

Guidance for Reporting Potential Deceased and Living Donor-Derived Disease Transmission Events (PDTE)

Summary and Goals

The Ad Hoc Disease Transmission Advisory Committee (DTAC) created this guidance document to outline the types of events that should be reported as potential donor derived disease transmission events (PDTE) as well as the timeline for successful reporting to promote patient safety. Reporting requirements apply to both deceased and living donors and any recipients of the reported donor. Since this resource is not OPTN policy, it does not carry the monitoring or enforcement implications of policy. It is not an official guideline for clinical practice, and it is not intended to be clinically prescriptive or to define a standard of care. This is a resource provided to members for voluntary use.

Background

The DTAC is charged with considering issues related to the transmission of disease through organ transplantation. It examines the individual potential disease transmission cases reported to the OPTN in an effort to confirm transmissions where possible and reviews aggregate data on all reported cases to assess the risk of donor disease transmission in organ transplantation in the United States with the goal of providing:

- education and guidance to the transplant community toward preventing future disease transmission; and
- input in developing policy to improve the safety of organ donation through the reduction of donor derived transmission events.

As part of this work, the DTAC may identify disease-transmission related patient safety issues to be addressed, as appropriate, by the OPTN.

Previous OPTN policy language outlined requirements for reporting suspected or confirmed PDTE, but did not specifically indicate that this requirement should be applied to both deceased and living donors suspected in a donor-derived disease transmission. The OPTN/UNOS Board of Directors approved modifications to Policy 4.5 (Post-Transplant Reporting of Potential Transmission of Disease or Medical Conditions, Including Malignancy) to clearly state that these requirements should be applied to **any** organ donor.

Purpose of Reporting PDTE

Potential donor-derived disease transmission event (PDTE) reports entered into the OPTN's Improving Patient Safety portal serve several purposes, with a common goal of enhancing patient safety. These reports allow for confirmation of recipient transplant program notification, and collection of donor and recipient information needed to classify the likelihood of donor-derived transmission. DTAC facilitates communication of information between providers for the recipients of organs from a specific donor, the Host OPO or living donor recovery center and relevant governmental agencies. Reporting is essential for this safety process to function. Lessons learned from review of aggregate information collected from PDTE may result in new policy or guidance that can be shared with living donor recovery centers, OPOs, and transplant

Guidance for Reporting Potential Deceased and Living Donor-Derived Disease Transmission Events (PDTE)

centers to enhance awareness regarding disease transmission in an effort to prevent future transmission events.

Communicating New Donor Information

Any new or changed test result (or other finding relevant to recipient care) in a deceased or living donor is critical for the Host OPO or Living Donor Recovery Center to communicate to any Transplant Center that implanted an organ from this donor. The Transplant Center's Patient Safety Contact should be notified as soon as possible, but not to exceed 24 hours.

- For deceased donors, this reporting requirement appears in OPTN Policy 2.4 (Follow-Up Testing).

Circumstances Where Reporting a PDTE is Required

OPTN Policy 4.5 (Post-Transplant Reporting of Potential Transmission of Disease or Medical Conditions, Including Malignancy) requires that a PDTE be reported if one or more of the following conditions are met:

1. Evidence of the same infection or disease in both the (deceased or living) donor and recipient; or
2. Substantive concern of potential disease of donor-origin in an organ recipient of a deceased or living donor; or
3. Evidence of similar disease in multiple recipients receiving organs from the same deceased donor.

