

## **OPTN Board of Directors**

### **Meeting Summary**

**October 7, 2021**

**Teleconference**

**Matthew Cooper, MD, FACS, President**  
**Jerry McCauley, MD, MPH, Vice President**

### **Introduction**

The Board of Directors met via teleconference 10/07/2021 to discuss the following agenda items:

1. Welcome, Roll Call, and Announcements
2. Region 9 Councilor and At-Large Director Appointments
3. Summer 2021 Public Comment Proposals

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

#### **1. Welcome, Roll Call, and Announcements**

The Board President welcomed all attendees. A quorum was present. An overview of the policy development process was provided, as the Board will be discussing new policy proposals at the meeting today.

#### **2. Region 9 Councilor and At-Large Director Appointments**

Jerry McCauley, Chair of the OPTN Nominating Committee, presented the proposed changes to Region 9 as a result of Maryjane Farr, the Region 9 Councilor, relocating to Region 4. The Region 9 Nominating Committee and the Board of Directors Nominating Committee recommended the appointment of Leway Chen, a current At-Large Board Member, to serve as Region 9 Councilor, and recommends MaryJane Farr to serve as At-Large Director in place of Leway Chen.

Both Maryjane Farr and Leway Chen are cardiologists, so there is no change in professional representation on the Board. It was clarified that Associate Councilors are elected by their regions. For Regional Councilors, by Dr. Farr leaving a vacancy prior to the end of the term, this led the Region 9 Nominating Committee to make a suggestion to the Board Nominating Committee, who now is making the recommendation to the Board. The Board has the authority to fill a partial term created by a midterm resignation. The At-Large vacancy left by Dr. Chen's movement would then open a second seat, so the Nominating Committee is recommending bringing back Dr. Farr to the second seat.

A motion was made and seconded for the Board of Directors to approve changes as recommended by the OPTN Nominating Committee.

- By a vote of 100% yes; 0% no; 0% abstained, it was RESOLVED, that Leway Chen is hereby appointed as Regional Councilor representing Region 9 to the OPTN Board of Directors, for the term of October 7, 2021 through June 30, 2022, to fill the vacancy created by the resignation of Maryjane Farr.
- By a vote of 100% yes; 0% no; 0% abstained, it was RESOLVED, that Maryjane Farr is hereby appointed as Member At-Large to the OPTN Board of Directors, for the term of October 7, 2021

through June 30, 2022, to fill the vacancy created by the appointment of Leway Chen as Regional Councilor representing Region 9 to the OPTN Board of Directors.

### **3. Summer 2021 Public Comment Proposals**

The Committee Chairs provided summaries of the Summer 2021 Public Comment Proposals.

- **Establishing Continuous Distribution of Lungs (Lung Committee):** This proposal is part of a larger effort to align all organs in a continuous distribution model. During public comment, feedback was requested on the Composite Allocation Score, the updated exception process, and changes that were made to the multiorgan allocation until the other organs move to continuous distribution. There was generally good support with very little opposition to the proposal. The strongest concern was over increased complexity to logistics. Other comments the Lung Committee will look into are regarding the composition of the review board, a suggested pediatric point sliding scale to address the pediatric priority point, and suggested changes to reduce or give more weight to prior living donors. The proposal will be finalized on 10/22/2021 for Board review in December.
- **Data Collection to Evaluate Organ Logistics and Allocation (Operations and Safety Committee):** Feedback was requested on data to evaluate current data elements and propose any new data elements to provide more insight into organ travel time, logistics, and allocation to inform future policy development, as well as to ensure efficiencies in data collection efforts are current and relevant. The proposal includes recommendations for three new data elements including organ check-out time, organ check-in time, and time of first anastomosis as an estimation of time from recovery for ischemic time, and a recommendation to remove disposition response code for why organs are not recovered. Overall, the proposal received support across all regions. Based on public comment received, the Operations & Safety Committee will work to clarify the data definitions of organ check-out time and time of first anastomosis, recommend to collect organ check-out time via TransNet, and organ check-in time to be collected on the transplant recipient registration form to help alleviate some data burden. A question was asked about time of reperfusion versus time of first anastomosis.

The Operations & Safety Committee did consider it, but the majority of feedback overall supported time of first anastomosis. In addition, it is more consistent with existing policies which define time of transplant at the time of first vascular anastomosis. One Board Member was recently asked to help Epic build better reports for HLA complex data, so inquired about using electronic medical records (EMR) systems for data collection and creation of automated reports with data from transplant records. APIs have been built on the OPTN side that allow hospitals to download a majority of their data and the work continues toward capturing the data automatically, but the OPTN can only build the receptacle and then the EMR system has to build the delivery end. The IT team would welcome any help from the Board in moving the work forward. The proposal will be finalized on 10/15/2021 for Board review.

- **Report Primary Graft Dysfunction (PGD) in Heart Transplant Recipients (Heart Committee):** PGD results in poor post-transplant outcomes and long-term complications. There is a concern that PGD is on the rise, but there is no post-transplant data captured related to PGD. During public comment, feedback was requested to involve the transplant community early in the process of deciding what data elements to collect, when to collect, and that the data are also applicable to pediatrics. There was overall strong support for the proposal. There were requests for donor-specific data elements, many of which are currently not collected, especially related to DCD donors. Based on public comment received, the Heart Committee just met yesterday to address

concerns over clarification of data definitions, adding of pediatric-specific indicators, reducing data elements to help with data burden, and collection and reporting of donor-specific data elements on the Transplant Recipient Registration Form.

