At-a-Glance

- **Proposal to Require Reporting of Unexpected Potential and Proven Disease Transmission Involving Living Organ Donors**

- **Affected/Proposed Policies:** Policy 4.5 (Post-Transplant Reporting of Potential Transmission of Disease or Medical Conditions, Including Malignancies) and Policy 12.2 (Informed Consent of Living Donors).

- **Living Donor Committee**

  Under this proposal, existing policy would be modified to require members to report to the OPTN Contractor any unexpected potential or proven living donor-derived disease transmission, including infections or malignancies. Current OPTN/UNOS policy requires specific infectious disease testing for all deceased organ donors. It also requires that any unexpected potential or proven disease transmission, including infections and malignancies, discovered after donation be reported to the OPTN Contractor.

  Although rare, unexpected potential or proven disease transmissions involving a living donor have occurred. The types of events reported to date include small renal cell carcinomas (RCC) found in the living donor during recovery and malignancies and viral infections identified in the recipient or the donor after donation. This policy change is being proposed to help improve the reporting of disease transmissions involving living donors.

- **Affected Groups**
  Directors of Organ Procurement
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  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 Living Donors and Candidates Affected**
  In 2010 there were 6562 living donors. A disease or malignancy transmission involving a living organ donor should be a rare event.

- **Compliance with OPTN Strategic Goals**
  The proposal meets strategic plan goals as it will:
  - Optimize a safe environment for living donor transplantation through an improved reporting process for unexpected potential and proven disease transmissions
  - Improve living donation through development and enactment of policies to enhance patient safety and preserve the public trust

Proposal to Require Reporting of Unexpected Potential and Proven Disease Transmission Involving Living Organ Donors

Affected/Proposed Policies: Policy 4.5 (Post-Transplant Reporting of Potential Transmission of Disease or Medical Conditions, Including Malignancies) and Policy 12.2 (Informed Consent of Living Donors).

Living Donor Committee

Summary and Goals of the Proposal:

Under this proposal, existing policy would be modified to require members to report to the OPTN Contractor any unexpected potential or proven living donor-derived disease transmission, including infections or malignancies. Current OPTN/UNOS policy requires specific infectious disease testing for all deceased organ donors. It also requires that any unexpected potential or proven disease transmission, including infections and malignancies, discovered after donation be reported to the OPTN Contractor.

Although rare, unexpected potential or proven disease transmissions involving a living donor have occurred. The types of events reported to date include small renal cell carcinomas (RCC) found in the living donor during recovery and malignancies and viral infections identified in the recipient or the donor after donation. This policy change is being proposed to help improve the reporting of disease transmissions involving living donors.

Background and Significance of the Proposal:

In November 2010, the OPTN/UNOS Board approved revisions to OPTN Policies 2.0 (Minimum Procurement Standards for an Organ Procurement Organization (OPO) and 4.0 (Identification of Transmissible Diseases in Organ Recipients). The revisions included rules for communication and reporting of all unexpected suspected potential or proven transmissions, including infections or malignancies. Many deceased donor events are reported when recipient illness develops and the donor is suspected as a source. Additionally, new deceased donor information such as final culture results received after donation or a tumor found post-recovery are required reporting as a suspected transmission.

There has been confusion about whether the 2010 policy revisions included living donor organs or whether they only applied to deceased donor organs. These policy revisions were intended to include living donor events, but did not specifically state this intent. Consequently, after these revised policies took effect, the Committee questioned if policy should be updated to clearly require the reporting of unexpected potential or proven transmissions involving living organ donors.

In the case of living donation, an unexpected transmission would be a condition that was not known or not detected prior to the recovery and transplant of a living donor organ. An expected or proven transmission would be a condition known prior to transplant. A CMV positive donor donating to a CMV negative recipient who is prophylaxed to prevent development of the illness would be an example of an expected disease transmission.

Current Policy 12.8.4 (Submission of Living Donor Death and Organ Failure Data) requires the reporting of living donor deaths, loss of native organ function, and the loss or redirection of any living donor organ through the Improving Patient Safety Portal (for two years post donation). The Committee first

considered modifying this policy to also require reporting any unexpected potential or proven living donor- derived disease transmission, including infections or malignancies for two years post donation.

The Committee consulted the Disease Transmission Advisory Committee (DTAC) for input on this proposal. DTAC recommended an alternate policy approach that would not require new policy but would modify existing policy 4.5 (Post-Transplant Reporting of Potential Transmission of Disease or Medical Conditions Including Malignancies) to require reporting any unexpected suspected or proven living donor- derived disease transmission, including infections or malignancies.

