

**OPTN/UNOS ETHICS COMMITTEE REPORT
SUMMARY**

I. Action Items for Board Consideration

- Transplant Tourism. The UNOS Corporate Board is asked to adopt a “Statement on Transplant Tourism” as recommended by the Ethics Committee. (Item 1, Page 3) [Action to be taken by the UNOS Corporate Board]

- Treatment of Patients Post-Transplant Tourism. The UNOS Corporate Board is asked to adopt the following position regarding treatment of patients who have received an organ through transplant tourism: In emergent situations, patients should be evaluated and treated according to the standard of care. While there may not be an obligation on the part of individual physicians to care for such patients in non-emergent situations, the medical community has an obligation to provide care for these patients. Physicians are encouraged to provide care for these patients. In the case of conscientious objections, the physician should help the patient locate an alternative physician and may terminate the physician patient relationship, in accordance with local professional practices. (Item 2, Page 6) [Action to be taken by the UNOS Corporate Board]

- Use of Organs from Executed Prisoners. The UNOS Corporate Board is asked to denounce the use of organs from executed prisoners for any form of transplantation. (Item 3, Page 7) [Action to be taken by the UNOS Corporate Board]

- Transplant Candidacy. The Board is asked to reaffirm that the eligibility for transplantation predicated on determinations of social worth is morally unjustified. Patients with disabilities should not be excluded from consideration for transplant solely by virtue of their disability. (Item 4, Page 7)

- Anencephalic Organ Donation. The Board is asked to reaffirm the 1989 position statement on anencephalic organ donation with limited modifications. (Item 5, Page 8)

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**REPORT OF THE OPTN/UNOS ETHICS COMMITTEE
TO THE BOARD OF DIRECTORS**

**June 26, 2007
Richmond, Virginia**

**Margaret R. Allee, R.N., M.S., J.D., Chair
Michael Shapiro, M.D., Vice-Chair**

The following report represents the Ethics Committee's deliberations and discussions at its meeting held on March 25-26, 2007:

1. Transplant Tourism. At the request of the OPTN/UNOS President, on May 18, 2006, the Committee met by conference call to discuss the emerging increase in transplant tourism, in light of comments from a transplant professional that appeared in the L.A. Times. The Committee unanimously approved the following resolution for consideration by the Executive Committee:

*RESOLVED, that the Ethics Committee endorses the following Statement Regarding Transplant Tourism and recommends that the Board of Directors endorse adoption of this statement as the official position of the OPTN/UNOS: *[Statement omitted]*

At the June 29-30, 2006, meeting of the Board of Directors, the Executive Committee discussed the proposed statement regarding transplant tourism. The Executive Committee raised a number of issues and opined that the OPTN should go on record as being opposed to transplant tourism and asked that the Ethics Committee further revise the position statement for the Board to consider at the Board's September 2006 meeting. The Board did not receive a copy of the Ethics Committee's proposed statement and upon recommendation of the Executive Committee, by a vote of 31 for, 0 against, and 0 abstentions, approved the following:

*RESOLVED, that the OPTN and UNOS are strongly opposed to practices in which patients in need of transplantation travel abroad to purchase an organ in exploitive situations.

The OPTN/UNOS President then requested that the Ethics Committee revise its proposed statement to include this exploitation aspect in the statement to be considered by the Board in September 2006.

For its August 6-7, 2006, meeting, the Committee was provided with a copy of the Board transcript discussing transplant tourism. The directive from the Board was to consider the exploitation of humans around the world. The Committee believed that the statement previously prepared and submitted to the Executive Committee adequately addressed the concerns voiced by the Board and proposed several prefatory comments to accompany the resolution. Thereafter, by a vote of 16 for, 1 against, and 0 abstentions, the Committee recommended the following resolution to be considered by the Board at the September 2006 Board meeting:

RESOLVED, that the OPTN/UNOS Board of Directors hereby adopts the "Statement on Transplant Tourism" as recommended by the OPTN/UNOS Ethics Committee, and makes the following observations:

- The statement emphasizes that the underground practice of transplant tourism exploits vendors and recipients alike;
- The statement reflects the circumscribed scope of the OPTN/UNOS vis a vis national, rather than international concerns;
- The statement avoids moral exceptionalism, avoiding the hazard of singling out individual examples of exploitation and possibly making other forms of exploitation appear more morally acceptable by comparison;

- Example: The systematic execution of political prisoners for the purpose of selling their organs should not be the salient measure of the moral acceptability of less violent forms of transplant tourism.
- The statement is offered as an overview, rather than an exhaustive treatment of the many ethical issues surrounding the practice of transplant tourism; and
- The statement is restricted to transplant tourism and is not intended to minimize the importance of corollary ethical issues such as human rights, justice, and post-tourism care that are all deserving of independent consideration.

