

Meeting Summary

OPTN Membership and Professional Standards Committee (MPSC) Meeting Summary February 23-24, 2022 Conference Call with GoToTraining

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Introduction

The Membership and Professional Standards Committee (MPSC) met by conference call in open and closed session via Citrix GoToTraining on February 23-24, 2022, and discussed the following agenda items during open session:

- 1. Modify Graft Failure Definition for VCA
- 2. Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation
- 3. Redesign Map of OPTN Regions
- 4. IT Overview of System Enhancements in Response to Safety Events
- 5. Performance Monitoring Enhancement (PME) Project
- 6. Educational Referrals Discussion of New Topics

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

1. Modify Graft Failure Definition for VCA, OPTN Vascularized Composite Allograft Transplantation Committee

A representative of the Vascularized Composite Allograft (VCA) Committee presented the committee's proposal "Modify Graft Failure Definition for VCA." The proposal includes specific definitions of VCA graft failure and planned removal of a VCA graft, as well as updates to data collection on VCA transplant outcomes. In a question and answer session following the presentation, the following topics were discussed:

- Data collection for removal of a uterus transplant will include fields to report the reason for removal, and whether it was planned or unplanned. The current standard for a planned removal of a uterus transplant is around 5 years at most.
- The VCA committee discussed that degree of function for some VCA transplants may exist on a spectrum, and determined that a lower degree of function (e.g., a "claw hand" from an upper limb transplant) would not be considered a graft failure unless the graft was removed.

MPSC members also shared the following feedback:

- The proposed definitions clearly distinguish between graft failure and planned removal of a graft.
- According to the proposed graft failure definition, a VCA recipient could be registered for a second VCA of the same type that is not intended to replace a failed transplant, and it would be considered a graft failure. The VCA committee representative stated this type of scenario is probably rare, but not impossible, and the committee will consider how to revise the definition to exclude this type of scenario.

2. Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation, OPTN Ad Hoc Multi-Organ Transplantation Committee

A representative of the Ad Hoc Multi-Organ Transplantation (MOT) Committee presented the committee's proposal "Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation." The proposal establishes candidate medical eligibility criteria for simultaneous heart-kidney and lung-kidney offers. It also establishes "safety net" criteria for heart or lung recipients to receive priority for a subsequent kidney transplant. The MOT Committee modeled these criteria after existing liver-kidney policies. The following topics were discussed during a question and answer session following the presentation:

- Multi-organ transplantation has not been factored into lung continuous distribution yet. It will be incorporated with each organ as each one shifts to the continuous distribution model.
- The safety net is available both for candidates who do not meet eligibility criteria for a simultaneous multi-organ transplant and for candidates for whom a simultaneous transplant might not be the best clinical option.
- The 500 nautical miles (NM) distance and limitation to heart statuses 1-3 in the simultaneous heart-kidney and lung-kidney eligibility criteria were implemented in a separate proposal. The MOT committee will be revisiting these criteria.

MPSC members also shared the following feedback:

- Several MPSC members expressed mixed opinions on the proposed glomerular filtration rate (GFR) threshold of 30 mL/min. One member commented that it was too low for heart candidates, and another commented that it was too high for lung candidates. A third member supported keeping the proposed policies aligned with the existing liver-kidney policy for simplicity. Another member explained that heart failure patients often receive continuous renal replacement therapy (CRRT) before transplant, which could raise a patient's eGFR over the eligibility threshold.
- Several MPSC members expressed concerns that the proposed safety net would not benefit seriously ill heart recipients who may not have enough kidney function to support their heart transplant while waiting to receive a kidney.
- Several MPSC members raised broader multi-organ allocation issues that need to be resolved. OPOs need guidance on how to allocate organs when multiple multi-organ candidates appear across match runs (e.g., a heart-liver candidate and a liver-kidney candidate). The amount of discretion OPOs currently have leads to wide variability in allocation that could be causing inequity. A member suggested prioritizing multi-organ candidates on the primary organ's match run to avoid situations where an organ needed by a multi-organ candidate on one match run is no longer available because a candidate on another match run has already accepted it. The MOT Committee representative said that a proposal scheduled for 2024 would address many of these issues.
- An MPSC member expressed concern that the proposal will have a negative impact on pediatric
 kidney waitlist mortality and suggested studying the effects of the proposed policy on children.
 The MOT Committee should also consider how to prioritize children who need a kidney
 transplant and who are starting to experience complications of dialysis.