An unintended and/or unexpected finding about an organ donor (living* or deceased) should be reported as a PDTE when it recognized after transplant of an organ and is relevant to acute recipient care. These findings may include infectious disease, malignancy and other conditions. *Acute recipient care is defined as requiring intensified clinical observation; diagnostic testing; or therapeutic intervention to diagnose, prevent or treat a potentially transmitted disease.*

***For living donors**, policy requires reporting during the first two years after donation. While new malignancies discovered during this time period may be relevant to recipient care, most infectious diseases of significance will be noted within the first six months after organ recovery. However, some diseases can have latent periods for many years and go unrecognized in an individual for some time. Conditions like Tuberculosis, Chagas Disease and Human T-lymphotropic virus Type I (HTLV-I) infection are examples that meet the following criteria:

- 1) Extended asymptomatic latency
- 2) Known to cause donor-derived infection in the past
- 3) Not uniformly screened for in donors

Guidance for Reporting Potential Deceased and Living Donor-Derived Disease Transmission Events (PDTE)

Living donor recovery centers should consider reporting beyond two years if they learn information that could potentially affect recipient health.

A suspected or confirmed disease, malignancy or other condition recognized in an organ recipient should be reported as a PDTE when there is substantial concern that it could be donor-related.

Condition Specific Guidance for Reporting a PDTE

Infectious Disease

An infectious disease should be reported as a PDTE when:

- **Standard potential deceased or living donor evaluation requirements are not met**, (i.e. when a donor is not screened or evaluated as outlined in OPTN Policy 2 for deceased donors or Policy 12 for living donors), **or there is an error or miscommunication in sharing donor information that is relevant to acute patient care** (i.e. requiring intensified clinical observation, diagnostic testing or therapeutic intervention to diagnose, prevent or treat a potentially transmitted disease) **and could result in unexpected PDTE**. Examples include, but are not limited to:
 - Incomplete donor screening tests required by policy (i.e. HIV, Hepatitis, etc).
 - Donor screening result reported or shared incorrectly with recipient centers that have transplanted organs from this donor.
 - Potential discordant test results received from tissue bank or other lab.
- **New serologic or molecular donor screening results that may negatively impact a recipient** (i.e. unexpected results from tests that OPOs or Living Donor Recovery Centers may send out to labs and not receive until after transplant). Examples include, but are not limited to:
 - Positive NAT (or other molecular test) result received post-transplant on a donor allocated with negative serology result.
 - Positive serologic status if changed from what was known at procurement.
 - For example, some OPOs may receive final CMV or EBV test results post-transplant. In such cases, transplant programs generally provide prophylaxis to recipients accordingly until status is known. Positive results for such testing would not be reported

Guidance for Reporting Potential Deceased and Living Donor-Derived Disease Transmission Events (PDTE)

as a PDTE **unless** there was an error or miscommunication in reporting. For example, if the transplant program was told that an organ was CMV negative and prophylaxis was not initiated for a CMV negative recipient, but results received after transplant indicated that the donor was actually CMV positive.

- **Positive donor culture results (i.e. blood, sputum, urine, wound, etc.) that were unknown at the time of transplant AND regarded as clinically significant and pertinent to acute patient care (i.e. requiring intensified clinical observation, diagnostic testing or therapeutic intervention to diagnose, prevent or treat a potentially transmitted disease) or have the potential to result in transmission to the recipient.** This may be a difficult distinction for the OPO/Living Donor Recovery Center or recipient transplant program to make. When in doubt, the OPO or Living Donor Recovery Center may wish to consult with its medical director or contact UNOS Patient Safety staff. Examples of results or infections that should be reported include but are not limited to:
 - Positive cultures or screening tests for tuberculosis
 - fungal infections such as Cryptococcus or Aspergillus
 - Parasites
 - Protozoa
 - Viruses other than CMV or EBV
 - Blood cultures positive for bacteria that are likely to cause disease

PLEASE NOTE: Only those culture results that would have modified allocation, prevented transplant of an organ, or are relevant to acute patient care (i.e. requiring intensified clinical observation, diagnostic testing or therapeutic intervention to diagnose, prevent or treat a potentially transmitted disease) must be reported as a PDTE) **should be reported.**

In most cases coagulase negative Staphylococci, Proprionibacterium acnes, and Bacillus species will not require reporting as a PDTE. However, the Host OPO must report (per OPTN Policy 2.4) all post-transplant final culture results and any other new deceased donor information to all recipient centers within 24 hours of receipt regardless of whether a PDTE report is made.

