Guidance for Reporting
Potential Donor-Derived Disease Transmission Events (PDDTE)

Summary and Goals

On November 8, 2010, the OPTN/UNOS Board of Directors approved a re-write of OPTN Policies 2.0 and 4.0. These policy changes were implemented on January 10, 2011. Part of this rewrite covered the communication and reporting of all suspected or confirmed donor-derived disease and malignancy transmissions in organ recipients.

To assist members in better understanding the changes in this area of policy, the Ad Hoc Disease Transmission Advisory Committee (DTAC) was charged with creating a guidance document to outline the types of events that should be reported as well as the timeline and sequence of events for successful reporting to promote patient safety. Since this resource is not considered 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 will not be used to determine member compliance with policy; rather it is a resource provided to members for voluntary use.

Background

The DTAC considers 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 U.S. 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.

Prior to the DTAC's November 2010 rewrite of Policy 4.0, a list of known conditions that might be transmitted by the donor organ which should be communicated to recipient centers was included within <u>former</u> Policy section 4.6.2 (Reporting). The list, while detailed, was not comprehensive.

As UNOS Patient Safety Staff worked on a daily basis with both OPO and transplant program staff, it became apparent that some members believed that this list was meant to indicate specific conditions that were to be reported as potential donor-derived disease transmission events. This is not the case, as <u>any</u> suspected donor derived transmission event (infection, malignancy, or other condition) should be reported per OPTN Policy 4.5. While an exhaustive list cannot be compiled, this document is meant to provide guidance regarding what and when to report to the OPTN's Improving Patient Safety reporting portal for members in Secure Enterprise[SM].

Purpose of Reporting PDDTE

Potential donor-derived disease transmission event (PDDTE) reports entered in to 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 in some cases suggestions regarding additional evaluations that may help to determine donor attribution. DTAC facilitates communication of information between providers for the recipients of organs from a specific donor, the Host OPO and relevant governmental agencies. Reporting is essential for this safety process to function. Lessons learned from review of aggregate information collected from PDDTE may result in new policy or guidance that can be shared with transplant centers and OPOs to prevent future transmission events.

Circumstances Where Reporting a PDDTE is Required

In general, there are two levels of handling of potential donor-derived disease transmission event (PDDTE):

1. Communication of the finding between the Host OPO and recipient Transplant Center Patient Safety Contact; or
2. Communication of the finding between the Host OPO and recipient Transplant Center Patient Safety Contact **and** reporting of the case through the Improving Patient Safety Portal in Secure Enterprise™.

When/if a new finding in a donor (i.e. a positive culture, new pathology diagnosis of malignancy) becomes known, it is critical (and required by OPTN Policy 2.2.5 (Follow Up on Donor Testing) to communicate the finding between the host OPO and recipient Transplant Center Patient Safety Contact as soon as possible but not to exceed 24 hours.

In determining whether to report the event to the Improving Patient Safety portal (as required by OPTN Policy 4.5 (Post-Transplant Reporting of Potential Transmission of Disease or Medical Conditions, Including Malignancies), there needs:

- Evidence of infection or disease in both the donor and recipient; or
- Substantive concern of potential donor-origin of disease in a recipient; or
- Evidence of similar disease in multiple recipients receiving organs from the same donor.

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

A **recipient** should be reported as a PDDTE when a suspected (or confirmed) infectious disease, malignancy or other condition is recognized, or related death occurs and there is substantial concern that it could be donor-related.

Please consider the following information when determining whether to report a recipient or donor PDDTE:

<u>Infectious Disease</u>

- Any time standard potential donor evaluation requirements are not met, i.e. when a donor is not screened or evaluated as outlined in OPTN policy 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 PDDTE. 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 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 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 as a PDDTE **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 on blood, sputum, urine, wound, etc. that are unknown at the time of transplant and are 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 or transplant program to make. When in doubt, the OPO may wish to consult with its medical director or contact UNOS Patient Safety Staff. Examples of results that should be reported might include but are not limited to:
  - Positive tests for tuberculosis, fungal infections such as Cryptococcus or aspergillus, parasites/protozoa, viruses other than CMV or EBV, blood cultures 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 PDDTE).*

In most cases coagulase negative Staphylococci, Proprionibacterium acnes, and Bacillus species will not require reporting as a PDDTE. However, the OPO must report (per OPTN Policy 2.2.5) all post-transplant final culture results and any other new donor information to all recipient centers within 24 hours of receipt regardless of whether a PDDTE 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 PTLD, are reported using the TRF form only.

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

- Cancer in 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 PTLD) arising in the recipient in the first 2 post-transplant years.
- 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.
- 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 PDDTE received through 2010 are listed at the end of this document. The recipient care team should report a new, unexpected condition as a PDDTE if there is substantial concern that it may be donor-derived.

In any instance, if you are unsure whether a specific situation should be reported as a PDDTE, it is recommended that you report in order to promote patient safety.

It is recommended that OPO staff talk with their Medical Director if they need additional guidance regarding whether to report a donor based upon final culture results or other new information learned post transplant.

Transplant programs 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 at their center. Transplant centers should always notify the OPO regarding the concern of potential donor-derived disease. This allows the Host OPO to contact any other recipient centers to determine if other recipients of this donor's organs have developed similar symptoms or disease.

UNOS Patient Safety Staff are available to assist you with questions during business hours or you may report directly into the Improving Patient Safety portal in Secure Enterprise℠.

When to Report a PDDTE

A transplant program should not wait until all final testing is in hand if a PDDTE is suspected, but rather notify the Host OPO and/or make a report to the Improving Patient Safety portal in Secure Enterprise℠ as soon as possible, and within 24 hours of suspecting donor-derived illness. This will alert the 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.

OPOs 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.

It is recommended that notifications related specifically to reported PDDTEs are made verbally, and not by fax or email unless a transplant program has requested this form of communication from the OPO specifically.

PDDTE Reports Received through 2010 include:
A list of reported PDDTE 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 PDDTE reporting.

Infectious Diseases
Acinetobacter baumanii*
Adenovirus
Amoebiasis
Aspergillus*
Babesiosis
Balamuthia mandrillis*
Brucella
Candidiasis
- Candida albincans*
- Candida glabrata
- Candida tropicalis*

Chagas (T. cruzi)*
Creutzfeldt-Jakob Disease (CJD)
Cytomegalovirus (CMV)*
Coccidioidomycosis (Valley Fever)*
Cryptococcus*
Ehrlichiosis (Ehrlichia chafeensis)*
Encephalitis
Enterobacter
- Enterobacter asburiae
- Enterobacter cloacae*

Enterococcus (VRE)*
Enterococcus gallinarum
Epstein-Barr Virus (EBV)
E. coli*
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*
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*
Pneumoniae
Pseudomonas*
Rabies
Rhizopus
Schistosomiasis*
Serratia marcescens*
Staphylococcus
Streptococcus
Strongyloides*
Syphilis
Toxoplasmosis*
Veillonella
West Nile Virus*
Zygomyocyte

Neoplasias
Adenocarcinoma*
Astrocytoma
Basaloid CA*
Breast CA
Cholangiocarcinoma*
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
Pineoblastoma
Prostate CA
Renal Cell Carcinoma*
Sarcoma
Small Bowel CA*
Small Cell CA*
Thyroid CA
Urothelial Cell CA

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