OPTN

Briefing to the OPTN Board of Directors on

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*
Board of Directors Meeting:	*June 9, 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 to provide accurate reporting of potential transmissions of unexpected pathogens, diseases, and malignancies. The OPTN Membership and Professional Standards Committee (MPSC) has requested the Committee amend OPTN policy and clarify transplant program reporting requirements when there is discovery of a potential transmission of an unexpected pathogen, disease, or malignancy. Transplant programs have raised questions 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 Patient Safety Reporting Portal and Organ Procurement Organizations (OPOs). This lack of clarity has also contributed to over- and under-reporting of potential transmissions of unexpected pathogens, donor-derived diseases, and malignancies. These inconsistent reporting practices may delay timely communication with other recipients who received organs from the same donor. The proposal seeks to incorporate a definition into *Policy 15:5: Transplant Program Requirements for Communicating Discovery of Potential Transmission of an Unexpected Disease or Malignancy* regarding when a potential transmission is unexpected, based on whether the pathogen, disease, or malignancy was known in the donor at the time of cross clamp.

Furthermore, the proposal seeks to specifically address the reporting requirements for lung transplant recipients. To clarify transplant program reporting requirements for lung recipients, the Committee proposed distinguishing reporting requirements between a lung recipient with clinical evidence of infection and a lung recipient with evidence of colonization but not showing clinical evidence of infection. Given that lungs are not sterile, there are complexities in determining whether an organism is merely colonizing or if a donor-derived infection exists. Colonization implies that the patient has high concentration of organisms at a site that can be detected, yet the organism is causing no signs or

[1] Meeting summary for March 5, 2024, OPTN Ad Hoc Disease Transmission Advisory Committee, https://optn.transplant.hrsa.gov (accessed May 12, 2025).

symptoms.[2] The Committee considers that mere colonization does not warrant reporting to the OPTN Patient Safety Reporting Portal because colonization does not pose the same risks as a true infection, except in circumstances where the pathogen is an organism on the Pathogen of Special Interest (POSI) list. To mitigate these issues, the Committee proposes defining clinical evidence of infection for lung recipients as follows: an organism has been isolated from the respiratory tract of a lung recipient and there is substantial concern that the organism is donor-derived and contributes to the lung recipient's illness, based on the judgment of the clinical team. The proposed reporting requirements for a lung recipient with clinical evidence of infection differ from the requirements for a lung recipient with evidence of colonization but no clinical evidence of infection. In this instance, reporting is not required unless the colonization indicates an organism on the POSI list or a malignancy.

The Committee considers that these proposed changes ultimately enhance the accuracy of reporting and promote consistent communication in cases of unexpected disease transmission.

Purpose

This project aims to clarify transplant programs' reporting requirements when there is discovery of a potential transmission of unexpected pathogen, disease, 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 proposed changes are more precise in describing what constitutes an unexpected transmission, to help transplant programs better understand what is asked of them 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.

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. This proposal intends to distinguish between lung recipients showing clinical evidence of infection and lung recipients with evidence of colonization but not showing evidence of infection 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 *Policy 2.0: Minimum Procurement Standards for an Organ Procurement Organization*, and *Policy 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*.

[2] Robinson J. Colonization and infection of the respiratory tract: What do we know? Paediatr Child Health. 2004 Jan;9(1):21-4. doi: 10.1093/pch/9.1.21. PMID: 19654976; PMCID: PMC2719511.
[3] OPTN Policy 15:5, Transplant Program Requirements for Communicating Post Transplant Discovery of Disease or Malignancy (May 12, 2025).
[4] Meeting Summary for November 8-9, 2010, OPTN Board of Directors Meeting, https://optn.transplant.hrsa.gov (accessed May 12, 2025).

Currently, OPTN *Policy 15.5.A* requires transplant programs to communicate any test results or information received post-transplant that indicate a donor-derived disease to the OPTN Patient Safety Reporting Portal and the OPO. Members have identified a need for more clarification about whether an event should be reported and the timeframe in which it should be reported if additional donor information is received post-transplant. Members also identified the need for more precise reporting requirements for lung recipients showing clinical evidence of infection and lung recipients with evidence of colonization but not showing evidence of infection. Consistent with member feedback, the MPSC requested that the Committee clarify when reporting is required for lung recipients and propose a definition of what constitutes an unexpected disease transmission.[5]

To address these issues, 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. The Workgroup clarified transplant program reporting requirements and advised the Committee on the proposed reporting standards. Their recommendation informed the proposed requirements for the OPTN Board consideration, as outlined in the following section.