Malignancy

Tumors suspected of being donor-transmitted are reported to the Improving Patient Safety Portal in Secure Enterprise™ and separately reported using the Transplant Recipient Follow-up (TRF) form. All other tumors, including PTLN, are reported using the TRF form only.

Guidance for Reporting Potential Deceased and Living Donor-Derived Disease Transmission Events (PDTE)

Some examples of when to suspect a donor-transmitted tumor include, but are not limited to, the following:

- Cancer in a recipient for which there is a specific suspicion of donor origin (e.g., use of organs from a donor with a known history of cancer)
- Discovery of malignancy in an organ donor during final pathology report review, tissue recovery, autopsy, etc
- Cancer (other than PTLN) arising in the recipient in the first two years post-transplant
- Cancer arising in the allograft organ in a patient with no history of carcinoma in the corresponding native organ
- Metastatic cancer arising in a transplant recipient, especially when a primary site cannot be identified
- Metastatic cancer of allograft type (e.g., renal cell carcinoma in a renal transplant recipient) in a recipient with no known history of that type of cancer
- Central nervous system (CNS) neoplasm, particularly if occurring outside of the CNS and particularly if in a transplant patient with no known history of CNS tumor
- Sex-specific cancer (e.g., choriocarcinoma, prostate carcinoma) arising in a transplant recipient of the opposite sex; or
- Age discordant cancer (e.g., pediatric tumor arising in an adult transplant recipient, or vice versa)

Other Conditions

In rare circumstances, there may be concern for transmission of other conditions outside of infectious disease or malignancy. Examples of such PDTE received through 2010 are listed at the end of this document. The recipient care team should report a new, unexpected condition as a PDTE if there is substantial concern that it may be donor-derived.

If you are unsure whether a specific situation should be reported as a PDTE, it is recommended that you report in order to promote patient safety.

The Host OPO or Living Donor Recovery Center staff should talk with their Medical Director if additional guidance is needed regarding whether to report a donor based upon final culture results or other new information learned post transplant.

Recipient transplant centers may wish to pose questions related to whether a disease or malignancy could be donor-derived to infectious disease or oncology/pathology personnel and the recipient's attending transplant surgeon. Recipient transplant centers should always notify the OPO/Living Donor Recovery Center regarding the concern of potential donor-derived disease. This allows the Host OPO/Living Donor Recovery center to follow up on donor

Guidance for Reporting Potential Deceased and Living Donor-Derived Disease Transmission Events (PDTE)

information as appropriate. This notification also allows the Host OPO to contact any other transplant centers to determine if any other recipients of this donor’s organs have developed similar symptoms or disease.

Where to Report a PDTE

Anyone with a username and password to Secure EnterpriseSM may report a PDTE using the Improving Patient Safety portal. UNOS Patient Safety staff members are available to assist you with questions during business hours at 804-782-4800. For emergency assistance outside of normal business hours, please contact the UNOS Organ Center at 800-292-9537. The Organ Center will contact the Patient Safety staff person on call to assist you.

