

OPTN/UNOS Ad Hoc Living Donor Committee Summary

I. Organ Availability Issues:

Action Items for Board Consideration:

- None

Other Significant Items:

- The Ad Hoc Living Donor Committee requests that the Board endorse the dissemination of “A Proposal to Increase Organ Donation” to state governments, the Secretary of Health and Human Services, and the Council of State Governments. (Item 8, page 11)

II. Patient Access Issues:

Action Items for Board Consideration:

- None

Other Significant Items:

- None

III. Other Issues:

Action Items for Board Consideration:

- The Board is asked to approve the Proposed Guidelines for Living Liver Donor Evaluation. (Item 2, page 4)
- The Board is asked to approve the Proposed Guidelines for Living Kidney Donor Evaluation. (Item 3, page 6)
- The Board will consider the recommended changes to the Living Donor Registration Form. (Item 12, page 12)

Other Significant Items:

- The Committee reviewed the public and regional comments to the Kidney and Pancreas Transplantation Committee’s proposed modifications to the Local Voluntary Alternative System for Assigning Priority in Kidney Allocation to Original Intended Candidates for Living Donor Kidneys. (Item 1, page 3)
- The Committee reviewed the Proposed Modifications to OPTN/UNOS Policy 3.1.4 (Patient Waiting List). The Committee agreed the policy should also apply to living donors and recipients. (Item 4, page 8)
- The Committee discussed the Living Donor Data Collection and agreed to form a Subcommittee to address the issue of incomplete forms. The Subcommittee will be charged with reviewing the data, establishing a threshold of completeness, and identifying centers with a high number of incomplete forms. (Item 6, page 9)

- The Committee reviewed a report from the Joint Subcommittee of the Ad Hoc Living Donor Committee and the Kidney and Pancreas Transplantation Committee. The Joint Subcommittee was formed to discuss the qualifying criteria for Live Donor Kidney Transplant Centers. (Item 7, page 9)
- The Committee discussed the issue of surrogate consent for living related organ donation. The Chairman of the Ethics Subcommittee agreed to contact the Chairman of the OPTN/UNOS Ethics Committee to initiate further discussion on this topic. (Item 9, page 11)
- The Committee reviewed a report from the Quality of Life Subcommittee. The Quality of Life Data Elements Collection and Living Donor Resource Center proposals have been sent to the Department of Transplantation for review and approval. (Item 10, page 11)
- The Committee reviewed a response from the Liver and Intestinal Organ Transplantation Committee regarding potential conflict of interest in living organ donor and recipient surgeries. (Item 11, page 12)
- The Committee discussed the rotation of members and the appointment of a Vice-Chair. (Item 14, page 12)
- The Committee reviewed its charges and priorities, and wishes to maintain its current membership and status as an *ad hoc* committee; the Committee will monitor its ongoing projects including the living donor registry initiative, data submission issues, surrogate consent, and living donor program guidelines. The Committee will meet again in the fall of 2004. (Item 14, page 12)

**REPORT OF THE OPTN/UNOS
AD HOC LIVING DONOR COMMITTEE
TO THE BOARD OF DIRECTORS**

**Minneapolis, Minnesota
June 24-25, 2004**

Andrew S. Klein, M.D., M.B.A., Chairman

The following report presents the OPTN/UNOS Ad Hoc Living Donor Committee's deliberations and recommendations on matters considered by the Committee during its May 10, 2004 meeting.

1. Review of Proposed Modifications to Local Voluntary Alternative System for Assigning Priority in Kidney Allocation to Original Intended Candidates for Living Donor Kidneys.

The Committee reviewed a public comment proposal to modify a generic alternative system that would provide priority in the kidney allocation system for original intended candidates (ICs) for living donor kidney due to crossmatch results or ABO blood type, when the living donors donate to candidates on the list of patients waiting for deceased donor kidneys. The board approved a previous proposal by the Kidney and Pancreas Transplantation Committee and the present proposal is intended to assign priority among ICs when more than one is on the list. Under the proposal, the ICs will be ranked in order of date of donation from the living donor, and the term "time waiting" would be eliminated so as not to be confused with the standard meaning of candidate waiting time.

Dr. Alan Leichtman, Chair of the Kidney and Pancreas Transplantation Committee, clarified that the modifications were to a previously approved policy. The modifications were proposed because of an issue raised during the programming phase for the Board-approved system. The issue was the intended meaning of "waiting time" used to prioritize ICs when there is more than one eligible IC, under the system. The Kidney and Pancreas Transplantation Committee determined that prioritizing ICs based on the date of the original intended donor living kidney donation was the best way to meet the objective of facilitating living donor donation.

Committee Consideration of Public and Regional Comments

As of April 29, 2004, 85 responses have been submitted to UNOS regarding this policy proposal. Of these, 40 (47.06%) supported the proposal, 1 (1.18%) opposed the proposal, and 44 (51.76%) had no opinion. Of the 41 who responded with an opinion, 40 (97.56%) supported the proposal and 1 (2.44%) opposed the proposal. All ten regions that commented were in favor of the proposal.

The only opposing public comment suggested the kidney should go to the candidate at the top of the cadaveric waiting list at the same program of the intended living donor recipient. The Committee response was that the comment is well taken but does not apply to this proposal. In addition, the system is voluntary and the center can still apply for an alternative local system that fits their needs. Committee vote on the response: 20 in favor, 0 opposed, 0 abstentions.

Another public comment addressed the concern of coercion. The Committee response was that they agree with the concern of coercion in all living donor procedures, however, it is the responsibility of the transplant center to educate the potential donor about the process and options, and to avoid the use of coercion. Committee vote on the response: 20 in favor, 0 opposed, 0 abstentions.

*RESOLVED, the Committee voted to support the proposal.

Committee vote: 20 in favor, 0 opposed, 0 abstentions.

2. Review of Proposed Guidelines for Living Liver Donor Evaluation.

The Committee reviewed its proposal to establish guidelines for potential living liver transplant recipient and donor evaluation, including provisions for an independent donor team, psychiatric and social screening, and appropriate medical, radiological, and anesthesia evaluation. **(Exhibit A)** While these are not being proposed as OPTN/UNOS Policy, the Ad Hoc Living Donor Committee believes that the guidelines could evolve into the standard of practice for living donor evaluation. Guidelines for living kidney donor evaluation are contained in the next proposal in this series.

Committee Consideration of Public and Regional Comments

As of April 29, 2004, 78 responses have been submitted to UNOS regarding this policy proposal. Of these, 34 (43.59%) supported the proposal, 1 (1.28%) opposed the proposal, and 43 (55.13%) had no opinion. Of the 35 who responded with an opinion, 43 (97.14%) supported the proposal and 1 (2.86%) opposed the proposal. Of the eight regions that reviewed the guidelines, six were in favor and two were opposed.

One region thought the proposal as written created a degree of ambiguity regarding the “independent team.” The Committee Members discussed the concern and the initial rationale for having an independent team was to avoid a conflict of interest. The Committee opined that the term independent was clearly defined within the text of the proposal. Committee vote on the response: 20 in favor, 0 opposed, 0 abstentions.

Another region approved the proposal with the following amendments:

- 2.a.iii- 1. *Physician/Surgeon*
- 4. *Strike (as appropriate)*
- 5. *Strike (as appropriate)*
- 2.a.vii- *These functions should be the responsibility of the Transplant team*
- 2.c.i.- *Strike “medical social worker” and replace with “medical professional”*

The Committee Members agreed to the addition to 2.a.iii. They did not agree to strike “as appropriate” because it allowed transplant centers the flexibility in deciding the members of the independent team. They did not agree to the requested change in 2.a.vii because they want these functions to reside with the independent team. There was some concern as to why a medical social worker should be the one required to perform the psychiatric and social screening when there are various individuals in a transplant center who have the qualifications to perform this evaluation. It was decided to replace “medical social worker” with “mental healthcare professional” in order to allow the transplant center some flexibility. The Committee vote on this regional response: 20 in favor, 0 opposed, 0 abstentions.

There was also a letter from the Association of Transplant Anesthesiologists’ Ad Hoc Committee on Transplant Anesthesia with recommended changes to the guidelines. They wanted to make sure the anesthesiologist was experienced in “transplant” anesthesia and that post-operative pain consultation should be available. The Committee agreed this change was appropriate.

One Committee Member suggested additional information be added to section 2.a.viii. The guidelines state “the team members should meet with the donor more than once during the evaluation process, separately from recipient appointments.” The concern was that the section did not clearly define the meeting be done without the presence of the recipient. The Committee agreed to add this language to avoid confusion. Changes the Committee made to the language that was sent out for public comment is delineated by strikethroughs or double underlines, and **bolded text**. The Committee submits the following resolution for consideration by the Board of Directors:

*****RESOLVED, that subsequent to the consideration of public comment, the Living Liver Donor Evaluation Guidelines, as described and amended below, shall be approved and implemented upon completion of programming in the UNOS system.**

Committee vote: 20 in favor, 0 opposed, 0 abstentions.

