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Public Comment Proposal

A White Paper Addressing Financial Incentives for Organ Donation

OPTN/UNOS Ethics Committee

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A White Paper Addressing Financial Incentives for Organ Donation

Affected Policies: *N/A*
Sponsoring Committee: *Ethics*
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Executive Summary

Beginning in 1993, the Ethics Committee (the Committee) developed a series of white papers that are available through the OPTN website. A white paper is an authoritative report or guide that informs readers concisely about a complex issue and presents the issuing body's philosophy on the matter. It is meant to help readers understand an issue, solve a problem, or make a decision.

In 2014, the Committee began a systematic review of these white papers to evaluate if each of the white papers were accurate and relevant, and therefore valuable resources for the transplant community. The original white paper addressing financial incentives for organ donation was produced in 1993 and had not been revised since that time. The Committee determined that this white paper was no longer accurate nor relevant. The original paper was based on literature, public surveys and polls more than 20 years old. The original white paper only addresses financial incentives for deceased organ donation and preceded new donation strategies including paired donation, donation after circulatory death and new organ allocation systems that evolved of the past 20 years.

This proposed new white paper addresses potential financial incentives for both deceased and living organ donation. This proposed new white paper is based on a thorough review of current literature and includes recent studies examining public perspectives on financial incentives for organ donation.

Of note, in both the original white paper and the proposed rewrite, the Committee deliberately refrains from taking a position as to whether a federally-regulated system of financial incentives would be ethically acceptable.

Is the sponsoring Committee requesting specific feedback or input about the white paper?

Would you support the type of pilot study proposed in the Call for Empirical Research and Conclusion sections of this white paper? Please provide specific feedback on why or why you would not support pilot studies.

What problem will this white paper solve?

The resource provides an ethical analysis of financial incentives for organ donation delineating four key ethical considerations associated with providing financial incentives in a federally regulated system, and the Committee evaluates the merits of arguments raised for and against each consideration. Specifically, the Committee highlights and critically appraises normative and social assumptions underlying these arguments, and describes how these assumptions may be tested.

The original white paper developed in 1993 is no longer accurate or relevant. A number of other relevant papers—empirical and theoretical—have been published since the 1993 white paper, which the Committee references in this resource. The overall climate in the transplant community has also evolved since the original 1993 publication.

Additionally, the original white paper only considered financial incentives for deceased organ donation and was written prior to the advent of new strategies that may impact the number of organ donors. This proposed white paper provides evidence and citations from the current literature. This resource should be a beneficial reference for families or surrogates of potential donors, organ procurement organizations, and donor hospitals.

Why should you support this white paper?

This proposed white paper demonstrates that the Ethics Committee continues to consider and provide guidance on important issues faced by the transplant community. This white paper will be a resource that members could consult when addressing questions concerning financial incentives for organ donation.

How was this white paper developed?

Beginning in 1993, the Ethics Committee (the Committee) developed a series of white papers that are available through the OPTN website. In spring 2014, the Policy Oversight Committee and OPTN/UNOS Board approved a proposed project to review all existing white papers to determine the accuracy and relevancy of each resource. The Committee began a systematic review of 11 white papers to determine if the papers remained accurate and relevant. Some of the more recently developed white papers were accurate and relevant while other papers were determined to need minor or substantive revision.

The white paper addressing financial incentives was determined to be out-of-date and the Committee favored proceeding with a complete rewrite of the original paper. Of note, the original white paper only considered potential financial incentives for deceased donation. The original paper preceded the new donation strategies including paired donation, donation after circulatory death and new organ allocation systems that evolved over the past 20 years.

Committee members performed a thorough literature review and identified numerous questions or issues that should be reconsidered in this new version of this white paper. The Committee chose to have the white paper focus on financial “incentives,” which are provided to donors as a direct benefit (or intervention) for the purpose of encouraging donation, over and beyond compensation for donation expenses. The Committee examined four key ethical considerations of providing financial incentives in a government-regulated system including 1) Undue Inducement to Donate, 2) “Crowding Out”, 3) Exploitation, and 4) Commodification.

