

**OPTN/UNOS Ethics Committee
Report to the Board of Directors
March 2-3, 2009
Houston, TX**

Summary

I. Action Items for Board Consideration

- The Board of Directors is asked to approve a paper entitled, “Restatement of General Principles for Allocating Human Organs,” which restates the 1991 White Paper. (Item 1, Page 3)
- The Board of Directors is asked to adopt the definitions of the Declaration of Istanbul for “organ trafficking,” “transplant commercialism,” “transplant tourism,” and “travel for transplantation.” (Item 2, Page 4)
- The Board of Directors is asked to adopt the Declaration of Istanbul on Organ Trafficking in its entirety. (Item 2, Page 6)
- The Board of Directors is asked to adopt a statement acknowledging that living donation from incarcerated individuals may be appropriate in limited circumstances. (Item 3, Page 6)
- The Board of Directors is asked to approve revisions to the statement entitled, “Considerations in Assessment for Transplant Candidacy.” (Item 4, Page 7)
- The Board of Directors is asked to approve a statement finding that it is ethically acceptable and appropriate to recover organs after cardiac death is pronounced in both adult and pediatric patients, with consent and in accordance with the “dead donor rule.” Further scientific investigation in adult and pediatric populations should be conducted to determine more precisely the minimum time needed to ensure the permanent cessation of circulatory function in the donor. (Item 5, Page 10)

II. Other Significant Items

- The Committee continues to review carefully the development of proposed concepts for use in a revised kidney allocation system. (Item 8, Page 12)

**OPTN/UNOS Ethics Committee
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Houston, Texas**

**Michael Shapiro, M.D., Chair
Alexandra Glazier, J.D., MPH, Vice-Chair**

The following report represents the Ethics Committee's deliberations and discussions at its meeting held on October 5-6, 2008, in Chicago, Illinois:

1. "Principles of Organ Allocation" White Paper Review Subcommittee

At the August 2006 meeting, in light of the discussion of Kidney Transplantation Committee (formerly Kidney Allocation Review Subcommittee (KARS)), it was agreed to form a working group to revisit the 1991 White Paper entitled "Principles of Organ Allocation" and to have revisions for the Committee to consider at its March 2007 meeting. The Subcommittee met several times by conference call and in a session prior to the full committee meeting. At its March 2007 meeting, the Committee discussed different versions of a revision to the white paper. It was suggested that equity does not equate to justice and that equity of access is not a sufficient claim of justice to satisfy the criteria of justice. It is important to distinguish between social utility and medical utility; and medical utility differs from economic justice. Social utility as an allocation principle should be rejected.

There was discussion about the path forward the committee should take with the previously reviewed and approved draft revisions to the 1991 white paper. It was suggested that the committee should instead seek to extract guiding overarching principles. It was noted that the Draft B contained certain desirable explanations of the legal framework for donation, the process to change allocation policies, and how the process is ethically monitored. It was suggested that the term "justice" should be replaced with the term "equity." It was noted that the paper should distinguish substantive justice from procedural justice. The paper should seek to eliminate the perceived conflict between justice and utility but alternatively, the competing interests should be acknowledged. The complementary tensions should be acknowledged.

Justice needs to be narrowly defined and is currently broadly defined to include the following concepts:

- Equity of access; equitable distribution of organs; fundamental fairness
- Medical need/medical urgency
- Should benefit the least well off (Rawlsian justice)
- Equal access to a good outcome
- Waiting time

Under even a bare minimum notion of justice, some features of justice (equity)/utility are always present. Justice may also be seen as the law tempered with compassion. Justice and utility may not always be balanced.

Dr. Shapiro acknowledged that he may have a conflict of interests with service on this subcommittee due to his simultaneous service on the Kidney Transplantation Committee. Lainie Ross, M.D., volunteered to work with Dr. Shapiro on the document. Constance Jennings, M.D. and Marie Csete, M.D., also agreed to work on the paper.

In March 2008, the Committee discussed the path forward for this effort. The Committee generally

agreed that the 1991 white paper on the principles of allocation was very well done and at a sufficiently high level that its value is lasting and that only minimal adjustments, if any, are necessary. It was suggested that the term “equity” should be substituted for the term “justice” as used in the 1991 Paper. The subcommittee convened and decided that it was not feasible to reconcile the competing drafts that had been prepared and submitted earlier. Instead, the subcommittee evaluated the 1991 paper line by line and suggested significant modifications to streamline and update the document. Notably, many of the examples of each of the competing principles were removed from the draft document.

The next day, the Committee extensively discussed the subcommittee’s proposed revisions to the original 1991 paper. There was extensive discussion as to the treatment of age as a factor to be considered in allocation. It was suggested that age should not be used in kidney allocation or that alternatively, ethnicity/race should be used in kidney allocation as a predictive medical criteria. There was further discussion about the decision of the kidney transplantation committee to remove race from the life years from transplantation (LYFT) allocation proposal.

A motion was made to add age to the list of factors that should be excluded in the proposed restated principles document however, this motion was defeated by a vote of 6 for, 9 against, and 1 abstention.

A separate motion to remove “age” as a factor to be considered in the application of the principle of medical utility failed for lack of a second.

After additional discussion, regarding further amendments to the restated document, by a vote of 14 for, 3 against, and 0 abstentions, the following resolution is recommended for consideration by the Board:

****RESOLVED, that the OPTN/UNOS Board of Directors hereby adopts the Restatement of General Principles for Allocating Human Organs, as set forth in Exhibit A.**

2. Transplant Tourism – “Organ Trafficking” and the Declaration of Istanbul

At the June 2007 Board of Directors meeting, the Board of Directors considered and approved resolutions regarding transplant tourism, as previously recommended by the Ethics Committee. At the time, the Board expressed concern that transplant tourism did not accurately reflect the practices described, and that there should be an approved definition of organ trafficking to clearly distinguish acceptable and unacceptable forms of transplant tourism. The Committee was asked to edit and approve a statement on “Organ Trafficking” for consideration by the Board in February 2007. Ms. Allee gave the background of this request from the Board for the Committee to revisit the term “transplant tourism.”

It was suggested that the definition for organ trafficking should consider cells and stem cells. The Committee considered the definition of organ trafficking from the World Health Organization. It was noted that we have no jurisdiction over the organ traffickers and that diverts attention away from the recipients over whom the OPTN/UNOS has authority.

The Committee spent considerable time drafting a proposed statement on organ trafficking to distinguish this practice from transplant tourism, which might be acceptable in some circumstances. It was suggested to revise the previously approved statement on transplant tourism. After considerable discussion, the Committee unanimously recommended the following statement for approval by the Board:

Statement on Organ Trafficking

“Organ trafficking” involves the violation of the human rights of individuals through exploitation and/or coercion of donors, recipients, and their families, for purposes of making organs available for transplantation. The long-term health, psychological, and socioeconomic consequences for donor and recipients are unknown; however, mounting anecdotal evidence suggests both donors and recipients may be harmed.

Exploitation entails the taking advantage of another individual’s vulnerability or precarious circumstances. (Agrawal 2003:S29). These precarious circumstances often include the extreme poverty and desperation of donors. Organ trafficking is predicated on exploiting the desperation of vendors, recipients and their families.

Coercion is based on the actions of one person toward another when the options presented to a person become unacceptably limited (Agrawal 2003) and “entails a threat that the person considers a worse circumstance if they do not do the desired action.” (Emanuel et al. 2005:337). In the context of organ trafficking, coercion may be financial and/or psychological and includes the abuse of power, or the abuse of an individual’s vulnerability to achieve the control over a person for the purpose of permitting the removal of organs for transplantation. Coercion may also take the form of recruitment, transport, transfer, harboring or receipt of persons, by means of threat, use of force or abduction, fraud, or deception to recover organs for transplantation.

References:

Agrawal M. Voluntariness in clinical research at the end of life. *Journal of Pain and Symptom Management* 2003; 25(4): S25-S32.

Emanuel EJ, Currie XE, Herman A. Undue inducement in clinical research in developing countries: is it a worry? *The Lancet* 2005; 366: 336-40.

