

At-a-Glance

Proposal to Improve UNetSM Reporting of Aborted Procedures and Non-Transplanted Organs

- **Proposed New or Modified Policies:** 18.1 (Data Submission Requirements), 18.6 (Reporting of Living Donor Adverse Events)
- **Living Donor Committee**

This proposal is intended to clarify and simplify reporting requirements for aborted living donor recovery procedures and incidents when a living donor organ is recovered but not transplanted and to ensure that follow-up forms are generated so no living donor is lost to follow-up.
- **Affected Groups**

Directors of Organ Procurement
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**

In 2013, 5988 living donors donated an organ for transplantation.
- **Compliance with OPTN Strategic Plan and Final Rule**

The proposed changes are consistent with the strategic plan goals to:

 - Optimize a safe environment for living donor transplantation
 - Identify process and system improvements that best support critical network functions, and work to disseminate them to all members who could benefit
- **Specific Requests for Comment**

The Committee is requesting feedback on specific elements of the proposal determined to be problematic for members to implement. For any identified problem, please provide potential solutions for the Committee to consider.

Proposal to Improve UNetsm Reporting of Aborted Procedures and Non-Transplanted Organs

Proposed New or Modified Policies:

18.1 (Data Submission Requirements), 18.6 (Reporting of Living Donor Adverse Events)

Living Donor Committee

Public comment response period: January 27, 2015 – March 27, 2015

Summary and Goals of the Proposal

To clarify and simplify reporting requirements for aborted living donor recovery procedures and incidents when a living donor organ is recovered but not transplanted and to ensure that follow-up forms are generated so no living donor is lost to follow-up.

Background and Significance of the Proposal

In November 2014, the OPTN/UNOS Board approved new policy that requires living donor recovery hospitals to report aborted living donor recovery procedures through the Improving Patient Safety Portal within 72 hours of the event (Policy 18.6: *Reporting of Living Donor Adverse Events*). Prior to the implementation of the policy, aborted living donor recovery procedures might not be reported to the OPTN until long after the event occurred or not at all.

Current policy does not specifically require reporting of two types of incidents in the UNetsm system: 1) aborted procedures that occur after the potential donor receives anesthesia and before the living donor organ is recovered (i.e., the potential donor does not actually donate), and 2) procedures where the living donor organ is recovered but the organ is not transplanted into any recipient. In both cases, the Living Donor Feedback/Add Donor Form should be amended to report these events to the OPTN and to generate appropriate living donor data submission forms for donors whose organs were recovered, but not transplanted into a recipient.

Policy 18.1: *Data Submission Requirements* requires living donor recovery hospitals to register a living donor using the Living Donor Feedback form prior to their organ recovery procedure. The Living Donor Feedback form requires the living donor recovery hospital to enter a response for the question "Aborted Procedure after Donor Received Anesthesia?" Options for responding to this required question include "Yes", "No", or "N/A." Instructions on the form direct the user to select "N/A" as the option to complete the form before surgery and to change the response to "Yes" if the recovery procedure is aborted after the donor received anesthesia.

Despite the instructions on the form, living donor recovery hospitals may not amend the form after surgery. Failing to amend the form after a successful recovery procedure: 1) does not result in a policy violation, because amending the form post-operatively is not specifically required in policy; and (2) may or may not be problematic because UNetsm automatically updates the form if the candidate was registered on the Waitlist prior to transplant as required by Policy 3.7.C: *Candidate Registration*.

The majority of living donor recovery procedures are successful. For successful recovery procedures, UNetsm automatically updates the Living Donor Feedback form to change the response to the aborted procedure question to "No" after the program uses the living donor's donor ID to remove the recipient from the Waitlist. When the Living Donor Follow-up form is automatically updated, UNetsm generates the Living Donor Registration form and subsequent required donor follow-up form.

However, if an aborted living donor recovery procedure should occur, not amending the answer to the aborted procedure item post-operatively is problematic. It is problematic: 1) because the

UNetsm System does automatically update the feedback form and 2) under current policy, aborted living donor recovery procedures may have been under-reported to the OPTN.