The white paper concludes with a call for empirical research which is prohibited under NOTA, and postulates that interpreting results from past studies is problematic because research participants’ responses in hypothetical scenarios may not reflect decisions that donors might make in real-world offers of financial incentives.

Several drafts of this revised white paper were developed and provided to Committee members for review and feedback. Due to the potential controversial nature of this paper, the Committee consulted UNOS senior leadership to gauge their support for sending this paper for public comment. UNOS senior

leadership provided several recommendations to improve the white paper. The Committee considered all feedback before finalizing the white paper.

The Committee met on December 15, 2016 and voted in support of sending this white paper for Board consideration.

Which populations are impacted by this white paper?

This resource could be helpful to families or surrogates, OPOs or hospitals considering the topic of financial incentives for organ donation.

How does this white paper impact the OPTN Strategic Plan?

1. Increase the number of transplants: If financial incentives for organ donation would be permitted at some point in the future, it could contribute to an increase the number of transplants. However, there are counter arguments, and some have argued that offering financial incentives could result in fewer transplants. The Ethics Committee discusses these counterarguments in the white paper, arguing that, without real-world studies, it is difficult to confidently assert that people will or will not behave in certain ways, or that financial incentives will or will not impact donation rates or costs.

2. Improve equity in access to transplants: There is no impact to this goal.

3. Improve waitlisted patient, living donor, and transplant recipient outcomes: There is no impact to this goal.

4. Promote living donor and transplant recipient safety: There is no impact to this goal.

5. Promote the efficient management of the OPTN: There is no impact to this goal.

How will the OPTN implement this white paper?

If this resource is approved it will be available through the OTPN website.

How will members implement this white paper?

Members will not need to take any action to implement this resource. Members could choose to consult this resource on a voluntary basis.

Will this white paper require members to submit additional data?

No, this resource does not require additional data collection.

How will members be evaluated for compliance with this white paper?

This resource does not affect member compliance. Members could consult this resource on a voluntary basis.

White Paper

Financial Incentives for Organ Donation

EXECUTIVE SUMMARY

The demand for organs available for transplantation greatly outpaces supply in the United States.[1] Several initiatives have been implemented to increase the number of transplantable organs. The initiatives have ranged from increasing education on living and deceased donation to broadening the potential donor pool to include paired donations, increased risk donor organs, and organ donation after circulatory determination of death. While these efforts have been helpful in closing the gap between the demand for organ transplants and available organs, they have not yet sufficiently met transplant needs.[2] The development of the Kidney Donor Profile Index (KDPI) >80 is another strategy that was recently implemented, the effectiveness of which remains to be determined. The removal of financial barriers or disincentives for living donation (LD) is an additional strategy that has gained traction in the transplant community and is in the midst of gaining policy support and implementation.[3] Moreover, scholars and members of the transplant community have proposed providing donors with financial incentives through a federally-regulated system over and beyond compensation for expenses incurred through donation, a proposal which gained momentum as a way to increase organ donation.[4]

Below, we delineate four key ethical considerations associated with providing financial incentives in a federally regulated system, and evaluate the merits of arguments raised for and against each consideration. Specifically, we highlight and critically appraise normative and social assumptions underlying these arguments, and describe how these assumptions may be tested.

The ethical debate remains at a standstill, and the prospect of advancing normative discourse about financial incentives is unlikely to occur for reasons enumerated below. The standstill is primarily driven by The National Organ Transplant Act (NOTA) of 1984, which prohibits the exchange of “valuable consideration” for organs.[5] In brief, NOTA does not legally permit donors to sell an organ. Although the exact meaning of ‘valuable consideration’ has undergone extensive interpretation, there is general agreement that NOTA prohibits research studies of financial incentives with actual organ donors.[6]

Because of NOTA, the extent of empirical investigation conducted thus far has been based on hypothetical scenarios involving potential living donors as research participants or extrapolating from data derived from markets in other countries or from unregulated markets. Accordingly, the transplant

community in the United States has been unable to conduct empirical research on the actual (non-hypothetical) effects that financial incentives may have on deceased or living donation.

