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Meeting Report

Incentives for Organ Donation: Proposed Standards for an Internationally Acceptable System

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Incentives for organ donation, currently prohibited in most countries, may increase donation and save lives. Discussion of incentives has focused on two areas: (1) whether or not there are ethical principles that justify the current prohibition and (2) whether incentives would do more good than harm. We herein address the second concern and propose for discussion standards and guidelines for an acceptable system of incentives for donation. We believe that if systems based on these guidelines were developed, harms would be no greater than those to today's conventional donors. Ultimately, until there are trials of incentives, the question of benefits and harms cannot be satisfactorily answered.

Key words: Incentives, organ donation

Abbreviations: ESRD, end-stage renal disease; GNP, gross national product.

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Introduction

Every country with an active kidney transplant system is working to increase organ donation. The reasons are clear—for patients with end-stage kidney disease (ESRD), a kidney transplant offers significant advantages compared to dialysis: increased longevity (1), a better quality of life (2) and cost-effectiveness (including cost saving for the health care system; Ref. 3). Patients can receive a kidney transplant from either a living (biologically related or unrelated) or deceased donor. However, kidneys from living (vs. deceased) donors are associated with better short- and long-term outcomes (4) and facilitate early or preemptive transplantation, thus avoiding the adverse consequences associated with dialysis (5).

Because of the benefits of transplantation, patients with ESRD increasingly opt for a transplant. Because of the increasing demand for a transplant and a relatively static supply of organs, there is a widening gap between the number of patients wanting a kidney and the number of available organs. This growing shortage persists in spite of efforts to prevent ESRD and the recent expansion of both deceased donation (through the use of such strategies as expanded donor criteria and donation after cardiac death) and living donation (through increased unrelated and nondirected donation, paired exchanges, ABO incompatible transplants, desensitization and transplant chains). Because of the ongoing shortage, many suitable transplant candidates suffer and ultimately die while waiting for a transplant.

In most countries donation is limited to "altruistic" donors (in the case of deceased donation, donor families) and by law, donors are not allowed to receive anything of material value in exchange for giving a kidney. Within some countries, only biologic relatives are permitted to be living donors. Yet, because of: (1) the shortage of kidneys, (2) the morbidity and mortality associated with long-term (or no) dialysis, (3) increasing desperation of many candidates and (4) the potential for profit, illegal and unregulated organ markets have developed throughout the world. Such underground, unregulated markets have been associated with exploitation of the poor and vulnerable.

Living donors who participate in these unregulated markets are often poorly informed about the procedure, deprived of appropriate screening and of quality postoperative and continuing medical care, and not compensated as agreed upon (6–9). At the same time, because of limited donor screening, some recipients have developed serious infections transmitted by the donor organ; others have received little postoperative care or immunosuppressive treatment and have returned to their native country with active rejection and no knowledge of which immunosuppressive medications they were given (9–13). Often, the medical and surgical details have not been sent with them, so that their home transplant center has tremendous difficulty with continuation of care. Thus, these unregulated markets have been associated with adverse consequences for both donors and recipients.

A regulated system of incentives for donation has the potential to increase both living and deceased donation while eliminating the harms of unregulated markets. When the concept of incentives was first proposed, almost 3 decades ago, there was immediate condemnation (14).

Table 1: Potential disincentives for a living donor

(1) Fear of financial hardship because of:
(a) Travel, accommodation, childcare and medication cost at the time of assessment and donation procedures;
(b) Loss of income at the time of donation and during the recovery phase;
(c) Loss of or difficulty obtaining health and life insurance after organ donation;
(d) Loss of employment opportunities after organ donation.
(2) Fear of death, disability or functional restriction. These fears encompass both short- and long-term sequelae of donation, including perceived effects on fertility and childbearing.
(3) Fear of a lost opportunity. Potential donors may prefer to retain a kidney for future potential recipients, especially children.