Living Liver Donor Evaluation Guidelines

1. Recipient evaluation

- a. Potential living liver donor recipients should derive potential benefit from transplantation.
- b. Potential living liver donor recipients should undergo evaluation process similar to deceased donor recipients.
- c. Potential living liver donor recipients should not have any absolute exclusionary criteria for liver transplantation at that transplant center.

2. Donor Evaluation

- a. Independent donor team
 - i. Keeps well-being of the donor as paramount responsibility
 - ii. At least one member should have no connection with the recipient's medical care or decision-making
 - iii. The program has a responsibility to have available to the potential donor an independent donor team that should consist of at least the following:
 1. Physician/Surgeon
 2. Transplant coordinator/nurse clinician
 3. Medical social worker
 4. Psychiatrist (as appropriate)
 5. Ethicist/Clergy (as appropriate)
 - iv. The team's status should not depend on the outcome of the donor evaluation
 - v. The team should have enough medical sophistication and awareness of current center experience and results to explain these adequately to the potential donor.
 - vi. The team should be experienced with donor evaluation.
 - vii. The team's function is:
 1. to educate the potential donor regarding the potential risks and benefits of donation.
 2. to provide counseling and support for the donor regarding family, disability, intellectual, emotional, or other pressures.
 3. to determine that the donor's decision to donate is voluntary, without coercion from within or outside the transplant center.
 4. to provide opportunities for the donor to "opt out" of the procedure without consequences.
 - viii. The team members should meet with the donor more than once during the evaluation process, separately from recipient appointments **and without the presence of the recipient.**
- b. Medical evaluation: An attending physician and surgeon should screen all potential donors.
- c. Psychiatric and Social Screening

- i. Dedicated ~~medical-social worker~~ **mental healthcare professional** familiar with transplantation and living donation should evaluate the potential donor for:

1. Psychosocial history
2. relationship between donor and recipient and potential areas where undue pressure or coercion may be applied.
3. presence of psychiatric disorders. In cases in question, psychiatric or psychologist consultation should be readily available.
4. the existence of a financial incentive as motivation for the donor.
5. presence of physical or sexual abuse of the donor in the past or the presence of active substance abuse in the donor.

d. Radiologic Evaluation

- i. Donor should undergo radiologic imaging to establish:
 1. There is adequate donor liver volume to supply a graft of suitable size for the recipient.
 2. There is adequate residual donor liver volume to support the donor in the immediate post-operative period.
 3. Determine the vascular anatomy of the donor liver to ensure maintenance of inflow and outflow in the graft and in the donor residual liver remnant.

e. Anesthesia Evaluation

- i. The potential donor should be evaluated by a staff anesthesiologist experienced in liver **transplant** ~~surgical~~ anesthesia and post-operative pain management **consultation should be available.**

3. Review of Proposed Guidelines for Living Kidney Donor Evaluation.

The Committee reviewed its proposal to establish guidelines for potential living kidney transplant recipient and donor evaluation, including provisions for an independent donor team, psychiatric and social screening, and appropriate medical, radiological, and anesthesia evaluation. **(Exhibit B)** The Committee reviewed the public/regional comments and a letter from the Association of Transplant Anesthesiologists'. Since the guidelines are similar for both liver and kidney, and the public/regional responses were similar as well, the Committee agreed to apply the same responses and modifications to the Living Kidney Donor Evaluation guidelines. Changes the Committee made to the language that was sent out for public comment is delineated by strikethroughs or double underlines, and **bolded text**. The Committee submits the following resolution for consideration by the Board of Directors:

*****RESOLVED, that subsequent to the consideration of public comment, the Living Kidney Donor Evaluation Guidelines, as described and amended below, shall be approved and implemented upon completion of programming in the UNOS system.**

Committee vote: 20 in favor, 0 opposed, 0 abstentions.

Living Kidney Donor Evaluation Guidelines

1. Recipient evaluation

- a. Potential living kidney donor recipients should derive potential benefit from transplantation.

- b. Potential living kidney donor recipients should undergo evaluation process similar to deceased donor recipients.
- c. Potential living kidney donor recipients should not have any absolute exclusionary criteria for deceased donor kidney transplantation at that transplant center.

2. Donor Evaluation

- a. Independent donor team
 - i. Keeps well-being of the donor as paramount responsibility
 - ii. At least one member should have no connection with the recipient's medical care or decision-making.
 - iii. The program has a responsibility to have available to the potential donor an independent donor team that should consist of at least the following:
 - Physician/Surgeon
 - Transplant coordinator/nurse clinician
 - Medical social worker
 - Psychiatrist (as appropriate)
 - Ethicist/Clergy (as appropriate)
 - iv. The team's status should not depend on the outcome of the donor evaluation.
 - v. The team should have enough medical sophistication and awareness of current center experience and results to explain these adequately to the potential donor.
 - vi. The team should be experienced with donor evaluation.
 - vii. The team's function is:
 - 1. to educate the potential donor regarding the potential risks and benefits of donation.
 - 2. to provide counseling and support for the donor regarding family, disability, intellectual, emotional, or other pressures.
 - 3. to determine that the donor's decision to donate is voluntary, without coercion from within or outside the transplant center.
 - 4. to provide opportunities for the donor to "opt out" of the procedure without consequences.
 - viii. The team members should meet with the donor more than once during the evaluation process, separately from recipient appointments **and without the presence of the recipient.**
- b. Medical evaluation: An attending physician and surgeon should screen all potential donors.
 - i. Donor kidney function should be tested to determine serum creatinine, calculated creatinine clearance, and urine protein excretion.
- c. Psychiatric and Social Screening
 - i. Dedicated ~~medical social worker~~ **mental healthcare professional** familiar with transplantation and living donation should evaluate the potential donor for:

1. Psychosocial history
2. relationship between donor and recipient and potential areas where undue pressure or coercion may be applied.
3. presence of psychiatric disorders. In cases in question, psychiatric or psychologist consultation should be readily available.
4. the existence of a financial incentive as motivation for the donor.
5. presence of physical or sexual abuse of the donor in the past or the presence of active substance abuse in the donor.

d. Radiologic Evaluation

i. Donor should undergo imaging studies to determine:

1. That there are two kidneys of normal size and appearance; and
2. To outline the renal vascular and urinary drainage anatomy.

ii. Donor should undergo assessment of surgical risk.

e. Anesthesia Evaluation

- i. The potential donor should be evaluated by a staff anesthesiologist experienced in renal ~~transplant surgical~~ **transplant** anesthesia and post-operative pain ~~management~~ **consultation should be available.**

4. Review of Proposed Modifications to OPTN/UNOS Policy 3.1.4.

The Committee reviewed a public comment proposal from the Ad Hoc Operations Committee on proposed modifications to OPTN/UNOS Policy 3.1.4 (Patient Waiting List). The proposed policies address: processes for ensuring the accuracy of a transplant candidate's ABO type on the waiting list; requiring transplant centers to enter and maintain transplant candidate data electronically using UNetsm; requiring transplant candidate ABO typing on two separate occasions prior to listing; and listing transplant candidates with their actual ABO type. This proposal also requests comment on the applicability of ABO verification processes for living donor transplant recipients and donors.

The Committee agreed there should be some type of dual verification of ABO type for living donors and recipients and it should follow the same policy applied to deceased donors and recipients. The Members deferred making recommendations until the Ad Hoc Operations Committee comes up with a mechanism to implement this process. The most important thing the Committee wanted to emphasize is that all verification should be done prior to the patients going to the operating room.

Motion: The Committee supports the proposal in principle, including the concept of dual verification of ABO type. The Committee wants to emphasize the importance of completing all verifications before the patients go to the operating room.

Committee votes: 20 in favor, 0 opposed, 0 abstentions.

5. Report from the May 6-7, 2004 Meeting of the U.S. Department of Health and Human Services Advisory Committee on Organ Transplantation.

Hui Hsing Wong, MD, JD, reported that there were no recommendations from the recent Advisory Committee meeting for the Ad Hoc Living Donor Committee.

6. Living Donor Data Collection

Mary D. Ellison, PhD, MSHA, reported on the government's appointment of a multi-agency task force to discuss the best approach to establishing a comprehensive living donor registry. The initial idea is to pull together existing sources of living donor data from institutions that already have a lot of follow-up information. The NIH will provide resources to link the data and the principal researchers from the institutions that are chosen to participate. The government feels that linking current sources of living donor data was a faster and more effective way to get to some of the issues and to possibly facilitate the creation of a comprehensive living donor registry.