The United States transplant community is in a state of equipoise on whether to empirically investigate a regulated system of financial incentives.[7] We contend that advancement in the ethical evaluation of a federally-regulated system of financial incentives cannot be made until the transplant community can scientifically assess whether and how normative concerns are grounded in actual behaviors and perceptions. The ethical soundness of any proposed strategy to increase organ availability must be grounded on empirical data, consistent with standard clinical medical ethics analytic approaches,[8] drawn from actual living kidney donors to anchor arguments for or against the proposal.[9]

We conclude that ethical debates about financial incentives will remain in a stalemate unless pilot studies are performed. We recognize that research on financial incentives would require amending NOTA. Specifically, we call for pilot studies on a federally-regulated system of financial incentives. Of note, we do not call for policy change enabling financial incentives *per se*, because there is no empirical U.S.-based evidence as to whether a regulated system is ethically permissible at this time.

The results of pilot studies among actual living kidney donors in the U.S. may suggest several courses of action: a) positive outcomes data that would justify moving forward with larger, randomized controlled trials; b) negative outcomes data that might lead to abandoning the idea of providing living kidney donors with financial incentives through a federally-regulated system, or c) incomplete or conflicting data with many variables of uncertainty. Thus, a larger, randomized controlled trial may be justified or, alternatively, the idea of a federally-regulated system of financial incentives may need to be abandoned, depending on where uncertainty emerges, and how that uncertainty could potentially be addressed in subsequent trials.

DEFINITIONS AND FOCUS

Our discussion is limited to “financial incentives” in a “federally-regulated system,” as distinct from other concepts that are related but often conflated with these terms. Financial “compensation” refers to reimbursement for expenses incurred as part of the donation process to make donors “financially whole,”[10] or to offset any and all costs associated with the donation. NOTA expressly permits compensation for expenses incurred in the process of donating, although there appears to be widespread misconceptions about if and how donors may receive financial compensation for their incurred expenses.[11] By contrast, this white paper focuses on financial “incentives,” which are provided to donors

as a direct benefit (or intervention) for the purpose of encouraging donation, over and beyond compensation for donation expenses.[12] Incentives can take diverse types including: a "lump sum" of cash, or another benefit such as a contributing to a donor's retirement funds or income tax credits.[13] The literature has not focused on reaching consensus on an exact type of incentive.

This white paper is not focusing on two areas for which we believe there is current consensus. First, we are not examining the removal of financial "disincentives." The American Society of Transplantation (AST) and American Society of Transplant Surgeons (ASTS) called for achieving "financial neutrality" for living donors by removing all financial disincentives that deter unpaid living donation, such as travel expenses and lost wages associated with donation.[14] Several workgroups and organizations have made significant headway in operationalizing this consensus.[15] We believe the transplant community has reached consensus that removing disincentives is ethically acceptable--if not obligatory--because the donor should not be made "worse off" from their donation.[16]

Second, we are not examining illegal organ markets with no oversight or regulation, including organ trafficking or organ tourism. There is widespread support for the idea that illegal markets are ethically impermissible due to a lack of safeguards to protect donors.[17] Instead, our focus is narrower and geared towards areas where there is a lack of ethical consensus: using a federally regulated system to provide material gain to donors according to standard criteria (on a fixed and transparent schedule), as well as the feasibility of empirically investigating such a system.

