OPTN

Public Comment Proposal

Standardize the Patient Safety Contact and Reduce Duplicate Reporting

OPTN Ad Hoc Disease Transmission Advisory

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Standardize the Patient Safety Contact and Reduce Duplicate Reporting

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Sponsoring Committee:	*Ad Hoc Disease Transmission Advisory*
Public Comment Period:	*January 23, 2024 – March 19, 2024*

Executive Summary

The 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 Organ Procurement and Transplantation Network (OPTN) Membership and Professional Standards Committee (MPSC) has 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. OPOs and transplant programs would be required to list a primary and secondary patient safety contact, both of whom must work at the OPO or transplant program. The proposed policy change would also require verification of the listed Patient Safety Contacts at least every six months. 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 transplant programs 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 other

[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.

transplant programs with recipients of the same donor and the requirement to report Pathogens of Special Interest to the OPTN Improving 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 leads to a single point of failure for reporting potential disease transmissions. The proposed changes create a standard 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 program will need to acknowledge that they have received notification and have reviewed the test results within 24 hours through the system enhancement. The system enhancement applies only to donor test results; any reportage of recipient illness should be shared through any form of communication practiced by the OPO or transplant program. Both the OPO and transplant program will need to verify the primary and secondary patient safety contact listed is accurate, at least every six months 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 aims 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 developed 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 and OPTN contractor staff voiced frustration in challenges locating the correct person to share information with regarding a potential disease transmission or

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

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]

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 center is informed of a concern for a possible or proven disease transmission related to the donor[5]

The Patient Safety Contact designates the 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 in OPTN bylaw language. Patient Safety Contact information must be exchanged between the OPO and transplant center to facilitate effective communication should a potential disease transmission or patient safety situation arise.

Public comment feedback gathered through *Improving Post-Transplant Communication of New Donor Information* in 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 to OPTN contractor staff.

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 by 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]

[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.
[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.

OPTN contractor staff noted the issues seen with OPTN Policy *15.1 Patient Safety Contact* are more qualitative than quantitative. The issues highlighted for the Committee are as follows:

- Listing a false email address to 'force' contact via phone
- Invalid phone numbers listed
- Listing pagers as phone numbers
- No backup contact listed when the primary contact is not available
- 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 why 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]

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 OPTN contractor staff. The number of canceled potential disease transmission events reported to the OPTN Patient Safety Reporting Portal due to duplicates ranged between 47 and 62 per year over a four year period beginning in 2018.[9] This number will continue to increase as potential disease transmission events increase.

In 2016, public comment feedback gathered through *Improving Post-Transplant Communication of New Donor Information*[10] asked for ways 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. However, data from 2018 to 2022 shows that this has instead resulted in an increased burden on the system and duplicate information being entered by OPOs and reviewed by OPTN contractor staff.[11]

[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
[11] "Improving Post-Transplant Communication of New Donor Information," OPTN, Briefing Paper, accessed November 2, 2023. https://bodandcommittees.unos.org/archive/Documents/Improving%20Post-Transplant%20Communication%20of%20New%20Donor%20Information%20-BP.pdf

The OPTN OPO, Transplant Coordinator, Living Donor, and Operations and Safety Committees voiced support for this proposal.

Overview of Proposal

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

- require OPOs and transplant programs list a secondary Patient Safety Contact,
- require the listed Patient Safety Contacts work at the OPO or transplant program for which they are listed,
- require verification of listed Patient Safety Contacts at least every six months,
- 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,
- and 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.

The Committee proposes modifications to OPTN Policy *15.4.A Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmission* to add the requirement that the host OPO must use the OPTN Data and Matching System to report all positive donor-derived test results.

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 Porta. The proposed modification will add a requirement to contact the affected transplant program's secondary contact listed if no confirmation of receipt of potential disease transmission notification is received within 24 hours.

The Committee proposes modifications to OPTN Policy *15.5.B Transplant Program Requirements for Reporting Post-Transplant Discovery of Recipient Disease or Malignancy* to require the transplant program notify the primary Patient Safety Contact at the OPO or the transplant program at which the living donor was recovered 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 within 24 hours of learning of the event. The Committee proposes the transplant program notify the secondary Patient Safety Contact at the OPO or the transplant program at which the living donor was recovered if no confirmation of receipt is received within 24 hours.

