

Why We Should Develop a Regulated System of Kidney Sales: A Call for Action!

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The main argument in favor of a regulated system of payment to living kidney sellers is simple: Financial incentives will increase donation, so fewer of our wait-listed transplant candidates will die while waiting. Wait-list deaths are a relatively new and increasingly severe problem for patients with ESRD. As recently as the early 1980s, the average wait for a deceased donor (DD) kidney transplant was <1 yr; currently, it is >5 yr. Despite decades of effort, there has been little increase in DD organ donation, and that increase has come from the use of expanded-criteria donor (ECD) kidneys (which are associated with decreased patient and graft survival rates and would have been rejected routinely 20 yr ago). In addition, Sheehy *et al.* (1) reported that even if every potential donor in the United States became an actual donor, there still would be a shortage of kidneys, yet the reality is that in countries such as Spain, which has maximized donation, only 75% of potentially available kidneys are recovered.

Associated with the increasing waiting time is an increased rate of candidate death while waiting. In 2001, Ojo *et al.* (2) reported that 6.3% of wait-listed candidates died each year; by 2005, this rate had increased to >8% per year (3). If the average wait is >5 yr, then >40% of wait-listed candidates may die before undergoing a transplant. Remember, these were acceptable candidates when listed. Review of our data at the University of Minnesota showed that the average (\pm SE) age of candidates who died while waiting for a kidney was 53 ± 11 yr; 70% were waiting for a first transplant, and 70% had a panel-reactive antibody level of <10% (4).

Other reasons abound for considering a regulated system of incentives for donation. First, unregulated systems that do not protect the seller currently exist in a number of countries. Many patients with ESRD, desperate for a transplant, travel to take advantage of these unregulated systems. Development of a regulated system may minimize or eliminate this “transplant tourism.” Second, compared with dialysis, a transplant increases the patient survival rate and improves quality of life; the sooner the transplant after development of ESRD, the better the posttransplant outcome (5–7). Increasing donation will

shorten (or eliminate) the waiting list, shorten waiting time, and improve the survival rate for our patients.

Considering a regulated system of sales does not preclude other ongoing attempts to increase donation (*e.g.*, Breakthrough Collaborative) or to find novel ways to use willing donors (*e.g.*, paired exchange, ABO-incompatible or crossmatch-positive transplants, nondirected donation), but even if all of these alternatives succeed, the projected number of transplants still would be insufficient to eliminate the donor kidney shortage. A viable regulated system has been described in detail elsewhere (8). The principles are as follows: (1) payment to the donor (hereafter, I use the term paid donation) by the government or insurance companies, (2) allocation of kidneys by a predefined algorithm (similar to the United Network for Organ Sharing algorithm) so that everyone on the list has an opportunity for a transplant, (3) full donor evaluation, (4) informed consent, (5) oversight, (6) long-term follow-up, and (7) treatment of the donor with dignity and appreciation for providing a lifesaving gift. The payment could be a fixed sum and/or include term life insurance, long-term health insurance, reimbursement for travel expenses and time out of work, or a tax deduction (9). Importantly, because dialysis is so much more expensive than a transplant, paid donation could be cost-neutral to the health care system (10). Such a regulated system likely would not be feasible in all countries but would work only in countries or in geographic areas (*e.g.*, Eurotransplant) where long-term donor health care and long-term follow-up could be guaranteed. For the same reason, donors would need to be limited to countries or geographic areas that could provide long-term health care and follow-up (*i.e.*, individuals could not come from elsewhere to be paid donors). It would be necessary to show that outcome for a paid donor does not differ from outcome for a traditional, unpaid living donor.

How would such a system work? National criteria could be established regarding tests and results to require in the donor evaluation. The evaluation could be coordinated by the regional organ procurement organization (OPO) and be reviewed at the OPO by a panel consisting of a transplant surgeon, a transplant physician, a social worker, an OPO coordinator, and a donor advocate. If the donor is accepted, then a regional negative-crossmatch list would be generated, the extant United Network for Organ Sharing algorithm would be run, and the kidney would be offered to the highest ranked candidate on the waiting list. (A policy decision would have to be made regard-

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ing whether to run a national list and give priority to 0 HLA mismatch candidates.) If the center and the potential recipient accept the offer, then the detailed donor evaluation would be sent to the center (which then again would have the opportunity to accept or reject the offer). If the center or the potential recipient refuses the offer, then the next candidate on the list would be offered the kidney. All bills that are generated by the donor evaluation, donor surgery, and donor follow-up would be sent to the OPO. The administration, including donor payment and long-term follow-up, would be done at the OPO level. When a transplant finally is scheduled and done, the center would be charged an acquisition fee by the OPO; this fee would be paid by the recipient's insurance or the government (e.g., Medicare). A similar mechanism of central evaluation and allocation has been established already in some OPOs for non-directed donation (11,12). Having the OPO coordinate donor evaluation, allocation, and follow-up will ensure national reporting and oversight.

