OPTN

Briefing to the OPTN Board of Directors on

Standardize the Patient Safety Contact and Reduce Duplicate Reporting

OPTN Ad Hoc Disease Transmission Advisory Committee

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Standardize the Patient Safety Contact and Reduce Duplicate Reporting

Affected Policies:	*15.1: Patient Safety Contact* *15.4.A: Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions* *15.4.B: Host OPO Requirements for Reporting Post-Procurement Discovery of Recipient 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 23, 2024 – March 19, 2024*
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Executive Summary

The Organ Procurement and Transplantation Network (OPTN) Ad Hoc Disease Transmission Advisory Committee (the Committee) aims to update OPTN Policy *15: Identification of Transmissible Diseases* to ensure the Patient Safety Contact requirements are described accurately and support timely reporting of notifications of potential disease transmission and related communication. The OPTN Membership and Professional Standards Committee (MPSC) identified issues through its monitoring activities related to inconsistently written protocols across organ procurement organizations (OPOs) and transplant programs, which can lead to difficulty and increased time spent contacting the Patient Safety Contact or receiving confirmation of successful notification of results.[1] Therefore, the Committee proposes revisions to policy to better define the responsibilities of Patient Safety Contacts and to standardize the process of reporting donor results in the OPTN Donor Data and Matching System. The proposed policy change would require verification of the listed Patient Safety Contacts bi-annually. Modifications to policy would require the use of a system enhancement to the OPTN Donor Data and Matching System for OPOs to administer notification of donor-derived test results and for transplant programs to confirm receipt of these notifications.

Additionally, OPTN Policy *15.4.B: Host OPO Requirements for Reporting Post-Procurement Discovery of Recipient Disease or Malignancy* and OPTN Policy *15.5.B: Transplant Program Requirements for Reporting Post-Transplant Discovery of Recipient Disease or Malignancy* require both OPOs and transplant programs to report any finding of recipient disease or malignancy to the OPTN Patient Safety Reporting Portal.[2] This has resulted in duplicative reporting to the OPTN. In response, the Committee proposes that transplant programs will be the only OPTN member type responsible for reporting recipient illness to the OPTN. This will not eliminate the OPO's responsibility to report recipient illness to

[1] OPTN Ad Hoc Disease Transmission Advisory Committee Meeting Summary for March 20, 2023, accessed November 2, 2023, available https://optn.transplant.hrsa.gov/media/senbcfna/20230320_dtac_summary.pdf.

[2] OPTN Policy *15.4.B: Host OPO Requirements for Reporting Post-Procurement Discovery of Recipient Disease or Malignancy* and *15.5.B: Transplant Program Requirements for Reporting Post-Transplant Discovery of Recipient Disease or Malignancy* (Accessed November 2, 2023) https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.

other transplant programs with recipients of the same donor and the requirement to report post-procurement Pathogens of Special Interest to the OPTN Improving Patient Safety Portal.
To address public comment concerns regarding the OPTN's scope of authority and the potential for added inefficiencies, the committee decided to remove the proposed requirement that the Patient Safety Contact must be an employee of the OPO or transplant program. The Committee considers that the current proposal still achieves its aim of improving the patient safety portal.

Purpose

The purpose of this project is to improve the effectiveness of the Patient Safety Contact and infectious disease and malignancy reporting processes. OPTN Policy *15.1: Patient Safety Contact* currently requires each OPO and transplant program to identify a Patient Safety Contact who is available 24 hours a day to receive, respond, and communicate regarding infectious disease and malignancy results.[3] The inconsistencies in protocols surrounding the Patient Safety Contact at transplant programs and OPOs can lead to a single point of failure for reporting potential disease transmissions. The proposed changes further standardize policy for timely reporting of potential disease transmissions, including notification, follow-up, and the receipt and dissemination of information. The standardization of this process involves a notification system that OPOs can initiate when donor results are obtained post-procurement that may affect the recipient. OPOs will be required to notify transplant hospitals of positive donor test results through the system enhancement. The transplant programs will need to acknowledge that they have received notification of the test results within 24 hours through the system enhancement. The system enhancement applies only to donor test results; any reports of recipient illness should be shared through any form of communication practiced by the OPO or transplant program. Both the OPOs and transplant programs will need to verify the primary and secondary patient safety contact listed is accurate bi-annually to ensure communication of infectious diseases and malignancy results are being reported to the correct patient safety contacts verified in the system.

As part of efforts to improve infectious disease and malignancy reporting processes, the Committee also proposes to eliminate the need for OPOs to report recipient illness to the OPTN Patient Safety Reporting Portal. This will reduce duplicative reporting of potential donor-derived transmission events since transplant programs already report this information.

Background

Patient Safety Contact

The *Proposal to Modify OPO and Transplant Center Requirements for Screening, Communicating and Reporting All Potential or Confirmed Donor-Related Disease and Malignancy Transmission Events* was approved by the OPTN Board of Directors in 2011 and introduced the Patient Safety Contact requirement for OPOs and transplant programs in OPTN Policy. This was implemented to enhance patient safety and ultimately improve recipient outcomes associated with potential donor-derived disease transmission events. OPTN members have voiced frustration in challenges locating the correct person to share information with regarding a potential disease transmission or safety event at an OPO or transplant program. As a result, the Committee proposed a new role, the Patient Safety Contact, at each OPO and transplant program to assume this responsibility.[4]

[3] OPTN Policy *15.1: Patient Safety Contact* (Accessed November 2, 2023) https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.

