OPTN

Public Comment Proposal

Clarify Requirements for Reporting a Potential Disease Transmission

OPTN Ad Hoc Disease Transmission Advisory Committee

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Clarify Requirements for Reporting a Potential Disease Transmission

Affected Policies:	*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*
Sponsoring Committee:	*Ad Hoc Disease Transmission Advisory*
Public Comment Period:	*January 21, 2025 – March 19, 2025*

Executive Summary

The Ad Hoc Disease Transmission Advisory Committee (the Committee) aims to update and clarify *OPTN Policy 15:5: Transplant Program Requirements for Communicating Post Transplant Discovery of Disease or Malignancy* to improve patient safety and accurate reporting of potential unexpected disease transmissions. The OPTN Membership and Professional Standards Committee (MPSC) has requested the Committee to amend OPTN policy and clarify transplant program reporting requirements when there is discovery of an unexpected donor-derived disease transmission. Transplant programs have expressed concerns regarding the distinction between expected and unexpected events, particularly concerning the timeframe during the transplant process when an event ceases to be classified as expected.[1] The absence of a precise definition for unexpected events has resulted in ambiguity and confusion about whether certain occurrences should be reported to the OPTN Improving Patient Safety Portal and host Organ Procurement Organization (OPO) or transplant program where a living donor was recovered. This lack of clarity has also contributed to over and under-reporting of a potential donor-derived disease transmission. These inconsistent reporting practices may create inefficiencies or delay timely communication with other recipients who received organs from the same donor. The proposal seeks to incorporate a definition of unexpected disease transmission into *Policy 15:5*, based on whether the potential disease was known in the donor at the time of organ recovery.

Furthermore, the proposal seeks to specifically address the reporting requirements for lung transplant recipients. Given that lungs are not sterile, there are complexities in determining whether an organism is merely colonizing or if a genuine donor-derived infection exists. The Committee considers that mere colonization does not warrant reporting to the OPTN Improving Patient Safety Portal or host OPO. To mitigate these issues, the Committee proposes to define a sick lung recipient as a recipient with an organism isolated from the respiratory tract that contributes to illness based on the clinical team's judgment. Reporting is required for sick lung recipients, but not for non-sick lung recipients unless the organism discovered is on the Pathogen of Special Interest (POSI) list.[2] The POSI is a list of reportable conditions maintained by the Committee in consultation with the Centers for Disease Control and Prevention. It includes microorganisms that can cause serious infections, spread easily, or resist current

[1] Ad Hoc Disease Transmission Committee, OPTN, meeting summary for March 5, 2024, accessed December 11, 2024 https://optn.transplant.hrsa.gov/media/mlxn3p4y/20240305_communicatingtxdisease_ms_final.pdf.
[2] OPTN. Pathogens of Special Interest. (Accessed December 18, 2024) https://optn.transplant.hrsa.gov/media/yyhnrkar/special_pathogens_list.pdf.

treatment. Overall, the proposed policy changes aim to provide more clarity on when potential donor-derived disease transmission events must be reported to the OPTN and other OPTN members.

Purpose

This project aims to clarify transplant programs' reporting requirements when there is discovery of a potential donor-derived disease infection or malignancy. *OPTN Policy 15:5: Transplant Program Requirements for Communicating Post Transplant Discovery of Disease or Malignancy* requires transplant programs to communicate any test results or information received post-transplant that may indicate donor-derived disease.[3] The purpose is to clarify reporting requirements by defining the difference between unexpected and expected transmission and being precise in describing what constitutes an unexpected transmission. The proposed clarifications will provide a definition for unexpected events and delineate a timeframe within the donation process after which these events are no longer deemed expected. The proposed changes will help transplant programs better understand what is required and ensure that appropriate events are reported. The changes should also reduce the reporting of expected events, which are unnecessary for review from a safety perspective.

Furthermore, this proposal intends to differentiate and clarify the reporting requirements for lung recipients categorized as sick versus non-sick. Lung transplant recipients frequently undergo airway sampling shortly after transplantation; however, not all organisms isolated from the respiratory tract are true pathogens leading to disease. The proposed policy includes definitions for sick and non-sick lung recipients, along with the corresponding reporting requirements for these individuals. Thus, it is crucial to distinguish between sick and non-sick lung recipients to ascertain the necessity of reporting and to ensure patient safety concerns are communicated.

