OPTN

Public Comment Proposal

Require Reporting of Patient Safety Events

OPTN Membership and Professional Standards Committee

Prepared by: Rebecca Brookman, MPH
UNOS Member Quality Department

Contents

Require Reporting of Patient Safety Events

Affected Policies:	*16.2: Packaging and Labeling Responsibilities*
	18.5: Reporting of Living Donor Events
Sponsoring Committee:	*Membership and Professional Standards Committee*
Public Comment Period:	*July 27, 2023 – September 19, 2023*

Executive Summary

The Organ Procurement and Transplantation Network (OPTN) contract requires the OPTN to notify leadership of the OPTN Membership and Professional Standards Committee (MPSC) and Health Resources and Services Administration (HRSA) of certain types of safety events within a specific time frame. However, OPTN policy does not explicitly require members to report some of these specific patient safety events. To ensure MPSC leadership and HRSA are aware of and can review potential patient safety situations, this proposal suggests updating OPTN policy to require members to report certain safety events. This proposal will also update the OPTN Improving Patient Safety Portal form instructions to list the events members will be required to report, making it easier for members to reference the events during the reporting process.

Purpose

The purpose of this proposal is to align OPTN members' patient safety reporting requirements with the OPTN Contractor's requirements to report certain patient safety events to MPSC leadership and HRSA, to better allow the MPSC to fulfill its charge to review events that present a potential risk to patient health, public safety, or the integrity of the OPTN. In addition, the proposal will consolidate patient safety reporting requirements into a centralized location in policy. While this is not a data collection project for quality improvement purposes, the MPSC will also be able to use available data from these reports to assess the prevalence of these concerning patient safety events and, provide guidance regarding effective practices to the transplant community to limit risk to transplant candidate, recipient, and living donor safety.

Background

In 2011, a letter from the HRSA Administrator, Mary Wakefield, to the OPTN President clarified expectations for the OPTN to report concerning patient safety events to HRSA.[1] These are referred to in this proposal as "HRSA criteria." The OPTN contract now requires the OPTN to notify HRSA of these concerning safety events within specified time frames, usually within 24 hours or one business day.[2] HRSA has asked that staff also include MPSC leadership on HRSA criteria notifications. Given the short notification timeframe, the report to HRSA and MPSC leadership typically occurs before an investigation; however, an investigation still occurs to gather more information regarding the event and to determine if there were any violations of OPTN Obligations by the member. Additionally, these criteria do not affect whether a case is later referred to the MPSC, which is a separate decision-making process that happens after an investigation.

By accepting membership in the OPTN, each member agrees to comply with all OPTN Obligations, which includes acting to "[a]void risks to patient health or public safety".[3] OPTN Bylaws, Article 1.1.G states that "[a]ny member who becomes aware of a potential noncompliance of OPTN Obligations must inform the OPTN as soon as the member becomes aware of the issue, including potential noncompliance by the member itself". Additional OPTN policies require members to report certain specific events to the OPTN contractors; however, not all "HRSA criteria" are explicitly defined as events that members must report to the OPTN.

Overview of Proposal

The MPSC proposes adding certain "HRSA criteria" and additional specifics concerning patient safety events to OPTN policy as required reports by OPTN members to ensure that the OPTN is aware of all incidences of these serious patient safety events.

This proposal clarifies specific patient safety events that members will be required to report through the OPTN Improving Patient Safety Portal so staff can notify key stakeholders of the event in a timely

[1] Wakefield, Mary K., Administrator, Department of Health and Human Services; Letter to Jack Lake, M.D., President, Organ Procurement and Transplantation Network, August 5, 2011.
[2] OPTN Performance Work Statement, Task 3.6.7, 2022.

[3] OPTN Bylaws, Article 1.1.E

fashion, investigate the event, and forward it to the MPSC for review. While this proposal specifies certain safety events members must report to the OPTN, the proposal does not absolve members from informing the OPTN of other types of potential non-compliance with OPTN Obligations when they become aware of the issue. So, if an event occurs that poses a risk to patient health or public safety but is not specifically listed in policy as a required report by members, the member must still report this event to the OPTN.

Once an event is reported, it will follow the same investigative process that currently exists.[4] The OPTN contractor will notify key stakeholders in a timely fashion and investigate the event. OPTN members must comply with any requests for information from the OPTN contractor during this investigative process. If appropriate, the OPTN contractor will consult with the MPSC during the investigation and/or submit the results of the investigation to the MPSC for review and action according to the OPTN Bylaws, Appendix L *Reviews and Actions*.