[4] "Proposal to Modify OPO and Transplant Center Requirements for Screening, Communicating and Reporting All Potential or Confirmed Donor-Related Disease and Malignancy Transmission Events," OPTN, Briefing Paper, accessed November 2, 2023. https://bodandcommittees.unos.org/archive/Documents/Proposal%20to%20Modify%20OPO%20and%20Transplant%20Center%20Requirements%20for%20Donor-Related%20Disease%20and%20Malignancy%20Transmission%20Events%20-BP.pdf.

Currently, the Patient Safety Contact is responsible for:

- Receiving pertinent medical information that may affect or change recipient care
- Communicating information to the appropriate medical professional responsible for clinical care of the recipient(s) at the transplant program as soon as possible, but no later than 24 hours after becoming aware of a potential disease transmission
- Facilitating communication about the current clinical status of any recipient for whom the program is informed of a concern for a possible or proven disease transmission related to the donor[5]

Oftentimes, a Patient Safety Contact can include more than one individual to support the role of receiving and communicating information regarding potential disease transmission. An individual who has patient safety contact system permission may designate a person or specific telephone number to contact related to patient safety communication. There are no specific requirements or qualifications that must be met to fulfill the position. This designation is not intended to be part of membership criteria and is not expected to become part of the membership process. As a result, it is not included as a requirement in the OPTN Bylaws. Patient Safety Contact information must be exchanged between the OPO and transplant programs to facilitate effective communication should a potential disease transmission or patient safety situation arise.

Public feedback gathered in response to the proposal entitled *Improving Post-Transplant Communication of New Donor Information,* on which public comment was received from January through March 2016,[6] highlighted the need for standardization where feasible to improve the quality of communication processes, including more agile processes for identifying and contacting Patient Safety Contacts. OPTN members have continued to voice these concerns.

The MPSC handles issues of member non-compliance with OPTN policy. When the MPSC notices trends in policy violations, they refer project ideas to other OPTN committees to help provide clarity and guidance to members. The MPSC asked the Committee to standardize the Patient Safety Contact notification process. As a result, the Committee discussed using an electronic notification system that requires confirmation of receipt and submission of updates about donor disease test results. They suggested that this voluntary system enhancement to the OPTN Donor Data and Matching System for automated notification and confirmation of post-procurement donor test results should be mandatory. The MPSC also asked the Committee to investigate opportunities to standardize processes for reporting culture results and potential disease transmissions, follow-up on those reports, and receipt and dissemination of information.[7]

The issues noted regarding the implementation of OPTN Policy *15.1: Patient Safety Contact* are more qualitative than quantitative. The issues highlighted for the Committee are as follows:

- Listing an invalid email address which 'forces' contact via phone
- Invalid phone numbers listed
- Listing pagers as phone numbers
- No backup contact listed when the primary contact is not available

[5] OPTN Policy *15.1: Patient Safety Contact* (Accessed November 2, 2023). https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.
[6] https://optn.transplant.hrsa.gov/media/1870/dtac_briefingpaper_posttx_201606.pdf.
[7] OPTN Ad Hoc Disease Transmission Advisory Committee Meeting Summary for March 20, 2023, accessed November 2, 2023, available https://optn.transplant.hrsa.gov/media/senbcfna/20230320_dtac_summary.pdf.

- OPOs spending excess time trying to reach someone/awaiting call-backs, or never getting an email acknowledgement
- Wider distribution identified as a contributing factor as members do not have the same relationship/contacts as they do with transplant hospitals within their donation service area (DSA)
- Utilization of on-call groups who do not understand the reason they are being contacted
- Currently, there is no audit or periodic request for members to review/update patient safety contact information
- Third party organizations listed as the Patient Safety Contact who either did not answer or instructed the OPO to contact someone else

The Committee formed the Standardize the Patient Safety Contact and Duplicate Reporting Workgroup (the Workgroup) to address these concerns. The Workgroup reviewed data in July 2023 that showed 101 transplant programs had not updated their Patient Safety Contacts since 2017.[8] While the data showed that some Patient Safety Contacts have not been updated recently, the accuracy of this data varies. Some Patient Safety Contacts have not changed since 2017 and are still current, while others list individuals who no longer work at the organization and are therefore inaccurate. It is critical to confirm this information is correct to ensure appropriate and timely communication occurs among Patient Safety Contacts at transplant programs and OPOs.

Duplicate Reporting

OPTN Policy *15.4.B: Host OPO Requirements for Reporting Post-Procurement Discovery of Recipient Disease or Malignancy* and OPTN Policy *15.5.B: Transplant Program Requirements for Reporting Post-Transplant Discovery of Recipient Disease or Malignancy* have resulted in duplicative reporting to the OPTN Patient Safety Reporting Portal, which leads to unnecessary burden on members and the OPTN. There were between 47 and 62 duplicate potential disease transmission events reported annually to the OPTN Patient Safety Reporting Portal over a four-year period beginning in 2018.[9] The number of duplicate reporting of transmission events may continue to increase if both OPTN member types continue to report recipient illness to the OPTN.