It is critical to differentiate a regulated system from *unregulated* systems in practice elsewhere. In an *unregulated* system, the buyer contracts with the seller to purchase a kidney (often through a broker). Only the rich can be buyers, with little oversight of the donor evaluation, no long-term donor follow-up, and no protection of either the buyer or the seller.

If a regulated system of payment would save lives, why has such a system not been implemented in the United States? Unfortunately, in 1984, Congress banned financial incentives for donation (13). This ban was enacted at a time when the waiting time for a kidney was short, in direct response to one individual's attempt to establish an *unregulated* broker service. It is time for Congress to reconsider this ban. The general public favors financial incentives: In fact, two national surveys (done when the waiting time was less of a problem) reported that the general public is much more willing than the medical community to accept sales (14,15). In 1991, Kittur *et al.* (14) found that 52% of the general public favored sales. Subsequently, Guttman and Guttman (15) found that 70% of the general public and 51% of medical students but only 25% of surveyed physicians and nurses favored sales.

Numerous arguments have been raised against a system of incentives, none of which is persuasive. I have grouped them into five categories (Table 1 and next). We already accept unpaid kidney donation; therefore, any persuasive argument against sales must nevertheless permit donation.

1. Arguments that do not distinguish between donation and sales include the following: (a) the paid donor could be harmed (but the operation would be identical to the unpaid donor operation); (b) there can be no genuine consent (but the information provided would be identical to that provided to an unpaid donor); and (c) we do not know enough about long-term risk to donors (but we know a great deal about the risk—perhaps not to the detail of 0.1%—but certainly enough to state that there is little increased long-term risk to donors).
2. Arguments with no supportive data include the following: (a) If there were sales, then donation would decrease. Even if

Table 1. Arguments against a regulated system of sales (paid donation)

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1. Arguments that do not distinguish between donation and sales
 - a. the paid donor would be harmed
 - b. there can be no genuine consent
 - c. we do not know enough about long-term risk to donors
 2. Arguments with no supportive data
 - a. donation would decrease
 - b. donation should be purely altruistic
 - c. the traditional doctor–patient relationship would be damaged
 3. Arguments that are not logical
 - a. *unregulated* systems have failed elsewhere
 - b. Congress and various professional societies have already voted for prohibition of sales
 - c. sale of blood failed
 - d. the church would object
 - e. a financial incentive is coercion
 - f. the system would be abused
 4. Commodification of the body
 5. Exploitation of the poor
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this were true, if the total number of available organs increased, then it would not matter; in addition, it would be good to remove family pressure to donate, pressure that might contribute to much of what we currently believe is “altruistic” donation; and, potentially, the elimination of the use of ECD kidneys would improve the overall outcome of transplantation. (b) Donation should be purely altruistic (there is no reason that this must be, and it is likely that there are many reasons, beyond pure altruism, for why individuals donate [16]). (c) The traditional doctor–patient relationship would be damaged (this has not been true for egg donation [which requires an operative procedure] or for surrogate motherhood).

3. Arguments that are not logical include the following: (a) *unregulated* systems have failed elsewhere (but this is not an argument against a regulated system); (b) Congress and various professional societies have already voted for prohibition of sales, so we should end discussion of the issue (but these votes occurred when the waiting time was short and there was a low likelihood of dying before receiving a transplant); (c) sale of blood failed (but this was before effective testing for HIV and hepatitis C); (d) the church would object (but we are supposed to have separation of church and state; moreover, major Western religions give priority to saving a life); (e) a financial incentive is coercion (but this is misuse of the word “coercion,” which means “persuasion [of an unwilling person] to do something by using force or threats” [17]; no potential paid donor can be coerced by the opportunity to sell an organ); and (f) the system would be abused—either by transplant personnel who would relax acceptance criteria because they want to do more transplants

or by paid donors who lie about their health history (but the potential for abuse would be minimized by appropriate screening and oversight [*e.g.*, potential paid donors could have viral screening twice, at 6-mo intervals; the donor evaluation and acceptance would be done by the OPO]; besides, the potential for abuse is not a sufficient reason to allow wait-listed patients to die: tax abuse has not led us to ban taxation).

