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VIEWPOINT

A regulated system of incentives for living kidney donation: Clearing the way for an informed assessment

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The kidney shortage continues to be a crisis for our patients. Despite numerous attempts to increase living and deceased donation, annually in the United States, thousands of candidates are removed from the kidney transplant waiting list because of either death or becoming too sick to transplant. To increase living donation, trials of a regulated system of incentives for living donation have been proposed. Such trials may show: (1) a significant increase in donation, and (2) that informed, incentivized donors, making an autonomous decision to donate, have the same medical and psychosocial outcomes as our conventional donors. Given the stakes, the proposal warrants careful consideration. However, to date, much discussion of the proposal has been unproductive. Objections commonly leveled against it: fail to engage with it; conflate it with underground, unregulated markets; speculate without evidence; and reason fallaciously, favoring rhetorical impact over logic. The present paper is a corrective. It identifies these common errors so they are not repeated, thus allowing space for an assessment of the proposal on its merits.

KEYWORDS
clinical trial design, donors and donation: incentives, donors and donation: living, editorial/personal viewpoint, kidney transplantation/nephrology, kidney transplantation: living donor, organ allocation, organ procurement and allocation, social sciences

The concept of incentives for living donation arose early in the history of kidney transplantation. In the 1960s, the framers of the Uniform Anatomical Gift Act noted "every payment is not necessarily unethical", but "until the matter of payment becomes a problem of some dimensions, the matter should be left to the decency of intelligent human beings".[1] In 1983, the matter of payment became a problem when, in response to the organ shortage, a physician (whose license had previously been revoked) established a company to broker international kidney sales. Impoverished residents of low-income countries were to be flown to the United States to sell their kidneys at a nominal price. This was met with general condemnation, and in part, led to passage of the National Organ Transplant Act (NOTA, Public Law 98–507) which made it a federal crime to "knowingly acquire, receive or otherwise transfer any human organ for valuable consideration for use in human transplantation…". At the same time, the World Medical Association, the World Health Organization, the Council of Europe, and the International Council of the Transplantation Society, among others, issued statements of opposition to the sale of organs.

Over subsequent decades, improving transplant outcomes led to expansion of candidacy criteria (e.g., older, more comorbidities), resulting in rapid growth in the number of patients on the kidney

Abbreviations: ESKD, end stage kidney disease; OPOs, organ procurement organizations.

transplant waiting list. However, there was not a commensurate increase in organ donation. As a consequence, there were long waiting times for a deceased donor transplant, a high waitlist mortality, and an increasing number of candidates being removed from the list because of becoming too sick to transplant. Innovations in living (e.g., nondirected donation, paired exchange) and deceased donation (e.g., donation after circulatory death) have led to a 45% increase in the number of kidney transplants in the last decade. Yet, this has made no dent in waitlist morbidity or mortality. Annually in the United States approximately 8000 waitlisted transplant candidates die or are removed from the list because they have become too sick to transplant.[2] Sadly, even this figure underestimates the extent of the shortage. In 2008, Schold et al. reported that over 135 000 patients on dialysis had >5-year life expectancy and were potentially good transplant candidates but were not listed.[3]

One consequence of the shortage has been the emergence of underground, unregulated markets for kidneys. Patients with end stage kidney disease (ESKD) from wealthy countries, aided by a broker, travel to poor- or middle-income countries to purchase a kidney. In these underground markets, neither donor nor recipient are protected. This practice is widely condemned by both the general and transplant communities.

This situation—increasing demand, limited supply—has prompted ongoing discussion of incentives. In 1989, bioethicist James Childress wrote "If a system of donation with various modifications proves to be insufficiently effective, then trials of sales could be considered."[4] In 1997, the Bellagio Task Force on Transplantation, Body Integrity, and the International Traffic in Organs found that the international proclamations condemning the purchase of organs failed to provide a rationale for their decision, instead issuing statements "in one or two short sentences with no supporting arguments".[5] The task force concluded that there was "no unarguable ethical principle that would justify a ban on sale under all circumstances". The next year, the International Forum for Transplant Ethics stated that the discussion of incentives should be re-opened; and given the potential benefit, the "burden of proof" rests on "the defenders of prohibition".[6] Later, in 2006, an Institute of Medicine report recommended that a pilot study of the effect of incentives should be undertaken "if other, less controversial strategies … have been tried and proven unsuccessful."[7]