At the June 2008 meeting, the Board of Directors declined to consider the recommended statement. In June, the Declaration of the Istanbul on Organ Trafficking and Transplant Tourism (the “Declaration of Istanbul”) had just been released and the Board believed that the proposed statement should be reconsidered for consistency with the Declaration of Istanbul. The Declaration of Istanbul was created as a result of an international summit on transplant tourism and organ trafficking convened by the Transplantation Society and International Society of Nephrology in Istanbul, Turkey on April 30-May 2, 2008.

In October 2008, the Committee reviewed the Declaration of Istanbul regarding transplant tourism and organ trafficking. The Declaration of Istanbul was released after the Board had recommended its proposed statement on organ trafficking for consideration by the Board however, the Declaration of Istanbul was released at the same time. The Board requested that the Ethics Committee reconsider the statement in light of the Declaration.

It was discussed whether the committee should recommend that the Board of Directors endorse the entire opinion of the Declaration of Istanbul. The Committee uniformly agreed with the principles of the Declaration of Istanbul but expressed concern that the Board would not or could not endorse the Declaration of Istanbul because of the potential international implications of some of the principles. The respective definitions of “organ trafficking” were compared side by side.

It was suggested that the committee recommend that the Board adopt the original, Committee-proposed statement on organ trafficking and then offer a separate proposal for the UNOS Board of Directors to

endorse the Declaration of Istanbul.

After additional discussion, by a vote of 18 for, 0 against, and 1 abstention, the following resolution was recommended for consideration by the Board:

****RESOLVED, that the OPTN/UNOS Board of Directors adopts the definitions of the Declaration of Istanbul on “organ trafficking,” “transplant commercialism,” “transplant tourism,” and “travel for transplantation” as set forth below:**

Definitions

Organ trafficking is the recruitment, transport, transfer, harboring or receipt of living or deceased persons or their organs 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 to, or the receiving by, a third party of payments or benefits to achieve the transfer of control over the potential donor, for the purpose of exploitation by the removal of organs for transplantation.

Transplant commercialism is a policy or practice in which an organ is treated as a commodity, including by being bought or sold or used for material gain.

Travel for transplantation is the movement of organs, donors, recipients or transplant professionals across jurisdictional borders for transplantation purposes. Travel for transplantation becomes transplant tourism if it involves organ trafficking and/or transplant commercialism or if the resources (organs, professionals and transplant centers) devoted to providing transplants to patients from outside a country undermine the country’s ability to provide transplant services for its own population.

Immediately thereafter, by a vote of 18 for, 0 against, and 1 abstention, the Committee recommends the following resolution for consideration by the Board of Directors:

****RESOLVED, that the UNOS Board of Directors endorses the Declaration of Istanbul, attached as Exhibit B, in its entirety.**

3. Prisoners as Living Organ Donors

The Committee acknowledged that it had previously considered issues of incarcerated prisoners as organ transplant candidates, and of executed prisoners as organ donors however, the committee has not previously formally considered the issue of incarcerated prisoners as living organ donors. It was suggested that the Committee should reconsider this issue at the January meeting to compile additional materials for the Committee to consider. It was agreed to consider this issue at the next meeting.

In March 2008, the Committee considered living donation from incarcerated individuals. There is a lack of authentic autonomy from which to make the decision to donate although donation to family members was identified as a more appropriate relationship to support a donation. What is the potential for suboptimal medical care following the donation? It was asked whether we should prohibit the possibility of prisoners being living organ donors? It was suggested that non-directed donation should be excluded but that living directed donation should be considered on the same basis as other living donations. The Committee approved a statement on incarcerated prisoners becoming a living organ donor for consideration of the Board at its June 2008 meeting. The Board declined to consider the proposal based on concerns shared by the Living Donor (LD) Committee.

After the June 2008 Board of Directors meeting, the Ethics Committee asked the LD Committee to provide feedback on its position statement on prisoners serving as living donors. In response, the LD Committee offers these comments:

- a. The LD Committee is concerned about the vulnerability of prisoners as living donors.
- b. Stating living donation is permissible under certain circumstances may be too vague. Could the position statement include examples of such circumstances, or suggest procedures for reviewing individual cases?
- c. The LD Committee agrees that non-directed donation is not ethically permissible for prisoners.
- d. The LD Committee agrees that there may be added risk for prisoners following living donation for not receiving optimal care without a means of recourse.
- e. Could the position statement be changed to read that an independent donor advocate *must* be utilized in the consent and medical evaluation of any potential incarcerated living donor (as specified in the OPTN/UNOS Bylaws).

An example was suggested of an incarcerated parent donating to their child, which the Committee felt would be an appropriate circumstance favoring the living donation. In response to concerns about an incarcerated prisoners receiving health care post-donation, it was noted that the prisoners may receive better health care than the 20% of living donors who don't have health insurance.

The Committee agreed that it is not inherently unethical for an incarcerated person to donate an organ and give informed consent. The Committee understands that there are operational challenges and increased costs inherent in prisoner becoming a living donor, but reiterated. Many of the ethical discussions gravitate toward a discussion of the financial implications.

By a vote of 15 for, 0 against, and 0 abstentions, the Committee recommends the following for consideration by the Board:

****RESOLVED, that the OPTN/UNOS Board of Directors acknowledges that living-related organ donation from persons currently incarcerated is ethical and should be permissible under certain circumstances. Prisoners present special concerns and vulnerabilities, and appropriate precautions are necessary to avoid coerced donation decisions. As with all living donors, an independent donor advocate should be appointed for all such potential donors.**

4. Transplant Candidacy

Also as part of the Committee's goals, the Committee reviewed and revised the historical position statement on transplant candidacy for consideration by the Board in February 2007. The paper was last considered in 1998 and was due for reconsideration by the Committee in light of developments in transplantation. The Committee discussed the "General Considerations in Assessment for Transplant Candidacy" and felt that the considerations remained valid. In June 2007, the Board of Directors approved a position on transplant candidacy for individuals with disabilities.

It was asked whether to add the role of social support to the General Considerations? It was also suggested to ask whether financial considerations should be included to ensure that the candidate will have adequate resources for follow up care and immunosuppression. Should alternative therapies be discussed?

Extensive discussion followed about what consideration should be given to social support systems. This

may translate into a bias against lower socioeconomic groups. It was noted that here is a “green screen” for some transplant candidates. Can the statement be approved intact and then consider what may be included to update the statement?

The statement was approved by the Committee with the intent to present it to the Board of Directors for approval in June 2008. OPTN leadership expressed concerns that the document was not based on objective medical criteria and referred the statement to the Ethics Committee for further consideration.

In October 2008, the Committee reconsidered the language of the statement. It was noted that CMS regulations and OPTN/UNOS bylaws require that a psychosocial evaluation be conducted of transplant candidates. The Committee understands the concerns that decisions on transplant candidacy must be based on objective medical criteria and believes that this statement is consistent with that principle. After additional discussion, the Committee unanimously recommended the following resolution for consideration by the Board:

****RESOLVED, that the following revisions to the statement entitled, “Considerations in Assessment for Transplant Candidacy” are hereby approved by the UNOS Board of Directors:**

~~UNOS Ethics Committee~~ General Considerations in Assessment for Transplant Candidacy

~~Note: This report is circulated for informational purposes and to stimulate discussion of a very important subject. The report has been presented to the OPTN/UNOS Board of Directors. It has not been adopted as policy.~~

~~Also, transplant centers are encouraged to develop their own guidelines for transplant candidate consideration. Each potential transplant candidate should be examined individually and any and all guidelines should be applied without any type of ethnicity bias.~~

Preamble

The concept of non-medical transplant candidate criteria is an area of great concern. Most transplant programs in the United States use some type of non-medical evaluation of patients for transplantation. Historically, psychosocial evaluations of potential transplant candidates have been conducted and the results have influenced the possible listing of these patients in a variety of ways. There is general agreement that non-medical transplant candidate criteria need to be evaluated. The legitimate substance of such an evaluation could cover a very wide range of topics. To the greatest extent possible, any acceptance criteria should be broad, ~~and~~ universal, and transparent.

