

**OPTN/UNOS Membership and Professional Standards Committee (MPSC)**  
**Meeting Minutes**  
**April 17, 2018**  
**Conference Call**

**Jeffrey Orlowski, MS, CPTC, Chair**  
**John Friedewald, M.D., Vice Chair**

**Introduction**

The Membership and Professional Standards Committee (MPSC) met via Citrix GoToTraining and teleconference on April 17, 2018, to discuss the following agenda items:

1. Modifications to OPTN Bylaws, Appendix L
2. Pancreas Islet update - pre-public comment review
3. Pancreas Functional Inactivity Update - pre-public comment review
4. Hospital-based OPO Voting Project
5. Committee Actions

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

**1. Modifications to OPTN Bylaws Appendix L**

The Committee reviewed the post-public comment changes made to the Bylaws language included in the Appendix L proposal. These post-public comment changes are all formatting edits or clarifications of language included in the original proposal. None of these changes reflect substantive content changes, and the public comments received in response to this proposal did not prompt any changes per the MPSC's review and discussion of those comments during its previous teleconference on March 27, 2018.

Reviewing the post-public comment changes, the MPSC did not raise any questions or comments. At the conclusion of this review, the Committee unanimously supported a resolution to approve the Bylaws changes offered in the Appendix L proposal, as provided in the meeting materials and discussed during the teleconference, for the Board of Directors' consideration at its June 2018 meeting (23 support, 0 oppose, 0 abstentions).

**2. Pancreas Islet Update - pre-public comment review**

The Chair of the Pancreas Transplantation Committee, made a presentation to the MPSC about that committee's work to revise the islet bylaws. The Islet Bylaws workgroup of the Pancreas Committee (the workgroup) was seeking preliminary feedback from the MPSC on their proposed revisions:

- Islet transplant programs would have a single clinical leader in lieu of a primary surgeon and primary physician
- Some expert medical personnel roles in the current bylaws would be revised and others would be replaced with different expert medical personnel roles
- Islet transplant programs could be free-standing programs without a required affiliation with a pancreas transplant program

The workgroup's idea behind the proposed changes was to allow islet transplant programs to be initiated and to develop without overly burdensome requirements, since islet programs are also subject to a large regulatory burden from the Food and Drug Administration (FDA) and Centers

for Medicare and Medicaid Services (CMS). After reviewing the details of the proposed revisions, the MPSC Chair opened the floor to questions.

The MPSC reviewed the proposed requirements for the primary personnel, which suggested that the primary surgeon or physician must have been involved with six islet cell transplant procedures. An MPSC member suggested that the number of people who have been involved with six islet transplants is relatively small, so the committee shouldn't be too restrictive in its requirements.

The Pancreas Committee Chair explained that the limited number of individuals with six islets transplants was why the workgroup recommends that only one islet transplant has to be an allogeneic transplant, and that transplant experience could be gained by visiting another program. The balance of the six transplants can be autologous transplants which may be performed by more hospitals.

Another MPSC member asked if a program could use their autologous transplant experience to count for their allogeneic experience?

The Pancreas Committee Chair stated that that would not be allowed, and reiterated that only one of the six transplants must be an allogeneic transplant while the other five could be autologous transplants. The workgroup felt that at least one allogeneic transplant was necessary because autologous and allogeneic transplants have procedural and clinical differences. For example, in autologous transplants, the prep is not usually purified, while it is in allogeneic transplants. There are differences in immunosuppressive effects on the graft, as well as issues related to recurrent autoimmunity and immunosuppression affecting the metabolism of the graft. There are relevant differences in terms of islet yields and the nature of the operative procedure. Finally, there are issues related to potential donor-derived infections in allogeneic transplants.

The MPSC member asked how the workgroup reached its decision on the possible one allogeneic and five autologous transplants and asked if one allogeneic transplant was enough given the differences between procedures.

The Pancreas Committee Chair replied that the number of procedures required was arbitrary, but the workgroup thought it was reasonable.

The MPSC then voted on several polling questions posed by the workgroup in order to provide feedback about the proposed changes to the islet bylaws:

- Does the MPSC agree with having only one person leading the islet program? The Committee agreed by a vote of 18 yes, 0 no, and 0 abstentions.
- Should expert medical personnel be considered primary personnel and be approved by the MPSC?