The following are the proposed patient safety events transplant hospitals will be required to report through the OPTN Improving Patient Safety Portal within 24 hours after becoming aware of the incident:

- A transplant of the incorrect organ into an organ recipient occurs.
- A transplant of an organ into the incorrect organ recipient occurs.
- A donor organ is identified as incorrect during pre-transplant processes conducted according to either Policy 5.8.A: *Pre-Transplant Verification Prior to Organ Receipt* or Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt.*
- The potential transplant recipient is identified as incorrect during pre-transplant processes conducted according to either Policy 5.8.A: *Pre-Transplant Verification Prior to Organ Receipt* or Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt.*
- An organ was delivered to the incorrect transplant hospital and resulted in non-use of the organ.
- The incorrect organ was delivered to the transplant hospital and resulted in non-use of the organ.
- An organ did not arrive when expected and resulted in the intended candidate not receiving a transplant from the intended donor because of the transportation issue.
- An ABO typing error or discrepancy is caught before or during pre-transplant processes conducted according to either Policy 5.8.A: *Pre-Transplant Verification Prior to Organ Receipt* or Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt*

The following are the proposed patient safety events OPOs will be required to report through the OPTN Improving Patient Safety Portal within 24 hours after becoming aware of the incident:

- An ABO typing error or discrepancy is caught after the OPO's deceased donor blood type and subtype verification process, as outlined in Policy 2.6.C: *Reporting of Deceased Donor Blood Type and Subtype.*

The following are the proposed patient safety events all OPTN members will be required to report through the OPTN Improving Patient Safety Portal within 24 hours after becoming aware of the incident:

- Any sanction is taken by a state medical board or other professional body against a transplant professional working for an OPTN member.

[4] OPTN Member Monitoring Processes. https://optn.transplant.hrsa.gov/media/gqrbxjba/optn_member_monitoring_processes.pdf

- Evidence is discovered of an attempt to deceive the OPTN or the Department of Health and Human Services (HHS).

Near Miss Event Definition

The "HRSA criteria" include a requirement for the OPTN Contractor to report within 24 hours either "a near-miss transplant of the wrong organ into an organ recipient" or "a near-miss transplant into the wrong organ recipient" and state "an event should be considered a 'near-miss' if the error is not caught before the recipient is brought to the surgery holding area". The MPSC felt this definition of a "near-miss" was too ambiguous and would not be consistent between transplant hospitals. The MPSC also noted this definition may not capture errors that are caught after the patient has been taken into the operating room (OR) and, depending on organ type or hospital practice, some potential transplant recipients may go straight into the OR bypassing the surgery holding area.[5] The MPSC considered multiple definitions to clarify when a donor organ or potential transplant recipient is identified as incorrect would be considered a "near miss". The following definitions were considered:

- An error caught after the recipient is brought into the surgery holding area prior to OR.
- An error caught between the index verification and secondary verification.
- An error caught during the pre-transplant verification upon organ receipt, as outlined in OPTN Policy 5.8: *Pre-Transplant Verification*.
- An error caught during pre-transplant processes conducted according to either Policy 5.8.A: *Pre-Transplant Verification Prior to Organ Receipt* or Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt*
- An error caught at any time from communication with potential transplant recipient to report to hospital for transplant through the pre-transplant processes conducted according to either Policy 5.8.A: *Pre-Transplant Verification Prior to Organ Receipt* or Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt*

As already mentioned, the MPSC felt the first bullet was too ambiguous, may vary between hospitals, and during deliberations on this definition, the MPSC noted that the pre-transplant processes vary for living and deceased donors, the type of organ being transplanted, and whether the recipient was already admitted to the hospital at the time of transplant.

The OPTN Living Donor Committee suggested the second option, defining near miss errors as errors caught between the index verification and the secondary verification. The MPSC believed that this may remove some of the variation when candidates for different organs are brought into the OR or surgical holding area. However, the MPSC felt the processes and terms may still vary between hospitals and lead to confusion and suggested tying the definition to a step in the process that is currently outlined in OPTN policy.[6]

The MPSC first considered using the definition "an error caught during the pre-transplant verification upon organ receipt, as outlined in OPTN Policy 5.8: *Pre-Transplant Verification*" but did not want to limit the definition to verifications done "upon organ receipt."

[5] MPSC Meeting Summary, May 4, 2023.
https://optn.transplant.hrsa.gov/media/d5sf1py4/20230504_mpsc_meeting_minutes_public.pdf.
[6] MPSC Meeting Summary, May 4, 2023.
https://optn.transplant.hrsa.gov/media/d5sf1py4/20230504_mpsc_meeting_minutes_public.pdf.

Next, the MPSC considered "an error caught during pre-transplant processes conducted according to either Policy 5.8.A: *Pre-Transplant Verification Prior to Organ Receipt* or Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt*". This removes "upon organ receipt" and allows the definition to be tied to either step in the process outlined in OPTN policy. This definition would then capture an error identified during the pre-transplant verification process prior to organ receipt as well as through the pre-transplant verification process upon organ receipt, although, in some instances, the recipient surgery may have begun at the time of those verifications. Committee members noted that these steps in the process are the last safety nets to identify incorrect organ or incorrect potential transplant recipient error.