ETHICAL CONSIDERATIONS AND ANALYSIS

There are at least four key ethical considerations of providing financial incentives in a government-regulated system:

1. ***Undue Inducement to Donate***

An undue inducement is an irresistible positive offer that "makes individuals do something that they would not otherwise do."[18] Inducements are not inherently unethical. An inducement becomes "undue," and therefore ethically problematic, when the offer of a welcomed good is so excessively desirable that it compromises judgment and leads people to engage in harmful actions that threaten or undermine their fundamental interests.[19]

Opponents of financial incentives argue that providing financial incentives would create an undue and likely unjust inducement.[20] The underlying assumption in the literature is that any amount of financial incentive would comprise an undue inducement to donate.[21]The essence of this argument is that

providing incentives, particularly as cash, would compromise an individual's perception of donation risks, thereby undermining fully informed consent.[22] Financial incentives would cause donors to make poor judgments that are not in keeping with their underlying values, goals, and preferences.[23]

Proponents contend that financial incentives do not necessarily introduce "bad judgments," because equating financial incentives with bad judgments would imply that any decision with economic implications compromises free choice and undermines informed consent. Economic considerations are integral to decisions that people make daily, ranging from modest purchasing decisions to long-term housing or educational decisions.[24]

Further, proponents contend that empirical investigation based on hypothetical scenarios suggests that a person's judgment is not compromised by financial incentives.[25] For instance, Halpern and colleagues used conjoint analysis in which participants assessed their own willingness to donate a kidney while experimentally varying the risk of end-stage renal disease (ESRD) from nephrectomy and levels of payment for donation.[26] The authors found no evidence that higher payments were associated with greater acceptance of ESRD risk from kidney donation. Instead, willingness to donate a kidney was reduced as ESRD risk rose, regardless of how much money was offered to donate. These findings suggest that payment for kidney donation is not an undue inducement.[27]

The Belmont report contends that undue influence occurs along a continuum from persuasion to coercion, but there is no clear indication along the continuum where undue influence occurs.[28] Accordingly, there may be a specific amount of money where potential donors perceive an undue inducement.[29] In Gordon et al.'s study of the general public, while half (52%) reported no compensation amount ($0) would be needed for them to begin to consider donating to someone they knew, those who reported an amount indicated a median of $5,000.[30] Similarly, while almost half (44%) reported no compensation amount ($0) would begin to make them perceive an undue inducement to donate to someone they knew, those who reported an amount indicated a median of $50,000. Thus, these findings suggest that: (1) not just any amount of monetary compensation can create an undue inducement to donation, and (2) a range in monetary amounts exists between motivating someone to donate versus unduly inducing someone to donate, such that some financial incentives could be provided without making people feel induced to donate.[31] Future research should further investigate the specific amounts of compensation or types of incentive that may lead potential donors to perceive an undue inducement.

A few proponents of financial incentives argue that, to fully respect autonomy, donors should have the choice to "sell" an organ or accept financial incentives. These proponents contend that limiting organ markets can be viewed as overly paternalistic.[32] It may be true that it is paternalistic to refuse to allow someone to sell a kidney. However, respect for autonomy should be balanced against other duties that healthcare professionals have to patients, including beneficence-based obligations. If there were an absolute right to donate an organ, then physicians would be obligated to procure offered organs upon request, irrespective of transplant risks or consequences of doing so. As moral agents, physicians should be responsible for the welfare of their patients and should consider patients' beneficence-based interests.[33]

Proponents also argue that, by accepting financial incentives or "selling" an organ, donors would be exercising their own free choice,[34] devoid of other considerations and external factors. However, people do not make decisions in a vacuum. Instead, an individual's (the decision maker's) interests are interwoven with societal, family, religious, or other considerations within the decision-making process in order to reach a decision, even in the context of donation and transplant decisions.[35]

2. *"Crowding Out"*

Another argument against financial incentives stems from a concern that potential donors who would donate in the current system may be dissuaded from doing so if financial incentives were introduced because providing money would introduce "repugnance" (i.e., repugnance towards introducing money to transactions previously conducted without money).[36] Danovitch and Delmonico argue that, if financial incentives were introduced, the ethical value of donation as a good act might be jeopardized, which in turn, may endanger public trust in transplantation and cause people to become disinclined to donate.[37] Danovitch and Delmonico's argument is largely based on the "crowding out" theory, in which certain kinds of desired behaviors would decline in response to the offer of an incentive. In the donation context, there is concern that donation rates would drop by "crowding out" donors who do not want or need financial incentives and become disinclined as a backlash against the regulated system.[38]

