

**OPTN/UNOS ETHICS COMMITTEE REPORT  
SUMMARY**

**I. Action Items for Board Consideration**

- The Board of Directors is asked to approve a Statement on Organ Trafficking. (Item 1, Page 3)
- The Board of Directors is asked to approve revisions to the statement entitled, “Considerations in Assessment for Transplant Candidacy.” (Item 2, Page 4)
- The Board of Directors is asked to approve a statement acknowledging that living-related organ donation from persons currently incarcerated is ethical and should be permissible under certain circumstances while recognizing that 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. (Item 3, Page 6)
- The Board of Directors is asked to adopt Restated Principles of Organ Allocation that update the 1991 White Paper. (Item 4, Page 7)

**II. Other Significant Issues**

- Upon request, the Committee reviewed additional material provided by the Region 1 Renal Transplant Oversight Committee and opposes the continuation of the Region 1 Kidney Variance and requests that the Kidney Transplantation Committee review the appropriateness of the continuation of this variance. (Item 9, Page 11)
- In response to a request to consider infectious disease testing, the Ethics Committee recognizes the obligation to protect recipients from donor-transmitted diseases. The Committee defers to the Operations and OPO Committees to review issues of infectious disease testing and screening of organ donors to determine potential best practices. (Item 10, Page 11)
- The Ethics Committee reaffirms the historical position on Repeat Transplantation that prior transplantation, in and of itself, should not exclude a patient from being considered for a repeat transplant. (Item 13, Page 14)

**REPORT OF THE OPTN/UNOS ETHICS COMMITTEE  
TO THE BOARD OF DIRECTORS  
June 19-20, 2008  
Richmond, VA**

**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 meetings held on September 23-24, 2007, and on March 9-10, 2008, in Chicago, Illinois:

1. Transplant Tourism – Revisited – “Organ Trafficking” – 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 statement on “Organ Trafficking” for consideration by the Board in February 2007. Ms. Allee gave the background of this request from 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 recommends the following resolution for consideration by the Board:

**\*RESOLVED, that the following “Statement on Organ Trafficking” is hereby approved by the Board of Directors:**

**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.

Approved 17-0-0

2. 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?

After considerable discussion, the Committee unanimously recommends the following resolution for consideration by the Board:

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

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

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~~**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 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~~ Past 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 15-0-0

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. It was noted that 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. The Committee had many unanswered questions including what is the potential for suboptimal medical care following the donation. It was asked whether the OPTN/UNOS should prohibit entirely the possibility of prisoners being living organ donors? It was suggested that living non-directed donation should not be permitted, and alternatively that living directed donation from incarcerated individuals should be considered on the same basis as other living donations.

After additional discussion, by a vote of 16 for, 0 against, and 2 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.**

The Committee declined to reconsider the 2003 position statement on consideration of prisoners as transplant candidates.

4. “Principles of Organ Allocation” White Paper Review Subcommittee. At the August 2006 meeting of the Ethics Committee, in light of the discussion of revisions to the national kidney allocation system by the 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 between 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; and
- Waiting time.

Under even a 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 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 LYFT allocation proposal.

A motion to add age to the list of factors that should be excluded on page 3 of the proposed restated principles document was not approved by a vote of 6 for, 9 against, and 1 abstention.

An additional motion to remove age from the principles restatement failed for lack of a second.

After further discussion of the revisions to the document and upon motion to recommend approval of the restated document to the Board in June 2008, by a vote of 14 for, 3 against, and 0 abstentions, it was:

**RESOLVED, that the OPTN/UNOS Board of Directors hereby adopts the 2008 Restated Principles of Organ Allocation as set forth in Exhibit 1.**

5. Goals and Planning – The Committee reviewed recent progress toward the HHS Program Goals (PART Goals) and the Board-approved Goals for the Ethics Committee. The Board-Approved Goals for the Ethics Committee are:

- a. Continue to monitor developing kidney allocation policy
- b. Complete revisions to 1991 White Paper on Principles for Allocating Organs for Transplantation
- c. Consider the ethics of using net benefit alone as driving force behind all allocation policies
- d. Consider Transplant Tourism related issues including:
  - i. informing patients on waiting list of safety issues if transplantation occurs outside of US; and
  - ii. revised nomenclature for “transplant tourism” and/or “organ trafficking”
- e. Provide plan for completion of work of subcommittee convened to re-consider a regulated market
- f. Provide plan for completion of work of subcommittee considering Stewardship/ownership of organs
- g. Revisit historical positions on Prisoners as living organ Donors, non-resident alien/undocumented resident transplantation; Repeat transplantation; and Ethical Considerations for Transplant Candidacy

At its March 2008 meeting, the Committee also reviewed goals for the committee and progress made toward each goal as charged by the OPTN/UNOS President. The Committee is making progress toward each of these goals and will continue to work toward completion of the work of the subcommittees.

6. Review of KARS and LYFT (Life Years Following Transplant) – Dr. Shapiro 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. Questions were raised about the impact of the various proposals on living donation. In particular, the Committee is concerned about the lack of modeling on the potentially negative effects on living donation.

At its March meeting, the Committee heard and vigorously discussed a presentation on the progress on a revised kidney allocation system from Dr. Alan Leichtman, of the SRTR. The Committee wishes to acknowledge the efforts of Dr. Leichtman

The Committee will request additional data from the SRTR that will show for each model being considered by the Kidney Transplantation Committee who is dying on the waiting list by the categories of gender; race; age; and whether the candidate has diabetes.

7. Financial Incentives for Organ Donation Subcommittee - Benjamin Hippen, M.D., Subcommittee chair, gave a brief discussion of the status of this subcommittee by telephone. It was discussed what product the subcommittee should strive to produce. The Committee discussed the IOM report “Organ Donation: Opportunities for Action” chapter on financial incentives for deceased donation. The Subcommittee was reconstituted with the following members: Benjamin Hippen, M.D., Chair; Pat McDonough; Pasala Ravichandran, M.D.; Kevin Myers, M.D.; Danny Cavett; and Gary Patton, PhD.

In March 2008, Dr. Hippen gave a presentation to the Committee 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.

This Subcommittee met extensively after the conclusion of the full committee meeting including Chair Dr. Shapiro, Drs. Ross, Csete, Demme, and Schaffer. The Committee discussed the draft revisions set forth below:

*Resolved, the UNOS Ethics Committee observes that the literature on financial incentives for organ procurement has grown substantially in the last four years. The interest in incentive proposals has been a response to the growing disparity between the need for organs and the available supply. Both the general public and the transplant community at large, is deeply divided on the defensibility of pursuing such alternatives, a division which is manifest within the UNOS Ethics Committee. Revisiting the principles and arguments outlined in the 1993 White Paper on Financial Incentives for organ procurement, we endorse the conclusion of that paper. But, with the hindsight of 15 years, we believe that condition (b) has been, or soon will be, met. Accordingly, and consistent with the 1993 White Paper, we agree that (a) there is nothing intrinsically unethical with financial incentives for organ procurement, and (b) other alternatives for organ procurement have been aggressively pursued with all due diligence.”*

*“We believe that at this time, the conditions discussed in the conclusion of the 1993 report have been met. We believe that it is ethically permissible to subject the safety and efficacy of appropriately designed incentive proposals to empirical scrutiny, subject to the usual guidelines governing human subjects research. We also recognize that for some in the transplant community, this is an imprimatur that should never be granted. This statement should not be*

*construed as minimizing the importance of other ethically sound efforts to improve organ procurement rates, and it should be emphasized that permission to test certain proposals under controlled conditions does not entail endorsement of any, or any one proposal.*

There was extended discussion about the 1993 white paper on financial incentives. In particular, if the paper implies that there is nothing inherently unethical about financial incentives for donation and that it may be appropriate to study the issue further if other ethical means to satisfy the organ demand have been exhausted.

A straw vote was taken to get a sense of the committee on a proposed resolution to affirm the conclusions of the 1993 white paper.

Regarding a potential path forward, the subcommittee discussed a proposal that the committee redraft the 1993 white paper and prepare a resolution for presentation to the board. An informal poll was taken of how many committee members believe that the committee should examine proposals for financial incentives. A small majority of the committee favored examining the issue further.

The charge of the subcommittee will remain as originally charged in April 2006, which is:

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.

Dr. Hippen has prepared a new white paper and agreed to distribute a draft of this white paper to the subcommittee for further discussion. See Exhibit 2.

The Subcommittee met by conference call and discussed the draft white paper. It was uniformly agreed that the draft document was too lengthy and extensive for the subcommittee’s purposes. Dr. Hippen agreed to revise and condense the document for distribution to the subcommittee, and the subcommittee would thereafter convene an additional conference call to review the draft revisions.

8. Stewardship/Ownership Subcommittee – Due to changes in committee membership, the Subcommittee was reconstituted as follows: Michael Shapiro, M.D., Chair; Elisa Gordon, PhD; Alexandra Glazier, Esq.; and Lainie Ross, M.D.

In March 2008, the Committee discussed the current membership of the committee. It was asked what these terms mean, “stewardship” or “ownership.” It was also suggested that this subcommittee should seek to answer the question of what is the relationship of the various parties to the organs recovered and transplanted.

A subcommittee meeting will be scheduled before the June 2008 Board of Directors meeting. Melissa

Doniger, J.D. agreed to serve on the subcommittee. Former Committee Chair, Mark Fox, M.D., will be asked to contribute to the subcommittee.

9. Region 1 – Renal Transplant Oversight Committee proposed modifications to renal alternative allocation system – At its September 2007 meeting, the Committee received and reviewed a request from the Region 1 Renal Transplant Oversight Committee for an alternative allocation system for kidneys in Region 1. There was discussion about the history of the Committee’s consideration of the variance. Thereafter, by a vote of 15 for, 2 against, and 1 abstention, it was

RESOLVED, that the Ethics Committee has reviewed additional material provided by the Region 1 Renal Transplant Oversight Committee and opposes the continuation of the Region 1 Kidney Variance and requests that the Kidney Transplantation Committee review the appropriateness of the continuation of this variance. The Ethics Committee feels that the existing variance and the proposed modifications disadvantage candidates that do not participate in the program assigning priority to incompatible intended candidates of living kidney donors.