The ~~UNOS Ethics Committee~~ OPTN/UNOS Board of Directors has chosen to address the criteria of life expectancy, organ failure caused by behavior, ~~compliance/adherence~~, repeat transplantation, ~~and~~ alternative therapies, and social and economic issues. The list is recognized as neither exhaustive nor immutable. The elements of non-medical transplant candidate evaluation will and should reflect changes that occur in technology, medicine and other related fields while reflecting the most current knowledge of scientific and social issues in transplantation. Therefore, the non-medical transplant candidate criteria should be continuously reassessed and modified as necessary. However, because we are serving individual human beings with highly complex medical situations, a process of *individual* evaluation must be maintained within the broad parameters. Where possible, barriers to transplant candidacy should be addressed and overcome.

~~The Ethics Committee also realizes the catalyst for all transplant candidate criteria is the shortage of~~

available organs for transplantation. Because donated organs are a severely limited resource the best potential recipients should be identified. The probability of a good outcome must be highly emphasized to achieve the maximum benefit for all transplants. Were there an ample supply of transplantable organs, nearly every person in need could be a transplant candidate. To this end, it is affirmed that transplantation is not a universal option. Medical professionals, while honoring the moral obligations to extend life and relieve suffering whenever possible, must also recognize the limitations of transplantation in meeting these ends.

Life Expectancy

While the ~~Committee~~ OPTN/UNOS Board of Directors would not recommend arbitrary age or co-morbidity limits for transplantation, ~~members generally concur that~~ transplantation should be carefully considered if the candidate's reasonable life expectancy with a functioning graft, based on factors such as age or co-morbid conditions, is significantly shorter than the ~~reasonably~~ expected "life span" of the transplanted organ.

Organ Failure Caused by Behavior

In social and medical venues, debate continues to focus upon alcoholism, drug abuse, smoking, eating disorders, and other behaviors ~~as or~~ diseases or character flaws. Such behaviors are associated with disease processes in many adults. ~~The Ethics Committee has historically supported the conclusion that p~~ast behavior that results in organ failure should not be considered a sole basis for excluding transplant candidates. However, additional discussion of this issue in a societal context may be warranted.

Compliance/Adherence

It is difficult to apply broad measures of ~~compliance~~ adherence to accepting transplant candidates, since empirical measures are limited and medical professionals often approach these issues subjectively. However, transplantation should be considered very cautiously for individuals who have demonstrated serious, consistent, and documented non-adherence to compliance in current or previous treatment. Potential candidates with organic or psychiatric co-morbidities that limit their anticipated ability to adhere to medical regimens should receive appropriate assessment.

Social and Economic Issues

Certain candidates may be disadvantaged by assessments made about their ability to adhere adequately to post-transplant care regimens. Such decisions may at times represent discriminatory judgments based upon the candidate's past behavior, socioeconomic status, or perceived availability or reliability of financial and/or social support.

Repeat Transplantation

~~The Ethics Committee acknowledges the issue of justice in considering repeat transplantation.~~ A prior transplant, in and of itself, should not exclude the patient from being considered for a repeat transplant. Graft failure, particularly early or immediate failure, evokes significant concerns regarding repeat transplantation. However, the likelihood of long-term survival of a candidate receiving a repeat transplant should receive ~~strong~~ consideration.

Alternative Therapies

The presence or absence of alternative therapies should be carefully weighed against other factors in evaluation. In some cases the need for a transplant may be delayed, even prevented, by judicious use of other medical or surgical procedures.

The Board of Directors also realizes the catalyst for all transplant candidate criteria is the shortage of available organs for transplantation. Because donated organs are a severely limited resource the best potential recipients should be identified. The probability of a good outcome must be highly emphasized to achieve the maximum benefit for all transplants. Were there an ample supply of transplantable organs, nearly every person in need could be a transplant candidate. To this end, it is affirmed that transplantation is not a universal option. Medical professionals, while honoring the moral obligations to extend life and relieve suffering whenever possible, must also recognize the limitations of transplantation in meeting these ends.

Approved 16-0-0

5. Donation after Cardiac Death and ECMO Issues

Based on recently reported DCD pediatric cases, the Committee discussed Donation after Cardiac Death and ECMO Issues at its October 2008. The Committee reviewed articles regarding a pediatric death protocol where the pediatric donor organs were recovered beginning only 75 seconds following the declaration of death. The Report of the National Conference on Donation after Cardiac Death recommended a period of two minutes following declaration of cardiac death prior to commencing organ recovery in order to confirm that there was no autoresuscitation.

There is wide disagreement of the exact time when someone is dead, and this time can vary widely under different measures. It was asked when is it morally acceptable to cease treatment and begin recovery of organs? It was noted that as a practical matter, there remains the need to draw lines and make distinctions.

Further discussion followed regarding the following general questions: when is it appropriate to withdraw life support; when is it appropriate to procure organs; and when is it appropriate to bury people?

It was suggested that when determining death, one must consider actions that cause death versus actions that permit death to occur such as removing artificial ventilation. Withdrawal of care is never the proximate cause of death. It was also suggested that the Committee should not provide any comments on the specific pediatric DCD protocol described in the journal articles.

It was questioned whether Catholics should agree that they might be declared dead by cardiac criteria. The Committee believes in the continued applicability of the dead donor rule (i.e., a patient must be declared dead before the recovery of organs for transplantation).

The work of the National Conference on DCD was discussed. When describing death, the conference report uses both “permanent” and “irreversible” interchangeably to describe “death.” The report of the National Conference states that in applying the cardiac death criteria, clinical examination would be sufficient to determine death in a non-DCD donor situation however, a DCD donor situation has time constraints.

Donations occur in very different types of hospitals. In general, it was felt that it is not a good idea to proscribe certain procedures for a national standard.

Should cardiac death be described as the loss of circulatory function, not the permanent cessation of the beating of the heart? This is an interpretation that would permit the recovery of hearts from donors declared dead by cardiac death criteria.

After considerable discussion, the Committee unanimously approved the following resolution for consideration by the Board of Directors:

****RESOLVED, that it is ethically acceptable and appropriate to recover organs after cardiac death is pronounced in both adult and pediatric patients, with consent and in accordance with the “dead donor rule.” Death should be established using current empirical data and standards established by the Institute of Medicine (IOM) and the Report of the National Conference on Donation after Cardiac Death. Further scientific investigation in adult and pediatric populations should be conducted to determine more precisely the minimum time needed to ensure the permanent cessation of circulatory function in the donor.**

Approved by a vote of 14-0-3

6. Stewardship/Ownership Subcommittee

In October 2008, the Committee discussed the current charge of the committee. Similar to financial incentives, it was suggested that the topic may be too large and should be broken down into smaller components.

It was asked what these terms mean, “stewardship” or “ownership.” What is the relationship of the various parties to the organs recovered and transplanted? This is a significant topic for many of the religious values. Due to changes in committee membership, the Subcommittee was reconstituted as follows: Randolph Schaffer, M.D., Remonia Chapman; Elisa Gordon, PhD; Alexandra Glazier, Esq.; Rachel Mackey, Dane Sommer, and Lainie Ross, M.D. The preexisting bibliography will be distributed to the full committee for reference.

7. Non-resident Alien/Undocumented Transplantation

As part of the Committee goals, in October 2008, the Committee revisited the historical position statement on non-resident alien transplantation to determine if contemporary revisions are necessary and helpful to assist the OPTN in achieving its strategic goals. It was noted that there is no limit on the number of non-resident alien transplants that can be performed however, if the number exceeds 5% of transplants, then the transplant program will be reviewed. It was noted that it may be more cost effective for hospitals to transplant undocumented residents than to provide ongoing dialysis.

It was asked whether there should be a distinction among transplant candidates based upon immigration status. It was noted that the Committee has just recommended endorsement of Declaration of Istanbul, and that it contains a principle that the treatment of patients from outside the country is only acceptable if such treatment does not undermine the ability of the country to provide transplant services for its own population. It was suggested that the Committee request the Ad Hoc International Relations Committee and/or the Membership and Professional Standards Committee to review the bylaws regarding non-resident alien transplantation and determine firmer guidance for the threshold for foreign national transplantation. It would be helpful to have data to assess whether the 5% cap is unacceptably low. It was also noted that if the threshold of review for non-resident aliens was set at either 0% or 100%, both thresholds would be unethical.

