OPTN

Notice of OPTN Policy Changes

Clarify Requirements for Reporting a Potential Disease Transmission

Sponsoring Committee:	**Ad Hoc Disease Transmission Advisory Committee**
Policies Affected:	***15.5: Transplant Program Requirements for Communicating Post Transplant Discovery of Disease or Malignancy*** ***15.5.A: Transplant Program Requirements for Post Transplant Discovery of Donor Disease or Malignancy*** ***15.5.B: Transplant Program Requirements for Reporting Post Transplant Discovery of Recipient Disease or Malignancy***
Public Comment:	**January 21, 2025 – March 19, 2025**
Board Approved:	**June 10, 2025**
Effective Date:	**August 1, 2025**

Purpose of Policy Changes

The purpose of this policy change is to improve patient safety by clarifying transplant programs' reporting requirements when there is discovery of a potential transmission of unexpected pathogen, disease, or malignancy. The policy changes more clearly define an unexpected transmission to help transplant programs understand requirements and ensure that appropriate events are reported.

In addition, the policy changes specifically address reporting requirements for lung transplant recipients. The policy changes distinguish between reporting requirements for lung recipients showing clinical evidence of infection and lung recipients with evidence of colonization but not showing evidence of infection to ensure patient safety concerns are properly communicated.

Proposal History

The Membership & Professional Standards Committee (MPSC) requested the Committee clarify the reporting requirements for transplant programs, proposed defining what constitutes an unexpected event to distinguish it from an expected occurrence.[5] This clarification was intended to help determine whether specific events should be reported to the OPTN Improving Patient Safety Portal and to the host Organ Procurement Organization (OPO). Additionally, the MPSC asked the Committee to identify specific reporting requirements for lung transplant recipients that would define when reporting is required: since lungs are not sterile, there are complexities in determining whether an organism is merely colonizing or if a genuine donor-derived infection exists.

The proposal was generally supported during public comment, with feedback requesting further clarification regarding lung recipient reporting requirements and some comments expressing concern about the timeframes for determining when an infection should be considered donor-derived. A few changes were made post-public comment, including refining the definitions for lung recipients and restructuring the policy language to enhance clarity and ensure consistency in transplant program reporting requirements. The updated policy now clearly states that transplant programs must report pathogens, diseases, and malignancies when specified criteria are met.

Summary of Changes

OPTN Policy *15:5: Transplant Program Requirements for Communicating Post Transplant Discovery of Disease or Malignancy* is updated to clarify that a potential transmission is unexpected if the pathogen, disease, or malignancy was not known in the donor at the time of cross-clamp. The policy is further updated to distinguish between and clarify specific reporting requirements for lung recipients with clinical evidence of infection and lung recipients with evidence of colonization but not showing clinical evidence of infection. For lung recipients who show clinical evidence of infection, transplant programs will follow existing reporting requirements if there is substantial concern that the potential transmission of an unexpected pathogen, disease, or malignancy is from the donor. For lung recipients who have evidence of colonization but are not showing evidence of clinical infection, transplant programs must report if the respiratory tract testing reveals an unexpected positive result for a pathogen on the Pathogen of Special Interest (POSI) list or a malignancy, and there is concern the pathogen or malignancy is from the donor. This distinction ensures that reporting is both clinically relevant and appropriately targeted.

Implementation

Transplant programs:

- Must be familiar with the proposed definitions of an unexpected disease transmission event, a lung recipient showing clinical evidence of infection, and a lung recipient with evidence of colonization but not showing clinical evidence of infection.
- Are required to report a potential transmission of an unexpected donor-derived pathogen, disease or malignancy to the OPTN Patient Safety Reporting Portal and host OPO for all non-lung recipients and lung recipients with clinical evidence of infection.
- Are required to report a potential transmission of an unexpected organism on the POSI list or malignancy to the OPTN Patient Safety Reporting Portal and host OPO for all lung recipients showing evidence of colonization but not showing clinical evidence of infection.

OPTN:

- The OPTN will plan for communication with its members to make them aware of this policy change and will provide educational materials to aid transplant programs in meeting compliance requirements.

Affected Policy Language

New language is underlined (<u>example</u>) and language that is deleted is struck through (~~example~~).

15.5 Transplant Program Requirements for Communicating ~~Post-Transplant~~ Discovery of <u>Potential Transmission of Unexpected Pathogen,</u> Disease, or Malignancy

A potential transmission of a pathogen, disease, or malignancy is unexpected if the pathogen, disease, or malignancy was not known to the transplant program by the time of donor cross-clamp.

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

15.5.A Transplant Program Requirements for ~~Post-Transplant~~ Discovery of Potential Transmission of Unexpected Donor Pathogen, Disease, or Malignancy

If the transplant program identifies any results indicative of unexpected pathogen, disease or malignancy from donor specimen testing collected pre-transplant ~~findings are from transplant program testing of the donor~~, then the transplant program must do *all* of the following:

1. Notify the host OPO or living donor recovery hospital of the findings within 24 hours of discovery.
2. Notify the recipients under care at the transplant program, or the recipient's agents, of the risk or confirmation of unexpected transmissible disease or malignancy.
3. Document the new information about the donor and potential risk or confirmation of unexpected transmissible disease or malignancy in the recipients' medical records.
4. Follow the notified recipients for the potential 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 Potential Transmission of Unexpected Recipient Pathogen, Disease or Malignancy

~~When an organ recipient is suspected to have, is confirmed positive for, or has died from an 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:~~

Transplant programs are required to report the discovery of a potential transmission for the following recipients:

- A non-lung organ recipient who:
  1. Is suspected to have, is confirmed positive for, or has died from any unexpected potential transmissible pathogen, disease, or malignancy, and
  2. There is substantial concern that the suspected or confirmed pathogen, disease, or malignancy could be from the transplanted organ
- A lung recipient who:
  1. Is suspected to have, is confirmed positive for, or has died from an unexpected potential transmissible pathogen, disease, or malignancy, and
  2. There is substantial concern that the suspected or confirmed disease, malignancy, or infection could be from the transplanted organ and
  3. There is clinical evidence of infection. A lung recipient is considered to have clinical evidence of infection based on the clinical judgment of the treating physician or team if:
     1. An organism is isolated from the respiratory tract or other site and
     2. There is substantial concern that the organism is donor-derived and contributes to the lung recipient's illness.

- A lung recipient who:
    1. Shows evidence of colonization but not clinical evidence of infection and
    2. Respiratory tract testing reveals an unexpected positive result identifying a Pathogen of Special Interest or malignancy, and
    3. There is substantial concern that the unexpected positive result is from the transplanted organ.

Transplant programs are required to report the discovery of a potential transmission of an unexpected recipient pathogen, disease, or malignancy meeting the criteria above by doing all of the following:

1. Notify the primary Patient Safety Contact at the host OPO of the deceased donor or transplant program at which the living donor was recovered and provide available documentation within 24 hours of learning of the event. If the primary Patient Safety Contact of the host OPO of the deceased donor or transplant program at which the living donor was recovered does not acknowledge receipt of the information within 24 hours, then the transplant program must notify the secondary Patient Safety Contact.
2. Report ~~the~~ as a disease transmission event through the OPTN Patient Safety Reporting Portal no more than 24 hours after learning of the event.
3. Provide additional related information or specimens if requested.
4. Update the host OPO and the OPTN disease transmission report in the OPTN Patient Safety Reporting Portal with any new information related to the event, including death of the recipient.