

OPTN Membership and Professional Standards Committee (MPSC)

Meeting Summary

April 24, 2023

Zoe Stewart Lewis, M.D., Chair

Scott Lindberg, M.D., Vice Chair

Introduction

The Membership and Professional Standards Committee (MPSC) met virtually via Citrix GoToTraining in open and closed session on April 24, 2023. The following agenda items were discussed during the meeting:

1. Require Reporting of Patient Safety Events Project
2. Performance Monitoring Enhancements

1. Require Reporting of Patient Safety Events Project

The Committee reviewed the purpose and proposal for the Require Reporting of Patient Safety Events project. The purpose of this project is to align OPTN members' reporting requirements with the OPTN contractor's requirement to report specific concerning patient safety events to MPSC leadership and HRSA. The project proposes adding requirements to OPTN Policy 18 to require members to notify the OPTN of the types of events that the contractor must report to HRSA, so staff can notify stakeholders in a timely fashion, fully investigate the event, and forward it for MPSC review.

The project proposes that the following patient safety events be required to be reported by OPTN members:

- The proposal requires transplant hospitals to report the following events within 24 hours of becoming aware of the incident:
 - A transplant of the wrong organ into an organ recipient occurs
 - A near miss transplant of the wrong organ into an organ candidate occurs
 - A transplant into the wrong organ recipient occurs
 - A near-miss transplant into the wrong organ candidate occurs
 - An organ did not arrive when it was expected without communication from the OPO, resulting in the intended candidate not receiving a transplant from the intended donor
- The proposal requires all OPTN members to report within 24 hours of becoming aware of the incident:
 - Evidence of an attempt to deceive the OPTN or the Department of Health and Human Services (HHS) is discovered (e.g., falsifying medical records)
 - A device is used for a condition, diagnosis, or procedure that is contraindicated by the Food and Drug Administration (FDA)
 - Any state medical board or other professional body sanctions a transplant professional working for an OPTN member

The Committee also reviewed the following feedback provided from OPTN Operations and Safety Committee leadership and the OPTN Living Donor Committee.

- OPTN Operations and Safety Committee leadership feedback
 - CMS Never Events
 - Agreed that these should be excluded from the required reports
 - Near Miss Definition
 - Concerns with requiring reporting of near misses (potential punitive consequence from MPSC) versus encouraging members to self-report near misses (quality improvement purposes).
 - Surgical Damage as a required report
 - Ultimately concluded that surgical damage should not be a required report since it should be dealt with at the originating OPO.
- OPTN Living Donor Committee feedback
 - Living Donor Events
 - Suggested adding a requirement for members to report when any living donor (specifically small bowel, pancreas, or lung) is added to the waiting list within two years after donation.
 - Near Miss definition
 - Typically, transplant hospitals have an index verification and a secondary verification so a near miss should be constituted as an error caught between the first and second verifications

Summary of discussion:

The Committee was asked if they agree with considering or incorporating the suggestions from OPTN Operations and Safety Committee leadership and the OPTN Living Donor Committees into the proposal and how they want to define “near miss”.

A member stated that they support the idea of trying to start capturing some of the transportation data but are concerned that the Committee won’t capture as much data as they think with the proposed transportation event. With the use of organ trackers becoming more and more common, it’s less common now that an OPO is unaware of a delay and is contacting the transplant hospital. So, it’s less common now that a transplant hospital doesn’t know that there is a delay.

Staff asked if the member would still propose capturing this event, but possibly rewording it, or if they don’t think it’s valuable to include. The member stated that their initial thought is that transportation issues are complex and capturing partial data could be more misleading than helpful.

A member stated that they have a concern about including the event “[a] device is used for a condition, diagnosis, or procedure that is contraindicated by the Food and Drug Administration (FDA)”. In lung transplant, surgeons commonly have to use metallic, self-expanding airway stents, especially the uncovered airway stents, which are contraindicated by the FDA in benign disease. 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 most appropriate or the only treatment available for them.