10. Infectious Disease Testing - At its September 2007 meeting, the Committee reviewed a request from Steven S. Geier, PhD, ABHI Diplomate, the Associate Director of Laboratories at Bonfils, to consider whether the OPTN/UNOS should require additional infections disease testing and specifically, NAT testing on all donors to improve the safety of organ transplantation. As a preliminary matter, it was asked whether this was a clinical or operational issue, rather than an ethical issue? Specifically, if there is a test available, is it ethical to provide any less than the best possible test in every circumstance.

It was noted that the source of this request may have a conflict of interest in promoting their testing services. There was discussion about whether this is a medical issue or an ethical issues. It was suggested that it is an ethical issue that is only being considered because there is a financial costs. It was also argued that it is a medical decision and the test takes time and has a certain amount of false positives. It has not become the standard of care. It was suggested that we should do the best tests available regardless of costs if the committee is focused on big picture principles rather than responding to a particular request about performing a specific test.

The Committee reviewed its charter and historical action document for prior actions taken regarding informed consent. There is a difference between the standard of care and providing the best testing available in all circumstances. It was noted that NAT testing is most frequently done on tissue donors and high risk organ donors.

The Committee approved the following resolution:

RESOLVED, that the Ethics Committee recognizes the obligation to protect recipients from donor-transmitted diseases. The Committee defers to the Operations and OPO Committees to review issues of infectious disease testing and screening of organ donors to determine potential best practices.

Approved 18-0-0

A response will be drafted and sent to Steven Geier, as well as to the OPO and Operations Committees.

11. Living Donation Issues – At its September 2007 meeting, the Committee reviewed a request from Director Tom Falsey dated July 13, 2007, to address several issues regarding living donation. Mr. Falsey has formally requested that the Ethics Committee address the following issues:

1. Ethics of using living donors on patients "too sick to transplant" deceased donor kidneys;
2. Ethics of using healthy [sic, presumably deceased donor kidneys] on patients "too sick to transplant";
3. Transplanting patients who are not candidates (...commentary omitted);
4. Whether transplant programs can "recruit" donors with propriety;
5. Whether it is permissible for one center to accept a donor who has been rejected at another center.

Concern (1) requires a more nuanced understanding of what constitutes "too sick to transplant." There are certainly situations in which a renal transplant from a living donor is preferable in patients for whom a therapeutic "window of opportunity" is believed to be more narrow than the otherwise typical recipient. So, for example, patients with blood type B, listed at a center where the waiting time for type B kidneys is especially long, may become "too sick to transplant" after an extended period on the waiting list. Certainly, there are categories of patients who tolerate delayed graft function, and the occasional concomitant intensification of immunosuppression less well than others. In this sense, the promise of a lower risk of delayed graft function, etc. certainly has therapeutic appeal. And, for nearly every combination of donor and recipient, a kidney from a living donor is superior to a kidney from a deceased donor. Still, the details in these cases matter a great deal, that it is ill-advised to address generalizations.

With respect to concerns (2) and (3) above, the Committee affirms that a patient deemed "too sick to transplant" is, by definition, not a candidate for transplantation, and suggests that the term "too sick to transplant" may be misapplied and/or misinterpreted.

As to concern (4), insofar as a transplant center performs the due diligence of informing recipients of the superior outcomes from living donor versus deceased donor transplantation, centers are at least complicit in soliciting donors. A more subtle case might involve advertising one's center as participating in non-directed living donation, though in that instance the "recruitment" is the moral equivalent of hanging a sign on one's door, rather than inviting individuals in off the street. Beyond that, and considering the federal proscription on valuable consideration, it is difficult to imagine how centers would otherwise "recruit" donors.

Concern (5) depends entirely on the rationale for rejection from the original rejecting center. There is and will remain controversies in criteria for living kidney donation. Said controversies will generate disagreement among knowledgeable participants in the process, each acting in good faith. Given the empirical uncertainties surrounding living kidney donation, it is a criterion of intellectual honesty not to accord the rejection of a donor from one transplant center the moral authority of an excommunication. Where evidence fails, prudence, clinical judgment, and a thorough evaluation is what is available for adjudicating individual cases. Acts which fall short of these virtues accumulate proportionate culpability for adverse outcomes.

The facts giving rise to these concerns are based on evidence not available to him, or to this Committee. His agitation that "no noticeable progress in this situation" has been made is notable for the odd assumption that he is entitled to summary judgments, based on his view of events, from various UNOS subcommittees, absent the completion of a thorough investigation of these accusations by the MPSC. This makes his backhanded comments about the motives of individual centers, and in regard to Dr. Montgomery in particular, distasteful. Any response made by the UNOS/OPTN Ethics Committee to Mr. Falsey's request should, at the least, include a comment about the ethical propriety of encasing his demands in tendentious rhetoric and unsupported, damaging assertions regarding individuals.

The Committee thanks Mr. Falsey for raising these important issues to living donation. The Committee will send a formal response to Mr. Falsey.

Following the September 2007 meeting, the Living Donor Committee asked the Ethics Committees address the following questions:

- Health status/appropriateness of participants in paired exchanges (are kidneys “wasted” on inappropriate recipients)
- Should transplant centers guarantee living donors the same level of treatment/follow-up they extend to transplant recipients?
- Are there absolute contraindications to living donation?
  - Age < 18 years
  - Psychiatric contraindications

The Committee discussed these issues at length at its March 2007 meeting. With respect to the first point, the health status/appropriateness of participants in paired exchanges (are kidneys “wasted” on inappropriate recipients), the Committee felt that the issue has been appropriately addressed and is unclear on what is being requested of the Committee.

Regarding whether transplant centers guarantee living donors the same level of treatment/follow-up they extend to transplant recipients, this issue is complicated by the system of healthcare in the United States. It was suggested that follow up care is offered to donors but that centers do not need to guarantee that donors receive follow up care. The healthcare system does not facilitate this care. It was noted that centers should follow up donors until they are healed from the donor procedure. Often, donors do not want to return to the transplant center for follow up visits, which frustrates follow up data collection, and the center is often faulted for this issue.

Finally, with respect to absolute contraindications to living donation, the committee had a wide range of thoughts. It was questioned whether an individual under age 18 has the capacity for consent. In some family situations, there might be tremendous benefit to the family to permit donation from a minor such as between identical twins. The Committee discussed the age of consent to donate, impact of emancipated minors, and the continuing requirement of competence by anyone making a decision to donate, regardless of age. Informed consent requires an assessment of the capacity of the donor giving consent. The committee generally believed that there exists such a wide variety of issues that establishing an absolute contraindication to donation based on donor age is not warranted at this time. As for psychiatric contraindications, this is appropriately addressed by the informed consent protections and an assessment of donor capacity for decision making that articulating an absolute standard of psychiatric health as a contraindication to donation is also not warranted.

12. Resource Document for the Medical Evaluation of Living Kidney Donors. In March 2008, the Committee reviewed the latest draft of the proposed Resource Document for the Medical Evaluation of Living Kidney Donors that was provided by the Living Donor Committee to the Board of Directors. The Committee was advised that this revised document will be presented for approval by the Executive Committee prior to consideration by the Board in June 2008 and without any further public comment. Specific comments include the following:

- Donor risk section should be expanded to reflect the kind of discussions that should happen during the consent process including:
- Concerned that the medical information is not evidence-based;
- How do you properly inform the living non-directed donor;
- Regarding donor risk, it is appropriate to have the discussion about the risk benefit analysis about the balance of the risk of transplantation to the donor against the benefit of transplantation to the recipient. The risk benefit can be acknowledged but cannot be

balanced. The benefit to the donor should be balanced against the risk to the donor – not the benefit to the recipient balanced against the risk to the donor;

- The Decision regarding donation section mixes donor risk and recipient benefit issues. The staged consent process is favorable;
- Donor risk sections should reference the full discussions that are a part of the informed consent process;
- Not assessing donor risk on the characteristics potential recipient (or unknown recipient);
- Research risk – there is immediate risk to the patient for eventual benefit to the general public;

The Committee requests the opportunity to comment on additional iterations of this document as it is considered and reconsidered by the Board and Executive Committee.

13. Repeat Transplantation – As part of the Committee’s long range planning, in September 2007, the Committee reconsidered the existing statement on the subject of repeat transplantation. The historical position approved by the Committee is that prior transplantation, in and of itself, should not exclude a patient from being considered for a repeat transplant. It was asked whether the decision to transplant a candidate after a first transplant is a medical decision? The utilitarian would argue that a person has already received a transplant. After brief discussion, the Committee unanimously approved the following resolution:

RESOLVED, that the Ethics Committee reaffirms the historical position on Repeat Transplantation.

Approved 18-0-0.

14. Non-resident Alien/Undocumented Resident Transplantation – As part of the Committee goals, the Committee intends to revisit older position statements to determine if contemporary revisions are necessary and helpful to assist the OPTN in achieving its strategic goals. Due to a shortage of time, the Committee will consider non-resident alien/undocumented resident transplantation at its next meeting in March 2008

In March 2008, the Committee discussed this issue. Policies currently require review of programs that exceed 5% transplantation of non-resident aliens. The Committee acknowledged that the 2003 position statement is sufficiently timely and does not warrant additional consideration at this time.

15. Donation after Cardiac Death and ECMO Issues - Due to a shortage of time, the Committee will consider Donation after Cardiac Death and ECMO Issues at a future meeting.

16. Kidney Pancreas Transplant Program Activity. At its March 2008 meeting, the Committee received information regarding a kidney pancreas transplant program and certain issues regarding organ quality. The Committee will respond to Dr. Esterl and let him know that the committee reviewed this and felt that there were no ethical issues requiring committee comment at this time.

17. Chair Remarks – Margaret Allee, RN, MS, JD, Committee Chair welcomed the committee and after brief introductions of the Committee members, briefly described the activities of the committee. She 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. Ms. Allee 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.

At the March 2008 meeting, Ms. Allee recognized the following committee members whose terms on the committee will expire in June 2008: Alexandra Glazier, Esq.; Benjamin E. Hippen, M.D.; Lainie F. Ross, M.D.; and Danny Cavett, MLA.

