

## ***At-a-Glance***

### **Proposal to Require the Reporting of Aborted Living Donor Organ Recovery Procedures**

- **Affected/Proposed Policy Proposed New or Modified Policies:** Policy 18.5. (Living Donor); Policy 18.5.A (Reporting Requirements after Donation); Policy 18.5.B (Submission of Living Donor Death and Organ Failure); Policy 18.5.C (Reporting of Non-transplanted Living Donor Organs); 18.5.D (Reporting of Living Donor Organs Not Transplanted in the Intended Recipient); 18.6. (Reporting of Living Donor Adverse Events)

- **Living Donor Committee**

Promoting patient safety is a critical component of the OPTN's mission. The OPTN seeks to protect the safety of transplant candidates, recipients, and living donors, but living donors are unique in that they put themselves at risk without any potential benefit to their own health. Due to a variety of reasons, including last minute recipient or donor health problems and unforeseen donor anatomy issues, living donor organ recovery procedures occasionally need to be aborted after anesthesia has been administered, but before the recovery of the organ. Monitoring the safety of these prospective donors is an important part of the OPTN's goal of promoting living donor safety.

The OPTN relies on the UNet<sup>SM</sup> Improving Patient Safety Portal for notification of patient safety concerns and living donor adverse events. Under this proposal, an aborted living donor organ recovery procedure would become a new category of living donor adverse event that recovery hospitals would need to report through the UNet<sup>SM</sup> Improving Patient Safety Portal. Additionally, the proposal would clarify current living donor adverse event reporting requirements by eliminating some redundant sections of policy.

#### **Affected Groups**

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

- **Number of Potential Candidates Affected**

The proposal would apply to all potential living donors who receive anesthesia for an organ recovery procedure. In 2012, there were 5867 living donor organ donors.

- **Compliance with OPTN Strategic Plan and Final Rule**

The proposal meets strategic plan goals as it will:

- Improve patient safety through promotion of safe, high-quality care for living donors
- Improve compliance through clarification of the policies in order to protect patient safety and preserve public trust.

- **Specific Requests for Comment**

Please provide any specific reason why aborted living donor organ recovery procedures should **not** be reported to the OPTN through the UNet<sup>SM</sup> Improving Patient Safety Portal.

## **Proposal to Require the Reporting of Aborted Living Donor Organ Recovery Procedures**

**Proposed New or Modified Policies:** Policy 18.5. (Living Donor); Policy 18.5.A (Reporting Requirements after Donation); Policy 18.5.B (Submission of Living Donor Death and Organ Failure); Policy 18.5.C (Reporting of Non-transplanted Living Donor Organs); 18.5.D (Reporting of Living Donor Organs Not Transplanted in the Intended Recipient); 18.6. (Reporting of Living Donor Adverse Events)

### **Living Donor Committee**

**Public comment response period:** March 14 – June 13, 2014

### **Summary and Goals of the Proposal**

Promoting patient safety is a critical component of the OPTN's mission. The OPTN seeks to protect the safety of transplant candidates, recipients, and living donors, but living donors are unique in that they put themselves at risk without any potential benefit to their own health. Due to a variety of reasons, including last minute recipient or donor health problems and unforeseen donor anatomy issues, living donor organ recovery procedures occasionally need to be aborted after anesthesia has been administered, but before the recovery of the organ. Monitoring the safety of these prospective donors is an important part of the OPTN's goal of promoting living donor safety.

The OPTN relies on the UNet<sup>SM</sup> Improving Patient Safety Portal for notification of patient safety concerns and living donor adverse events. Under this proposal, an aborted living donor organ recovery procedure would become a new category of living donor adverse event that recovery hospitals would need to report through the UNet<sup>SM</sup> Improving Patient Safety Portal. Additionally, the proposal would clarify current living donor adverse event reporting requirements by eliminating some redundant sections of policy.

