

## **OPTN Membership and Professional Standards Committee (MPSC)**

### **Meeting Summary**

**August 25, 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 session via Citrix GoToTraining on August 25, 2020, to discuss the following agenda items:

1. Further Enhancements to the National Liver Review Board (NLRB)
2. Align OPTN Policy with U.S. Public Health Service Guideline, 2020
3. COVID-19 Emergency Policies and Data Collection
4. Membership Requirements Revision Project

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

#### **1. Further Enhancements to the National Liver Review Board (NLRB)**

The Chair of the Liver/Intestinal Organ Transplantation Committee (LIC) presented further enhancements to the NLRB that are currently out for Summer Public Comment. The presentation focused on the proposed changes to *Policy 9.5.1.i Initial Assessment and Requirements for HCC Exception Requests*. MPSC members asked several questions about the process and the threshold for sending cases to the MPSC and the Liver Committee Chair responded as summarized below.

- What is the time frame for the 10% of forms that do not have evidence or treatment of HCC that the LIC will review?

Response: One year.

- What happens when you identify a program that is substantially not in compliance?

Response: If the program is transplanting people inappropriately this would likely become an MPSC issue.

- An MPSC member then commented that if somebody is going to list a patient with a certain amount of information, it's usually radiologic. Once transplanted, there will be explant pathology. This proposal is going to look retrospectively at the pathology, which the member didn't have when they listed them, and this is unfair. The information they see after the transplant is not what they had in order to proceed with the transplant. The MPSC/LIC will have more information retrospectively than what the member actually had before the transplant.

Response: The Liver Committee will initially review a program when more than 10% of the forms do not have evidence of treatment. If the program is out of compliance, it would go to the MPSC.

Committee members also offered the following comments:

- This proposal seems clearer than what other people have been struggling with and that the intent is to catch programs that are gaming the system. If there is no evidence of treatment, the program must submit additional documentation/imaging confirming HCC, which would be the pre-transplant imaging.
- A member stated that he agreed with the proposal in which the LIC reviews the cases and if they find more than 10% not meeting the criteria, they would refer that member to the MPSC.
- If the MPSC is going to be involved, it should be written into the policy as a “must,” not a “should.”
- The LIC needs metrics for when members do this regularly and deviate from accepted practice.
- The policy should include what the LIC wants to achieve by referring members to the MPSC.

The MPSC took a sentiment vote of 7 strongly support, 22 support, 1 neutral/abstain, 1 oppose, and 0 strongly oppose.

## **2. Align OPTN Policy with U.S. Public Health Service Guideline, 2020**

The past Chair of the Ad Hoc Disease Transmission Advisory Committee (DTAC) presented the proposal “Align OPTN Policy with U.S. Public Health Service Guideline, 2020.” Following the presentation, the MPSC members offered the following questions and comments.

- The proposal overview specifically referred to HIV and hepatitis B (HBV) nucleic acid tests (NAT), but did not mention hepatitis C (HCV) NAT. Is that because HCV NAT is already required, and HIV and HBV NAT are new components, or is HCV NAT no longer required?

Response: The 2013 PHS Guideline made HCV NAT mandatory for all donors because NAT significantly improved the timeframe for detecting HCV compared to antibody testing. HIV NAT was previously only required for increased risk donors, and HBV NAT was not required at all. Approximately 99% of donors are already tested for all three diseases via NAT.

- The MPSC member then asked which of the risk criteria from the 2013 Guideline were removed from the 2020 Guideline, aside from hemodialysis and hemodilution.

Response: The DTAC representative listed several criteria that have been removed:

- A woman who has had sex with a man who has had sex with another man
  - A child who is born to a woman with an increased risk of HIV, HBV, and HCV infection, although a child born to a woman with HIV, HBV, or HCV is still one of the risk criteria
  - A child who is breastfed by a woman with an increased risk of HIV infection, although a child breastfed by a woman with HIV is still one of the risk criteria
  - A person with certain newly diagnosed sexually transmitted diseases, such as syphilis and gonorrhea
- An MPSC member asked for confirmation that the specimen requirement is 96 hours. If the OPO initially performs testing at 90 hours before cross-clamp and then has to repeat testing, is the OPO expected to hold the donor O.R. until the results from the repeated tests return?  
Response: No, there would be no reason to hold procurement.
  - Would the archived specimen be collected within 24 hours of procurement? Is there a reason it can't be from the same specimen that was tested?