Proposal for Board Consideration

The Committee proposes updates to Policy 15.5: *Transplant Program Requirements for Communicating Post Transplant Discovery of Disease or Malignancy* to clarify transplant program reporting requirements by defining an unexpected disease transmission event and a lung recipient showing clinical evidence of infection.

The Committee proposes differentiating between lung recipients who experience an infection versus those with colonization of an organism but without clinical evidence of infection to clarify transplant program reporting requirements. Feedback from the public suggested avoiding the term "sick" and using more patient-friendly language than what the Committee originally proposed in their public comment proposal.[6] The Committee agrees and proposes to refer to lung recipients with clinical evidence of infection instead of ‘sick’ lung recipients. Similarly, the Committee proposes referring to lung recipients with evidence of colonization but without evidence of infection instead of ‘non-sick’ lung recipients. This change aims to reflect the clinical status of the lung recipient based on the transplant program's medical judgement, while using terminology that is clearer and more appropriate.

The Committee proposes the definition of a lung recipient who has clinical evidence of infection based on the clinical judgment of the treating physician 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. Lung recipients with evidence of colonization, but not clinical evidence of infection, whose respiratory tract testing reveals an unexpected positive result identifying a POSI or malignancy, are not considered to show evidence of donor-derived infection. The Committee proposes that transplant programs still report any organism on the POSI list or evidence of malignancy for a lung

[5] Meeting Summary for April 4, 2023, OPTN Ad Hoc Disease Transmission Advisory Committee, https://optn.transplant.hrsa.gov (accessed December 11, 2024).
[6] *Clarify Requirements for Reporting a Potential Disease Transmission*, OPTN Ad Hoc Disease Transmission Advisory Committee, January 2025, https://optn.transplant.hrsa.gov (accessed May 19, 2025).

recipient who shows evidence of colonization but not clinical evidence of infection to the OPTN and OPO.

No changes were made to the proposed definition of an unexpected transmission event, which identifies a potential transmission as unexpected if the pathogen, disease, or malignancy was known in the donor at the time of cross-clamp. Any information received by the transplant program at the time cross-clamp or beyond this time is required to be reported to the OPTN and host OPO. The policy language was restructured for maximum clarity and to ensure the language is clear regarding transplant programs reporting requirements. Additionally, policy was updated to consistently state that pathogens, diseases, and malignancies must be reported by transplant programs if criteria are met. The change ensures appropriate reporting still occurs when a pathogen is discovered in the absence of a disease, and clarifies that the requiring disease reporting incorporates the reporting of infections. These updates are essential to ensure the policy is both comprehensive and consistent in outlining reporting requirements. Additionally, educational materials will be available to transplant programs for further guidance on these reporting requirements.

Overall Sentiment from Public Comment

The proposal was released for public comment from January 21, 2025 – March 19, 2025. The Committee welcomed all input on *Clarify Requirements for Reporting a Potential Disease Transmission*, and asked for the following specific feedback during public comment:

- 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?

The proposal received support from various OPTN committees and stakeholder organizations as indicated in **Table 1**. Generally, public comment participants supported the proposal with a few areas of clarification for consideration.

Table 1: Public Comments from OPTN Committees and Stakeholder Organizations

OPTN Committees	Stakeholder Organizations
Organ Procurement Organization (OPO)	American Society of Transplant Surgeons (ASTS)
Membership and Professional Standards Committee (MPSC)	American Nephrology Nurses Association (ANNA)
Transplant Coordinator Committee (TCC)	The Society of Thoracic Surgeons (STS)
Lung Transplantation Committee	North American Transplant Coordinators Organization (NATCO)
Patient Affairs Committee	American Society for Histocompatibility and Immunogenetics (ASHI)

Sentiment in Public Comment

Sentiment by Region (OPTN Regional Meetings)

Sentiment is collected on public comment proposals and is measured on a 5-point Likert scale from strongly oppose to strongly support (1-5).

Figure 1 shows the overall sentiment captured during OPTN regional meetings, based on a total of 234 responses. Overall, feedback has been supportive of the proposal, reflected in an average sentiment score of 4.2.