Proponents highlight a critical assumption in opponent's arguments: that the donation must be "altruistic" (maximizing good consequences for others except the donor) in order for it to be a genuine and acceptable donation.[39] Instead, living donors—like individuals in most decision-making contexts—have many motives for choosing to donate, such as a desire to help a loved one, a sense of inherent responsibility, family expectations, personal growth and self-worth, and spiritual confirmation.[40] Even

families of deceased donors donated to gain closure on the death of loved ones, rather than just to help others.[41] In sum, altruism is not always central to donor's decision making.

Proponents of financial incentives also question the legitimacy of the crowding-out theory and its applicability to donation. Specifically, the crowding-out theory relies heavily on the work of Richard Titmuss and his examination of financial incentives for blood donation. Titmuss concluded that monetary and some nonmonetary incentives had a corrosive effect on altruistic donation for blood donation. Hippen and others, however, have argued that Titmuss relied heavily on anecdote and incomplete data, and that a more accurate interpretation would suggest that donors have many motives in their donation decisions.[42]

Empirical research based on hypothetical questions casts some doubt on whether crowding out would occur. Gordon and colleagues found that most survey respondents' willingness to donate would 'probably' or 'definitely' stay the same (70% and 69%) if financial incentives were introduced, or in some cases, increase, among those who would 'probably' or 'definitely' donate to a family/friend or a stranger (29% and 31%), respectively.[43] The researchers concluded that their findings suggest that financial incentives would make little difference in individuals' decisions to donate, undermining the crowding-out theory.[44] Similarly, Bryce and colleagues found that 71%-76% of potential donors maintained their willingness to donate regardless of whether financial incentives were offered, with some variability based on the type of financial incentive.[45]

Thus, evidence from hypothetical scenarios suggests that the overwhelming majority of potential donors under the current system would not be dissuaded from donating under a regulated system of financial incentives. However, these data may also be interpreted to suggest that, if the rationale for financial incentives is solely to increase provision of organs, the transplant community may be disappointed by the outcome of a pilot study because there may not be a large increase in organ efficiency, at least based on what can be gleaned from some empirical studies using hypothetical scenarios and potential living donors as research participants.

3. *Exploitation*

Exploitation is the use of unequal bargaining power by the stronger party to take advantage of the weaker one, resulting in the stronger party being able to attain its goal without equivalent exchange benefitting the weaker one. In situations of exploitation, one party to the interaction is typically in a weak

position due to poverty or ignorance, and the other party is able to take advantage of this weak position and offer few benefits to the other party.[46]

Opponents of financial incentives posit that people of lower socioeconomic means would be more likely to donate to alleviate their financial strain compared to people of higher socioeconomic means.[47] Opponents typically draw on the work of Goyal and colleagues' and other scholars' observations of other countries' experiences with unregulated organ markets.[48] Goyal and colleagues conducted a cross-sectional survey among 305 individuals who had sold a kidney in India through an illegal, unregulated market where different dollar amounts were provided.[49] Most donors who lived below the poverty line sold their kidneys to pay off debt, with the majority of participants still in debt at the time the survey was conducted (approximately 6 years after donation occurred). The researchers concluded that "in developing countries, such as India, potential donors need to be protected from being exploited."[50]

Proponents of financial incentives contend that exploitation requires having two parties of unequal bargaining power present during the exchange, with one side clearly getting more. Exploitation, then, is a real concern for organ markets in developing countries where the financial incentive is *per se* exploitative by virtue of unfair distributions. But, in a federally-regulated system, to eliminate exploitation, the financial incentives would be distributed equally in absolute terms to all donors.[51] Thus, it would be up to the individual involved in the exchange to determine whether they perceive the exchange as exploitative. It could be argued that distributing financial incentives equally may not eliminate exploitation or undue hardship because the financial incentives may be more significant to people of lesser means.