Background

In November 2010, the OPTN Board of Directors approved modifications to former OPTN Policies 2.0, *Minimum Procurement Standards for an Organ Procurement Organization*, and 4.0, *Acquired Immune Deficiency Syndrome (AIDS) and Human Pituitary Derived Growth Hormone*.[4] These modifications included additional language to clarify and improve OPO and transplant program screening requirements for communicating and reporting potential or confirmed donor-related disease transmission events. Following the implementation of these policies in 2011, the OPTN Board of Directors approved a comprehensive rewrite of these policies, resulting in a renumbering of these sections. These updated policies are now in *OPTN Policy 15: Identification of Transmissible Diseases*. Currently, *OPTN Policy 15.5.B* requires programs to report recipient illness from any potential donor-derived disease to the OPTN Improving Patient Safety Portal and the host OPO or transplant program where a living donor has been recovered. Members have identified several needs for policy clarification about what potential donor-derived events must be reported to the OPTN and affected members.

The MPSC is responsible for evaluating and supporting OPTN members by providing feedback and recommendations to improve members' performance and compliance, including addressing risks to

[3] *OPTN Policy 15:5:Transplant Program Requirements for Communicating Post Transplant Discovery of Disease or Malignancy* https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.
[4] Board of Directors Meeting, OPTN, Executive summary for November 8-9, 2010, accessed December 11, 2024, https://optn.transplant.hrsa.gov/media/1799/executivesummary_1110.pdf.

patient safety The MPSC may refer project ideas to other OPTN committees to help provide clarity and guidance to members. The MPSC has requested that the Committee clarify the reporting requirements for transplant programs, particularly concerning lung transplants, and has proposed defining what constitutes an unexpected event to distinguish it from an expected occurrence.[5] They also asked the Committee to identify specific reporting requirements for lung transplant recipients that would define when reporting is required.

The Committee formed the *Requirements for Communicating Transplant Disease Workgroup* (the Workgroup) with representatives from the OPTN Lung, OPO, Transplant Coordinator, and Operations and Safety Committees to clarify transplant program reporting requirements.

Overview of Proposal

The Committee proposes definitions of an unexpected transmission event and a sick lung recipient.[6] The Committee also proposes specific reporting requirements for lung recipients. The Committee recommends amending *OPTN Policy 15.5: Transplant Program Requirements for Communicating Post-Transplant Discovery of Disease or Malignancy*, to incorporate a definition of an unexpected transmission event. The Committee proposes changes to *OPTN Policy 15.5.B: Transplant Program Requirements for Reporting Post-Transplant Discovery of Recipient Disease or Malignancy*, to mandate that unexpected events, rather than expected events, be reported to the host OPO (or living donor recovery hospital) and OPTN Improving Patient Safety Portal. The Committee also proposes defining a sick lung recipient as 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 judgment of the treating physician or team. All other lung recipients not meeting these criteria would be considered non-sick lung recipients. These clarifications differentiate between sick and non-sick lung recipients to help programs understand what is required to be reported for each lung recipient type. All events involving a sick lung recipient would continue to be a required reporting event. For non-sick lung recipients, the proposed changes would require reporting to the OPTN and impacted members only when a pathogen listed on the POSI[7] is identified.

Unexpected Transmission Event

The Committee has put forth a definition for an unexpected potential donor-derived transmission event and proposes to amend policy to require reporting only when events are unexpected. The Committee agreed that an unexpected transmission event should be clearly defined in OPTN policy to distinguish it from an expected event.[8] The Committee proposes defining an unexpected transmission event as a pathogen, disease, or malignancy that was not known in the donor at the time of cross-clamp. Establishing a specific timeframe within the transplant process is essential to determine when an event is no longer considered expected. The time of donor cross-clamp was chosen as it provides a consistent reference point for transplant programs to use in determining if reporting is necessary. This clarity will help ensure that all organs are evaluated based on the same knowledge available at that moment. Any