The MPSC Chair asked if staff felt that they could administer that requirement. Staff replied that it could be done, but islet programs would need to be educated that they would be required to notify UNOS of changes to the personnel. Staff further clarified that the workgroup was recommending that the expert medical personnel did not need to be individually approved by the MPSC. The Pancreas Committee liaison explained that while the workgroup considers the expert medical personnel to be key to a viable islet program and feels that an islet program should not be active without these personnel, the personnel should not require MPSC approval. Instead, islet programs should be required to name individuals to the expert medical personnel roles and notify UNOS if the individuals filling those roles change or leave the program.

After this discussion, the Committee voted 14 yes, 1 no, and 0 abstentions in support of the workgroup's recommendation.

- Does the MPSC agree with the workgroup's recommendation to allow free-standing islet programs? The MPSC agreed via a vote of 12 yes, 0 no, and 0 abstentions.

Finally, the MPSC discussed whether a requirement for the person leading the islet transplant program to have a "background in transplantation medicine, immunosuppression management, beta cell biology, immunology management, or endocrinology" would be sufficiently documented by letters of recommendation as suggested by the workgroup. MPSC members expressed concern that the requirement as written was too vague. If the requirement exists, there should be a demonstration of the required expertise, and the MPSC recommended that the workgroup refine the definition of "background" to more specifically outline the minimum requirements, such as completion of a fellowship.

### **3. Pancreas Functional Inactivity Update - pre-public comment review**

The Vice Chair of the MPSC and one of the MPSC representatives to the Pancreas Functional Inactivity Work Group of the Pancreas Committee, gave an update on the progress of the work group. This work group is identifying areas of improvement for classifying and reviewing functionally inactive pancreas transplant programs. The presentation provided information on the concepts the work group is proposing and requested feedback from the MPSC.

The work group has recommended that the threshold for functional inactivity be revised to 2 transplants in 12 months rather than 1 transplant in 6 months. The work group opined that a program may transplant all the patients on the waiting list and then take more than 6 months to get additional patients on the waiting list ready to transplant. Programs that were identified for review based on this threshold would not receive an inquiry unless the average waiting time at the program is higher than the national average waiting time.

Most Committee members were supportive of the change to 2 transplants in 12 months rather than 1 transplant in 6 months. Two Committee members supported extending the time period to 1 in 9 months or 2 in 18 months, as it would reduce the work load of the MPSC. One member also noted that pancreas transplant volume is decreasing so any requirement that would reduce the number of pancreas transplant programs may have long term impacts on access to transplant for patients with type 1 diabetes. The MPSC Vice Chair noted that the goal of the project was not only to reduce the work load of the MPSC but was also was to look at the quality and patient safety issue. The problem with further reducing the number of transplants required to remain functionally active is that the data reviewed demonstrated that quality decreases as programs' activity decreases. As a result, the work group did not believe it was appropriate to reduce the number of transplants required to remain functionally inactive. Instead, the work group believes it is important to require the patient letter include more information to fully inform the patients of what is going on at the functionally inactivate program and explain to patients they may be better served elsewhere.

The work group had recommended that additional information regarding geographic proximity of other in-state programs and program waiting time compared to a national median should be included in the patient notification letters. Additionally, they recommended that the contact information for other pancreas transplant programs in the same state be added to the letter. Finally, the work group suggested that program inactivation should be requested for programs that are flagged multiple times for inactivity.

A few MPSC members expressed concern with adding average waiting time compared to national average to the threshold for inactivity and to the letter. The members felt that average waiting time could be affected by geographic differences, local population characteristics and

the competitive climate between the transplant hospitals in a particular area. The MPSC Vice Chair reminded the Committee that the average waiting time would only come into play if the program had not performed at least 2 transplants in a 12 month period.

