

Improving Post-Transplant Communication of New Donor Information

Sponsoring Committee:	Ad Hoc Disease Transmission Advisory Committee
Policy/Bylaws Affected:	Policies 2.9 (Required Deceased Donor Infectious Disease Testing), 2.11.C (Required Information for Deceased Heart Donors), 2.13 (Post Procurement Follow Up and Reporting), 15.4 (Reporting of Potential and Proven Disease Transmissions), 15.5 (Requirements for Post-Transplant Discovery of Donor Disease or Malignancy), 15.6 (Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors)
Public Comment:	January 25, 2016 – March 25, 2016
Effective Date:	September 1, 2016 except changes to Policies 2.9 (Required Deceased Donor Infectious Disease Testing) and 2.11.C (Required Information for Deceased Heart Donors) to be determined; UNOS will notify members at least 30 days in advance of implementation.

Problem Statement

Review of potential donor-derived disease transmission events (PDDTE) by both the Ad Hoc Disease Transmission Advisory Committee (DTAC) and UNOS staff since 2006 has highlighted instances where communication delays or failures regarding new donor information learned after transplant led to transplant recipient morbidity or mortality.

In 2011, policy revisions added reporting requirements and a requirement to have a 24/7 patient safety contact to handle reports. Data have shown significant increases in reporting since that time, yet some of the increased reporting has not led to gains in prevention, since a significant number of reports end up not being reviewed. Reporting practices vary greatly by region and Donation Service Area (DSA). The manpower required for current reporting and follow-up tasks may not be the best use of limited resources. Reports from transplant patient safety contacts indicate that significant time and energy are being spent on non-relevant reports. This may be causing reporting fatigue or desensitization, thus taking away from the focus on reporting and following relevant results.

These changes should decrease the number of reports that OPOs must make to the OPTN PDDTE reporting system and transplant hospital patient safety contacts within 24 hours. Negative test results must be reported to the OPTN via uploading results to DonorNet® but will not need to be reported urgently to the transplant hospital patient safety contact. OPO reporting of certain specified positive results, such as positive blood cultures, only will need to be communicated to the transplant hospital patient safety contact, but not to the OPTN PDDTE reporting system. In addition, some types of positive results will only need to be reported to certain organ specific transplant program patient safety contacts,

such as positive urine cultures (bacterial or *Candida* species) reported urgently only to transplant programs receiving lungs or head and neck VCAs. Table 1 below provides more details.

Summary of Changes

The changes further specify what OPOs must report and to whom. OPOs will also need to conduct toxoplasma IgG testing.

Table 1: Summary of OPO Reporting Requirements

Results	Where Reported	Time Frame
Adds toxoplasma IgG testing and reporting	New field on infectious disease screening tab in DonorNet®	ASAP
All testing (including negatives)	Upload to DonorNet®	ASAP
<ul style="list-style-type: none"> • Pathogens of Special Interest • Malignancy or other findings highly suggestive of malignancy recognized after procurement 	<ul style="list-style-type: none"> • Recipient(s) Transplant Program Patient Safety Contact (PSC) • OPTN Improving Patient Safety Portal (IPS) 	ASAP, but no later than 24 hours after receipt
<p>POSITIVE results for the following:</p> <ul style="list-style-type: none"> • Serologic, NAT, or antigen results indicating presence of parasites, virus, or fungi • Cultures from the following specimens: <ul style="list-style-type: none"> • Ascites • Blood • Cerebrospinal fluid (CSF) • Deep wound • Genital • Pericardial • Pleural fluid • Mycobacterial smears and cultures • Fungal smears and cultures with the exception of <i>Candida</i> species • Respiratory samples (bacterial or <i>Candida</i> species) only to transplant programs receiving lungs or head and neck VCAs • Urine cultures (bacterial or <i>Candida</i> species) only to transplant programs receiving kidneys or genitourinary VCAs • Histopathology results • All <i>final</i> culture information for any culture results that were reported according to these requirements • Other psycho-social history, medical history, autopsy, testing, and laboratory findings identifying infectious conditions that may adversely affect a potential transplant recipient 	<ul style="list-style-type: none"> • Recipient(s) Transplant Program Patient Safety Contact (PSC) 	ASAP, but no later than 24 hours after receipt

A seven-day reporting timeframe was placed for living donor recovery hospitals making PDDTE reports.

What Members Need to Do

OPOs, transplant hospitals, and living donor recovery hospitals must familiarize staff responsible for PDDTE reporting with the new policy.

