

OPTN Membership and Professional Standards Committee (MPSC) Meeting Summary September 29, 2020 Conference Call with GoToTraining

Ian Jamieson, Chair Heung Bae Kim, M.D., Vice Chair

Introduction

The Membership and Professional Standards Committee (MPSC) met by conference call in open and closed session via Citrix GoToTraining on September 29, 2020, to discuss the following agenda items:

- 1. Membership Requirements Revision Project
- 2. Performance Monitoring Enhancement Project
- 3. Other Significant Items

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

1. Membership Requirements Revision Project

Staff provided an update on the work that has been completed since the July Committee meeting. The Membership Requirements Revision Project subcommittee met on August 31, and made recommendations on Appendix D topics. During its meeting on October 2, the subcommittee will focus on the last topic for Appendix D and work on questions from the July meeting regarding the transplant program key personnel requirements.

Staff provided the August 31 subcommittee meeting summary and a revision table for Appendix D for the members of the Committee to review.

The Committee discussed the following topics:

• Removal or retention of Appendix D Sections on Routine Referral Procedures & Donation after Cardiac Death (DCD) Protocols:

In November 2019, the Committee initially supported removal of these two sections based on the fact that the OPTN does not have legal authority over donor hospitals.

In spring 2020, the subcommittee suggested retaining these provisions and requested additional feedback from the Committee. The subcommittee recommended retention of these two sections based on a belief that transplant hospitals should serve as models for donor hospitals.

One Committee member strongly believed both protocols should remain in the requirements. The requirements are model elements for donation programs in any hospital. The committee member noted that his OPO had a very difficult time getting approval for DCD at one transplant hospital. He opined that we must prevent issues at future hospitals by requiring that transplant hospitals have a policy that allows DCD to be performed in their hospitals. If a hospital wants to do transplantation, they should be leading the pack on the donation side. There are still a lot of donor hospitals that do not allow DCD to occur.

Another Committee member stated that this is a good idea but the alternative view is that this creates additional rules for transplant programs. He noted that he is not against it, but raised concerns about continuing to expand what is required of transplant programs in terms of their

applications. Sends a dangerous message if transplant programs have to be very involved in the donation process. The Chair agreed with the concerns regarding transplant program involvement in donation process.

Another Committee member stated he believed that it is not necessary to mandate it through the OPTN bylaws. He opined that it should not be the responsibility of the transplant program to ensure that these protocols exist in the hospital.

Another Committee member clarified that the bylaws currently contain these requirements and the Committee is being requested to decide on whether to remove the protocol requirements from the bylaws.

Another Committee member stated that she agrees that the transplant department should not be required to develop these protocols. However, the hospital needs to be "totally in" on donation. Another Committee member agreed that the transplant programs should not be responsible but transplant hospitals should be. The bylaw requirement helps leverage the development of these protocols by the hospital. A Committee member stated that having the bylaw in place helped to convince his hospital to put a protocol in place. The transplant program had minimal involvement.

The Committee completed two polls on whether to remove these two sections from the OPTN bylaw requirements for transplant hospitals.

Table 1: Results on polls on whether to remove requirements that transplant hospitals have routine
donor referral policies and DCD protocols.

	Should routine donor referral bylaw be removed from transplant hospital requirements?	Should requirement for DCD protocols be removed from transplant hospital requirement bylaws?
Yes	30%	25%
No	62%	75%
Abstain	8%	0%

• Revisions to Medical Expert Support Requirement

The Committee reviewed feedback and recommendations from the subcommittee on the revisions to the medical expert support requirement for transplant programs. The Final Rule requires evidence of collaborative involvement with a list of experts in certain fields. The OPTN bylaws mirror the list of experts contained in the Final rule. The Committee and the subcommittee found that the list is not reflective of current practice and does not include a range of medical experts that transplant programs need to collaborate with to provide care to transplant patients. However, when evaluating additions to the list of experts, the subcommittee realized that there is no way to create an exhaustive list of all disciplines. The subcommittee recommended that the Committee consider retaining the list as it appears in the Final Rule and potentially adding language in the introduction that would recognize that a program should collaborate with additional experts.

One Committee member stated that making revisions could be problematic because the list could become extensive and we cannot completely remove the list because it is in the final rule.

Another Committee member stated the language "as appropriate" that is contained in the Final Rule is confusing and suggested that if the language means "as appropriate" then a list with specific organs we transplant should suffice. If the language "as appropriate" is situational based, then we need an extensive list. "As appropriate" is ambiguous language. Does it mean the organ that is transplanted or

does it mean just in case, you need to have all the experts on standby? Another MPSC member noted that individual programs are required to show that they have transplant experts and support, so this list is more generic support.

Another Committee member stated that he believes there should be some major components of subspecialties placed in the bylaws. It is important to look at complications in each organ we transplant.

Another Committee member stated that not all hospitals have every medical expert readily available, so the wording is important.

Another Committee member supports retaining the list and adding language to the introduction that references the need for other medical experts.

The Committee responded to a poll to determine how to move forward on this language.

Table 2: Results of poll on the medical	l expert support bylaw language.
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Which option for medical expert support bylaw do you support?		
Add medical expert support fields to list	18%	
Revise intro language; retain list from Final Rule	41%	
No revisions - mirror Final Rule	41%	

• Addition of Definition For "On site"

The Committee continued its review of the use of the term "on site" in the bylaws. There has been some confusion on the term and its meaning. According to previous Committee discussions, the term is difficult to define. A final decision has not been made on the language, and as to whether the definition of "on site" should be included in Appendix M. Centers for Medicare and Medicaid Services (CMS) language includes the definition "immediately available" and includes regulations of a surgeon and physician being within 60 minutes of the transplant hospital.

