OPTN

Notice of OPTN Policy Changes

Standardize the Patient Safety Contact and Reduce Duplicate Reporting

Sponsoring Committee:	**Ad Hoc Disease Transmission Advisory Committee**
Policies Affected:	***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***
	15.4.C: ***Host OPO Requirements for Post-Reporting Follow-Up***
	15.5.B: ***Transplant Program Requirements for Reporting Post-Transplant Discovery of Recipient Disease or Malignancy***
Public Comment:	**January 23, 2024 –March 19, 2024**
Board Approved:	**June 17-18, 2024**
Effective Date:	**July 25, 2024: Policy 15.1 (partial)**
	Pending implementation and notice to OPTN members: Policies 15.1, 15.4.A, 15.4.B, 15.4.C, 15.5.B

Purpose of Policy Changes

These policy changes aim to improve the effectiveness of the Patient Safety Contact (PSC) required by OPTN policy. In addition, the purpose is to increase efficiency and effectiveness in infectious disease and malignancy reporting and communication processes.

Proposal History

This project originated from a Membership Professional Standards Committee (MPSC) March 2023 referral to DTAC requesting review and update of OPTN policy regarding potential donor-derived infectious disease reporting and the role of the PSC. The MPSC shared that inconsistencies in protocols surrounding the PSC at transplant programs and OPOs can lead to a single point of failure for reporting potential disease transmissions. The MPSC noted the need for "consistent policy for reporting disease transmissions, including notification, follow-up and the receipt and dissemination of information…to effectively ensure timely communication of potential disease transmissions."[1] The MPSC recommended

[1] OPTN Ad Hoc Disease Transmission Advisory Committee Meeting Summary for March 20, 2023, accessed November 2, 2023, available 03/20/2023 OPTN Disease Transmission Advisory Committee In Person Meeting Summary (hrsa.gov).

requiring the use of an electronic notification system within the OPTN Computer System for submission and confirmation of receipt on donor disease test results received post-procurement.

The DTAC formed a workgroup with representatives from several OPTN Committees including MPSC, OPO, Data Advisory and Transplant Administrators. The proposal developed and released for Winter 2024 public comment included requiring transplant programs and OPOs to list a secondary PSC and electronically verify that all names and contact information is correct twice per year. The proposal included a provision that the PSC be employed by the institution. In addition, the proposal included mandatory use of electronic notifications and acknowledgements in the OPTN Computer System for donor test results. It further specified timeframes for reporting and required acknowledgements. Lastly, the proposal removed the duplicative reporting by both OPOs and transplant programs when there is recipient illness.

The proposal was generally supported during public comment. Given the mixed sentiment on one provision, DTAC made post-public comment changes to remove policy that would require the PSC to be an employee at the OPO or transplant program. At the June 2024 Board of Directors meeting, an amendment was passed clarifying that while OPOs are not responsible for reporting recipient events, the OPOs must still complete the current form documenting notifications to all transplant programs and tissue banks for each potential disease transmission event reported to the OPO through the OPTN Improving Patient Safety Portal within 24 hours. The Board identified that the requirement for a secondary PSC in Policy *15.1* be implemented faster because it did not require programming changes; consequently, implementation for this change is July 25, 2024 while the rest of the policy will be implemented pending implementation and notice to members.

Summary of Changes

This proposal will have a split implementation. In order to prioritize changes that can be accomplished without a technical implementation, policy will require OPOs and transplant programs to list both a primary and secondary PSC (effective 7/25/2024). Other changes will be implemented along with technical system changes and notification to the community. PSC contact information will have to be verified through a self-audit process twice per year. OPOs will be required to utilize the OPTN Donor and Data Matching System to communicate donor-derived positive results received post procurement. Transplant programs will be required to use that system to acknowledge confirmation within 24 hours of receipt. Additionally, OPOs will no longer be responsible for reporting recipient illness to the OPTN Improving Patient Safety Reporting Portal. However, OPOs will still need to complete the potential disease transmission report form for each potential disease transmission event reported to the OPO through the OPTN Improving Patient Safety Portal. Transplant programs must report to the OPTN all cases of potential donor-derived disease transmission involving recipient illness.

Implementation

OPOs

- Required to list a secondary Patient Safety Contact *(effective July 25, 2024)*
- Required to conduct a self-audit biannually to ensure the contacts listed are up to date in the OPTN system. *(pending implementation and notice to members)*
- Required 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. *(pending implementation and notice to members)*

Transplant Programs

- Required to list a secondary Patient Safety Contact (effective July 25, 2024)
- Required to conduct a self-audit biannually to ensure the contacts listed are up to date in the OPTN system. *(pending implementation and notice to members)*
- Required to use a system enhancement in the OPTN Donor Data and Matching System to confirm receipt and acknowledge post-procurement donor results sent by OPOs using a system enhancement in the OPTN Donor Data and Matching System. *(pending implementation and notice to members)*
- Required to notify the secondary PSC at the host OPO or transplant program at which the living donor was recovered if the primary patient safety contact does not acknowledge receipt of information provided within 24 hours. *(pending implementation and notice to members)*

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

15.1 Patient Safety Contact

Each OPO and transplant program must identify a primary and secondary ~~p~~Patient ~~s~~Safety ~~c~~Contact[2] 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.

[2] This line item will go into effect on July 25, 2024.

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.~~

15.4.C Host OPO Requirements for Post-Reporting Follow-Up

For each potential disease transmission event reported ~~If the host OPO reports test results or other relevant information to the OPTN~~ through the OPTN Improving Patient Safety Portal, ~~then~~ the host OPO must ~~also~~ do *all* of the following:

1. Complete and submit the *Potential Disease Transmission Report Form* no later than 24 hours after ~~reporting~~ the event is reported to the OPO through the OPTN Improving Patient Safety Portal.
2. Contribute to a follow up review of the event, in partnership with OPTN patient safety staff.
3. Provide additional information or specimens related to the deceased donor if requested.

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.