3. Redesign Map of OPTN Regions, OPTN Executive Committee

On behalf of the OPTN Executive Committee, a staff member presented information on the committee's concept paper "Redesign Map of OPTN Regions". She explained that the intent of the concept paper is to gather feedback from the community on options for updating the map of OPTN regions and to share the vendor's final report on the regional review project.

The Executive Committee proposes that if a new map is drawn, it should preserve continuous regions and should be more balanced than the current OPTN regions. The concept paper includes maps created by equally distributing several factors: percentages of population, donors, members, recipients, and transplants.

At the conclusion of the presentation, committee members asked questions and provided feedback on the concept paper:

- Larger and fewer regions risk diluting individual voices within a region. It may be harder for members to represent their unique challenges (e.g., a member serving patients in a sparsely populated region), and it could dilute patient and donor family voices.
- The current structure has served the OPTN very well. Several committee members questioned
 whether changing the regions would further any of the OPTN strategic goals. Another
 committee member expressed concern about losing the ability to meet and discuss local
 practices in regional meetings if the regions increased in size.
- The metrics used omit the key issue of diversity of representation. They seem to focus more on equality than equity and do not address socioeconomic factors.

4. IT Overview of System Enhancements in Response to Safety Events

During a previous meeting, the Committee discussed common themes from certain serious safety events that the Committee has reviewed in recent years. Staff previously provided an overview and demonstration of TransNetsm for transplant hospitals to provide MPSC members with a good understanding of how TransNetsm works for transplant hospitals. Staff previously discussed how enhanced automated solutions could be used to minimize the likelihood of recurrent safety events.

At this meeting, staff continued the discussion and reviewed a number of potential improvements to the match lists for MPSC members to consider. Staff explained that the changes are centered on improving patient identification when transplant hospitals are considering organ offers, and when accepting and transplanting organs. Staff reviewed the potential changes, which included:

- Adding the Center Patient ID to the match results allowing for easier patient lookup in hospital electronic health records (EHR).
- Adding candidate Waitlist ID
- Adding a warning to the match results page when a candidate share an identical or similar name to another patient listed at the same program – regardless of if that other patient is on the match run.

Committee members stated that the Center Patient ID would be very useful. A committee member stated that the Center Patient ID would ease workload due to all of the patient information being displayed on one screen. Additionally, Committee members stated that the Waitlist ID would not be as helpful, as that ID is not something that is looked at or used very often. Committee members commented on the other enhancements and stated that the warning on the match results page would also be very helpful to identify the right patient.

At the conclusion of the presentation, staff thanked the Committee members for their feedback.

5. Performance Monitoring Enhancement (PME) Project

Staff provided an update on the Performance Monitoring Enhancement project and introduced Amit Mathur as the new co-chair of the Performance Monitoring Enhancement Subcommittee. She summarized the project tasks for the Implementation and Evaluation phases of the project, which are to:

- Finalize performance improvement ("yellow") zone for each metric
- Revise current performance review process
- Education and resources for members
- Evaluation of post-implementation monitoring data

The staff member also reviewed the implementation plan with the committee and explained that there will be a phased implementation of the metrics in the proposal. The earliest date for implementation of the two post-transplant metrics will be in July 2022, the offer acceptance metric in July 2023, and the pre-transplant mortality metric in July 2024. Staff noted that two topics, establishment of the performance improvement (yellow) zone parameters and review of the post-implementation monitoring plan. Staff mentioned the topics and goals for today. She mentioned that the Scientific Registry of Transplant Recipients (SRTR) would be presenting information on yellow zone boundaries. She also noted that the committee will vote on the performance improvement (yellow) zone boundaries and will review the post-implementation monitoring plan to finalize the data request.