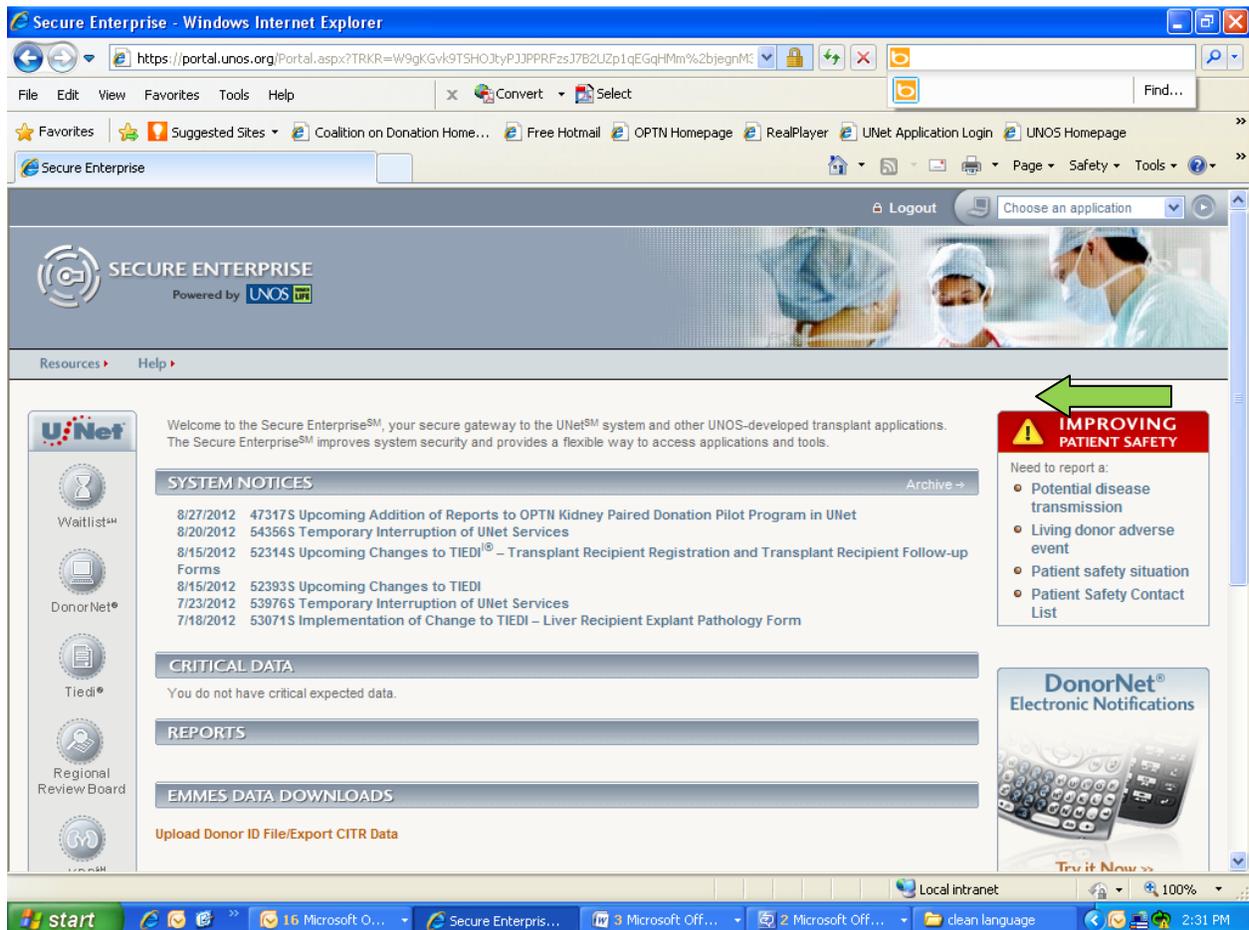


Figure 1: Screen Shot of Reporting Portal in Secure Enterprise

Guidance for Reporting Potential Deceased and Living Donor-Derived Disease Transmission Events (PDTE)

When to Report a PDTE

A recipient transplant center should not wait until all final testing is in hand if a PDTE is suspected, but rather notify the Host OPO or Living Donor Recovery Center and make a report to the Improving Patient Safety portal in Secure EnterpriseSM as soon as possible, and within 24 hours of suspecting donor-derived illness. This will alert the Host OPO and allow them time to initiate contact with other transplant programs that transplanted organs from this donor to pass information along that may impact recipient testing, treatment or prophylaxis.