This proposal would also clarify reporting requirements when the living donor organ is recovered but the organ is not transplanted to any recipient. Under this scenario, living donor recovery centers typically contact the OPTN for assistance because 1) current policy does not address how to report the event using the Living Donor Feedback form, and 2) if the event is not reported, the living donor ID would not be matched with a recipient on the Waitlist; consequently, the UNetsm System would not generate the Living Donor Registration (LDR) and Living Donor Follow-up (LDF) forms so that the living donor recovery center could report required donor follow-up.

The Committee anticipates that recovery hospitals may question why they would be required to report an aborted recovery procedure or non-transplanted organ through the Improving Patient Safety Portal and separately to UNOS. Under current policy, living donor recovery hospitals must already report these events through the Improving Patient Safety Portal and separately to the OPTN Contractor via the Living Donor Feedback form. Any adverse event reported via the Improving Patient Safety Portal is considered confidential, so separate reporting using the Living Donor Feedback form is also required so the event is included in the OPTN dataset.

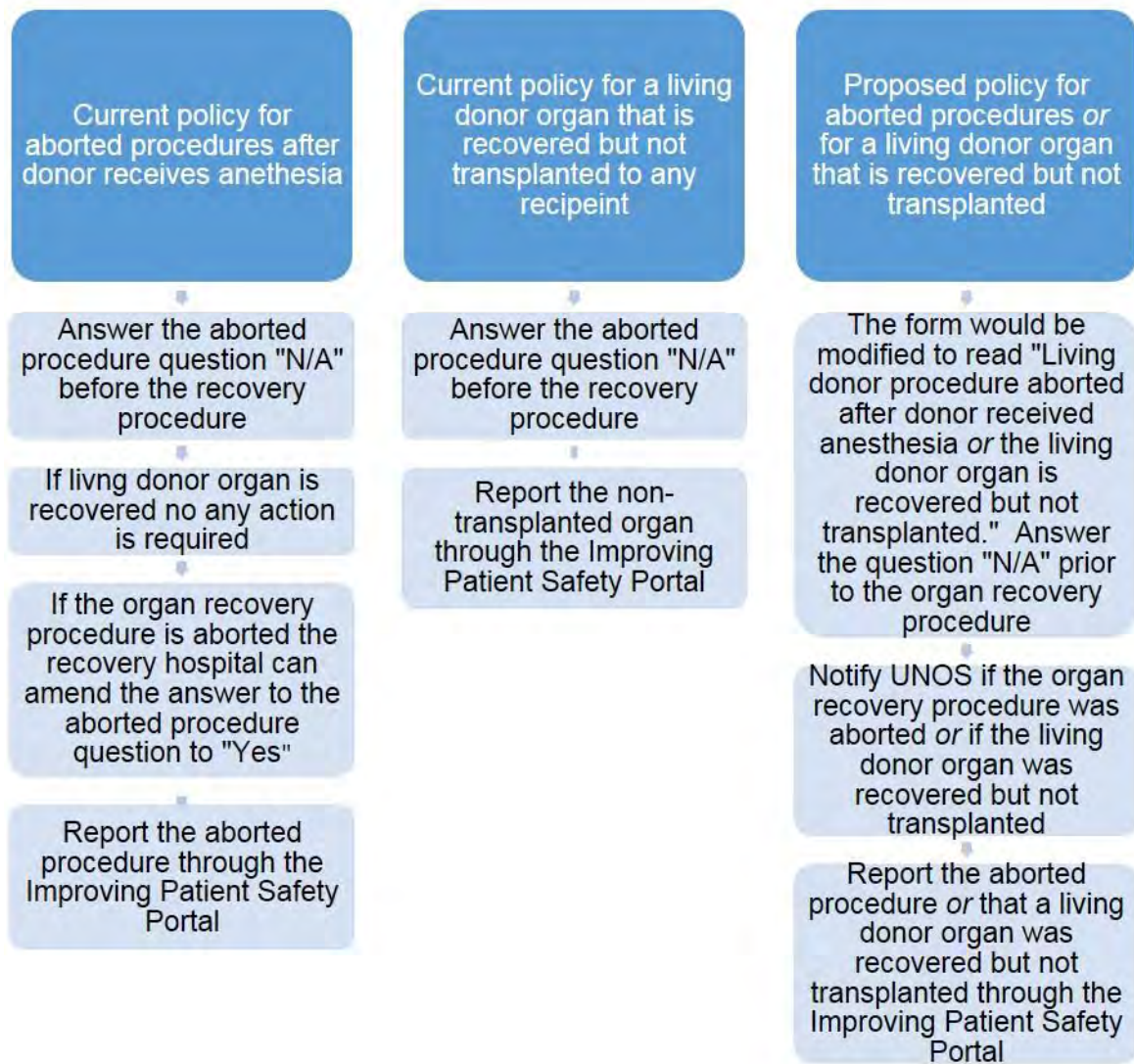
A comparison of these scenarios and proposed options for addressing each scenario follow.

