

OPTN/UNOS Membership and Professional Standards Committee (MPSC)
Meeting Minutes
February 27-March 1, 2018
Chicago, Illinois

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Introduction

The Membership and Professional Standards Committee met in Chicago, Illinois, on February 27-March 1, 2018, to discuss the following agenda items:

1. Pancreas Program Functional Inactivity Work Group Update
2. Modifications to OPTN Bylaws Appendix L
3. Request to Change the Voting Status of Hospital-Based OPOs
4. Review of Public Comment Proposals
5. Collaborative Innovation Improvement Network (COIIN) Update
6. Member Related Actions
7. Living Donor Events
8. Living Donor Follow-up Reporting
9. Due Process Proceedings
10. Member Education Opportunities Identified
11. Committee Actions

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

1. Pancreas Program Functional Inactivity Work Group Update

Staff updated the Committee on the Pancreas Program Functional Inactivity Work Group's ongoing discussions to address the relatively large number of functionally inactive pancreas programs (as compared to the number of functionally inactive transplant programs for other organ groups). This is a project sponsored by the Pancreas Transplantation Committee and includes MPSC representatives on the work group. In its recent discussions, the work group has considered a multi-factor analysis to determine which functionally inactive pancreas programs the MPSC should review. Possible factors that have been considered for this determination include waiting list time comparisons, organ turndown rate comparisons, whether the program is geographically isolated. The work group has also considered more robust requirements for the patient notification letter that programs identified by the MPSC as functionally inactive are required to send to transplant candidates on their waiting list.

2. Modifications to OPTN Bylaws Appendix L

Staff reminded the Committee that its proposal to revise OPTN Bylaws Appendix L is out for public comment until March 23. Staff shared the feedback received thus far, which has been positive and supportive, including unanimous support at the five regional meetings that occurred before the MPSC meeting and minimal discussion during the national webinar that the Chair presented this proposal.

The Committee reviewed preliminary feedback provided by individual commenters that recommended limiting the time or number of deferred disposition periods and limiting the maximum amount of time for informal discussions, interviews, and hearings. The Committee discussed that it had previously considered time maximums during the development of this

proposal, but ultimately decided against their inclusion in the proposal. During the proposal's development the Committee decided any maximum determinations should be the responsibility of the MPSC and MPSC Chair when it interacts with the member. This aligns with a general theme of this proposal of allowing the MPSC appropriate flexibility to tailor its review to the particular circumstances of any given case.

Following this discussion staff alerted the MPSC that it is scheduled to review all of the feedback provided in response to this proposal, and consider any necessary post-public comment changes, during a March 27 teleconference.

3. Request to Change the Voting Status of Hospital-Based OPOs

The MPSC Chair alerted the Committee about a letter sent to the OPTN from the Executive Directors of the seven hospital-based OPOs. The letter requested Bylaws changes to grant hospital-based OPOs individual voting rights. Currently, the OPTN Bylaws Appendix M (Definitions) states that a hospital-based OPO is, "An organ procurement organization that is not independent from the transplant hospital it serves...Hospital-based OPOs are held to the same standards and requirements as OPO members, but do not have a vote on OPTN business separate from the vote granted the transplant hospital member with whom it is associated." The letter from the hospital-based OPOs Executive Directors explained a number of arguments why they believe the current Bylaws are no longer appropriate regarding this matter, and requested that changes be made so that each hospital-based OPO could vote on OPTN matters separately from its affiliated transplant hospital.

The Chair informed the Committee about past MPSC discussions about this topic. Hospital-based OPOs had sent a similar letter to the MPSC in June 2009. At that time, the MPSC simultaneously considered voting changes for hospital-based OPOs and hospital-based histocompatibility laboratories. The MPSC tabled the issue at that time due to concerns that potential changes would result in non-transplant hospitals accounting for the majority of the vote in some regions.

MPSC members expressed concerns about the prospect of hospital-based histocompatibility labs also getting separate votes. Members stated that these changes would be problematic if they lead to similar Bylaws changes that apply to hospital-based histocompatibility labs. With that, the Chair suggested that current considerations of this matter focus on the merit of the specific request in the letter. UNOS Staff also commented that, that the OPTN had previously used an elector system for histocompatibility labs, and an elector system is currently used for public organizations and individual members. Reconsidering an elector system for histocompatibility labs for the purpose of maintaining a relative percentage of votes would be a possibility.

