OPTN Membership and Professional Standards Committee (MPSC)
Meeting Summary
October 16, 2023
Virtual Meeting

Zoe Stewart Lewis, M.D., Chair
Scott Lindberg, M.D., Vice Chair

Introduction

The Membership and Professional Standards Committee (MPSC) met via Webex in open session on October 16, 2023. The Committee discussed the following agenda item during the meeting:

1. Require Reporting of Patient Safety Events Public Comment Feedback

The following is a summary of the Committee's discussions.

1. Require Reporting of Patient Safety Events Public Comment Feedback

The Committee continued its discussion of potential post-public comment revisions to the proposal. OPTN Contractor staff provided a brief overview of the purpose of the proposal and the potential post-public comment revisions based on comments received on the proposal. In preparation for this conference call, the Committee participated in a survey about potential language.

The Committee's potential post-public comment changes include:

- To expand the 24-hour reporting time frame to 48 or 72 hours. The Committee decided during its September 27 conference call to extend the time frame to 72 hours.
- Clarify what is meant by the "organ did not arrive when expected and resulted in the intended candidate not receiving a transplant from the intended donor." The Committee discussed potential changes to this provision during its September 27 conference call, but the issue was not resolved.
- Add that an ABO typing error or discrepancy was discovered after the Organ Procurement Organization (OPO) has executed a match run in addition to after the OPO performed the verification required by Policy 2.6.C.
- Add that the deceit was related to transplant and the required reporting of evidence discovered of an attempt to deceive the OPTN or the Department of Health and Human Services
- Clarify the definition of "sanction" and "other professional body" for the required reporting of sanctions against a transplant professional.

<u>Data Summary:</u>

Twenty-four responses to the survey conducted prior to this conference call were received.

- 20 out of 24 of Committee respondents supported adding "and after the OPO has executed a match run" to the OPO ABO typing or discrepancy provision.
- Out of the 24 responses to the survey, 15 MPSC members supported option 1 and 9 supported option 2 as shown below.

    - Option 1: An intended candidate was unable to receive a transplant from the intended donor because the organ arrived too late.
    - Option 2: An organ arrived too late resulting in non-use of the organ.
- Out of 24 Committee respondents, 12 supported the option to leave the language on attempts to deceive the OPTN and Department of HHS as it appeared in the public comment document and 12 supporting the option that limits it to organ donation or transplant patient care.
- Out of 24 Committee respondents, 9 respondents supported option 1 requiring reporting of sanctions that restrict a transplant professional's ability to practice, 8 respondents supported option 3 to remove it from the proposal, 6 respondents supported option 2 for reporting of public sanctions, and 1 respondent proposed different language that would require reporting of forfeiture of license to practice medicine by state licensing board or any other credentialing agency.

Summary of discussion:

Decision #1: The Committee supported adding "and after the OPO has executed a match run" to the OPO ABO typing or discrepancy provision.

Decision #2: The Committee decided to remove the required report when "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" from the proposal. The MPSC will pursue a referral to an appropriate OPTN committee for data collection on transportation issues to determine the scope of the issue that can then be used to determine the scope of a required report for patient safety purposes.

Decision #3: The Committee was unable to draft appropriate replacement language for the required reports of sanctions against a transplant professional and attempts to deceive the OPTN or Department of HHS and supported removal of these provisions from the proposal so that the other important patient safety reporting requirements could move forward.

Decision #4: The Committee voted to send the Require Reporting of Patient Safety Events proposal, as amended, to the OPTN Board of Directors for approval.

Decision #1: The Committee supported adding "and after the OPO has executed a match run" to the OPO ABO typing or discrepancy provision. The Committee received feedback during public comment that, for OPOs, a patient safety concern does not arise until a match run has been executed, allocation has begun, and after the verification process outlined in *Policy 2.6.C*: *Reporting of Deceased Donor Blood Type and Subtype*. Following a description of the feedback received during public comment and an overview of the results of the pre-meeting survey, the Committee did not express any concern with the addition of language that would require execution of a match run as well as the verification outlined in *Policy 2.6.C. Reporting of Deceased Donor Blood Type and Subtype*.

Decision #2: The Committee decided to remove the required report when "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" from the proposal. The MPSC will pursue a referral to an appropriate OPTN committee for data collection on transportation issues to determine the scope of the issue that can then be used to determine the scope of a required report for patient safety purposes. During its discussions, the Committee noted the desire of the community to have more comprehensive data on the effect of transportation issues or delays and expressed a desire to be able to understand the

scope of effect of transportation issues prior to determining the appropriate scope for a patient safety-based reporting requirement other than non-use due to the organ arriving at the wrong hospital or wrong organ arriving at the hospital. The Committee concluded that reporting through the OPTN Patient Safety Portal is not an adequate avenue for collection of data that could be used to evaluate transportation issues and determine how to address these issues effectively. The information collected through the OPTN Patient Safety Portal form is limited and would require inquiry of the involved OPTN members to gather the circumstances of the transportation issue and concluded that data collection on transportation issues is the better route to determine the scope of transportation issues.

