-dialysis patients, perhaps with an extra allocation point given to favor patients already receiving active dialysis treatment.
- It is discriminatory and is probably not feasible to exclude high risk patients from this program if they are already on the cadaver kidney waiting list. On the other hand, patients should be given the option to wait only for a living donor kidney. They should be made aware that the waiting time for such a kidney would probably be longer than for those willing to accept any kidney.

Recipient consent

The Recipient Consent Form should include agreement that the recipient has no right to legal or other claims against a kidney donor.

Immunologic assessment

Cross-matching tests of recipient serum against donor lymphocytes should be negative, as performed by sensitive laboratory techniques.

Donor follow-up

This should be conducted at the harvesting center until the immediate postoperative period is complete. Thereafter it should be performed annually at a nephrology clinic of the donor's choice. The donor will receive instructions and will agree to notify the National Transplant Center of his/her annual follow-up status (see Donor Consent).

Institutions

1. It is recommended that only transplant teams in academic institutions receive Ministry of Health approval to participate in this program.
2. To prevent donor-recipient identification, it is recommended that kidney harvesting and kidney transplantation be performed in separate departments.
3. It is recommended that the National Transplant Center arrange for prescreening tests of all donors who thereafter are referred to the selected recipient's listed transplant center.

Another possibility is to designate a donor department and then one of three alternatives:

- The recipient will be transplanted in the donor's center
- The donor will be sent to the recipient's listed transplant center
- The donor kidney will be sent to the recipient's listed transplant center.

4. The possibility of laparoscopic donor nephrectomy may influence the choice of the institution performing donor nephrectomy.

Financing

1. The National Transplant Center undertakes to cover all expenses of the donor for pre-donation screening tests, hospitalization and post-donation follow-up including annual long-term follow-up. These costs should be recovered from the recipient's sick insurance and should be independent of the result of the transplantation.
2. The National Transplant Center undertakes to pay the donor an agreed sum (fixed by the Center) before his/her discharge from hospitalization. This payment will be tax-free. [Note: The actual amount of money may be restricted by a law already tabled in the Knesset (Israeli Parliament). However, in my opinion, a fee of $20,000 would be reasonable. There would be very few non-altruistic donors who would be interested in expenses only, for tax or educational benefits or other marginal benefits. Furthermore, the sum must compete with the offers of private entrepreneurs currently operating. Those worried by the ethics of paying donors, who after all are saving the lives of patients, are saving the country a huge amount of money and are shortening the kidney transplant waiting list] [should read references 1–4]. Other donor benefits are mentioned and include full insurance (below) and long-term follow-up (above). These are not available in current private extraterritorial practices.
3. Life-long medical and life insurance for the donor will be covered by the National Transplant Center, but only for those complications directly connected to kidney donation.
4. The National Transplant Center will seek full agreement of other insurance agencies, including National Insurance, that the donor's insurance status is in no way compromised by kidney donation.
5. Expenses incurred as a result of donor evaluation and operation (lodging, travel, and meals) will be covered by the National Transplant Center.

Public relations

It is recommended that a consensus be reached at the National Transplant Center concerning terminology and information procedures related to this program. This is important since advertising of this program may be misconstrued as solicitation and exploitation.

Quality control

The results of this program should be reviewed annually and be presented to the National Transplant Center. The review should include medical results for both the recipient and the donor, review of medical complications, logistic complications and review of any unforeseen consequences of the program, medical or otherwise. At any time, the Center should be prepared to stop the program or change its format if adverse unforeseen consequences occur.

Finally

Encouragement of cadaver kidney donation and altruistic living donor kidney donation, perhaps also with incentives, should continue. Also, while I recommend that this experimental program be initiated only for Israeli citizens, extension to include permanent residents, foreign workers, Palestinians without Israeli identity and even tourists might be considered.

In other countries, including the United States, paid donor kidney transplants are widely performed albeit surreptitiously with no donor rights. This program is transparent and regulated and gives the donors full screening and long-term follow-up. Should non-Israeli citizens be allowed to participate in the future, apart from the follow-up and insurance problems that may arise, it is hoped that the image of the Israeli medical community would not be damaged by "donor tourism." I would suggest that our image may even be enhanced by the program's originality, its attempt to solve a modern medical dilemma, and its honesty.

Hans Schlitt has recently written an excellent considered opinion [8] in which he tabulates the pros and cons of paid kidney donation. Apart from public fears about commercialization and potential problems if practiced universally, he finds no good counter-arguments to the possible advantages (relief of donor shortage, economic benefits for the donor and society, organizational for transplant centers, better results than with cadaver donation, works well under defined conditions). This proposed protocol is not intended for universal practice and public relations are included, which may allay public fears. Schlitt's list of disadvantages (exploitation, risk to donor, wealthy recipients' advantage, decrease in cadaver donations, regional differences in financial rewards leading to "donor tourism") is counter-argued by donor autonomy, a low risk equivalent to related altruistic donors and non-directed donation. Regional differences in rewards are present in all sectors of life, and a decrease in cadaveric donation is speculative and is dependent on the public relations.

Adoption of the protocol may not prevent impatient patients from seeking more rapid private solutions abroad, but it does present a legitimate alternative available to all, and appears to answer the aims as listed in the introduction and most counter-arguments. It is hoped that it will serve as a concrete basis for wide-based discussion.

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Appendix 1*

Non-directed donation

Meeting of donor and recipient only if mutual agreement and only after transplantation

- Psychosocial assessment of donor can be conducted in local community if distant from transplant center
- No directed donation allowed – kidney given only according to protocol
- Admission in different areas of same hospital
- Health insurance premiums unaffected
- Small donor expenses (lodging, travel, and meals) covered by transplant center.
- Recipients for first or second transplants only and no non-compliant patients
- Directed altruistic donation still allowed.

* Based on non-directed kidney donation from living donors [9]

Appendix 2*

Explanation to donor of procedure of kidney donation including financing and follow-up

- Description of the evaluation, surgical procedure and recuperative period
- Short and long-term follow-up care
- Potential complications
- Potential impact of donation on health and life insurance
- Potential impact of donation on life style and employment
- Selection and expected outcome of recipient – non-directed donation
- Alternative treatments for recipient
- Transplant center statistics for recipient and donors
- Expenses for donor
- Financing of donor
- Withdrawal of donor consent at any time
- Agreement to be signed by donor before hospitalization [Appendix 4].

* Based on Consensus Statement on the Live Living Donor, *JAMA* 2000;284:2919–26.

Appendix 3

Consent form for prospective donor screening to include:

- Agreement to be interviewed by the National Transplant Center ethical committee
- Donor may withdraw consent at any time.

Appendix 4

Pre-operative agreement with donor

This should include acknowledgment of a full explanation of surgical procedures and their consequences, financial arrangement and agreement to notify the National Transplant Center annually of post-donation status. Also to include a "no claim" clause against the recipient, to forego the right to know the identity of the recipient (this may be arranged 6 months after the operation, but only with the full signed informed consent of ***both*** donor and recipient) [Appendix 6] and to include the right of the donor to withdraw consent at any time.
This form must be signed by the donor, a physician in the surgical team performing the nephrectomy and the National Transplant Center

Appendix 5

Permission form for living donor kidney donation from the National Transplant Center

Appendix 6

Consent form for donor-recipient meeting

This may be arranged six months after the operation – but only with the full signed informed consent of ***both*** donor and recipient. The National Transplant Center is absolved from responsibility for any possible negative effects resulting from such a meeting. Prior counseling is advised.