For a near miss involving an incorrect potential transplant recipient, the MPSC considered including "an error identified at any time from communication with potential transplant recipient to report to hospital for transplant through the pre-transplant processes conducted according to either Policy 5.8.A: *Pre-Transplant Verification Prior to Organ Receipt* or Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt.*" Committee members noted calling the correct patient to report to the hospital for transplant is the first and a critical step in the verification process and agreed that calling in the incorrect patient can escalate to transplanting the incorrect recipient. However, some Committee members noted this definition would not allow hospitals' protocols and procedures to work to catch these errors before labeling it a "near miss." This definition would also not provide clarity for candidates that are already admitted to the hospital.[7] For these reasons, the MPSC did not support including the requirement to report calling the incorrect patient to report to the hospital as a "near miss".

The MPSC is aware that the proposed definition of a "near-miss" will include instances where the transplant hospitals' pre-transplant verification protocols and procedures worked as intended to identify and prevent the transplant of the incorrect organ or incorrect potential transplant recipient. However, the MPSC noted that these steps are intended to be the final safety checks and believes hospital processes should identify the correct organ and/or intended recipient prior to the final verifications.

While the MPSC may take an action if the Committee's review identifies a specific noncompliance with OPTN Obligations, the existence of a "near miss" report would not automatically result in an action from the MPSC beyond the required notice to HRSA. While reviewing "near miss" events, the MPSC will evaluate all processes leading up to the final verifications to minimize chances of the "near miss" error happening again. Identification of these improvements is consistent with the MPSC's charge to evaluate and support OPTN members by providing feedback on and recommendations to improve members' performance, compliance, and quality systems.

Living Donors Added to Waiting List Within Two Years After Donation

The MPSC sought feedback from the OPTN Living Donor Committee (LDC) about any modifications to the living donor reporting requirements that are currently in Policy 18.5: *Reporting of Living Donor Events*. The LDC noted that Policy 18.5 currently requires members to report when a living liver donor is listed on the liver waitlist within two years of organ donation or when a living kidney donor is listed on the kidney waitlist or begins regularly administered dialysis as an end-stage renal disease (ESRD) patient within two years of organ donation. The LDC recommended modifying the requirements to require

[7] MPSC Meeting Summary, May 22, 2023.
https://optn.transplant.hrsa.gov/media/s3ri1hfi/20230522_mpsc_meeting_minutes_public.pdf.

reporting any time any living donor is added to any wait list, regardless of the organ type, within two years of donation.

The MPSC unanimously agreed to change the requirement to "a living donor is listed on the waitlist within two years after organ donation." This reporting would be required for living donors other than kidney and liver living donors and for any waitlist, not just the waitlist for the organ the living donor donated. Recovery hospitals would still be required to report when a kidney living donor begins regularly administered dialysis as an ESRD patient within two years after organ donation. MPSC members understood that this is a rare occurrence but mentioned that the broadening of this requirement would allow the MPSC to review situations where there may have been safety issues within the living donor evaluation processes. For example, if a living liver donor needs a kidney within two years after donation, then something could have been overlooked or missed in the living donor evaluation process.[8]

Transportation Events

Though the "HRSA criteria" do not specifically include transportation-related events, the Wakefield letter does note that an organ that goes to the wrong destination might lead to the transplant of the wrong organ or wrong patient. Additionally, the MPSC is aware of ongoing discussions in the transplant community about the impact of transportation-related events on the utilization of recovered organs. The MPSC discussed the types of transportation-related events that should require reporting and based its decisions on its observations that (1) transportation-related events should never be the reason a donated organ is not used for transplant and (2) non-utilization is a patient safety event because a candidate who should have received a transplant did not. All transportation events that are included in this proposal are required to be reported if the event results in non-utilization or the intended candidate did not receive a transplant from the intended donor:

- An organ was delivered to the incorrect transplant hospital and resulted in non-use of the organ.
- The incorrect organ was delivered to the transplant hospital and resulted in non-use of the organ.
- An organ did not arrive when expected and resulted in the intended candidate not receiving a transplant from the intended donor because of the transportation issue.

The MPSC considered including an alternative event "the accepted organ was not delivered to the accepting transplant hospital"; however, the MPSC felt this description was too broad and determined the most serious events where an accepted organ was not delivered to the accepting transplant hospital would already be reported based on the other proposed events.

The MPSC recognizes that, in most instances, the transplant hospital that will be required to report these transportation-related events will not bear any responsibility for the event; however, these events are concerning enough that the MPSC would like to know when they happen so the event can be investigated.

[8] MPSC Meeting Summary, May 4, 2023.
https://optn.transplant.hrsa.gov/media/d5sf1py4/20230504_mpsc_meeting_minutes_public.pdf.