An MPSC member asked if there is any way to address programs that have had many inactive patients on the waiting list for years. The MPSC Vice Chair responded that one of the purposes of the work group was to make sure that patients that are appropriate for pancreas transplant get access to high quality pancreas transplant services. The work group had talked briefly about ways to encourage programs to become more active and move patients from inactive status to active status but that has not been the central purpose of this work group. The MPSC member commented that it would be in the patient's best interest to move to a more active program that can proactively work on moving the patient from an inactive waiting list status to active. The same Committee member noted that the suggestion to add more information to the letter may help with this issue. One of the committee members pointed out that there may be valid reasons for inactive patients to be on the wait list, such as not currently meeting criteria for pancreas transplant, or not having insurance to pay for the transplant or necessary medications.

One Committee member expressed concern that the proposal does not adequately address many of the issues related to pancreas functional inactivity and he did not think that the proposal would make much difference.

Another Committee member noted that he did not expect the work group's recommendations would immediately impact the volume of MPSC functional inactivity reviews. Instead, the Committee member noted the number of reviews would come down if programs that had been under review for multiple cycles closed. Improvements to the patient notification letter will be helpful, but the real key is to have an endpoint. The programs need to know that if they do not increase volume within one or two cycles, the program will need to close.

The MPSC chair, noted that functionally inactive pancreas programs can slow down the organ placement process, because OPOs are required to offer pancreas to these programs even though they are not actively or aggressively pursuing pancreas transplants.

The MPSC then participated in polls on the questions posed by the work group.

- Does the MPSC agree with changing the transplant threshold from 1 in 6 months to 2 in 12 months? Of the 22 MPSC members on the conference call, 20 voted Yes, 1 No and 1 Abstained.
- Does the MPSC agree with adding waiting time average compared to national average to the functional inactivity definition? Of the 22 MPSC members on the conference call, 15 voted Yes and 7 No.
- Does the MPSC agree with adding waiting time average compared to national average to the letter? Of the 22 MPSC members on the conference call, 17 voted Yes and 5 No.
- Does the MPSC agree with adding geographic proximity to in-state large or medium volume programs? Of the 22 MPSC members on the conference call, 16 voted Yes, 5 No and 1 abstained.
- Does the MPSC agree with recommending inactivation for programs flagged multiple times for functional inactivity? Of the 22 MPSC members on the conference call, 18 voted Yes and 2 No. The MPSC members who voted "Yes" noted that their vote expressed support for guidance rather than a specific bylaw requirement.
- Does the MPSC feel the recommended metric for flagging is monitorable? Of the 22 MPSC members on the conference call, 16 voted Yes and 4 No.

#### **4. Hospital-based OPO Voting Project**

The Committee received a brief update on recent developments pertaining to its review of hospital-based OPO voting considerations in the Bylaws. The MPSC work group formed to discuss this topic met the previous day and discussed potential approaches for establishing appropriate separation between the transplant hospital and OPO located at the same hospital for the purposes of providing the OPO an independent vote on OPTN matters. The MPSC had previously agreed that assuring this separation would be a critical component of Bylaws changes that provide hospital-based OPOs an independent OPTN vote. The work group's discussion yielded the following three considerations:

- The OPO must be CMS certified
- The OPO's executive director cannot serve in a leadership role at the transplant hospital
- The body (e.g., Board of Directors) overseeing the OPO must be independent of transplant hospital representation or it must include equal representation of all the transplant hospitals in the OPO's donation service area

UNOS staff is working to draft language to incorporate these concepts into the Bylaws, and for the work group to consider further.

Staff also updated the MPSC on the Policy Oversight Committee's (POC's) review of this project. The POC raised a number of concerns regarding the exclusion of hospital-based histocompatibility laboratories in this project, and whether the output of these efforts may set a precedent for future considerations about the voting rights of hospital-based histocompatibility laboratories. A lot of these concerns were similar to comments raised by the MPSC during its discussion of this topic at its March 2018 in-person meeting. Ultimately, the POC supported recommending that the Executive Committee approve this project to move forward. The POC's feedback highlighted that all future discussions about this project and the proposal itself will need to address these concerns at the forefront to provide proactively the MPSC's perspectives on its decisions regarding the focus of this project.

#### **5. 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 21 Yes, 0 No, 1 Abstention.

#### **Upcoming Meetings**

- June 26, 2018, 3:00 – 5:00pm, ET, Conference Call
- July 17-19, 2018, Chicago
- October 16-18, 2018, Chicago