[5] Ad Hoc Disease Transmission Advisory Committee, OPTN, meeting summary for April 4, 2023, accessed December 11, 2024, https://optn.transplant.hrsa.gov/media/e1idagpd/20230404_dtac_summary.pdf.
[6] Ad Hoc Disease Transmission Advisory Committee, OPTN, meeting summary for October 8, 2024, accessed December 11, 2024, https://optn.transplant.hrsa.gov/media/u2lmrq5m/20241008_optn_dtac_summary.pdf.
[7] Ibid.
[8] Ad Hoc Disease Transmission Advisory Committee, OPTN, meeting summary for April 2, 2024, accessed December 11, 2024, https://optn.transplant.hrsa.gov/media/cm1anmaf/20240402_communicatingtxdisease_ms.pdf.

potential transmission information emerging after this point in time would be considered relevant to all organs and defined as unexpected. All unexpected potential donor-derived transmission events must be reported both to the host OPO or transplant program where a living donor has been recovered and to the OPTN Improving Patient Safety Portal.

Sick vs. non-sick lung recipients

The Committee proposes defining a sick lung recipient as 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 judgment of the treating physician or team. All other lung recipients not meeting these criteria would be considered non-sick lung recipients.[9] This proposed definition aims to clearly distinguish between lung recipients who are sick due to a potential donor-derived pathogen and those who are not. This distinction is important for consistent reporting and alters the reporting duties of transplant programs based on whether the recipient is considered sick with a potential donor-derived pathogen or not.[10] Furthermore, the Committee proposes that programs report organisms identified on the POSI list identified in non-sick lung recipients. While the Committee acknowledges these recipients may not be ill due to a donor-derived infection, POSI findings must still be reported due to their potential relevance. This approach aims to streamline reporting requirements and prevent transplant programs from having to report every positive culture obtained from a lung recipient. It also aims to promote efficiency without having a negative impact on patient safety.

NOTA and Final Rule Analysis

The Committee submits this proposal under the authority of the National Organ Transplantation Act (NOTA), which states that the OPTN shall "adopt and use standards of quality for the acquisition and transportation of donated organs"[11] as well as under the authority of the OPTN Final Rule, which states the OPTN Board of Directors shall be responsible for developing "….policies, consistent with recommendation of the Centers for Disease Control and Prevention, for the testing of organ donors and follow-up of transplant recipients to prevent the spread of infectious diseases."[12] OPTN Policy outlines the transplant program's obligations to communicate test results or information received post-transplant that may indicate donor-derived disease. This proposal will clarify reporting requirements for unexpected disease transmission events and add more specific requirements for lung transplant recipients to improve consistent reporting of a potential disease transmission event.

Implementation Considerations

Member and OPTN Operations

This proposal would impact transplant programs and the OPTN, but would not impact organ procurement organizations or histocompatibility laboratories.

[9] Ad Hoc Disease Transmission Advisory Committee, OPTN, meeting summary for June 13, 2024, accessed December 11, 2024, https://optn.transplant.hrsa.gov/media/1q2dlt0l/20240613_communicatingtxdisease_ms.pdf.
[10] Ibid.
[11] 42 USC 274(b)(2)(E).
[12] 42 CFR Part 121.4(a)(2).

Operations affecting Transplant Hospitals

Transplant programs will need to be familiar with the proposed definitions of an unexpected event, a sick lung recipient, and a non-sick lung recipient. Transplant programs will be required to report potential unexpected transmission events to the OPTN Improving Patient Safety Portal and host OPOs. Transplant programs will be required to report organisms on the POSI list for all non-sick lung recipients.

Operations affecting Organ Procurement Organizations

This proposal is not anticipated to affect the operations of organ procurement organizations.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

Operations affecting the OPTN

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

Potential Impact on Select Patient Populations

There is no potential impact on select patient populations. This proposal will affect all donors and recipients.

Projected Fiscal Impact

The Fiscal Impact Advisory Group, comprised of representatives from histocompatibility laboratories, organ procurement organizations, and transplant hospitals, reviewed this proposal and completed a survey to estimate anticipated costs. They rated this project as low, medium, or high based on the estimated staffing and/or training, overtime, equipment, or IT support needed in the implementation of this proposal.

This proposal was determined to have a low overall fiscal impact on organ procurement organizations and transplant hospitals. No significant fiscal impacts were recorded for histocompatibility labs.

Projected Impact on Transplant Hospitals

This proposal is not expected to have a significant impact on transplant programs since programs have a reporting process in place.

