

Confidential Medical Peer Review
OPTN Membership and Professional Standards Committee (MPSC)
Meeting Summary
December 6, 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 both open and closed session on December 6, 2023. The following agenda items were discussed during the open session of the meeting:

1. OPO Performance Monitoring Project
2. OPTN Exeditious Task Force: PDSA Variances

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

1. OPO Performance Monitoring Project

The OPO Performance Monitoring Enhancement Workgroup Chair and OPTN staff reviewed the updates made to the draft OPO referral data collection tool since the last report to the MPSC at its November meeting. The updates included:

- Added death record review capture for ventilated patients 75 years or younger
- Updated DCD Evaluation section based on OPTN Lung Committee member feedback
 - List of causes of primary injury when patient has a primary non-neurological injury
 - Removed "cystic fibrosis" and revised "respiratory failure" to "respiratory failure due to pulmonary disease"

OPTN staff provided an overview of the themes contained in the concept paper and requested feedback from the Committee. Finally, the Committee reviewed and voted on whether to release the following concepts for public comment in winter 2024:

- Development of standardized module that incorporates consistent definitions, use of yes/no question logic and algorithms that can be incorporated into OPOs' electronic donor records
- Data capture as reflected in draft data capture tool
- Requirement to capture data on referral process using OPTN specifications
 - OPTN will work with EDR vendors/OPOs to develop modules for their systems
- Electronic upload to OPTN Computer System
- Potential data collection from transplant hospitals on in-hospital deaths and ICD-10 diagnosis codes

Finally, OPTN staff described a recent request from Health Resources and Services Administration (HRSA) for input from the MPSC OPO Performance monitoring Enhancement Workgroup on additional data collection ventilated referrals.

Summary of Discussion:

Decision: The Committee approved the release of the OPO data capture concepts for the phases of donation that precede donor registration for winter 2024 public comment.

Decision: The Committee approved the release of the OPO data capture concepts for the phases of donation that precede donor registration for winter 2024 public comment.

The Committee did not provide any suggestions for additions or changes to the concept paper and did not have any questions about the concepts included in the concept paper for public comment. The Committee unanimously approved releasing the concepts for public comment in the winter 2024 public comment period by a vote of 27 for, 0 against, 0 abstentions.

2. OPTN Expeditious Task Force: PDSA Variances Update

OPTN Staff provided an update from the December 8, OPTN Expeditious Task Force meeting.

- Proposed changes to the Governance of Variance Process were reviewed including adding the ability for OPTN Committees to propose new variances without a member application, removing the requirement for members to solicit at least 75% support from any other members impacted by the proposed variance, and changing the reporting requirements from final report after completion of variance, to regular reporting as outlined in the variance.
- The proposed new variance will work by charging a committee to develop protocols for expedited placement. This approach will allow the OPTN to review multiple protocols simultaneously. Approved protocols must include:
 - Explicit clinical criteria for kidneys eligible for expedited placement
 - Explicit criteria for candidates eligible to receive expedited placement offers
 - Explicit conditions for the use of expedited placement
 - Any OPO and transplant hospital responsibilities
- A variance will have a one year run time, with a potential shorter run time for each protocol. The sponsoring committee will evaluate the utilization rate and non-use rate over time as measures of success. Options will include open and closed protocols and could include all organ types. The special public comment period will start at the beginning of 2024.
- The staff reviewed outstanding questions related to the new variance including if and how the MPSC would want to monitor allocations compliance with the protocols. The Committee considered the following: requiring the participating OPOs to perform self-audits, the possibility of the MPSC reviewing the self-audits, and the MPSC reviewing aggregate data, the need to allow participating members to opt out if desired. There will be an amendment of OPTN Policy 1.3.A (5) (*Acceptable Variances*) allowing the OPTN Board of Directors to extend, amend, or terminate a variance at any time.

Summary of Discussion:

- The MPSC Vice-Chair raised concerns about the potential additional workload on committee volunteers and staff if reviewing additional allocation cases. What if there are dozens of protocols to review? A staff member commented that it is being investigated. Staff are also looking at ways to reduce the burden of reviewing allocation out of sequence cases.
- Another member asked if it would be possible to flag or exclude cases where a variance is used and noted that members need to consider what unintended consequences might result from the use of these variances.

- A member supported the idea of requiring members participating in the variance to perform self-auditing for compliance with the protocol, to decrease burden from the MPSC even if it not an ideal solution.
- Another member asked if the SRTR is involved in the process to date and if their numbers would not include variance data. OPTN staff were unsure as to whether that would be possible or not.

Upcoming Meetings

- January 19, 2024, 2-4 pm, ET, Conference Call
- January 29, 2024, 1-3pm, ET, Conference Call
- February 16, 2024, 2-5 pm, ET, Conference Call
- March 5-7, 2024, Detroit
- March 29, 2024, 2-5pm, ET, Conference Call
- April 23, 2024, 3-6 pm, ET, Conference Call
- May 21, 2024, 2-5 pm, ET, Conference Call
- June 28, 2024, 2-5pm, ET, Conference Call
- July 23-25, 2024, Detroit

Attendance

- **Committee Members**
 - Alan Betensley
 - Kristine Browning
 - Anil Chandraker
 - Chad Ezzell
 - Robert Fontana
 - Rich Formica
 - Roshan George
 - Darla Granger
 - Lafaine Grant
 - Dipankar Gupta
 - Shelley Hall
 - Robert Harland
 - Rich Hasz
 - Kyle Herber
 - Victoria Hunter
 - Michelle James
 - Peter Kennealey
 - Peter Lalli
 - Carolyn Light
 - Scott Lindberg
 - Melinda Locklear
 - Amit Mathur
 - Deborah McRann
 - Nancy Metzler
 - Regina Palke
 - Martha Pavlakis
 - Deidre Sawinski
 - Malay Shah
 - Zoe Stewart Lewis
 - J. David Vega
 - Mark Wakefield
 - Candy Wells
 - James Yun
- **HRSA Representatives**
 - Jim Bowman
 - Shannon Dunne
 - Marilyn Levi
 - Arjun Naik
 - Kala Rochelle
- **SRTR Staff**
 - Ryutaro Hirose
 - Jonathan Miller
 - Jon Snyder
 - Bryn Thompson

- **UNOS Staff**
 - Robert Albertson
 - James Alcorn
 - Stephanie Anderson
 - Sally Aungier
 - Tameka Bland
 - Elinor Carmona
 - Robyn DiSalvo
 - Liz Friddell
 - Jasmine Gaines
 - Caroline Hales
 - Asia Harden
 - Houlder Hudgins
 - Elias Khalil
 - Lee Ann Kontos
 - Krissy Laurie
 - Amy Minkler
 - Heather Neil
 - Samantha Noreen
 - Rob Patterson
 - Melissa Santos
 - Laura Schmitt
 - Sharon Shepherd
 - Courtney Skeen
 - Chris Stadolnik
 - Sarah Stevenson
 - Juanita Street
 - Stephon Thelwell
 - Marta Waris
 - Betsy Warnick
 - Trevi Wilson
 - Emily Womble
 - Karen Wooten
 - Amanda Young
- **Other Attendees**
 - None