In 2016, public comment received on the proposal titled *Improving Post-Transplant Communication of New Donor Information*[10] asked for ways for OPOs and transplant programs to receive feedback on cases or have search abilities to identify previously reported cases to avoid unnecessary duplicative reporting. During this time, the Committee did not change the current policy that requires both OPOs and transplant hospitals to report to avoid the greater harm and potential for missing reports.

Proposal for Board Consideration

The Committee proposes the following modifications to Policy *15.1: Patient Safety Contact:*

1. Require OPOs and transplant programs to list a secondary Patient Safety Contact
2. Require verification of listed Patient Safety Contacts and contact information biannually

[8] OPTN Data Request. July 2023.
[9] OPTN Data Request. March 20, 2023.
[10] https://optn.transplant.hrsa.gov/media/1870/dtac_briefingpaper_posttx_201606.pdf.

3. Require the use of a system enhancement to the OPTN Donor Data and Matching System for OPOs to administer notification of positive donor test results post-procurement.
4. Require the transplant program's Patient Safety Contact to acknowledge receipt of notification of post-procurement donor results through the OPTN Donor Data and Matching System within 24 hours of receipt.
5. Require the receiving Patient Safety Contact to acknowledge all information communicated between OPOs and transplant programs within 24 hours of receipt.

The Committee no longer recommends that the Patient Safety Contact work at the OPO or transplant program for which they are listed. Some public comments supported the proposed requirement, while other comments opposed it and expressed the onerous responsibilities that would be put on transplant programs if mandated. Comments also stated that employment status is determined by the institution and not the OPTN. The Committee concluded that it is not necessary for the Patient Safety Contact to work at the OPO or transplant program for which they are listed in order to accomplish the aims of the proposal, ensuring patient safety while improving efficiency.

Further, not including a requirement that the Patient Safety Contact work at the OPO or transplant program would allow the transplant program to list individual(s) from a third-party organization as the Patient Safety Contact. However, the Patient Safety Contact listed still must have a valid email address and phone number to communicate when there is a notification of urgent potential disease transmission information. Group emails may be used, as long as the Patient Safety Contact listed is reachable at that email address listed. The OPTN member institution is responsible for ensuring that the individual(s) listed as the Patient Safety Contact at the third-party vendor acknowledges receipt of all information from the OPO that may affect the recipient's care within 24 hours of receipt.

Additionally, the Committee proposes modifications to OPTN Policy *15.4.B: Host OPO Requirements for Reporting Post-Procurement Discovery of Recipient Disease or Malignancy* to remove the requirement for OPOs to report recipient illness to the OPTN Patient Safety Reporting Portal. Current policy requires that transplant programs also report the recipient's illness to the OPTN Patient Safety Reporting Portal. The proposed updates would require transplant programs to be the only OPTN member type to report recipient illness to the OPTN.

Overall Sentiment from Public Comment

The Committee welcomed all input on *Standardize the Patient Safety Contact and Reduce Duplicate Reporting*, and asked for the following specific feedback during public comment:

- Do you support the additional requirements for the Patient Safety Contact?
- Do you support the requirement of a listed secondary contact?
- Do you support the requirement that a listed Patient Safety Contact must work at the OPO or transplant program for which they are listed?
- Are there any additional requirements the Committee should consider for the Patient Safety Contact?
- Does eliminating the need for OPOs to report recipient illness to the OPTN open the potential for missed reporting to the OPTN Patient Safety Reporting Portal?
- Is the monitoring plan for this policy change sufficient?

During the public comment cycle, the Committee received support and appreciation for its efforts to standardize the patient safety contact process and ensure accurate and timely reporting between OPOs and transplant programs. The proposal received 312 sentiment responses which included responses from various member types and 11 regions. In addition, **Table 1** represents the 6 OPTN Committees and stakeholder organizations that provided feedback on the proposal.

Table 1: Public Comments from OPTN Committees and Stakeholder Organizations

OPTN Committees	Stakeholder Organizations
Organ Procurement Organization (OPO)	American Society of Transplant Surgeons (ASTS)
Vascularized Composite Allograft (VCA) Committee	Associations of Organ Procurement Organizations (AOPO)
Transplant Coordinator Committee (TCC)	American Society of Transplantation (AST)
Transplant Administrator Committee (TAC)	North American Transplant Coordinators Organization (NATCO)
Living Donor Committee	American Nephrology Nurses Association (ANNA)
Membership & Professional Standards Committee (MPSC)	International Society for Heart and Lung Transplantation (ISHLT)

Figure 1 shows the sentiment received from all respondents (regional meeting, online, and email) by their stated member type. Most member types supported or strongly supported the proposal, demonstrated by an overall sentiment score of 4.2, in which transplant programs accounted for most responses. A minority of respondents expressed opposition. The opposing few included representation from patients, stakeholder organizations, and transplant hospital member types.

