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Special Article

The Declaration of Istanbul: Review and Commentary by the American Society of Transplant Surgeons Ethics Committee and Executive Committee

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The American Society of Transplant Surgeons (ASTS) was asked to endorse the 'The Declaration of Istanbul on Organ Trafficking and Transplant Tourism.' The document has been reviewed by the ASTS Ethics Committee and their ensuing report was presented, discussed and approved by the ASTS Council. The ASTS vigorously supports the principles outlined in the Declaration and details specific current obstacles to implementation of some of its proposals in the United States.

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In spring 2008, The Transplantation Society and The International Society of Nephrology invited transplant professionals to attend an 'International Summit on Transplant Tourism and Organ Trafficking' in Istanbul, Turkey. The document issued from that meeting, 'The Declaration of Istanbul on Organ Trafficking and Transplant Tourism' (Declaration of Istanbul) (1) was subsequently circulated to transplant-related professional organizations, including the American Society of Transplant Surgeons (ASTS), with a request to endorse the document as written.

The ASTS strongly agrees with much in the Declaration of Istanbul, including the need to: (1) maximize the use of deceased donor organs; (2) encourage countries with established deceased donor programs (or living donor programs, for that matter) to share their knowledge with countries that lack these programs; (3) protect vulnerable populations from abusive acts; (4) ensure the equitable allocation of donor organs based on sound ethical principles and (5) prevent organ trafficking. In fact, the ASTS vigorously supports and endorses each of the principles espoused in the Declaration.

The ASTS applauds the efforts of the participants in the summit meeting, and fully supports the general intent of the Declaration of Istanbul. This was a much needed effort by the international transplant community to discuss issues that concern us all. The ASTS is strongly and unequivocally opposed to organ trafficking and to the exploitation of vulnerable individuals. We recognize that this is an international problem that must be addressed by a diverse set of jurisdictions, laws and international conventions.

We also wish to point out several statements in the Declaration, particularly in the proposals section, whose interpretations may limit their applicability in the United States.

Should the Provision of Insurance to Living Donors Be Mandated?

The Declaration of Istanbul mandates that live donors be provided with several types of insurance. Proposal 5 (subsection a) states that 'the provision of disability, life, and health insurance related to the donation event is a necessary requirement ....' The provision of health, life and disability insurance coverage for live donors who do not otherwise have access to it is not currently a requirement of all transplant programs in the United States. By stating that provision of this coverage is a 'necessary requirement,' the Declaration implies that failure to do so should preclude a center from performing live donor transplants. Whereas some transplant programs choose to accept live donors who do not have their own health coverage, others do not, relying on the recipient's coverage for payment in the event that the donor requires treatment for complications of organ donation.

Barriers to the provision of additional insurance to those who do not already have such policies include added cost, variety and scope of carriers, variety and scope of policies and incomplete data on long-term outcomes following living donation leading to uncertainty about the limits and duration of any new coverage. It is not clear whether or not the provision of insurance as a *quid pro quo* for live donation constitutes a violation of Section 301 of the

National Organ Transplant Act (NOTA). In the United States, NOTA prohibits 'any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation . . .' (NOTA, Sect. 274e, 2008). There are various interpretations of this section, ranging from lax (i.e., NOTA was never intended to prohibit provision of government-provided compensation) to rigid (i.e., it is illegal to offer anything of value). In many segments of United States society and government (2), the rigid interpretations have prevailed.

There is one organization, the Living Organ Donor Network (LODN) of the American Foundation for Donation and Transplantation (formerly the Southeast Organ Procurement Foundation) based in Richmond, Virginia, which offers a catastrophic insurance policy to living kidney donors (3). This policy can be purchased by an individual live donor or can be provided by an LODN participating member transplant program to their live donors. A policy has been available through LODN since 2000 and, at a current cost of US$ 550, provides coverage only for catastrophic events such as accidental death or significant disability as a result of an organ donation (personal communication, LODN). It is not intended to cover other, more common complications (such as infection or cardiovascular complications) that might otherwise be covered under the recipient's policy or other health care coverage. It is term limited at 5 years, and thus may not address unknown future complications attributable to living kidney donation. These shortcomings notwithstanding, it is the first attempt to provide coverage for live donors that we are aware of in this country.