ABO Typing Error or Discrepancy

Currently, OPTN members are not required to report the identification of ABO typing errors or discrepancies; however, MPSC review of past reported ABO typing errors or discrepancies have raised serious patient safety concerns. As a result, the MPSC believes that these events should be required reports and determined that OPOs and transplant hospitals should be required to report these events since they are both required to perform and report ABO typing.[9] This error is also alluded to in the HRSA letter as an error that could contribute to the transplant of the incorrect organ or other safety events.

Again, the MPSC wants to provide a clear definition of what needs to be reported. Transplant hospitals would be required to report the identification of an ABO typing error or discrepancy "before or during the pre-transplant processes conducted according to either Policy 5.8.A: *Pre-Transplant Verification Prior to Organ Receipt* or Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt."* As noted in the context of near misses, these two pre-transplant verification steps are the last checkpoint prior to transplant.

OPOs must perform a deceased donor blood type and subtype verification, as outlined in Policy 2.6.C: *Reporting of Deceased Donor Blood Type and Subtype*, which occurs prior to the match run and must be completed by two different qualified health care professionals. The MPSC determined that if an ABO typing error or discrepancy is identified after this verification process, then OPOs should be required to report this error as a patient safety event.

24-Hour Reporting Timeframe

During the February 2023 MPSC meeting, the MPSC discussed the timeframe for OPTN members to report these events.[10] Committee members agreed that OPTN members should have 24 hours once they become aware of the event to report. This gives members time to assess the situation, gather information, and talk to individuals who might have been involved in the event to provide a more comprehensive report to the OPTN. Committee members also agreed that this requirement aligned well with the OPTN's requirement to report these events to HRSA and MPSC leadership within 24 hours.

"HRSA Criteria" Exclusions from Proposal

The MPSC intentionally excluded certain criteria that the OPTN Contractor must report to HRSA according to the "HRSA Criteria" from the proposal. Though the Committee understands that the OPTN Contractor has an obligation to notify HRSA and MPSC leadership of these events, the MPSC does not believe OPTN policy should require OPTN members to report these events to the OPTN Improving Patient Safety Portal as these events may be too proscriptive, may not directly relate to transplant, and could create inefficiencies in the patient safety reporting process.

As previously mentioned, OPTN members are required to act to avoid risks to patient health and public safety and must inform the OPTN when they become aware of a potential noncompliance of OPTN Obligations. Although these events are excluded from this proposal as required reports by members,

[9] MPSC Meeting Summary, May 4, 2023.
https://optn.transplant.hrsa.gov/media/d5sf1py4/20230504_mpsc_meeting_minutes_public.pdf.
[10] MPSC Meeting Summary, February 16, 2023.
https://optn.transplant.hrsa.gov/media/t5blemrw/20230216_mpsc_meeting_minutes_public.pdf.

this does not absolve members from their duty to report events that pose a threat to patient health or public safety. Reports to the OPTN that meet the excluded "HRSA Criteria" will still be reported to MPSC leadership and HRSA.

Centers for Medicare and Medicaid Services (CMS) "Never Events"

"HRSA Criteria" require that "[a]ny "Never Event," as included in the Centers for Medicare and Medicaid Services' (CMS) policies for selected hospital-acquired conditions (HACs), in an OPTN member hospital that impacts transplant patients or living organ donors (including those under evaluation for living organ donation)" must be reported to HRSA within 24 hours. Committee members expressed concern about requiring OPTN members to report all CMS "Never Events" to the OPTN since some of the events may not directly relate to transplant and since members are already required to report such events to CMS or other oversight groups.[11] For example, members thought requiring reporting every time a transplant patient or living donor fell in the hospital, even if it did not lead to serious harm to the patient, would not directly relate to transplant and would significantly increase the number of reports that the OPTN receives and the MPSC reviews. A MPSC member also noted that requiring members to report some of the "never events" in the 24-hour timeframe may bog down the system and lead to inefficiencies with monitoring for compliance. Additionally, most hospitals have their own reporting policies and definitions regarding "never events."

The Committee sought feedback from the OPTN Operations and Safety Committee about the inclusion of CMS defined "Never Events" in this proposal. Operations and Safety Committee leadership agreed that requiring OPTN members to report CMS defined "Never Events" would increase the burden on and confusion for members.

As previously stated, the MPSC expects members to report events that are CMS "Never Events" and also pose a threat to patient health and public safety.