Establishing Performance Improvement Zones

Staff provided a review of the purpose and goals of the performance improvement zones and then introduced Jon Snyder, SRTR Director, who provided information on the options for yellow zone parameters. He stated the objectives in choosing parameters and reviewed the criteria established for MPSC interaction (red) zone for each metric. The Director stated that the subcommittee suggested the following potential parameters for the performance improvement (yellow) zone at its last subcommittee meeting:

- Adult and Pediatric Pre-Transplant Mortality Greater than 50% probability that the program's waitlist mortality rate is greater than 1.5 or 50% higher than expected, but below 1.75.
- Adult Offer Acceptance Greater than 50% probability that the program's offer acceptance rate is lower than 0.40, 60% lower than expected, but above 0.30.
- Pediatric Offer Acceptance Greater than 50% probability that the program's offer acceptance rate is lower than 0.45 or 55% lower than expected, but above 0.35.
- Adult 90-Day Graft Survival Greater than 50% probability that the program's 90-day graft failure rate is greater than 1.5, 50% higher than expected, but below 1.75.
- Pediatric 90-Day Graft Survival –Greater than 50% probability that the program's 90-day graft failure rate is 1.35, 35% higher than expected, but below 1.60.
- Adult 1-Year Conditional Graft Survival Greater than 50% probability that the program's conditional 1-year graft failure rate is greater than 1.5, 50% higher than expected, but below 1.75.
- Adult 1-Year Conditional Graft Survival Greater than 50% probability that the program's conditional 1-year graft failure rate is 1.35, 35% higher than expected, but below 1.60.

All of the proposed yellow zone boundaries for pre-transplant mortality, 90-day graft survival and 1-year conditional graft survival hazard or rate ratios are .25 below the MPSC interaction boundary. For offer acceptance, the performance improvement rate ratio is .10 below the MPSC interaction boundary.

Committee members discussed the recommended parameters for the performance improvement zone, asked follow-up questions, and provided feedback. Some committee members mentioned their support for the recommended parameters. One committee member stated that the parameters are a great starting point and reminded the committee that the performance improvement zone is an operational rule that can be changed over time, if needed. Other committee members stated concerns about staff's capacity to manage a high volume of members who fall within the performance improvement zone. A staff member addressed committee members concerns stating that staff have discussed their bandwidth and are working to reshuffle and allocate resources to the appropriate teams. Another committee member responded that there are a wide variety of resources, some individual and group focused, that staff can provide to OPTN members.

At the conclusion of the presentation, the recommendation for performance improvement zone boundaries was approved by a vote of 29 For, 3 Against, and 0 Abstentions.

Post-Implementation Monitoring Plan

A staff member reviewed the post-implementation monitoring plan with the committee. She explained the goal and the scope of the monitoring plan and stated that there are many potential outcomes to monitor, so OPTN and SRTR staff have drafted a post-implementation monitoring plan that focuses on several analyses. The staff member provided information on the metrics of interest and noted previous discussions about monitoring for the Performance Monitoring Enhancement proposal. Previous discussions emphasized assessing changes at many different levels of the system. The staff member reviewed seven metrics with a specific focus on the first five, which included:

- 1. Deceased-donor utilization rates
- 2. Rates of new waitlist additions
- 3. Offer acceptance rates
- 4. Pre-transplant mortality rates
- 5. Post-transplant mortality rates

The staff member summarized the metric analysis and reported that the analysis of each metric is broken down into subgroups based on variables intended to capture. She provided a table of the five metrics and the sub-analyses for each metric. She also provided an example of how the analyses would be presented in the report. Committee members provided no comments or feedback at this time.

Discussion of Next Steps

A staff member summarized the next steps of the implementation phase. She mentioned that the subcommittee would evaluate the process for post-transplant graft survival review and staff will conduct member outreach to determine effective practices.

6. Educational Referrals - Discussion of New Topics

A staff member discussed the MPSC's educational referrals with the Committee. She explained the purpose of the discussion, which was for the committee members to provide ideas and feedback regarding any topics for which it would be beneficial to further educate or communicate about to members. She reviewed some of the educational referrals that are completed and that are currently in progress. Committee members suggested education for and about designated patient safety contacts.