A Committee member asked if the language could say "As deemed appropriate by the MPSC?" We cannot anticipate all of the possible permutations so this gives the MPSC the ability to use medical judgement.

The Chair advised that CMS suggests in their regulations that a primary must be "immediately available", within 60 minutes to the transplant hospital, and does not impact the viability of the organ.

Another Committee member believes that language "60 minutes" should mimic CMS.

Another Committee member stated that CMS criteria does not state a "primary" but only a surgeon or physician. He does not understand why the staff on call cannot be responsible for organs and transplants rather than the primary surgeon and physician.

The Committee responded to a poll as to whether a definition of on site should be included in the bylaws.

A definition of on site should be included in Appendix M.		
Strongly Agree	21%	
Agree	61%	
Neutral	6%	

Disagree	6%
Strongly Disagree	6%

The Committee supported adding a definition into Appendix M, *Definitions*. The content of the definition will be discussed at the October MPSC meeting.

2. Performance Monitoring Enhancement Project

The Committee was given an overview of the Performance Monitoring Enhancement Project kick off meeting.

The Performance Monitoring Enhancement Subcommittee Conference call was held on September 11, 2020. The subcommittee reviewed the project plan and timeline, and scope of the project. The goal is finalize a proposal by the June 2021 meeting for summer 2021 public comment. The Scientific Registry for Transplant Recipients (SRTR) Director gave a presentation to the subcommittee on scorecard development, which included factors to consider when choosing appropriate metrics, differences between system and program metrics, and absolute (unadjusted) vs. relative (risk-adjusted) evaluations. The SRTR also provided a tool to explore the relationship between different metrics. The tools has been made available to the subcommittee and the Committee.

The subcommittee chair stated that the subcommittee feels strongly that whatever metrics are chosen must measure things that are within the control of the center. The subcommittee chair provided an example of transplant rate vs. acceptance rate. The subcommittee chair also reported that step two of the process is to determine where the flagging thresholds are. There are only a few things that we can look at in the short run.

One Committee member asked how we could get other organizations such as the AST engaged as early as possible. It is important to obtain input from societies before getting too far along in the project. The subcommittee chair responded that we have created a list of involved societies. We plan to solicit societies for input before the public comment stage. We are looking at ways to involve other societies and members of the community.

Another Committee member stated that there are organ specific issues that come up and one size may not necessarily fit all when it comes to metrics. There has to be consideration of organ-specific issues when looking at metrics.

3. Other Significant Items

None

Upcoming Meetings

- o October 27-29, 2020, Virtual
- o November 9, 2020, 2-4:00pm ET
- December 15, 2020, 1-3:00pm ET
- February 23-25, 2021, Chicago
- o July 20-22, 2021, Chicago

Attendance

o Committee Members

- o Sanjeev K. Akkina
- o Mark L. Barr
- Nicole Berry
- Christina D. Bishop
- o Errol Bush
- o Matthew Cooper
- o Theresa M. Daly
- o Maryjane A. Farr
- Richard N. Formica Jr
- o Adam M. Frank
- Catherine Frenette
- o Jonathan A. Fridell
- Michael D. Gautreaux
- o PJ Geraghty
- o David A. Gerber
- o Alice L. Gray
- o John R. Gutowski
- Edward F. Hollinger
- o lan R. Jamieson
- o Christy M. Keahey
- o Mary T. Killackey
- o Heung Bae Kim
- o Jon A. Kobashigawa
- o Anne M. Krueger
- o Jules Lin
- o Didier A. Mandelbrot
- Virginia(Ginny) T. McBride
- o Clifford D. Miles
- Willscott E. Naugler
- o Matthew J. O'Connor
- o Nicole A. Pilch
- o Jennifer K. Prinz
- o Scott C. Silvestry
- o Lisa M. Stocks
- Parsia A. Vagefi
- o Gebhard Wagener
- o Rajat Walia

• HRSA Representatives

- o Marilyn Levi
- o Arjun U. Naik
- o Raelene Skerda
- SRTR Staff
 - o Nicholas Salkowski
 - o Jon J. Snyder
 - o Bryn Thompson

o Andrew Wey

o UNOS Staff

- o Sally Aungier
- o Matt Belton
- o Nicole Benjamin
- o Tameka Bland
- o Tory Boffo
- o Robyn DiSalvo
- o Nadine Drumn
- o Demi Emmanouil
- o Katie Favaro
- o Amanda Gurin
- o Asia Harris
- o Danielle Hawkins
- o David Klassen
- o Kay Lagana
- o Krissy Laurie
- o Marc Leslie
- o Ellen Litkenhaus
- o Jason Livingston
- o Sandy Miller
- o Amy Minkler
- o Steven Moore
- Sara Moriarty
- o Alan Nicholas
- Delaney Nilles
- Jacqui O'Keefe
- o Rob Patterson
- o Michelle Rabold
- o Liz Robbins
- o Sharon Shepherd
- o Leah Slife
- o Mike Tapscott
- o Olivia Taylor
- o Stephon Thelwell
- o Susan Tlusty
- o Roger Vacovsky
- o Chad Waller
- o Marta Waris
- o Betsy Warnick
- o Trevi Wilson
- o Emily Womble
- o Karen Wooten
- o Other Attendees
 - o None