Figure 1: Sentiment by Member Type

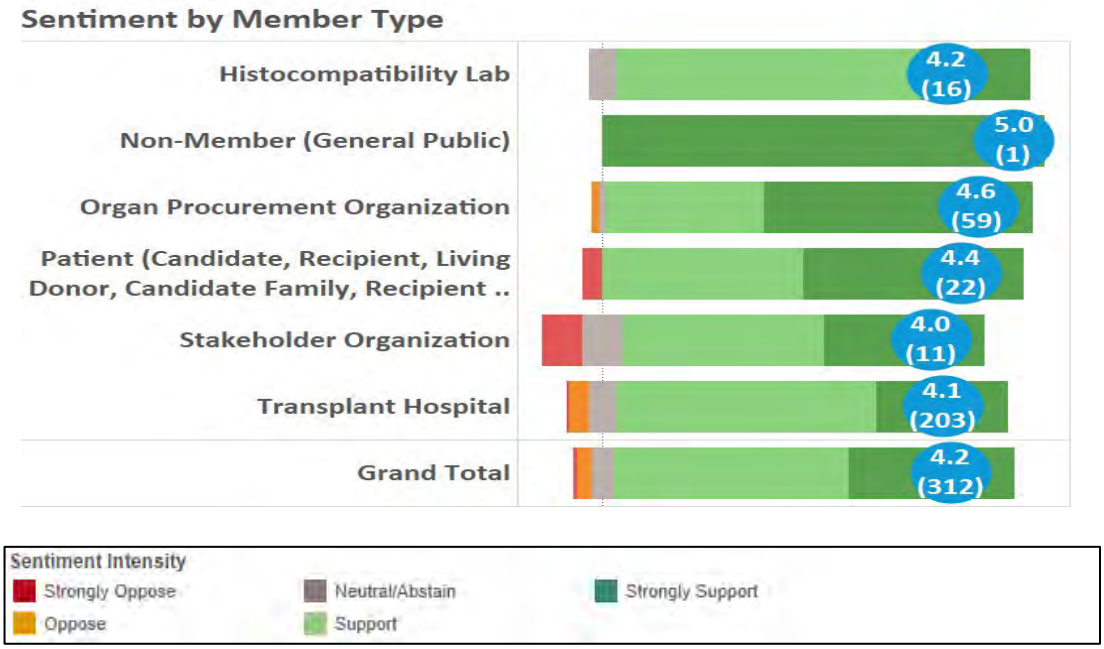
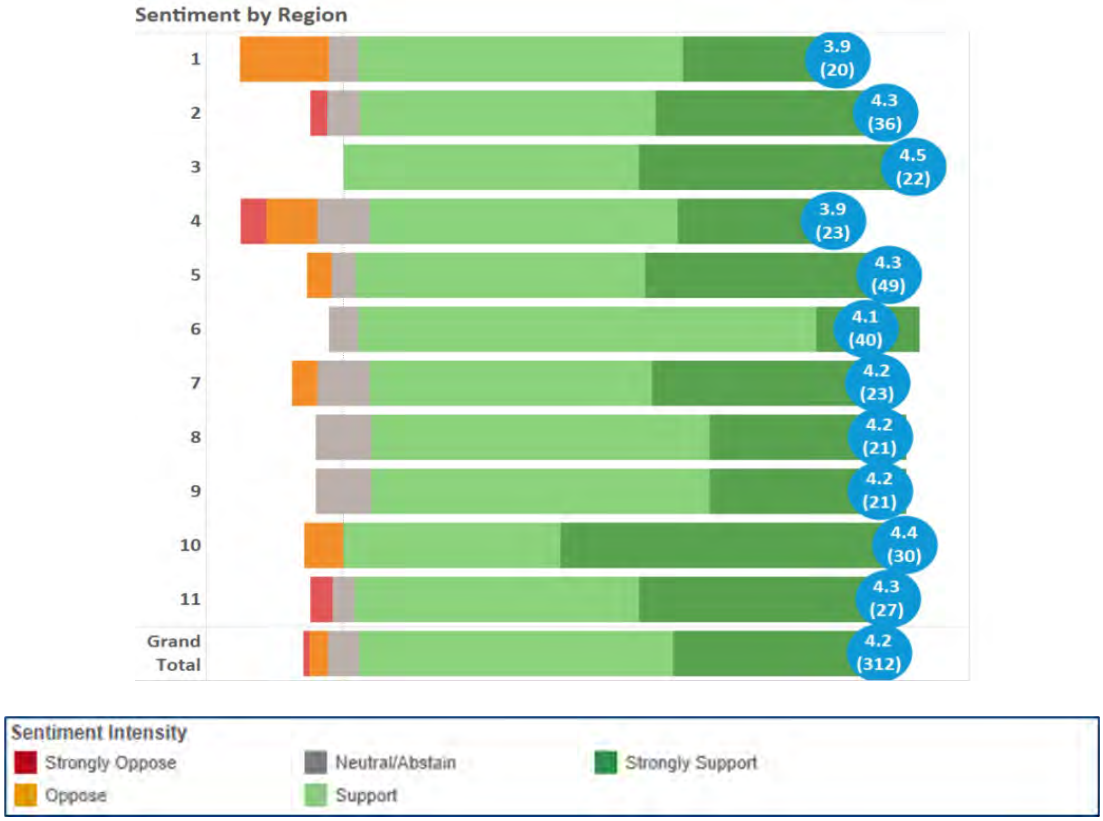


Figure 2 shows the sentiment received from each of the 11 regions. The proposal received majority support with a minority of opposing scores in all regions; regions 3, 6, 8 and 9 had no opposition recorded.

Figure 2: Sentient by OPTN Region



Themes in Public Comment

Duplicate reporting

The Committee proposed removing the requirement for OPOs to report recipient illness to the OPTN Improving Patient Safety Reporting Portal. Comments received showed full support for the removal of this requirement from policy. Comments aligned with the Committee's decision that the transplant program should be the only member type to report recipient illness to the OPTN.

