At-a-Glance

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

- **New Proposed Policies: Reporting of Non-utilized Living Donor Organs (Policy 12.8.5) and Reporting of Redirected Living Donor Organs (Policy 12.8.6)**

- **Living Donor Committee**

  These proposals require that the organ recovery center report all instances of:
  - living donor organs recovered but not utilized for transplant;
  - living donor organs recovered but then redirected and transplanted into a recipient other than the intended recipient.

  These events would be reported through the UNet[SM] Patient Safety System. If a living donor organ is transplanted into a recipient other than the intended recipient, all required donor and recipient information must still be submitted through Teidi.

- **Affected Groups**

  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  PR/Public Education Staff
  Transplant Program Directors
  Transplant Social Workers
  Transplant Coordinators
  Independent Donor Advocates
  Organ Recipients
  Organ Candidates
  Living Donors
  Donor Family Members
  General Public

- **Specific Requests for Comment**

  The Living Donor Committee welcomes feedback on all aspects of this proposal.

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

New Proposed Policies: Reporting of Non-utilized Living Donor Organs (Policy 12.8.5) and Reporting of Redirected Living Donor Organs (Policy 12.8.6)

Living Donor Committee

Summary and Goals of the Proposal:

These proposals require that the organ recovery center report all instances of:

- living donor organs recovered but not utilized for transplant;
- living donor organs recovered but then redirected and transplanted into a recipient other than the intended recipient.

These events would be reported through the UNet[SM] Patient Safety System[1]. If a living donor organ is transplanted into a recipient other than the intended recipient, all required donor and recipient information must still be submitted through Tiedi[2].

Background and Significance of the Proposal:

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 UNet[SM] 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 OPTN/UNOS Living Donor Committee (the 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;

[1]UNeT stands for 'UNOS network' and is an umbrella term for a set of related software applications, each dealing with a specific part of organ transplantation. The Patient Safety System is a centralized tool for reporting possible/known donor transmitted diseases, medical conditions, malignancies, and other patient safety or organ placement concerns.

[2]TIEDI stands for Transplant Information Electronic Data Interchange. TIEDI is the OPTN data entry system for transplant centers, histocompatibility labs and organ procurement organizations across the country.

- 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 and UNOS staff considered several options for the reporting of non-utilized and redirected living donor organs. The first option was to record these events through the UNet^{SM} 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 UNet^{SM} Patient Safety System. Under the proposal, if a living donor organ is reported as non-utilized or redirected in the UNet^{SM} 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. Surgery to remove an organ from a living donor subjects that donor to risk. Living donors weigh the risk of donation against the benefit their intended recipient would receive from transplantation. 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.

Supporting Evidence:

To date, the Committee is aware of this single case of a non-utilized living donor organ reported through the Patient Safety System. Under current reporting requirements, there is not an immediate way to determine when a living donor organ is recovered and not ultimately transplanted into the intended recipient.

The Committee believes there is a risk associated with the transport of living donor organs that may contribute to the non-utilization or redirection of living donor organs. The Committee based its concerns on the current level of transportation failures seen in the transport of deceased donor organs.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

The Final Rule states, "nothing shall prohibit a transplant program from transplanting an organ into any medically suitable candidate if to do otherwise would result in the organ not being used for transplantation. The transplant program shall notify the OPTN (and the OPO which made the organ offer) of the circumstances justifying each such action within such time as the OPTN may prescribe[3]."

- Patient Safety
    - The proposed policy would help identify risks associated with living organ donation and promote awareness at organ recovery centers to provide safe, high-quality care for living donors.

- Best Use
    - The proposed policy will help ensure the best use of living donor organs. New reporting requirements under the proposed policy would contribute to the refinement of OPTN policies by incorporating objective, measurable criteria related to concepts of donor risk/quality and recipient benefit.

- Operational Effectiveness
    - The proposed policy modification would help determine the incidence of non-utilized and redirected living donor organs, assist the OPTN with identifying process and system improvements that best support critical transplant network functions, and work to disseminate them to members who would benefit.

[3] **ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN) FINAL RULE AS REVISED BY AMENDMENTS.** October 20, 1999. § 121.7 Identification of organ recipient. (e)

Plan for Evaluating the Proposal:

The Committee will monitor the total number of cases of non- utilized and redirected living donor organs reported through the Patient Safety System. Details of individual cases reported through the Patient Safety System will be reviewed by the Membership and Professional Standards Committee and reported to the OPTN/UNOS Board of Directors.

Additional Data Collection:

Under the proposal, additional data collection would be required. The organ recovery center would be required to report through the UNeT^{sm} Patient Safety System, all instances of living donor organs recovered but not utilized and all instances of living donor organs recovered but redirected and not ultimately transplanted into the intended recipient. If a living donor organ is ultimately transplanted into a recipient other than the intended recipient, then all required donor and recipient information still must be submitted through Tiedi.

The proposal meets the following data collection principles:

- Develop transplant, donation, and allocation policies
- Determine member-specific performance
- Ensure patient safety when no alternative sources of data exist
- Fulfill the requirements of the OPTN Final Rule

Expected Implementation Plan:

Based on public comment, these proposed new policies may be considered by the OPTN/UNOS Board of Directors at its November 8-9, 2010 meeting. If considered and approved by the Board, the policies would become effective at some future date dependent on when required programming could be completed.

Communication and Education Plan:

Communication Activities			
Type of Communication	**Audience(s)**	**Delivery Method(s)**	**Timeframe**
Policy Notice	Transplant Administrators Transplant Data Coordinators Transplant Physicians/Surgeons PR/Public Education Staff Transplant Program Directors Transplant Social Workers Transplant Coordinators Independent Donor Advocates Organ Recipients Organ Candidates	E-mail	30 days after Board approval

	Living Donors Donor Family Members General Public Members		

Monitoring and Evaluation:

The UNOS Department of Evaluation and Quality (DEQ) staff will evaluate member compliance with the Policy.

How members are expected to comply:

The DEQ will investigate reported occurrences during on-site and desk reviews.

Policy or Bylaw Proposal:

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 UNeT^{SM} 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 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 through Tiedi. The Membership and Professional Standards Committee will review and report all cases of redirected living donor organs to the Board of Directors.