Is the issue the absolute number of foreigners who are trying to get into the system or is the issue maintaining the integrity of the U.S. transplant system? It was asked what is the ethical issue that this policy addresses? Is the issue whether we want to embrace the whole question of transplantation of non-resident aliens or is the present policy of review sufficient. Does the Committee want to reaffirm the 2003 statement or does the Committee want to pursue the statement further in light of the clause included in the Declaration of Istanbul? The discussion was tabled for discussion of living donation issues.

8. Review of Proposal to Revise the Kidney Allocation System (KARS)

Robert Wolfe, M.D., SRTR, gave a presentation to the Committee regarding the most recent modeling and analysis performed by the Kidney Transplantation Committee regarding potential revisions to the kidney allocation system. Dr. Wolfe also provided an explanation of the present iteration of the KAS model, which includes the following elements:

- Age is not represented
- Race/ethnicity is not used in calculation and minorities may be harmed by this system
 - Many factors used to calculate LYFT. Factors were excluded if they failed to meet criteria for objectivity, statistical significance, clinical importance, or data quality. The Kidney Committee decided not to include race in the calculation based on these factors
 - We are going to pretend that race does not affect LYFT
- African Americans would likely receive more transplants under the proposed KAS system
- KAS system allocates a few more organs to blood type O and blood type B candidates
- The SRTR's intent is to show the data rather than convince anyone of a particular conclusion
- Diabetes group would see the largest reduction in the number of transplants. Fewer organs to diabetic patients over age 50
 - The longer you are on dialysis, the lower the LYFT score
- Here are a couple concerns about the LYFT proposal:
 - Older patients (age 59+) are disproportionately more in need of transplantation than younger patients, yet they are less likely to receive as many as in the current system, they are more likely to wait longer for a kidney than in the current system, and they are more likely to receive worse quality kidneys than in the current system. The same concerns may also apply to diabetics

The Committee discussed the presentation at length. It was noted that any revision to the kidney allocation system only redistributes the same kidneys and the system will not result in more transplants. Candidates will continue to accrue points with waiting time. The Kidney Transplantation Committee recognized that "hope" was an important factor in the proposed system.

It was asked what are the cost consequences of this proposal to Medicare costs? Would there be a benefit since patients on dialysis might receive transplants sooner? It was noted that it costs less money over several years to have a transplant for a patient to remain on dialysis.

The Committee asked if there was a set of PowerPoint slides that presented the KAS in a more simple fashion using lay terminology? These concerns will be communicated to the Kidney Transplantation Committee

9. Financial Incentives for Organ Donation Subcommittee

In March 2008, the Committee received a presentation on the options for a path forward for this effort including the options for advancing this issue consistent with the approved committee goals.

It was suggested that UNOS should be responsible for the allocation of organs including the creation of allocation policy and the principles supporting those allocation policies. Institutionally, there was not a relationship between the Kidney Transplantation Committee and the Ethics Committee. It was suggested that a representative of the Ethics Committee should participate in other major policy questions discussed in other committees as an opportunity for improvement in other significant policy development efforts.

There was extended discussion about the 1993 white paper on financial incentives. The Committee discussed whether the paper implies that there is nothing inherently unethical about financial incentives for donation. The Committee previously directed that the subcommittee redraft the 1993 white paper for approval by the Committee. The subcommittee was originally charged in April 2006, as follows:

RESOLVED, the OPTN/UNOS Ethics Committee recognizes that the issue of financial incentives for organ procurement is a vast and complicated subject, about which much has been written in the thirteen years since the previous White Paper was published. The Committee hereby moves to form a new subcommittee on Financial Incentives for Organ Donation, tasked with but not limited to addressing the following topics:

- (a) Distinguish between several different proposals collected under the rubric of “financial incentive;”
- (b) Distinguish between proposals addressed toward deceased donors and living donors;
- (c) Review a representative sample of the new literature on topics deemed by the subcommittee or the committee as a whole as worthy of special consideration;
- (d) Compose a new White Paper reflecting (a) - (c) for consideration and approval by the full committee.

The Subcommittee prepared and discussed a new white paper and agreed that the paper was too lengthy and very complex. The subcommittee agreed to revise and condense the draft of this white paper for further discussion.

At its October 2008 meeting, a copy of the previously prepared white paper was submitted to the Committee for discussion. The Committee discussed the following concerns about the draft paper:

- While the text makes the distinction between providing financial incentives within a gift model, purchasing organs, and removing financial disincentives, it does not use these distinctions. It seems to request a “blank check” of support from the Ethics Committee for proposals involving a financial dimension.
- HRSA Breakthrough Collaborative hospitals that follow best practices often exceed consent rates of 75% without financial incentives.
- Do we assume that we have a right to the organs of the remaining 25% of people who decline donation?
- Do we assume that those who decline have no reason for declining other than a lack of financial profit? The draft report belittles current reasons for opposing donation. Deep-seated mistrust and confusion over death criteria should not be “resolved” by paying people to ignore them. Rather, they should be resolved by being trustworthy and educating.

- Together with the 1993 report, this draft overreaches in claiming “there is nothing intrinsically unethical with financial incentives for organ procurement.” First, as the report itself notes, the term “financial incentives” is too vague. Nearly everyone thinks removing disincentives is legitimate, but many think an outright purchase model is intrinsically wrong, including major religious groups such as Islam and the Catholic Church. A weaker statement should be made.
- The report ignores that financial incentives would be supported and/or paid by the government, i.e., by taxpayer dollars. In such cases, many believe a higher threshold of public support should be used than when controversial policies depend solely or primarily on private funding.
- At least one Committee member disagreed with the statement that “other alternatives for organ procurement have been aggressively pursued with all due diligence.” The 2006 IOM Committee rejected the use of financial incentives at the time, and recommended instead pursuing a new and huge potential pool of donors (victims of unexpected cardiac arrest via rapid organ recovery or uncontrolled DCD). HRSA has funded a few demonstration projects, but we have not exhausted this option, which could more than double the amount of kidneys available, rather than slightly increasing consent rates within a static or diminishing pool of standard donors.
- The report ignores the financial conflicts of interest that would arise for family members in the context of DCD.
- The issue of financial incentives must be addressed separately for deceased and living organ donation. The ethical and social issues are very different.
- We have data from Iran on payments for living organ donation. Payments have increased rates of donation. Data also suggest that concerns about exploiting the poor are well founded and some data suggest that most donors experience the process as “commodifying” or disrespecting them (i.e., such concerns are not merely theoretical or poetic).
- If the report refers to a plurality of the Ethics Committee who would support financial incentives, perhaps it should refer to a plurality who oppose them (at least at this time or in some forms).

The Committee discussed the goal of this process and whether this discussion should set a foundation of future discussion?

It was emphasized that donors must be respected and honored under any system.

The Committee also discussed a draft bill from Senator Arlen Specter to amend NOTA to expand the potential for providing financial incentives for transplantation paid by the government while increasing the penalties for providing valuable consideration in exchange for an organ transplant. It was noted that this bill was only a draft that had been circulated for discussion among the transplant community.

It was asked whether families of deceased donors should be compensated with valuable consideration? It was noted that there are not any disincentives for deceased donors.

Donor family members present concurred with that assessment and offered that the addition of financial incentives would not have affected their decision to donate organs. It was also noted that although it did not affect their decisions, a less-affluent donor family could be swayed by the financial incentive.

It was asked what would be the source of the money used to “remove disincentives”?

A motion to dissolve the subcommittee failed by a vote of 0 for, 16 against and 0 abstentions.

A motion was made to re-charge the subcommittee to narrow the focus of the subcommittee to removing disincentives to living donation. The motion was approved by a vote of 17 for, 0 against, and 0 abstentions.

The Subcommittee was reconstituted with Drs. Ravichandran, Gordon, Myer, Constance Jennings, and Patton. Dr. Jennings will serve as the subcommittee chair.