Patient Safety Contact must be an employee at the institution

The proposed requirement that the patient safety contact listed must be an employee at the institution received mixed sentiment. Various stakeholder organizations, including American Society Transplant Surgeons, expressed support that the Patient Safety Contact must work at the institution and stated that the contracted employees who work for a third party should be included under the rubric of those who qualify as employees of the transplant program or OPO. Comments noted that the requirement would address concerns expressed by OPOs regarding delays and process inefficiencies in communicating with

transplant programs. Feedback highlighted that having a Patient Safety Contact as a direct employee of the institution is crucial to avoiding delays when communicating pertinent information. Oftentimes, an individual at the third-party vendor may not be reachable or may not know how to facilitate communication of potential disease transmission information. By contrast, some comments received by stakeholders, societies, and OPTN Committees, including UC Davis Transplant Center, NATCO, and the OPTN Transplant Coordinators Committee, opposed mandating that the individual(s) be a direct employee of the institution. Comments expressed that programs employ third-party organizations to assist with after-hour calls and utilize these organizations to avoid overburdening staff at the institution. Additionally, there were concerns about whether the OPTN has oversight to provide direction on who could be considered an employee of the institution.

The Committee considered the mixed sentiments and decided not to go forward with the proposed requirement. The Committee agreed that the patient safety contact process could still be improved and standardized without this requirement. The Committee also highlighted that the Patient Safety Contact is responsible for proper communication to medical staff that may affect the recipient's care, including the individual listed as the Patient Safety Contact at the third-party vendor. Therefore, the transplant program is accountable for ensuring confirmation of notification and dissemination of information.

Listed phone number and email address

The majority of respondents agreed that a valid phone number and email address are needed when communicating urgent potential disease transmission information. This allows for multiple methods of communication between the institutions. Feedback suggested clarifying that group emails are acceptable and can be used as long as the patient safety contact is reachable at this email address.

Six month-self audit Timeframe

There was mixed sentiment about the six-month self-audit requirement. While there was support for the requirement that the Patient Safety Contact information be verified every six months for accuracy, other comments expressed that six months may be too frequent and recommended an annual review of this information. Comments also highlighted that the patient safety contact should be updated when there is a change in Patient Safety Contact at the institution. The Committee discussed various timeframes to conduct the self-audit. Ultimately, the Committee decided that the six-month timeframe is appropriate, and the scrutiny and oversight is something that the Committee would like to maintain.

Timeframe for Acknowledging of Confirmation of Notification

The feedback received recommended that the Committee reconsider the time frame for acknowledging confirmation of receipt from 24 hours to 72 hours. Comments supporting a 72-hour time frame included:

> *"An attendee expressed some concern with the requirement to confirm receipt in 24 hours, as 80% or more of these reports do not result in any change in clinical practice. They suggested a 72-hour requirement instead."*

The Committee decided to maintain the 24-hour timeframe to acknowledge notification of receipt to shed light on the urgency of communicating patient safety concerns and increasing efficiency while standardizing the process.

Post-Public Comment

After considering all public comment, the Committee decided to remove the proposed requirement to require the Patient Safety Contact to be an employee at the OPO or transplant program. The Committee will maintain their decisions for all other requirements, including verification of the patient safety contact information biannually and maintaining the 24 hours timeframe for Patient Safety Contacts to acknowledge confirmation of receipt within the 24-hour timeframe.

Compliance Analysis

NOTA and OPTN Final Rule

The Committee submits this proposal for consideration under the authority of the OPTN Final Rule. The Final Rule requires the OPTN to develop policies "consistent with recommendations of the Center for Disease Control and Prevention, for the testing of organ donors and follow up of transplant recipients to prevent the spread of infectious diseases."[11] This proposal will establish additional requirements for OPO and transplant program Patient Safety Contacts and the communication regarding donor testing results and other information related to potential disease transmissions. This will help improve recipient follow up and the prevention of infectious disease through organ transplantation.

This proposal also aligns with the 2011 directive from the Secretary of the Department of Health and Human Services. The Secretary directed the OPTN to, "...consider the development of a single OPTN Patient Safety Reporting Policy that outlines the reporting obligation of each OPTN member (obligations that are currently included in several policies and the OPTN Bylaws). The OPTN may wish to include new reporting requirements, if appropriate, consistent with this letter and in the interest of protecting patient safety."[12] This proposal outlines reporting obligations for OPOs and transplant programs through standardization and monitoring of *OPTN Policy 15.1: Patient Safety Contact.*

OPTN Strategic Plan

The proposed updates align with the strategic plan to promote living donor and transplant recipient safety by updating and clarifying the role and responsibilities of the Patient Safety Contact to ensure accurate and timely reporting of notifications of potential disease transmission and related communication.

Standardizing this notification process will ensure patient safety contacts are receiving notifications of potential disease transmissions and the recipient is receiving the appropriate care and treatment in a timely manner. This standardization could also result in a decrease in potential disease transmissions. Through the OPTN Donor Data and Matching System, OPOs will be required to notify patient safety contacts of positive test results. Clarifying these policies would allow transplant hospitals to focus on the potential donor-derived transmissions that pose a risk to other recipients and efficiently notify the other recipients' hospital so the recipient can receive the appropriate care.