Statement on Transplant Tourism

The disparity between demand for and supply of organs for transplantation occupies the attention of the international transplant community, especially for the recipients whose lives hang in the balance. The plight of those awaiting a transplant has engendered numerous strategies to increase the number of available organs.

Transplant tourism is the purchase of a transplant organ abroad that includes access to an organ while bypassing laws, rules, or processes of any or all countries involved. Transplant tourism remains a refuge for desperate recipients of means, and there is anecdotal evidence that the practice is growing. It is the considered view of the OPTN/UNOS Ethics Committee that the current practice of transplant tourism is predicated on exploiting the desperation of vendors, recipients and their families. Reports of outcomes from transplant tourism are necessarily anecdotal, given the underground nature of the exchange, but it is pertinent that with few exceptions, [1, 2] the literature on the subject is nearly uniform in reporting adverse consequences for vendors and recipients. [3-11] Brokers of transplant tourism leverage the underground nature of the practice, exploiting the parties involved by obscuring the risks. Transplant tourism typically operates in countries where the rule of law is absent, or incompletely enforced. [9] The practice of transplant tourism, by design, manifestly undermines the ethical principle of non-maleficence.

The OPTN/UNOS Ethics Committee condemns the practice of transplant tourism. Furthermore, it is the position of the Ethics Committee that a recommendation from a licensed health care professional to engage in such a practice cannot be defended on ethical or current empirical grounds. However, the Committee would be remiss in failing to observe that the practice of transplant tourism might not exist but for the growing disparity between the demand for and supply of organs. It is the solemn obligation of the transplant community, not only to publicly condemn the exploitative practices of transplant tourism, but to endorse ethically defensible policies which will ultimately render such practices unnecessary.

[Citations omitted]

At the September 20, 2006, meeting of the Board of Directors, Chair Allee agreed to withdraw the proposed resolution on transplant tourism, as well as two other related resolutions regarding post-transplant tourism medical care and the use of organs from executed prisoners, pending further discussion by the Ethics Committee to address patient safety issues. In the alternative, the Executive Committee proposed and the Board unanimously approved the following resolution:

RESOLVED, that the OPTN/UNOS support the World Health Organization and the international societies in improving the safety of transplantation worldwide and eliminating the exploitation of organ donors.

At its March 25-16, 2007, meeting, the Ethics Committee considered the comments received to date and continues to feel that its originally proposed resolution and statement on transplant tourism is responsive to the concerns expressed by the Executive Committee.

By a vote of 14 for, 0 against, and 0 abstentions, the Committee respectfully recommends the following resolution for consideration by the UNOS Corporate Board:

****RESOLVED, that the UNOS Board of Directors hereby adopts the “Statement on Transplant Tourism” as set forth below, and makes the following observations:**

- **The statement emphasizes that the underground practice of transplant tourism exploits vendors and recipients alike;**
- **The statement reflects the circumscribed scope of the OPTN/UNOS vis a vis national, rather than international concerns;**
- **The statement avoids moral exceptionalism, avoiding the hazard of singling out individual examples of exploitation and possibly making other forms of exploitation appear more morally acceptable by comparison;**
 - **Example: The systematic execution of political prisoners for the purpose of selling their organs should not be the salient measure of the moral acceptability of less violent forms of transplant tourism.**
- **The statement is offered as an overview, rather than an exhaustive treatment of the many ethical issues surrounding the practice of transplant tourism; and**
- **The statement is restricted to transplant tourism and is not intended to minimize the importance of corollary ethical issues such as human rights, justice, and post-tourism care that are all deserving of independent consideration.**

Statement on Transplant Tourism

The disparity between demand for and supply of organs for transplantation occupies the attention of the international transplant community, especially for the potential recipients whose lives hang in the balance. The plight of those awaiting a transplant has engendered numerous strategies to increase the number of available organs.

Transplant tourism is the purchase of a transplant organ abroad that includes access to an organ while bypassing laws, rules, or processes of any or all countries involved. Transplant tourism remains a refuge for desperate recipients of means, and there is anecdotal evidence that the practice is growing. It is the considered view of the UNOS Ethics Committee that the current practice of transplant tourism is predicated on exploiting the desperation of vendors, recipients and their families. Reports of outcomes from transplant tourism are necessarily anecdotal, given the underground nature of the exchange, but it is pertinent that with few exceptions, [1, 2] the literature on the subject is nearly uniform in reporting adverse consequences for vendors and recipients. [3-11] Brokers of transplant tourism leverage the underground nature of the practice, exploiting the parties involved by obscuring the risks. Transplant tourism typically operates in countries where the rule of law is absent, or incompletely enforced. [9] The practice of transplant tourism, *by design*, manifestly undermines the ethical principle of non-maleficence.