Use of A Device That Is Contraindicated by the Food and Drug Administration (FDA)

"HRSA Criteria" require that "[u]se of a device for a condition, diagnosis, or procedure that is contraindicated by the Food and Drug Administration (FDA)" must be reported to HRSA within 24 hours. While it is required that the OPTN report these events to MPSC leadership and HRSA, the Committee felt that this event was too proscriptive for the purview of the MPSC and decided to exclude it from the events members are required to report to the OPTN.[12]

Committee members noted that it is common to use FDA-contraindicated devices. For example, in lung transplant, surgeons commonly must use metallic, self-expanding airway stents, especially the uncovered airway stents, which are contraindicated by the FDA for benign airway disease.[13] Also, there are situations where surgeons are implanting Zephyrs one way into the bronchial valves in which they would be listed as contraindicated by the FDA, but for certain lung transplant patients it may be the

[11] MPSC Meeting Summary, February 16, 2023. https://optn.transplant.hrsa.gov/media/t5blemrw/20230216_mpsc_meeting_minutes_public.pdf.
[12] MPSC Meeting Summary, April 24, 2023. https://optn.transplant.hrsa.gov/media/2qylxchl/20230424_mpsc_meeting_minutes_public.pdf.
[13] Sinha T, Ho TA, van der Rijst N, Lashari B, Weir M. Safety of hybrid bronchial stents in transplant airway complications: a single center experience. J Thorac Dis. 2022 Jun;14(6):2071-2078. doi: 10.21037/jtd-21-2003. PMID: 35813722; PMCID: PMC9264061.

most appropriate or the only treatment available for them.[14] The MPSC felt requiring members to report these would be overstepping members' clinical judgement and, since it is very common, could create an inefficiency in the reporting and MPSC decision-making process.

As previously stated, the MPSC expects members to report events that include the use of a device that is contraindicated by the FDA and also pose a threat to patient health and public safety.

Update to Improving Patient Safety Portal Instructions

Additionally, the MPSC proposes updating the OPTN Improving Patient Safety Portal Safety Situation and Living Donor Event form instructions to include the list of safety events members will be required to report. This should help streamline the reporting process and provide an immediate reference for members when submitting a report.

NOTA and Final Rule Analysis

The Committee submits this proposal under the authority of the National Organ Transplant Act (NOTA) (42 U.S.C. §274(b)(2)(E), (I)) and the OPTN Final Rule (42 C.F.R. §121.10(b)(1)(iii), which states that "[t]he OPTN shall design appropriate plans and procedures, including survey instruments, a peer review process, and data systems, for purposes of: . . . (iii) Conducting ongoing and periodic reviews and evaluations of each member OPO and transplant hospital for compliance with these rules and OPTN policies." Further, the 2011 HRSA letter to the OPTN stated that '[t]he OPTN may wish to include new reporting requirements, if appropriate, consistent with this letter and in the interest of protecting patient safety."[15] This proposal will require member organizations to report events that may impact patient safety to the OPTN. Doing so will improve the MPSC's ability to identify and investigate risks to patient safety, public health or integrity of the OPTN; support the MPSC's charge to evaluate and provide feedback on and recommendations to improve members' performance, compliance, and quality systems; and promote patient safety by informing the MPSC of how often these safety events occur so that the MPSC can provide guidance and communication to the transplant community regarding best practices to limit risks to patient safety.

One component of the OPTN's ongoing and periodic reviews and evaluations of OPOs and transplant hospitals is monitoring and reviewing reported potential patient safety issues. This responsibility is further defined by the OPTN Contract Task 3.6 **OPTN member compliance and performance monitoring, quality improvement, and sanctioning**, which states:

The Contractor shall monitor OPTN member performance, including threats to patient health and public safety, maintain and develop efforts to improve OPTN member performance, and impose sanctions when warranted.
The Contractor shall develop processes to:

- monitor and review OPTN member performance, including threats to patient health and public safety;

[14] Food and Drug Administration (FDA) News Release, June 29, 2018. https://www.fda.gov/news-events/press-announcements/fda-approves-novel-device-treating-breathing-difficulty-severe-emphysema.
[15]Wakefield, Mary K., Administrator, Department of Health and Human Services; Letter to Jack Lake, M.D., President, Organ Procurement and Transplantation Network, August 5, 2011.

- evaluate, assess, and monitor over time all OPTN members for compliance with the requirements of NOTA, the OPTN final rule, OPTN Bylaws and policies;
- educate and encourage OPTN member compliance with the requirements of NOTA, the OPTN final rule, OPTN Bylaws, and OPTN policies; and
- Promote member performance improvement to meet OPTN strategic planning goals as identified in Task 3.2.7.

The Contractor shall ensure that these processes encourage member self-reporting of potential compliance problems and provide incentives to report issues by assisting members in identifying root causes of issues and developing appropriate corrective actions.

In the event OPTN members are unable to increase compliance, improve performance, or mitigate threats to patient health or public safety, or unless otherwise determined to be appropriate, the Contractor shall develop processes consistent with the requirements of NOTA, the OPTN final rule, OPTN Bylaws, and OPTN policies to:

- impose OPTN sanctions as determined by the OPTN MPSC and BOD; and
- refer members to the Secretary when federal sanctions may be warranted.