Response: The DTAC representative explained that the current PHS Guideline asks for the archived sample to be collected within 24 hours before procurement and suggested including the question in the committee's comment.

- Is the intent for the OPO to report the individual risk factors in DonorNet?

Response: Yes, it is.

- An MPSC member commented that some of the requirements seem excessive given the level of risk. If there is a one-in-a-million chance of infecting a recipient with universal donor NAT, why require post-transplant testing of all recipients? These changes would impose a significant burden not only on transplant hospitals but also on patients. Transplant recipients will have to deal with the uncertainty and emotional stress of getting additional, relatively unnecessary testing and then waiting for the results. The changes also impose a burden on living donors, who will be asked to provide blood for storage. Transplant hospital do not have a mechanism to counsel and consent living donors for donating blood for potential future use. Overall, the increased cost and workflow for transplant hospitals is going to be very significant, and the requirement violates the role of protecting living donors and the sanctity of their gift of life.

Response: The DTAC representative thanked the MPSC member for their comments. She pointed out that living donors are consented for testing up front, but encouraged the MPSC to share those comments in their response.

- Does the DTAC has a specific timeframe in mind for the required candidate testing, which the proposal says is during hospital admission for transplant, but before transplant?

Response: The DTAC representative explained that the proposed policy language mirrors the PHS Guideline language. The purpose is to have a baseline blood sample available because there have been instances in the past when a recipient's last pre-transplant HBV or HCV test occurred years before transplant, and it was difficult to determine whether disease transmission had occurred via the donor organ or whether the recipient had contracted the disease via other means. The intent is to obtain a sample as close to the transplant time as is feasible, but the tests do not have to be run or resulted before transplant.

- The MPSC member agreed with the reasoning for obtaining a baseline blood sample and asked again whether the DTAC had considered providing a more specific timeframe, since the current language could be interpreted a number of ways.

Response: The committee left the timeframe open, but they will discuss further so they can provide the best education possible to members.

- The MPSC member also cautioned against removing the hemodilution calculation from policy entirely. The information may not be necessary for HIV, HBV, and HCV NAT, but it is valuable in the laboratory for interpretation and other assessments.
- The MPSC member then addressed the 96-hour sample collection for deceased donor testing. If sample collection did not fall within that window, would the OPO have to do repeat testing? This could lead to interpretation issues if the two sets of results do not agree and could lead to allocation issues. DTAC should consider the policy language and guidance regarding repeat testing vs. confirmatory testing, and what to do if tests are re-run and return conflicting results.
- An MPSC member commented that he was in favor of advancing the discussion of infectious risk factors and trying to get patients to understand the comparator of staying on dialysis or staying on the waiting list. However, the mandate to vaccinate and document vaccination for HBV in the

proposal is confusing and creates more work for transplant hospitals. It could also inadvertently be a barrier for listing and transplanting people, especially people who need kidneys.

Response: The DTAC representative clarified that the policy does not mandate HBV vaccination. Programs must assess whether the patient is protected against HBV, such as by performing an HBV surface antibody test. This is because the available data appear to indicate that recipients who had been vaccinated against HBV and had a titer over 10 did not contract HBV inadvertently transmitted by a donor, while recipients of organs from that donor who were not vaccinated did contract HBV.

Following the discussion, the MPSC took a sentiment vote on the proposal. The results were 7 strongly agree, 19 agree, 3 neutral/abstain, 1 oppose, and 1 strongly oppose.

### **3. COVID-19 Emergency Policies and Data Collection**

UNOS staff presented the Executive Committee's proposal "COVID-19 Emergency Policies and Data Collection." Following the presentation, the MPSC offered questions and comments.

- An MPSC member stated he thinks UNOS' actions have been exemplary, and the level of transparency and responsiveness in response to the emerging crisis has been outstanding. The OPTN should extend the regulatory relief and give the Board of Directors or Executive Committee the leeway to use evidence-based criteria such as disease prevalence or hospital admissions to determine when the emergency policy actions should end.
- Another MPSC member said she thought the actions taken by the Executive Committee gave relief during a key period of time. However, they also give the impetus for hospital administration to put a care team member on furlough, leading to that person seeking another position and the care team having to find and recruit a new employee. Her organization has struggled to retain staff and to continue advocating bringing employees back to work while the emergency policy actions continue.
- A UNOS staff member asked the MPSC member to elaborate on her comment, since nobody else has raised the issue. What would she recommend to the Executive Committee?