4. Sales would be commodification of the body and therefore are wrong. Those who present this argument imply that putting a value on a body part and objectifying the body would result in loss of human dignity, but sperm donors, egg donors, and surrogate mothers have not suffered loss of dignity. As Gill and Sade (18) stated, “my kidney is not my humanity.” In part, dignity is something that we convey by our behavior and attitudes. If we establish a regulated system of sales, then it is our responsibility to create a culture of dignity for the paid donor. Many have suggested that the term “paid donation” or “rewarded gifting” be used to confer dignity to the procedure (19,20). An extension of this argument is the concept that establishing a system of sales would harm society, because an individual’s value would shrink to be the sum value of his or her body parts. In reality, the court system (*e.g.*, damage claims) has already established a value on loss of or damage to various body parts or functions; this legal valuation has not resulted in loss of appreciation of the value of an individual. Similarly, establishment of the systems for sperm donation, egg donation, and surrogate motherhood have not harmed society.
5. The final argument used against sales is that they would lead to exploitation of the poor. There is little doubt that the poor would be more likely to be paid donors, but is this exploitation if the individual makes an autonomous decision (after being fully informed) and receives something of value in return? We do not prevent the poor from taking jobs with risk that the rich do not take (*e.g.*, as miners, firefighters, police, military), and in all other areas of our society, we allow the poor to make autonomous decisions. With kidney sales, “in a surprising contravention of our usual ideas about individual liberty, we prevent adults from entering freely into contracts from which both sides expect to benefit, and with no obvious harm to anyone else” (21). By prohibiting the poor from selling a kidney, we leave them poor and remove an opportunity for them to better their lives.

Unfortunately, those who argue against sales have (erroneously) touted a recent Institute of Medicine (IOM) report as supporting their cause (22). The IOM was asked by the Health Resources and Services Administration and the Greenwall Foundation to study the issues involved in increasing the rates of DD organ donation “in light of the ethical, religious, and moral standards commonly found in the United States.” The report, which was thoughtful in its analysis of the issues, has been criticized by many as being too timid in its recommendations (23–25). In regard to financial incentives, the report stated (Recommendation 8.1): “The use of financial incentives to increase the supply of transplantable organs from deceased indi-

viduals should not be promoted *at this time*” (italics added). The report went on to state that “the committee’s deliberations have been influenced by the recent success of donation initiatives that do not rely upon donor incentives,” yet, as described previously, even if all potential DD donors became actual donors, there still would be a shortage (1). The IOM authors acknowledged the lack of data on the impact of incentives but suggested that if pilot trials are initiated to obtain the data, the consequences might be hard to reverse: “If people begin to view their organs as valuable commodities that should be purchased, then altruistic donation may be difficult to invigorate” (22), but why should this matter if the number of transplants increases and more lives are saved?

Those who are opposed to a regulated system of sales imply that they are taking the moral high ground by protecting the potential paid donor (from exploitation? from the harm of surgery?) or by protecting society (from loss of human dignity?). The end result, however, is that they are sentencing many of our transplant candidates to death.

There is no avoiding this tremendous ethical dilemma. Yes, kidney donation has risks, albeit small; yes, the poor are more likely to be the paid donors, but prohibition of incentives now results in the (preventable) death of many of our patients (and it prevents the potential paid donor from receiving a payment that might have significant benefit). Even opponents of sales recognize this dilemma and waffle when discussing the issue. Delmonico *et al.* (26) proposed an “ethical incentive”—payment of \$300 to consenting families of potential DDs for funeral expenses. Terasaki (27) proposed a gold medal, one with significant value (\$10,000), that could be sold.

Beauchamp and Childress (28) defined four principles to apply in bioethics discussions: (1) respect for autonomy; (2) beneficence, including the obligation to benefit others (positive beneficence) and to maximize good (utility); (3) justice (fair and equitable distribution of benefits and burdens); and (4) nonmaleficence (the obligation not to inflict harm). They argued that when the principles conflict (*e.g.*, kidney donation), they must be balanced. We clearly accept that the advantages of unpaid living donation (respect for autonomy and maximized outcome for patients with ESRD) outweigh the harm (risk to the donor). When applied to kidney sales, these principles similarly conflict, yet the equation is very similar to unpaid donation: The benefits of permitting financial incentives (respect for autonomy, maximized outcome for patients with ESRD, and benefit to the paid donor [*e.g.*, payment, health care]) outweigh the harm (risk to the paid donor).

I argue that the moral high ground is to eliminate the ban on financial incentives so that we can increase the number of transplants, significantly decrease or eliminate wait-list deaths, and improve the overall survival rate and quality of life for patients with ESRD. It is time for those who are involved with the care of patients with ESRD to unite and to call on Congress to eliminate this ban. Transplants are cost-effective compared with dialysis, and a system of financial incentives could be cost-neutral to the health care system. Once the ban on incentives is lifted, we can initiate pilot trials to determine whether

incentives would increase the number of available kidneys for our wait-listed transplant candidates.

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