

Clarify Requirements for Reporting a Potential Disease Transmission

OPTN Ad Hoc Disease Transmission Advisory Committee

Purpose of Proposal

- Clarify transplant program requirements for reporting a potential donor-derived disease transmission event (PDDTE).
 - Referral from the OPTN Membership & Professional Standards Committee (MPSC) to define an unexpected PDDTE and clarify lung reporting requirements.
 - Differentiate between an unexpected and expected PDDTE to determine reporting requirements.
 - Distinguish between colonization of an organism vs. a donor-derived infection in the respiratory tract to clarify sick and non-sick lung reporting requirements.

Proposal

- Defines a potential unexpected transmission event.
 - Unexpected is defined as a pathogen, disease, or malignancy not known in the donor at the time of cross-clamp.
 - Definition aims to establish a specific time period in the donation process when an event is no longer considered an expected event and deemed reportable to the OPO and OPTN Improving Patient Safety Portal.

Proposal

- Distinguishes between and identifies reporting requirements for sick and non-sick lung recipients.
 - Distinction allows identification of when there is colonization of an organism (non-sick) vs when there is a donor-derived infection (sick) discovered in the respiratory tract.
 - Sick lung recipient is a lung recipient with an organism isolated from the respiratory tract or other site that directly contributes to the lung recipient's illness based on the clinical judgement of the treating physician or team. All other lungs not meeting these criteria are considered non-sick lung recipients.
 - Only organisms on the Pathogens of Special Interest list should be reported for non-sick lung recipients

Rationale

- **Unexpected Timeframe:**

- Creates a consistent timepoint for when an event is considered unexpected, so that reporting requirements are clarified for transplant programs

- **Sick Lung Recipient:**

- Given that organisms isolated from the respiratory tract do not always result in donor-derived infection, distinguishing colonization from infection may result in under/over-reporting a PDDTE

Member Actions

- Require transplant programs to report a potential unexpected transmission event to the OPO and OPTN Improving Patient Safety Portal.
- Require transplant programs to report any pathogen on the Pathogen of Special Interest list for non-sick lung recipients to the OPO and OPTN Improving Patient Safety Portal.

What do you think?

- Do you support the proposed definition of an unexpected transmission event? Do you agree with the time frame in which an event should no longer be considered expected?
- Does the definition of sick lung recipient clarify when reporting should occur?
- Do the reporting requirements for non-sick lung recipients reflect the appropriate level of reporting and avoid over and under-reporting?

FAQs

- Do expected disease transmissions need to be reported?

Additional Questions?

- Please Contact Tamika Watkins at Tamika.Watkins@unos.org

Provide Feedback

Submit public comments on the OPTN website:

- January 21, 2025-March 19, 2025
- **optn.transplant.hrsa.gov**