A member reiterated that they understand the intent of including the event “[a] device is used for a condition, diagnosis, or procedure that is contraindicated by the Food and Drug Administration (FDA)”, but there are a lot of things that surgeons do routinely that would be captured within this required report and the member wasn’t sure if that is the intent of the Committee.

A member stated that the required reporting of near misses is important – the Committee wants to encourage members to report near misses, but if a member hasn’t violated any policy or bylaw then there should be some assurance that there will not be an adverse action from the MPSC.

A member asked staff to provide some background information regarding the transportation event. Staff stated that this started when the Senate Finance Committee asked questions about the MPSC's oversight. Some stakeholders believe that the MPSC knows every time something like this happens and have an expectation that the MPSC should know every time this happens. Stakeholders have started to articulate the expectation that a viable organ should never be non-utilized because of transportation issues. This project acknowledges that there isn't a formalized reporting system that allows the MPSC to say with certainty that they know every time this happens. So, this was just an idea to provide some of this data to those stakeholders and ensure that the MPSC is aware when these events happen. Staff stated that this event was meant to be more of a discussion about whether the MPSC wanted this data to alleviate some of the criticisms.

A member stated that they aren't sure if this is the best forum to introduce this transportation reporting, because it seems to be a different severity compared to the other events the MPSC is asking members to report.

There was no further discussion.

Next Steps:

- May 4, 2023 meeting
 - Continue this discussion and define near miss
 - Review policy language
- May 22, 2023 meeting
 - Vote to send this proposal out for public comment

2. Performance Monitoring Enhancements

Staff provided an update on the work of the Performance Monitoring Enhancement Subcommittee. The Committee was asked to approve the draft offer acceptance questionnaire and the data that will be provided to reviewers in the staff summary in the offer acceptance performance review packets and to members in the initial inquiry.

Staff reviewed a slide that provided information on the number of programs that would have been identified for offer acceptance rate ratio in the last three program specific report cycles. A member asked whether the numbers for each cycle reflected new distinct programs each cycle or whether there were programs that were identified for multiple cycles. Staff replied that there are some programs that were identified during multiple cycles. Following the consideration of the offer acceptance questionnaire, staff reported that there were 32 programs that were identified in more than one cycle, 17 of those in all three cycles. Twenty-two programs were identified in only one cycle.

At its February meeting, the Committee reviewed a draft of the offer acceptance questionnaire. A couple of Committee members requested an opportunity to provide additional feedback prior to the Committee voted on the questionnaire. The offer acceptance questionnaire was reviewed and revised at the March 24, 2023, Subcommittee meeting. The Subcommittee reviewed the updates at its April 14, 2023, meeting and recommended that the questionnaire be approved by the Committee for use beginning in July. During the April 24 meeting, Staff reviewed the questionnaire noting changes that had been made since the February meeting. Staff reminded the Committee that the questionnaire can be modified as needed if the Committee identifies needed changes following the first reviews for offer acceptance. The Committee did not have any questions or further comments. A motion to approve was made, seconded, and approved by a vote of 28 For, 0 Against, 1 Abstention.

Staff reported that the Subcommittee has recommended supporting data that should be provided in the staff summary and to member programs in the initial inquiry. As with the questionnaire, the

Subcommittee noted that it is difficult to determine the data that would be helpful without having reviewed programs for offer acceptance. The Committee can request additional data be included or removed in the staff summary following the initial set of reviews. Staff noted that the Subcommittee considered data sources for more recent performance data and concluded that more recent data on offer acceptance is not needed since there is a short 6-month lag, unadjusted data would not be useful in evaluating programs' recent performance, and it would not be appropriate for the Committee to request CUSUM data from the Scientific Registry of Transplant Recipients (SRTR) for purposes of monitoring. Historically, the Committee has not requested SRTR CUSUM data since the SRTR produces this data for programs' internal quality review. The Subcommittee recommended that a waiting list description and the following additional other performance metrics be provided:

- Pre-transplant mortality
- Transplant rate
- Time to transplant
- Transplant volume over time to evaluate volume trends