### **Background and Significance of the Proposal**

Beginning in 2006, OPTN policy required members to report living donor adverse events for two years post-donation if one of the following events occurs:

- A living donor dies
- A living liver donor is listed on the liver waitlist
- A living kidney donor is listed on the kidney waitlist or begins dialysis

In 2010, the living donor adverse event reporting requirements were expanded to include the following events:

- A living donor organ is recovered, but not transplanted
- A living donor organ is recovered and transplanted into someone other than the intended recipient

These categories of living donor adverse events currently must be reported through the UNet<sup>SM</sup> Improving Patient Safety Portal.

In July 2013, the Living Donor Committee (the Committee) received a request to consider whether aborted living donor organ recovery procedures should be a new type of living donor adverse event and reported to the OPTN through the UNet<sup>SM</sup> Improving Patient Safety Portal. A potential living donor's medical evaluation and surgery to recover an organ expose 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 an aborted living donor organ recovery procedure, the donor experiences risk, but their intended recipient receives no benefit from transplantation. Collecting this safety information will help quantify the risk associated with living donation and provide information that potential living donors need as a component of the informed consent process. Although these prospective donors do not meet the OPTN's definition of living donor (i.e., they have not had an organ recovered for the purpose of transplant), they have put themselves at risk by receiving anesthesia for the purpose of donating an organ, and the Committee believes that the OPTN should monitor these events.

During this same time period, the Committee was aware of media reports on a series of aborted living donor organ recovery procedures at a member program occurring between 2008 through 2010. The aborted procedures were primarily related to intraoperative bleeding.

The Committee questioned if aborted living donor organ recovery procedures were reported to the OPTN, and if so, how the OPTN handles these events. The Committee was informed that the Living Donor Feedback form must be submitted to the OPTN contractor prior to any living donor organ recovery procedure, and that the form contains a question addressing if the recovery procedure was aborted after the donor received anesthesia. The Committee questioned if aborted living donor recovery procedures could be under-reported because reporting an aborted procedure requires revising the Living Donor Feedback form post operatively, which could fail to occur.

The Committee understands that there may be many mitigating circumstances that explain why an aborted living donor organ recovery procedure could occur, including unanticipated anatomy or health problems with the potential donor or intended organ recipient, which could create a need to discontinue the donation surgery. An aborted living donor organ recovery procedure does not necessarily reflect poorly on a recovery hospital. The Committee expects that aborted living donor organ recovery procedures will be rare events.

### ***Reporting Requirement***

After a thorough review of this issue, the Committee recommended that all aborted living donor organ recovery procedures should be reported via the UNet<sup>SM</sup> Improving Patient Safety Portal. Under the proposal, if a living donor organ recovery procedure is aborted, the member reporting the event will provide a written description of the event that will be reviewed upon receipt by UNOS staff and investigated as necessary. The events are reported to the Membership and Professional Standards Committee.

### ***Policy Clarification***

During review of the current categories of living donor adverse events that must be reported through the UNet<sup>SM</sup> Improving Patient Safety System, the Committee supported proposing to eliminating several sections of policy ((Policy 18.5.B (Submission of Living Donor Death and Organ Failure); Policy 18.5.C (Reporting of Non-transplanted Living Donor Organs); 18.5.D (Reporting of Living Donor Organs Not Transplanted in the Intended Recipient)) because these requirements are also included in Table 18.4 (Living Donor Adverse Event Reporting) and

consequently were considered redundant. The new proposed reporting requirements under this proposal would be added to Table 18.4.

On December 12, 2013, the Committee met by web conference to review final draft policy language for this proposal and consider whether the proposal should be distributed for public comment. The Committee chair led a review of the proposed policy language, and the committee voted to approve sending the proposal for public comment.

### **Alternatives considered**

The Committee considered that an aborted living donor organ recovery procedure technically is not a living donor adverse event because a living donor organ was not recovered. However, because these prospective donors have put themselves at risk by receiving anesthesia for the purpose of donating an organ, the Committee unanimously agreed that an aborted living donor organ recovery procedure should be a reportable living donor adverse event.