Secondary contact

The Committee proposes requiring a listed secondary Patient Safety Contact to ensure timely communication of potential disease transmission information. The Committee proposes changing the name of 'backup' contact to 'secondary' contact to align with similar roles in the transplant system. The primary or secondary Patient Safety Contact must be available 24 hours a day, so if the primary Patient Safety Contact is unavailable, the secondary contact must be reachable. The Workgroup discussed OPOs and transplant programs that have group email addresses listed. This group email may be listed for both the primary and secondary Patient Safety Contact if they are both able to be reached at this email

address. Two different institutional employees must be listed for the primary and secondary Patient Safety Contact.

Patient Safety Contacts are employees at the institution

The Committee proposed the listed primary and secondary Patient Safety Contacts must be employees of the OPO or transplant program for which they are listed. This was a response to the MPSC referral received by the Committee that voiced concern about listed Patient Safety Contacts who are third-party contractors of the OPO or transplant program. These individuals are often not reachable or do not know how to facilitate communication of potential disease transmission information. This creates inefficiencies and puts patient safety at risk when the medical team responsible for the recipient's care is not rapidly made aware of this information.

Listed phone number and email address

The Committee proposes a valid phone number and email address must be listed for the primary and secondary Patient Safety Contact. This allows OPOs and transplant programs to have multiple methods of communication when alerting each other of urgent potential disease transmission information.

Confirmation of receipt

The Committee proposes a requirement of acknowledgment of potential disease transmission information through confirmation of receipt by transplant programs. Confirmation of receipt related to donor results will be administered through a system enhancement to the OPTN Donor Data and Matching System. Confirmation of receipt related to a recipient's illness must be acknowledged by any method of communication practiced by the OPO or transplant program. Requiring confirmation of receipt creates a feedback loop for OPOs to make sure the medical team responsible for the recipient's care is aware of all potential disease transmission information. This will ensure more accurate and timely notifications from OPOs to transplant programs.

Self-audit

After considering various solutions, the Committee proposes OPOs and transplant programs must verify the primary and secondary Patient Safety Contacts listed through the OPTN Computer System every six months. This will help ensure the listed Patient Safety Contacts are accurate and current.

Enhancement to OPTN Donor Data and Matching System

The Committee proposes mandating an upcoming system enhancement in the OPTN Donor Data and Matching System that allows for automated communication of donor post-procurement results that may affect the recipient. This will allow OPOs to communicate these results through the OPTN Donor Data and Matching System and transplant programs to confirm receipt of these results through the system as well. A report will be generated to ensure all notifications are confirmed by the transplant program's Patient Safety Contact within 24 hours of receipt.

Recipient illness reporting to the OPTN

The Committee proposes the requirement for OPOs to report post-procurement discovery of recipient disease or malignancy to the OPTN to be removed from OPTN Policy 15.4.B. This is already required for transplant programs in OPTN Policy 15.5.B and will eliminate duplicative reporting to the OPTN Patient Safety Reporting Portal. OPOs will still be required to report any recipient illness to other transplant programs with recipients from the same donor. Reporting of potential recipient illness will require any method of communication practiced by the transplant program and OPO.

NOTA and Final Rule Analysis

This project is authorized by NOTA which states the OPTN shall "...provide information to physicians and other health professionals regarding organ donation..."[12] This proposal will facilitate effective communication of patient safety events between physicians and other health professionals regarding organ donation. The Final Rule states,"(a) The OPTN Board of Directors shall be responsible for developing, with the advice of the OPTN membership and other interested parties, policies within the mission of the OPTN as set forth in section 372 of the Act and the Secretary's contract for the operation of the OPTN, including: (2) Policies, consistent with recommendations 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..."[13] This proposal aims to standardize the process of reporting donor results in the OPTN Donor Data and Matching System to help aid in the prevention of the spread of infectious diseases.