OPOs: OPOs must develop a protocol for reporting that includes:

- Testing all deceased donors for toxoplasma IgG (not in effect until programming completed and members notified)
- Obtaining all results for any deceased donor testing conducted
- Uploading all deceased donor testing results to DonorNetsm
- Sharing deceased donor test results with tissue banks
- Reporting results that indicate evidence of disease on the Special Pathogens of Interest list
- Reporting certain positive test results to the transplant hospital patient safety contact and the OPTN as soon as possible but no later than 24 hours of receipt according to the new policy requirements

Transplant hospitals: Transplant hospitals must continue to report suspected cases of donor-derived transmissions.

Living donor recovery hospitals: Living donor recovery hospitals must:

- Report all risk of potential transmission of disease or malignancy as soon as possible but no more than seven days after receiving the new information
- Continue to report suspected cases of donor-derived transmissions

Affected Policy/Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through~~.

2.9 Required Deceased Donor Infectious Disease Testing

The host OPO is responsible for ensuring that *all* of the following infectious disease testing is completed in CLIA-certified laboratories, or in laboratories meeting equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS):

1. Blood and urine cultures
2. Infectious disease testing for all potential deceased organ donors using FDA licensed, approved or cleared tests, as listed below:
 - a. HIV antibody (anti-HIV) donor screening test *or* HIV antigen/antibody (Ag/Ab) combination test
 - b. Hepatitis B surface antigen (HBsAg) donor screening test
 - c. Hepatitis B core antibody (anti-HBc) donor screening test
 - d. Hepatitis C antibody donor screening test (anti-HCV)
 - e. Hepatitis C ribonucleic acid (RNA) by donor screening or diagnostic nucleic acid test (NAT)
 - f. Cytomegalovirus (CMV) antibody (anti-CMV) donor screening *or* diagnostic test
 - g. Epstein-Barr Virus (EBV) antibody (anti-EBV) donor screening *or* diagnostic test
 - h. Syphilis donor screening *or* diagnostic test
 - i. Toxoplasma Immunoglobulin G (IgG) antibody test
3. If the donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to *the U.S. Public Health Services (PHS) Guideline*. HIV RNA by donor screening or diagnostic NAT or HIV antigen/antibody (Ag/Ab) combination is *also* required unless *either of the following* is true:
 - The donor has already been tested for HIV using the HIV Ag/Ab combination test according to section 2.a above.

- The donor's only increased risk factor is having received hemodialysis within the past 12 months.

2.11.C Required Information for Deceased Heart Donors

The host OPO must provide *all* the following additional information for all deceased donor heart offers:

1. Height
2. Weight
3. Vital signs, including blood pressure, heart rate, and temperature
4. History of treatment in hospital including vasopressors and hydration
5. Cardiopulmonary, social, and drug activity histories
6. Details of any documented cardiac arrest or hypotensive episodes
7. 12-lead interpreted electrocardiogram
8. Arterial blood gas results and ventilator settings
9. Cardiology consult or echocardiogram, if the hospital has the facilities
10. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to the final organ acceptance
11. ~~Toxoplasma antibody (Ab) test result or an appropriate donor sample sent with the heart for testing at the transplant hospital~~

For heart deceased donors, if a transplant program requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and document the request. The OPO must provide the HLA information listed above and document that the information was provided to the transplant program.

The heart recovery team must have the opportunity to speak directly with the responsible ICU personnel or the onsite donor coordinator in order to obtain current information about the deceased donor's physiology.

2.13 Post Procurement Recovery Follow Up and Reporting

~~The host OPO must establish and implement procedures to do *both* of the following:~~

- ~~1. Obtain post recovery deceased donor test results.~~
- ~~2. Report all positive screening or diagnostic tests to the transplant hospital's patient safety contact, within 24 hours of receipt by the OPO.~~

2.13.A Reporting Requirements

~~The host OPO is responsible for timely follow up and reporting of any new or changed deceased donor test results received after procurement. The host OPO must develop and comply with written protocols to do *all* of the following:~~

- ~~1. Obtain and report all deceased donor test results to the OPTN Contractor relevant transplant programs. The host OPO must report to the transplant programs *all* of the following:~~
- ~~2. Report all positive test results and relevant information according to Policy 15.4: Host OPO Requirements for Reporting Post-Procurement Test Results and Discovery of Potential Disease Transmissions~~
- ~~3. Report relevant test results and other information to tissue banks receiving donor tissue~~
 - ~~1. Updates, such as the identification of any potential disease causing organism and the sensitivity of the deceased donor to that organism, as the host OPO receives the information.~~
 - ~~2. Medical-social history, testing, and laboratory assessments that identify malignant or infectious~~