Over the ensuing years, the pros and cons of incentive programs have been debated. At first, many opposed incentives as a matter of principle, claiming that an incentive for donation was wrong in itself. Yet, numerous scholars and consensus conferences have concluded that there are no ethical principles by which incentives should be rejected under all circumstances (15–19). Surveys have shown that the public: (1) support incentives and (2) would be more likely to donate if incentives were offered (20,21). More recently, critics of donor incentives have argued on utilitarian grounds that incentives should be prohibited because they would do more harm than good (22). However, the "evidence" used as the basis of that argument has almost entirely been drawn from observation of unregulated organ markets. We are fully cognizant of the harms that have occurred with unregulated markets and unreservedly condemn the practice of organ trafficking (23). However, there are no data to suggest that similar harms would occur in a carefully controlled, transparent and regulated system of incentives.

The debate surrounding the principle of incentives *per se* will no doubt continue. Our view, however is that there is no objection of principle and that a system of incentives for donation could potentially provide enormous benefit to both recipients and donors and is worthy of systematic investigation. Instead of treating the hypothetical harms as a reason for forgoing these benefits outright, we believe the international community should try to devise ways of identifying and eliminating the dangers while maximizing the benefits. To further the discussion, we propose principles and guidelines that would, assuming legal frameworks were changed to make this permissible, provide the basis for an acceptable system of incentives. While not intended as definitive, we suggest that any system that conformed to the proposed guidelines would meet the standards, which both supporters and opponents of incentives could agree are necessary (if not sufficient) for any system of donation and are consistent with the standards that we have developed for current conventional donation.

Donor Motivation

The discipline of transplantation is suffused with assumptions of an idealized vision of current motives for donation: that is, all organs are and must henceforth be, given in the spirit of pure "altruism". There are two problems with this reasoning. The first is that any realistic discussion of donation must acknowledge the many different and overlapping motives that underlie donation within and outside of families (24). Although we speak of the "gift-of-life", we also recognize that current donors often have alternative or additional motives or external pressures, e.g. a sense of obligation, a need to be accepted or valued by family and friends or even an easily identifiable secondary gain (24–28). If we were to limit donation to those motivated only by pure altruism, it is likely that donors would be few and far between. Conversely, it is entirely possible were incentives permitted, incentivized donors might use the reward for altruistic purposes (such as the care of sick family members). Rather than confirming a dichotomy of altruism versus no altruism, experience is most consistent with a continuum of motivation to donate organs, ranging from complete selflessness to blatant self-interest.

The second problem with the mandate for "altruism" is that there is no other context in which it is stipulated that something urgently needed must be given without payment or not given at all. Creating such a principle of altruism for organ donation is totally arbitrary and ignores the fact that our current donors frequently receive secondary gain or other unspoken tangible reward. We must also recognize that many highly motivated potential donors do not come forward or do not progress through the evaluation and donation process because of the substantial financial and logistical obstacles (Table 1). Others, though initially motivated by the opportunity to help another, might be even more likely to come forward if there were incentives.

Today's Situation

Current, unregulated markets that do not offer protection for either the donor or recipient are abhorrent. Yet the arbitrary requirement for what is deemed "altruistic" donation must be viewed against the backdrop of the organ shortage and its tragic consequences for transplant candidates. In countries able to afford dialysis, waiting time from listing until transplant continues to increase, as does mortality on the wait list. In developing countries, where health care costs are assumed largely by the patients themselves, lifetime dialysis is not an option. Some can manage to afford limited and intermittent dialysis by scraping together resources, a response that typically results in inadequate care and places a severe burden on the financial well being

of their families. In such countries, because of its significantly lower long-term costs, transplantation is the only realistic path to long-term survival. Without a significant increase in donor kidneys, in both developed and developing nations, preventable morbidity and mortality in patients with renal failure will continue.

Although we have focused on kidney donation, the same concerns (lack of sufficient organs; candidates dying while waiting) apply to other solid organ transplant candidates. Most liver, lung and pancreas transplants and all heart transplants, come from deceased donors. Incentives for deceased donation may also help provide more extrarenal transplants.