Table 1. Living Donor Organ Recovery Scenarios, Current System, and Proposed Solution

Scenario	Current System	Proposed Solution
1. Living donor receives anesthesia and his or her donor organ is recovered and transplanted to a recipient. (vast majority of LD cases)	UNet sm system automatically changes the answer to the aborted procedures question from “N/A” to “No” when the recovery hospital uses the donor ID to remove the recipient from the Waitlist.	None – current system is sufficient. Proposed policy change would not affect this scenario.

Scenario	Current System	Proposed Solution
<p>2. Living donor receives anesthesia but his or her organ is not recovered either due to an unanticipated problem with either the donor or the intended recipient. (expected to be rare events)</p>	<p>Current policy requires the recovery center to report the aborted procedure through the Improving Patient Safety Portal. (Policy 18.5.D)</p> <p>The program should amend the answer to the aborted procedure question from “N/A” to “Yes” and provide information on why the procedure was aborted. However, amending the Living Donor Feedback form is not specifically required in current OPTN Policy.</p> <p>Under this scenario, a living donor transplant would not occur and no candidate on the Waitlist would be impacted.</p>	<p>Follow current policy, which requires the recovery center to report the aborted procedure through the Improving Patient Safety Portal.</p> <p>Modify existing policy to require the program to contact the OPTN to have the Living Donor Feedback form amended. The OPTN will change the aborted procedure question from “N/A” to “Yes” and record the reason(s) why the procedure was aborted.</p>
<p>3. Living donor receives anesthesia and his or her organ is recovered, but the organ is not transplanted into any recipient. (expected to be rare events)</p>	<p>Current policy requires the recovery center to report the non-transplanted living donor organ through the Improving Patient Safety Portal. (Policy 18.5 D)</p> <p>Under this scenario, a living donor transplant would not occur and no candidate on the Waitlist would be impacted.</p>	<p>Follow current policy which requires the recovery center would report the non-transplanted living donor organ through the Improving Patient Safety Portal</p> <p>Modify existing policy to require the program to contact the OPTN to have the Living Donor Feedback form amended. The OPTN will amend the form so the UNetsm System will generate the Living Donor Registration (LDR) and Living Donor Follow-up (LDF) forms so the living donor recovery center can report required donor follow-up</p>

Exhibit 1. Graphic Illustrating Living Donor Organ Recovery Scenarios, Current System, and Proposed Solution using the Living Donor Feedback Form or Contacting the OPTN



Alternative Considered

The Living Donor Feedback form includes a question (and instructions for answering the question) regarding aborted living donor recovery procedures. The Committee understands that living donor recovery centers have the ability to amend the aborted procedure question on the Living Donor Feedback form to notify the OPTN when an aborted procedure occurs. However, based on past experience, recovery programs frequently need to contact the OPTN because they are uncertain how to amend the Living Donor Feedback form for aborted procedures.

Under the current reporting system, living donor recovery hospitals are not able to use the Living Donor Feedback form to notify the OPTN if a living donor organ is recovered but not transplanted into a recipient.

