

**AMENDED Recommendations of the
OPTN/UNOS Living Donor Committee to the
Board of Directors
November 8-9, 2010
St. Louis, MO**

Summary

I. Action Items For Board Consideration

- The Board of Directors is asked to approve new Policies 12.8.5 (Reporting of Non-utilized Living Donor Organs) and 12.8.6 (Reporting of Redirected Living Donor Organs). These policies would require the organ recovery center to report all instances of living donor organs recovered but not utilized for transplant, and living donor organs recovered but then redirected and transplanted into a recipient other than the intended recipient through the Patient Safety System. This proposal was circulated for public comment, all comments were reviewed, and the proposal is recommended for Board consideration. (Item 1, Page 3)

- The Board of Directors is asked to approve new Policy 12.5.6 (Placement of Non-Directed Living Donor Kidneys). This policy would establish procedures for the placement of non-directed living donor kidneys. Under the proposal, transplant centers would select the recipient of non-directed living donor kidneys based on a list generated by the OPTN computer system used to identify potential recipients for transplant. This proposal was circulated for public comment, all comments were reviewed, and the proposal is recommended for Board consideration. (Item 2, Page 5)

II. Other Significant Items

- None

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**Connie Davis, MD, Chair
Amy Waterman, PhD, Vice Chair**

The following amended report represents the selected recommendation of the Living Donor Committee to the Board of Directors.

I. Action Items for Board Consideration

1. Proposal to Require Reporting of Non-utilized and Redirected Living Donor Organs.

A transplant center recently reported a situation where a living donor kidney was recovered, but the organ was too damaged during the surgery to be transplanted. The center self-reported the case through the Patient Safety System as a Living Donor Adverse Event. Current OPTN policy does not require a transplant center to report that a living donor kidney could not be utilized.

Upon notification of this case, the Living Donor Committee questioned how frequently living donor organs are recovered and then discarded or transplanted into a recipient other than the intended recipient, and if these events should be reported to the OPTN. Based on the experience of the transplant professionals serving on the Committee, the Committee identified some possible causes of these instances during its deliberations, including but not limited to:

- Accidental damage to the living donor organ during or after recovery;
- Unanticipated medical condition in the living donor organ after recovery;
- Sudden change in the health status of the intended recipient preventing transplant;
- Death of the intended recipient;
- Transportation failures (mechanical problems, flight delays or cancellations);
- Packaging errors;
- Human error; and
- Inclement weather.

After considering this issue, the Committee recommended that reporting requirements should be expanded to include all instances of 1) living donor organs recovered but not utilized for transplant and 2) living donor organs recovered but then redirected and transplanted into a recipient other than the intended recipient.

During the development of this proposal, the Operations and Safety Committee was asked to comment on the issue of reporting non-utilized and/or redirected living donor organs to the OPTN. The Operations and Safety Committee commented that the issue of surgical damage to recovered organs remains largely unexplored. In addition to creating a new policy, clear communication with members about the types of instances that need to be reported is necessary. Without this additional communication, it is unlikely that the majority of these instances will be reported correctly. A benefit of reporting these events is that the information collected will be used to improve patient safety and system efficiency.

The Committee considered several options for the reporting of non-utilized and redirected living donor organs. The first option was to record these events through the Patient Safety System by expanding the type of adverse event reporting required under Policy 12.8.4 (Submission of Living Donor Death and Organ Failure) to include non-utilized and/or redirected living donor organs. Policy 12.8.4 requires the reporting of major health complications (death and loss of native organ function) in living donors for a period of two years. These major health complications are distinct from the issues of discarding living donor organs or transplantation of a living donor's organ into a recipient other than the intended recipient because they are longer-term. The issues of concern in this proposal are different because they occur immediately in the post-operative period. The transplant professionals responsible for the care of the living donor during the post-operative period and longer term may be different and so these instances would be better addressed under a distinct policy. Consequently, the Committee did not support modification of Policy 12.8.4 to require reporting of non-utilized or redirected living donor organs.

The non-utilization or redirection of a living donor organ is a type of adverse event that could impact the psychological, psychosocial, and short and long term health of the living donor and his or her intended recipient. The Committee preferred that reporting requirements for both types of events be addressed under separate and specific policies. As such, the Committee is proposing that both events be considered as two new categories of adverse events captured through the Patient Safety System. Under the proposal, if a living donor organ is reported as non-utilized or redirected in the Patient Safety System, the system will generate a list of possible reasons why the event occurred. The user reporting the event will also have the option of providing a written description of the event.

Currently, the OPTN does not collect data to determine the number of living donor organs recovered but not utilized or when living donor organs are recovered but not ultimately transplanted into the intended recipient. In the unfortunate circumstance of non-utilization or redirection of a living donor organ, the donor experiences risk and their intended recipient receives no benefit from transplantation. Collecting this data will help quantify the risk associated with living donor transplantation, and is information that should be provided to potential living donors as a component of the consent process.