The moral justification for incentivized donation is, in part, the same as that which justifies non-incentivized donation. The potential benefits to the recipient, the waiting list and society, and the informed autonomous decision of the donor candidate are balanced against the potential harm to the donor. Living kidney donation has long been allowed, even encouraged. We find it admirable and appropriate that a father might donate a kidney to his daughter suffering from ESKD. But suppose that his daughter needed cancer treatment and he sought to exchange his kidney in order to finance it. Here, too, we should regard the father's conduct as admirable and appropriate. The mere involvement of an incentive does not transform his life-saving act into a moral transgression. Of course, the fact that incentivized donation *could* be morally justified does not imply that, in practice, it would be. The questions, then, are these: Can a regulated system of incentives be designed to operate ethically? Is it reasonable to undertake trials of incentives to assess benefits and risks? Is there a specific reason or combinations of reasons not to move forward with trials (assuming they were legal)?

1 | CONSIDERATION OF TRIALS OF A REGULATED SYSTEM

Given the continuing morbidity and mortality on the waiting list, and the potential benefits of a regulated system of incentives, trials have been proposed.[8–10] Trials would answer many outstanding questions: whether living donation increases; whether conventional living donation decreases, and whether that matters; whether disadvantaged and marginalized populations exclusively participate; whether donor and recipient outcomes differ from conventional donation; whether incentivized donors feel exploited or regretful; whether deceased donation decreases.[8–10]

Guidelines for a regulated system of incentives trials have been developed (Table 1).[8,11] The essential characteristics are as follows. There would be thorough screening of donor candidates with well-defined acceptance criteria; rigorous informed consent procedures; provision of follow-up care; and anonymity between donor and recipient. To ensure long-term follow-up care is provided, and to facilitate continued study of the program's effects, only legal residents could participate. Allocation of kidneys would be by an algorithm similar to that of deceased donor kidneys in the United States so that *everyone on the list* has a fair opportunity to receive a transplant. The system would be subject to governmental oversight, including the legal framework necessary to ensure transparency and accountability. The incentive would be provided by the government, or a government appointed third party. Finally, the arrangement would be subject to ongoing research and include a built-in moratorium to ensure that the arrangement continues only if results are positive. Critically, such a system is only acceptable in countries or geographic areas that meet these conditions.

A practical approach for implementing a regulated system has been described.[11] The system could use the infrastructure currently developed for deceased donor organ procurement and allocation. National criteria would be established for incentivized donation, thereby permitting transparency, as well as government and Organ Procurement and Transplantation Network oversight. Existing organ procurement organizations (OPOs) could be expanded to administer and oversee the system. The donor evaluation and candidacy approval, and organ allocation would be done by the OPO. The OPO would be responsible for distributing the incentive, completing ongoing research, and ensuring long-term donor follow-up care.

2 | BARRIERS TO ASSESSING THE PROPOSED SYSTEM

In light of the stakes, the proposal warrants careful consideration. Unfortunately, to date, meaningful discussion has been derailed by

TABLE 1 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.
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, and there should be no contact between donor and recipient.
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.
9. 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.
10. 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.
11. 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.
12. The program (donors and recipients) should be limited to citizens and legal residents. This will allow long-term donor medical care and follow-up.
13. The donor should understand the need for long-term follow-up and should consent to follow-up.
14. 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.

Source: Working Group on Incentives for Living Donation et al.[8]
Abbreviation: UNOS, United Network for Organ Sharing.

arguments that: fail to engage with the proposal; conflate it with the unregulated, underground trade that is universally condemned; and offer rhetoric in place of evidence-based argument.[12–20] By identifying these problematic arguments, we hope to steer the conversation in a more productive direction.