The MPSC member replied that she would recommend being careful with language. An indefinite suspension of certain policies is hard to explain to hospital administration, and budgets can be affected if the suspension crosses fiscal years. She recommended that the Board and Executive Committee explain that OPTN policies are long-term requirements and this is a short-term pause, so transplant hospitals should not have a reduction in workforce based on the emergency policy changes.

- A third MPSC member suggested it might be time to start to get back to normal. Programs need to be able to manage operations with the amount of staff they have available, but the current environment is going to continue for a while. Aside from the staffing issues already mentioned, a lot of data may end up going missing.

Following the discussion, the MPSC took a sentiment vote on the proposal. The results were 7 strongly agree, 19 agree, 4 neutral/abstain, 1 oppose, and 0 strongly oppose.

### **4. Membership Requirements Revision Project**

The Committee has been working on phase 1 of this project since November 2019. Phase 1 includes a comprehensive review and proposed revisions to the membership applications review bylaws, the bylaws containing the membership requirements for OPOs and histocompatibility laboratories, and the bylaws containing the general membership requirements for transplant hospitals and transplant programs. In addition, the Committee is reviewing and proposing changes to the general format used to

develop organ specific requirements for training and experience of transplant program key personnel. At its July 2020 meeting, the Committee provided feedback for the Membership Requirements Revision Subcommittee on many of the topics related to a new general format for transplant program key personnel training and experience.

At the August 2020 meeting, staff provided a brief summary of the July 2020 Committee feedback that included:

- Support for requirements for degree, state license, and acceptance on hospital staff for both primary transplant surgeons and physicians.
- Support of concept for the primary transplant surgeon and physician to be on-site – meaning the individual is located in the geographical area of hospital, readily available and involved in day-to-day operations
- Disagreement among Committee members on the utility of the board certification requirement for both primary transplant surgeons and physicians
- Support for a pathway for foreign trained individuals but disagreement among Committee members on whether some level of experience with the US system is needed.
- Lack of strong support for requirements for letters of reference, letters of recommendation, and letters of qualification by proposed individual for both primary transplant surgeons and physicians.
- Support for requiring recent experience and having experience in all phases (pre, peri, & post) of transplant care for transplant physicians recognizing a need for clear definition of the phases.
- Support for extending primary transplant physician patient evaluation requirements to all organs. A suggestion was made to consider incorporating patient evaluation into the primary transplant physician requirement of primary care of X number of patients.

The Committee then provided feedback on additional topics that were not discussed at the July meeting due to time limitations. The Committee provided feedback on the current primary transplant physician requirements for observation of transplants and procurements. These requirements did not get significant support in the previous survey completed by Committee members in November 2019. In addition, concerns have been expressed by members that it is quite difficult for professionals to meet the observation requirements. The Committee members responded to two polls during the meeting. One poll gauged the support of the Committee for a requirement that all proposed primary transplant physicians be required to observe a certain number of transplants and procurements. The poll results were:

<b>Strongly Agree</b>	<b>Agree</b>	<b>Neutral</b>	<b>Disagree</b>	<b>Strongly Disagree</b>
13%	26%	22.5%	22.5%	16%

The second poll asked whether proposed primary transplant physicians without previous experience as a primary should be required to observe a certain number of transplants and procurements. The poll results were:

<b>Strongly Agree</b>	<b>Agree</b>	<b>Neutral - Abstain</b>	<b>Disagree</b>	<b>Strongly Disagree</b>
35%	32%	6%	23%	3%

There was some discussion over whether the questions posed in the polls were clear so this topic will be revisited by the subcommittee at its next meeting.