When a product is desired, a market (legal or illegal) will develop; prohibition simply drives markets further underground (29,30). The tangible harms of organ trafficking can be directly traced to its illicit, underground features: lack of control, regulation and oversight. These elements conspire to disenfranchise and damage vulnerable donors and ensure suboptimal outcome in recipients. Clamping down on unlawful organ sales without expanding the organ pool will not result in less criminal activity. Patients will continue to die as purveyors of this corrupt trade go further underground and other markets develop elsewhere around the globe.

Proposed Solution

Regulated systems that remove disincentives to donation and reward donors have the potential to increase donation, save lives and reduce or eliminate the unregulated markets and the harm they cause. We herein propose for discussion principles and guidelines for development of acceptable systems of incentives for deceased and living donation.

(1) Removal of Disincentives
Donors (or donor families) should suffer no short- or long-term financial burden as a consequence of organ donation. Disincentives for living donation should be eliminated. At a minimum, this would entail reimbursement of expenses and lost income, along with provision of term disability insurance, term life insurance and care of donation-related complications.

In some countries, there may also be financial disincentives to deceased donation (e.g. cost of family travel to the medical center to give consent). These should be addressed and abrogated. Within each country, policies to maximize the benefit of deceased donor programs should be enacted. This is particularly important for those waiting for extrarenal transplants, where living donation is not an option.

(2) A Regulated System of Incentives
An acceptable system of incentives for donation must ensure—for both the donor (and donor family, in the case of deceased donation) and recipient—respect, benefit and protection from harm. More specifically:

(i) the donor (or family) is respected as a person who is able to make choices in his or her best interest (autonomy);
(ii) the potential donor (or family) is provided with appropriate information to support informed decision making (informed consent);
(iii) donor health is promoted at every step, including evaluation and medical follow-up (respect for person);
(iv) the live donor incentive should be of adequate value (and able to improve the donor's circumstances);
(v) gratitude is expressed for the act of donation.

Critical elements of such a system would be protection, regulation, oversight and transparency under the auspices of the appropriate government or government-recognized body.

(1) Protection: Risk to the donor should be in accord with currently accepted standards as defined for our current donors (31). The donor benefit (in addition to helping another person) must be an opportunity to improve their own (or their family's) life. Therefore, the donor must be fully informed, understand the risks, understand the nature of the incentive and how it will be distributed and receive the benefit. There must be follow-up and an opportunity to redress any wrongdoing.

(2) Regulation and Oversight: Each country will need to enact guidelines for evaluation and selection of donors, institution of the program of incentives and oversight. Regulations and oversight processes must be clearly defined and available for outside review, whether national or international. There must be clearly defined policies for follow-up, outcome determination and for detection and correction of irregularities. There should be defined consequences for entities within the system that do not adhere to policies.

(3) Transparency: Although, for political and legislative reasons, regulation and oversight are only possible at a national level, there must be transparency so that international observation is possible.

Guidelines for Development

Guidelines for development of acceptable regulated incentive systems for deceased or living donation are specified in Table 2. Critical (in addition to protection, regulation, oversight and transparency) are that the donation should be anonymous and nondirected, allocation should be to the first person on the list (using a predefined and transparent algorithm) and the incentive be provided by the state or state-recognized 3rd party. Additional guidelines for living

Table 2: Guidelines for development of a regulated system of incentives for deceased and living donation

(1) Each country implementing a system of incentives should have a legal and regulatory framework for the process.
(2) The entire process must be transparent and subject to government and international oversight.
(3) The incentive should be provided by the state or state-recognized third party. Under well-defined, transparent and regulated circumstances, prospective recipients may help fund a charity that supports the program. There is no direct payment from the recipient to the donor and supporting the charity will not result in advancement on the waiting list.
(4) Allocation of the organ(s) should be performed according to the single recognized system of that country (similar to UNOS in the United States) using a predefined and transparent algorithm so that everyone on the list has an opportunity to be transplanted. Kidneys would be allocated to the number 1 person on the list (as determined by defined and transparent criteria).
(5) There should be a plan for administration and for rigorous oversight to ensure that criteria for evaluation, acceptance, allocation and provision of the incentive to the donor (or donor family) are being followed.
(6) The donation should be anonymous and nondirected.
(7) No other solid organ donor incentive plan would be legal.
(8) There should be legislation to govern wrongdoing and how centers would be censured, including criminal sanctions and fines, if wrongdoing is identified.

donor systems are specified in Table 3. Key items include informed consent, screening similar to our conventional donors, a fixed "incentive" to the donor, limitation to citizens and legal residents and long-term follow-up studies.