10. Living Donation Ethical Issues

Dr. Connie Davis, member of the Living Donor Committee, attended a portion of the meeting to present requests from the Living Donor Committee. Dr. Davis relayed that two goals of the Living Donor Committee are to work with the Ethics Committee to develop position statements for: the level of treatment and follow up given to living donors; and the health status of recipients in kidney paired exchanges.

In regards to the *treatment and follow up of living donors*, the Living Donor Committee recommends that the Ethics Committee provide a statement reflecting the position that the transplant center recovering an organ from a living donor organ should not deny or limit care for a living donor who experiences complications related to the act of donation. Furthermore, the Living Donor Committee suggested the care should be offered regardless of the time since donation, and/or the donor's ability to pay.

Additionally and as a separate question, the Living Donor Committee asks the Ethics Committee to support a mechanism to provide healthcare for the donor's lifetime after donation, to include coverage for preventative and maintenance healthcare.

With respect to the issue of the *health status of recipients in paired exchanges*, the Living Donor Committee asked for the development of a position statement from the Ethics Committee addressing if kidney paired exchanges should be equipoise in the selection of donor recipient pairs for living donor exchange transplants. The Living Donor Committee supports the principle of comparable benefit to donor and recipient pairs in paired exchange transplantation.

The Committee discussed applying net benefit concepts to paired living donor exchanges. It was suggested that ethics requires a certain amount of transparency so that donor-recipient pairs can make an informed decision. From the public's perspective, there are concerns that the selection of participants in the exchange programs are not always ideal.

The recipient quality portion should be left out of the equation and the focus should be on the donors. The Committee asked: why would the donor have any need to know about the recipient – what would be the purpose? Why does the living donor in a paired donation donate the organ? If that donor donated the kidney and the recipient died, as long as the original intended recipient received a kidney and survived, that donor would likely be satisfied. How "equal" are living donors?

LYFT in the living donor equation may not be a good indicator. There may likely not be equipoise in the quality of organs. The process could suggest that information about the donor and recipient be de-identified. E.g. If I bring in a 25 yr. old daughter as my original intended recipient of my kidney, I might not want her to get an organ from a 65 year old donor from the other donor-recipient pair.

There are differences in evaluation of donors and acceptance of organs. Living donors do care about the

result of their donated organ and want it to last. Living donors may choose where it goes and the issue is one of autonomy. It was suggested that donors should be able to request de-identified information about the recipient as a component of the informed consent process.

It was suggested that a succinct overview of the ethical issues around paired donation be developed.

The continued availability and Medicare coverage of immunosuppressants and universal health care was also briefly discussed.

The Committee established a subcommittee to develop a statement on the ethical considerations of paired donation. The members will be: Maggie Allee, Subcommittee Chair; Richard Demme, M.D., and Sondra Cohen. Additional members offered to review and contribute to the process.

11. Media Guidance

At the October 2008 meeting, Michael Shapiro, M.D., Chair, welcomed the committee and after brief introductions of the Committee members, briefly described the activities of the committee. He explained that the Committee members may be called upon by the media to provide commentary and that in such circumstances, the UNOS Communications Department staff should be notified and are extremely helpful in preparing individuals for media requests. Dr. Shapiro noted that it was important for individuals to clarify where the comments are the individual member's comments versus comments made on behalf of the committee or the OPTN/UNOS.

12. Goals and Planning

The Committee reviewed recent progress toward the HHS Program Goals (PART Goals) and the Board-approved Goals for the Ethics Committee. At its October 2008 meeting, the Committee also reviewed goals for the committee and progress made toward each goal as charged by the OPTN/UNOS Presidents.

13. Committee Orientation

At its October 5 meeting, Mary D. Ellison, PhD, UNOS OPTN Project Director provided the Committee with a comprehensive orientation on the following subject areas for the benefit of new and existing committee members: Introduction to OPTN/UNOS Committee Service; OPTN/UNOS Regulatory and Contractual Framework; overview of the policy development process; and progress toward reaching the HHS Program Goals.

14. New Business

Protocols for Rapid Recovery of Organs - Uncontrolled DCD was discussed as a potential source of a significant amount of organs from deceased donors.

**Attendance at the Ethics Committee Meeting
October 5-6, 2008
Chicago, IL**

Committee Members Attending:

Michael Shapiro, M.D.	Chair
Alexandra K. Glazier, J.D., M.P.H.	Vice-Chair
Matthew G. Nuhn, M.D.	Region 1
Melissa J. Doniger, J.D.	Region 2
Alison Silva, RN, BSN, CCTC	Region 3
Nathalie G. Murray, M.D.	Region 4
Randolph L. Schaffer, III, M.D.	Region 5
Pasala Ravichandran, M.D.	Region 6 (by telephone)
Sondra E. Cohen, MSW, LCSW	Region 7
Lauris C. Kaldjian, M.D., Ph.D.	Region 8
Richard Demme, M.D.	Region 9
Constance A. Jennings, M.D.	Region 10
Elisa J. Gordon, Ph.D., MPH	At Large (by telephone)
Remonia Chapman	At Large
James M. Dubois, Ph.D., DSc	At Large
Rachel Mackey	At Large
Kevin E. C. Meyers, M.D.	At Large
Lainie F. Ross, M.D., Ph.D.	At Large
Dane Sommer, D.Min., BCC	At Large
Margaret R. Allee, R.N., J.D.	<i>Ex officio</i>
Bernard Koslosvsky, M.D.	<i>Ex officio</i>

Committee Members Unable to Attend:

Gary L. Patton, Ph.D.	Region 11
Marie Csete, M.D., PhD	At Large
Daniel J. Lebovitz, M.D.	At Large
Robert Mazor, M.D.	At Large

Board Liaisons

Donna G. Banks
Mark C. Norquist

UNOS Staff:

Jason P. Livingston, Esq.	UNOS
Gloria Taylor	UNOS
Mary D. Ellison, PhD, MSHA	UNOS

SRTR Staff:

Robert Wolfe, M.D.	SRTR
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**Restatement of General Principles
for Allocating Human Organs
(Revised October 6, 2008)**

OPENING STATEMENT

The ethics of allocating human organs for transplantation is a specific application of ethical norms to social practices. The principles involved are essentially the same as those that apply to other areas of human conduct. They reflect the conclusions of American public bodies which have examined general principles of ethics. In particular, although we use slightly different language, the principles we articulate are essentially the same as those that appeared in the Belmont Report¹, the report of the federal government's National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

The principles provide a general framework for local, regional, and national policy decisions related to allocating organs, including any formulas used in such allocations. They are not meant necessarily to describe precisely what the current norms are nor are they meant to dictate precise formulas for reforming current practices. Moreover, they do not necessarily reflect the personal ethical positions of individual members of the OPTN/UNOS Ethics Committee. Rather these principles and the guidelines that follow them are meant to represent our recommendations for norms that are optimal for matters of public policy in a pluralistic society in which individuals hold a variety of conflicting, yet not unreasonable, positions on organ allocation.

Ethical principles are general prescriptive norms identifying characteristics of human actions or practices that tend to make them morally right. We view the rightness of these principles as prima facie that is, they characterize elements of actions or practices that are right insofar as one considers only a single dimension of the action or practice. Since in many actual cases principles will conflict, we shall be able to discern whether an action or practice is right "all things considered" only after all the relevant principles are taken into account.

In this paper we first identify the principles most directly applicable to organ transplantation. Then we address the challenge of resolving conflicts among principles.

GENERAL ETHICAL PRINCIPLES

1 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Washington, D.C.: U.S. Government Printing Office, 1978.

2 Quality-adjusted life years are years of life adjusted for the quality of those lives. Zeckhauser, Richard, and Donald Shepard. "Where Now for Saving Lives?" Law and Contemporary Problems 40 (1976):5-45; Torrance, George W. "Measurement of Health State Utilities for Economic Appraisal: A Review." Journal of Health Economics 5 (1986): 1-30; Menzel, Paul. Strong Medicine: The Ethical Rationing of Health Care. New York: Oxford University Press, 1990, pp. 79-93.