Dr. Ellison also reported on the incompleteness of living donor follow-up forms. Follow-up forms are considered complete when all the necessary fields are filled out and the form is submitted on UNet[®]. However, after reviewing the information on the completed forms it was discovered that approximately fifty percent of the forms contain incomplete information or information carried over from an earlier follow-up form. UNOS staff contacted some of the centers that have a completion rate of over ninety percent to find out what they do to complete the forms. These centers made a real commitment to contact their patients in order to provide the most complete and up-to-date information. It was suggested that the Committee look into adding language to OPTN/UNOS Policy 7.1.5 that specifies if the information is not within three months of the one-year follow-up, the form would not be considered complete.

Additionally, there is an issue of forms marked "lost to follow-up", which the system will consider complete but contains no information. There is concern that centers are not making the effort to contact patients and are simply marking the forms "lost to follow-up" in order to be in compliance with the data submission policies. A suggested method for dealing with these forms would be to require the centers to have documentation of their attempts to contact the patient for follow-up. Additionally, it was suggested that UNOS staff attempt to contact patients of transplant centers with a high number of forms submitted in this manner.

The main concern of the Committee is the lack of living donor data being submitted on the follow-up forms. The information serves a vital role in educating future living donors as well as providing quality data for research. Dr. Klein emphasized that one of the initial mandates of the Committee was to assure the public that transplant centers were not forgetting about the living donors after the transplant. He felt something should be put in place that reassures the public that something is being done; one way being to insist that follow-up forms be submitted with complete information. It was suggested that a Subcommittee be formed to review the data and make recommendations for future data submission requirements.

Motion: The Committee agreed to establish a Subcommittee to review the living donor data, establish a threshold for completeness of forms, and identify centers with a large number of incomplete forms or forms marked as "lost to follow-up."

Committee vote: 20 in favor, 0 opposed, 0 abstentions.

7. Report from the Joint Subcommittee Meeting (Ad Hoc Living Donor and Kidney/Pancreas Committee)

Dr. Alan Leichtman, Chairman of the Kidney and Pancreas Transplantation Committee, reported on the results of the Joint Subcommittee conference call held on April 29, 2004. Implementation of the present criteria for living donor kidney programs as outlined in OPTN/UNOS By-Laws, Appendix B, Section IV, Part A, was deferred by the Board of Directors during its November 2003 meeting pending additional review by the committees. After discussion, the Joint Subcommittee agreed unanimously to support modifications indicated by double underlines and **bolded text** below.

Live Donor Transplant Programs.

A. Live Donor Kidney Transplant Centers

1. A live kidney donor transplant center must demonstrate the following:

- a) That the center meets the qualifications of a renal transplant center as set forth in UNOS By-Laws B, Section III.1; and
- b) In order to perform open donor nephrectomies, a qualifying renal donor surgeon must be on site and must meet the criteria of (i) and/or (ii) below: That the qualifying renal donor surgeon on site has:
 - i. Completed an accredited ASTS fellowship with a certificate in kidney, or
 - ii. Performed no fewer than 10 open nephrectomies (to include deceased donor nephrectomy, removal of polycystic or diseased kidneys, etc.) as primary surgeon or first assistant ~~over a minimum of three years and a maximum of five years~~ within the prior 5-year period.
- e) If the center wishes to perform laparoscopic donor nephrectomies, ~~the~~ qualifying renal donor surgeon must be on site and must have:
 - (i) ~~Performed no fewer than 15 hand-assisted laparoscopic nephrectomies over a minimum of three years and a maximum of five years; or~~
 - (ii) (i) Acted as primary surgeon or first assistant in performing no fewer than 15 laparoscopic nephrectomies ~~over a minimum of three years and a maximum of five years~~ within the prior 5-year period.

If the laparoscopic and open nephrectomy expertise resides within different individuals then the program must demonstrate how both individuals will be available to the surgical team. It is recognized that in the case of pediatric living donor transplantation, the live organ donation may occur at a center that is distinct from the approved transplant center.

All surgical procedures identified for the purpose of surgeon qualification must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, and the role of the surgeon in the operative procedure. ~~It is recognized that in the case of pediatric living donor transplantation, the live organ donation may occur at a center that is distinct from the approved transplant center.~~

There was some concern about how the application process would cover both open and laparoscopic donor nephrectomies. For example, what happens when a center approved to perform open donor nephrectomies wants to start doing laparoscopic donor nephrectomies? This can be addressed during the development of the application form by specifying a center is approved to perform only open donor nephrectomies, and in order to perform laparoscopic donor nephrectomies, a new application must be submitted with a qualifying surgeon listed on the form. Centers approved for laparoscopic donor nephrectomies will be required to qualify for open procedures as well in case the laparoscopic procedure needs to be converted to an open procedure.

*RESOLVED, the Committee supports the modifications proposed by the Joint Subcommittee.

Committee vote: 18 in favor, 0 opposed, 0 abstentions.

8. Report from the Financial Incentives Subcommittee

Stuart Greenstein, MD, reported on the Subcommittee's efforts to nationalize some of the legislation passed in other states, including Wisconsin. This legislation allows living donors in Wisconsin a \$10,000 state income tax deduction to help cover expenses. They also discussed "A Proposal to Increase Organ Donation" (**Exhibit C**) which was approved by the UNOS Board of Directors in November 2003. This proposal called for the Federal Government to reimburse up to one month's wages lost by living donors and to allow living donation to become a covered event under the provisions of the Family and Medical Leave Act (FMLA). The Subcommittee wants to urge UNOS to communicate this proposal to state governments, the Secretary of Health and Human Services, and the Council of State Governments. The Committee approved the following resolution for consideration by the Board of Directors:

*****RESOLVED, that the Board of Directors supports the OPTN/UNOS disseminating "A Proposal to Increase Organ Donation" to State Governments, the Secretary of Health and Human Services, and the Council of State Governments.**

Committee votes: 18 in favor, 0 opposed, 0 abstentions.

9. Report from the Ethics Subcommittee

Robert S. Brown, Jr., MD, reported on the issue of surrogate consent for living organ donations. The question was raised whether this situation occurs enough to warrant consideration? It was noted that surrogate consent should only be applied under extenuating circumstances and should involve patients in a persistent vegetative state, involve non-vital organs, be applied with the standards of the patient's life wishes, and have no potential gain for the individual who is the surrogate providing consent. One Member commented that the standard for these types of cases is the discontinuation of life support and the use of non-heart beat donor protocol. Several Committee Members had experienced similar situations in their centers. There was considerable discussion on the various scenarios in which surrogate consent could be applied and how the situation should be handled. Dr. Brown agreed that this issue required further discussion and he would contact the Chair of the Ethic Committee to initiate a future meeting.

Motion: That the Ethics Subcommittee meet to further discuss this issue.

10. Report from the Quality of Life Subcommittee

Amanda Pfeiffer, MSW, reported that the Quality of Life Data Elements Collection proposal and budget as well as the Living Donor Resource Center proposal and budget have been sent to the Department of Transplantation for review and approval. The only change to the Living Donor Resource Center proposal since the last meeting was the creation of an editorial board to assist with the development. This board will consist of members from the Ad Hoc Living Donor Committee, Patient Affairs Committee, living donor transplant professionals, living donors, and living recipients. The Subcommittee is also in the process of drafting two letters as part of the Quality of Life Survey. One will be sent to the transplant coordinators to inform them about the purpose of the survey and what their role will be. The second letter will be sent to the living donors six months post-donation to remind them that they have signed the consent form that allows UNOS to contact them directly, to give them some background on the survey, and outline the three options they will have to complete the survey. The three options available to the donors will be by mail, telephone survey, and the Internet.

11. Response from the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee Regarding Potential Conflict of Interest in Living Organ Donor and Recipient Surgeries.

The Ad Hoc Living Donor Committee approved the following motion in 2003 and asked that the organ specific and relevant constituent Committees review this recommendation and comment upon what would constitute “best practice” regarding this issue.

RESOLVED, that it is desirable that, whenever, possible, the donor and recipient surgeries be Performed by different surgeons having primary responsibility for either the donor or recipient. It is recognized that in some circumstances (e.g., fulminant patients) this may not always be practical.

The Liver Committee agreed with the principle that the donor and recipient surgeries should be performed by different surgeons if possible. They felt the resolution is consistent with the criteria for living donor programs and supported the resolution by unanimous vote.

12. Living Donor Registration Form and Living Donor 6-Month/Annual Follow-up Form

The Committee was provided a copy of the revised Living Donor Forms. Upon review of the forms, Richard Freeman, MD, recommended the following changes.

- Change the functional status on both the living donor registration form and living donor follow-up form to a Karnofsky score. It was noted that the Data Advisory Committee would be sending this change out for public comment.
- It was recommended that the “history of cigarette use” section be added to all living donor registration forms and moved to the general medical information section. This information is currently listed only on the pre-donation lung form; however, Committee members felt the information was important enough to have on all registration forms.
- It was recommended that the biliary complication section of the liver donor registration form be incorporated into the reoperation section to eliminate the need to provide biliary complication information in two separate sections. If the biliary complication box is checked, then the center will be required to enter information about the specific type of complication.