Despite its availability, however, only a small percentage of live donors have been insured through this program. There were 55 896 live donor kidney transplants recorded by the U.S. Organ Procurement and Transplantation Network (OPTN) between 2000 and 2008 (4). In that same time period, only 672 (1.2%) of these donors obtained insurance from LODN (personal communication, LODN). We can only speculate why this program has not been used more widely. It may be that most living donors already have insurance or the cost is too high for the benefits provided. It is very likely that there is a lack of knowledge about its availability. Some transplant programs may opt not to offer the policy because of the LODN requirement for member institutions to participate in a donor follow-up registry. In any case, it is a resource not often used.

There is a wide range of opinion as to whether the provision of insurance to live donors should be mandatory. However, in the absence of universal health care insurance in the United States, to mandate its provision is not practical. As an alternative to a paid private health insurance policy, ASTS has proposed provision of Medicare beneficiary eligibility by the federal government to all live organ donors or the ability for donors to 'buy in' to this coverage if they lack private sector health care coverage (5). These measures would not meet the entire 'necessary requirement' for life, health and disability insurance expressed in Section 5 of the Declaration of Istanbul, but would provide a mechanism by which donors could receive coverage. Requiring eligible donors to buy into a relatively less expensive policy may not violate the ban on outright value under the 'valuable consideration' clause of NOTA, so such a policy would be consistent with the Declaration's proposal 5. In the unlikely event it was determined that provision of even this coverage to a donor constituted a NOTA violation, there would be no legal way at present to meet the requirements of proposal 5 without a change in United States law. In any event, the ASTS is committed to work toward the laudable goal of ensuring the provision of various forms of insurance to all live donors.

Does the Declaration of Istanbul Allow for Any Trials of Donor Incentives?

The ASTS supports amending NOTA to allow for limited trials of measures to provide incentives for organ donation in the United States. It is possible that a limited trial of incentives for live donation in the form of provision of health care coverage by Medicare, if it were made or deemed to be legal, would address this international concern as well as afford the opportunity to assess its impact on the organ shortage. An analogous situation is the recent ruling by the U.S. Department of Justice regarding paired donor kidney exchanges that paved the way for passage of Public Law 110–144, also known as the Charlie W. Norwood Living Donation Act, which amended NOTA and clarified that participation in a paired donor kidney exchange does not constitute valuable consideration, and thereby established its legality. A similar ruling and NOTA amendment may be required to provide insurance coverage as a potential incentive to living organ donation.

The Declaration of Istanbul does not specifically address the possibility or propriety of a limited, controlled trial of donor incentives as a means to increase organ donation. The ASTS recently conducted a survey of its membership regarding their attitudes toward donor incentives (Rodrigue et al., in press). The majority of respondents personally supported, and believed that the ASTS should support, government-regulated strategies in the United States to stimulate both deceased and living organ donation. Supporters believe this can be done safely and scientifically in the regulated environment that exists in the United States and that donor incentives should be rigorously examined in the setting of a clinical trial. In fact, several versions of draft legislation have been circulated within the transplant community that might pave the way for this very activity. This would require a close reexamination of the 2006 Institute of Medicine report on organ donation (2), which left little room for regulated trials in the United States (6). ASTS leadership believes such trials may be possible in the closely regulated environment that exists in the United

States but is unclear whether even closely regulated trials may run afoul of the Declaration of Istanbul.

Additional Points in the Declaration of Istanbul That Require Clarification

There are several statements in the Declaration that are ambiguous or open to wide interpretation, and therefore require clarification. The three examples below highlight our concerns.

Principle 2 of the declaration refers to 'the recovery of organs . . . and the practice of transplantation, consistent with international standards.' While this statement is laudable, there is no mention of the existence of, or a plan for, developing such standards. There are individual national and organizational standards but, at the present time, there are no international standards to which this statement can be applied. The ASTS strongly supports development of such standards and believes our membership can lend valuable expertise to such an effort. We suggest that the World Health Organization and the various national and international transplantation societies including the ASTS agree to work toward this goal.