Another member suggested that histocompatibility labs are a similar situation. If they are subject to UNOS policy, then they should have a voice in those discussions. If the lab only serves one transplant hospital, it seems reasonable for that pair to only have one vote; however, if the lab serves multiple hospitals and OPOs, there are likely separate administrations- similar to hospital-based OPOs. In response to this comment, the Committee clarified that regional votes are not determinant, and serve as feedback for Board of Directors final consideration. There are numerous opportunities and arenas for members to have a voice on OPTN policy development other than the formal voting process.

The Committee expressed support for granting hospital-based OPOs individual votes separate from the transplant hospitals they are affiliated with. Members noted that they are directly responsible for supplying organs for transplant, and account for more than eight percent of all the organs transplanted. Acknowledging this support, the Committee also noted that any Bylaws

changes must include language to assure a formal disconnect between the two entities. Although the seven hospital-based OPOs represent a small number of votes, the Committee believes it is necessary to assure independence between the OPO and transplant programs, and to assure that the OPO is not beholden to or functioning as an arm of the transplant programs at the same hospital.

To conclude this discussion, five MPSC members volunteered to participate on a work group to work on this topic further.

4. Review of Public Comment Proposals

Align VCA Transplant Program Requirements with Requirements of Other Solid Organ Transplant Programs (VCA)

The Committee listened to a presentation by Linda Cendales, Vice Chair, VCA Committee, and asked a few clarifying questions, which Dr. Cendales answered.

In general, the MPSC cautioned the VCA Committee to be sensitive to stifling innovation while expressing concern about the ability to ensure that surgeons are current and adequately trained when non-VCA surgeons are primary surgeons. They also encouraged the VCA Committee to create more predictable program types earlier rather than later.

The MPSC supported aligning the requirements for VCA with other solid organ key personnel requirements.

Clarify Informed Consent for Transmissible Disease (DTAC)

The MPSC heard a presentation by Dr. Cameron Wolfe, Chair of the DTAC. The Committee thanked the DTAC for addressing its questions about the current informed consent policy and for the DTAC's efforts to clarify the policy.

The MPSC did not express a strong preference between documentation of patient consent in the medical record or an actual patient signature. One MPSC member did explain that changing the policy to require a patient signature could require transplant programs to create new consent forms or revise existing consent forms. This process can be complex since changing consent documents often requires multiple layers of hospital review and approval.

The MPSC did not offer any suggested changes to the list of conditions tied to the candidate screening policy and re-execute the match policy. They both use the same list of conditions. Some MPSC members did have comments about the idea of tying the informed consent requirements to a specific set of infectious disease tests:

- Since risks of disease transmission evolve based on both the identification of new diseases and the development of new treatments for existing diseases, a specific list of conditions requiring informed consent may have to be updated. If this list changes frequently, the MPSC will need to manage those changes when reviewing member compliance. One MPSC member suggested investigating whether there are ways to change the list of conditions requiring informed consent in the future without having to go through the entire policy development process.
- Several MPSC members suggested that if the main intent of an informed consent requirement is to make sure each transplant program has a consent process in place, then an alternative to a national standard of a specific list of conditions requiring informed consent could be to require that each transplant program have and follow its hospital's own informed consent policy. Hospital policies are updated regularly and often include other locally relevant diseases and conditions.

- Another MPSC member thought that the currently specified diseases in the proposal were still relevant for a minimum national standard, and transplant programs could add locally relevant diseases to their consent process as needed on top of the national standard.

The MPSC also discussed the complexities of discussing disease transmission risks with patients. The risk of harm from the transplant surgery itself is higher than the risk of contracting the specific diseases that would require informed consent. Additionally, not all risks have to be communicated and consented for at the time of organ offer. Patients may make inferences about the quality of an organ being offered, which could lead to late organ turn-downs.

Extra Vessels: Reducing Reporting Burdens & Clarifying Policies (OSC)

The Committee viewed a webinar presentation from the Operations and Safety Committee about its proposal “Reduce reporting burdens and clarify policies on extra vessels”. The MPSC expressed agreement with the goal of making the most up to date infectious disease testing results available to hospitals when they are using vessels. However, the MPSC suggested that there were major technology and training barriers to expecting use of a barcode.