By a vote of 20 in favor, 0 opposed, and 0 abstentions, the Committee agreed to the changes and submits the following resolution for consideration by the Board of Directors:

*****RESOLVED, that the recommendations to modify the Living Donor Registration Form, based on the changes described below, shall be approved and implemented upon completion of programming in the UNOS system.**

- **Changing the functional status to a Karnofsky score.**
- **Adding the “history of cigarette use” section to all living donor forms and making it a part of the general medical information section.**
- **Incorporating the biliary complication section of the liver donor registration form into the reoperation section.**

13. Number of Living Donor Transplants

There was some discussion about the number of adult living donor liver procedures being done each year. Richard Freeman, MD, verified there was a brief decline in living liver donor procedures during 2002 but the numbers are slowly increasing.

14. Committee Member Rotation and Committee Status

Since the Committee has been around for approximately 2 years, it was suggested that a method for rotating members off the board be discussed. Suggestions included rotating one third of the members off

each year in order to maintain continuity. There was also a suggestion that a Vice-Chair be appointed to facilitate the transition to a new Chairman.

The Committee reviewed its charges and priorities, and wishes to maintain its current membership and status as an *ad hoc* committee; the Committee will monitor its ongoing projects including the living donor registry initiative, data submission issues, surrogate consent, and living donor program guideline. The Committee will meet again in the fall of 2004.

OPTN/UNOS AD HOC LIVING DONOR COMMITTEE

**Chicago, Illinois
May 10, 2004**

Committee Members in Attendance

Andrew S. Klein, MD, MBA
Lynt B. Johnson, MD
John J. Curtis, MD
Kristene K. Gugliuzza, MD
Mark L. Barr, MD
Mark B. Adams, MD
James F. Trotter, MD
Lewis W. Teperman, MD
Juan D. Arenas, MD
Richard T. Stravitz, MD
Patricia L. Adams, MD
Rhonda R. Boone
Richard B. Freeman, MD
Ruth Parker
Kimberly L. Tracy, RN
Robert M. Veatch, PhD
Robert S. Brown, Jr., MD
Lesley A. Johnson, RN, BSN
Stuart M. Greenstein, MD

Chairman
Regional Rep. Reg. 2
Regional Rep. Reg. 3
Regional Rep. Reg. 4
Regional Rep. Reg. 5
Regional Rep. Reg. 7
Regional Rep. Reg. 8
Regional Rep. Reg. 9
Regional Rep. Reg. 10
Regional Rep. Reg. 11
At Large
At Large

DOT Staff in Attendance

Hui-Hsing Wong, MD, JD
Laura St. Martin, MD

Ex-Officio- Government Liaison
Ex-Officio- Government Liaison

UNOS Staff in Attendance

Doug A. Heiney, Director of Membership and Policy
Ann M. Harper, Policy Analyst
Robert A. Hunter, Policy Analyst
Mary D. Ellison, PhD, MSHA
William Lawrence, JD
Anne Paschke, Media Specialist
Amanda Pfeiffer (via teleconference)
Sally Aungier (via teleconference)
Jane Koonce (via teleconference)
Cliff McClenney (via teleconference)

SRTR Staff in Attendance

Alan B. Leichtman, MD (for Friedrich K. Port, MD)
Tempe Hulbert-Shearon

Committee Members Unable to Attend

Ronald W. Busuttill, MD, PhD
Riccardo A. Superina, MD
Edward Y. Zavala, MBA
Kim M. Olthoff, MD
Cheryl Jacobs, ACSW
Robert L. Wilburn, MD
Francis L. Delmonico, MD

At Large
At Large
At Large
At Large
At Large
Regional Rep. Reg. 6
Regional Rep. Reg. 1

Guest

Deborah Shelton

St. Louis Post-Dispatch

Briefing Paper
Proposed Guidelines for Living Liver Donor Evaluation

Summary

The Ad Hoc Living Donor Committee has proposed guidelines for potential living liver transplant recipient and donor evaluation, including provisions for an independent donor team, psychiatric and social screening, and appropriate medical, radiologic, and anesthesia evaluation. While these are not being proposed as OPTN/UNOS Policy, the Committee believes that the guidelines could evolve into the standard of practice for living donor evaluation. This briefing paper summarizes the proposal that was circulated for public comment in March 2004, the Committee's responses to the public and regional comments received, and the Committee's final recommendation to the OPTN/UNOS Board of Directors.

Background

The Ad Hoc Living Donor Committee was formed in 2002 and identified "establishing minimum criteria for donor work-up" as a priority for its future work. In September 2002, the Standards and Personnel Subcommittee was established in order to provide recommendations regarding standards for living donor transplant programs, training, and experience guidelines for live donor surgeons, and minimum criteria for donor workup. Having provided criteria for live liver donor transplant programs (By-Laws, Appendix B, approved in November 2003), the Subcommittee began to develop guidelines for living donor and recipient evaluation. In doing so, the Subcommittee considered a report from the New York State Committee on Quality Improvement in Living Liver Donation to the New York State Transplant Council and New York State Department of Health, which included donor medical evaluation criteria, informed consent criteria, and independent donor advocacy structures.

Proposed Recipient Evaluation

The guidelines include a section relating to potential living donor candidate evaluation, which specifies the following:

- Potential living donor recipients should derive potential benefit from transplantation.
- Potential living donor recipients should undergo evaluation process similar to deceased donor recipients.
- Potential living donor recipients should not have any absolute exclusionary criteria for liver transplantation at that transplant center.

The original draft of the liver evaluation guidelines, as reviewed by the Ethics Subcommittee, contained specific exclusionary criteria (e.g., MELD score > 25, fulminant liver failure, retransplantation, etc.), modeled after the New York State proposal. The Subcommittee agreed that potential living liver donor recipients should not have any absolute exclusionary criteria, but discussed whether recipients deemed to be "too well" or had exclusionary criteria from deceased donor transplantation should be considered as potential living donor recipients. The consensus of the full Committee was that the candidate for living donor transplantation should derive benefit from the transplant procedure, and removed the additional exclusionary criteria. The Committee opined that the evaluation of potential living liver donor recipients may not be identical to that of candidates for deceased donor organs, but that the evaluation should be similar.

Proposed Donor Evaluation

The Personnel and Standards Subcommittee proposed that an independent team be part of the donor evaluation process, as recommended by the New York State Committee and the Advisory Committee on Transplantation (ACOT). The section relating to evaluation of potential living donors specifies that the primary responsibility of the independent donor team is the well-being of the potential donor. Other key provisions of the donor team are as follows:

- The independent team donor advocate team's status at the transplant center should not be affected by decisions made on behalf of the donor.
- The team should have enough medical sophistication and awareness of current center experience and results to explain these adequately to the potential donor.
- The team should be experienced with donor evaluations.
- The team's function is: to educate the potential donor regarding the potential risks and benefits of donation; to provide counseling and support for the donor regarding family, disability, intellectual, emotional or other pressures; to determine that the donor's decision to donate is voluntary, without coercion from within or outside the transplant center and; to provide opportunities for the donor to "opt out" of the procedure with out consequences.
- The team members should meet with the donor more than once during the evaluation process, separately from recipient appointments.

The proposal also includes recommendations for the potential donor's medical, radiologic, and anesthesia evaluation as well as psychiatric and social screening. There are organ-specific differences in the guidelines for medical and radiologic evaluations for liver versus kidney; for example, the medical evaluation for a potential kidney donor specifies that donor kidney function (i.e., serum creatinine, creatinine clearance, and urine protein excretion) should be tested.

During a conference call on September 10, 2003, the Standards and Personnel Subcommittee also added a section on Psychiatric and Social Screening. These specify that a dedicated medical social worker familiar with transplantation and living donation should evaluate the potential donor for:

- psychosocial history;
- relationship between donor and recipient and potential areas where undue pressure or coercion may be applied;
- presence of psychiatric disorders
- the existence of a financial incentive as motivation for the donor; and
- presence of physical or sexual abuse of the donor in the past or the presence of active substance abuse in the donor.

The Ethics Subcommittee reviewed the guidelines and felt they were ethically appropriate. The full Committee reviewed the guidelines during its October 2003 meeting and gave its approval, with minor modifications.

Policy Proposal

After considering the document and with modifications, the Committee approved the following motion:

***RESOLVED**, that the Living Liver Donor Evaluation Guidelines shall be circulated for public comment.

Accomplished in one Committee vote: 20 in favor, 0 opposed, 0 abstentions.