~~conditions that may adversely affect a potential transplant recipient.~~

- ~~3. Any known or suspected infectious or neoplastic conditions that may be transmitted to transplant recipients.~~

~~The host OPO must report to the OPTN Contractor's Patient Safety Portal any new disease or malignancy in the deceased donor that may be transmitted to transplant recipients.~~

15.4 Host OPO Requirements for Reporting Post-Procurement Test Results and Discovery of Potential and Proven Disease Transmissions

Host OPOs must report any test results or information received post-procurement that indicate there may be a possibility for donor-derived disease as follows.

15.4.A Transplant Program Requirements

~~When an organ recipient is suspected to have, is confirmed positive for, or has died from a potential transmissible disease or medical condition, including infections and malignancies, and there is substantial concern that it could be from the transplanted organ, then the transplant program must do *both* of the following:~~

- ~~1. Notify the institution that recovered the organ (OPO or living donor recovery hospital), without waiting for all medical documentation that may eventually become available. The transplant program must notify the living donor hospital or host OPO by phone and provide documentation as soon as possible but no later than 24 hours after learning of the event.~~
- ~~2. Report the event through the OPTN Improving Patient Safety Portal.~~

~~Any transplant program treating recipients that received organs from a donor who is the subject of a potential disease transmission report is responsible for *all* of the following:~~

- ~~1. Responding to host OPO, living donor recovery hospital, and OPTN patient safety staff requests for information regarding all recipients in a timely fashion and communicating updated information regarding recipient condition, test results, diagnosis, and plans for treatment and follow up.~~
- ~~2. Submitting copies of any relevant test results including cultures, infectious disease testing results, imaging studies, or autopsy results to OPTN patient safety staff.~~
- ~~3. Notifying recipients involved in cases of confirmed disease transmissions and documenting this notification in the recipient medical record according to *15.3.A: Donors with Additional Risk Identified Pre-transplant*.~~
- ~~4. If requested by the Ad Hoc Disease Transmission Advisory Committee, submission of a *Potential Disease Transmission Recipient Follow-Up Report* within 45 days of the initial date the potential transmission was reported.~~

~~OPTN patient safety staff may request additional information related to the recipient beyond 45 days, in an effort to determine the probability of donor-derived disease transmission, depending on the potentially transmitted disease or malignancy.~~

15.4.A Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions

The host OPO must report all positive test results and other relevant information received post-procurement for each donor as soon as possible but no later than 24 hours after receipt as follows:

1. All results indicating Pathogens of Special Interest must be reported to the receiving transplant program’s patient safety contact and the OPTN Improving Patient Safety Portal. The OPTN Contractor provides a list of Pathogens of Special Interest, including any results that can be excluded from reporting. The OPTN Contractor reviews and updates this list at least annually.
2. All other positive test results and relevant information must be reported according to *Table 15-1 below*.

Table 15-1: Host OPO Reporting Requirements for Positive Post-Procurement Donor Results and Discovery of Potential Disease Transmissions

<u>The host OPO must report <i>all</i> of the following positive results:</u>		<u>To:</u>
<u>Samples relevant to all recipients</u>	<u>Serologic, NAT, or antigen results indicating presence of parasites, virus, or fungi</u>	<u>The receiving transplant program’s patient safety contact</u>
	<u>Cultures from the following specimens:</u> <ul style="list-style-type: none"> • <u>Ascites</u> • <u>Blood</u> • <u>Cerebrospinal fluid (CSF)</u> • <u>Deep wound</u> • <u>Genital</u> • <u>Pericardial</u> • <u>Pleural fluid</u> 	<u>The receiving transplant program’s patient safety contact</u>
	<u>Mycobacterial smears and cultures</u>	<u>The receiving transplant program’s patient safety contact</u>
	<u>Fungal smears and cultures with the exception of <i>Candida</i> species</u>	<u>The receiving transplant program’s patient safety contact</u>
<u>Relevant information</u>	<u>Respiratory samples (bacterial or <i>Candida</i> species) only to transplant programs receiving lungs or head and neck VCAs</u>	<u>The receiving transplant program’s patient safety contact</u>
	<u>Urine cultures (bacterial or <i>Candida</i> species) only to transplant programs receiving kidneys or genitourinary VCAs</u>	<u>The receiving transplant program’s patient safety contact</u>
	<u>Malignancy or other findings highly suggestive of malignancy recognized after procurement</u>	<ol style="list-style-type: none"> 1. <u>The receiving transplant program’s patient safety contact</u> 2. <u>The OPTN Improving Patient Safety Portal</u>
	<u>Histopathology results reported post-procurement</u>	<u>The receiving transplant program’s patient safety contact</u>
	<u>All <i>final</i> culture information for any culture results that were reported according to these requirements</u>	<u>The receiving transplant program’s patient safety contact</u>
	<u>Other psycho-social history, medical history, autopsy, testing, and laboratory findings identifying infectious conditions that may adversely affect a potential transplant recipient</u>	<u>The receiving transplant program’s patient safety contact</u>