**Attendance at the Ethics Committee Meeting  
September 23-24, 2007  
Chicago, IL**

Committee Members Attending:

Margaret R. Allee, R.N., J.D.		Chair
Michael Shapiro, M.D.	Vice-Chair	
Alexandra K. Glazier, J.D., M.P.H.	Region 1	
Melissa J. Doniger, J.D.	Region 2	
Alison Silva, RN, BSN, CCTC		Region 3
Danny Cavett, Chaplain, MLA		Region 4
Randolph L. Schaffer, III, M.D.		Region 5
Pasala Ravichandran, M.D.		Region 6
Sondra E. Cohen, MSW, LCSW		Region 7
Lauris C. Kaldjian, M.D., Ph.D.		Region 8
Patricia M. McDonough, R.N., CPTC, CCTC		Region 9
Constance A. Jennings, M.D.		Region 10
Gary L. Patton, Ph.D.		Region 11
Marie Csete, M.D.		At Large
Elisa J. Gordon, Ph.D.		At Large
Douglas W. Hanto, M.D., Ph.D.		At Large
Benjamin E. Hippen, M.D.		At Large (by telephone)
Robert Mazor, M.D.		At Large
Kevin E. C. Meyers, M.D.		At Large
Lainie F. Ross, M.D., Ph.D.		At Large
Chris McLaughlin		<i>Ex officio</i>
Bernard Koslosvsky, M.D.		<i>Ex officio</i>

Committee Members Unable to Attend:

Remonia Chapman		At Large
Balaji Singh, Ph.D.		At Large

UNOS Staff:

Jason P. Livingston, Esq.		UNOS
Gloria Taylor		UNOS

SRTR Staff:

Alan Leichtman, M.D.		SRTR
Erik Roys		SRTR (by telephone)

**Attendance at the Ethics Committee Meeting  
March 9-10, 2008  
Chicago, IL**

Committee Members Attending:

Margaret R. Allee, R.N., J.D.	Chair
Michael Shapiro, M.D.	Vice-Chair
Alexandra K. Glazier, J.D., M.P.H.	Region 1
Melissa J. Doniger, J.D.	Region 2
Danny Cavett, Chaplain, MLA	Region 4
Randolph L. Schaffer, III, M.D.	Region 5
Pasala Ravichandran, M.D.	Region 6
Sondra E. Cohen, MSW, LCSW	Region 7
Constance A. Jennings, M.D.	Region 10 (by telephone)
Gary L. Patton, Ph.D.	Region 11
Marie Csete, M.D.	At Large
Elisa J. Gordon, Ph.D.	At Large (by telephone)
Douglas W. Hanto, M.D., Ph.D.	At Large
Benjamin E. Hippen, M.D.	At Large (by telephone)
Robert Mazor, M.D.	At Large
Kevin E. C. Meyers, M.D.	At Large
Lainie F. Ross, M.D., Ph.D.	At Large
Bernard Koslosvsky, M.D.	<i>Ex officio</i>

Committee Members Unable to Attend:

Alison Silva, RN, BSN, CCTC	Region 3
Lauris C. Kaldjian, M.D., Ph.D.	Region 8
Patricia M. McDonough, R.N., CPTC, CCTC	Region 9
Remonia Chapman	At Large
Balaji Singh, Ph.D.	At Large

UNOS Staff:

Jason P. Livingston, Esq.	UNOS
Gloria Taylor	UNOS

SRTR Staff:

Alan Leichtman, M.D.	SRTR (by telephone)
Erik Roys	SRTR (by telephone)

## Restatement of General Principles for Allocating Human Organs

### I. 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 Report<sup>1</sup>, 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 resolution of conflict among principles. We conclude with a series of illustrations to aid in determining how various factors sometimes proposed as bases for allocation should be taken into account.

### II. GENERAL ETHICAL PRINCIPLES

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 as 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.

#### A. 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. Surely, one characteristic of an allocation that tends to make it right is that it will do good. Generally, the principle of utility holds that an action or practice tends to be right if it does as much or more aggregate good than any alternative action or practice.

In some contemporary ethics literature this notion is referred to as the principle of beneficence, the principle of doing good. Sometimes an ethical principle of nonmaleficence, of avoiding doing of harm, is also considered. Some might argue that avoiding harm is morally the more weighty consideration.<sup>1</sup> We take the principle of utility to include both of these dimensions. The principle of utility, applied to the allocation of organs, thus specifies that an allocation will tend to be right insofar as the expected net amount of overall good done is maximized while minimizing 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)<sup>2</sup> 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. Rather the benefits and harms should be limited to those deemed medical. 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.

Although there is wide acceptance of excluding social usefulness and predictors of group outcomes from consideration, the reasons for such acceptance are not clear. Two possible reasons are relevant. 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. Similarly, 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 medical good as possible.

## B. 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 donate organs among transplant centers and among patients medically qualified for an organ transplant.”<sup>3</sup> The Task Force specifically recommended that selection of patients for waiting lists and allocation of organs be fair,<sup>4</sup> and UNOS has generally continued to express concern for equity or 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.

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 QALY’s 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.

## C. 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 one of the characteristics of actions or practices that tends to make them right is that they respect autonomy, 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 respect 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; and 3) Allocation by Directed Donation.

### III. 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.

Several 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 always possible to envisage a situation in which adhering to it would seem absurd. A small increase in utility may in some circumstances require monumental injustices and violations of autonomy; a modest gain in terms of equity or autonomy may require enormous costs in terms of utility; and so on.

Another possibility is to consider all the *prima facie* principles at the same time and try to balance them intuitively coming up with a single conclusion that integrates all the relevant principles. This approach has some unfortunate implications, however. 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.

#### A. 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.<sup>5</sup> 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.

#### B. Autonomy

It is often not necessary in transplantation to include the principle of autonomy in our method of conflict resolution among the principles, because often autonomy will not be in conflict with utility and equity. In some cases, however, it may be. 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.

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.

### IV. CONCLUSION

Medical utility, equity, and autonomy are the foundational principles to be used in the allocation of scarce organs for transplantation. The relation of autonomy to the other principles is complex, but in many specific situations, its relative priority is uncontroversial. The interplay between medical utility and equity is complex. It is unacceptable for an allocation policy to maximize aggregate medical 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. Allocation policies should strive to balance medical utility and equity.

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 and to assure that their use is consistent with the proper application of these principles with due consideration being given to the balance

among them.

Financial Incentives Subcommittee Discussion Paper  
Initial Draft

Benjamin Hippen, M.D.  
Chair, Financial Incentives Subcommittee

## Introduction

In 1991, the UNOS/OPTN Ethics Committee visited and evaluated the topic of offering valuable consideration in exchange for organs from both living and deceased donors. The conclusion of the authors of the 1991 report was that valuable consideration offers were not “intrinsically unethical” but that a system reform to routinely offer valuable consideration was “not preferable at this time,” leaving the ethical permissibility open for a system of consideration if “...if there is *nothing inherently unethical* about this approach, and it is found to be ethically *preferable to all other feasible* options.” (emphasis added). Other options considered in *lieu* of a system of consideration included various strategies for increasing rate of procurement from donors living and deceased through established, conventional means, and revisiting the ethical defensibility of a spectrum of proposals under the rubric of presumed consent.

The purpose of this report is to revisit the “open question” as formulated by our predecessors, and to re-examine several key premises and concerns outlined in the 1991 report. The first section critically reviews the claims of the 1991 report and offers a series of arguments in favor of a change in terminology for the purpose of clarity. The next section provides a critical examination of moral distinctions between offers of valuable consideration *qua* incentive, and offers proffered in an effort to remove a disincentive for organ procurement. The third section recapitulates, discusses, and reaffirms the standard of proof offered in the 1991 report for the ethical permissibility of valuable consideration offers (not inherently unethical, and the requisite proof of ethical preferability to other feasible options), discusses the question of whether other means of increasing the supply of organs constitute “feasible options” for resolving the growing disparity between the demand for and supply of organs, and extends the discussion of the 1991 report with updated arguments for and against specific types of valuable consideration offers, drawing on a wealth of recent literature on the subject. The final section serves as an executive summary of the arguments offered in the report.

### Section 1: Suggested terminological reforms:

The history of the debate over “financial incentives” for organ “donation” is the history of a debate hampered by ambiguous terms and the occasional linguistic travesty. What follows is a series of suggestions for terminological changes:

1. Elimination of “financial incentives” or “payment” in favor of *valuable consideration*. Routine use of the term “valuable consideration” has several advantages. First, “valuable consideration” is identical to the language employed by the National Organ Transplant Act, which proscribes the exchange of such consideration for organs, and has the advantage of situating the debate within the existing terminological framework of pertinent federal law. Second, it is abundantly clear that the diversity of proposals under consideration in this discussion is too broad to be captured by the rubric of “financial incentives” without doing damage to accuracy, a point recognized by the authors of NOTA. Thus, non-monetary

consideration of value, even if the consideration is not readily fungible, is still valuable consideration, and should be considered as such. This point is an important one in considering the ethical differences between offering consideration as a positive incentive to give up an organ, and removing a disincentive to giving up an organ, a topic reviewed later in the report. Finally, because the concept valuable consideration could refer to either monetary or non-monetary goods and/or services, the routine use of this term requires delving into further detail (“What *kind* of consideration is under discussion?”), a requirement which is more conducive to transparency, and less subject to misinterpretation.

2. Employing a routine distinction between “*donor*” and “*vendor*.” Since swaths of the debate regarding valuable consideration for organs hinges on premises regarding the meanings of donating an organ, in comparison to selling or exchanging<sup>1</sup> an organ, clarity demands expunging confusing phrases such as “payment for organ donation,” “rewarded gifting,” or “ethical incentives.” (Delmonico, NEJM) .
3. Individuals might be referred to as organ donors or organ vendors, and strategies to increase either organ donation and/or organ vending might be better understood under a common concept of organ *procurement*. Procurement policies can refer without confusion to procurement of organs from either living or deceased donors, and refer to procurement from either donors or vendors, without doing violence to conventional distinctions between conventional and unconventional relationships between donors, vendors, and recipients.