Proposal 6d states that '[the live donor's] out-of-pocket expenses should be administered by the agency handling the transplant rather than paid directly from the recipient to the donor.' In the United States system, where there is not a single payer, it is unclear which agency would be responsible: a private insurance company, Medicare, Medicaid, the local organ procurement organization, the transplant program or the OPTN? Here, the concern is that 'the agency handling the transplant' could be interpreted as the transplant program, thus making it their responsibility to reimburse donor out-of-pocket expenses. We are concerned that this could produce a conflict of interest between a transplant program and a prospective donor, where the program may contribute to donor coercion by offering provision of these funds. In fact, recipient coverage of donor out-of-pocket expenses is expressly permissible under United States law. NOTA contemplated recipient reimbursement of donors for out-of-pocket expenses to avoid this donor disincentive and to keep the transplant program removed from the process. The ASTS, along with the University of Michigan, has been the provider for a trial program funded by the U.S. Department of Health and Human Services for live donor financial assistance called the National Living Donor Assistance Center (NLDAC) (7). NLDAC provides for means-tested reimbursement of out-of-pocket travel expenses incurred by living donors. The means testing explicitly requires the recipient to be considered as a potential source of funds for donor reimbursement, with the NLDAC program as a reimbursement source of last resort. It is clear that NLDAC is not 'the agency handling the transplant,' so we are left to wonder whether this established and successful program would be considered to be in compliance with this provision of the Declaration of Istanbul.

The statement that '[a] positive outcome for a recipient can never justify harm to a live donor' (page 2, paragraph 1) is perhaps viewed differently by surgeons and nonsurgeons. Although we recognize that this statement is likely meant to refer to harm done to a vulnerable individual via any unscrupulous act or to an individual not adequately informed of the risks, it carries with it a different connotation from a surgical perspective. When we operate on individuals whose only indication for the procedure is the voluntary donation of an organ, there is always a finite risk of harm. The only way to justify this risk is that the donor, in an informed and uncoerced way, accepts it.

Recent statements from The Transplantation Society indicate their intention to enforce the Declaration of Istanbul '1) to require presenters at educational meetings to disclose their position about the Declaration or their compliance to it, 2) to have funding agencies and pharmaceutical companies refuse to fund hospital or other organization clinical studies that do not implement the provisions of the Declaration, and 3) to have a disclosure statement submitted to medical journals to attest that reports of clinical trials have been conducted in compliance with the Declaration.' (8). If, for example, a presenter or an author of a study involving living donors did not ensure that the living donors had health, life or disability insurance, would he or she be out of compliance with the Declaration? Because it is not likely that most transplant programs or the United States government will be providing insurance to living donors in the near future, enforcement of this section of the Declaration may effectively prevent United States living donor programs from presenting their work at scientific meetings. Along these same lines, if the National Institutes of Health, or a pharmaceutical firm, does not ensure that living donors are provided insurance within a clinical trial for which these funding entities are providing support, will The Transplantation Society see this as an unacceptable trial? We think it unlikely that The Transplantation Society intends to preclude presentation of data from such studies at its meetings or in its publications. In our opinion, The Transplantation Society needs to clarify these statements so that they do not have unintended consequences.

In conclusion, the ASTS Ethics Committee and Executive Committee agree enthusiastically with the general goals and directions outlined in the Declaration of Istanbul. We strongly endorse all of its stated principles. The ASTS is firmly opposed to exploitation associated with human organ trafficking. Certain policy proposals that cannot be reasonably accomplished in the United States at this time, such as universal provision of insurance, will require concerted effort at a societal level. Finally, on the basis of the expressed opinions of the majority of the ASTS membership, we continue to endorse limited trials of donor

incentives to improve organ donation rates. We agree with Evans (9) that caution must be exercised when 'signing on' rather than 'listening in' to a discussion, especially when that discussion becomes a position statement that may place good intentions in the path of pragmatism.

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