2.1 | Failing to engage with the proposal

While critiquing the proposal, information relevant its evaluation is ignored, including: a regulated system of incentives has the potential to improve and extend countless lives; multiple surveys show that the public (in the United States, Canada, and Europe) are in favor of, or not opposed to incentives,[21–26] and a survey of the American Association of Transplant Surgeons supported trials[27]; studies suggest that incentives would increase the likelihood of donation *without* changing appreciation of risk[28,29]; current donors act on many motivations apart from altruism (one can act altruistically while receiving an incentive); and our conventional donors often feel pressure to donate.[30]

In addition, objections are leveled that simply fail to engage with the proposed regulations. It is claimed, for example, that: wealthy people waving cash around would induce the impoverished[12]; "the amount paid would vary according to each person's income"[14]; recipients would pay more for access to preferable organs or to undergo transplantation more quickly[13,14,18]; "financial entrepreneurs" would take a cut of donors' compensation[14]; and donors' consent would be coerced, or otherwise involuntary.[12,15,16,19] The regulated system outlined in Table 1 includes measures designed specifically to avoid these problems (e.g., Table 1 - #3,4,5,9,10,11). Yet, rather than addressing those measures—explaining why they are inadequate—these objections simply proceed as if no such measures exist. Alternatively, objections are made that diminish and misrepresent its regulations. For example, consider the claim that "the heart of 'regulating' the market in organs" is that "payments would be in a deferred form" and of an appropriate amount.[14] In reality, the "heart" of the system includes the extensive regulations, transparency and oversight outlined in Table 1.

2.2 | Conflating the regulated system with unregulated, underground markets

In a similar vein, many arguments proceed as if the regulated system under consideration were no different than the unregulated, underground markets defended by no one. Consider the oft-repeated objections that incentivized donors and their recipients would be harmed by their participation[15–17]; and that donors would be left worse off financially.[15,16] These assertions are supported—in every instance—with reference to evidence from illicit, unregulated markets bearing no resemblance to the system under consideration. The reason participants in underground markets have not benefitted—e.g., inadequate screening, ignorance about the procedure and its risks, meager compensation (and less than was promised), compromised medical care—is directly attributable to the absence of the very regulations that have been proposed.

It is asserted that trials with incentives are unnecessary in light of decades of experience.[13,18] Yet, we have no experience with anything remotely similar to the proposed regulated system. These objections refer to the international experience with underground,

unregulated markets. This objection, like the others, assumes regulation is irrelevant. In any other context, such reasoning would rightly be dismissed. We are not tempted to conclude, for example, that, since in the 1920s Prohibition brought about an increase in political corruption and organized crime, the sale of alcohol, when legal and regulated, would do the same. For the same reason, we should not be tempted to conclude that, since participants in unregulated markets were swindled by outlaws, incentivized donors in a regulated system will fare the same.

It should be noted that this argumentative strategy—conflating the regulated system with an illicit market—is not without consequence. For example, one objection condemns the proposal on the grounds that it would involve "permitting the poor and vulnerable in any community to part with a kidney for the wealthy sick."[13] This is false, as has been repeatedly stated (Table 1, #4). But further, this misrepresentation, pretending concern for the poor and vulnerable, has the opposite effect. Given that ESKD disproportionally affects people with lower socioeconomic status, members of that class—and not the "wealthy sick"—would benefit most from the regulated system.

2.3 | Arguing without evidence

Another barrier to assessing the proposal is that many arguments offered against it are speculative, without supporting data. For example, it is predicted that: medical criteria for eligible donors would be relaxed[14,16]; those who engage in illegal transactions would likely not be held accountable[14,16,17]; residency requirements will be unenforceable[14–16]; incentivized donors may be blackmailed[16] or have their payments diverted into others' retirement accounts[24]; a price could not be set for kidneys[13–15]; and that the incentives offered in the United States would be doubled or tripled elsewhere, resulting in an international auction.[17] (Interestingly, those forwarding this objection elsewhere claim that incentives would be as low as possible.[18]) These objections are offered without evidence. They reveal nothing about the merits of the regulated system. Instead, they fail to engage with the proposal, which includes measures responsive to these concerns (Table 1, #5,8,11,12).

Sometimes a series of speculative claims are combined in a single argument. Consider the assertion that "a regulated market today means accepting organs as market commodities a few years hence."[14] This outcome is claimed to follow from an elaborate sequence of imagined events—if any incentives are permitted, then additional payment from the recipients will be allowed (n.b., prohibited in the guidelines: Table 1; #3,6,7,8), then authorities will cease to enforce limits on incentives, then we will discover that incentives have not increased donation, then we will decide we cannot return to a system without incentives, then all restrictions will be abandoned, and finally, at the bottom of a very long and slippery slope, we embrace unregulated kidney markets.[14] Given the proposed guidelines, there is no reason to believe that the first event in the chain will occur, much less the entire series. As we are contemplating a policy change with profound implications, we should favor evidence over imagination.