Figure 1: Overall Sentiment (OPTN Regional Meetings)

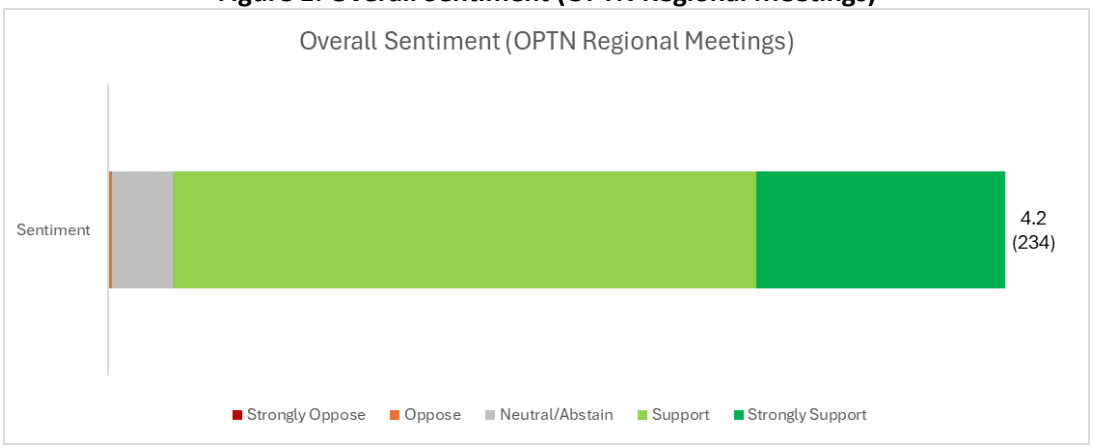


Figure 2 displays the sentiment scores of various member types from regional meetings. Overall, the sentiment is predominantly supportive across all member types.