- ***Collaboration:*** The Committee consulted and received valuable feedback from the DTAC during development of the proposal. The DTAC voted to endorse the modifications to Policy 4.5 in this proposal. The Operations and Safety Committee, Transplant Administrators Committee, and Transplant Coordinators Committee were offered an opportunity to review and provide feedback on the proposal prior to the public comment period. The Policy Oversight Committee reviewed and approved distributing this proposal for public comment.

- ***Alternatives considered:*** The Committee discussed whether the reporting of unexpected potential or proven disease transmissions, including infections or malignancies, involving living donors should be limited to some specific post donation period of time. The Committee considered recommendations from the Disease Transmission Advisory Committee which supported no time limit for reporting unexpected suspected or proven living donor-derived disease or malignancy transmission, and commented that there is no time limit for suspected or proven deceased donor-derived disease or malignancy transmission.

  Under current policy, living donor follow-up is required for two years post donation. After considering the issues of donor privacy, and whether or not a living organ donor should be obligated to have unlimited reporting of unexpected suspected or proven living donor-derived disease or malignancy transmission, the Committee ultimately supported limiting the reporting of unexpected suspected or proven living donor-derived disease or malignancy transmission to two years.

- ***Strengths and weaknesses:*** At this time, there are no OPTN/UNOS policy requirements for infectious disease testing for potential living donors. New requirements for infectious disease testing for potential living kidney organ donors have been proposed, distributed for public comment, and may soon be considered by the OPTN/UNOS Board. If ultimately approved by the Board at its June 2012 meeting, the new testing requirements would take effect in September 2012.

  The implementation of policy to standardize the infectious disease testing for potential living donors should reduce the risk or incidence of living donor-derived infectious disease transmissions.

  Many living donor programs repeat infectious disease testing for all potential living donors in the immediate preoperative period which should also reduce the incidence of possible living donor-derived infectious disease transmission.

  The proposal would clarify existing policy by explicitly requiring any unexpected potential or proven disease transmission involving a living donor to be reported to the OPTN Contractor.

This practice should allow the living donor recovery program providing living donor follow-up to notify the recipient program regarding an unexpected potential disease or malignancy transmission. Reporting unexpected potential or proven disease transmission involving a living donor to the OPTN Contractor could contribute to new policy or guidance that could be shared with the transplant community.

- ***Description of intended and unintended consequences**:* Under this proposal, a Living Donor Recovery Center would be required to report information regarding a living donor that may indicate a potential transmission of an infectious disease or malignancy discovered during the first two years of living donor follow-up. The Committee questioned how it could provide guidance for determining what information may indicate a living donor-derived infectious disease or malignancy. The Committee considered directing Living Donor Recovery Centers to the existing guidance document. However, the Committee concluded that the existing guidance document does not address the special circumstances and proposed policy requirements that may be involved in a potential or proven living donor-derived disease transmission.

  In response, the Committee and DTAC plan to collaborate to update the existing guidance document so it can assist both OPOs and Living Donor Recovery and Living Donor Recipient Centers in determining which infectious disease or malignancies, for both living and deceased donors, should be considered pertinent to recipient care and reported to the OPTN Contractor through the Improving Patient Safety Portal. An updated resource will be completed over the next few months and made available to the transplant community before any related policy modifications could take effect.

  The proposal creates a need to modify recently proposed policy for living donor consent. The recently proposed policy (which has already completed public comment) for living donor consent is limited to the time frame between donor evaluation through organ recovery. A living donor may be found to have an unexpected potential or proven disease that may be relevant to acute recipient care and that may have been transmitted through organ donation. For such cases, it will be necessary to have the donor consent that such information would be reported to local, state or federal public health authorities, the OPTN Contractor and/or disclosed to their organ recipient transplant center for a period of up to two years post donation. This new consent requirement is addressed in the planned modifications to Policy 12.2 in this proposal.

Supporting Evidence:

As shown in Table 1 below, a total of 15 unexpected potential living donor-derived disease transmissions were reported to the OPTN from 2006 through 2011. All were reviewed by the DTAC. The types of events reported include potential Hepatitis B, Hepatitis C and HIV transmission and malignancies found in the living donor (at recovery or post-donation) or in a recipient post-transplant. The most common malignancy reported was small renal cell carcinoma. It should be noted only 1/3 of these cases were ultimately classified as probable or proven transmissions by the DTAC, with the remainder having insufficient evidence to support living donor-disease transmission.

Table 1.
Living Donor Transplants Reported to the Improving Patient Safety Portal
As a Potential Disease Transmission: 2006-2011

Year	Total	Malignancy	Infections	Case Initiated From Disease in Recipient	Case Initiated From Disease in Donor
2006	1	1	0	0	1
2007	1	1	0	0	1
2008	1	0	1	0	1
2009	1	1	0	1	0
2010	2	1	1	1	1
2011	9	4	5	4	5
Total	15	8	7	6	9

Based on OPTN data as of January 13, 2012.