A better real-world example, proponents note, might be Iran where there is a partially federally regulated kidney market. In Iran, there is no broker or agency, as is the case with India. Donors receive an award of health insurance from the government. Proponents contend that the number of kidney transplants has increased since the system was implemented,[52] although Harmon, et al. (among other opponents) argue that that the Iranian data should be interpreted far less favorably, particularly given the lack of procedural safeguards.[53]

Proponents also argue that there is some evidence suggesting that poorer people are more willing to donate independent of payment.[54] In Barnieh et al.'s study, respondents from lower income households were *less likely* to consider donating for a hypothetical reward of $10,000 or $100,000 than those from higher income households.[55] These findings, along with the work of Gordon et al. and Halpern

et al., suggest that all persons, regardless of income bracket, are willing to donate when higher amounts of incentives are offered, casting doubt on unjust inducement concerns.[56]

4. *Commodification*

Commodification refers to making something of inestimable intrinsic value an object of exchange when it morally should not be.[57] Opponents assert that certain morally valuable attitudes about people would be eroded by practices that, in effect, make the value of significant parts of human bodies commensurate with 'any object' that one might exchange for money.[58] Opponents contend that commodification concerns are complex, interweaving normative standards and culturally-based deep-rooted conceptualizations of human nature, personhood, personal identity, and the body, which may be challenging to test empirically.

Proponents of financial incentives argue that opponents' perceptions of commodification and its boundaries are not well articulated. Specifically, it would seem that commodification concerns would apply equally to payments for surrogate motherhood, research participation, sperm, or other contexts where the "body" or a part of it is an object of exchange.[59] Proponents argue that whether and how there are ethically relevant distinctions between these scenarios is not clear. Distinctions might be made on the basis of rejuvenation, in which body parts that can rejuvenate are deemed ethically permissible to "sell" as an object of exchange because of the perceived lesser long-term harm inflicted on the donor. However, this distinction seems unfounded. It is unclear why rejuvenation should hold significant ethical weight, especially given that some practices and procedures that are currently financially incentivized (and can rejuvenate) carry similar if not greater procurement short-term harm compared to some types of organ donation.[60]

PUBLIC AND CLINICIAN OPINIONS OF FINANCIAL INCENTIVES

Public Opinion

Early empirical research conducted in the 1990s assessing public opinion on financial incentives showed mixed results with a wide range of public support. Public support for financial incentives ranged from 12% to 52%.[61] The varied results may be attributed to methodological differences in the studies, as well as unclear variable constructs and definitions within the surveys. Often, researchers did not distinguish between federally-regulated systems and other types of markets, which could have impacted interpretation of the survey questions, and also the results.[62] In the 2000s, the survey questions became increasingly nuanced. The increased specificity in the surveys allowed for

elucidation of participants' perspectives on the types of financial incentives and the amount of money that should be offered.

More recently, research suggests that most people support a federally-regulated system on financial incentives, with some variability based on the type of incentive. Barnieh and colleagues conducted a web-based Canadian survey assessing perspectives of potential donors (n=2004), healthcare professionals (n=339), and people affected by kidney disease (n=268) with regard to different types of financial incentive.[63] The majority of respondents believed that financial incentives for living and deceased organ donation were acceptable (>62%). The researchers found greater support for funeral expenses for deceased donors (>45%) and a tax break for living donors (>40%) compared to monetary cash payment to the donor's estate. Support for direct payment for living donors was 45%, 14%, and 27%, as reported by potential donors, healthcare professionals, and people affected by kidney disease, respectively.[64]