Figure 2: Sentiment by Member Type

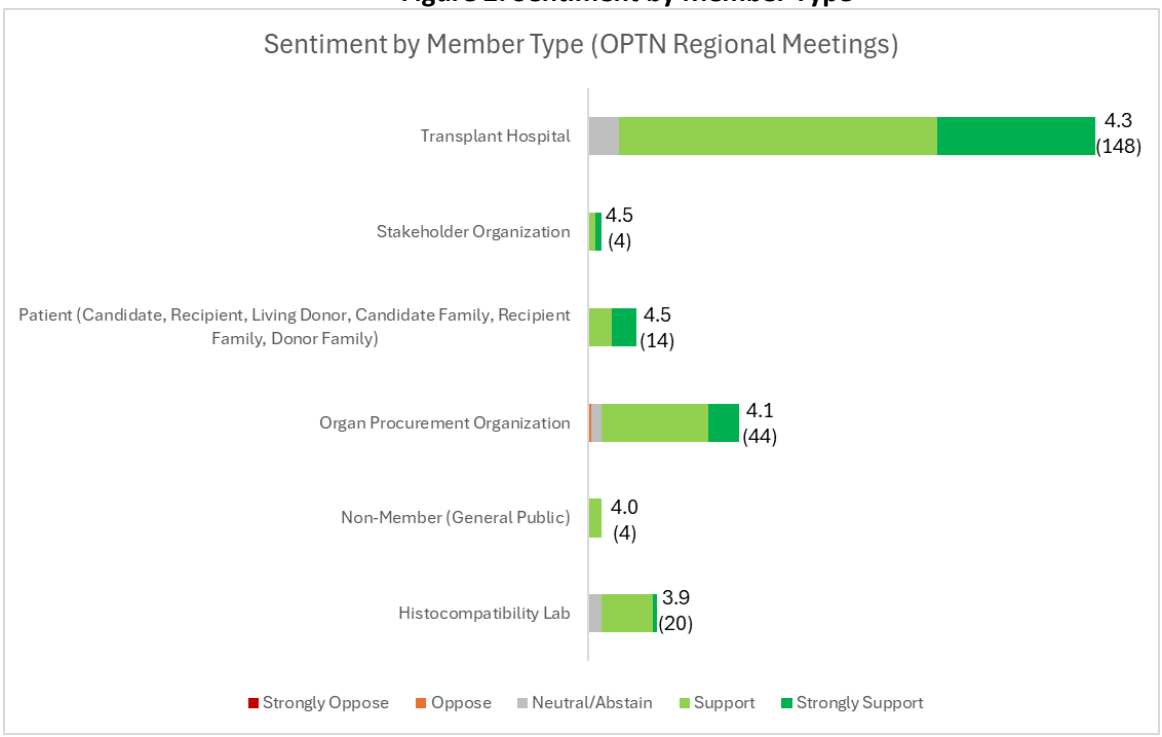
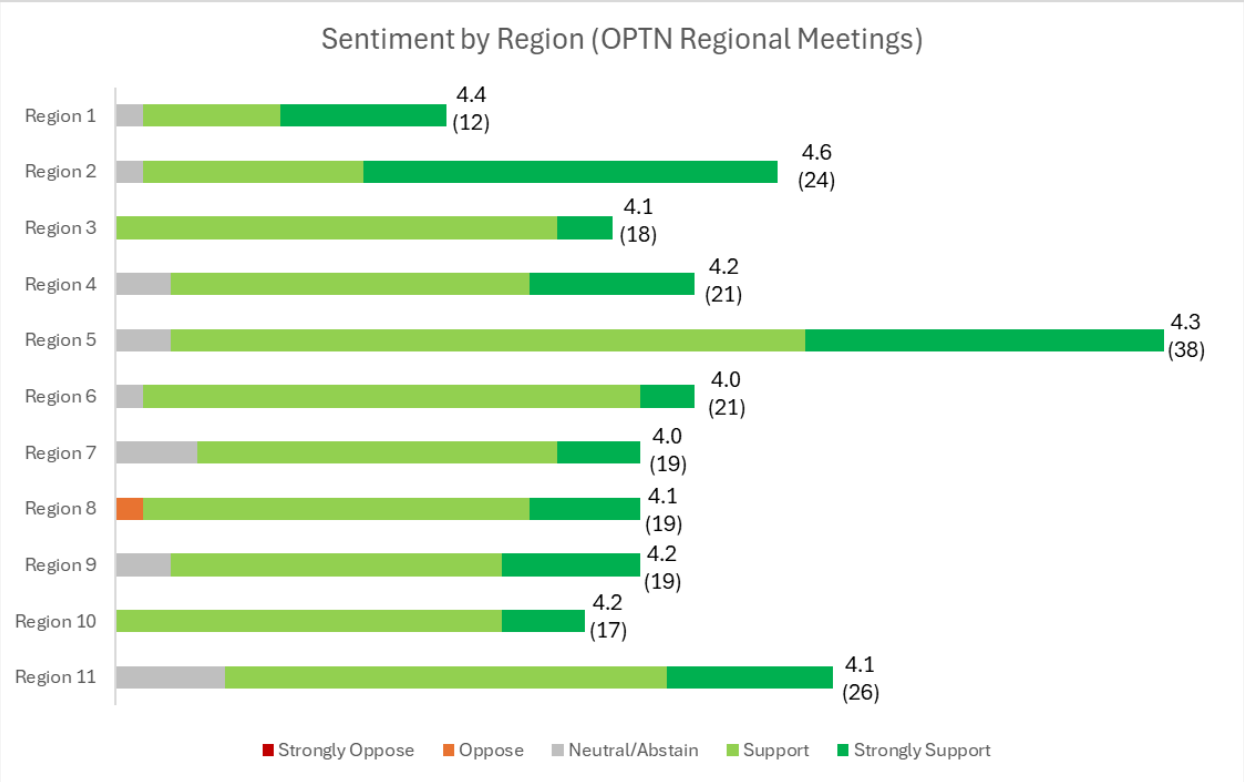


Figure 3 shows sentiment by region. Overall, all regions showed support for the proposal across all regions with slight opposition indicated by Region 8.