The Subcommittee also recommended that the SRTR program specific report data for offer acceptance rate ratio subgroups and any recommended filters in the OPTN Offer Filter Discovery Tool for kidney programs that are not using offer filters be included in the staff summary and be provided to the members in the initial inquiry. This data is relevant to assessing areas for improvement. Staff reviewed the SRTR subgroups and noted the Subcommittee requested that the offer acceptance rate ratio be provided as well as the underlying data regarding the number of offers received and offers accepted. A Subcommittee member had requested that we evaluate whether the heart subgroup for ejection fraction less than 60 could be changed to less than 50. For the member inquiry, staff also plan to provide a summary of the OPTN tools available to programs to review offer acceptance behavior and an offer for the member to set up a session for a staff member to review the tools with them.

Discussion

One member addressed the potential change for ejection fraction and suggested that the Committee not use a different ejection fraction parameter than what is made publicly available by the SRTR. He was concerned this would cause confusion.

Another member asked if the national average would also be included in the subgroup data. Staff responded that the national average could be included in that data. The member noted that the national data would be helpful as a benchmark for the program.

The SRTR Director noted that the ejection fraction used in the public reports had been less than 60 for a number of years. When the SRTR first developed the subgroups, the SRTR cardiac senior staff were consulted. The SRTR would take the recommendation of the MPSC or the OPTN Heart Committee to alter that cutoff in the future. A Committee member suggested that it would be useful to re-evaluate the ejection fraction cutoff as the community is pushing to use more organs noting that 55 would be a reasonable number. He also noted that getting the predicted heart mass calculation hardwired would make allocation more efficient.

The SRTR Director also asked whether the adjusted offer acceptance rate ratio for the subgroups would be provided and noted that it may also be helpful to provide a visual representation of where the program falls in the national distribution of programs. The SRTR will work with the Committee to provide those visuals.

A motion to approve was made, seconded, and approved by a vote of 27 For, 0 Against, 1 Abstention.

Upcoming Meetings

- May 4, 2023, 9am-3pm, CT, Chicago
- May 22, 2023, 3-5pm, ET, Conference Call
- June 21, 2023, 3-5pm, ET, Conference Call
- July 25-27, 2023, Detroit, MI

Attendance

- **Committee Members**
 - Alan Betensley
 - Emily Blumberg
 - Todd Dardas
 - Robert Fontana
 - Reginald Gohh
 - Barbara Gordon
 - Robert Harland
 - Rick Hasz
 - Kyle Herber
 - Victoria Hunter
 - Ian Jamieson
 - Andrew Kao
 - Peter Kennealey
 - Catherine Kling
 - Michael Kwan
 - Carolyn Light
 - Scott Lindberg
 - Melinda Locklear
 - Gabriel Maine
 - Kenneth McCurry
 - Nancy Metzler
 - Dan Meyer
 - Bhargav Mistry
 - Regina Palke
 - Sara Rasmussen
 - Pooja Singh
 - Jason Smith
 - Zoe Stewart Lewis
 - Laura Stillion
 - J. David Vega
 - Candy Wells
- **HRSA Representatives**
 - Jim Bowman
 - Arjun Naik
- **SRTR Staff**
 - Ryo Hirose
 - Jonathan Miller
 - Jon Snyder
 - Bryn Thompson
- **UNOS Staff**
 - Robert Albertson
 - Sally Aungier
 - Tameka Bland
 - Rebecca Brookman
 - Roger Brown

- Robyn DiSalvo
- Demi Emmanouil
- Katie Favaro
- Liz Friddell
- Jasmine Gaines
- Rebecca Goff
- Lauren Guerra
- Asia Harden
- Madeline Holder
- Krissy Laurie
- Trung Le
- Ann-Marie Leary
- Sandy Miller
- Amy Minkler
- Sara Moriarty
- Samantha Noreen
- Jacqui O'Keefe
- Rob Patterson
- Michelle Rabold
- Shawn Richman
- Laura Schmitt
- Sharon Shepherd
- Kay Sheranek
- Stephon Thelwell
- Betsy Warnick
- Trevi Wilson
- Claudia Woisard
- Emily Womble
- Karen Wooten
- Amanda Young
- **Other Attendees**
 - None