Living Liver Donor Evaluation Guidelines

1. Recipient evaluation
 - a. Potential living liver donor recipients should derive potential benefit from transplantation.
 - b. Potential living liver donor recipients should under go evaluation process similar to deceased donor recipients.
 - c. Potential living liver donor recipients should not have any absolute exclusionary criteria for liver transplantation at that transplant center.
2. Donor Evaluation

- a. Independent donor team
 - i. Keeps well-being of the donor as paramount responsibility
 - ii. At least one member should have no connection with the recipient's medical care or decision-making
 - iii. The program has a responsibility to have available to the potential donor an independent donor team that should consist of at least the following:
 - 1. Physician
 - 2. Transplant coordinator/nurse clinician
 - 3. Medical social worker
 - 4. Psychiatrist (as appropriate)
 - 5. Ethicist/Clergy (as appropriate)
 - iv. The team's status should not depend on the outcome of the donor evaluation
 - v. The team should have enough medical sophistication and awareness of current center experience and results to explain these adequately to the potential donor.
 - vi. The team should be experienced with donor evaluation.
 - vii. The team's function is:
 - 1. to educate the potential donor regarding the potential risks and benefits of donation.
 - 2. to provide counseling and support for the donor regarding family, disability, intellectual, emotional, or other pressures.
 - 3. to determine that the donor's decision to donate is voluntary, without coercion from within or outside the transplant center.
 - 4. to provide opportunities for the donor to "opt out" of the procedure without consequences.
 - viii. The team members should meet with the donor more than once during the evaluation process, separately from recipient appointments.
- b. Medical evaluation: An attending physician and surgeon should screen all potential donors.
- c. Psychiatric and Social Screening
 - i. Dedicated medical social worker familiar with transplantation and living donation should evaluate the potential donor for:
 - 1. Psychosocial history
 - 2. relationship between donor and recipient and potential areas where undue pressure or coercion may be applied.
 - 3. presence of psychiatric disorders. In cases in question, psychiatric or psychologist consultation should be readily available.
 - 4. the existence of a financial incentive as motivation for the donor.
 - 5. presence of physical or sexual abuse of the donor in the past or the presence of active substance abuse in the donor.

d. Radiologic Evaluation

- i. Donor should undergo radiologic imaging to establish:
 1. There is adequate donor liver volume to supply a graft of suitable size for the recipient.
 2. There is adequate residual donor liver volume to support the donor in the immediate post-operative period.
 3. Determine the vascular anatomy of the donor liver to ensure maintenance of inflow and outflow in the graft and in the donor residual liver remnant.

e. Anesthesia Evaluation

- i. The potential donor should be evaluated by a staff anesthesiologist experienced in liver surgical anesthesia and post-operative pain management.

Public Comment Response

As of April 29, 2004, 83 responses have been submitted to UNOS regarding this policy proposal. Of these, 37 (44.58%) supported the proposal, 1 (1.20%) opposed the proposal, and 45 (54.22%) had no opinion. Of the 38 who responded with an opinion, 37 (97.37%) supported the proposal and 1 (2.63%) opposed the proposal. Of the eight regions that reviewed the guidelines, six were in favor and two were opposed.

One region thought the proposal as written created a degree of ambiguity regarding the “independent team.” The Committee members discussed the concern and the initial rationale for having an independent team was to avoid a conflict of interest. The Committee opined that the term independent team was clearly defined within the text of the proposal.

Another region approved the proposal with the following amendments:

- 2.a.iii- 1. Physician/Surgeon*
- 4. Strike (as appropriate)*
- 5. Strike (as appropriate)*
- 2.a.vii- These functions should be the responsibility of the Transplant team*
- 2.c.i.- Strike “medical social worker” and replace with “medical professional”*

The Committee Members agreed to the addition to 2.a.ii. They did not agree to strike “as appropriate” because it allowed transplant centers the flexibility in deciding the members of the independent team. They did not agree to the requested change in 2.a.vii because they want these functions to reside with the independent team. There was some concern as to why a medical social worker should be the one required to perform the psychiatric and social screening when there are various individuals in a transplant center who have the qualifications to perform this evaluation. It was decided to replace “medical social worker” with “mental healthcare professional” in order to allow the transplant center some flexibility.

There was also a letter submitted by the Association of Transplant Anesthesiologists’ Ad Hoc Committee on Transplant Anesthesia with recommended changes to the guidelines. They wanted to make sure the anesthesiologist was experienced in “transplant” anesthesia and that post-operative pain consultation should be available. The Committee agreed these changes were appropriate.

One Committee Member suggested additional information be added to section 2.a.viii. The guidelines state “the team members should meet with the donor more than once during the evaluation process, separately from recipient appointments.” The concern was that the section did not clearly define the meeting be done without the presence of

the recipient. The Committee agreed to add this language to avoid confusion.

Final Proposal

Changes the Committee made to the language that was sent out for public comment is delineated by strikethroughs or double underlines and **bolded text**. The Committee submits the following resolution for consideration by the Board of Directors:

*****RESOLVED, that subsequent to the consideration of public comment, the Living Liver Donor Evaluation Guidelines, as described and amended below, shall be approved and implemented upon completion of programming in the UNOS system.**

Living Liver Donor Evaluation Guidelines

1. Recipient evaluation

- a. Potential living liver donor recipients should derive potential benefit from transplantation.
- b. Potential living liver donor recipients should under go evaluation process similar to deceased donor recipients.
- c. Potential living liver donor recipients should not have any absolute exclusionary criteria for liver transplantation at that transplant center.

2. Donor Evaluation

a. Independent donor team

- i. Keeps well-being of the donor as paramount responsibility
- ii. At least one member should have no connection with the recipient's medical care or decision-making
- iii. The program has a responsibility to have available to the potential donor an independent donor team that should consist of at least the following:
 1. Physician/Surgeon
 2. Transplant coordinator/nurse clinician
 3. Medical social worker
 4. Psychiatrist (as appropriate)
 5. Ethicist/Clergy (as appropriate)
- iv. The team's status should not depend on the outcome of the donor evaluation
- v. The team should have enough medical sophistication and awareness of current center experience and results to explain these adequately to the potential donor.
- vi. The team should be experienced with donor evaluation.
- vii. The team's function is:
 1. to educate the potential donor regarding the potential risks and benefits of donation.
 2. to provide counseling and support for the donor regarding family, disability, intellectual, emotional, or other pressures.
 3. to determine that the donor's decision to donate is voluntary, without coercion from within or outside the transplant center.

4. to provide opportunities for the donor to “opt out” of the procedure without consequences.
- viii. The team members should meet with the donor more than once during the evaluation process, separately from recipient appointments **and without the presence of the recipient.**
- b. Medical evaluation: An attending physician and surgeon should screen all potential donors.
 - c. Psychiatric and Social Screening
 - i. Dedicated ~~medical social worker~~ **mental healthcare professional** familiar with transplantation and living donation should evaluate the potential donor for:
 1. Psychosocial history
 2. relationship between donor and recipient and potential areas where undue pressure or coercion may be applied.
 3. presence of psychiatric disorders. In cases in question, psychiatric or psychologist consultation should be readily available.
 4. the existence of a financial incentive as motivation for the donor.
 5. presence of physical or sexual abuse of the donor in the past or the presence of active substance abuse in the donor.
 - d. Radiologic Evaluation
 - i. Donor should undergo radiologic imaging to establish:
 1. There is adequate donor liver volume to supply a graft of suitable size for the recipient.
 2. There is adequate residual donor liver volume to support the donor in the immediate post-operative period.
 3. Determine the vascular anatomy of the donor liver to ensure maintenance of inflow and outflow in the graft and in the donor residual liver remnant.
 - e. Anesthesia Evaluation
 - i. The potential donor should be evaluated by a staff anesthesiologist experienced in liver **transplant surgical anesthesia** and post-operative pain management **consultation should be available.**

Summary of Public Comments

Proposed Guidelines for Living Liver Donor Evaluation (Item 1 of 2) (Ad Hoc Living Donor Committee)

As of 4/29/2004, 83 responses have been submitted to UNOS regarding this policy proposal. Of these, 37 (44.58%) supported the proposal, 1 (1.20%) opposed the proposal, and 45 (54.22%) had no opinion. Of the 38 who responded with an opinion, 37 (97.37%) supported the proposal and 1 (2.63%) opposed the proposal. Comments on the proposal received to date are as follows:

I: Individuals Comments:

Comment 1:
vote: Support

Proposal 19, 2 e. i. states "The potential donor should be evaluated by a staff anesthesiologist experienced in liver surgical anesthesia and post-operative pain management". The Ad Hoc Committee recommends, "The potential donor should be evaluated by an anesthesiologist experienced in liver transplant anesthesia and post operative pain consultation should be available."

Committee Response: The Committee agreed to make these changes.

Comment 2:
vote: Support

Approve - no comments.

