

**OPTN/UNOS ETHICS COMMITTEE MEETING**  
**Conference Call**

**March 17, 2011**  
**3:00 – 4:00 p.m. Eastern Time**

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

1. Review Concepts for Kidney Allocation distributed for public comment and provide feedback to the Kidney Transplantation Committee, as appropriate, by April 1, 2011. Dr. Shapiro gave a brief introduction to the Committee about the Concepts for Kidney Allocation document issued by the Kidney Transplantation Committee (“Kidney Committee”). He explained that the Kidney Committee has been working for many years on an evolving set of concepts for a new kidney allocation system.

There are valid concerns with the mechanics of the proposal. There could be extensive discussion by the Committee on the merits and flaws of the proposal without ever reaching a consensus.

The Committee briefly discussed two recent articles in the NEJM by Lainie Ross et al and Alan Leichtman et al. regarding arguments for and against the proposed kidney allocation concepts. The issues were well-developed in those articles so the Committee sought instead to find areas of common ground with respect to the proposal.

It was noted very clearly that the proposed kidney allocation concept document does not address the issues of geography. It was suggested that this proposal is not the right proposal, right now. All of the simulation modeling has been using national data that has sharing regionally and nationally so the data is not appropriate.

The NEJM article points out that the current system varies in terms of impact of the way points are distributed. In certain DSAs, the effects of the additional points for allocation vary widely.

The Kidney Committee originally planned to develop an allocation system and then address the problem of geography because it is a large problem. The core issue is that allocation of high quality kidneys to patients whose lifespan is biologically limited does not make sense. A system should be developed to do a better job at maximizing the life years of the limited supply of kidneys. Leaving geography out is a mistake but the current algorithm is not acceptable either.

It is important to acknowledge that there is no control over living donors who provide 40% of the total donor kidneys. There are likely to be unintended consequences of having fewer total living donor kidneys and second, that living donor kidneys are going to be going into older recipients. Nationally, historically fewer than 2% of all kidneys go to recipients older than age 70. Based on the post Share 35 policy behavior with respect to living donors, the number of living donors decreased and living donor kidneys were allocated to older recipients.

In Los Angeles, the waiting times are so long that the fears are not likely to materialize but in Oregon where waiting times are short, the unintended consequences are very relevant.

It was argued that since whites live longer than blacks; wealthy live longer than poor people; women live longer than men - why is it okay to discriminate on the basis of age when those other characteristics also indicate expected life years? There is a lack of transparency in the modeling. There is a significant ethical

difference in using age as a strong predictor of survival than using gender, race, or socioeconomic characteristics.

It was suggested that it may be illegal discrimination to use age as a factor in organ allocation. It was noted that presently immunosuppressant medications are only covered for three years, which results in a significant number of graft failures per year. It was suggested that the system should address geography first, and then other system issues such as providing lifetime coverage for immunosuppressants.

Concerns were also shared about the arbitrariness in determining the top 20% of potential recipients. We cannot determine with specificity the difference between a patient in the top 20.1% versus a patient at 19.9% based on the current modeling based on national data.

Generally, younger patients lose their graft because the graft fails while older patients lose their allograft because they die. The age matching portion of the proposal makes sense and eliminates the SCD and ECD distinction.

It was asked what is the role of the Ethics Committee with respect to this proposal and what is unethical about the proposal? There may be legitimate objections to the proposal but those may not be ethical objections. It may not be intrinsically unethical or ethical.

It is unethical because it discriminates on the basis of age. There is no justification for distinguishing between individuals at certain levels since we cannot do that with any certainty. Third, it ignores living donors and fails to consider the overarching issue of justice. The living donor system will either reduce overall or shift living donor kidneys to older recipients.

In general, this policy has a reasonable ethical basis. Concerns were shared by several members about the effect of this system on the behavior of living donors, as well as the number and projected recipients of living donor kidneys.

Concerns were also shared that the kidney proposal is trying to do survival matching. Survival matching is easy to do at the extreme age ranges, but very difficult to accomplish in the middle range where most of the transplants will occur. This proposal may succeed in extending the lives of people who need a transplant but a fairly large proportion of people would be misclassified because the models are limited at the individual level.

To determine whether a consensus exists, the Ethics Committee unanimously agreed that the Committee remains concerned with the lack of consideration given to the broader geographic sharing of kidneys and recommends that the Kidney Transplantation Committee make consideration of broader geographic sharing of kidneys a high priority.

By consensus, the Ethics Committee finds no overt ethical problems with the proposed kidney concept. The current system may be unethical and the proposed system is no more unethical than the current system.

It was suggested that the proposed system is more unethical because it discriminates on the basis of disease. While the Committee finds the proposal is ethical, there are still concerns about the effects on living donation rates which may render this proposal ethically suspect. Further simulation modeling should be done in order to allay these potential ethical concerns.

Finally, the Ethics Committee has significant concerns over the potential effects of the proposed kidney allocation system on living donation. There were concerns that the effects on living donors may be an ethical problem or may simply be deemed a statistical problem.

The Committee offered the following three motions which were circulated electronically to the Ethics Committee for their votes. The final votes follow each respective Motion (See Exhibit 1):

Motion 1:

In reviewing the new kidney allocation proposals, the Ethics Committee remains concerned with the lack of attention to geographic disparities in access to kidney transplantation. The Ethics Committee recommends that the KI committee make broader geographic sharing of kidneys a high priority when proposing any new system for kidney allocation.

Approved: 11 for, 3 against, and 0 abstentions

Motion 2:

The Ethics Committee finds no overt ethical problems with the proposed kidney allocation concept document

Approved: 10 for, 4 against, and 0 abstentions

Motion 3:

Implementation of a kidney allocation system based on survival matching could lead to decreased kidney donation from live donors. Decreased living donation would decrease the overall pool of kidneys available for transplantation and therefore impede access to kidney transplantation. The Ethics Committee believes that live donation rates must be closely monitored following implementation of any new kidney allocation system.

Approved: 14 for, 0 against, and 0 abstentions

**Attendance at the Ethics Committee Meeting  
March 17, 2011  
Conference Call**

Committee Members Attending:

Michael Shapiro, M.D.	Chair
Alexandra K. Glazier, J.D., M.P.H.	Vice-Chair
Peter Reese, M.D.	Region 2
Natalie G. Murray, M.D.	Region 4
Gabriel M. Danovitch, MB, LRCP, MRCS	Region 5
Lisa Florence, M.D.	Region 6
Deborah B. Adey, M.D.	Region 9
Amy Pope-Harman, M.D.	Region 10
Jack Berry	At Large
Richard Demme, M.D.	At Large
Kay Kendall, MSW, LISW	At Large
Lainie F. Ross, M.D., Ph.D.	At Large
Dane Sommer, D.Min., BCC	At Large
Bernie Kozlovsky, M.D.	HRSA, <i>ex officio</i>

UNOS Staff:

Jason P. Livingston, Esq.	UNOS
Gloria Taylor	UNOS

SRTR

Tabitha Leighton  
Maryam Valapour

Unable to attend

Matthew G. Nuhn, M.D.	Region 1
Carlos F. Zayas, M.D.	Region 3
Bargav M. Mistry, M.D.	Region 7
Erik Schadde, M.D.	Region 8
Robert M. Sade, M.D.	Region 11
Ronald E. Domen, M.D.	At Large
James M. DuBois, Ph.D, DSc	At Large
Rachel Mackey	At Large
Liz Lehr, BSN, MHA	At Large
Robert M. Veatch, Ph.D.	At Large