[11] 42 USC §121.4(a)(2).
[12] Secretary Mary K. Wakefield, PhD., R.N. HRSA Administrator to Dr. John Lake, President, OPTN and CEO, UNOS, August 5, 2011.

Implementation Considerations

This proposal would impact Organ Procurement Organizations, transplant programs, and the OPTN, but would not impact histocompatibility laboratories.

Organ Procurement Organizations

Operational Considerations

OPOs will be required to list a secondary Patient Safety Contact (in addition to the primary contact) and conduct a self-audit biannually to ensure the contacts listed are up to date in the OPTN system. OPOs will need to use a system enhancement in the OPTN Donor Data and Matching System to communicate post-procurement donor results to transplant programs primary and secondary Patient Safety Contact simultaneously. The OPO will be notified if the patient safety contact at the transplant hospital has not acknowledged receipt of information within 12 hours of the 24 hours requirement to acknowledge confirmation of receipt.

Fiscal Impact

This proposal is not expected to have a significant impact on OPOs since it was indicated that OPOs have many of this processes in place.

Transplant Programs

Operational Considerations

Transplant programs will be required to list a secondary Patient Safety Contact (in addition to the primary contact) and conduct a self-audit at least every six months to ensure the contacts listed are up to date in the OPTN system. Transplant programs will have to confirm receipt and acknowledge post-procurement donor results through a system enhancement in the OPTN Donor Data and Matching System. Transplant programs will still be required to notify the primary Patient Safety Contact at the host OPO or transplant program at which the living donor was recovered when there is a recipient illness. The transplant program must notify the secondary patient safety contact at the host OPO or transplant program at which the living donor was recovered if the primary patient safety contact at the host OPO or transplant program at which the living donor was recovered does not acknowledge receipt of the information within 24 hours.

Fiscal Impact

This proposal is not expected to have significant impact on transplant hospitals since it was indicated the transplant hospitals have many of this processes in place.

OPTN

Operational Considerations

The OPTN will ensure the Patient Safety Contact self-audit is completed biannually. Members who do not complete the self-audit requirements will be contacted by OPTN to become compliant with the policy requirements. The OPTN will use the reports generated through the system enhancement in the

OPTN Donor Data and Matching System to make sure post-procurement donor results were confirmed by transplant programs within 24 hours.

Resource Estimates

It is estimated that 1770 hours would be needed to implement this proposal. Implementation would involve preparing educational materials and inter-departmental staff collaboration. In addition, implementation would cover updates in management and compliance monitoring of member patient safety contact information and reports. It is estimated that 680 hours would be needed for ongoing support. Ongoing support will include committee monitoring.

Post-implementation Monitoring

Member Compliance

Members will be expected to comply with the requirements in the proposed policy language. Member compliance includes ensuring that the Patient Safety Contact information listed is complete and verified. All elements required by policy may be subject to OPTN review and members are required to provide documentation as requested. The OPTN will conduct Patient Safety Contact audits bi-annually and members will be required to complete self-attestations.

Policy Evaluation

The Committee will review data on the number of duplicate reports of potential donor-derived disease transmission events reported through the OPTN Improving Patient Safety Portal pre- and post-policy implementation. This key metric will assess the compliance rate of the proposed changes to OPTN Policy. The Committee will also review data on how many Patient Safety Contacts have not acknowledged confirmation of receipt within the required 24-hour timeframe.

Conclusion

This policy proposes updates to OPTN Policy *15: Identification of Transmissible Diseases* to ensure the Patient Safety Contact requirements are described accurately and support timely reporting of notifications of potential disease transmission and related communication. These proposed updates would require that a secondary patient safety contact be listed for OPOs and transplant hospitals, in addition to the primary patient safety contact. An individual with system permissions will be required to verify biannually (twice each year) that the patient safety contact information listed is accurate. This includes ensuring that the information listed includes a valid email address and phone number in order to be contacted regarding potential disease transmissions.

Additionally, the Patient Safety Contact will be required to acknowledge receipt of any information that may affect or change recipient care within 24 hours of receipt. Separately, the policy will require OPOs and transplant programs to utilize the OPTN Donor and Data System. OPOs will be required to communicate donor-derived positive results to transplant programs, and transplant programs will be required to acknowledge confirmation of receipt through the OPTN Donor and Data System. Based on the feedback received during the public comment cycle, this policy update would exclude requiring the patient safety contact to be an institution employee.

Furthermore, OPTN Policy *15.4.B: Host OPO Requirements for Reporting Post-Procurement Discovery of Recipient Disease or Malignancy* and OPTN Policy *15.5.B: Transplant Program Requirements for Reporting Post-Transplant Discovery of Recipient Disease or Malignancy* require both OPOs and transplant programs to report any finding of recipient disease or malignancy to the OPTN Patient Safety Reporting Portal.[13] This has resulted in duplicative reporting to the OPTN. In response, these policies will be revised to require transplant programs to be the only OPTN member type responsible for reporting recipient illness to the OPTN.

[13] OPTN Policy 15.4.B Host OPO Requirements for Reporting Post-Procurement Discovery of Recipient Disease or Malignancy and 15.5.B Transplant Program Requirements for Reporting Post-Transplant Discovery of Recipient Disease or Malignancy (Accessed November 2, 2023) https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.