Committee Response: No Committee response

Comment 3:
vote: Support

At this time, many programs do not perform living liver transplants d/t fear of poor outcomes. If this is a practice that is supported by UNOS, by all means there should be UNOS printed guidelines for evaluation of potential candidates.

Committee Response: The Committee agreed.

March 2004

REGIONAL COMMENT SUMMARY

PROPOSAL 19: *Proposed Guidelines for Living Liver Donor Evaluation and Proposed Guidelines for Living Kidney Donor Evaluation. (Ad Hoc Living Donor Committee).*

Sponsoring Committee: Ad Hoc Living Donor Committee

Description: This proposal would establish specific guidelines for potential living liver transplant recipient and donor evaluation, including provisions for an independent donor team, psychiatric and social screening, and appropriate medical, radiologic, and anesthesia evaluation. While these are not being proposed as OPTN/UNOS Policy, the Ad Hoc Living Donor Committee believes that the guidelines could evolve into the standard of practice for living donor evaluation. Guidelines for living kidney donor evaluation are contained in the next proposal in this series.

DATE THIS DOCUMENT MODIFIED: 5/3/04

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (See Below)	Approved by Consensus	Did Not Consider
1	3/22/04	13 yes, 0 no, 0 no opinion			
2	5/7/04	29 yes, 0 no, 2 no opinion			
3	3/26/04	9 yes, 7 no, 1 no opinion			
4	4/2/04	1 yes, 25 no, 3 no opinion			
5	4/30/04	21 yes, 11 no, 1 no opinion, 3 no vote			
6	4/2/04	49 yes, 1 no, 1 no opinion, 2 no vote	45 yes, 6 no, 0 no opinion, 2 no vote		
7	4/23/04	18 yes, 0 no, 0 no opinion			
8	4/02/04	17 yes, 0 no, 0 no opinion			
9	4/21/04	17 yes, 0 no, 0 no opinion			
10	4/30/04	nion			
11	3/26/04	6 yes, 10 no, 4 no opinion			

COMMENTS:

Regions 3 & 11: The members felt that there is no data that supports vii (Team Function), c (Psychiatric and Social Screening) Section 5 (*presence of physical or sexual abuse of the donor in the past or the presence of active substance abuse in the donor*). There was also concern that these guidelines could eventually become policy and that some centers may use them as policy.

Committee response: These are guidelines that will hopefully evolve into the standard of practice for living donor evaluation.

Region 4: The region felt that the intent of the proposed guidelines is understood, but the proposal as written creates a degree of ambiguity regarding the interpretation of “dedicated team” vs. “independent team.” Additionally, the donor anesthesiology evaluation should be performed by anesthesiology personnel that are trained in liver transplantation.

Committee response: Independent team is clearly defined in the text.

Region 5: Although the region approved the proposal, the following concerns were raised:

- The transplant team could ignore the donor teams evaluation and proceed to transplant
- There are no guidelines specific to pediatric patients
- The guidelines need to be more extensive and medically based

Region 6: The Region approved the policy with the following amendments:

- 2. a. iii- 1. *Physician/Surgeon*
- 4. *Strike “(as appropriate)”*
- 5. *Strike “(as appropriate)”*
- 2. a. vii- *These functions should be the responsibility of the Transplant team*
- 2. c. i.- *Strike “medical social worker” and replace with “medical professional”*

Committee response: The Committee Members agreed to the addition to 2.a.iii. They did not agree to strike “as appropriate” because it allowed transplant centers the flexibility in deciding the members of the independent team. They did not agree to the requested change in 2.a.vii because they want these functions to reside with the independent team. There was some concern as to why a medical social worker should be the one required to perform the psychiatric and social screening when there are various individuals in a transplant center who have the qualifications to perform this evaluation. It was decided to replace “medical social worker” with “mental healthcare professional” in order to allow the transplant center some flexibility.

Region 10: The region felt that the intent of the proposed guidelines is understood, but the proposal as written creates a degree of ambiguity regarding the interpretation of “dedicated team” vs. “independent team.” The region also felt that although they understood that these are “guidelines” they would be interpreted as policy by outside entities.

Committee response: Independent team is clearly defined in the text.

Briefing Paper
Proposed Guidelines for Living Kidney Donor Evaluation

Summary

The Ad Hoc Living Donor Committee has proposed guidelines for potential living kidney transplant recipient and donor evaluation, including provisions for an independent donor team, psychiatric and social screening, and appropriate medical, radiologic, and anesthesia evaluation. While these are not being proposed as OPTN/UNOS Policy, the Committee believes that the guidelines could evolve into the standard of practice for living donor evaluation. This briefing paper summarizes the proposal that was circulated for public comment in March 2004, the Committee's responses to the public and regional comments received, and the Committee's final recommendation to the OPTN/UNOS Board of Directors.

Background

The Ad Hoc Living Donor Committee was formed in 2002 and identified "establishing minimum criteria for donor work-up" as a priority for its future work. In September 2002, the Standards and Personnel Subcommittee was established in order to provide recommendations regarding standards for living donor transplant programs, training, and experience guidelines for live donor surgeons, and minimum criteria for donor workup. Having provided criteria for live liver donor transplant programs (By-Laws, Appendix B, approved in November 2003), the Subcommittee began to develop guidelines for living donor and recipient evaluation. In doing so, the Subcommittee considered a report from the New York State Committee on Quality Improvement in Living Liver Donation to the New York State Transplant Council and New York State Department of Health, which included donor medical evaluation criteria, informed consent criteria, and independent donor advocacy structures. A proposed set of guidelines for living liver donor evaluation was initially provided to the Ethics Subcommittee for its consideration; guidelines for living kidney donor evaluation were subsequently drafted using the revised liver guidelines as a template.

Proposed Recipient Evaluation

The guidelines include a section relating to potential living donor candidate evaluation, which specifies the following:

- Potential living donor recipients should derive potential benefit from transplantation.
- Potential living donor recipients should undergo evaluation process similar to deceased donor recipients.
- Potential living donor recipients should not have any absolute exclusionary criteria for liver transplantation at that transplant center.

The original draft of the evaluation guidelines, as reviewed by the Ethics Subcommittee, contained specific exclusionary criteria. The Subcommittee agreed that potential living kidney donor recipients should not have any absolute exclusionary criteria, but discussed whether recipients deemed to be "too well" or had exclusionary criteria from deceased donor transplantation should be considered as potential living donor recipients. The consensus of the full Committee was that the candidate for living donor transplantation should derive benefit from the transplant procedure, and removed the additional exclusionary criteria. The Committee opined that the evaluation of potential living kidney donor recipients may not be identical to that of candidates for deceased donor organs, but that the evaluation should be similar.

Proposed Donor Evaluation

The Personnel and Standards Subcommittee proposed that an independent team be part of the donor evaluation process, as recommended by the New York State Committee and the Advisory Committee on Transplantation (ACOT). The section relating to evaluation of potential living donors specifies that the primary responsibility of the

independent donor team is the well-being of the potential donor. Other key provisions of the donor team are as follows:

- The independent team donor advocate team's status at the transplant center should not be affected by decisions made on behalf of the donor.
- The team should have enough medical sophistication and awareness of current center experience and results to explain these adequately to the potential donor.
- The team should be experienced with donor evaluations.
- The team's function is: to educate the potential donor regarding the potential risks and benefits of donation; to provide counseling and support for the donor regarding family, disability, intellectual, emotional or other pressures; to determine that the donor's decision to donate is voluntary, without coercion from within or outside the transplant center and; to provide opportunities for the donor to "opt out" of the procedure with out consequences.
- The team members should meet with the donor more than once during the evaluation process, separately from recipient appointments.

The proposal also includes recommendations for the potential donor's medical, radiologic, and anesthesia evaluation as well as psychiatric and social screening. There are organ-specific differences in the guidelines for medical and radiologic evaluations for liver versus kidney; for example, the medical evaluation for a potential kidney donor specifies that donor kidney function (i.e., serum creatinine, creatinine clearance, and urine protein excretion) should be tested.

During a conference call on September 10, 2003, the Standards and Personnel Subcommittee also added a section on Psychiatric and Social Screening. These specify that a dedicated medical social worker familiar with transplantation and living donation should evaluate the potential donor for:

- psychosocial history;
- relationship between donor and recipient and potential areas where undue pressure or coercion may be applied;
- presence of psychiatric disorders
- the existence of a financial incentive as motivation for the donor; and
- presence of physical or sexual abuse of the donor in the past or the presence of active substance abuse in the donor.

The Ethics Subcommittee reviewed the guidelines and felt they were ethically appropriate. The full Committee reviewed the guidelines during its October 2003 meeting and gave its approval, with minor modifications.

Policy Proposal

After considering the document and with modifications, the Committee approved the following motion:

***RESOLVED**, that the Living Kidney Donor Evaluation Guidelines shall be circulated for public comment.

Accomplished in one Committee vote: 20 in favor, 0 opposed, 0 abstentions.