## **Section 2: An overview of the current situation in kidney transplantation**

Since 1991, the disparity between the demand for and supply of kidneys for transplantation has grown. In the interval, several factors in varying degrees of importance, contributed to this disparity.

Though the rate of growth of organ procurement from deceased donors has increased since 1995, the demand for organs has continued to outstrip the available supply. This rate of growth has increased somewhat in the last few years, with the increased use of kidneys from extended-criteria donors (cit), from donors after cardiac death, and the promulgation of best practices between organ procurement organizations through the efforts of the Organ Donor Collaborative. Still, the number of available organs from deceased donors appears largely limited in the foreseeable future by the number of deceased donors by whole-brain death criteria, a number recently estimated to be between 10,000- 13,500.<sup>2</sup>

- The rate of growth of the number of organs from living donors, ascending steadily since 1995, has flattened in the last two years, for unclear reasons. Despite well-advertised arrangements such as non-directed donation and paired-exchange donation, and positive-crossmatch deconditioning protocols, the number of transplants achieved by these means have not meaningfully attenuated the growing demand.
- Concomitant improvements in immunosuppression have expanded the cohort of patients with ESRD who might benefit (as understood by relative improvement in quality and quantify of life relative to dialysis) from transplantation, increasing demand.

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<sup>1</sup> Here, the “exchange” of an organ may encompass the exchange of an organ for valuable consideration, or the exchange of an organ in the course of a paired-exchange or (now less common) list-paired exchange arrangement. Whether the latter exchanges are a species of valuable consideration is a matter of debate, though no longer a matter of potential violation of federal statute.

<sup>2</sup> Procurement of organs from donors after cardiac death remains limited to a few hundred kidneys per year, and even robust estimates from HRSA estimate the number of donors from DDCD to be approximately 2,016 by 2013 (cit).

- The dominance of calcineurin-inhibitor based immunosuppression in non-renal solid organ transplantation has led to a novel cohort of patients with advancing renal insufficiency (Ojo, NEJM), and by extension a growing population of patients being considered for kidney transplantation.
- The number of candidates for retransplantation (12,000 of the 73,000) are expected to increase as allografts fail. The use of organs from extended-criteria donors, an increasing proportion of deceased donor organs from previous years, will likely contribute to the increase in rates of retransplantation.
- The prevalence of patients with ESRD continues to increase (caveat about reduced rate of growth). It may be the case that improvements in preventive measures may have the unintentional consequence of sparing people from death long enough to require renal replacement therapy. By 2010, it is estimated that there will be 520,000 patients with ESRD, and without a transplant. By 2015, that number is expected to approach 700,000, up from the current prevalence of 380,000. Precise estimates of the effect of this growth on the deceased-donor waiting list are not available, but it seems plausible to assume that the list will increase proportionate to the growth of the cohort of patients requiring renal replacement therapy. Given that the current waiting list is 73,000 patients, the current projection of a waiting list of 100,000 potential recipients by 2010 remains a plausible estimate. (cits)

This state of affairs has led to a series of unintended consequences, each of which are relevant to the discussion at hand:

- Time to transplantation on the waiting list continues to increase, with physiologic consequences disproportionately borne by those with less-common blood groups and highly-sensitized recipients.
- The rate of death on the waiting list for a deceased-donor transplant has steadily increased, to 8%, or 4,000 potential recipients, in 2005.<sup>3</sup>
- Considerable regulatory attention to the development of protocols facilitating deceased donation after cardiac death, along with a concerted effort on the part of UNOS/OPTN to assuage public and professional concerns regarding this practice.
- Serious consideration paid to revising the current system of kidney allocation to focus on the maximization of “life-years after transplantation” generally, rather than whether transplantation is superior to dialysis for specific individuals.
- A proliferation various forms of public solicitation which have generated intense popular interest and attendant controversy. (cite Hanto et.al. NEJM re:MDO)
- The continued flourishing of international organ trafficking in developing countries, and the execution-on-demand of political religious dissidents in at least one country, all of which continues despite unanimous condemnation of the practice by professional transplant organizations and governments alike.

In 1991, the above conditions and factors either did not pertain or did not pertain to the degree they now do in the intervening 17 years. Consequentialist arguments for and against various systems of valuable consideration should begin with the premise that while a conclusion in favor of consideration may or may not ameliorate, in part or in whole, the above states of affairs, a conclusion against consideration will almost certainly perpetuate the current trends outlined herein.

### **Section 3: The 1991 Report – A critical review of premises, arguments and conclusions**

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<sup>3</sup> Note that death on the waiting list does not include recipients who were initially active on the waiting list for a transplant and subsequently removed for reasons other than receiving a transplant. The OPTN database provides for several other reasons for removal, including “too sick to transplant.” Which, if such removal results in elimination of future consideration for transplantation, is functionally equivalent to “death” on the waiting list.

The 1991 report reviews several possible forms of valuable consideration, though in general the report narrowly considers valuable consideration as monetary remuneration. These arguments are reproduced in the order presented.

### **A. Types of remuneration for organs from the deceased**

The 1991 report considers several forms of payment for organs from the deceased: (1) Fixed payment to the next of kin either as an option or as a matter of routine; (2) Fixed payment to the estate of the decedent, disposed of along with the rest of the decedent's estate; (3) Payment limited to the funeral expenses of the decedent, leaving open the question of whether said payment is fixed or variable, (4) a prearrangement by the decedent for a fixed remuneration upon their death to be offered to the decedent's estate. (Lloyd Cohen option)

Arguments proffered in favor of such a system in the 1991 report include: (1) increased the number of organs procured from the (qualified) deceased, (2) a reduction in alienation/distrust from otherwise reluctant donors and families by virtue of remunerating the only party (among the physicians, nurses, and procurement professionals, and recipient) not currently compensated for the procurement, and (3) increase the rate of transplantation of various minorities and groups otherwise dispossessed by the current system. Arguments against a system of payment for organs from the deceased include (1) a reduction in the autonomy of the next-of-kin by an "irresistible" financial offer, (2) a system of payment would encourage an ethos of self-interest over and against communitarian understandings of obligations to others, (3) a system of payment would fatally undercut a culture of altruism, thus eliminating the opportunity to receive the gratitude of the community for the donor's gift, (4) payment would reduce the human body to a (mere) fungible commodity, with attendant costs to our collective humanity, (5) payment would register such popular disgust as to reduce the overall rate of organ procurement, (6) payment does not address the problem of a failure to solicit the families of potential donors for organ donation (or payment). (1991 report p. 2-6).

In each instance, it is worth examining, in a way the 1991 report does not, how each argument for and against is falsifiable. That is, what state of affairs would have to be the case in order to conclude that the argument under consideration is false? Unfalsifiable arguments are not arguments at all.

The arguments in favor of payment for organs from the deceased (OD) rest on several falsifiable premises:

- Payment for OD will increase the total number of organs;
- Payment for OD will reduce mistrust in/alienation from the medical profession;
- Payment for OD will increase transplantation in minorities and dispossessed groups.

Conspicuously, the first premise has never been formally tested to anyone's satisfaction, since, ironically, the first premise can neither be affirmed nor falsified unless the argument that such a system should at least be tried is conceded.<sup>4</sup> This is a recurring theme in the debate regarding valuable consideration, and is one without a mutually satisfactory solution. Proponents of consideration are left to offer analogies with the success of other kinds of markets, denying (without evidence) any relevant differences as applied to organ procurement, and opponents are left to either (a) proffer examples of market failures as the inevitable consequence of consideration for organs or (b) concede the general success of market mechanisms but assert (without evidence) moral or empirical differences when such mechanisms are applied to organ procurement.

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<sup>4</sup> An exception is evidence now available from the 20-year-old system of organ vending in Iran. For an overview of the available evidence, see Hippen, B. Organ Sales and Moral Travails: Lessons from the Living Kidney Vendor Program in Iran.

The second premise has been very indirectly explored,<sup>5</sup> and while the etiologies have not been established with any confidence, several surveys have demonstrated a greater willingness on the part of (for example) AAs to consider payment for the organs of deceased relatives, at least in theory. Still, the coherence of the second premise is dubious, and has led more than one commentator to conclusions of notable fatuity.<sup>6</sup> Authentic mistrust and alienation are not remediable by a simple payment, any more than such compartments are born of a single experience of oppression or injustice, and shallow is the man whose social disaffection can be relieved with the purchase of a family member's organ.

- The kernel of truth in the second premise is that there is an established relationship between the willingness of donor families to consent to donation, and whether donor families
- The truth of the third premise is entirely dependent on the truth of the first premise: insofar as the total number of organs increases through implementation of a system of financial incentives, so too will the rate of transplantation of minorities and other dispossessed groups.
- Each of the arguments offered in favor of consideration for OD are consequentialist in structure. Nowhere in the 1991 report is the notion of property as it applies to the body discussed. A discussion of the body as property is by no means stacked in favor of those who would assert robust forbearance rights on the part of those possessing a property right in a part of the body to dispose of it as they choose. The issue of who (or what) holds property rights in parts of the body, is an important component of any discussion of financial incentives for organ procurement. If property rights in an organ don't exist, it is difficult to imagine how any system of financial incentives could be justified.

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### **A critical review of arguments against consideration for organ procurement in the 1991 Report.**

Consideration as an *irresistible offer* – The premise underlying the claim that consideration constitutes an irresistible offer can be construed in different ways, each with different implications, depending on how “irresistible” is understood. For example, irresistibility can be understood the claim that an offer of consideration reduces the autonomy of an organ vendor by rendering the vendor *incapable* of refusing the offer (call this the capability version of irresistible) or that consideration is a constraining option, by offering a choice that the vendor might be *capable* of refusing, but because the array of choices the vendor has is very limited, the introduction of an additional and very tempting choice renders it implausible that the vendor could refuse the offer.

It is fairly easy to dispense with the first (capacity) version of irresistibility. The obvious counterexample is the potential vendor who simply declines consideration. Most opponents of consideration are obliged to

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5 Siminoff and Sanders-Stern (Ken Inst Eth 10(1) 59-74) found that AAs were far more favorably disposed to payment for the organs of deceased kin compared to Caucasians (43.2% vs. 12.9% Caucasians  $p < 0.01$ ), a finding also noted by Bryce (AJT 5(9) 2999-3008) and Boulware (AJT 6(11), 2774-85).