The UNOS Ethics Committee condemns the practice of transplant tourism. Furthermore, it is the position of the Ethics Committee that a recommendation from a licensed health care professional to engage in such a practice cannot be defended on ethical or current empirical

grounds. However, the committee would be remiss in failing to observe that the practice of transplant tourism might not exist *but for* the growing disparity between the demand for and supply of organs. It is the solemn obligation of the transplant community, not only to publicly condemn the exploitative practices of transplant tourism, but to endorse ethically defensible policies which will ultimately render such practices unnecessary.

1. Reddy, K.C., et al., *Unconventional renal transplantation in India*. Transplant Proc, 1990. 22(3): p. 910-1.
2. Thiagarajan, C.M., et al., *The practice of unconventional renal transplantation (UCRT) at a single centre in India*. Transplant Proc, 1990. 22(3): p. 912-4.
3. Chugh, K.S.a.V.J., *Commerce in transplantation in Third World countries*. Kidney Int, 1996. 49: p. 1181-1186.
4. Ivanovski, N., et al., *Renal transplantation from paid, unrelated donors in India--it is not only unethical, it is also medically unsafe*. Nephrol Dial Transplant, 1997. 12(9): p. 2028-9.
5. Lawrence, R., *Abuse of live related kidney transplantation*. Nephrol Dial Transplant, 1997. 12(9): p. 2028.
6. Chugh, K.S. and V. Jha, *Problems and outcomes of living unrelated donor transplants in the developing countries*. Kidney Int, 2000. 57(s74): p. 131-135.
7. Goyal, M., et al., *Economic and health consequences of selling a kidney in India*. Jama, 2002. 288(13): p. 1589-93.
8. Higgins, R., et al., *Kidney transplantation in patients traveling from the UK to India or Pakistan*. Nephrol Dial Transplant, 2003. 18(4): p. 851-2.
9. Jha, V., *Paid transplants in India: the grim reality*. Nephrol Dial Transplant, 2004. 19(3): p. 541-3.
10. Sever, M.S., et al., *Outcome of living unrelated (commercial) renal transplantation*. Kidney Int, 2001. 60(4): p. 1477-1483.
11. Zargooshi, J., *Quality of life of Iranian kidney "donors"*. J Urol, 2001. 166(5): p. 1790-9.

Subsequently, the Committee was advised of the following United Nations definitions of Organ Trafficking and exploitation: “the recruitment, transport, transfer, harboring or receipt of persons, by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purpose of exploitation by the removal of organs, tissues or cells for transplantation. Exploitation shall include, at a minimum, the exploitation of the prostitution of others or other forms of sexual exploitation, forced labour or services, slavery or practices similar to slavery, servitude or the removal of organs.” Several members of the Committee commented on whether and how to include elements of these definitions into the current proposed statement. It was felt that organ trafficking and human trafficking for organ and tissue transplantation purposes have several issues related issues to transplant tourism however, human trafficking is an important topic with significant differences from transplant tourism such that it should be considered separately and thoroughly by the Committee.

2. Post-Transplant Tourism Care. At its August 2006 meeting, the Committee also discussed the conundrum facing physicians who are asked to provide follow-up care to patients who have traveled abroad to receive an organ transplant. For purposes of rendering care, physicians do not distinguish between conditions caused by lifestyle choices such as liver failure caused by alcohol abuse. The Committee discussed the obligation of physicians to treat “the patient in front of us” as well as an obligation to inform patients of the

risks posed by transplant tourism, including the risk of not receiving follow-up care by the same physician due to an objection to circumventing the waiting list. There is no individual physician obligation to continue the relationship with a patient in a non-emergent situation. This was one of the proposals withdrawn by request at the Board's September 2006 meeting. After reconsideration by the Ethics Committee at its March 25-26, 2007, meeting, by a vote of 14 for, 0 against, and 0 abstentions, the Committee respectfully recommends the following resolution for consideration by the UNOS Corporate Board:

****RESOLVED, that the UNOS Board of Directors hereby adopts the following position regarding treatment of individuals who have received an organ through transplant tourism: In emergent situations, patients should be evaluated and treated according to the standard of care. While there may not be an obligation on the part of individual physicians to care for such patients in non-emergent situations, the medical community has an obligation to provide care for these patients. Physicians are encouraged to provide care for these patients. In the case of conscientious objections, the physician should help the patient locate an alternative physician and may terminate the physician patient relationship, in accordance with local professional practices.**