Living Kidney Donor Evaluation Guidelines

1. Recipient evaluation

- a. Potential living kidney donor recipients should derive potential benefit from transplantation.
- b. Potential living kidney donor recipients should under go evaluation process similar to deceased donor recipients.

- c. Potential living kidney donor recipients should not have any absolute exclusionary criteria for deceased donor kidney transplantation at that transplant center.

2. Donor Evaluation

a. Independent donor team

- i. Keeps well-being of the donor as paramount responsibility
- ii. At least one member should have no connection with the recipient's medical care or decision-making
- iii. The program has a responsibility to have available to the potential donor an independent donor team that should consist of at least the following:
 - 1. Physician
 - 2. Transplant coordinator/nurse clinician
 - 3. Medical social worker
 - 4. Psychiatrist (as appropriate)
 - 5. Ethicist/Clergy (as appropriate)
- iv. The team's status should not depend on the outcome of the donor evaluation
- v. The team should have enough medical sophistication and awareness of current center experience and results to explain these adequately to the potential donor.
- vi. The team should be experienced with donor evaluation.
- vii. The team's function is:
 - 1. to educate the potential donor regarding the potential risks and benefits of donation.
 - 2. to provide counseling and support for the donor regarding family, disability, intellectual, emotional, or other pressures.
 - 3. to determine that the donor's decision to donate is voluntary, without coercion from within or outside the transplant center.
 - 4. to provide opportunities for the donor to "opt out" of the procedure without consequences.
- viii. The team members should meet with the donor more than once during the evaluation process, separately from recipient appointments.

b. Medical evaluation: An attending physician and surgeon should screen all potential donors.

- i. Donor kidney function should be tested to determine serum creatinine, calculated creatinine clearance, and urine protein excretion.

c. Psychiatric and Social Screening

- i. Dedicated medical social worker familiar with transplantation and living donation should evaluate the potential donor for:
 - 1. Psychosocial history
 - 2. relationship between donor and recipient and potential areas where undue pressure or coercion may be applied.
 - 3. presence of psychiatric disorders. In cases in question, psychiatric or psychologist consultation should be readily available.
 - 4. the existence of a financial incentive as motivation for the donor.
 - 5. presence of physical or sexual abuse of the donor in the past or the

presence of active substance abuse in the donor.

d. Radiologic Evaluation

i. Donor should undergo imaging studies to determine:

1. That there are two kidneys of normal size and appearance; and
2. To outline the renal vascular and urinary drainage anatomy

ii. Donor should undergo assessment of surgical risk.

e. Anesthesia Evaluation

- i. The potential donor should be evaluated by a staff anesthesiologist experienced in renal surgical anesthesia and post-operative pain management.

Public Comment Response

As of April 29, 2004, 83 responses have been submitted to UNOS regarding this policy proposal. Of these, 37 (44.58%) supported the proposal, 1 (1.20%) opposed the proposal, and 45 (54.22%) had no opinion. Of the 38 who responded with an opinion, 37 (97.37%) supported the proposal and 1 (2.63%) opposed the proposal. Of the eight regions that reviewed the guidelines, six were in favor and two were opposed.

One region thought the proposal as written created a degree of ambiguity regarding the “independent team.” The Committee members discussed the concern and the initial rationale for having an independent team was to avoid a conflict of interest. The Committee opined that the term independent team was clearly defined within the text of the proposal.

Another region approved the proposal with the following amendments:

2.a.iii- 1. Physician/Surgeon

4. Strike (as appropriate)

5. Strike (as appropriate)

2.a.vii- These functions should be the responsibility of the Transplant team

2.c.i.- Strike “medical social worker” and replace with “medical professional”

The Committee Members agreed to the addition to 2.a.ii. They did not agree to strike “as appropriate” because it allowed transplant centers the flexibility in deciding the members of the independent team. They did not agree to the requested change in 2.a.vii because they want these functions to reside with the independent team. There was some concern as to why a medical social worker should be the one required to perform the psychiatric and social screening when there are various individuals in a transplant center who have the qualifications to perform this evaluation. It was decided to replace “medical social worker” with “mental healthcare professional” in order to allow the transplant center some flexibility.

There was also a letter submitted by the Association of Transplant Anesthesiologists’ Ad Hoc Committee on Transplant Anesthesia with recommended changes to the guidelines. They wanted to make sure the anesthesiologist was experience in “transplant” anesthesia and that post-operative pain consultation should be available. The Committee agreed these changes were appropriate.

One Committee Member suggested additional information be added to section 2.a.viii. The guidelines state “the team members should meet with the donor more than once during the evaluation process, separately from recipient appointments.” The concern was that the section did not clearly define the meeting be done without the presence of the recipient. The Committee agreed to add this language to avoid confusion.

Final Proposal

Changes the Committee made to the language that was sent out for public comment is delineated by strikethroughs or double underlines and **bolded text**. The Committee submits the following resolution for consideration by the Board of Directors:

*****RESOLVED, that subsequent to the consideration of public comment, the Living Kidney Donor Evaluation Guidelines, as described and amended below, shall be approved and implemented upon completion of programming in the UNOS system.**

Living Kidney Donor Evaluation Guidelines

1. Recipient evaluation

- a. Potential living kidney donor recipients should derive potential benefit from transplantation.
- b. Potential living kidney donor recipients should under go evaluation process similar to deceased donor recipients.
- c. Potential living kidney donor recipients should not have any absolute exclusionary criteria for deceased donor kidney transplantation at that transplant center.

2. Donor Evaluation

a. Independent donor team

- i. Keeps well-being of the donor as paramount responsibility
- ii. At least one member should have no connection with the recipient's medical care or decision-making
- iii. The program has a responsibility to have available to the potential donor an independent donor team that should consist of at least the following:
 1. Physician/Surgeon
 2. Transplant coordinator/nurse clinician
 3. Medical social worker
 4. Psychiatrist (as appropriate)
 5. Ethicist/Clergy (as appropriate)
- iv. The team's status should not depend on the outcome of the donor evaluation
- v. The team should have enough medical sophistication and awareness of current center experience and results to explain these adequately to the potential donor.
- vi. The team should be experienced with donor evaluation.
- vii. The team's function is:
 1. to educate the potential donor regarding the potential risks and benefits of donation.
 2. to provide counseling and support for the donor regarding family, disability, intellectual, emotional, or other pressures.
 3. to determine that the donor's decision to donate is voluntary, without coercion from within or outside the transplant center.
 4. to provide opportunities for the donor to "opt out" of the procedure without consequences.

viii. The team members should meet with the donor more than once during the

evaluation process, separately from recipient appointments and without the presence of the recipient.

b. Medical evaluation: An attending physician and surgeon should screen all potential donors.

i. Donor kidney function should be tested to determine serum creatinine, calculated creatinine clearance, and urine protein excretion.

c. Psychiatric and Social Screening

i. Dedicated ~~medical-social worker~~ mental healthcare professional familiar with transplantation and living donation should evaluate the potential donor for:

1. Psychosocial history
2. relationship between donor and recipient and potential areas where undue pressure or coercion may be applied.
3. presence of psychiatric disorders. In cases in question, psychiatric or psychologist consultation should be readily available.
4. the existence of a financial incentive as motivation for the donor.
5. presence of physical or sexual abuse of the donor in the past or the presence of active substance abuse in the donor.

d. Radiologic Evaluation

i. Donor should undergo imaging studies to determine:

1. That there are two kidneys of normal size and appearance; and
2. To outline the renal vascular and urinary drainage anatomy

ii. Donor should undergo assessment of surgical risk.

e. Anesthesia Evaluation

i. The potential donor should be evaluated by a staff anesthesiologist experienced in renal transplant ~~surgical~~ anesthesia and post-operative pain management consultation should be available.

Summary of Public Comments

Proposed Guidelines for Living Kidney Donor Evaluation (Item 2 of 2) (Ad Hoc Living Donor Committee)

As of 4/29/2004, 83 responses have been submitted to UNOS regarding this policy proposal. Of these, 32 (38.55%) supported the proposal, 7 (8.43%) opposed the proposal, and 44 (53.01%) had no opinion. Of the 39 who responded with an opinion, 32 (82.05%) supported the proposal and 7 (17.95%) opposed the proposal. Comments on the proposal received to date are as follows:

I: Individuals Comments:

Comment 1:
vote: Oppose

We oppose this proposal as stated. What does "independent" mean? Who can best evaluate living donors for transplant but physicians who are knowledgeable in transplantation. Sending potential donors to physicians with little working knowledge of organ donation and transplantation exposes the donor to decisions based upon limited knowledge of clinical transplantation practice.

Committee Response: The term independent team is clearly defined in the text.

Comment 2:
vote: Support

Approve - no comments.