Projected Impact on Organ Procurement Organizations

This proposal is not expected to have a significant impact on OPOs since OPOs have a reporting process in place.

Projected Impact on Histocompatibility Laboratories

This proposal is not anticipated to have any fiscal impact on histocompatibility laboratories.

Projected Impact on the OPTN

It is estimated that $26,547 is needed for the development of this proposal. Development includes committee preparation and facilitation, proposal development, research and analysis, presentations, and compliance evaluation. It is estimated that $20,168 would be needed to implement this proposal.

Implementation would involve specific implementation related communications and educational materials, updates to OPTN documents, templates, and processes. It is estimated that $5,144 will be needed for ongoing support. Ongoing support will include member support, monitoring, and post-implementation evaluation. The total for development, implementation, and ongoing support is estimated to be $51,859.[13]

Post-implementation Monitoring

Member Compliance

The Final Rule requires that allocation policies "include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program."[14] This proposal will not change the current routine monitoring of OPTN members. The OPTN Contractor will continue to review and assess all reports of potential disease transmission or malignancy sent through the OPTN Patient Safety Reporting Portal. In the event that the OPTN Contractor identifies a test result or information that indicates potential unexpected donor-derived disease or malignancy and the result or information was not reported to the OPTN Patient Safety Reporting Portal, the OPTN Contractor will request that the transplant program report the result or information to the OPTN Patient Safety Reporting Portal. Any data entered in the OPTN Computer System may be reviewed, and members are required to provide documentation as requested.

Policy Evaluation

The Committee will consider the overall volume of unexpected transmission events and unexpected events involving lung recipients reported to the OPTN Improving Patient Safety Portal as key metrics to assess the proposed changes to OPTN Policy. OPTN Contractor staff will review the unexpected transmission events per the Committee's request.

Conclusion

The DTAC seeks to clarify transplant program reporting requirements to facilitate prompt communication regarding any potential unexpected donor-derived transmission events. These clarification efforts include an update to *OPTN Policy 15:5: Transplant Program Requirements for Communicating Post Transplant Discovery of Disease or Malignancy* to include a definition of an unexpected transmission event. Furthermore, efforts to clarify reporting requirements for lung transplants involve distinguishing between a sick and non-sick lung recipient, leading to updates in *OPTN Policy 15.5.B: Transplant Program Requirements for Reporting Post-Transplant Discovery of Recipient Disease or Malignancy.* This policy revision will define a sick lung recipient and outline the specific reporting obligations for these individuals. Overall, these policy enhancements are designed to foster accurate reporting of unexpected transmission events and ensure timely communication of potential patient safety concerns among transplant programs, OPOs, and the OPTN.

[13] Resource estimates are calculated by the current contractor for that contractor to perform the work. Estimates are subject to change depending on a number of factors, including which OPTN contractor(s) will be performing the work, if the project is ultimately approved.

[14] 42 CFR §121.8(a)(7).

Considerations for the Community

The DTAC is requesting public comment feedback, including input on the following questions:

- 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?

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

15.5 Transplant Program Requirements for Communicating Potential Unexpected ~~Post-Transplant~~ Discovery of Disease or Malignancy

A potential transmission is unexpected if the pathogen, disease, or malignancy was not known in the donor at the time of 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 Unexpected Donor Disease or Malignancy

If the transplant program identifies any results indicative of unexpected 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 Unexpected Recipient Disease or Malignancy

A 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 judgment of the treating physician or team. All other lung recipients not meeting these criteria are considered non-sick lung recipients.

Because lung transplant recipients often have routine surveillance bronchoscopy, policy differentiates the recovery of positive testing in those with and without illness in the reporting requirements.

When an organ recipient or sick lung recipient is suspected to have, is confirmed positive for, or has died from an unexpected 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 according to *Table 15-3 below*.

Table 15-3: Transplant Program Reporting Requirements for Discovery of Recipient Disease Transmissions

Type of Recipient	If the following occurs:	Then the TX program must do *all* of the following:
All organ recipients other than non-sick lung recipients	If suspected to have, is confirmed positive for, or has died from any unexpected potential transmissible disease, malignancy, or infection and there is substantial concern that it could be from the transplanted organ	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 within 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.
Non-Sick Lung Recipient	Respiratory tract testing reveals an unexpected positive result identifying a Pathogen of Special Interest or malignancy	

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