This proposal aligns with the directive from the Secretary of the Department of Health and Human Services and the OPTN Final Rule. 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."[14] This project outlines reporting obligation of each member through standardization and monitoring of *OPTN Policy 15.1: Patient Safety Contact.*

Implementation Considerations

Member and OPTN Operations

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

Operations affecting Organ Procurement Organizations

OPOs 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. 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. The OPO will also be required to

[12] 42 U.S.C. §274(b)(2)(H).
[13] 42 CFR Part 121.4(a)(2).
[14] Secretary Mary K. Wakefield, PhD., R.N. HRSA Administrator to Dr. John Lake, President, OPTN and CEO, UNOS, August 5, 2011.

communicate an affected organ recipient's test results to any transplant program's primary Patient Safety Contact and tissue banks that received organs or tissue from the donor that may impact the recipient. OPOs must notify the transplant program's secondary Patient Safety Contact if the primary Patient Safety Contact at the transplant program does not acknowledge receipt of the information within 24 hours.

Operations affecting Transplant Programs

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 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.

Operations affecting the OPTN

The OPTN will ensure the Patient Safety Contact self-audit is completed every six months. 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. Members who do not complete the audit requirements will be contacted directly by the OPTN Contractor to become compliant with the policy requirements.

Operations affecting Histocompatibility Laboratories

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

This proposal requires the submission of official OPTN data that are not presently collected by the OPTN. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in §121.11 of the OPTN Final Rule will be collected through OMB approved data collection forms. Therefore, after OPTN Board approval, the forms will be submitted for OMB approval under the Paperwork Reduction Act of 1995. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

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 proposal was determined to have a low overall fiscal impact on the OPTN, organ procurement organizations and transplant hospitals. No fiscal impact was recorded for histocompatibility labs.

Projected Impact on Histocompatibility Laboratories

There is no expected fiscal impact on histocompatibility laboratories.

Projected Impact on Organ Procurement Organizations

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

Projected Impact on Transplant Hospitals

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

Projected Impact on the OPTN

The OPTN contractor estimates that 1,780 hours would be needed to implement this proposal. Implementation would involve updates to previous patient safety contact policy and the OPTN Donor Data and Matching System so OPOs may administer, and transplant programs may confirm receipt of these notifications. The OPTN contractor estimates 520 hours for ongoing support. Ongoing support includes oversight of Patient Safety Contact six-month self-audits, ongoing review of confirmed post-procurement results by transplant programs, and answering member questions.

Post-implementation Monitoring

Member Compliance

Members will be expected to comply with the requirements in the proposed policy language. All elements required by policy may be subject to OPTN review and members are required to provide documentation as requested. OPTN Contractor staff will conduct Patient Safety Contact audits every six months and members will be required to complete self-attestations.

Policy Evaluation

The committee will consider how often the patient safety contact is updated and the number of duplicate reporting of potential donor-derived disease transmission events reported through the OPTN Improving Patient Safety Portal as key metrics to assess the compliance rate of the proposed changes to OPTN Policy.

Conclusion

The Ad Hoc Disease Transmission Advisory Committee (the Committee) aims to update OPTN Policy *15.1 Patient Safety Contact* to ensure more accurate and timely reporting of notifications of potential disease transmission and related communication. Also, OPTN Policy 15.4.A *Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions* will require the use of the OPTN Donor and Data Matching System to report donor-derived results and notification of confirmation of this information this will help to standardize the process of reporting donor results.

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.[15] This has resulted in duplicative reporting to the OPTN, so the Committee proposes transplant programs are the only OPTN member type responsible for reporting recipient illness to the OPTN. These policy revisions will allow for more efficient communication of potential disease transmission through organ transplantation between OPOs and transplant programs and to the OPTN.

Considerations for the Community

- 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?

[15] 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, and cross-references affected by the numbering of these policies will be updated as necessary.

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 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.
3. The receiving primary or secondary Patient Safety Contact must acknowledge the receipt of medical information within 24 hours after receipt.
4. The transplant program's Patient Safety Contact must acknowledge receipt 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.
5. 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. A valid phone number and email address must be listed for both the primary and secondary Patient Safety Contact.
7. The OPO and transplant program must verify all of their primary and secondary Patient Safety Contacts listed are accurate through the OPTN Computer System 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 Contact through the OPTN Donor Data and Matching System as soon as possible but no later than 24 hours after receipt.

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.

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 following	OPO must report *all* of the *positive* 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
	Malignancy or other findings highly suggestive of malignancy recognized after procurement	The receiving transplant program's patient safety contact 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* 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 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. 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:

2. 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.
3. 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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