6 Siminoff and Sanders-Stern, explaining their findings discussed in the above footnote, assert “The current U.S. organ procurement system is based on values that reflect the attitudes and beliefs of the dominant white majority. The primary moral basis of this system is altruism.” Notice the planted axioms: Altruism as a virtue is a component of a homogeneous “white majority” culture, but not of (an equally homogeneous) “black” culture, altruism is installed as an institutional value because it serves the powerful, rather than because altruistic action is valued as a virtue in its own right, or might be deemed virtuous by individuals or individual families who do decide to donate. For a detailed discussion of the explanatory impoverishment of sweeping social generalizations in the discussion of consideration for organs, see Hippen, JMP 602-610 and Hippen, “Commentary on Danovitch,” Transplantation.

grant the veracity of this counterexample, since most opponents of organ markets who view consideration as an irresistible offer also worry that consideration will result in a reduction in the number of available organs due to a sense of repugnance over the very idea that consideration is being offered in exchange for organs. The latter argument is coherent only insofar as potential vendors are *capable* of refusing offers of consideration.

Opponents of consideration do rejoin that vendors in *dire financial circumstances* are rendered incapable of refusing substantial offers of consideration. Still, segregating a subset of vendors as incapable of refusing offers poses grave conceptual difficulties. First, it poses additional problems for how the moral agency of the “incapable” vendor. If the capacity for decision-making for a potential vendor is so impaired by the mere *offer* of consideration, how fragile is this same decision-making capacity in response to a whole host of other potential challenges to autonomous decision-making? Should such vendors be sheltered from a host of other potentially capacity-challenging offers which may render them less than autonomous? Whole categories of decision-making (employment, marriage, children, voting in elections, associations with others), circumscribed by poor financial/socioeconomic circumstances might require truncation based on the same concern. Such a fragile view of the capacity of certain vendors to exercise their autonomy might require enumeration of the decisions such persons are actually *capable* of making, since the range of decisions such persons are *potentially incapable* of making would seem to be substantial.<sup>7</sup> It seems *prima facie* implausible to assert that consideration proffered to next-of-kin for the organs of their deceased loved-one holds some metaphysically unique place in the pantheon of decisions requiring the capacity for autonomy. Therefore, understanding an offer of consideration as impinging on the capacity of a vendor to refuse such an offer is implausible without accepting a series of additional premises which do not withstand scrutiny.

Presumably, then, it is not the capacity for autonomous decision-making which is at issue regarding offers of consideration. Another way in which consideration might be irresistible is if it results in a “constraining option.”<sup>8</sup> Here, the vendor remains capable of refusing an offer of consideration, but the vendor is deemed to be less autonomous as a consequence of introducing a particularly attractive option arrayed with other far less attractive options. Indeed the very attractiveness of the offer may be impermissible insofar as it renders a series of already bad options worse in comparison. The more general conclusion is that there is not always a direct relationship between the magnitude of available options and the expanse of autonomous decision-making, and that some choices reduce rather than expand the range of choices, sometimes resulting in a “forced choice.”

Several difficulties arise, though not all proponents of the constraining option view will tend to see what follows as difficulties. First, the argument that certain attractive offers render other options so unattractive as to essentially eliminate them from a range of choices for a given vendor entails proscribing any offers which might render other existing options too unattractive.<sup>9</sup> Offers would only be autonomy-enhancing if the broader range of choices were within a given range of one another in attractiveness. The ironic result is that offers of consideration are only permissible when the vendor is well-enough off to avoid viewing the consideration offer as significantly reducing the attractiveness of other possible choices. Offers of substantial consideration may only be made to the less-well-off insofar as the choice for consideration is so fraught with

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<sup>7</sup> Furthermore, there are abundant counterexamples of impoverished people who regularly demonstrate their capacity for refusing to make choices which may be in their short-term financial interest, but are undesirable for other reasons. That there are impoverished persons who choose to not engage in robbery, prostitution, the selling of illegal narcotics, etc. suggest that having a series of undesirable choices does not thereby render such persons *incapable* of choosing.

<sup>8</sup> See the exchange between Paul Hughes (pro) and James Stacey Taylor (con) on the subject of whether consideration offered for organ constitutes a constraining option (cit).

<sup>9</sup> Another approach, not explored here, is to argue that neither the preservation nor the constraint of a vendor’s autonomy should be understood as morally salient to the discussion of consideration for organs from the deceased.

risks for concomitant unattractive outcomes as to render it less attractive relative to the range of other choices, and therefore not a constraining option.

Stepping back from the theoretical discussion at this point, how does this apply to the vendor being offered consideration for the organs from their deceased loved-one? Based on the previous discussion, the stronger view that considerations offers may render vendors incapable of refusing offers should be discarded in favor of thinking about such offers as a constraining option on the array of possible choices of the vendor. Before an offer of consideration, the vendor has two options:

1. Refuse to donate the organs;
2. Agree to donate the organs.

With a consideration offer, the vendor would now have the following options:

3. Accept the offer of consideration;
4. Decline the offer of consideration and refuse to donate the organs;
5. Decline the offer of consideration and agree to donate the organs.

On the constraining option view, the offer of consideration renders the previous decision, whether or not to agree to donate the organs, as deeply unattractive in comparison. But viewed from the standpoint of the consequence of the autonomous decision (however constrained) accepting the offer of consideration is only constraining insofar as, all things being equal, the likely choice of the vendor without the offer of consideration would have been to refuse to donate the organs. If the likely pre-offer choice of the vendor was to donate the organs, it is difficult to understand how the offer of *consideration* was a constraint on the vendor's autonomous choice.<sup>10</sup> The offer of consideration in this instance is not "an offer [he] can't refuse," because the decision to donate the organs would have been affirmed *regardless* of whether or not consideration was offered. The more plausible scenario is where the pre-offer decision of the vendor is to refuse to donate the organs, and the offer of consideration renders the choice of the refusal to donate very unattractive. So unattractive, in fact, as to render refusal implausible, though still possible. But, if a consideration offer is somehow impermissible in this circumstance because it renders the option of refusal implausible, the impermissibility of the offer must depend on some obligation to protect the relative attractiveness of the option to refuse to donate the organs of their loved one. Of course, organ procurement organizations devote substantial resources, effort, targeted appeals and official propaganda ("Donate Life!") *precisely* toward the end of making the meaning of refusal socially unattractive. As discussed in the previous section, the (small) literature on why *refusniks* refuse to donate their loved-one's organs demonstrates that the usual reasons are frequently rooted in some amalgam of mistrust, undifferentiated fears and outright false assumptions about key concepts such as brain death. So, it is not entirely clear why the already unattractive option of refusing donation based on unprincipled, undifferentiated and often false premises should be nurtured. In this sense, the offer of consideration does not appear to make what is already a generally unattractive decision (refusal to donate) any worse.

Would a system of consideration encourage an ethos of self-interest over and against a communitarian understanding of obligations to others? One might begin by wondering whether this is a concern which properly occupies the attention of policy makers for organ transplantation. From the vantage of the consequentialist goal of increasing the number of organs, there is a sense in which a concern with cultivating altruism or avarice just misses the point. If a system of consideration increases the number of organs and thereby reduces suffering and death on the waiting list, whether this occurs from the promotion of avarice

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<sup>10</sup> An exception is if the autonomy of the vendor was constrained a consideration by rendering the vendor incapable of donating the organs qua gift. This concern is addressed elsewhere.

over and against altruism is of subsidiary concern. But, insofar as a system of consideration fails to increase the number of organs (either through the offer of consideration being an insufficient incentive for refusniks to sell, or through the discouragement of those inclined to donate absent a system of consideration) the fostering of avarice or altruism may be of *instrumental* value. If a system of incentives either failed to increase the number of organs, or resulted in a reduction in the total number of organs through attrition from otherwise willing altruistic donors, the case for offering consideration on consequentialist grounds would fail. In this sense, productive reflection on non-consequentialist concerns regarding the moral appeal of cultivating communitarian rather than self-interested behavior is predicated on the answer to an empirical question: Is a system which fosters altruism, or a system which fosters avarice more successful in increasing the number of organs from deceased donors? Unfortunately, the answer to this question is not available, and will not be available absent without empirical validation. If it turns out that financial incentives *fail* to increase the number of available organs, the non-consequentialist objections to incentives become moot.

Of course, an instrumental approach to avarice/altruism question will appear cynical, even forthrightly sinister to those critics who view the fostering of altruism over and against avarice as an obligatory social endeavor, quite apart from whether this obligation results in increasing the number of organs. The point here is not that an instrumental view of altruism and avarice has a lot to be recommended. The point is that instrumentalist views of altruism and avarice (i.e. viewed through the lens of increasing organ procurement) is an important component of consequentialist arguments in favor of organ *donation* (in the form of successfully consenting and converting potential organ donors into actual organ donors) and organ *purchase* (through straightforward appeals to financial self-interest. Non-consequentialist moral objections to organ procurement, such as the argument that consideration cultivates avarice rather than altruism, trades on the instrumental argument in favor of cultivating altruism, which is that successfully cultivating (or cultivating the impression) of altruism is a successful organ procurement strategy. If cultivating altruism were not a very successful procurement strategy, non-consequentialist arguments in favor of cultivating altruism would not have much *cache* for transplant policy makers.

The concern that offers of consideration fosters avaricious self-interest over altruistic, and more communitarian concerns may be rendered in several ways. One plausible version is to phrase the objection as an empirical assertion which might be tested and falsified: Introducing a system of consideration into organ procurement will result in vendors making judgments which inevitably privilege self-interested concerns relative to obligations to a larger community. Here, defining the terms (What counts as an avaricious concern? What counts as a concern for the larger community?) in ways that at least are not obviously circular becomes quite important. It cannot be the case that *every* decision made in response to an offer of consideration is thereby a self-interested decision. If that were so, it would not be possible to act outside of concerns for self-interest in response to an offer of consideration, since self-interested concerns would be the explanation for both the acceptance of and refusal of offers of consideration.