Specifically, a committee member stated that the community could benefit from additional training on the role and responsibilities of individuals listed as a patient safety contact on the Improving Patient Safety Portal. The committee member also suggested implementing electronic notifications to patient safety contacts to decrease the amount of time it takes to address patient safety issues. A staff member noted that a similar topic – challenges in reporting information to patient safety contacts and a request for automated electronic notifications – was recently brought up by another committee member to committee leadership. MPSC leadership subsequently sent a referral to other committees to encourage a project on this topic. Staff stated they would update the referral to include the additional comments and further encourage work on applicable projects. At the conclusion of the discussion, the staff member encouraged committee members to reach out at any time with additional educational referrals.

Upcoming Meetings

- o March 25, 2022, 1-3pm, ET, Conference Call
- o April 22, 2022, 1-3pm, ET, Conference Call
- o May 31, 2022, 3-5pm, ET, Conference Call
- o June 29, 2022, 1-3pm, ET, Conference Call
- o July 12-14, 2022, Chicago

Attendance

o Committee Members

- o Mark Barr
- o Nicole Berry
- o Christina Bishop
- Emily Blumberg
- o Theresa Daly
- o Todd Dardas
- o Richard Formica
- Catherine Frenette
- o Reginald Gohh
- o Barbara Gordon
- Alice Gray
- o John Gutowski
- Nicole Hayde
- o lan R. Jamieson
- o Christopher Jones
- o Andrew Kao
- Christy Keahey
- Mary Killackey
- o Anne M. Krueger
- o Jules Lin
- Scott Lindberg
- o Gabriel Maine
- o Amit Mathur
- o Virginia (Ginny) McBride
- Jerry McCauley
- Kenneth McCurry
- Dan Meyer
- o Bhargav Mistry
- Willscott Naugler
- o Michael Pham
- o Steven Potter
- o Elizabeth Rand
- o Sara Rasmussen
- o Pooja Singh
- o Jason Smith
- o Zoe Stewart Lewis
- o Laura Stillion
- o Parsia Vagefi
- o Sean Van Slyck
- o Gebhard Wagener

HRSA Representatives

- o Marilyn Levi
- o Arjun Naik
- o Raelene Skerda

SRTR Staff

- o Jonathan Miller
- o Jon Snyder
- o Bryn Thompson
- o Ryutaro Hirose
- o David Zaun

UNOS Staff

- o Sally Aungier
- Dawn Beasley
- o Matt Belton
- o Tameka Bland
- o Lloyd Board
- o Tory Boffo
- o Shawn Brown
- O Shawii biowii
- o Tyrone Brown
- o Wida Cherikh
- o Tommie Dawson
- o Robyn DiSalvo
- o Nadine Drumn
- o Demi Emmanouil
- o Katie Favaro
- o Liz Friddell
- o Shavon Goodwyn
- o Lauren Guerra
- o Isaac Hager
- o Asia Harris
- o Kristina Hogan
- o David Klassen
- o Kay Lagana
- o Trung Le
- o Ann-Marie Leary
- o Ellen Litkenhaus
- o Maureen McBride
- o Sandy Miller
- o Amy Minkler
- o Steven Moore
- o Sara Moriarty
- o Rene Morgan
- o Alan Nicholas
- o Delaney Niiles
- o Samantha Noreen
- o Jacqui O'Keefe
- o Rob Patterson
- o Sarah Payamps
- o Michelle Rabold
- o Liz Robbins Callahan
- Laura Schmitt
- o Louise Shaia

- o Brian Shepard
- o Sharon Shepherd
- o DeeDee Simmons
- o Leah Slife
- o Kaitlin Swanner
- o Stephon Thelwell
- o Roger Vacovsky
- o Marta Waris
- Betsy Warnick
- o Trevi Wilson
- o Claudia Woisard
- o Emily Womble
- o Karen Wooten
- o Amanda Young
- Other Attendees
 - o Sandi Amaral
 - o Marie Budev