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, cross-references, and footnotes affected by the numbering will be updated as necessary.

15.1 Patient Safety Contact

Each OPO and transplant program must identify a primary and secondary ~~p~~Patient ~~s~~Safety ~~c~~Contact and develop and comply with a written protocol for the Patient Safety Contact to fulfill all the following responsibilities:

~~1. Be available 24 hours a day.~~
~~2. Receive notifications of potential disease transmission and related communication from the OPTN.~~
~~3. Receive relevant medical information that may affect or change recipient care.~~
~~4. Communicate any information regarding potential disease transmissions to the medical staff responsible for the recipient's clinical care at the transplant program as soon as possible, but no later than 24 hours after becoming aware of the potential disease transmission.~~
~~5. Facilitate communication about the current clinical status of any recipient when the transplant program is notified of a potential or proven disease transmission that may affect the recipient.~~

1. A Patient Safety Contact must be available 24 hours a day.
2. The OPO's primary or secondary Patient Safety Contact must communicate medical information that may affect recipient care to the Patient Safety Contact at the recipient's transplant program as soon as possible, but no later than 24 hours after receipt.
3. The transplant program's primary or secondary Patient Safety Contact must communicate medical information that may affect recipient care to the medical staff responsible for the recipient's clinical care at the transplant program as soon as possible, but no later than 24 hours after receipt.
4. The receiving primary or secondary Patient Safety Contact must acknowledge the receipt of any information that may affect or change recipient care within 24 hours of receipt.
5. The transplant program's Patient Safety Contact must acknowledge receipt of post-procurement donor results, through the OPTN Donor Data and Matching System, within 24 hours of notification of post-procurement donor results reported in accordance with OPTN *Policy 15.4.A Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions.*
6. OPOs and transplant programs must report to the OPTN a valid phone number and email address for both the primary and secondary Patient Safety Contacts.
7. OPOs and transplant programs must verify their primary and secondary Patient Safety Contacts are accurate through the OPTN Computer System during the biannual OPTN audit.

15.4.A Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions

The host OPO must report all positive test results and other relevant information received post-procurement for each donor to all the receiving transplant programs' Patient Safety Contacts through the OPTN Donor Data and Matching System as soon as possible but no later than 24 hours after receipt ~~as follows:~~

1. All results indicating Pathogens of Special Interest must also be reported ~~to the receiving transplant program's patient safety contact and~~ through the OPTN Improving Patient Safety Portal. The OPTN Contractor provides a list of Pathogens of Special Interest, including any results that can be excluded from reporting. The OPTN Contractor reviews and updates this list at least annually.

[…]

15.4.B Host OPO Requirements for Reporting Post-Procurement Discovery of Recipient Disease or Malignancy

If the host OPO is notified that an organ recipient is suspected to have, is confirmed positive for, or dies from a potential transmissible disease, infection, or malignancy and there is substantial concern that it could be from the transplanted organ, then the host OPO must do *all* of the following:

1. Communicate the suspected donor's and affected organ recipient's test results and diagnosis that may be relevant to acute patient care as soon as possible but no more than 24 hours after receipt, to ~~any~~ all transplant programs' primary ~~p~~Patient ~~s~~Safety ~~c~~Contacts and tissue banks that received organs or tissue from the donor. This includes any test results that were not available at the time of procurement or that were performed after procurement. ~~The host OPO must document that this information is shared with all receiving transplant programs and tissue banks.~~ If the transplant program's primary Patient Safety Contact does not acknowledge receipt of the information within 24 hours, then the host OPO must notify the transplant program's secondary Patient Safety Contact.
2. Document that this information is shared with all receiving transplant programs and tissue banks. ~~Report the event to the OPTN Improving Patient Safety Portal as soon as possible but no more than 24 hours after notification or receipt of recipient test results or diagnosis.~~

15.5.B Transplant Program Requirements for Reporting Post-Transplant Discovery of Recipient Disease or Malignancy

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

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. ~~Notify host OPO or living donor recovery hospital that procured the organ without waiting for all medical documentation that may eventually become available. The transplant program must notify the host OPO or living donor recovery hospital by phone and provide documentation as soon as possible but no more than 24 hours after learning of the event.~~
2. Report the event through the OPTN Patient Safety Reporting Portal ~~as soon as possible but~~ within 24 hours after learning of the event.
3. Provide additional related information or specimens if requested.

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Appendix A: Post-Public Comment Changes

New language that was proposed following public comment is underlined and highlighted (example); language that is proposed for removal following public comment is struck through and highlighted (~~example~~).

15.1 Patient Safety Contact

Each OPO and transplant program must identify a primary and secondary Patient Safety Contact and develop and comply with a written protocol for the Patient Safety Contact to fulfill all the following responsibilities:

1. A Patient Safety Contact must be available 24 hours a day.
2. The OPO's primary or secondary Patient Safety Contact must communicate medical information that may affect recipient care to the medical staff responsible for the recipient's clinical care at the transplant program as soon as possible, but no later than 24 hours after receipt.
3. The transplant program's primary or secondary Patient Safety Contact must ~~receive and~~ communicate medical information that may affect recipient care to the medical staff responsible for the recipient's clinical care at the transplant program as soon as possible, but no later than 24 hours after receipt.
4. The receiving primary or secondary Patient Safety Contact must acknowledge the receipt of any ~~medical~~ information that may affect or change recipient care within 24 hours after receipt.
5. The transplant program's Patient Safety Contact must acknowledge receipt ~~of notification~~ of post-procurement donor results, through the OPTN Donor Data and Matching System, within 24 hours of notification of post-procurement donor results reported in accordance with OPTN *Policy 15.4.A Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions* ~~through the OPTN Donor Data and Matching System within 24 hours of receipt.~~
6. ~~The transplant program's Patient Safety Contact must acknowledge receipt of discovery of recipient disease or malignancy within 24 hours of receipt.~~

~~2. Receive notifications of potential disease transmission and related communication from the OPTN.~~

~~3. Receive relevant medical information that may affect or change recipient care~~.