The Host OPO or Living Donor Recovery Center should communicate any new donor information to all recipient transplant programs as soon as possible and within 24 hours to allow recipient care teams to determine if additional testing, treatment or prophylaxis will benefit the recipient(s) as the result of this new information.

Notifications related specifically to reported PDTEs should be made verbally, and not by fax or email unless a transplant program has requested this form of communication from the Host OPO/Living Donor Recovery Center specifically.

PDTE Reports Received through 2011 include:

A list of reported PDTE received since the Improving Patient Safety portal was implemented in March 2006 appears below. Items marked with an asterisk have resulted in at least one event classified as a probable or proven donor-derived transmission.

This is not an exhaustive list of what to report, but may be helpful as members consider PDTE reporting.

Infectious Diseases

Acinetobacter baumannii*

Actinomyces

Adenovirus

Amoebiasis

Aspergillus*

Babesiosis

Balamuthia mandrillii*

Brucella

Candidiasis

- Candida albicans*
- Candida glabrata
- Candida tropicalis*

Chagas (T. cruzi)*

Creutzfeldt-Jakob Disease (CJD)

Cytomegalovirus (CMV)*

Guidance for Reporting Potential Deceased and Living Donor-Derived Disease Transmission Events (PDTE)

Coccidioidomycosis (Valley Fever)*
Cryptococcus*
Ehrlichiosis (Ehrlichia chafeensis)*
Encephalitis
Enterobacter

- Enterobacter asburiae
- Enterobacter cloacae*

Enterococcus (VRE)*
Enterococcus gallinarum
Epstein-Barr Virus (EBV)
E. coli*
HHV-8*
Hepatitis B
Hepatitis C*
Hepatitis E
Herpes Simplex Virus
Human herpesvirus 8 (HHV8)
Histoplasmosis
Human Immunodeficiency Virus (HIV)*
Human T-cell lymphotropic virus (HTLV)*
Influenza A
Influenza A – H1N1
Klebsiella*
Legionella
Listeria monocytogenes
Lung blastomycosis
Lyme Disease
Lymphocytic choriomeningitis (LCMV)*
Meningitis
Methicillin-resistant Staphylococcus aureus (MRSA)*
Mycobacterium

- Mycobacterium abscessus
- Mycobacterium avium complex (MAC)
- Mycobacterium gordonae
- Mycoplasma hominis
- Mycobacterium intracellulare
- Mycobacterium kansasii
- Mycobacterium tuberculosis (TB)*

Neisseria meningitides
Nocardia
Parvo B19*

Guidance for Reporting Potential Deceased and Living Donor-Derived Disease Transmission Events (PDTE)

PneumoniaPseudomonas*
Rabies
Rhizopus
ScedosporiumSchistosomiasis*
Serratia marcescens*
Staphylococcus
Streptococcus
Strongyloides*
Syphilis
Toxoplasmosis*
Veillonella
West Nile Virus*
Zygomycyt

Neoplasias

Adenocarcinoma*
Astrocytoma
Basaloid CA*
Bladder CA
Breast CACHolangiocarcinoma*
Choriocarcinoma*
Dermatofibroscarcoma protuberans
Epithelioid Angiomyolipoma
Gastrointestinal stromal tumor (GIST)
Glioblastoma*Kaposi's Sarcoma
Leukemia*
Liposarcoma
Liver CA*
Lung CA*
Lymphoma*
Medullablastoma
Melanoma*
Mesothelioma*
Neuroendocrine CA*
Oncocytoma*
Ovarian CA*
Pancreatic CA
Paraganlioma*
Pineoblastoma
Prostate CA
Renal Cell Carcinoma*
Sarcoma

**Guidance for Reporting
Potential Deceased and Living Donor-Derived
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Small Bowel CA*
Small Cell CA*
Thyroid CA
Urothelial Cell CA

Other

Amyloidosis
Hemochromatosis*
Ornithine Transcarbamylase (OTC) Deficiency*
Sarcoidosis*