The current bylaw requirement for primary transplant physician working knowledge and direct involvement in transplant in the last 2 years includes a list of organ specific knowledge areas. The Committee was asked in a poll if this list of knowledge areas should be combined into the requirements for caring for a certain number of patients within a certain number of years. The poll results were:

<b>Strongly Agree</b>	<b>Agree</b>	<b>Neutral - Abstain</b>	<b>Disagree</b>	<b>Strongly Disagree</b>
19%	58%	13%	10%	0%

The Committee then discussed the surgeon-specific requirements in the bylaws. Staff noted that the requirement for a surgeon to have performed a specific number of transplants received substantial support on the November 2019 Committee member survey. There was a little less support for requiring a specific number of procurements but it still received support from three-quarters of the respondents. Committee members were asked to respond to two polls to determine whether a specific number of procurements should be required for all proposed primary surgeons regardless of previous experience or only those proposed primary surgeons who did not have previous experience as a primary surgeon. The poll results for whether all proposed primary surgeons should provide documentation of procurements were:

<b>Strongly Agree</b>	<b>Agree</b>	<b>Neutral - Abstain</b>	<b>Disagree</b>	<b>Strongly Disagree</b>
28%	47%	9%	6%	6%

The poll results for whether only new proposed primary surgeons with no previous primary experience should provide documentation of procurements were:

<b>Strongly Agree</b>	<b>Agree</b>	<b>Neutral - Abstain</b>	<b>Disagree</b>	<b>Strongly Disagree</b>
63%	37%	0%	0%	0%

Finally, Committee members had previously provided suggestions for alternative or additional requirements for transplant program primary transplant surgeons and physicians. The Committee was asked to provide feedback on which of these suggestions the subcommittee should consider. The poll results were:

- 94% supported considering a requirement for participation in an OPTN orientation for potential key personnel.
- 69% supported considering a requirement that the program to notify the OPTN of any license actions by a state or federal agency.
- 34% supported considering a requirement for transplant CME or attendance at one national meeting.
- 34% supported considering a requirement for a letter from the local OPO for the program last served.
- 28% supported considering if there are program indicators such as program volume or outcomes from programs the proposed primary has been associated with that could be relevant.

The results of all Committee feedback will be used by the Membership Requirement Revisions Subcommittee to develop a sample format for transplant program key personnel experience and training.

#### **Upcoming Meetings**

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

## Attendance

- **Committee Members**
  - Sanjeev K. Akkina
  - Mark L. Barr
  - Nicole Berry
  - Christina D. Bishop
  - Matthew Cooper
  - Theresa M. Daly
  - Maryjane A. Farr
  - Richard N. Formica Jr
  - Adam M. Frank
  - Jonathan A. Fridell
  - Michael D. Gautreaux
  - PJ Geraghty
  - David A. Gerber
  - Alice L. Gray
  - John R. Gutowski
  - Edward F. Hollinger
  - Ian R. Jamieson
  - Christy M. Keahey
  - Mary T. Killackey
  - Jon A. Kobashigawa
  - Anne M. Krueger
  - Jules Lin
  - Didier A. Mandelbrot
  - Virginia(Ginny) T. McBride
  - Clifford D. Miles
  - Willscott E. Naugler
  - Matthew J. O'Connor
  - Nicole A. Pilch
  - Steven R. Potter
  - Jennifer K. Prinz
  - Scott C. Silvestry
  - Lisa M. Stocks
  - Gebhard Wagener
  - Rajat Walia
- **HRSA Representatives**
  - Arjun U. Naik
  - Raelene Skerda
- **SRTR Staff**
  - Nicholas Salkowski
  - Jon J. Snyder
  - Bryn Thompson
  - Andrew Wey



- **UNOS Staff**

- James Alcorn
- Sally Aungier
- Matt Belton
- Nicole Benjamin
- Tameka Bland
- Torry Boffo
- Matt Cafarella
- Robyn DiSalvo
- Nadine Drumn
- Demi Emmanouil
- Katie Favaro
- Betsy Gans
- Amanda Gurin
- Asia Harris
- Danielle Hawkins
- Chelsea Haynes
- Krissy Laurie
- Ann-Marie Leary
- Marc Leslie
- Ellen Litkenhaus
- Maureen McBride
- Anne McPherson
- Sandy Miller
- Amy Minkler
- Steven Moore
- Sara Moriarty
- Alan Nicholas
- Delaney Nilles
- Jacqui O'Keefe
- Rob Patterson
- Michelle Rabold
- Liz Robbins
- Sharon Shepherd
- Leah Slife
- Olivia Taylor
- Stephon Thelwell
- Susan Tlusty
- Gabe Vece
- Roger Vacovsky
- Betsy Warnick
- Trevi Wilson
- Emily Womble
- Karen Wooten

- **Other Attendees**

- Marian Michaels
- James Trotter