Requiring OPTN members to report potential patient safety events is the OPTN's approach to identifying issues at OPOs and transplant programs that may implicate a patient safety concern. To efficiently identify and evaluate the transplant programs most likely in need of assistance to avoid potential risks to patient health and public safety, the MPSC proposes requiring reporting of the aforementioned patient safety events so the OPTN can inquire with the member, determine the root causes of the event, and help prevent the event from occurring again.

Implementation Considerations

Member and OPTN Operations

Operations affecting Transplant Hospitals

Members will need to be familiar with the proposed patient safety reporting requirements and will be required to report the events, as outlined in the proposal, within 24 hours after becoming aware of the event.

Operations affecting Organ Procurement Organizations

Members will need to be familiar with the proposed patient safety reporting requirements and will be required to report the events, as outlined in the proposal, within 24 hours after becoming aware of the event.

Operations affecting Histocompatibility Laboratories

Members will need to be familiar with the proposed patient safety reporting requirements and will be required to report the events, as outlined in the proposal, within 24 hours after becoming aware of the event.

Operations affecting the OPTN

The OPTN will continue to review and investigate events reported through the OPTN Improving Patient Safety Portal and notify HRSA and MPSC leadership of reported events that meet the "HRSA Criteria." The OPTN can expect to receive an increased number of reports that meet the "HRSA Criteria;" however, the MPSC does not anticipate a significant increase. From August 2022 through May 2023, there have been approximately seventeen reports that would meet the proposed requirements, which are more expansive than the "HRSA Criteria". Typically, the OPTN receives approximately fifteen reports per year that meet "HRSA Criteria."

The OPTN will provide members with a notice of pending implementation after Board approval, which will be 30 days prior to implementation, and a communication the day of implementation.

Projected Fiscal Impact

Overall Projected Fiscal Impact

This proposal is expected to have a low overall fiscal impact on the OPTN, transplant hospitals, and organ procurement organizations. No fiscal impact was recorded for histocompatibility laboratories. The general expectation of burden is that since these patient safety events are ideally few and far between, and any additional burden or costs are acceptable given the seriousness of such events.

Projected Fiscal Impact on the OPTN

This proposal is expected to use 20 hours for IT programming to update the OPTN Improving Patient Safety Portal instructions. Member Quality anticipates 20 implementation hours to develop appropriate areas of inquiry for the new required patient safety events and resource materials for members.

Projected Fiscal Impact on Organ Procurement Organizations

There were no significant fiscal impacts indicated with this proposal; however, there could be an increased cost associated with response time and investigation. Additional training of OPO staff may also be necessary to ensure comprehension of definitions, policy, and procedure relating to patient safety events. Furthermore, efforts should be made to communicate patient safety events to other OPTN members so that potential errors or mistakes can be avoided, enabling these members to continuously improve and prevent future patient safety events before they occur.

Project Fiscal Impact on Transplant Hospitals

There were no significant fiscal impacts indicated with this proposal; however, additional training of staff may be necessary to ensure comprehension of definitions, policy, and procedure relating to patient safety events. It was noted that some transplant hospitals already report similar items, so their additional reporting burden would not be of real fiscal or temporal significance. This proposal was positively received.

Projected Fiscal Impact on Histocompatibility Laboratories

There is no expected fiscal impact on Histocompatibility Laboratories.

Post-implementation Monitoring

Member Compliance

Member Quality staff will continue to send inquiries on behalf of the MPSC to OPTN members who report these patient safety events and will request information about the program/safety event, such as:

- Procedures and protocols
- Quality review processes
- Plans for improvement

The MPSC will continue to review the information submitted by the program and may request that the member submit additional information about certain aspects of the program or submit a plan for quality improvement. The MPSC may also request that a member participate in additional engagement with the MPSC, such as an informal discussion or a peer visit. In rare circumstances where the MPSC identifies a potential ongoing risk to patient health or public safety, the MPSC may request that a member inactivate or withdraw a transplant program or a component of a program to mitigate the risk.

Conclusion

By aligning OPTN members' reporting requirements with the OPTN contractor's requirement to report specific concerning patient safety events to HRSA and MPSC leadership, the MPSC will better understand the prevalence of these events and will continue to fulfill their charge of reviewing events identified as presenting a risk to patient safety, public health, or the integrity of the OPTN. Over time, the MPSC will be able to provide guidance to the community regarding effective practices to limit risks to living donor, transplant candidate and recipient safety. The MPSC does not anticipate that these new requirements will pose a significant increased burden to members since, historically, the OPTN received about fifteen reports per year that must be reported to HRSA and MPSC leadership. And from August 2022 to May 2023, the OPTN has received about seventeen reports that would meet the proposed requirements, which are more expansive than the "HRSA Criteria". While this number is expected to slightly increase with these new requirements, the MPSC believes these events are concerning enough that they must be reported and investigated to limit risks to patient safety. There will be no change in the MPSC's investigative process or decision-making process. The MPSC will make decisions and take actions based on its assessment of member compliance with OPTN Obligations, a member's actions in response to any potential noncompliance, the likelihood of recurrence, and documentation of mitigating factors.

