

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

*Ad Hoc Disease Transmission
Advisory Committee*

*Dr. Michael Green, MD, MPH, Chair
November 12-13, 2012*

Background

OPTN policy, implemented in Jan 2011, outlined updated requirements for reporting suspected or confirmed PDTE

- Did not specifically indicate that this applies living donors and their recipients
- Guidance document made only general reference to living donors

Background

Living Donor Committee took modifications to OPTN Policy 4.5 to specifically include living donor PDTE reporting requirements to Board in November 2012

- Outlined LD recovery center and LD transplant hospital responsibilities

Document Development

The Living Donor Committee requested that current guidance on reporting PDTE be updated to include living donors and their recipients.

- Staff from both committees developed revisions
- Updates reviewed by DTAC
- Language refined for easier reading
- Both Committees reviewed and approved final document

Summary of Guidance

OPTN Policy 4.5 now requires that a PDTE be reported if one or more of the following conditions are met:

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

Summary of Guidance

Document includes:

- Host OPO/Living Donor Recovery Center and Transplant Hospital guidance
- Condition specific guidance for reporting a PDTE
- Assistance on where and when to report a PDTE
- A list of reported PDTE received since the Improving Patient Safety portal was implemented, March 2006

If approved...

- Guidance document will be posted on the OPTN website as a professional resource
- Will be highlighted in UNOS Update and DTAC News e-newsletter

Unanimous DTAC Support for BOD Consideration

RESOLVED, that the updated guidance document “**Guidance for Reporting Potential Deceased and Living Donor-Derived Disease Transmission Events (PDTE)**,” as set forth in Resolution 5, is hereby approved, effective November 12, 2012.

Committee vote: 18 in favor, 0 opposed, 0 abstentions

Questions?

Thank you.

Guidance for Identifying Risk Factors for *Mycobacterium tuberculosis* (MTB) During Evaluation of Potential Living Kidney Donors

*Ad Hoc Disease Transmission
Advisory Committee*

*Dr. Michael Green, MD, MPH, Chair
November 12-13, 2012*

Background

Living Donor Committee recommended TB testing as part of potential living kidney donor evaluation

- Targeted rather than universal testing for MTB was felt to be the most efficient way to identify infected potential donors
- Guidance needed within the LD recovery community to identify potential donors at increased risk of infection with MTB

MTB Prevalence

Up to 1/3 of the world's population is infected with MTB

- Infection in the U.S. is much less common.
- Reported cases of active tuberculosis have been declining in the U.S. since 1992, with the majority of cases occurring in foreign born persons

After initial infection with MTB, most people do not develop active tuberculosis; the infection disseminates throughout the body and remains dormant.

- called latent tuberculosis infection (LTBI).
- An estimated that 4.2% of the U.S. population has latent TB infection.

Latent TB Risk

Since initial infection does result in live MTB in many organs, MTB can be transmitted by donor organs

- Transmission could occur from a LD who has never had clinical signs or symptoms of active TB!
- Determining risk of exposure and screening is critical in preventing living donor-derived transmission of disease

Donor-Derived TB

As of September, 2012, 30 cases of possible, probable, or proven donor-derived TB in organ transplant recipients have been described in the literature or confirmed by DTAC.

- 4 of these were from living kidney donors
- Death occurred in 17% of recipients
 - Disease was often extra-pulmonary and diagnosis was sometimes delayed.
- Treatment of active TB in recipients can be difficult

Guidance Document Includes:

- FDA-approved tests for Latent TB
- Risk factors for active and latent TB
- Importance of careful potential donor history
- Recent published data on incidence and management of donors

If approved...

- Guidance document will be posted on the OPTN website as a professional resource
- Will be highlighted in UNOS Update and DTAC News e-newsletter

Unanimous DTAC Support for BOD Consideration

RESOLVED, that the guidance document “Guidance for Identifying Risk Factors for *Mycobacterium tuberculosis* (MTB) During the Evaluation of Potential Living Kidney Donors,” is hereby approved as set forth in Resolution 6, effective November 12, 2012.

Committee vote: 18 in favor, 0 opposed, 0 abstentions

Questions?

Thank you.