This proposal was released for public comment between March 19, 2010, and July 16, 2010. The Committee considered all public comments received on the proposal at its September 13, 2010, meeting. Overall, there was strong support for the proposal. All regions supported the proposal, and all other Committees providing comments approved the proposal. All comments are provided in the mini brief. (**Exhibit A**). The Resource Assessment and Impact Statement for this proposal can be found in **Exhibit B**.

The Committee approved the final version to be considered by the Board. Committee vote: 25-0-0

**** RESOLVED, that new Policies 12.8.5 (Reporting of Non-utilized Living Donor Organs) and 12.8.6 (Reporting of Redirected Living Donor Organs) set forth below, are hereby approved, effective pending distribution of notice:**

12.8.5 Reporting of Non-utilized Living Donor Organs. The organ recovery center must report all instances of living donor organs recovered but not transplanted and all instances of living donor organs recovered but redirected and not ultimately transplanted to the intended recipient. Transplant centers must report these incidents through the UNeTSM Patient Safety System within 72 hours of organ recovery. The Membership and Professional Standards Committee will review and report all cases of non-utilized and redirected living donor organs to the Board of Directors.

12.8.6 Submission Reporting of Redirected Living Donor Organs. If a living donor organ is ultimately transplanted to a recipient other than the intended recipient, then all required donor and recipient information must still be submitted reported through Tiedi[®]. The Membership and Professional Standards Committee will review and report all cases of redirected living donor organs to the Board of Directors.

2. Proposal for the Placement of Non-Directed Living Donor Kidneys

Currently, there is no existing to direct the placement of organs from non-directed living donors. Due to the infrequency of non-directed liver and lung donation, the Living Donor Committee is proposing a policy limited to living kidney donors at this time. Additionally, the current proposal will not apply to non-directed living kidney donors who consent to participate in a Kidney Paired Donation arrangement. Based on available information, the Committee understands that the transplant center providing the non-directed living donor evaluation typically also selects the recipient when donation occurs.

As one of its 2007-2008 goals, the Committee was asked to consider if components of the Ethics Committee white paper titled Living Non-Directed Organ Donation (2004) should become policy. The white paper proposed “*that non-directed organs from living donors be allocated according to the existing algorithm governing the allocation of cadaveric organs within the appropriate sharing unit,*” and is available for review at <http://www.unos.org/resources/bioethics.asp>.

The Ethics Committee white paper was published prior to the 2006 federal regulation that directed the OPTN to develop policies for the equitable allocation of living donor organs. The Committee determined that policies for the placement of non-directed living donor organs were needed, and considered whether those policies should be based on the existing algorithm used to direct allocation of deceased donor organs.

Over the past several years, the Committee worked to develop an evidence based policy proposal to direct the placement of non-directed living kidney donors. Work on this policy issue was complicated and the Committee struggled with the following issues:

- Does the provision and financing of the medical evaluation of a potential living kidney donor entitle a transplant center to direct placement of that kidney?
- Should non-directed living donor kidneys be offered to the best candidates on a local, regional or even national level?

The Committee reviewed studies on the effects of cold ischemia time on living donor kidneys and did not find that the biological risk to the organ was great enough to warrant limitation to the recovery center. However, there is a small but increased risk of damage or loss of a living donor kidney if transported outside of the organ recovery center. Therefore, the Committee determined that placement at the evaluating and recovery center is appropriate.

Due to the high cost associated with evaluating a potential living kidney donor (estimated at \$15,000 to \$25,000 by Committee members familiar with the evaluation of living donors), the Committee ultimately supported allowing the center that evaluates a non-directed living kidney donor to place that kidney with one of its own candidates on the waiting list. Additionally, the Committee is

proposing that the placement of non-directed living donor kidneys be based on the existing algorithm used for allocation of deceased donor organs. In developing this recommendation, the Committee considered the small but increased risk of damage or loss of a living donor kidney if transported outside the organ recovery center.

The proposal will not affect how transplant centers select, evaluate and/or approves potential non-directed living kidney donors. When a transplant center approves a non-directed living kidney donor for donation, the center would continue to add donor information in UNetsm with the Living Donor Feedback Form in Tiedi[®] to obtain a donor identification (ID) number.

This proposed policy outlines the following process for placement of a kidney from a non-directed living kidney donor:

- The transplant center will contact the Organ Center to request a match for a non-directed living kidney donor;
- The transplant program will complete and return a form to the Organ Center with the following required donor information:
 - the donor ID
 - ABO testing, including two separate verifications and supporting documentation
 - HLA typing with supporting documentation
 - donor height and weight
 - serological testing (Anti-HCV, Anti-HBcAb, and optional Anti-HTLV 1/II)
 - history of hypertension or diabetes
- The Organ Center will update the donor's record in DonorNet[®] with the data required for the match run;
- The transplant center will be asked to verify all information that will be used for the match run;
- If verified, the Organ Center will complete the match run to generate the match ID;
- The Organ Center will close the match at zero, and forward the Match ID to the Transplant Center (closing the match at zero, will prevent the match from appearing on any reports generated by the Organ Procurement Organization);
- The transplant center will use the Match ID to access a list of potential recipients on its waitlist;
- The center will select a recipient from its waitlist candidates to receive the non-directed living donor kidney; and
- If the center deviates from the match run, it must document the criteria used to direct placement of the kidney, and make the documentation available if requested by the OPTN contractor.