Similarly, Bryce and colleagues measured U.S. public opinion (n=971) regarding five different types of financial incentives.[65] The researchers found moderate support for financial incentives (59%) and removing disincentives, with the level of support being significantly higher for funeral benefits, charitable contributions, travel/lodging expenses, and medical expenses (81%, 73%, 78%, 84%, respectively), and lower support for direct payment (53%). Non-white respondents were slightly more positive than whites about donor benefits.[66] Different perspectives between race/ethnic populations as also been demonstrated through the work of Boulware and colleagues, who found that African Americans (n=102) and Hispanics (n=130) were more likely than Whites (n=550) to be in favor of some incentives for deceased donation (>11%, >9% >5%, respectively).[67] Gordon et al. also surveyed the general public in Chicago (n=210) about their preferences for a government-regulated system, and found that most respondents perceived financial incentives as acceptable (74%),[68] which is a similar finding to Peters' and colleagues study.[69] Direct payment (61%) and paid leave (21%) were the two most preferred types of incentive.

Healthcare Professionals' Opinions

Barnieh and colleagues' survey results indicate that healthcare professional respondents (n=339) considered financial incentives to be acceptable (14-62%), depending on the type of incentive.[70] Like members of the public, healthcare professionals considered reimbursement of funeral expenses for deceased donors and a tax break for living donors to be most acceptable (>40%), with only 14% of

healthcare professionals finding direct payment acceptable.[71] Ghahramani and colleagues conducted a web-based survey with 1,280 international nephrologist respondents.[72] They found that nearly half favored some type of incentive, but that only a minority (26%) believed that financial incentives, broadly speaking, were acceptable.[73]

Tong and colleagues qualitatively interviewed 110 transplant nephrologists and surgeons from 12 countries across 43 transplant units in Europe, North America, and Australia about organ markets broadly.[74] The interviewees generally supported removing disincentives, but most interviewees believed that direct payments were less acceptable than other incentives, although the survey did not distinguish between regulated and unregulated systems. The interviewees raised concern that financial incentives would compromise human dignity and value and erode trust. Some interviewees contended that financial incentives could be ethically legitimate in a regulated system.[75]

Rodrigue et al. conducted a web-based survey of 449 members of the American Society of Transplant Surgeons to assess their perspectives on financial incentives for living and deceased donors.[76] Many respondents (10-42%) supported one or more federally-regulated financial incentives. Their survey findings suggest that members preferred certain types of incentives (e.g., funeral expense reimbursement, income tax credits) over other types (direct cash payments to donors or their surviving family members, for either living or deceased donation).[77]

Taken together, these empirical studies suggest that the public generally considers federally-regulated financial incentives acceptable, with some variability based on the type of financial incentive. The studies on healthcare professionals' perspectives show more mixed results, which could suggest that healthcare professionals are more equivocal.

CALL FOR EMPIRICAL RESEARCH

Opponents claim that financial incentives in a government-regulated system introduces at least four ethical concerns: undue inducement, crowding out, exploitation, and commodification. Proponents of financial incentives have commonly countered opponents' claims through reference to empirical investigation of opponents' assumptions about: (a) how people make decisions, and (b) how donation rates could be affected by financial incentives. Proponents argue that several of the theoretical concerns about financial incentives (e.g., undue inducements and crowding out) are not corroborated by empirical evidence.[78] A significant limitation of empirical studies reviewed above is that they are based on hypothetical scenarios, because NOTA prohibits financial incentives with actual donors. A challenge in

interpreting results from the reviewed studies is that research participants' responses in hypothetical scenarios may not reflect decisions that donors might make in real-world offers of financial incentives.