Some arguments solely aim to persuade with emotion and rhetoric. Kidney donation is morally permissible. What is up for debate is whether it should be incentivized. Yet, it is stated that the use of incentives "is akin to…fixing a price for voluntary slavery."[13] Invocations of slavery are, in fact, common.[12,13,15] This comparison may pack a rhetorical punch, but it is fundamentally flawed. Its logic implies, perversely, that the free donation of slaves is morally unproblematic. It locates the evil of slavery, not in the ownership of people, but in their exchange for money. But that institution would be no less morally reprehensible if, rather than sold on a market, slaves were altruistically donated.

2.4 | Contradicting previous claims

Consider the objection that candidate donors might withhold information for fear of disqualification, resulting in worse outcomes than those of conventional donation.[15–19] Regulation, it is claimed, cannot solve this problem.[15–19] Yet, those who level this objection elsewhere express great confidence in the power of regulation. Discussing the current paired-exchange system in which an advanced or nondirected donor can designate five individuals to receive a "voucher" for a future kidney transplant, they hold that donors should be permitted to "designate or change a beneficiary at any time."[31] Such a policy, of course, is vulnerable to the same objection—participants might withhold information for fear of disqualification. Further, they might also transfer their voucher in exchange for payment. But here it is claimed that regulation *can* solve the problem. As they explain, "the same processes used to evaluate the relationship and motivations of contemporaneous donor–recipient pairs could be used to evaluate voucher donors and beneficiaries."[31] No reason is given to think that regulation would work with vouchers but not incentives.

In another example, it is objected that a regulated system would be too expensive.[14] Yet elsewhere—acknowledging reams of data showing that transplantation is less expensive than dialysis—these same authors admit that "kidney transplantation is not only better for patients than long-term dialysis but costs much less."[19,20]

3 | THE RISK OF INACTION

The proposal calls for *trials* of incentives, not a permanent change. Such trials would be subject to study and review and include a built-in moratorium to ensure that the use of incentives continues only if results are positive (Table 1). Still, some oppose even this provisional departure from the status quo on the grounds it is too risky.[18] However, this thinking fails to account for the risk of *inaction*. If we retain the present arrangement, we forgo the benefits we may secure by incentives, which are considerable. First and foremost are the benefits enjoyed by transplant recipients. If successful, the proposed system would increase rates of living donation. The waiting list, and time spent on it,

would both be shortened. This would reduce morbidity and mortality for those awaiting a transplant, and, by minimizing pretransplant dialysis time, improve transplant results. Second, there are the potential benefits conferred to the incentivized donors whose lifesaving contributions make so much possible. They might report that their own lives were improved by the incentive; and that they would make the same decision if they had it to do over. Finally, there is the benefit to society. Compared to patients on chronic dialysis, far more transplant recipients return to the work force. And, given that transplantation is significantly less expensive that dialysis, a regulated system might be cost-saving to the health care system.[32] From this perspective, inaction appears to be the far riskier course.

4 | CONCLUSION

If the proposed regulated system is defective, that should be revealed by an assessment of its merits. That task is considerably complicated when the conversation is dominated by arguments that fail to engage with the proposal, conflate it with underground, unregulated markets, and offer rhetoric in place of evidence. As noted above, the International Forum on Transplant Ethics concluded that the burden of proof "*rests on the defenders of prohibition.*" Yet, over 2 decades later, no such proof has been provided.

At the only joint meeting of the American Society of Transplant Surgeons and the American Society of Transplantation devoted to this topic, participants noted "we believe it is important not to conflate the illegal market for organs, which we reject in the strongest possible terms, with potential in the United States to … critically consider testing the impact and acceptability of incentives to increase organ availability."[10] They stated, "there is 'no a priori reason not to work … toward a plan for pilot projects in offering incentives."[10] That work has begun. The regulated system described in Table 1 represents the first step. What is required now is its fair assessment. Given its potential—countless lives may be improved and extended—its merits should be discussed with a commensurate level of rigor.

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