Expected Impact on Living Donors or Living Donation:

In 2010, there were 6562 living donors. Disease transmission involving a living organ donor is anticipated to be a rare event. This proposal would improve identification and reporting if disease transmissions due occur.

Expected Impact on Specific Patient Populations:

The proposal should help safeguard living donor organ recipients by improving the identification and reporting of living donor-derived disease or malignancy transmissions.

Expected Impact on Program Goals:

OPTN Key Goal	Related Indicators
Improve post-transplant survival	Patient survival - an unexpected potential or proven living donor-derived disease transmission could impact post transplant survival
	Rates of death with a functioning graft (kidney/liver) - an unexpected potential or proven living donor-derived disease transmission could contribute to a recipient death with a functioning graft
Promote transplant patient safety	Post-transplant complication rates • Primary graft non-function • Patient death rates less than 30 days
	Disease transmission rate (proven or probable)
Promote living donor safety	Number of living donor deaths within 90 days - an unexpected potential or proven living donor-derived disease transmission could cause death
	Post-surgical complication rates - an unexpected potential or proven living donor-derived disease would be a post-surgical complication

Plan for Evaluating the Proposal:

The Disease Transmission Advisory Committee will continue to investigate all reported unexpected potential or proven disease transmissions involving a living donor. The Living Donor Committee may request a report of aggregate data for unexpected potential or proven disease transmission involving living donors, in order to determine if the number of cases reported increases if the policy is ultimately implemented.

Additional Data Collection:

Any potential or proven disease transmission will need to be reported through the Improving Patient Safety Portal. Transplant Centers or OPOs will not be required to complete any additional fields on existing data collection forms.

Expected Implementation Plan:

Transplant programs must inform the Living Donor Recovery Center of all potential or actual unexpected disease transmissions within 24 hours of the time they become aware of the risk of potential transmission. They must also report all potential or actual unexpected disease transmissions in the UNet[SM] Improving Patient Safety Portal.

Living Donor Recovery Centers must inform the Recipient Transplant Center and report in the UNet[SM] Improving Patient Safety portal all potential or actual unexpected disease transmissions within 24 hours (of the time they become aware of the risk of potential transmission through follow up with a donor during the first two years after donation).

Living donor transplant programs will need to develop and implement procedures to comply with new requirements for reporting unexpected potential or proven disease transmission involving a living donor.

Communication and Education Plan:

While this would be a new responsibility for member institutions, the reporting process itself should be familiar to the audiences most directly affected. For this reason, the primary intent of communication to members would be creating awareness of the added responsibility. A potential message to both members and interested members of the public would be that this requirement is intended to increase knowledge of disease transmission incidence and aid in treatment of affected transplant recipients.

The following activities would be planned:

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Policy Notice following Board Approval	OPTN Members and the public	OPTN and UNOS Websites	1 month after Board approval

UNet℠ System Notice upon implementation	OPTN UNet℠ Users	E-mail, UNet℠ notice	30 days before the implementation and again upon implementation
UNOS Update Article	OPTN Members and the public	E-mail	Earliest monthly issue after policy change is approved.
Article in e-newsletter in the policy-related category	OPTN Members	e-newsletter and accessing URL of member archive	Earliest monthly issue after policy change is approved.
Presentation of Proposed Policy at Regional Meetings	OPTN Members	In person	During the public comment period

Compliance Monitoring:

When UNOS staff becomes aware of an unexpected potential disease transmission, they will verify that it was properly reported in the UNet℠ Improving Patient Safety Portal and to other transplant centers. UNOS staff will also verify that all follow-up forms were properly submitted.

Policy Proposal:

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

4.5 POST-TRANSPLANT REPORTING OF POTENTIAL TRANSMISSION OF DISEASE OR MEDICAL CONDITIONS, INCLUDING MALIGNANCIES. In order to promote prompt notification of potential risk of disease transmission through organ transplantation, all events involving unexpected potential or proven transmission of a medical condition, including infections and malignancies, discovered after procurement of a deceased donor organ or recovery and transplant of a living donor organ must be reported to the OPTN Improving Patient Safety ~~System~~℠ portal.

- When an organ recipient is suspected to have, is confirmed positive for, or has died from a potential transmissible disease or medical condition for which there is substantial concern that it could be of donor origin, then the transplant program must notify the Living Donor Recovery Center (for living donor recipients) or Host OPO (for deceased donor recipients) by phone and provide available documentation to the Living Donor Recovery Center or Host OPO as soon as possible, but, at the latest, within ~~and not to exceed~~ 24 hours of ~~this~~ their knowledge~~/concern~~ of the event. The transplant center that suspects potential transmission should not wait for all medical documentation that may eventually be available, but must inform:

    - the Living Donor Recovery Center or Host OPO and
    - the OPTN Improving Patient Safety ~~System~~ portal.