15.4.B Requirements for Living Donor Recovery Hospital and Host OPOs

The living donor recovery hospital or host OPO is responsible for *all* the following:

1. ~~Communication of the suspected donor's and affected recipient's test results and diagnosis that may be relevant to acute patient care as soon as possible, but no more than 24 hours after receipt, to any transplant programs, patient safety contacts, and tissue banks that received organs or tissue from the donor. This includes any test results that were not available at the time of procurement or that were performed after recovery. The living donor recovery hospital or host OPO must document that this information is shared with all receiving transplant programs and tissue banks.~~
2. ~~Notification of the event to the OPTN Improving Patient Safety Portal as soon as possible, but no later than 24 hours after receipt of test results or diagnosis.~~
3. ~~Potential disease transmission follow up communication as follows, including:~~
 - a. ~~For deceased donors, completion and submission of the *Potential Disease Transmission Report Form* no later than 24 hours after reporting the event through the OPTN Improving Patient Safety Portal. This must include:~~
 - i. ~~The specific receiving transplant program patient safety contact and tissue bank staff that were notified of the potential transmission~~
 - ii. ~~Disposition of all organs, tissues, and vessels~~
 - iii. ~~Any preliminary information available regarding any remaining deceased 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 deceased donor.~~
4. ~~A follow up review of the event, in partnership with OPTN patient safety staff, to determine whether the deceased or living donor was diagnosed with a potentially transmissible disease or condition.~~

~~For all living and deceased donors, the Ad Hoc Disease Transmission Advisory Committee may request submission of a *Potential Disease Transmission Donor Follow-Up Report* 45 days after the initial reporting date. Patient safety staff may request additional information related to the living donor beyond 45 days, including pending test results, depending on the potentially transmitted disease or condition.~~

~~If a host OPO learns new information regarding a deceased donor as part of its required donor follow up that indicates risk of potential transmission of disease or malignancy, the host OPO must report the information through the OPTN Improving Patient Safety Portal.~~

~~If a recovery hospital learns new information about a living donor during the first two years post donation that indicates risk of potential transmission of disease or malignancy, then the recovery hospital must do *at least* the following:~~

1. ~~Disclose to the living donor that a potential disease transmission or malignancy must be reported to the receiving transplant program and the OPTN Improving Patient Safety Portal~~
2. ~~Notify the receiving transplant program~~

- ~~3. Report the potential transmission through the OPTN Improving Patient Safety Portal~~

~~The recovery hospital may also need to report the new information to local, state, or federal public health authorities.~~

15.4.B Host OPO Requirements for Reporting Post-Procurement Discovery of Recipient Disease or Malignancy

If the host OPO is notified that an organ recipient is suspected to have, is confirmed positive for, or dies from a potential transmissible disease, infection, or malignancy and there is substantial concern that it could be from the transplanted organ, then the host OPO must do all the following:

1. Communicate the suspected donor's and affected organ recipient's test results and diagnosis that may be relevant to acute patient care, as soon as possible but no more than 24 hours after receipt, to any transplant program patient safety contacts and tissue banks that received organs, vessels, or tissue from the donor. This includes any test results that were not available at the time of procurement or that were performed after procurement. The host OPO must document that this information is shared with all receiving transplant programs and tissue banks.
2. Report the event to the OPTN Improving Patient Safety Portal as soon as possible but no more than 24 hours after notification or receipt of recipient test results or diagnosis.