Considerations for the Community

The Committee encourages all interested individuals to comment on this proposal in its entirety, but specifically asks for feedback on the following:

- Based on the "near miss" definitions considered for incorrect organ or incorrect potential transplant recipient, do you have any concerns with the proposed definition?
    - If so, which of the definitions considered would you prefer and why?
    - Is there another definition that should be considered for "near miss" transplant of the incorrect organ or incorrect potential transplant recipient?

- Do you agree with requiring reporting for living donors placed on the wait list for any organ within two years after donation?
- Do you think the transportation events included in this proposal as required reports are appropriate?
- Are there other definitions for ABO typing errors or discrepancies that the MPSC should consider?

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.

16.2 Packaging and Labeling Responsibilities

The host OPO or recovery hospital is responsible for packaging and labeling organs and tissue typing materials that travel outside the recovery facilities.

The host OPO must complete labeling and packaging using the OPTN organ tracking system. The OPO must develop and comply with a written protocol for an alternative labeling and packaging process if, for any temporary reason, the OPTN organ tracking system is not used. This written protocol must fulfill all the requirements according to *Policy 16: Organ and Extra Vessels Packaging, Labeling, Shipping, and Storage* and the host OPO must document the reasons the OPTN organ tracking system was not used.

Transplant hospital staff may not leave the operating room without allowing the host OPO to package and label deceased donor organs and tissue typing specimens as required.~~, or the host OPO will be required to submit a report about the event through the OPTN Improving Patient Safety Portal.~~ OPOs are required to report these events according to *Policy 18.5: Reporting of Patient Safety Events*.

If a transplant hospital repackages an organ for transport, it must package, label, and transport the organ according to *Policy 16: Organ and Extra Vessels Packaging, Labeling, Shipping, and Storage,* except that the use of the OPTN organ tracking system is not required. The transplant hospital must immediately notify the host OPO of the repackaging.

18.5 Reporting of ~~Living Donor Events~~ Patient Safety Events

18.5.A Required Reporting by Transplant Hospitals

Transplant hospitals must report the following events to the OPTN according to *Table 18-3* below.

Table 18-3: Required Reporting by Transplant Hospitals

Transplant hospitals must report if:	To the:	Within 24 hours after:
A transplant of the incorrect organ into an organ recipient occurs	Improving Patient Safety Portal	The transplant hospital becomes aware
A transplant of an organ into the incorrect organ recipient occurs	Improving Patient Safety Portal	The transplant hospital becomes aware
A donor organ is identified as incorrect during pre-transplant processes conducted according to either *Policy 5.8.A*: *Pre-Transplant Verification Prior to Organ Receipt* or *Policy 5.8.B: Pre-Transplant Verification Upon Organ Receipt*	Improving Patient Safety Portal	The transplant hospital becomes aware
The potential transplant recipient is identified as incorrect during pre-transplant processes conducted according to either *Policy 5.8.A: Pre-Transplant Verification Prior to Organ Receipt* or *Policy 5.8.B: Pre-Transplant Verification Upon Organ Receipt*	Improving Patient Safety Portal	The transplant hospital becomes aware
An organ was delivered to the incorrect transplant hospital and resulted in non-use of the organ	Improving Patient Safety Portal	The transplant hospital becomes aware
The incorrect organ was delivered to the transplant hospital and resulted in non-use of the organ	Improving Patient Safety Portal	The transplant hospital becomes aware
An organ did not arrive when expected and resulted in the intended candidate not receiving a transplant from the intended donor because of the transportation issue	Improving Patient Safety Portal	The transplant hospital becomes aware
An ABO typing error or discrepancy is caught before or during pre-transplant processes conducted according to either *Policy 5.8.A: Pre-Transplant Verification Prior to Organ Receipt* or *Policy 5.8.B: Pre-Transplant Verification Upon Organ Receipt*	Improving Patient Safety Portal	The transplant hospital becomes aware

18.5.B Required Reporting of Living Donor Events by Recovery Hospitals

Recovery hospitals must report living donor events through the Improving Patient Safety Portal or the OPTN according to *Table 18-4* below.

Table 18-4: Living Donor Event Reporting

Recovery hospitals must report if:	To the:	Within 72 hours after:
A living donor organ recovery procedure is aborted after the donor has begun to receive general anesthesia.	Improving Patient Safety Portal and the OPTN	The aborted organ recovery procedure
A living donor dies within 2 years after organ donation	Improving Patient Safety Portal	The hospital becomes aware
A living ~~liver~~ donor is listed on the ~~liver~~ wait list within 2 years after organ donation	Improving Patient Safety Portal	The hospital becomes aware
A living kidney donor ~~is listed on the kidney wait list or~~ begins regularly administered dialysis as an ESRD patient within 2 years after organ donation	Improving Patient Safety Portal	The hospital becomes aware
A living donor organ is recovered but not transplanted into any recipient	Improving Patient Safety Portal and the OPTN	Organ recovery
A living donor organ is recovered and transplanted into someone other than the intended recipient	Improving Patient Safety Portal	Organ recovery

~~The Membership and Professional Standards Committee will review all cases reported according to *Table 18-4* above and report to the OPTN Board of Directors.~~

18.5.C Required Reporting by OPOs

OPOs must report the following events to the OPTN according to *Table 18-5* below.