Decision #3: The Committee was unable to draft appropriate replacement language for the required reports of sanctions against a transplant professional and attempts to deceive the OPTN or Department of HHS and supported removal of these provisions from the proposal so that the other important patient safety reporting requirements could move forward. During public comment, it became clear that significant clarification of these two provisions was needed. Although commenters recognized that these two events were patient safety events, they noted that the provisions were vague and broad and do not provide sufficient guidance to members regarding what should be reported. Commenters noted that the failure to define the term “sanctions” and “other professional body” could result in the requirement to report confidential actions such as agreements to participate in substance abuse programs and less serious sanctions such as failure to meet a board continuing medical education (CME) requirement in a timely fashion or discipline by a hospital’s credentialing committee for failure to complete patient care notes in a timely fashion. Commenters also noted that it is unclear what “other professional body” means. Clarification of this provision is also complicated by the fact that criteria for sanctions, the process for evaluating potential sanctions, and how those sanctions are reported varies by state. Additionally, commenters noted that the broad language for the requirement to report attempts to deceive the OPTN could conceivably require reporting of any attempt to deceive the Department of HHS that occurs in any service line within the hospital. The commenters noted that transplant program staff are unlikely to know of or become aware of or have the ability to gather information on these attempts to deceive. Therefore, it was suggested that this requirement to report to the OPTN be limited to attempts to deceive that are related to transplant. In addition, since hospitals are obligated under other federal agency regulations to report fraud, the Committee felt this requirement should be narrow in scope to avoid overlap. The MPSC agreed that both of these provisions needed clarification. After discussion of several alternative language options for each of these proposed requirements, the Committee was unable to draft appropriate replacement language prior to a final vote on the proposal to be sent to the Board. Therefore, these two provisions were removed from the proposal so that the other important patient safety event reporting requirements could move forward. The Committee will continue to evaluate language for consideration in a future proposal.

Decision #4: The Committee voted to send the Require Reporting of Patient Safety Events proposal, as amended, to the OPTN Board of Directors for approval with a vote of 24 Yes, 1 No, 0 Abstain.

Next Steps:

- The Require Reporting of Patient Safety Events proposal will be considered by the OPTN Board of Directors for approval at its December 4, 2023, meeting.

Upcoming Meetings

- November 1-3, 2023, Chicago, IL
- December 6, 2023, 2-4:00pm, ET, Conference Call
- January 19, 2024, 2- 4pm, ET, Conference Call

- February 16, 2024, 2-4pm, ET, Conference Call
- March 5-7, 2024, Detroit, MI
- March 29, 2024, 2-4pm, Conference Call
- Apr 23, 2024, 3-5pm, ET, Conference Call
- May 21, 2024, 2-4pm, ET, Conference Call
- June 28, 2024, 2-4pm, Conference Call
- July 23-25, 2024, Detroit, MI

Attendance

- **Committee Members**
  - Alan Betensley
  - Kristine Browning
  - Anil Chandraker
  - Hannah Copeland
  - Roshan George
  - Darla Granger
  - Lafaine Grant
  - Shelley Hall
  - Robert Harland
  - Rich Hasz
  - Kyle Herber
  - Victoria Hunter
  - Michelle James
  - Catherine Kling
  - Peter Lalli
  - Raymond Lee
  - Scott Lindberg
  - Melinda Locklear
  - Nancy Metzler
  - Saeed Mohammad
  - Regina Palke
  - Deirdre Sawinski
  - Malay Shah
  - Zoe Stewart Lewis
  - J. David Vega
  - Mark Wakefield
  - Candy Wells
- **HRSA Representatives**
  - Marilyn Levi
  - Arjun Naik
  - Daniel Thompson
- **SRTR Staff**
  - Jonathan Miller
  - Bryn Thompson
- **UNOS Staff**
  - Sally Aungier
  - Matt Belton
  - Elinor Carmona
  - Robyn DiSalvo
  - Katie Favaro
  - Liz Friddell
  - Jasmine Gaines
  - Rachel Hippchen
  - Houlder Hudgins

- Elias Khalil
    - Lee Ann Kontos
    - Krissy Laurie
    - Ann-Marie Leary
    - Jon McCue
    - Amy Minkler
    - Rebecca Murdock
    - Samantha Noreen
    - Jacqui O’Keefe
    - Michelle Rabold
    - Liz Robbins Callahan
    - Melissa Santos
    - Laura Schmitt
    - Sharon Shepherd
    - Tynisha Smith
    - Stephon Thelwell
    - Marta Waris
    - Betsy Warnick
    - Trevi Wilson
    - Claudia Woisard
    - Emily Womble
    - Karen Wooten
    - Amanda Young
- **Other Attendees**

    None