The Committee and UNOS staff considered if the Living Donor Feedback form could be used to monitor aborted living donor recovery procedures. OPTN policy requires that the Living Donor Feedback form must be completed prior to the living donor recovery procedure. However, current policy does not specifically require updating the form to report if the procedure was aborted after the donor received anesthesia. Consequently, the Committee determined that this option would be problematic because aborted living donor recovery procedures could be under-reported if the Living Donor Feedback form is not revised post-operatively.

### **Supporting Evidence**

The OPTN does not have a reliable count of aborted living donor organ recovery procedures. Since 2003, 12 cases have been reported where a donation surgery was aborted because of a threat to the donor's health after anesthesia was administered.

### **Expected Impact on Living Donors or Living Donation**

Recovery hospital reporting of aborted living donor organ recovery procedures could help quantify the risks associated with living kidney donation.

### **Expected Impact on Specific Patient Populations**

There should be no negative impact for living organ donors or candidates for living donor transplant.

## Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule

<i>HHS Program Goals</i>	<i>Strategic Plan Goals</i>
<b>Patient Safety</b>	The OPTN will promote safe, high-quality care for transplant candidates, transplant recipients, and living donors
<b>Best Use</b>	To achieve the best use of donated organs, the OPTN will refine policies by incorporating objective, measurable criteria related to concepts of donor risk/quality and recipient benefit
<b>Operational Effectiveness</b>	The OPTN will identify process and system improvements that best support critical network functions, and work to disseminate them to all members who could benefit

### Plan for Evaluating the Proposal

One year after implementation of the policy, the Committee will request a report on the total number of aborted Living Donor recovery procedures reported in the UNet<sup>SM</sup> Improving Patient Safety Portal. The Committee will consider if policy modification or educational efforts are needed to assist members with policy compliance.

### Additional Data Collection

If this proposal is approved by the Board of Directors, the proposal will require adding a new option under “Living Donor Adverse Event” in the UNet<sup>SM</sup> Improving Patient Safety Portal. The new option would read “Recovery Procedure Aborted after Donor Received Anesthesia.” Until this new programming occurs, recovery centers would report aborted living donor procedures as an “other” event and provide a description in the free text field.

The proposal would require recovery hospitals to report aborted living donor recovery procedures via the UNet<sup>SM</sup> Improving Patient Safety Portal. This proposal would allow the OPTN to provide potential living donors with accurate information on the frequency of this type of event.

The Principles of Data Collection require institutional members to provide sufficient data to the OPTN to allow it to ensure patient safety when no alternative sources of data exist

### Expected Implementation Plan

If public comment is favorable, this proposal will be submitted to the OPTN Board of Directors in November, 2014. If approved, this proposal will become effective on February 1, 2015.

Recovery hospitals will begin to report aborted living donor recovery procedures as Living Donor Adverse Events through the UNet<sup>SM</sup> Improving Patient Safety Portal.

### Communication and Education Plan

The proposal addresses new requirements and expectations for member reporting. Communication and education efforts will address awareness of the new requirements as well as processes needed to fulfill them.

Information about the new requirements would be included in an ongoing effort to provide educational webinars to members regarding patient and living donor safety, with particular emphasis on practices at living donor transplant programs. It also would be incorporated into the OPTN Evaluation Plan and addressed in the context of ongoing member notification as the plan is periodically updated.

In addition, notification of the amended policy requirements would be included in the following routine communication vehicles:

- Policy notice
- System notice
- UNOS Update article
- Member e-newsletter/blog article
- Notification to a list serve group for transplant administrators

### **Compliance Monitoring**

UNOS will investigate all reported instances of aborted living donor organ recoveries in order to verify that policy requirements were followed, including reporting through the UNet<sup>SM</sup> Improving Patient Safety Portal within 72 hours following the aborted procedure.

### **Policy Proposal**

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

#### **18.5 ~~Living Donor~~ 18.5.A Living Donor Reporting Requirements after Donation**

The follow up period for living donors will be a minimum of two years.