Comments from Board Members reaffirmed the importance of the data collection because it serves a purpose to improve patient outcomes. The data elements included in the proposal were chosen after reviewing publications of risk factors of transplant surgery and pre- and post-transplant recipient and donor. The data elements primarily focus on capturing the severe (needing a mechanical pump), whether a device was implanted or not and if so, what type and what side of the heart was not functioning, as well as drips that are utilized. All organs have some degree for measure of primary graft dysfunction. The data will be needed to weigh risk factors in the future for the continuous distribution scoring system. One comment was that they should still be sensitive to the enormous numbers of granular data elements collected in this policy. The Heart Committee is aware of the concern and tried to make the data capture as efficient as possible. One Board Member commented regarding having the data collection be run as a pilot project instead, but the Heart Committee's understanding is that that is not a feasible approach at this time. The proposal will be finalized on 10/19/2021 for Board review.

- Enhance Transplant Program Performance Monitoring System (Membership and Professional Standards Committee (MPSC)): The purpose of the proposal is to develop a more holistic review of transplant program performance, identify real-time patient safety issues, expand support and collaboration to transplant programs for opportunities for improvement by the OPTN, and evaluate proposed systems to support increasing number of transplants, equitable access to transplantation, and innovation. The proposal is based on four metrics: waitlist mortality and offer acceptance, 90-day graft survival and 1-year graft survival conditional on 90-day survival. In terms of program review, there is a two-step process: red zone where intervention will occur and yellow zone where a program has the option to partner with the OPTN to review possible performance improvement options. The proposal has nothing to do with the SRTR public website. Public comment revealed better support than was forecasted, including support for using separate pediatric and adult, support for appropriately adjusting for program volume, and concern of too few or too many programs being flagged for patient safety issues. Having the metrics risk-adjusted was clearly supported by those who understand risk adjustment, but there was feedback where risk adjustment was not well understood. The waitlist mortality metric was most contentious among transplant programs, but no kidney transplant programs were flagged for waitlist mortality in the modeling. One suggestion was that post-transplant outcomes should evaluate patient survival versus graft survival. Of note, there was significant support for future use of longer-term outcome measures, such as 5-year survival. Based on public comment received, the MPSC will replace the term "waitlist mortality" to "pretransplant mortality."

One Board Member felt greater consideration should be given to the donor waitlist issue because the flagging could be to be a barrier to access to transplantation. It was clarified that there is no fixed number of programs that has to be flagged. Another comment was patient survival may be of more value than graft survival, but data reveal failed graft will not put a strong program over the threshold of being flagged. The development of organ offer filters will help keep programs accountable for their organ offer acceptance decisions will help lead to the point of getting organs to teams that will use them more expeditiously. The proposal will be finalized on 10/26/2021 for Board review.

- Update on OPTN Regional Review Project (Executive Committee). This is not a formal policy, but the purpose is to gather feedback on different ways in which regions could be structured, how

governance occurs, current responsibilities for regions, and how geography could be set up in terms of the governance and responsibility. The EY project team created three different potential models. The idea was to keep the groups in a similar region, but change the sizing of the region based on something other than state lines versus dividing like individuals into communities of common interest and allowing them to have their own conversations and report up to the Board level, thereby ensuring that all voices are equal. The public comment summary revealed that in general, people were pleased with how the regional meetings allow for multidisciplinary conversation. People felt the system is not broken, but there is opportunity to make some improvements. Other public comment themes were around increasing patient and donor affair member representation on the Board, feedback on restructuring/resizing the Board, new CMS metrics for OPOs have expanded OPO/transplant program relationships, and the need for two separate ways of looking at things: operations and policy development and representation. There was not a lot of enthusiasm for perspective-specific workgroups, such as a kidney and patient group, because it would defeat the purpose of getting the community together. The feedback will be used to developing a concept paper for Winter 2022 Public Comment period.

The Board President gave a brief overview of the other Summer 2021 Public Comment items that the Board will consider in December.

Over the next few weeks, Committees will be finalizing their proposals based on public comment. Board Members are encouraged to reach out and contact Committee members or UNOS staff with any questions or comments about the proposals. Invitations to the Board Policy Groups have gone out, which will be on November 10th and 12th, 2021, where Board Members will review and discuss smaller subsets of proposals to make recommendations to the Board President on agenda placement for those items and whether to approve or decline the proposals. All these steps will lead up to the in-person December Board meeting. A survey will be going out this afternoon, which all Board Members are encouraged to fill out to help with the decision making for the December 2021 meeting.

### **Upcoming Meeting**

- December 6, 2021

## Attendance

- **Board Members**
  - Matthew Cooper
  - Jerry McCauley
  - William Bry
  - Richard Formica
  - Maryjane Farr
  - Adam Frank
  - Jim Sharrock
  - Annette Jackson
  - Ian Jamieson
  - Alan Langnas
  - Erika Lease
  - David Mulligan
  - Pono Shim
  - Keith Wille
  - Valinda Jones
  - Pam Gillette
  - Amishi Desai
  - Brad Kornfeld
  - Jonathan Fridell
  - Andrea Tietjen
  - Stacey Lerret
  - Leway Chen
  - Mindy Dison
  - R. Patrick Wood
  - David Gerber
  - Linda Cendales
  - Kim Rallis
  - Merry Smith
  - Jan Finn
  - Patrick Healey
  - Irene Kim
  - Lisa Stocks
  - Melissa McQueen
  - Laurel Avery
  - Ed Hollinger
  - Earnest Davis
  - Brian Shepard, UNOS - Ex Officio, Non-Voting
- **HRSA Representatives**
  - Chris McLaughlin
  - Vanessa Arriola
- **SRTR Staff**
  - Jon Snyder
- **UNOS Staff**
  - Susie Sprinson
  - Susan Tlusty

- Matt Prentice
- Alex Tulchinsky
- **Other Attendees**
  - Erika Lease
  - Ian Jamieson
  - Shelley Hall
  - Chris Curran