Figure 3: Sentiment by Region



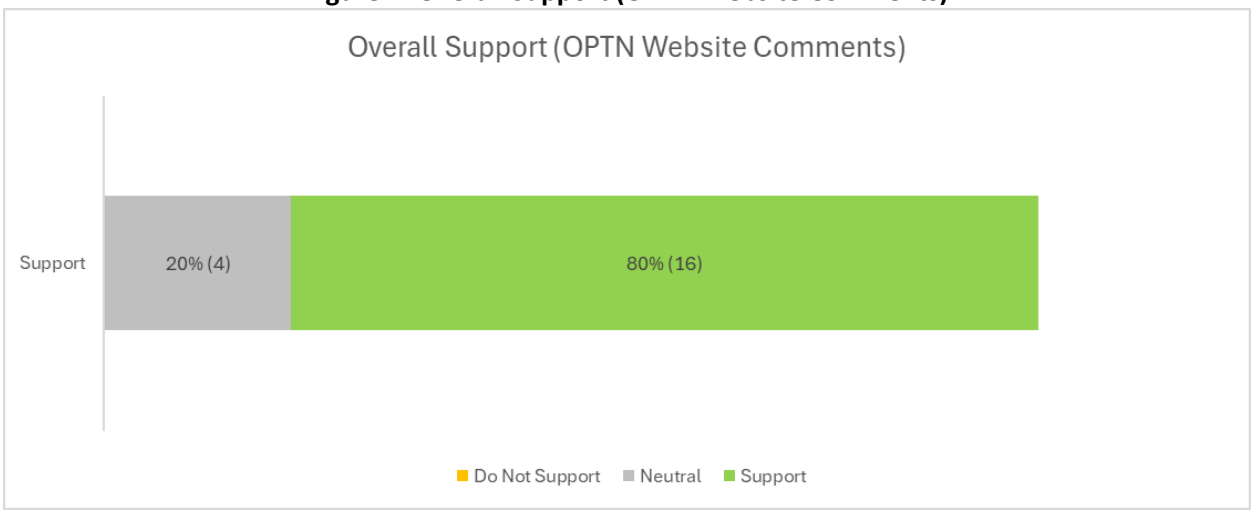
Support on OPTN Website

The public comments submitted on the OPTN website were categorized based on the sentiment expressed in the text submitted. Each comment was analyzed to identify whether it conveyed support, opposition, or neutrality towards the proposal. The following definitions were used to ensure clarity and consistency in the categorization process:

- **Support:** The text of the public comment expressed a positive stance towards the proposal. Supportive comments typically contained language that endorsed, agreed with, or advocated for the proposal.
- **Do Not Support:** The text of the public comment expressed a negative stance towards the proposal. Comments that do not support the proposal contained language that opposed or disagreed with the proposal.
- **Neutral:** The text of the public comment did not clearly express a positive or negative stance towards the proposal. Neutral comments lacked definitive "support" or "not support" language or presented balanced viewpoints on the proposal.

Figure 4 shows overall support from the OPTN website, with 80% (16) of comments being supportive and 20% (4) of comments being neutral.

Figure 4: Overall Support (OPTN Website Comments)



Themes in Public Comment

Clarify unexpected disease transmission definition

Feedback generally supported the definition of an unexpected event as a pathogen, disease, or malignancy not known in the donor at the time of cross-clamp. However, some feedback indicated the need for a clearer timeframe to determine when an event is no longer considered donor-derived.

The Committee acknowledges that potential donor-derived transmissions can be discovered at varying times post-transplant, depending on the type of organism. Some potential disease transmissions are discovered early post-transplant, while others are discovered late post-transplant. This variability makes it difficult to define a precise timeframe for when an event is no longer considered donor-derived. Furthermore, imposing a strict timeframe could result in missed opportunities for reporting a potential donor-derived disease transmission. The Committee therefore affirmed its decision to not include a point at which an event is no longer considered as a donor-derived disease transmission to avoid potential donor-derived disease transmissions going unreported.

The Committee also affirmed its use of cross-clamp as a standard reference point from which to consider the discovery of potential donor-derived disease as unexpected. The use of cross-clamp creates consistency across organ type and reduces the potential for misinterpretation of policy by creating a standardized point at which a potential transmission is considered unexpected. No changes were made to the proposed definition.

Clarify sick lung recipient definition

Feedback indicated concerns about defining a lung recipient as "sick," due to the term's ambiguity and the challenge of accurately assessing a recipient's clinical status based on such a vague term. Lung recipients may experience varying degrees of illness, and attempting to define a "sick" lung recipient

could lead to multiple interpretations. Consequently, the Committee decided to use alternative terminology to provide clearer guidelines, defining a lung recipient with clinical evidence of infection (previously known as sick) and a lung recipient with evidence of colonization but not showing clinical evidence of infection (previously known as non-sick) to distinguish between lung recipients and clarify reporting requirements.