The Committee recognizes that some transplant centers work with a local OPO to match non-directed living kidney donors and recipients. In such cases, the transplant center may obtain the match run of its waitlist candidates from the OPO. Transplant centers, that do not work with an OPO to match non-directed kidney donors with potential recipients will not have the ability to generate a match run of their wait list candidates, and consequently would be required to use the Organ Center. The Committee would support possible future enhancements to DonorNet[®] to permit transplant centers to complete match runs of their own waitlist candidates.

An overarching goal of the policy proposal is that a match run is generated and followed for the placement of all non-directed living donor kidneys. The current matching system used for deceased organ donors was designed to improve patient safety. The system checks for donor/recipient compatibility. Using a match run can improve patient safety by increasing the likelihood that the donor and recipient are truly compatible.

The Committee understands that medical judgment is an important factor in selecting the most appropriate candidate to receive a non-directed living donor kidney. Therefore, the policy proposal permits a center to direct a non-directed living donor kidney to a candidate who may not appear first on the center's match run. If the center deviates from the match run, it must document the criteria for this decision. This policy proposal requires that the center maintain such documentation and that the documentation be made available to the OPTN Contractor if requested. The intent of the proposal is that such documentation will only be requested should there be a need to investigate the placement of a non-directed living donor organ.

During the early development of the policy proposal, the Committee asked the Policy Oversight Committee to review and comment on components of the proposal on three separate occasions. The Policy Oversight Committee interpreted the proposal as a recommendation for transplant centers to obtain a match run of their waitlist candidates and that the non-directed kidney would be placed according to the match run, thus allowing the OPTN contractor to verify the non-directed living donor kidney was directed to the most appropriate waitlist candidate. The Committee also sought comment on whether these organs should be offered to the best match at the local, regional or national level.

When the Policy Oversight Committee considered the proposal there were 511 non-directed living donors in the OPTN database. The Policy Oversight Committee commented that 1) the number of non-directed donors could increase with kidney paired donation, 2) we have a fair and equitable national allocation system and should want to ensure fair allocation for non-directed donation, 3) if a person makes a non-directed donation to a center, that act may take the decision out of the realm of the national policy.

During the development of this policy proposal the American Society of Transplant Surgeons (ASTS) Ad Hoc Committee on Living Donation issued a statement regarding the placement of non-directed living donor organs which is similar in scope and intent to this proposal. **(Exhibit C)**

When this proposal was released for public comment it contained a Monitoring and Evaluation Plan that included information on Future Monitoring Efforts which read as follows:

Once programming is complete and centers are able to run their own match runs, DEQ will monitor all living donor match runs that resulted in a transplant. To ensure equitable allocation, DEQ will verify that the center evaluated the available organ according to the sequential printout of the match for each potential transplant recipient. DEQ will also verify that all candidates appearing before the actual recipient of the organ are documented with an appropriate refusal code. The match run must show acceptance to the candidate for whom the organ is ultimately accepted. All potential policy violations identified will be sent to the MPSC for review.

The Committee requests that this plan not be considered in any action the Board of Directors may take on this proposal.

The Board is asked to consider the following updated monitoring plan in any action it may take on this proposal:

DEQ will monitor for the presence of match run documentation and documentation of justification for deviations during on-site and desk reviews.

All potential policy violations identified will be sent to the MPSC for review.

This proposal was released for public comment between March 19, 2010, and July 16, 2010. The Committee considered all public comments received on the proposal at its September 13, 2010, meeting. Responses from the general public were mixed, and those in opposition generally wanted all non-directed kidney donors to participate in kidney paired donation systems. All comments are provided in the briefing paper (**Exhibit D**). One respondent questioned if the match run would give different results for donors greater than 60 years of age. In response the Committee requested additional testing of the proposed system, and results of the testing are provided in **Exhibit E**. The Resource Assessment and Impact Statement for this proposal can be found in **Exhibit F**.

The Committee approved the final version to be considered by the Board. Committee vote: 25-0-0

**** RESOLVED, that a new Policy 12.5.6 (Placement of Non-Directed Living Donor Kidneys) set forth below, is hereby approved, effective pending distribution of notice:**

12.5.6 Placement of Non-directed Living Donor Organs

Prior to determining the placement of a non-directed living donor kidney, the transplant center must acquire a match run of its waitlist candidates. The transplant center may obtain the match run from its local OPO or the Organ Center of the OPTN Contractor. The transplant center must document the ~~eriteria~~ rationale used to place the non-directed living donor kidney. If the transplant center deviates from the sequence defined by the match run, the transplant center must document its rationale for not following the match run in addition to documenting the criteria used to select the kidney recipient. This documentation must be maintained and made available to the OPTN contractor upon request. This policy does not apply to non-directed living kidney donors who consent to participate in a Kidney Paired Donation arrangement.