(3) The argument that consideration undermines the possibility of offering organs as a gift for those who wish to do so are complex. Taken literally, the argument is false, in that an offer of consideration, *qua* offer, neither obligates the vendor to accept, nor does it preclude the vendor from declining the consideration in favor of donation. Typically, this argument relies on the possibility that the very possibility that consideration might have been offered to a vendor will lead to the (false) perception on the part of others that consideration was accepted, even in instances where consideration was declined in favor of donation. (Delmonico, Youngner NEJM) The prevalence of such a false perception thereby prevents the altruistic vendor from receiving the moral credit for donating rather than making an exchange for the OD.

There are several problems with this argument. First, it challenges a strict separation between avaricious and altruistic action, since the argument rests on the premise that part of the moral reward of altruistic action is reaping public approval for such action. But, the benefit of receiving public approval of an altruistic act is

clearly a self-interested benefit. Indeed, if public approval of an altruistic act represents the underlying motive for donation, it calls the other-directed features of the act into question. In crucial ways, assuring the other-directed nature of actions requires that the act be undertaken *independent* of the public perception of such actions.<sup>11</sup> In addition, vendors who elect to donate organs typically cite facets of the donor's belief system which either confirm the donor's commitment to organ donation prior to death, or in the absence of that knowledge, confirm the compatibility of organ donation with the donor's broader system of values, or consented in the belief that organ donation would redound positively to the decedent's memory. (cit) In each of these instances, consenting to organ donation is, whatever else it may also be, also an act of self-interest on the part of the donor. In an important way, restricting permissible forms of organ donation to a purely other-directed action would render impermissible *most* kinds of consent currently employed for organ donation.

So, kinds of consent for organ donation typically conceived of as altruistic really rests on a definition of altruism that isn't nullified by the concomitant fulfillment of other self-interested concerns. It does no violence to the typical use of the term "altruism" to say that those who declare themselves to be organ donors after death act in an altruistic way, even though the moral credit reaped by such a designation redounds to the benefit of self-interest. But if it is the case that both other-directed and self-interested concerns can coincide without difficulty, it calls into question the strict conceptual separation between altruistic and avaricious concerns that many opponents of consideration wish to preserve. Opponents of consideration are then required to make distinctions between different types of acceptable concomitant self-interested actions that remain compatible with altruism, but it is difficult to avoid the charge of either arbitrariness or circularity in making these distinctions.

Another version of this criticism was recently offered (referring to living donation) by David and Sheila Rothman (Cit R&R, AJT), rendered here as the "crowding out" objection. The example they use is reproduced in full below:

One intriguing experiment turned an Israeli day care center into a research site. It was not unusual for some parents to arrive late to pick up their children; center administrators complained but levied no penalties. The researchers first took a baseline measure of the frequency of lateness and then had the center post a notice on its bulletin board: 'The official closing time. . . is 1600. Since some parents have been coming late, we. . . have decided to impose a fine. . . NIS 10 (\$2.50) will be charged every time a child is collected after 1610. The fine will be calculated monthly, and is to be paid with the regular monthly payment'. Although one might have predicted that late pickups would decline, the number actually increased. And even when several weeks later the researchers had the center cancel the late charge, the higher level of lateness persisted.

To explain these outcomes, the researchers proposed that in the pre-fine days, parents interpreted the extra time that the teacher spent taking care of the children as 'a generous, nonmarket activity'; they did their best to arrive on time because the teacher was considerate and should 'not be taken advantage of'. Once the fine was levied, the added time of child care had a price and parents believed they could purchase it as often as necessary. 'When help is offered for no compensation in a moment of need, accept it with restraint. When a service is offered for a price, buy as much as you find

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<sup>11</sup> The paradox of acting altruistically for avaricious reasons poses challenges for a host of other proposed "non-monetary incentives" such as a "donor medal of honor" or a certificate of merit for organ donation. In each instance, the offer of these kinds of "incentives" poses a vexing problem: For the already committed donor, such incentives are entirely unnecessary, and run similar risks of clouding the "perception" that such donors donated altruistically. (In this case, rather than personal enrichment, the charge would be the unseemly demand for attention to one's act). On the other hand, were such incentives to truly function as *incentives*, in the sense of causing the donation of organs which otherwise would not have been donated, it would be difficult to characterize such actions as altruistic.

convenient'. Moreover, the lateness persisted after the elimination of the charge because there was no reverting to the older norm once the charge had been levied: 'Once a commodity, always a commodity'. (R & R, p. ...)

The introduction of incentives into a situation where none previously existed (a) changes the meaning of the exchange from a "generous, non-market" activity to a commodity, reducing the former in favor of the latter, (b) once incentives are introduced, the response to the incentive becomes ingrained. Hence, the introduction of incentives results in the "crowding out" of altruistic behavior, even after the incentive has been withdrawn, because a series of expectations were imported along with the introduction of the incentives. The application to organ procurement is clear: Once an incentive is introduced, the expectation of receiving consideration is also introduced, and the expectation may persist regardless of whether the incentive remains available. In this way, the consideration itself, along with the expectation of the consideration, "crowds out" altruistic donation.

In a trivial sense, it is true that the introduction of incentives results in a reduction in altruistic donation, insofar as one can identify a single instance of someone who would have donated without consideration actually accepting consideration. Insofar as this state of affairs doesn't result in a reduced number of organs procured overall, this is of less concern on consequentialist grounds.<sup>12</sup> However, the issue at hand is whether not the general expectation of consideration will result in a general perception that all forms of organ procurement (gifts and exchanges) will be perceived as exchanges by default. This line of concern once again leads to paradox: On the one hand, to whom should it matter whether the altruistic act of donation is publicly recognized and lauded as such? Truly other-directed action doesn't require reward for reasons other than self-interested ones. In this sense, a truly other-directed action is its own reward. On the other hand, if self-interests and other-directed interests frequently intersect, then the singular importance of publicly rewarding altruistic action (which redounds to the benefit of self-interest) needs to be defended on grounds that don't also permit other ways in which self- and other-directed interests might intersect (such as in the exchange of consideration, which redounds both to the self-interest of the vendor, and the interest of the recipient).

On non-consequentialist grounds, the fact that the expectation of consideration may persist whether or not an incentive is available doesn't eliminate the possibility that individual donors are not *obliged* to expect consideration. Donors may still choose to donate, rather than receive consideration, even if consideration is available. *Prima facie*, the introduction of even the expectation of incentives does not reduce the possibility of altruistic choices, even if it is the case that such expectations reduce altruistic action in practice. Most non-consequentialists will concede that individuals may choose wrongly, and may have morally problematic expectations. But, if alternative choices can plausibly be made, and if morally problematic expectations can plausibly be recognized as such and rejected, it satisfies the central non-consequentialist concern, which is that the choice of altruistic donation would be foreclosed by the introduction of incentives.

4) Consideration for organs results improperly commodifies something that ought not to be commodified – These kinds of arguments are typically (and notoriously, for many secular bioethicists) rendered in elegant literary *aperçues*, rather than in the vernacular of deductive reasoning and analytically precise concepts. This should be understood less as a complaint than as an observation. Critics who employ this argument might assert that the commodification of *organs* is identical with, or is an inexorable step on the slope toward the commodification of *persons*. Alternatively, the harm is sometimes construed as inimical to the dignity associated with *being human*, or sometimes the dignity associated with *human flourishing*, or as *eroding one's humanity*. The latter is captured in the criticism that commodification transmogrifies persons into "a mere repository of spare parts." All of these arguments presume that commodification somehow *limits* the

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<sup>12</sup> The issue of whether the introduction of incentives would result in an overall reduction in the number of procured organs is taken up in Section 5.

value of an organ to its exchange value, as though a commodity cannot possibly be judged on axes of value *other* than cash value. Conversely, so the argument goes, when organs are gifted, the value of the exchange is wholly determined by the fact that it is a gift. One ready-to-hand counter-example is a wedding ring: One's wedding ring surely has a cash value, but the idea that the value of one's wedding ring to an individual is thereby limited to its cash value is perverse. One's wedding ring has a cash value, but might also represent a public expression of a solemn religious commitment, a constant reminder of one's love for another, a reminder (or a relic) of one's present or past. To lose a wedding ring and receive restitution from an insurance company is hollow comfort indeed. On the other hand, a wedding ring might possess significant cash value, but evince painful reminders of one's failures, or a squandered opportunity, or an involuntary, painful loss of another. To receive remuneration to rid oneself of such painful totems might be merely incidental. In keeping with a "literary" response to a "literary" objection to commodification, the assertion that commodities are routinely only reduced to cash value is aesthetically shallow!

Organ vendors may sell or exchange their organs for any number of reasons, but the objection from commodification studiously (and superficially) ignores all reasons other than avaricious, debased motives. In so doing, the objection from commodification is represents an exercise in question-begging. Benjamin Hippen offers a series of possible reasons why someone might sell or exchange their organs:

- "Someone exchanges their organ for a \$25,000 donation in their name to a charity to which they are morally attached;
- Someone exchanges their organ for a \$50,000 deposit in their child's 529 tax-sheltered college account;
- Someone engages in an organ "swap," with another donor/recipient pair so that their loved-one might receive a transplant;
- Someone exchanges their organ for a lifetime health-care and prescription drug benefit, or a deposit in an HSA, which they may or may not have had before;
- Someone exchanges their organ for \$50,000, and purchases a sports car."(cit TNA)

A richer, more sympathetic view of the plurality of motives of organ vendors might render those sympathetic to the priority of the principle autonomy to *permit* any of these exchanges, while morally *endorsing* fewer of them. The point is that a generous interpretation would concede that organ vendors might vend for a great many reasons, some of which really do embody a species of moral valor, some rather less so, and some not at all. As the above examples show, the conceptual elegance of the term "valuable consideration," is that it has far more interpretive flexibility than "exchange value," which simply implies cash money. And, the value of an organ can be assessed along many different axes of value. An inexhaustive list of the values of an organ includes: The value to the recipient of the organ in terms of the quality and quantity of life gained, the value of the recipient's family, friends and loved ones from his improved condition, and the value of the "valuable consideration" to the vendor, whether that consideration is destined for the vendor, or others. Only an aggressively *uncharitable* interpretation is required to understand all of these means of valuing an organ procured in a market transaction as simply or merely reduced to its "exchange value."