The MPSC expressed concern that the proposal is overly complicated and unclear. They were concerned that it would be difficult to implement in transplant hospitals because of:

- limited availability of compatible barcode scanners
- lack of ability to relabel with TransNet
- the fact that vessel use after storage or sharing is infrequent enough that it won't be routine practice
- the fact that this would require a major process change for hospitals.

Guidance for ABO Subtyping of Blood Type A and AB Organ Donors (OSC)

The MPSC viewed a webinar presentation from the Operations and Safety Committee about its proposal “Guidance for ABO Subtyping Organ Donors for Blood Groups A and AB.” MPSC members stated that due to the wide variability in how blood banks report subtyping results, there is still a lot of confusion in the community in how to correctly interpret the results. Blood banks also have wide variability in their policies on subtyping after a red blood cell transfusion. The guidance document acknowledges this variability for both issues, and offers advice that OPOs should consult with their local blood banks. However, the actual variability between blood banks is not likely to change as a result of this guidance document, so the community may continue to be confused and commit errors when interpreting and reporting donor subtyping results.

MPSC members were asked whether it would be helpful to add a recommendation to the guidance document describing how much time should elapse after a red blood cell transfusion for it to be appropriate to subtype a donor, but the MPSC did not reach consensus on this question. One MPSC member stated that if OPOs do not have some sort of guidance or policy to reference that they can put into their own policies for OPO personnel to follow, then people will continue to be confused. However, another MPSC member pointed out that there did not seem to be enough data available to make a recommendation, so it seemed appropriate to leave those decisions to OPOs and the labs they work with.

Concept Paper on Expedited Organ Placement (OPO)

The MPSC heard a presentation from Jennifer Prinz, Chair of the OPO Committee on this concept paper. The MPSC thanked the OPO Committee for its work so far in trying to create consistent processes for members to follow. The MPSC hopes that these processes will not only reduce the number of expedited placement cases that it reviews, but will in turn reduce

members' burden in responding to inquiries and providing additional information that is currently needed for these reviews.

MPSC members agreed that separate triggers for pre-O.R. expedited placement and in-O.R. expedited placement are reasonable. One MPSC member stated that in general, cold ischemic time is the factor that ultimately decides whether an organ is used or discarded, so it would be an important variable to consider. If an offer is made post-cross-clamp, a hospital's geographic proximity to the donor will likely help determine whether or not the offer is accepted. Another MPSC member recommended that a trigger based on offers made to a certain number of candidates may be easier to implement than a trigger based on offers made to a certain number of hospitals because the number of hospitals in a certain geographic area is inconsistent, as is the number of candidates on any hospital's waiting list.

Some MPSC members were concerned about basing eligibility for expedited offers on past program organ acceptance behavior because behavior can change over time, not only due to a program's decision to change its behavior, but also due to staffing changes and recently implemented or pending allocation changes that may impact the number and types of organs available to a program. Other MPSC members stated that limiting the number of programs receiving expedited offers would be necessary in order to increase the chance that an organ is placed instead of discarded. Additional suggestions included:

- Developing criteria for programs to meet that would let them demonstrate changed behavior if they are initially excluded from receiving expedited offers
- Using modeling to determine the right balance between the number of programs receiving expedited offers and the desired decrease in discarded organs
- Moving towards the OPO Committee's additional concept of incorporating the probabilities of discard and acceptance into the allocation algorithm as the ultimate solution for decreasing the number of discarded organs

The MPSC believes that transparency and accountability are both crucial in the development of the expedited placement processes, and committee members offered the following feedback:

- The types of organs that would be eligible for expedited placement, as well as the eligibility criteria to receive expedited offers, should be precisely described and explained to the community.
- The triggers for expedited placement should be written in policy, and it should be clear in the computer systems when a threshold for expedited placement has been met. The MPSC supports automating the expedited placement process as much as possible, with the hope that they would only need to review expedited placement cases that do not follow policy.
- If the expedited placement processes start to move allocation of certain types of organs to program-specific offers instead of candidate-specific offers, then the proposal should be transparent in discussing this idea.
- Transparency in hospitals' acceptance practices is also important because patients may not know that their hospital is passing on certain types of organs.
- The OPTN previously studied hospital organ acceptance practices, and the results showed that many hospitals' stated acceptance criteria were broader than the hospitals' actual acceptance practices. The results were communicated to the hospitals, but few changes in behavior were observed. Until members are held accountable for their acceptance practices, the proposed process improvements may not be effective.
- After the expedited placement processes are implemented, the OPO Committee should be sure to do a "big picture" review of the effects of expedited placement to make sure

that increased efficiency in placing organs hasn't resulted in certain parts of the community being underserved.