Proponents contend that financial incentives would increase the number of at least living donors and possibly deceased donations. However, the transplant community cannot estimate how financial incentives would impact donation rates or healthcare costs. Available economic calculations based on theoretical modeling have conflicting results.[79] A study conducted by Becker and colleagues posits that financial incentives could increase the organ supply so much that large organ waiting lists could be mitigated.[80] Conversely, Wellington and Sayre examined two state laws allowing financial compensation in the form of tax deductions and paid leave for living donors.[81] They found no evidence to support that those laws affected organ donation rates. Barnieh and colleagues argue that financial incentives for living kidney donors could be cost-effective, even with only modest increases in donation rates, due to a reduction in the number of people on dialysis.[82] Matas and colleagues have made similar arguments to those of Barnieh and colleagues.[83]

Without real-world studies, it is difficult to confidently assert that people will or will not behave in certain ways, or that financial incentives will or will not impact donation rates or costs. To advance arguments on financial incentives, many in the transplant field have called for a pilot study aimed at assessing the feasibility and impact of a federally-regulated system utilizing financial incentives on donation rates.[84]

The UNOS Ethics Committee posits that pilot studies can advance ethical understanding by empirically investigating key outcome measures: (a) living donors' perceptions of undue influence, exploitation, and commodification, and (b) the impact of incentives on donation rates.[85] Specifically, a pilot study could potentially assess whether there are unintended consequences (e.g., perceptions of exploitation or undue influence); whether assumptions about donor behavior hold true (e.g., crowding out); whether the results from empirical studies using hypotheticals accord with actual donor behavior; whether donation rates could be increased; whether there are potential cost-savings; and whether financial incentives generate a negative public reaction or negatively impact donors psychologically.[86]

As a result of such research, at least three distinct conclusions may arise, for which the transplant community should be prepared:

1. Results from pilot studies may be overwhelmingly positive, and show widespread donor and public support for a federally-regulated system, an increase in organ supply, no unforeseen costs,

and no donor perceptions of exploitation or undue influence. In this scenario, the results would likely be compelling enough to justify moving forward with larger, randomized controlled trials.

2. Results from pilot studies may demonstrate profound negative perceptions by donors in terms of reporting experiences of undue inducement, exploitation, commodification, and/or public distrust. Accordingly, an increase in organ supply alone would likely not be compelling enough to justify a system of federally-regulated financial incentives because transplant utility, while important, should be balanced against other competing ethical considerations such as equity and autonomy. In this situation, the idea of a federally-regulated system of financial incentives would likely need to be abandoned.
3. There is also a third outcome in which pilot studies reveal drawbacks, benefits, and many variables of uncertainty. An ethical assessment of whether something is or is not ethically permissible requires a particular evaluation of consequences including risks/benefit tradeoffs, and an evaluation of autonomous-based considerations (e.g., donor behavior and psychological sequelae). The data from a pilot study may be incomplete or conflicting to provide a thorough ethical assessment necessary to justify moving forward with a federally-regulated system of financial incentives. A larger, randomized controlled trial may be justified or, alternatively, the idea of a federally-regulated system of financial incentives may need to be abandoned, depending on where uncertainty emerged, and how that uncertainty could potentially be addressed in subsequent trials.

CONCLUSION

Arguments for and against a federally-regulated system are rooted in theoretical and hypothetical constructs and, as such, dialogue on the issue has reached a point of stalemate. We conclude that the transplant community will remain at a stalemate unless pilot studies are performed, recognizing that NOTA would need to be congressionally amended before such research could be legally permitted. But, as has been noted by others, the “provisions of NOTA are not immutable,” and they have been modified at least twice before.[87] Additionally, the financial and transplant-system based logistics of carrying out a pilot study with necessary ethical oversight and precautions would also need to be solidified before undertaking a pilot study, as others have discussed.[88]

We deliberately refrain from taking a position as to whether a federally-regulated system of financial incentives would be ethically acceptable. An ethical assessment as to whether a federally-

regulated system of financial incentives would be ethically sound, is at least partly contingent upon information learned from a pilot trial.[89] To engage in a responsible and well-informed discussion, the transplant community should engage in scientific research and use those data to advance and inform ethical judgments and decisions. We recognize that empirical research may not be able to dispel some ethical concerns, but pilot studies should still be pursued because there are testable hypotheses embedded within each of the four ethical considerations we outlined. Pilot studies could provide critical information as to whether larger, randomized controlled trials can be conducted in an ethically defensible manner.

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