The recovery hospital must report accurate, complete, and timely follow up data for donor status and clinical information using the LDF form for at least:

- 60% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 70% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 80% of their living kidney donors who donate after December 31, 2014

The recovery hospital must report accurate, complete, and timely follow up kidney laboratory data using the LDF form for at least:

- 50% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 60% of their living kidney donors who donate between January 1, 2014 and December 31, 2014

- 70% of their living kidney donors who donate after December 31, 2014

**Donor Status and Clinical Information**

1. Patient status
2. Working for income, and if not working, reason for not working
3. Loss of medical (health, life) insurance due to donation
4. Has the donor been readmitted since last LDF form was submitted?
5. Kidney complications
6. Maintenance dialysis
7. Donor developed hypertension requiring medication
8. Diabetes
9. Cause of death, if applicable and known

**Kidney Laboratory Data**

1. Serum creatinine
2. Urine protein

The OPTN Contractor will calculate follow up rates separately, and at least annually, for the submission of the six-month, one-year, and two-year LDF forms.

**18.6 Reporting of Living Donor Adverse Events**

**18.6.A Reporting of Living Donor Adverse Events through the Improving Patient Safety Portal**

Recovery hospitals must report these living donor adverse or unanticipated events through the Improving Patient Safety Portal according to Table 18-4

**Table 18-4: Living Donor Adverse Event Reporting**

Recovery hospitals must report to the Patient Safety System when:	To the Improving Patient Safety Portal within 72 hours after:
<u>A living donor organ recovery procedure is aborted after the donor has received anesthesia.</u>	<u>The aborted organ recovery procedure</u>
A living donor dies within 2 years after organ donation	The program becomes aware
A living liver donor is listed on the liver waitlist within 2 years after organ donation	The program becomes aware
A living kidney donor is listed on the kidney wait list or begins dialysis within 2 years after organ donation	The program becomes aware
A living donor organ is recovered but not transplanted	Organ recovery
A living donor organ is recovered and transplanted into someone other than the intended recipient	Organ recovery

The Membership and Professional Standards Committee will review all cases reported under *Policy 18.5.B through 18.5.D* according to Table 18-4 above and report to the OPTN Board of Directors.

**18.5. B Submission of Living Donor Death and Organ Failure**

Recovery hospitals must report all instances of a living donor's death or failure of the living donor's remaining organ function within 72 hours after the hospital becomes aware of the living donor death or failure of the living donor's remaining organ function. Living donors' remaining organ failure is defined as registering for liver transplant for liver donors, and as transplant, listing for transplant, or the need for dialysis for kidney donors. Recovery hospitals must report these incidents through the OPTN Contractor's Improving Patient Safety System for a period of two years from the date of the donation. The MPSC will review and report all adverse events to the OPTN Board of Directors.

**18.5.C Reporting of Non-transplanted Living Donor Organs**

The recovery hospital must report any time a living donor organ is recovered but not transplanted into any recipients. Recovery hospitals must report these incidents through the OPTN Patient Safety System within 72 hours of organ recovery. The MPSC will review and report all cases of non-transplanted living donor organs to the OPTN Board of Directors.

**18.5.D Reporting of Living Donor Organs Not Transplanted in the Intended Recipient**

If a living donor organ is recovered for an intended recipient but ultimately redirected and transplanted to a different recipient, then all required donor and recipient information must still be reported to the OPTN Contractor.

Transplant hospitals must report these incidents through the OPTN Improving Patient Safety System within 72 hours of organ recovery. The Membership and Professional Standards Committee will review and report all cases of redirected living donor organs to the OPTN Board of Directors.

**Table 18-4: Living Donor Adverse Event Reporting**

Recovery hospitals must report to the Patient Safety System when:	Within 72 hours after:
A living donor dies within 2 years after organ donation	The program becomes aware
A living liver donor is listed on the liver waitlist within 2 years after organ donation	The program becomes aware
A living kidney donor is listed on the kidney wait list or begins dialysis within 2 years after organ donation	The program becomes aware
A living donor organ is recovered but not transplanted	Organ recovery
A living donor organ is recovered and transplanted into someone other than the intended recipient	Organ recovery

The Membership and Professional Standards Committee will review all cases reported under *Policy 18.5.B through 18.5.D* and report to the OPTN Board of Directors.