~~to transfer knowledge/concern as soon as possible to~~

- ~~all other centers that received organs from the same donor.~~

- If ~~When~~ a Host OPO learns ~~of~~ new information regarding a deceased donor, (~~i.e.~~ including but not limited to final culture results, information from autopsy report~~, etc.~~) as part of its donor follow-up (See Policy 2.2.5) that indicates risk of potential transmission of disease or malignancy, then the Host OPO must report the donor result through the OPTN Improving Patient Safety ~~System~~[SM] portal.

- If a Recovery Center learns new information regarding a living donor, during the first two years post donation, (including but not limited to new or follow-up testing results, donor death or autopsy reports) that indicates risk of potential transmission of disease or malignancy, then the Recovery C~~c~~enter:

    - may need to report the new information to local, state or federal public health authorities;
    - must disclose to the living donor that a potential disease transmission or malignancy must be reported to the recipient transplant center and the OPTN Improving Patient Safety portal;
    - must notify the recipient transplant center; and
    - must report the potential transmission through the OPTN Improving Patient Safety portal.

4.5.1 Living Donor Recovery Center and Host OPO Responsibilities. The Living Donor Recovery Center or Host OPO shall be responsible for:

i. Communication of test results and diagnosis from a suspected donor and/or affected recipient(s) that may be pertinent to acute patient care as soon as practicable, not to exceed 24 hours, to any transplant program(s) Patient Safety Contact and tissue bank(s) that received an organ(s) or tissue from the donor who is the subject of the investigation. This includes results of all tests that were not available at the time of procurement or recovery (i.e. cultures, final pathology, etc) or subsequently performed after recovery and documenting that this information is shared with all recipient centers and tissue banks.

ii. Notification of the event to the OPTN Improving Patient Safety ~~System~~[SM] portal as soon as possible, not to exceed 24 hours.

iii. Follow-up Communication of Potential Disease Transmission

•For deceased donors, completion and submission of the Potential Disease Transmission Report Form (a form that will be sent to the Host OPO after OPTN staff receives the electronic notification from the OPTN Improving Patient Safety ~~System~~ portal) to OPTN Patient Safety Staff within 24 hours of reporting the event through the Improving Patient Safety ~~System~~[SM] portal to identify:

o The specific Patient Safety Contact at the recipient transplant program(s) and tissue bank(s) personnel that were notified of the potential transmission;

o Disposition of all organs, tissues and vessels; and

o Any preliminary information available regarding any remaining donor samples for additional testing, notification to

state or local health department as appropriate for nationally notifiable infectious diseases, and whether an autopsy was performed on the donor.

- For all donors, ~~If requested by~~ the Ad Hoc Disease Transmission Advisory Committee~~,~~ may request submission of a Potential Disease Transmission DONOR Follow-Up Report (a form that will be sent ~~to the Host OPO~~ by OPTN contractor staff) 45 days after the initial reporting date; OPTN Patient Safety Staff may request additional information related to the donor beyond 45 days, including pending test results depending on the potentially transmitted disease or condition.

iv. Management of the review, in partnership with OPTN Patient Safety Staff, to determine whether the organ donor was diagnosed with a potentially transmissible disease or condition;

4.5.2 Transplant Program Responsibilities. Any transplant program treating recipient(s) that received organ(s) from a donor who is the subject of a potential disease transmission report is responsible for:

i. Responding to Host OPO, Living Donor Recovery Center, or OPTN Patient Safety Staff requests for information regarding recipient(s) in a timely fashion and communicating updated information regarding recipient condition, test results, diagnosis, and plans for treatment and follow-up.

ii. Submitting copies of any pertinent test results (including cultures, serologies, imaging studies, autopsy results, etc.) to OPTN Patient Safety Staff.

iii. Notifying recipient(s) involved in cases of confirmed transmissions and documenting this notification in the recipient medical record as required in Policy 4.3.

iv. If requested by the Ad Hoc Disease Transmission Advisory Committee, submission of a Potential Disease Transmission RECIPIENT Follow-Up Report (a form that will be sent to the transplant program by OPTN staff) within 45 days of the initial reporting date.

OPTN Patient Safety Staff may request additional information related to the recipient beyond 45 days, (including pending test results, long term follow-up testing, and/or screening results, etc.) depending on the potentially transmitted disease or condition in an effort to determine the probability of donor-derived disease transmission.

12.2 Informed Consent of Living Donors

…

L. Disclosure that any infectious disease or malignancy pertinent to acute recipient care discovered during the potential donor's first two years of post-operative follow-up care:

- will be disclosed to the donor;
- may need to be reported to local, state or federal public health authorities;
- will be disclosed to their recipient's transplant center; and

- will be reported through the OPTN Improving Patient Safety Portal.

…