Furthermore, as Renee Fox and Judith Swazey poignantly taught us in their travelogue through transplantation, the moral significance of a donated organ is not exhaustively understood by conceiving of donation as simply a gift. Complex interactions of guilt, residual resentments on the part of the recipient for persistent feelings of indebtedness toward the donor, family pressures on both the donor to donate and the recipient to accept the donation and (justifiably or not) accept the moral responsibility for its success or failure all contribute to what Fox and Swazey have called the "Tyranny of the Gift":

5) Might payment for organs *reduce* the overall rate of organ procurement? Certainly many critics of consideration believe this to be the case, with arguments ranging from mere assertion to more sophisticated concerns. Framed as a hypothesis, the answer is not knowable without testing. The connection between surveys and actual behavior is uncertain, though for whatever it is worth, recent surveys on the subject have generally yielded either positive or net-neutral views of incentives by potential organ donors. (cit Bryce, cit Boulware, cit Siminoff) Since testing would entail bracketing other objections to consideration for organs, it is unlikely that the empirical question will be solved to anyone's satisfaction. Absent formal testing, the debate is relegated to a focus on *a priori* concerns predicated on analogies with other studies or other systems, such as the blood and blood product procurement system.<sup>13</sup>

Critics have raised several prudential concerns regarding the potential negative effect of consideration on organ procurement. Rothman and Rothman, for example, draw on recent work in economic psychology examining the effect of introducing an incentive into situations which had previously relied solely on altruistic behavior. The basic findings of this work is that introducing a small, fixed incentive into a situation which previously relied on altruistic behavior to function resulted in reduced productivity:

Another research team divided a group of teenagers who had been volunteering to collect contributions for disabled children into three different cohorts: one was not paid for their service, the second was paid a small amount, and the third was paid a more substantial amount. Using the total funds that each group collected as the outcome measure, they found that the best returns came from the volunteers, the next best from the substantially paid, and the least from the lowest paid. Financial incentives, the investigators concluded, proved less effective than moral commitments. (R & R p...)

The implication from this study is that consideration for organ procurement would not be as successful as a sole reliance on altruism. As regards OD procurement, several observations might be made about this study. First, the implication that consideration has an identical effect on all individuals is false. Supporters of incentives can freely concede that consideration cannot, by definition, improve on procurement from those morally committed to donation. The salient issue is whether consideration can improve on procurement for those not morally committed to donation. Second, the work cited by the Rothmans, which showed a decrease in productivity after the introduction of a fixed, small incentive, disappeared when the incentive increased. Uri Gneezy and Bruno Frey (cit) demonstrated that the relationship between the magnitude of incentives and productivity was not linear, but a positive correlation was nevertheless confirmed. The salient conclusion to draw from this research is that introducing small, fixed payments into a situation which previously relied solely on altruism is the least effective system of consideration. Third, a review of the effects of legal living organ vending on deceased donation in Iran suggests that different systems, predicated on different motivations, can co-exist and flourish.<sup>14</sup>

The 1991 report discusses the concern that the introduction of incentives would result in a sense of disgust on the part of individuals who otherwise would have been donors, resulting in a net shortfall of organs relative to continuing with the current system. The available survey data (perhaps the only way to meaningfully assess the claim), does not support this claim. In what is perhaps the best study, Bryce and colleagues confirmed the observation that the vast majority of those morally committed to organ donation were not swayed positively or negatively by the presence or absence of consideration. Bryce, et.al. also surveyed a cohort of individuals

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<sup>13</sup> The analogy between organ procurement and blood procurement with regard to the effect of incentives is especially instructive. For an extended rebuttal of the regnant view influenced by Titmuss, see Healy (2006) p. 90-95, Goodwin (2006) p. 152-160, and Hippen (2005) p. 600-602.

<sup>14</sup> After legislation passed recognizing brain death as death in 2000, organ procurement from uncompensated deceased donors in Iran increased 10-fold in 6 years, and in 2006 comprised 15% of all organs procured, compared to 1.8% in 2000.

who were not registered to be organ donors, and found that the introduction of a wide spectrum of incentives (ranging from funeral expenses to direct payment) resulted in a greater willingness to consent to organ procurement (in nearly all cases, > 50% of the cohort) among those previously not registered to be organ donors. (See Table 6) To sum up, neither analogies with the blood procurement system, nor the literature on “crowding out,” nor the available survey data support the prudential concern regarding a reduction in organ procurement after the introduction of incentives. On the contrary, each example provides nuance to an otherwise *prima facie* positive correlation between the introduction of consideration and an increase in organ procurement. Absent empirical testing, this is perhaps as far as an analytical discussion can be productively taken without engaging in unfounded speculation.

(6) The final concern raised in the 1991 report is that incentives may be undertaken to the detriment of alternative approaches to organ procurement. In 1991, the salient concern was with the sub-optimal rates of solicitation for organ donation, a state of affairs that has happily improved through the subsequent demise of required request policies in favor of the professionalization of OPO personnel (cit Caplan on required request) and more recently, the efforts of the Organ Donor Collaborative. Since 1991, a series of novel approaches to organ procurement have been examined and implemented, including:

- Greater efforts to identify critically ill potential organ donors early;
- The re-evaluation, design and implementation of protocols for facilitating donation after cardiac death (cit IOM, cit consensus conference AJT);
- The expanded use of so-called “extended criteria” donors;
- Paired and list-paired exchanges (cit Delmonico, AJT; edit. Lainie, AJT)

[I can expand on this at length if it is the sub-committee’s pleasure.]

It is conspicuous that despite each of these efforts in tandem, interest in and attention to systems of consideration for organ procurement has grown in recent years. The most obvious reason for this interest has to do with evolving trends in kidney transplantation since the 1991 report, most especially the rapid growth of the prevalence of ESRD. Ironically, the manifest success of efforts to increased rates of organ procurement from deceased donors has reduced the margin of improvement which might be accomplished by providing consideration for organ procurement. OPOs with 80% rates of consent are unlikely to yield many more organs with a structure of incentives. This fact may prove to be a crucial argument against providing incentives for organs from the deceased: Given the manifest success of the current multiple strategies, the additional return from a system of incentives might be quite small, and ultimately not worth the effort required to fund, regulate and maintain a system for organs from the deceased alone.<sup>15</sup> The intervening 16 years has resulted in aggressive efforts to increase organ procurement from deceased donors; it cannot be said that creative, plausible alternatives have not been extensively explored.

### Summary

- Both arguments for and against consideration in the 1991 report had significant weaknesses;
- Several arguments in the 1991 report were more applicable to conditions in 1991 than in 2007;
- If the 1991 Committee was correct in arguing that there was nothing intrinsically unethical about a system of consideration for organs, the standard of proof in favor of such a system requires reflection on the foreseeable consequences of implementing a given system, which in turn requires a detailed understanding of what sort of incentives might be offered;

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<sup>15</sup> Of course, it does not foreclose a system of incentives for organs from living vendors, which might also be available for organs from the deceased.

-----possible resolution

“Resolved, the UNOS Ethics Committee observes that the literature on financial incentives for organ procurement has grown substantially in the last four years. The interest in incentive proposals has been a response to the growing disparity between the need for organs and the available supply. Both the general public and the transplant community at large, is deeply divided on the defensibility of pursuing such alternatives, a division which is manifest within the UNOS Ethics Committee. Revisiting the principles and arguments outlined in the 1993 White Paper on Financial Incentives for organ procurement, we endorse the conclusion of that paper. But, understood in context of the current and growing demand for organs, a plurality of the committee believes that the inadequacy of current and even optimistic projections of future rates of organ procurement, we believe that condition (b) may have been, or soon will be, met. Accordingly, and consistent with the 1993 White Paper, we agree that (a) there is nothing intrinsically unethical with financial incentives for organ procurement, and (b) other alternatives for organ procurement have been aggressively pursued with all due diligence.

A plurality of the Ethics Committee members believe that at this time, the conditions discussed in the conclusion of the 1993 report may have been met. We believe that it is ethically permissible to subject the safety and efficacy of appropriately designed incentive proposals to empirical scrutiny, subject to the usual guidelines governing human subjects research. We also recognize that for some in the transplant community, this is an *imprimatur* that should never be granted. This statement should not be construed as minimizing the importance of other ethically sound efforts to improve organ procurement rates, and it should be emphasized that permission to test certain proposals under controlled conditions does not entail endorsement of any, or any one proposal. “

## Appendix A: A Note on Public opinion surveys:

The 1991 report made special reference to public opinion regarding the issue of consideration for organ procurement. It should be clear that the content of public opinion, should not be understood as being identical to offering an ethical argument for or against such proposals, but could be understood as a useful, if flawed measure of the evolution of the degree to which the general public is receptive of such proposals. Arguably, significant and consistent opposition to such proposals would beg the empirical question of how effective such proposals would be in increasing the number of available organs.

With that *caveat*, a series of recent surveys suggest that the general public is amenable to such proposals. Surveys typically focus on two general questions: (1) Attitudes regarding either a general policy or specific, detailed policies designed to remunerate vendors, and (2) personal assessments regarding whether payment offers would influence the questioned individual's decision regarding organ donation. Only one poll posed the more urgent question of what respondents would actually do if they themselves or a close relative had a fatal disease and needed organ to be cured, which found that fifty six percent of respondents said they would "purchase the necessary organ or tissue." 16

*Incentives as Policy* - One of the earliest polls conducted diverged from the contemporary general trend of amenability towards the use of incentives. In this 1986 government survey a robust majority, 78 percent rejected the idea that families should be compensated for granting permission to retrieve organs. 17 Notably, the survey presented a scenario in which grieving families were offered money at the time of their loved one's death, which could have been interpreted as insensitive. In contrast, a joint UNOS/NKF survey published in 1992 found that 48 percent felt that some form of financial or non-financial compensation should be offered to increase the number of deceased organs available for donation. 18 Among respondents who were between 18-24 years old, sixty-five percent were in favor. In response, the NKF vice chairman said that "some states should be convinced to conduct pilot studies" on offering financial incentives. 19

A series of more recent surveys have identified between half and three-quarters of respondents amenable to incentives as a general policy. 20 A survey from the Johns Hopkins School of Public Health published in 2006 surveyed attitudes toward the acceptability of incentives across member of different (self-identified) ethnic groups. Among individuals already willing to become living donors they found that between fifty and seventy percent of African Americans and about half of Hispanics endorsed tax breaks, payment from government or payment by employer to living donors. 21 A 2007 online poll conducted by Harris Interactive for the Wall Street Journal online found that forty nine percent of all adults reported being somewhat or

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16 Yankelovich Clancy Shulman. The Ethical Questions of Organ Donation. Poll for Time/CNN, June 4-5, 1991.