For ethical principles to be useful in practical problem solving they need to be general enough to apply to a wide range of decisions and simple enough to be easily understood. We identify three principles of primary importance in the allocation of human organs: utility, equity, and autonomy. Both utility and equity represent different conceptions of justice. Utility refers to the maximization of benefit to the community and equity refers to the fair distribution of benefits. The principle of autonomy holds that actions or practices tend to be right insofar as they respect autonomous choices. This should not be taken to imply that these are the only principles and rules that could be relevant. However, the three principles provide an adequate framework for most allocation decisions.

Utility

The entire enterprise of organ procurement and transplantation is undertaken in order to benefit a group of critically ill patients. The overall good that is done to benefit that group is the very reason of the program. The principle of utility holds an action or practice to be right if it promotes as much or more aggregate good than any alternative action or practice. The principle of utility, applied to the allocation of organs, specifies that an allocation should maximize the expected net amount of overall good while minimizing harm, thereby incorporating the principle of beneficence (do good) and the principle of non-maleficence (do no harm).

Among the good consequences of transplantation are the saving of life, the relief of suffering and debility, the removal of psychological impairment, and the promotion of well-being. Data measuring predicted graft survival, predicted years of life added (both from time listed and time transplanted), and even better, predicted quality adjusted life years (QALY's) added will be relevant to such determinations.

Among possible harmful consequences are the acute effects of transplantation surgery including possible mortality, but also any long-term effects related to rejection, side-effects of medication, and so forth. The goal of allocation, from a utilitarian perspective, should be to do as much (net) good as possible. Developing actual allocation policy will require that the various goods be compared in some manner so that at least a rough estimate can be made determining which allocation produces the greatest good.

Generally, the principle of utility takes into account all possible goods and harms that could be envisioned (considering the quantity and discounting for the probability of the various outcomes). These goods and harms are not limited to what could be called "medical goods." Factors to be considered in the application of the principle of medical utility are: 1) Patient Survival; 2) Graft Survival; 3) Quality of Life; 4) Availability of Alternative Treatments; and 5) Age.

But in public policy related to allocation of organs there is a widespread consensus that certain social aspects of utility should not be taken into account. In particular, the social usefulness of the lives of potential recipients should not be considered. Moreover, in determining predicted medical benefits and harms, there also is a consensus that it is unacceptable to use variations among social groups as a basis for predicting individual outcomes. For example, even if it can be shown that survival rates of one racial, gender, or socioeconomic group exceed those of another, these factors should be excluded from models used to justify allocation decisions.

There is wide acceptance of excluding social usefulness and predictors of group outcomes from consideration, and there appear to be two main reasons for such acceptance. First, in many cases such considerations are likely to conflict with the principle of equity. That one person is more useful to society than another is often a matter of his or her good fortune in the random distribution of natural and socially cultivated talents and abilities, not his or her superior effort. We add insult to injury when we withhold the benefits of transplantation to those who are not as likely to benefit society as those more fortunately endowed. Second, that a particular individual is a member of a social group that generally does poorly with transplantation, does not entail that this individual will do poorly. Considerations of equity therefore require that patients be assessed individually rather than by group membership.

This does not necessarily rule out the use of objective medical predictors of outcome (such as tissue-typing and PRA levels) even if it is known that these are not randomly distributed among racial or gender groups. It does, however, rule out excluding individual members of a social group or giving them low priority simply because the group has statistically poorer outcomes. In the application of the principle of utility, there must be evidence that the particular individual has a medical condition (high PRA with positive cross match, for example) that leads to a prediction of poorer outcome.

The principle of utility (interpreted as net medical benefit) is so obvious to many in the transplant community that they may assume that well-grounded prediction of good medical outcome is the only reasonable principle upon which an ethical allocation could be based. We believe, however, it is crucial that other ethical principles be recognized as important considerations in deciding what is an ethical allocation of human organs. In particular, the principles of equity and autonomy will sometimes lead to a justifiable decision that will not necessarily allocate organs in a manner that will do as much aggregate medical good as possible.

Equity

The National Organ Transplant Act (NOTA), in its mandate for the establishment of the Task Force on Organ Procurement and Transplantation, specifically expressed concern for “equitable access by patients to organ transplantation and for assuring the equitable allocation of donated organs among transplant centers and among patients medically qualified for an organ transplant.”² The Task Force specifically recommended that selection of patients for waiting lists and allocation of organs be fair,³ and UNOS has generally continued to express concern for equity in organ allocation. These views reflect a national commitment to a general principle of equity that merits inclusion as a basic principle of an ethic of allocation.

Equity, as used here, refers to fairness in distribution of the benefits and burdens of an organ procurement and allocation program. Thus we are concerned not exclusively with the aggregate amount of medical good that is produced, but also with the way in which that good is distributed among potential beneficiaries. This does not mean treating all patients the same, but it does require giving equal respect and concern.

³Public Law 98-507, October 19, 1984. National Organ Transplant Act 98 Stat. 2339.

⁴Task Force on Organ Transplantation. Organ Transplantation: Issues and Recommendations. Washington, D.C.: United States Department of Health and Human Services, 1986, pp. 8-9.

In a public program, all members of the public are morally entitled to fair access to its benefits. This means that even if we can determine precise measures of medical goods such as predicted quality adjusted years of life added, it may not always be the case that the allocation that maximizes QALYs will be the morally right allocation, all things considered. It is for this reason that allocation schemes routinely consider medical need as well as medical benefits and give consideration to the medically sickest patients even if it is predictable that some other patients who are not as sick will have better outcomes.

Many other factors might be included in an allocation policy not because they promote medical utility, but because they seem necessary to treat potential recipients fairly, to give everyone a fair chance of getting an organ when they are in need. Factors to be considered in the application of the principle of equity are: 1) Medical Urgency; 2) Likelihood of Finding a Suitable Organ in the Future; 3) Waiting Time; 4) First vs. Repeat Transplants; and 5) Age.

It is important to realize that sometimes the principle of equity will be in conflict with the principle of utility; in such cases both are worthy of consideration and can play a role in shaping a decision about what is the morally correct allocation.

Autonomy

A third basic principle plays a controversial and sometimes ambiguous role in deciding what is a morally appropriate allocation. In a free society, autonomy of individuals is given great importance. Autonomy can be used both to describe a psychological state of persons and as a moral principle of self-government or self-determination.

The principle of autonomy holds that actions or practices tend to be right insofar as they respect autonomous choices. Defenders of such a principle recognize that persons and their actions are never “fully” autonomous, but nevertheless believe it is possible to recognize certain individuals and their decisions as more or less substantially autonomous.

If respect for autonomy is one of the characteristics that tends to make an action or practice right, then it is possible that certain policies could be morally right, at least *prima facie*, even if they do not maximize utility and do not promote equitable distributions. We shall see that when it conflicts with other ethical principles sometimes, on balance, it deserves to be the deciding factor and sometimes it must give way. Factors to be considered in the application of the principle of autonomy are: 1) The Right to Refuse an Organ; 2) Free Exchanges among Autonomous Individuals; 3) Allocation by Directed Donation; and 4) Transparency of processes and allocation rules to enable stakeholders to make an informed decision.

RESOLUTION OF CONFLICT AMONG PRINCIPLES

The ideal allocation would be one that simultaneously maximized the aggregate amount of (medical) good, distributed the good equitably, respected the autonomous decisions of persons, and was in accord with any other ethical principles that might come into play. Unfortunately, as the foregoing discussion has noted, these principles sometimes come into conflict.

Different strategies are available when this happens. One approach is to try to rank the principles in some priority (or lexical) order. For example, someone who was a pure utilitarian would give absolute priority to utility over equity and autonomy. On reflection, lexical ordering among these three principles is very difficult to defend. Whatever prior ordering is proposed, it is possible to envisage a situation in which adhering to it would seem wrong. As examples, a small increase in utility may in some circumstances require monumental injustices and violations of autonomy, and a modest gain in terms of equity or autonomy may require enormous costs in terms of utility.