Discussion

The test of any regulated system of incentives for organ donation would be its provision of clear benefit to both donors and recipients. Patients who desperately need organs would obviously benefit if more were available and there is no reason to doubt that many donors would benefit from receiving an incentive under properly controlled circumstances. Permitting incentives would allow competent, properly informed adults to make their own judgments about their own best interests—widely regarded as an essential feature of respect for human dignity.

Many types of incentives that would meet these criteria are potentially acceptable and some donors (within the same system) might prefer different incentives than others. The form and substance should be determined by individual governing bodies commensurate with the principles outlined above. For deceased donation, it would need to be decided if the plan should include predeath benefits (which has the disadvantage that many receiving benefits would not be able to donate at the time of death), an incentive for registering as a donor where the benefit only accrues in the event that the signatory actually becomes a donor, or simply to provide benefits (e.g. funeral expenses) at the time of donation. For living donation, in addition to removal of disincentives (23), benefits could include (but would not be limited to): long-term health care, tax credit, tuition or job training; provision of a job; or payment (which could be a small payment and then additional annual small payments when returning for follow-up visits). Implementing a regulated system of incentives will clearly be simplest within societies that already have an adequate social safety net, registries of health outcomes and provision of long-term health care for all citizens and legal residents.

Table 3: Additional guidelines for development of a regulated system of incentives for living donation

(1) There should be a clear and transparent process for providing information about risks to the donor, ensuring that the donor understands the operation and its risks and obtaining donor consent.
(2) There should be a thorough donor screening evaluation using defined (and widely available) protocols. There should be well-defined and transparent criteria for donor acceptance.
(3) There should be a fixed "incentive" to the donor so that all donors (in any one country) receive equal value. The package of incentives may vary from one geographic region to another but should be designed to improve the life of the donor. Even within the same region, it may be possible to have a choice of benefits recognizing that some incentives may be of value to some donors but not others.
(4) The program (donors and recipients) should be limited to citizens and legal residents. This will allow long-term donor medical care and follow-up.
(5) The donation should remain anonymous and there should be no contact between donor and recipient.
(6) The donor should understand the need for long-term follow-up and should consent to follow-up.
(7) There should be a well-defined and transparent method to follow incentivized donors and study outcomes. There should be:
(a) Studies of the impact of incentivized donation on the number of deceased and living donors, the number of transplants (covering all organs), the wait list and waiting time for a deceased donor transplant;
(b) Comparisons of short- and long-term outcomes (including quality-of-life) of incentivized versus nonincentivized donors;
(c) Studies of whether the incentive had an impact on the donor's life.

The absolute value of the incentive might legitimately differ from one country to another but, for living donors, it should be sufficient to significantly improve the donor's well-being. The GNP and cost of living vary from country to country and the level of benefits within any one country (or geographic area) would obviously have to reflect local economic conditions. Given that incentive programs would be limited to citizens and legal residents (for both donors and recipients; Table 3), travel to another country to receive a greater incentive would not be possible. In addition, there could be a "cooling-off period" between initial evaluation and donation (so that some tests [e.g. viral testing] could be repeated and those seeking an instant payment would have sufficient time to carefully consider the risks).

Whether provision of health care is an incentive or removal of a disincentive is controversial. Most developed countries (the United States is an exception) provide government-sponsored long-term health care for everyone; in these countries the issue is moot. Most developing countries cannot afford universal lifelong health care. At a minimum, donors should be provided with health care for all donation-related issues (23). Yet, in reality, it will be difficult to determine whether or not many health care issues are related to the donor event. Ideally, long-term health care should be provided as a benefit to all donors. Publically financed health care would: (1) be of major benefit to citizens of all societies and (2) allow donor follow-up and therefore permit the transplant community to prospectively identify and correct any unintended consequences of a program of incentives.