The Committee considered several options to change policy or data submission forms that included:

- 1) Modifying current policy to specifically require living donor recovery hospitals to change the response to the aborted procedure question on the Living Donor Feedback form “N/A” to “Yes” after an aborted procedure occurs
- 2) Modifying current policy to specifically require living donor recovery hospitals to report whenever a living donor organ is recovered but the organ is not transplanted to any recipient using the Living Donor Feedback form
- 3) Modifying the Living Donor Feedback form so it could be used to report both aborted procedures and if a living donor organ is recovered but not transplanted to any recipient
- 4) Modifying policy and requiring recovery hospitals to contact UNOS to report aborted procedures or if a living donor organ is recovered but not transplant to any recipient, with UNOS making necessary changes to the Living Donor Feedback form

Ultimately, the Committee favored the fourth option because recovery hospitals would follow the same and simplified process for reporting aborted procedures and non-transplanted living donor organs.

As proposed, living donor recovery hospitals would continue to answer the aborted procedure question as “N/A” before the living donor organ recovery procedure occurs, but will not need to amend the form regardless of the outcome of the organ recovery procedure. As proposed, living donor recovery centers would only use the Living Donor Feedback form to report pre-operative information. The Committee recommends changing the aborted procedure question and instructions on the form so users are not instructed to amend the aborted procedure question post-operatively, but are instead instructed to call UNOS.

The Committee recommends changing the question on the Living Donor Feedback form to read “living donor procedure aborted after donor received anesthesia *or* living donor organ recovered, but not transplanted”. The Committee also recommends that the instructions on the form be updated to read:

****Check N/A before surgery. Contact the OPTN Contractor to amend the form if:**

- The procedure was aborted after the donor received anesthesia or
- The living donor organ was recovered but not transplanted to any recipient

If and when possible, the Committee would support programming to prevent members from amending the Living Donor Feedback form post-operatively, as this would prevent potential policy violations should a member amend the form rather than contact the OPTN to report an aborted living donor recovery procedure.

Supporting Evidence

Current policy does not specifically require reporting aborted living donor recovery procedures on the Living Donor Feedback form. Consequently, the OPTN may not have a complete count of aborted living donor organ recovery procedures. Since 2003, 12 cases have been reported using the UNet system where a donation surgery was aborted because of a threat to the donor’s health after anesthesia was administered.

Similarly, the OPTN may not have a complete count of living donor organs that are recovered but not transplanted to any recipient. Policy 18.5.D: *Reporting of Non-transplanted Living Donor Organs* requires such events must be reported through the Improving Patient Safety Portalsm but such events are considered confidential and are not included in the UNOS data available for research.

Expected Impact on Living Donors or Living Donation

Recovery hospital reporting of aborted living donor organ recovery procedures and non-transplanted living donor organs could help quantify the risks associated with living 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

This proposal adheres to the OPTN Key Goals to “Promote living donor safety through Key Goals, Objective B: Minimize risk to living organ donors.” Improved reporting of aborted living donor organ recovery procedures and non-transplanted organs:

- Should promote safe, high-quality care for living donors and transplant candidates
- Could lead to refinement of policies by incorporating objective, measurable criteria related to concepts of donor risk/quality and recipient benefit
- Should help 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 and non-transplanted living donor organs. The Committee could evaluate if the total number of these events reported to UNOS match the number of events reported to the Improving Patient Safety Portal. The Committee could consider if policy modifications or educational efforts are needed to assist members with policy compliance.

Additional Data Collection

Living donor recovery centers will need to contact UNOS if an aborted procedure should occur or if a living donor organ is recovered and not transplanted.

Expected Implementation Plan

This proposal would require changes to the Living Donor Feedback form. As proposed, the form would be modified to read "Living donor procedure aborted after donor received anesthesia *or* the living donor organ is recovered but not transplanted. Answer the question "N/A" prior to the organ recovery procedure."

Based on favorable public comment, this proposal should be considered by the OPTN Board of Directors in June 2015. If approved, this policy would become effective on September 1, 2015.