Another possible approach is to consider all the *prima facie* (“at first view”) principles at the same time and try to balance them by arriving at a single conclusion that integrates all the relevant principles to the best degree possible. This approach is not without challenges as one endeavors to decide how much relative weight to grant each principle in a given context and how, in practical terms, that weight will be manifested. If, for example, utility can be weighed against all other principles, then in cases in which enough good can be predicted, it would be ethical to conscript subjects against their will for risky medical research. If we keep imagining projects with more and more envisioned potential benefit, eventually we would reach the point at which the utility of forced participation outweighed the violation of autonomy. Likewise, taking organs against consent (conceivably even from live persons) could theoretically be ethical in cases in which a sufficient amount of good would be done.

Working out a full theory of resolving conflict among ethical principles is beyond the scope of this analysis. However, we can develop and defend a plausible accommodation among these principles—one reflecting society’s pluralism on such matters—for the purposes of public policy in cases involving allocation of organs.

Utility and Equity

While members of the transplant community hold diverging positions regarding the ethically correct relation between utility and equity, a consensus has been reached for purposes of public policy relative to organ allocation: there needs to be a balance between utility and equity. This means that it is unacceptable for an allocation policy to single-mindedly strive to maximize aggregate medical good without any consideration of equity in distribution of the good or for a policy to be single-minded about promoting equity at the expense of the overall (medical) good.

Determining the implications for specific allocations will require additional work.

Some would insist on higher priority for utility; others for equity. In fact whole classes of people might be so inclined to invariably favor one of these principles or the other. The fact that one group would give very heavy weight to one or the other of the principles cannot, for public policy purposes, settle the matter. Inasmuch as: (1) neither side can provide conclusive arguments for its position, (2) each side can provide plausible arguments for its position, and (3) ours is a pluralistic society in which individual views cover the entire spectrum, from pure utilitarianism to extreme egalitarianism, we believe that balancing equity and utility is a fair and workable compromise.

As suggested earlier, some other possible principles appear to be accounted for adequately by this combined consideration of utility and equity. For example, we are aware that many clinicians feel morally obliged to give great weight, perhaps absolute weight, to saving a life. They would give priority to a potential recipient whose case was medically so urgent that death was imminent without transplant (assuming there was a significant chance of saving the life for a significant period with the transplant). Where such considerations seem reasonable, we believe it is because they can be justified by appeal to principles of equity and/or utility. Considering utility, if one considers the saving of a life to be an extremely great medical good, then utility would partially account for priority for extremely urgent, life-saving cases. (Note, however, that if the change in the probability of saving a life was greater if the organ went to another patient whose case was not as urgent, then utility would apparently favor giving the organ to the better off patient rather than the one whose case most threatened death.)

Equity might also partially explain why we might give priority to a patient for whom death was imminent without transplant. One dominant version of the principle of equity holds that the just or fair arrangement is the one that identifies the worst off persons or groups and arranges social practices so as to benefit that group.⁴ If organ allocation can be taken to be a practice governed by this interpretation equity, this would explain a policy of giving priority to patients whose condition is so urgent that death was imminent. In fact, it would explain such a policy even if more medical good could be done by giving the organ to a healthier patient. Thus we believe that even though other general principles such as the principle of preserving life may appear relevant, we can account adequately for those appearances, through the use of the principles of utility and equity.

Autonomy

It is often not necessary in transplantation to include the principle of autonomy in our method of conflict resolution among the principles, because autonomy will not be in conflict with utility and equity. Where autonomy is in conflict with utility or equity, there usually seems to be general agreement on what the priority rules should be even if we cannot always agree on the underlying reasons for the assigning of the priority. For example, an individual who would be entitled to an organ based on consideration of utility and equity may decide that he or she does not want the organ. In some cases the patient may simply decide the major surgical procedure is not worth it. In other cases, he or she may decline because the timing is not right. In such cases it seems clear that autonomy should take priority over both utility and justice. Even if more good could be done by forcing the transplant on such a person, the transplant should not be forced. Even if a more equitable distribution of the goods from the program would result, it still should not be forced. In contrast, an unrestricted principle of autonomy might be seen as supporting the right of an autonomous adult to sell his organs to another autonomous person willing to buy at some mutually acceptable price. However, to date, there is a virtual ban on such sales based on justice concerns of exploitation.

While this discussion of the relation of utility, equity, and autonomy does not provide a full theory of resolution of conflict among basic principles, it gives us a basis for proposing some guidelines for allocation.

4 Rawls, John. A Theory of Justice. Cambridge, Massachusetts: Harvard University Press, 1971.

CONCLUSION

Utility, equity, and autonomy are the foundational principles to be used in the allocation of scarce organs for transplantation. Allocation policies should strive to balance utility and equity. It is unacceptable for an allocation policy to maximize aggregate utility without considering equity. It is also unacceptable for an allocation policy to promote equity without consideration of overall medical good. The relationship of autonomy to these principles is complicated, although in many specific situations, its relative priority is uncontroversial.

All factors that emerge as plausible considerations in an organ allocation policy can be identified as serving one or more of these basic principles. It is the responsibility of those adapting allocation formulas to understand which principle or principles support the use of various factors such as age, quality of life, or PRA. It is also their responsibility to assure that their use is consistent with the proper application of these principles with due consideration being given to the balance among them.

**The Declaration of Istanbul
on Organ Trafficking and Transplant Tourism**

**Participant in the International Summit on Transplant Tourism and Organ Trafficking convened
by the Transplantation Society and International Society of Nephrology in Istanbul, Turkey, April
30-may 2, 2008**

Preamble

Organ transplantation, one of the medical miracles of the twentieth century, has prolonged and improved the lives of hundreds of thousands of patients worldwide. The many great scientific and clinical advances of dedicated health professionals, as well as countless acts of generosity by organ donors and their families, have made transplantation not only a life-saving therapy but a shining symbol of human solidarity. Yet these accomplishments have been tarnished by numerous reports of trafficking in human beings who are used as sources of organs and of patient-tourists from rich countries who travel abroad to purchase organs from poor people. In 2004, the World Health Organization, called on member states “to take measures to protect the poorest and vulnerable groups from transplant tourism and the sale of tissues and organs, including attention to the wider problem of international trafficking in human tissues and organs” (1).

To address the urgent and growing problems of organ sales, transplant tourism and trafficking in organ donors in the context of the global shortage of organs, a Summit Meeting of more than 150 representatives of scientific and medical bodies from around the world, government officials, social scientists, and ethicists, was held in Istanbul from April 30 to May 2, 2008. Preparatory work for the meeting was undertaken by a Steering Committee convened by The Transplantation Society (TTS) and the International Society of Nephrology (ISN) in Dubai in December 2007. That committee’s draft declaration was widely circulated and then revised in light of the comments received. At the Summit, the revised draft was reviewed by working groups and finalized in plenary deliberations.

This Declaration represents the consensus of the Summit participants. All countries need a legal and professional framework to govern organ donation and transplantation activities, as well as a transparent regulatory oversight system that ensures donor and recipient safety and the enforcement of standards and prohibitions on unethical practices.

Unethical practices are, in part, an undesirable consequence of the global shortage of organs for transplantation. Thus, each country should strive both to ensure that programs to prevent organ failure are implemented and to provide organs to meet the transplant needs of its residents from donors within its own population or through regional cooperation. The therapeutic potential of deceased organ donation should be maximized not only for kidneys but also for other organs, appropriate to the transplantation needs of each country. Efforts to initiate or enhance deceased donor transplantation are essential to minimize the burden on living donors. Educational programs are useful in addressing the barriers, misconceptions and mistrust that currently impede the development of sufficient deceased donor transplantation; successful transplant programs also depend on the existence of the relevant health system infrastructure.

Access to healthcare is a human right but often not a reality. The provision of care for living donors before, during and after surgery—as described in the reports of the international forums organized by TTS in Amsterdam and Vancouver (2-4)—is no less essential than taking care of the transplant recipient. A positive outcome for a recipient can never justify harm to a live donor; on the contrary, for a transplant with a live donor to be regarded as a success means that both the recipient and the donor have done well.