Epidemiologic studies have reported that poverty is associated with increased chronic kidney disease, poorer health and shorter life expectancy (32). This is of concern given the likelihood that the majority of incentivized donors will come from lower income groups. However, the same data suggest that the health risks associated with poverty are related to increased rates of hypertension and diabetes as well as to reduced access to medical care. Currently, low income is not a contraindication to conventional "altruistic" donation and our current selection processes eliminate potential donors at increased risk. If we use the same cautious selection and approval process for all donors, long-term outcomes are likely to be comparable. In fact, the provision of long-term follow-up and long-term health care—as one of the benefits of incentivized donation—has the potential to improve overall health of the donors. It is difficult to conceptualize an incentive system in which low income is a contraindication to participation. However, if follow-up studies were to show that low income incentivized donors had worse outcome than nonincentivized donors, an income threshold could become a requirement for future participation. All arrangements should be adjustable in the light of experience.

Would it be necessary to provide an incentive to all donors, directed and nondirected? Each country would have to make that decision. Clearly, disincentives should be removed for all donors. However, as discussed above, directed donation has potential benefits to the donor. For example, a husband donating to his wife benefits from having a healthy spouse. It may be that the optimal system would occur if all donors receive incentives; it may be that the optimal system is a two-tier system with more incentives for nondirected than directed donors. Trials are necessary to answer this question.

As with any proposal for change, there are potential strengths and weaknesses. The major potential advantages of a regulated system of incentives for donation are increased organ availability for candidates on the waiting list combined with provision of benefits for the donors (or donor families). However, until there are trials, we have no means of knowing under precisely what circumstances such a proposal would best succeed. Thus one concern is that the total number of transplants (especially for extrarenal organs) might decrease. This concern would, however, be mitigated if the opportunity to alter variables within the incentive system were used. The reason we do not know which incentives might be suitable and effective is the historical blanket prohibition of all such efforts. If this prohibition were set aside as we propose, an iterative approach could address all aspects of the process so that it is improved over time.

A second concern is that, today, most unregulated markets occur in countries that prohibit incentives for donation, but lack the appropriate control or willingness to enforce the prohibition. Arguably, similar lack of control could limit the success of our proposed system. Our proposal requires clear legislation and national framework, strong government control and safe and transparent procedures and screenings. For each country, before a system of incentives is tested, policy and guidelines must be developed and a system for their strict implementation must be put in place. Donor and recipient protection is paramount. The single greatest threat to a regulated system of incentives for donors would be that dishonest individuals or groups would seek to subvert that regulation for personal gain, a risk that applies to any legal enterprise. Ways of mitigating this threat would include minimizing transaction fees and making all payments transparent and open to regular audit.

Whereas every possible circumstance cannot be anticipated, this document outlines the broad intent of an ethical framework for a regulated system of incentives for donation. For example, the guidelines (Table 3) limit participation (both donor and recipient) to citizens and legal residents. In theory, a country could grant rapid citizenship for the purpose of either donating or receiving a kidney. This clearly contravenes the spirit and intent of this document and such a practice would not meet international acceptance, a criterion that the group felt was an essential component of any ethical system. In addition, some countries (e.g. the United States) currently allow

transplant centers to allocate a percentage of deceased donor organs to nonresident foreigners (33). If regulated systems of incentives are developed for such countries, it will need to be determined if kidneys from incentivized donors could be allocated to foreign nationals.

We recognize that this document—like others of its kind—represents the consensus opinion of the coauthors. Even within our group, some would be more restrictive, some more liberal. However, all agreed on the basic principles outlined herein and that any arrangement that fulfilled all of these criteria would be ethically acceptable. We present it as a pragmatic foundation for developing acceptable systems of incentives for donation.

International experience with transparent, government approved, fully regulated systems, is limited. Once such systems have been developed and tested, the guidelines may need modification; however, the overarching principles—protection (donor and recipient), regulation, oversight and transparency—will remain applicable.

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