OPTN Strategic Plan

The Committee expressed appreciation for the rearrangement of the order of the strategic goals, the focus on improving the efficiency of transplant (not just the OPTN), and the move toward equalization of goals 3-5. The MPSC stated that this could help decrease the likelihood of important projects getting put on the backburner just because they don't fit nicely.

The MPSC suggested keeping an eye on the longer view (beyond 2-3 years). They suggested that more emphasis needs to be placed on:

- survival beyond 3 years
- acceptance practices
- access to transplant (prior to listing), especially in rural areas
- reducing the time between donor consent and recovery
- reducing organ discards
- balancing longevity of grafts and equity

Improving the OPTN and UNOS Committee Structure

The Committee expressed appreciation for the work that has been done so far on this concept as a good start. Some members expressed that this kind of change may be difficult, but is needed.

The MPSC believed that the framework outlined suits some areas better than others. Specifically, they mentioned that a structure that allowed experts rather than regional representation on the Finance Committee would be helpful, but that the Pediatric Committee should not be a council, and has been very helpful as a committee.

There were a few other concerns that came out of the discussion:

- Perception of groups that are being turned into expert councils are being marginalized and that this would move from a community to a strict corporate structure
- Potential for creating silos and excluding diverse opinions if a single person or small group decide who is on a committee or council
- There is a lot of value in holding in-person meetings and monthly calls for keeping work progressing and committees working well as a group. Moving to infrequent online-only meetings could make groups less effective. The MPSC doesn't want what's working well to be lost.
- If this results in a two-step process, with committees doing development work, and then adding a new process of expert councils reviewing after that, it would hurt the policy development process
- Groups of over 100 people are unlikely to be effective or able to do anything purposeful
- Some of the difficulties that are currently encountered are just because the problems the OPTN is trying to solve are complicated, not because the current system is broken
- There is a need to define what is meant by diversity so that it is clear what is trying to be increased

5. Collaborative Innovation Improvement Network (COIIN) Update

UNOS Organizational Excellence staff, provided an update on the Collaborative Innovation and Improvement Network (COIIN) project. The purpose of the update was to review preliminary results from the first cohort of transplant hospitals, summarize the Relational Coordination and feedback survey results, discuss the next steps for COIIN's evaluation year which concludes

September 30, 2018, and provide information about the upcoming, August 2018 Learning Congress.

6. Member Related Actions

Membership Application Actions- Consent Agenda

The Committee is charged with determining whether member clinical transplant programs, organ procurement organizations, histocompatibility laboratories, and non-institutional members meet and remain in compliance with membership criteria. During each meeting, it considers actions regarding the status of current members and new applicants.

The Committee reviewed the applications and status changes listed below and will recommend that the Board of Directors take the following actions when it meets in June:

- Fully approve renewal of 2 public organizations for a two year term
- Fully approve renewal of 6 medical/scientific organizations for a two year term
- Fully approve renewal of 2 individual member for a two year term
- Fully approve 2 new transplant programs
- Fully approve reactivation of 1 living donor component

In addition, the Committee also reviewed and approved the following actions:

- 53 Changes in transplant program and living donor component personnel
- 150 Changes in histocompatibility lab personnel (implemented primary general supervisor)
- 6 Changes in histocompatibility lab personnel

The Committee also received notice of the following membership changes:

- 1 Transplant program and 3 living donor components inactivated
- 5 Transplant program and 2 living donor components withdrew
- 2 Changes in OPO personnel

The full Committee reviewed the membership consent agenda and passed the following resolution:

RESOLVED, that the Membership and Professional Standards Committee approves the membership consent agenda.