Committee Response: No committee response

Comment 3:
vote: Support

I feel that even though an evaluation was performed for my living donor that the evaluation process seemed to be lacking in consistency. Everyone knew that the evaluation process was required. However, I feel that an outcomes guideline would have been very helpful for everyone involved including the donor and recipient of the kidney.

Committee Response: No Committee response

Comment 4:
vote: Support

Need to spell out what is involved in surgical risk and whether or not person is suitable candidate for scope vs. open procedure. the independent advocate is key and does not need to be an MD. Nurses can fill this role just as a case manager with QI experience. Need to address who on the team is responsible for reporting outcomes to UNOS

Committee Response: Educating patients on surgical risks and options should already be a standard practice. Outcomes are addressed in the follow-up forms.

Comment 5:
vote: Support

Proposal 20, 2 e. i. states "The potential donor should be evaluated by a staff anesthesiologist experienced in renal surgical anesthesia and post-operative pain management." The Ad Hoc Committee then recommends, "The potential donor should be evaluated by an anesthesiologist experienced in renal transplant anesthesia and post operative pain consultation should be available."

Committee Response: The Committee agreed to make these changes.

Comment 6:
vote: Support

See my comments in 19.

March 2004

REGIONAL COMMENT SUMMARY

PROPOSAL 20: Proposed Guidelines for Living Kidney Donor Evaluation (Item 2 of 2) (Ad Hoc Living Donor Committee)

Sponsoring Committee: Ad Hoc Living Donor Committee

Description: This proposal would establish specific guidelines for potential living liver transplant recipient and donor evaluation, including provisions for an independent donor team, psychiatric and social screening, and appropriate medical, radiologic, and anesthesia evaluation. While these are not being proposed as OPTN/UNOS Policy, the Ad Hoc Living Donor Committee believes that the guidelines could evolve into the standard of practice for living donor evaluation.

DATE THIS DOCUMENT MODIFIED: 5/3/04

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (See Below)	Approved by Consensus	Did Not Consider
1	3/22/04	13 yes, 0 no, 0 no opinion			
2	5/7/04	30 yes, 1 no, 0 no opinion			
3	3/26/04	9 yes, 7 no, 1 no opinion			
4	4/2/04	1 yes, 25 no, 3 no opinion			
5	4/30/04	20 yes, 11 no, 2 no opinion, 3 no vote			
6	4/2/04	49 yes, 1 no, 1 no opinion, 2 no vote	45 yes, 6 no, 0 no opinion, 2 no vote		
7	4/23/04	18 yes, 0 no, 0 no opinion			
8	4/02/04	17 yes, 0 no, 0 no opinion			
9	4/21/04	17 yes, 0 no, 0 no opinion			
10	4/30/04	inion			
11	3/26/04	6 yes, 10 no, 4 no opinion			

COMMENTS:

Regions 3 & 11: The members felt that there is no data that supports vii (Team Function), c (Psychiatric and Social Screening) Section 5 (*presence of physical or sexual abuse of the donor in the past or the presence of active substance abuse in the donor*). There was also concern from some Region 11 Members that these guidelines could eventually become policy.

Committee response: These are guidelines that will hopefully evolve into the standard of practice for living donor evaluation.

Region 4: The region felt that the intent of the proposed guidelines is understood, but the proposal as written creates a degree of ambiguity regarding the interpretation of “dedicated team” vs. “independent team.”

Additionally, the donor anesthesiology evaluation should be performed by anesthesiology personnel that are trained in renal transplantation.

Committee response: Independent team is clearly defined in the text.

Region 6: The Region approved the policy with the following amendments:

- 2. a. iii- 1. *Physician/Surgeon*
- 4. *Strike "(as appropriate)"*
- 5. *Strike "(as appropriate)"*
- 2. a. vii- *These functions should be the responsibility of the Transplant team*
- 2. c. i.- *Strike "medical social worker" and replace with "medical professional"*

Committee response: The Committee Members agreed to the addition to 2.a.iii. They did not agree to strike "as appropriate" because it allowed transplant centers the flexibility in deciding the members of the independent team. They did not agree to the requested change in 2.a.v.ii because they want these functions to reside with the independent team. There was some concern as to why a medical social worker should be the one required to perform the psychiatric and social screening when there are various individuals in a transplant center who have the qualifications to perform this evaluation. It was decided to replace "medical social worker" with "mental healthcare professional" in order to allow the transplant center some flexibility.

Region 10: The region felt that the intent of the proposed guidelines is understood, but the proposal as written creates a degree of ambiguity regarding the interpretation of "dedicated team" vs. "independent team." The region also felt that although they understood that these are "guidelines" they would be interpreted as policy by outside entities

Committee response: Independent team is clearly defined in the text.

A PROPOSAL TO INCREASE ORGAN DONATION
SUBMITTED BY THE
UNITED NETWORK FOR ORGAN SHARING

For many years there has been a shortage of organ donation relative to the growth of the waiting list of persons with end stage diseases who can only be treated by organ transplantation. The list now exceeds 82,000 people, with more than 55,000 suffering end stage renal disease. While the list has more than doubled in the past decade, the only significant increase in organ donation has come from the growth in donations from living donors, almost all of whom are kidney donors. Even so, the gap between needy patients and available organs continues to widen, and unnecessary barriers to living organ donation exist.

UNOS therefore proposes that Congress promptly enact two initiatives.

First, provision should be made for the Federal Government to reimburse up to one month's wages lost by living donors, especially low-income donors. If the donor uses sick leave to cover his/her lost wages, then compensation should still be made.

Second, living donation should become a covered event under the provisions of the Family and Medical Leave Act (FMLA), which guarantees uncompensated time off from employment for certain family and medical situations. This provision should also provide that compensation equal to that paid the donor shall be made to the employer for loss of the employee during the donation and recovery period.

Taken together, and assuming an employee annual salary of \$40,000.00, the cost to the Federal government under this plan would average less than \$6,800.00 per eligible donor, while the Government would save about \$281,000.00 per new living donor.

There are many reasons to remove barriers to living organ donation. In terms of patient benefits, statistics show that organs donated by living donors function better and last longer after transplant, thus eliminating or postponing the recipient's return to the wait list. Further, the recipient receives the transplant before he/she suffers the debilitating effects of many years of dialysis and the inevitable progression of his/her disease. For example, for diabetic patients, who often suffer from ESRD, this can often mean avoidance of such disease-related problems as blindness, loss of limbs, and the failure of other organ systems. Additionally, each instance of living donation makes available to the general waiting list an organ that otherwise would have gone to the living donor recipient, thus stretching the availability of organs from deceased donors.

The financial benefits of enactment of these proposals would be enormous for Medicare. Dialysis and its related costs are covered by Medicare for all ESRD patients. These costs have been estimated by UNOS to be about \$72,000.00 per year for each

patient. The current median waiting time from listing (at the stage of their disease where dialysis becomes necessary) to transplantation for ESRD patients on the wait list now exceeds 4 years. Thus, Medicare pays an average of \$288,000.00 in dialysis-related costs alone for each of the 55,000 ESRD patients while they languish on the list. However, for ESRD patients who are able to secure a living donor kidney, transplantation usually comes at the stage of their disease where they would have to start dialysis and there is no dialysis-related cost to Medicare.

Put simply, on average, Medicare avoids about \$288,000.00 in outlays for every living kidney donor transplant. Significant additional savings also accrue to the Federal and state governments, such as from the return of many of these patients to full time employment, avoidance of SSI claims, avoidance of unemployment claims and other Medicaid and welfare costs, etc.

Obviously, it is extremely desirable to encourage people to become living organ donors. Unfortunately, there are instances in which a candidate who is willing to be a living donor is precluded from doing so because of financial inability to sustain a month of lost wages. This is particularly true in areas where the population earns relatively lower incomes. Even for potential donors who can weather the loss of wages, there is often an inability to leave the workplace for the time necessary for donation and recovery without losing his/her job.

While the number of such willing but unable donors is not possible to calculate with precision, a number of transplant centers have given estimates to UNOS that removing these two barriers to donation could increase living donors in the range of ten to twenty percent. In 2002 there were more than 6,600 living donors. This would suggest that the total number of living donors could potentially increase by an additional 660 to 1320 donors if lost income were compensated and time off from work guaranteed. It should be noted that while these are best estimates, they do not need to be exact to support the UNOS proposal. If the estimated number of additional living donors turns out to be greater than estimated, then the savings to Medicare will be greater than estimated. If it turns out to be fewer, Medicare still saves an enormous amount. If there is not a single additional donor, then there are no savings but neither are there any costs because a person must donate to be eligible for these benefits. It is a win-only posture for Medicare.

While this proposal is necessarily based in part on estimated values, the impact of enactment by Congress is undeniable. UNOS would be happy to discuss this proposal and urges its immediate consideration.