Table 18-5: Required Reporting by OPOs

Host OPOs must report if:	To the:	Within 24 hours after:
Transplant hospital procurement staff leave the operating room without allowing the host OPO to package and label deceased donor organs and tissue typing specimens as required	Improving Patient Safety Portal	The OPO becomes aware

Host OPOs must report if:	To the:	Within 24 hours after:
An ABO typing error or discrepancy is caught after the OPO's deceased donor blood type and subtype verification process, as outlined in *Policy 2.6.C: Reporting of Deceased Donor Blood Type and Subtype*	Improving Patient Safety Portal	The OPO becomes aware

18.5.D Required Reporting by all OPTN Members

OPTN members must report the following events to the OPTN according to *Table 18-6* below.

Table 18-6: Required Reporting by all OPTN Members

Members must report if:	To the:	Within 24 hours after:
Any sanction is taken by a state medical board or other professional body against a transplant professional working for an OPTN member	Improving Patient Safety Portal	The member becomes aware
Evidence is discovered of an attempt to deceive the OPTN or the Department of Health and Human Services (HHS)	Improving Patient Safety Portal	The member becomes aware

#

Appendix A: Update to OPTN Improving Patient Safety Portal Instructions

Safety Situation Event Form Instructions

What is a Safety Situation?
A situation or activity that affected or could have affected patient safety.

What to report:
Transplant hospitals must report the following events within 24 hours of becoming aware of the event:

- A transplant of the incorrect organ into an organ recipient occurs
- A transplant of an organ into the incorrect organ recipient occurs
- A donor organ is identified as incorrect during pre-transplant processes conducted according to either Policy 5.8.A: *Pre-Transplant Verification Prior to Organ Receipt* or Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt*
- The potential transplant recipient is identified as incorrect during pre-transplant processes conducted according to either Policy 5.8.A: *Pre-Transplant Verification Prior to Organ* Receipt or Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt*
- An organ was delivered to the incorrect transplant hospital and resulted in non-use of the organ
- The incorrect organ was delivered to the transplant hospital and resulted in non-use of the organ
- An organ did not arrive when expected and resulted in the intended candidate not receiving a transplant from the intended donor because of the transportation issue
- An ABO typing error or discrepancy is caught before or during pre-transplant processes conducted according to either Policy 5.8.A: *Pre-Transplant Verification Prior to Organ Receipt* or Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt*

OPOs must report the following events within 24 hours of becoming aware of the event:

- Transplant hospital procurement staff leave the operating room without allowing the host OPO to package and label deceased donor organs and tissue typing specimens as required
- An ABO typing error or discrepancy is caught after the OPO's deceased donor blood type and subtype verification process, as outlined in OPTN Policy 2.6.C: *Reporting of Deceased Donor Blood Type and Subtype*

All OPTN members must report the following events within 24 hours of becoming aware of the event:

- Any sanction is taken by a state medical board or other professional body against a transplant professional working for an OPTN member
- Evidence is discovered of an attempt to deceive the OPTN or the Department of Health and Human Services (HHS)

In general:
Please report such situations in a timely manner:

- Any patient safety situation
- Any other situation that causes a safety concern from a transplantation, donation, and/or quality perspective.

Living Donor Event Form Instructions

What is a Living Donor Event?
Situations or activities that affected a living donor.

All required donor and recipient information must still be submitted through TIEDI

This information must be reported within 72 hours of the aborted recovery procedure:

- A living donor organ recovery procedure is aborted after the donor has begun to receive general anesthesia.

This information must be reported within 72 hours of the transplant program's knowledge of the event:

- A living donor dies within two years after organ donation
- A living ~~liver~~ donor is listed on the ~~liver~~ waitlist within two years after organ donation
- A living kidney donor ~~is listed on the kidney waitlist or~~ begins regularly administered dialysis as an ESRD patient within two years after organ donation

This information must be reported within 72 hours of organ recovery:

- A living donor organ is recovered but not transplanted into any recipient
- A living donor organ is recovered and transplanted into someone other than the intended recipient

Please reference OPTN policy for more information on living donor event reporting requirements.

All reported Living Donor Events falling into the above categories will be reviewed by the Membership and Professional Standards Committee and reported to the OPTN Board of Directors. Situations or events that are related to living donors but not listed above, but cause concern from a transplantation, donation, and/or quality perspective should be reported to the Safety Situation Portal.