17 Poll commissioned by the Health Care Financing Administration; as cited in Prottas JM. Buying human organs – Evidence that money doesn't change everything. *Transplantation* 1992; 53:1371-1373

18 Network for Organ Sharing. Public attitudes on organ donation: quantitative results of a UNOS/NKF Study. UNOS Update, 1992.

19 *Transplant News* vol 2 (23) Dec 17, 1992 p.2.

20 Kittur DS, Hogan MM, Thukral VK, et al. Incentives for organ donation? *Lancet* 1991; 338:1441-1443. Guttman A, Guttman RD. Attitudes of healthcare professionals and the public towards the sale of kidneys for transplantation. *J Med Ethics* 1993; 19:148. Adams AF III, Barnett AH, Kaserman, DL. Markets for organs: The question of supply. *Contemp Econ Policy* 1999; 17:147-155. Bryce CL, Siminoff LA, Ubel PA, et al. Do incentives matter? Providing benefits to families of organ donors. *Am J Transplant* 2005; 5:2999-3007. Sehgal AR, LeBeau SO, Youngner SJ. Dialysis patients attitudes toward financial incentives for kidney donation. *Am J Kidney Dis* 1997; 29:410-418. Boulware LE, Troll MU, Wang NY, et al. Public attitudes toward incentives for organ donation: A national study of different racial/ethnic and income groups. *Am J Transplant* 2006; 6:2774-2785.

21 Boulware LE, Troll MU, Wang NY, et al. Public attitudes toward incentives for organ donation: A national study of different racial/ethnic and income groups. *Am J Transplant* 2006; 6:2774-2785.

strongly in favor of incentives.<sup>22</sup> The survey's questions implied a traditional free market which would advantage the wealthy because they could afford to purchase organs. A recent poll from the Netherlands found that sixty-two percent were unopposed to a more general system of procurement based on compensation. (cit)

*Incentives and influence on personal decision-making* - Across surveys, most respondents report that incentives would not affect their willingness to donate, but among those who say incentives would affect the respondent's behavior, the net effect is generally to increase motivation, especially among young adults.<sup>23</sup> In 1993 and again in 2005, Gallup pollsters asked a random sample of citizens whether they would be more or less likely to donate their own or family members' organs after death if compensation were available. The first survey disclosed a net gain of five percent of respondents who changed their mind in the direction of being "more likely to give" their own organs and four percent net gain in the direction of willingness to give loved ones' organs.<sup>24</sup> The 2005 repeat of the Gallup poll Organization found eight percent and ten percent net gains in willingness to donate one's own organs or family members', respectively.<sup>25</sup> Notably, increases in motivation were highest among younger respondents. For example, there was a 23 percent net gain in willingness to donate one's own organs within the 18 to 24 year old cohort in the 1993 survey. In 2005, among an 18 to 34 year old cohort the net gain was 28 percent – thirty four percent reported that incentives would make them "more likely" to donate while six percent said less likely.<sup>26</sup>

In summary, the preponderance of survey evidence (with the *caveat* regarding the uncertain relationship between survey responses and actual behavior) regarding attitude about the acceptability of incentives as motivators for donation, at both policy and personal levels, is positive. Younger cohorts seem to be especially receptive. None of the polls were designed to inquire about the acceptability of a donor compensation system in which all patients, not just the financially well-off who could afford to purchase organs, benefited. If those conditions had been presented to respondents, thereby allaying concerns about uneven distribution of organs, it is plausible that higher endorsement rates would have been obtained.

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22 Bright B. Americans Are Divided on Offering Financial Incentives to Organ Donors. Wall Street Journal Online; May 17, 2007. [http://online.wsj.com/article\\_print/SB117889765086700017.html](http://online.wsj.com/article_print/SB117889765086700017.html)

23 Jasper J. The public's attitudes toward incentives toward organ donation. *Trans Proc* 1999; 31: 2181-2184. DeJong W, Drachman J, Gortmaker SL, et al. Options for increasing organ donation: The potential role of incentives, standardized hospital procedures, and public education to promote family discussion. *Milbank Quarterly* 1997; 73:463-479. Bryce CL, Siminoff LA, Ubel PA, et al. Do incentives matter? Providing benefits to families of organ donors. *Am J Transplant* 2005; 5:2999-3007. Rodrigue JR, Cornell DL, Howard RJ. Attitudes toward financial incentives, donor authorization, and presumed consent among next-of-kin who consented vs. refused organ donation. *Transplantation* 2006; 81:1249-1256. Haddow G. Because you're worth it? The taking and selling of transplantable organs. *J Medical Ethics* 2006; 32:324-328.

24 Partnership for Organ Donation and Harvard School of Public Health. The American Public's Attitudes Toward Organ Donation and Transplantation. 1993; table 32. [http://www.transweb.org/reference/articles/gallup\\_survey/gallup\\_index.html](http://www.transweb.org/reference/articles/gallup_survey/gallup_index.html)

25 Gallup Organization. National Survey of Organ and Tissue Donation Attitudes and Behaviors. Poll for the U.S. Department of Health and Human Services. Summer/fall 2005; 24. <http://www.organdonor.gov/survey2005/>

26 Gallup Organization. National Survey of Organ and Tissue Donation Attitudes and Behaviors. Poll for the U.S. Department of Health and Human Services. Summer/fall 2005; 24. <http://www.organdonor.gov/survey2005/>

## B. Types of incentives for increasing organ procurement:

Examine in greater detail the moral distinctions (if any) between removing disincentives and providing incentives for organ procurement

- Distinction was made and accepted in the 1991 report
- Current exemption from NOTA (2003) for remuneration for lost wages;
- AJT article by Gaston, Danovitch, Epstein, Matas
- Current legislation - \$5,000 tax credit – H.R. 1035
- Need for sound empirical research on what actually functions as a disincentive for donation
- State-level exemptions from the ‘valuable consideration’ clause in NOTA for the purpose of pilot procurement programs, subject to approval by Secretary of HHS.

Re-examine this premise from the 1991 report: “Providing financial incentives would be ethically justifiable if there is *nothing inherently unethical* about this approach, and it is found to be ethically *preferable to all other feasible* options.”

- Should the “nothing inherently unethical” clause be reaffirmed? – [LONG section]
  - Definition of financial incentives;
  - Expansion of definition to “valuable consideration,” with explanation of the expanded definition (i.e. diversity of what might be exchanged).
  - Recapitulation of past and current criticisms of financial incentives;
    - In the 1991 report
    - From the 2006 IOM report: “Opportunities for Action.”
  - Review of recent work in defense of introducing valuable consideration in to strategies for organ procurement, integrated into the criticism section.
    - JS Taylor – Stakes and Kidneys
    - MJ Cherry – Kidney for Sale by Owner
    - M. Goodwin – Black Markets
    - B. Hippen – In defense of a regulated market....
    - A. Matas – In defense of kidney sales
    - R. Veatch/J. Childress – If valuable consideration for organs are not preferable “at this time,” when and under what circumstances would such an arrangement *become* preferable?
    - Others (A. Friedman)
  - The body as property – Competing views.
  - Summary – Case for re-affirming the “nothing inherently unethical” clause;
  - Summary – Case for repudiating the “nothing inherently unethical” clause;
- Should “feasible” be the standard?
  - A feasible method of procuring organs need not necessarily be an especially successful method of procuring organs.
  - Possible revision – “Insofar as an ethically defensible and feasible method of procuring organs is not successful at meeting the current and future demand for transplantable organs, it follows that such a method is not ethically preferable to methods that are likely to be more successful. Furthermore, it does not follow that conventional and novel approaches to organ procurement are mutually exclusive.”
- Review the options included in the 1991 report, which include: (a) Improvements in the current system and (b) presumed consent.
  - Overview of the current demand for and supply of organs by organ type
  - Presumed consent
    - Ethical concerns (e.g. Childress, IOM Ch. 7)

- Taxonomic confusion – Literature on presumed consent encompasses efforts which might be construed as standard practices by procurement professionals all the way to conscription (e.g. Aaron Spital).
    - Practical concerns – Simply not enforced in the majority of countries with PC laws on the books, and a lack of correlation between success in rates of organ procurement attributable to use of presumed consent.
- Review efforts to increase the supply of organs which have emerged since 1991
  - Efforts at promulgating “best practices” through the efforts of the Organ Donor Collaborative
    - Efforts to re-examine the empirical basis for rejecting organs
  - Paired exchanges
    - Overview and discussion of the philosophical implications of the recent exemption of paired exchanges from the “valuable consideration” clause in NOTA – Norwood-Inslee bill.
    - Estimates and challenges to broad paired-exchange efforts.
  - Extended-criteria donation
  - Donation after Cardiac Death
  - Expansion of conventional living-unrelated donation, and expansion of the definition of same since 1991;
  - Proposals to introduce utility models into allocation - LYFT
  - Summary – Review of the achieved and potential improvements in organ procurement since 1991.
- Recapitulation – Assessment of current, ongoing efforts to procure organs, reviewed through the lens of the current and future demand for organs.
  - Epidemiology of ESRD – 2010 and 2015
  - Liver
  - Heart/Heart-Lung
- Recapitulation – Assessment of the unintended but foreseeable consequences of the current system – (Hippen – President’s Council on Bioethics testimony)
- Conclusions
  - Reassessment of the 1991 report – What we affirm, what we have revised, what we reject.
  - Other conclusions.

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<sup>1</sup> 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.

<sup>2</sup> 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.

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

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

<sup>5</sup> Rawls, John. A Theory of Justice. Cambridge, Massachusetts: Harvard University Press, 1971.