3. Donation from Executed Prisoners. At the August 2006 meeting, the Committee reviewed correspondence regarding the execution of Falun Gong practitioners in China for the purpose of procuring organs for transplant – most likely into foreign nationals traveling to China for an organ transplant. The Committee also reviewed a statement from The Transplantation Society stating its opposition to the transplantation of organs from executed prisoners. It was noted that these documents present only one side of issue and that there is a distinction between the executions of prisoners for the purpose of providing transplantable organs versus the use of organs for transplant from prisoners who have been executed for other reasons. While this is an international issue that may exceed the purview of the OPTN, the Committee believes that it is appropriate for UNOS to comment in its capacity as a distinct corporate entity. This was one of the proposals withdrawn by request at the Board's September 2006 meeting. After reconsideration by the Ethics Committee at its March 25-26, 2007, meeting, by a vote of 13 for, 0 against, and 0 abstentions, the Committee respectfully recommended the following resolution for consideration by the Board:

****RESOLVED, that the OPTN/UNOS Board of Directors denounces the use of organs from government-sponsored executions for any form of transplantation. This practice is morally reprehensible and should be censured.**

Upon consultation with UNOS leadership, the Committee by consensus agreed to recommend the following revisions to the resolution for consideration by the UNOS Corporate Board, as indicated by underlines and strikethroughs:

****RESOLVED, that the ~~OPTN~~UNOS Board of Directors denounces the use of organs from ~~government-sponsored executions for any form of executed prisoners for the purposes of transplantation.~~ The execution of prisoners for the purposes of transplantation. ~~This practice is morally reprehensible and should be censured.~~**

4. Transplant Candidacy – Mental Competency. The Committee reviewed its historical action document for guidance on evaluating potential candidates for eligibility for transplantation. Recent publicity has highlighted the issue of the consideration of mental competency when evaluating patients for eligibility to be listed for a transplant. The OPTN/UNOS has not previously provided guidance specifically regarding mental disabilities and eligibility for transplant. The Committee noted that all mental disabilities are not the same. In

some cases, from the parent's perspective, the transplant may not impact the capacity of the child but might improve the quality of life of the parent as a caregiver for a profoundly disabled child. It was also noted that patients suffering from dementia are routinely dialyzed. It was suggested that consideration for transplantation should require a determination of benefit (perhaps defined as significant therapeutic benefit) to the individual patient. It was noted that evaluation for transplant remains a local issue and it remains appropriate to consider a patient's ability to comply with their post-transplant medical regimen. As a threshold question, the evaluating center should determine whether the patient will receive a significant/meaningful medical benefit. After additional discussion, by a vote of 14 for, 0 against, and 0 abstentions, the Committee recommends the following resolution for consideration by the Board.

****RESOLVED**, the OPTN/UNOS Board of Directors reaffirms that the eligibility for transplantation predicated on determinations of social worth is morally unjustified. Patients with disabilities should not be excluded from consideration for transplant solely by virtue of their disability.

Upon consultation with OPTN/UNOS leadership, revisions to the resolution were made as indicated by underlines and strikethroughs, and the following revised resolution is recommended for consideration by the Board:

****RESOLVED**, the OPTN/UNOS Board of Directors reaffirms that ~~the eligibility for transplantation predicated on determinations of social worth is morally unjustified. Patients with disabilities should not be excluded from consideration for transplant solely by virtue of their disability.~~

5. Anencephalic Donors. The Committee re-evaluated the existing position on anencephalic donation set forth in the 1989 position paper. The Committee agreed that the 1989 position paper entitled "The Anencephalic Infant as an Organ Source: Medical and Ethical Considerations," should be affirmed and agreed that additional points should be clarified based on the refinement of brain death and cardiac death criteria. The position paper is attached hereto as Exhibit A. After additional discussion, by a vote of 15 for, 0 against, and 0 abstentions, the Committee recommends the following resolution for consideration by the Board:

****RESOLVED**, that the Board of Directors hereby adopts the following modifications to the 1989 position paper entitled "The Anencephalic Infant as an Organ Source: Medical and Ethical Considerations," which are intended to clarify, update, and to the extent that there is a conflict, supersede the 1989 position paper on anencephalic organ donation. In all other respects, the 1989 position paper is reaffirmed:

1. Infants with anencephaly do not meet the criteria for brain death;
2. The creation and application of unique brain death criteria for these infants are not appropriate; and
3. Infants with anencephaly may be considered for organ donation after cardiac death under the usual criteria/procedures.