This Declaration builds on the principles of the Universal Declaration of Human Rights (5). The broad representation at the Istanbul Summit reflects the importance of international collaboration and global consensus to improve donation and transplantation practices. The Declaration will be submitted to relevant professional organizations and to the health authorities of all countries for consideration. The legacy of transplantation must not be the impoverished victims of organ trafficking and transplant tourism but rather a celebration of the gift of health by one individual to another.

Definitions

Organ trafficking is the recruitment, transport, transfer, harboring or receipt of living or deceased persons or their organs 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 to, or the receiving by, a third party of payments or benefits to achieve the transfer of control over the potential donor, for the purpose of exploitation by the removal of organs for transplantation (6).

Transplant commercialism is a policy or practice in which an organ is treated as a commodity, including by being bought or sold or used for material gain.

Travel for transplantation is the movement of organs, donors, recipients or transplant professionals across jurisdictional borders for transplantation purposes. Travel for transplantation becomes **transplant tourism** if it involves organ trafficking and/or transplant commercialism or if the resources (organs, professionals and transplant centers) devoted to providing transplants to patients from outside a country undermine the country's ability to provide transplant services for its own population.

Principles

1. National governments, working in collaboration with international and non-governmental organizations, should develop and implement comprehensive programs for the screening, prevention and treatment of organ failure, which include:
 - a. The advancement of clinical and basic science research;
 - b. Effective programs, based on international guidelines, to treat and maintain patients with end-stage diseases, such as dialysis programs for renal patients, to minimize morbidity and mortality, alongside transplant programs for such diseases;
 - c. Organ transplantation as the preferred treatment for organ failure for medically suitable recipients.
2. Legislation should be developed and implemented by each country or jurisdiction to govern the recovery of organs from deceased and living donors and the practice of transplantation, consistent with international standards.
 - a. Policies and procedures should be developed and implemented to maximize the number of organs available for transplantation, consistent with these principles;
 - b. The practice of donation and transplantation requires oversight and accountability by health authorities in each country to ensure transparency and safety;
 - c. Oversight requires a national or regional registry to record deceased and living donor transplants;
 - d. Key components of effective programs include public education and awareness, health professional education and training, and defined responsibilities and accountabilities for all stakeholders in the national organ donation and transplant system.
3. Organs for transplantation should be equitably allocated within countries or jurisdictions to suitable recipients without regard to gender, ethnicity, religion, or social or financial status.
 - a. Financial considerations or material gain of any party must not influence the application of relevant allocation rules.
4. The primary objective of transplant policies and programs should be optimal short- and long-term medical care to promote the health of both donors and recipients.

- a. Financial considerations or material gain of any party must not override primary consideration for the health and well-being of donors and recipients.
5. Jurisdictions, countries and regions should strive to achieve self-sufficiency in organ donation by providing a sufficient number of organs for residents in need from within the country or through regional cooperation.
 - a. Collaboration between countries is not inconsistent with national self-sufficiency as long as the collaboration protects the vulnerable, promotes equality between donor and recipient populations, and does not violate these principles;
 - b. Treatment of patients from outside the country or jurisdiction is only acceptable if it does not undermine a country's ability to provide transplant services for its own population.
 6. Organ trafficking and transplant tourism violate the principles of equity, justice and respect for human dignity and should be prohibited. Because transplant commercialism targets impoverished and otherwise vulnerable donors, it leads inexorably to inequity and injustice and should be prohibited. In Resolution 44.25, the World Health Assembly called on countries to prevent the purchase and sale of human organs for transplantation.
 - a. Prohibitions on these practices should include a ban on all types of advertising (including electronic and print media), soliciting, or brokering for the purpose of transplant commercialism, organ trafficking, or transplant tourism.
 - b. Such prohibitions should also include penalties for acts—such as medically screening donors or organs, or transplanting organs—that aid, encourage, or use the products of, organ trafficking or transplant tourism.
 - c. Practices that induce vulnerable individuals or groups (such as illiterate and impoverished persons, undocumented immigrants, prisoners, and political or economic refugees) to become living donors are incompatible with the aim of combating organ trafficking, transplant tourism and transplant commercialism.

Proposals

Consistent with these principles, participants in the Istanbul Summit suggest the following strategies to increase the donor pool and to prevent organ trafficking, transplant commercialism and transplant tourism and to encourage legitimate, life-saving transplantation programs:

To respond to the need to increase deceased donation:

1. Governments, in collaboration with health care institutions, professionals, and non-governmental organizations should take appropriate actions to increase deceased organ donation. Measures should be taken to remove obstacles and disincentives to deceased organ donation.
2. In countries without established deceased organ donation or transplantation, national legislation should be enacted that would initiate deceased organ donation and create transplantation infrastructure, so as to fulfill each country's deceased donor potential.
3. In all countries in which deceased organ donation has been initiated, the therapeutic potential of deceased organ donation and transplantation should be maximized.
4. Countries with well established deceased donor transplant programs are encouraged to share information, expertise and technology with countries seeking to improve their organ donation efforts.

To ensure the protection and safety of living donors and appropriate recognition for their heroic act while combating transplant tourism, organ trafficking and transplant commercialism:

1. The act of donation should be regarded as heroic and honored as such by representatives of the government and civil society organizations.
2. The determination of the medical and psychosocial suitability of the living donor should be guided by the recommendations of the Amsterdam and Vancouver Forums (2-4).
 - a. Mechanisms for informed consent should incorporate provisions for evaluating the donor's understanding, including assessment of the psychological impact of the process;
 - b. All donors should undergo psychosocial evaluation by mental health professionals during screening.
3. The care of organ donors, including those who have been victims of organ trafficking, transplant commercialism, and transplant tourism, is a critical responsibility of all jurisdictions that sanctioned organ transplants utilizing such practices.
4. Systems and structures should ensure standardization, transparency and accountability of support for donation.
 - a. Mechanisms for transparency of process and follow-up should be established;
 - b. Informed consent should be obtained both for donation and for follow-up processes.
5. Provision of care includes medical and psychosocial care at the time of donation and for any short- and long-term consequences related to organ donation.
 - a. In jurisdictions and countries that lack universal health insurance, the provision of disability, life, and health insurance related to the donation event is a necessary requirement in providing care for the donor;
 - b. In those jurisdictions that have universal health insurance, governmental services should ensure donors have access to appropriate medical care related to the donation event;
 - c. Health and/or life insurance coverage and employment opportunities of persons who donate organs should not be compromised;
 - d. All donors should be offered psychosocial services as a standard component of follow-up;
 - e. In the event of organ failure in the donor, the donor should receive:
 - i. Supportive medical care, including dialysis for those with renal failure, and
 - ii. Priority for access to transplantation, integrated into existing allocation rules as they apply to either living or deceased organ transplantation.

6. Comprehensive reimbursement of the actual, documented costs of donating an organ does not constitute a payment for an organ, but is rather part of the legitimate costs of treating the recipient.
 - a. Such cost-reimbursement would usually be made by the party responsible for the costs of treating the transplant recipient (such as a government health department or a health insurer);
 - b. Relevant costs and expenses should be calculated and administered using transparent methodology, consistent with national norms;
 - c. Reimbursement of approved costs should be made directly to the party supplying the service (such as to the hospital that provided the donor's medical care);
 - d. Reimbursement of the donor's lost income and out-of-pockets expenses should be administered by the agency handling the transplant rather than paid directly from the recipient to the donor.

7. Legitimate expenses that may be reimbursed when documented include:
 - a. the cost of any medical and psychological evaluations of potential living donors who are excluded from donation (*e.g.*, because of medical or immunologic issues discovered during the evaluation process);
 - b. costs incurred in arranging and effecting the pre-, peri- and post-operative phases of the donation process (*e.g.*, long-distance telephone calls, travel, accommodation and subsistence expenses);
 - c. medical expenses incurred for post-discharge care of the donor;
 - d. lost income in relation to donation (consistent with national norms).

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5. Universal Declaration of Human Rights, adopted by the UN General Assembly on December 10, 1948, <http://www.un.org/Overview/rights.html>.
6. Based on Article 3a of the Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children, Supplementing the United Nations Convention Against Transnational Organized Crime, http://www.uncjin.org/Documents/Conventions/dcatoc/final_documents_2/convention_%20traff_eng.pdf.