15.4.C Host OPO Requirements for Post-Reporting Follow Up

If the host OPO reports test results or other relevant information to the OPTN Contractor through the OPTN Improving Patient Safety Portal, then the host OPO must also do all the following:

1. Complete and submit the *Potential Disease Transmission Report Form* no later than 24 hours after reporting the event through the OPTN Improving Patient Safety Portal.
2. Contribute to a follow up review of the event, in partnership with OPTN patient safety staff.
3. Provide additional information or specimens related to the deceased donor if requested.

15.5 Transplant Program Requirements for Communicating Post-Transplant Discovery of Donor Disease or Malignancy

~~If any new, clinically relevant findings about a deceased or living donor are discovered after transplant, the transplant program must complete all of the following:~~

- ~~1. Notify the recipient, or the recipient's agent, of the risk of transmissible disease that was not previously identified and is noted as clinically relevant by the recipient's care team.~~
- ~~2. Document new information about the donor and potential risk for disease or malignancy in the recipient's medical record.~~
- ~~3. Follow a recipient at increased risk for disease or malignancy for the development of the disease or malignancy after transplant.~~
- ~~4. Offer the recipient additional testing, monitoring, and treatment as appropriate, in addition to routine follow up care.~~

Transplant programs must communicate any test results or information received post-transplant that indicate donor-derived disease is possible as follows.

15.5.A Transplant Program Requirements for Post-Transplant Discovery of Donor Disease or Malignancy

1. If the findings are from transplant program testing of the donor, then the transplant program must notify the host OPO or living donor recovery hospital of the findings.
2. Notify the recipients under care at the transplant program, or the recipient's agents, of the risk or confirmation of transmissible disease or malignancy.
3. Document the new information about the donor and potential risk or confirmation of transmissible disease or malignancy in the recipients' medical records.
4. Follow the notified recipients for the development of the disease or malignancy after transplant.
5. Offer the recipients additional testing, monitoring, and treatment as appropriate, in addition to routine follow up care.

15.5.B Transplant Program Requirements for Reporting Post-Transplant Discovery of Recipient Disease or Malignancy

When an organ recipient is suspected to have, is confirmed positive for, or has died from a potential transmissible disease, infection, or malignancy and there is substantial concern that it could be from the transplanted organ, then the transplant program must do *all* of the following:

1. Notify host OPO or living donor recovery hospital that procured the organ without waiting for all medical documentation that may eventually become available. The transplant program must notify the host OPO or living donor recovery hospital by phone and provide documentation as soon as possible but no more than 24 hours after learning of the event.
2. Report the event through the OPTN Improving Patient Safety Portal as soon as possible but no more than 24 hours after learning of the event.
3. Provide additional related information or specimens if requested.

15.5.C Transplant Program Requirements for Post-Reporting Follow-Up

If the transplant program has a recipient that involved in an OPTN Improving Patient Safety Portal report, then the transplant program must also do *all* of the following:

1. Submit any relevant test results including cultures, infectious disease testing results, imaging studies, or autopsy results to OPTN patient safety staff.
2. Respond to host OPO, living donor recovery hospital, and OPTN patient safety staff requests for information regarding the recipient and communicate updated information regarding recipient condition, test results, diagnosis, and plans for treatment and follow up.
3. Contribute to a follow up review of the event in partnership with OPTN patient safety staff.
4. Provide additional related information or specimens if requested.

15.6 Living Donor Recovery Hospital Requirements for Reporting Post-Donation Discovery of Disease or Malignancy

Living donor recovery hospitals must report any post donation test results or information that indicate there may be a possibility for donor-derived disease.

15.6.A Living Donor Recovery Hospital Requirements for Reporting Post-Donation Discovery of Living Donor Disease or Malignancy

If a living donor recovery hospital learns new information about a living donor during the first two years post donation that indicates risk of potential transmission of disease or malignancy, then the living donor recovery hospital must do *all* of the following:

1. Disclose to the living donor that the potential disease transmission or malignancy will be reported to the receiving transplant program and the OPTN Improving Patient Safety Portal.
2. Notify the receiving transplant program.
3. Report the potential transmission through the OPTN Improving Patient Safety Portal.

15.6.B Living Donor Program Requirements for Post Reporting Follow-Up

If the living donor recovery hospital reports test results or other information to the OPTN Contractor through the Improving Patient Safety Portal, then the recovery hospital must also do *all* of the following:

1. Contribute to a follow up review of the event in partnership with OPTN patient safety staff.
2. Provide additional information or specimens related to the living donor if requested.

15.67 Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]