The Committee voted 29 Yes, 0 No, 0 Abstentions

Histocompatibility Lab General Supervisor Implementation

The Committee reviewed the proposal to implement the position of primary general supervisor as part of the Histocompatibility Bylaws rewrite approved by the OPTN Board of Directors in June 2015. In July 2017, work for this position was completed in the Membership Database and the OMB cleared the new application for use. UNOS staff notified the Histocompatibility Labs on October 2, 2017, that the general supervisor key personnel applications would be sent to all approved laboratories on November 2, 2017. The completed applications were due back by December 2, 2017, with the expectation that all applications would be reviewed and presented for approval by the MPSC. The general supervisor key personnel requirement will be effective upon the MPSC's vote on the General Supervisor Consent Agenda.

RESOLVED, that the Membership and Professional Standards Committee approves the histocompatibility laboratory general supervisor consent agenda.

The Committee voted 30 Yes, 0 No, 0 Abstentions.

7. Living Donor Events

The Committee reviewed eleven items that were placed on the consent agenda, which included eight aborted procedures, two deaths of a living donor, and one redirected organ. Eight of these items were closed with no action, and three received Notices of Uncontested Violation. The Committee approved the consent agenda by a vote of 33 Yes, 1 No, 0 Abstentions.

The Committee also reviewed two items on discussion. One death and one aborted procedure. The Committee voted to close both items with no action by a vote of 34 Yes, 0 No, 0 Abstentions.

8. Living Donor Follow-up Reporting

In the ongoing review of living donor follow-up, the Committee received an update on two members under review. At its October meeting, the Committee requested that two members participate in an informal discussion to review their process for collecting the information. After the informal discussions, the work group recommended that one program be released from close monitoring, while recommending that the other submit an additional update on its progress with its corrective action plan and data submission.

RESOLVED, that the Membership and Professional Standards Committee approve the Living Donor Follow-up consent agenda

The Committee voted 31 Yes, 0 No, 0 Abstentions.

9. Due Process Proceedings

During the meeting, the Committee conducted one interview with an OPO and an informal discussion with a transplant hospital.

10. Member Education Opportunities Identified

Throughout its meeting, MPSC members identified the following topics that require follow up and/or should be addressed in through educational efforts in the transplant community:

The MPSC requested that staff follow-up on OPTN requirements for packaging deceased organs when the organs are recovered and transplanted in the same facility. The MPSC noted that policy currently address packaging for living donor organs that are recovered in the same facility but not deceased donor organs. The MPSC suggested educating members on the policy requirements, once they are clarified.

The MPSC requested that staff educate the committee on the commonality of routine site survey violations and share that information in the case packet. For example, if a program has ABO verification errors on a site survey, the MPSC requested the report include an assessment of how frequently centers also violate that policy.

The MPSC requested clarification on OPTN policy, state and federal regulations regarding directed donation before their July meeting. The MPSC suggested educating members on various directed donation scenarios that are permissible, and educating members on how to interact with family members who make a request not permitted by policy or regulations.

The MPSC noted that the presentation SRTR staff shared with the MPSC at this meeting would be beneficial for others in the transplant community to receive. SRTR and UNOS staff in attendance noted that they are preparing a similar session for the April 2018 Transplant Management Forum in Austin, Texas.

The MPSC suggested UNOS staff develop educational efforts to share effective practices to identify and call in the correct patient for transplant. Though this is a seemingly low frequency event, calling in a patient who has the same name as the intended recipient can have potentially

disastrous effects and could happen if members do not have adequate checks in place. Therefore, members should be aware of effective ways to reduce the likelihood of human error and minimize this risk.

The MPSC acknowledged member confusion surrounding site survey practices, specifically what OPO site surveyors review on site for appropriate documentation of brain death. UNOS staff noted that site survey and UNOS Communications are working on an article to be released via TransplantPro in during National Patient Safety Week. The article will not only highlight recent improvements to the OPO survey process, but will also explain what OPO surveyor will review on site for brain death declaration and will refer members to the OPTN Evaluation Plan for additional clarification.

11. Committee Actions

The Committee unanimously agreed that actions regarding Bylaws, Policy, and program-specific decisions made during the OPTN session would be accepted as UNOS actions.

RESOLVED, that the Committee accepts those program specific determinations made during the meeting as UNOS recommendations.

FURTHER RESOLVED, that the Committee also accepts the recommendations made relative to Bylaw and Policy changes.

The Committee voted 32 Yes, 0 No, 0 Abstentions.

Upcoming Meetings

- March 27, 2018, 3-4pm conference call
- April 17, 3-5pm, conference call
- July 17-19, 2018, Chicago
- October 16-18, 2018, Chicago