Additionally, there were concerns about the timing of reporting a donor-derived disease transmission for lung recipients. Feedback raised concerns about differentiating donor-acquired infections from those acquired post-transplant and recommended establishing a specific timeframe to determine when an infection should be considered donor-derived, as it may be difficult to discern whether the recipient is ill due to a donor-derived infection. The Committee acknowledged the difficulty in providing a specific timeframe for when a lung recipient shows clinical evidence of infection, as pathogens, malignancies, and fungal organisms are identified over varying time periods. These differences in timing can be challenging to standardize in policy. While the Committee did not specify a more precise timeframe, they emphasized in the policy language that reporting is required when there is substantial concern that the organism is donor-derived and contributes to the lung recipient's illness. Furthermore, the definition provides flexibility to allow the clinical judgment of the treating team/physician to determine when an event requires reporting. Additionally, further guidance and educational resources will be provided to clarify reporting requirements.

Compliance Analysis

NOTA and OPTN Final Rule

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"[7] 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."[8] 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.

OPTN Strategic Plan

The proposed updates align with the strategic plan to enhance OPTN efficiency by clarifying reporting requirements to further improve the accuracy of reporting of potential disease transmission. Clarifying reporting requirements will help programs distinguish whether a potential donor-derived transmission poses a risk to the recipient and requires reporting or not, while mitigating either overreporting and underreporting to the OPTN. The project aims to clarify the policy reporting requirements process to make the process more efficient by accurately and timely reporting a potential disease transmission.

[7] NOTA, 42 U.S .C 274(b)(2)(E).
[8] 42 C.F.R Part 121.4(a)(2).

Implementation Considerations

This proposal would impact transplant programs, OPOs, and the OPTN, but would not impact histocompatibility laboratories.

Transplant Programs

Operational Considerations

Transplant programs will need to 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. Transplant programs will be required to report potential unexpected donor-derived transmission events to the OPTN Patient Safety Reporting Portal and host OPOs for all non-lung recipients and lung recipients with clinical evidence of infection. Transplant programs will be required to report organisms on the POSI list or malignancies 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. Since lung transplant recipients often undergo routine surveillance bronchoscopy, policy differentiates the recovery of positive testing in those with and without clinical evidence of infection in the reporting requirements. Furthermore, no reporting is required if a lung recipient has evidence of colonization but does not have clinical evidence of infection and the organism is not on the POSI list or a malignancy.

Fiscal Impact

This proposal is expected to have low fiscal impact on transplant hospitals, with minimal education needed to update staff on reporting requirements.

Organ Procurement Organizations

Operational Considerations

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

Fiscal Impact

This proposal is expected to have a low impact on OPOs, with minimal education needed to update staff on reporting requirements.

Histocompatibility Laboratories

Operational Considerations

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

Fiscal Impact

The proposal is not expected to have any significant fiscal impact on histocompatibility laboratories.

OPTN

Operational Considerations

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.

Resource Estimates

It is estimated that $20,536 would be needed to implement this proposal. Implementation would involve reviewing and preparing implementation communications and educational materials, updating the Evaluation Plan and process documents, and community outreach. It is estimated that $4,731 will be needed for ongoing support. Ongoing support includes member support, education, and compliance monitoring. The total for implementation and ongoing support is estimated to be $25,267.[9]

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."[10] 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 pathogen, disease or malignancy transmission 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 pathogen, 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 Patient Safety Reporting Portal as key metrics to assess the proposed changes to OPTN Policy. OPTN Contractor staff will review the unexpected transmission events at the Committee's request.

Conclusion

This policy proposes updates to 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 transmission events. This policy clarifies that a potential transmission is

[9] 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.

[10] See 42 C.F.R. 121.8(a)(7).

unexpected if the pathogen, disease, or malignancy was not known in the donor at the time of cross-clamp.

Additionally, this policy distinguishes between and clarifies 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 recipients who show clinical evidence of infection, transplant programs would be required to follow existing reporting requirements if there is substantial concern that the potential pathogen, disease, or malignancy is from the donor. In contrast, lung recipients who have evidence of colonization but are not showing evidence of clinical infection, reporting is only required if the respiratory tract testing reveals a pathogen on the POSI list or a malignancy. This distinction ensures that reporting is both clinically relevant and appropriately targeted.

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 ~~Post-Transplant~~ Discovery of Potential Transmission of Unexpected Pathogen, 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.

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