~~4. Communicate any information regarding potential disease transmissions to the medical staff responsible for the recipient's clinical care at the transplant program as soon as possible, but no later than 24 hours after becoming aware of the potential disease transmission.~~

6. ~~The primary and secondary Patient Safety Contact listed must be employees at the institution.~~ OPOs and transplant programs must report to the OPTN ~~A~~ a valid phone number and email address ~~must be listed~~ for both the primary and secondary Patient Safety Contact.
7. ~~The~~ OPOs and transplant programs must verify all of their primary and secondary Patient Safety Contacts ~~listed~~ are accurate through the OPTN Computer System during the biannual OPTN audit. ~~every six months.~~

15.4.A Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions

The host OPO must report all positive test results and other relevant information received post procurement for each donor to all the receiving transplant programs' Patient Safety Contacts through the OPTN Donor Data and Matching System as soon as possible but no later than 24 hours after receipt as follows:

1. All results indicating Pathogens of Special Interest must also be reported through the OPTN Improving Patient Safety Portal. The OPTN Contractor provides a list of Pathogens of Special Interest, including any results that can be excluded from reporting. The OPTN Contractor reviews and updates this list at least annually.

2. All other positive test results and relevant information must be reported according to Table 15-2 below.

Table 15-2: Host OPO Reporting Requirements for Positive Post-Procurement Donor Results and Discovery of Potential Disease Transmissions

The host OPO must report *all* of the *positive* following results:		To:
Samples relevant to all recipients	Serologic, NAT, or antigen results indicating presence of parasites, virus, or fungi	The receiving transplant program's patient safety contact
	Cultures from the following specimens: • Ascites • Blood • Cerebrospinal fluid (CSF) • Deep wound • Genital • Pericardial • Pleural fluid	The receiving transplant program's patient safety contact
	Mycobacterial smears and cultures	The receiving transplant program's patient safety contact
	Fungal smears and cultures with the exception of *Candida* species	The receiving transplant program's patient safety contact
Relevant information	Respiratory samples (bacterial or *Candida species*) *only* to transplant programs receiving lungs or covered head and neck VCAs	The receiving transplant program's patient safety contact
	Urine cultures *(*bacterial or *Candida species) only* to transplant programs receiving kidneys or covered genitourinary organ VCAs	The receiving transplant program's patient safety contact

The host following	OPO must report *all* of the *positive* results:	To:
	Malignancy or other findings highly suggestive of malignancy recognized after procurement	1. The receiving transplant program's patient safety contact 2. The OPTN Improving Patient Safety Portal
	Histopathology results reported post-procurement	The receiving transplant program's patient safety contact
Relevant information	All *final* culture information for any culture results that were reported according to these requirements	The receiving transplant program's patient safety contact
	Other psycho-social history, medical history, autopsy, testing, and laboratory findings identifying infectious conditions that may adversely affect a potential transplant recipient	The receiving transplant program's patient safety contact

15.4.B Host OPO Requirements for Reporting Post-Procurement Discovery of Recipient Disease or Malignancy

If the host OPO is notified that an organ recipient is suspected to have, is confirmed positive for, or dies from a potential transmissible disease, infection, or malignancy and there is substantial concern that it could be from the transplanted organ, then the host OPO must do *all* *of* the following:

1. Communicate the suspected donor's and affected organ recipient's test results and diagnosis that may be relevant to acute patient care, as soon as possible but no more than 24 hours after receipt, to any transplant program~~'~~s' primary Patient Safety Contact~~s~~ and tissue banks that received organs or tissue from the donor. This includes any test results that were not available at the time of procurement or that were performed after procurement. If the transplant program's primary Patient Safety Contact does not acknowledge receipt of the information within 24 hours, then the host OPO must notify the transplant program's secondary Patient Safety Contact.
2. ~~The host OPO must d~~ Document that this information is shared with all receiving transplant programs and tissue banks.

3. ~~Report the event to the OPTN Improving Patient Safety Portal as soon as possible but no more than 24 hours after notification or receipt of recipient test results or diagnosis.~~

15.5.B Transplant Program Requirements for Reporting Post-Transplant Discovery of Recipient Disease or Malignancy

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

1. Notify the primary Patient Safety Contact at the host OPO or transplant program at which the living donor was recovered ~~that procured the organ~~ and provide available documentation ~~without waiting for all medical documentation that may eventually become available~~. ~~The transplant program must notify the host OPO or living donor recovery hospital by phone and provide documentation as soon as possible but no more than 24 hours after learning of the event.~~ within 24 hours of learning of the event. If the primary Patient Safety Contact of the host OPO 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 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.

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