Communication and Education Plan

Communication and education efforts will inform members of the changes and will provide guidance about the steps members need to take to fulfill them.

Information about the changes would be included in ongoing efforts to inform members about OPTN monitoring for compliance and patient safety, and to address areas of concern. The information would be incorporated into the OPTN Evaluation Plan.

Notification of policy changes would be included in the following routine communication vehicles:

- Policy notice
- System notice
- Article on OPTN website and member e-newsletter
- Notification to listserv groups

Monitoring and Evaluation

The proposed language will not change the current routine monitoring of OPTN members. Any data entered in UNetSM may be subject to OPTN review, and members are required to provide documentation as requested.

Policy Proposal

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

18.1 Data Submission Requirements

OPOs must provide donor information required for organ placement to the OPTN Contractor in an electronic data format as defined and required by the computer system. Deceased donor information required for organ placement must be submitted prior to organ allocation.

Members must report data to the OPTN using standardized forms. *Table 18-1* shows the member responsible for submitting each data form and when the Member must submit the following materials to the OPTN Contractor.

This policy does not apply to VCA-only donors or VCA information for donors and recipients; however, for VCA-only procurements, host OPOs must submit to the OPTN Contractor the deceased donor registration (DDR) within 30 days after the procurement date.

Table 18-1: Data Submission Requirements

<i>The following member:</i>	<i>Must submit the following materials to the OPTN Contractor:</i>	<i>Within:</i>	<i>For the following groups:</i>
Histocompatibility Laboratory	<i>Donor histocompatibility (DHS)</i>	30-days after the OPO submits the deceased donor registration	For each donor typed by the laboratory
Histocompatibility Laboratory	<i>Recipient histocompatibility (RHS)</i>	<i>Either of the following:</i> <ul style="list-style-type: none"> • 30-days after the transplant hospital removes the candidate from the waiting list because of transplant • 30-days after the transplant hospital submits the <i>recipient feedback</i> 	For each transplant recipient typed by the laboratory

<i>The following member:</i>	<i>Must submit the following materials to the OPTN Contractor:</i>	<i>Within:</i>	<i>For the following groups:</i>
OPOs, all	<i>Death notification records (DNR)</i>	30-days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	For all imminent neurological deaths and eligible deaths in its DSA
OPOs, all	<i>Monthly Donation Data Report: Reported Deaths</i>	30-days after the end of the month in which a donor hospital reports a death to the OPO	For all deaths reported by a hospital to the OPO
Allocating OPO	<i>Potential transplant recipient (PTR)</i>	30-days after the match run date by the OPO or the OPTN Contractor	For each deceased donor organ that is offered to a potential recipient
Host OPO	<i>Deceased donor feedback</i>	5 business days after the procurement date	
Host OPO	<i>Deceased donor registration (DDR)</i>	30 days after the <i>deceased donor feedback</i> form is submitted and disposition is reported for all organs	For all deceased donors and authorized but not recovered potential deceased donors
Recovery Hospitals	<i>Living donor feedback</i>	The time prior to donation surgery	For each potential living donor who donates an organ recovered at the hospital
Recovery Hospitals	<i>Living Donor Feedback</i> <u>Members must contact the OPTN Contractor to amend this form according to <i>Policy 18.6: Reporting of Liver Donor Adverse Events</i></u>	<u>72 hours after the donor organ recovery procedure</u>	<u>For any potential living donor who received anesthesia but did not donate an organ or whose organ is recovered but not transplanted into any recipient</u>
Recovery Hospitals	<i>Living donor registration (LDR)</i>	60 days after the Recovery Hospital submits the <i>living donor feedback</i> form	For each living donor organ recovered at the hospital
Recovery Hospitals	<i>Living donor follow-up (LDF)</i>	60 days after the six-month, 1-year, and 2-year anniversary of the donation date	For each living donor organ recovered at the hospital

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 or OPTN Contractor according to Table 18-4.

Table 18-4: Living Donor Adverse Event Reporting

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

The Membership and Professional Standards Committee will review all cases reported according to Table 18-4 above and report to the OPTN Board of Directors.