

OPTN Board of Directors

Meeting Summary

August 5, 2021

Conference Call

Matthew Cooper, MD, President
Jerry McCauley, MD, Vice President

Introduction

The Board of Directors met via teleconference on 08/05/2021 to discuss the following agenda items:

1. Agenda Overview and Board Member Engagement
2. Summer 2021 Public Comment Proposals

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

1. Agenda Overview and Board Member Engagement

Dr. Matthew Cooper, President, welcomed the Board to the pre-public comment briefing. UNOS staff reminded the Board that public comment is now open, and all items are available for review on the OPTN website. Registration is open for regional meetings. Meetings through the end of the August have been converted to virtual. UNOS staff encouraged Board members to engage early and often during the summer 2021 public comment cycle by sharing feedback during regional meetings, on the public comment website, or by contacting the sponsoring committee. Following the close of public comment, the Board will convene again to review public comment received throughout the cycle. Dr. Cooper reminded members of the Board that they are influential leaders in the donation and transplantation community, they should make sure to engage with proposals outside of their area of expertise. Board members should offer concrete feedback to enhance proposals.

2. Summer 2021 Public Comment Proposals

Dr. Erika Lease presented the *Establish Continuous Distribution of Lungs* proposal on behalf of the Lung Transplantation Committee. Dr. Lease explained that this proposal is part of a larger effort to align all organs in a more patient-centric allocation system and move from hard boundaries to considering individual candidates holistically. The proposal replaces classification based allocation with a composite allocation score (CAS) for each candidate. The score is comprised of several attributes. This proposal also includes changes to the exception request process and multi-organ allocation. Dr. Maryjane Farr asked how heart is part of the proposed multi-organ allocation system, and Dr. Lease explained that the first step is similar to the current system: all status 1 and 2 within 500 NM, then the OPO has some advice on how to allocate heart or heart-lung. They can allocate to any heart candidate with a CAS of 28 or higher before offering to status 3. The CAS of 28 would be a high score for lung, and the committee wanted to give those patients an opportunity to get a heart. Dr. David Mulligan explained that an important part of continuous distribution will be planning for multi-organ allocation. Charlie Alexander is leading the Ad Hoc Multi-Organ Transplantation Committee in this effort.

Dr. Martha Pavlakis presented the *Update on Continuous Distribution of Kidneys and Pancreata* concept paper on behalf of the Kidney Transplantation Committee and the Pancreas Transplantation Committee. This concept paper introduces the community to the project of transitioning from a classification-based system to a points based system. The paper updates the community on progress made to date, and

seeks feedback to help inform the new allocation framework. The committees are seeking a more equitable approach to matching kidney and pancreas candidates and donors. Continuous distribution will remove hard boundaries that prevent kidney and pancreas candidates from being prioritized further on the match run, and will consider multiple patient attributes through a CAS instead of within categories by sequence. It will also establish a system that is flexible enough to work for each organ type and make future policy changes more efficient. The concept paper asks the community many questions and solicits concrete feedback on a variety of topics. Dr. Jonathan Fridell asked if this is premature because there may not be enough information to evaluate the impact of broader distribution. Dr. Fridell noted that the document seemed focused heavily on kidney and less on pancreas. Dr. Pavlakis explained that there is a preliminary data report with information on broader distribution, and that this concept paper is a stepping stone in a long transition process to continuous distribution. The Kidney and Pancreas Committees have been working on this project both jointly and independently.

Ms. Merry Smith asked Dr. Pavlakis to explain the hard boundaries in the current allocation system. Dr. Pavlakis provided the examples that the current system rates candidates based on an estimated post-transplant survival score, and that deceased donor kidneys are rated by KDPI. Dr. Adam Frank asked about linear and nonlinear donors, and Dr. Pavlakis explained that CPRA goes from 0-100, but if you awarded points linearly, that is not biologically relevant, because the difficulty in getting transplanted goes up exponentially. Dr. Annette Jackson noted that many centers are hesitant to move to virtual crossmatch due to CMS regulations that require crossmatch prior to placement of a kidney. Dr. Jackson is hoping to work with CMS to update the regulations.

Dr. Matthew Cooper presented the *Update on OPTN Regional Review Project* on behalf of the Executive Committee. The purpose of the request for feedback is to gather community input on consultant recommendations and evaluate the structure, processes, performance, and effectiveness of regions. The consultants, EY, provided three potential options for new structural models. The OPTN, community, and allocation policies have changed significantly since regions were created. This project was launched pursuant to OPTN Contract Task 3.3.3. Dr. Fridell noted that it will be important to consider representation on the Board to ensure that regional concerns are brought forward. Dr. Cooper noted that the goal is to end up in a place that there are no regional concerns as allocation shifts to continuous distribution. Mr. Jim Sharrock noted that one model is similar to the current committee structure. Dr. David Mulligan and Dr. Cooper noted that this request is an important part of the community conversation about this project.

Mr. Ian Jamieson presented the *Enhance Transplant Performance Monitoring System* proposal on behalf of the Membership and Professional Standards Committee. The goal of this proposal is to develop a holistic review of transplant program performance, identify real-time patient safety issues, and provide support and collaboration to transplant programs for identified opportunities for improvement. Dr. Cooper thanked Mr. Jamieson for his work on this project and encouraged the Board to view the resources available on the OPTN website. Ms. Andrea Tietjen asked if the process for performance monitoring will be modified to be less manual and laborious. Mr. Jamieson explained that the performance monitoring process will continue to be a partnership between the OPTN and the institution.

Mr. Chris Curran presented the *Data Collection to Evaluate Organ Logistics and Allocation* on behalf of the Operations and Safety Committee. This proposal will ensure efficiencies in data collection efforts are current and relevant. It evaluates current data elements and proposes new data elements to provide more insight into organ logistics and allocation in order to inform future policy development. Dr. Marian Michaels noted that this project is timely and important. Dr. Cooper noted that the data from this proposal will help to inform continuous distribution. Mr. Jeff Orłowski noted his appreciation for the

project and encouraged the committee to explore the use of timestamps to verify data. Mr. Curran replied that some data from TransNet can be used to verify times. Dr. Cliff Miles asked if the committee considered tracking case times. Mr. Curran replied that much of that data is available in DonorNet and UNet and should be assessed to evaluate case times. Dr. Annette Jackson asked if data is collected on crossmatch requests, and Mr. Curran noted that this is a very important topic but was not in the scope of this project.

Dr. Paulo Martins presented the *Reassess Race in eGFR Calculation* request for feedback on behalf of the Minority Affairs and Kidney Transplantation Committees. The Committees are seeking additional information on the use of the Black race coefficient in the eGFR calculation as it relates to wait time criteria in kidney allocation. Research suggests the use of the Black race coefficient disadvantages Black patients being treated for chronic kidney disease. eGFR calculators only offer Black/not Black with no distinction for mixed race or multi-race individuals. Dr. Celeste Williams asked Dr. Martins if he thinks the proposed changes will increase access to transplant for the Black race. Dr. Martins replied that modeling indicates an increase in access to transplant for African Americans.

Ms. Susan Tlusty, UNOS staff, provided a brief overview of the remaining public comment proposals. Dr. Cooper encouraged the Board to review all items on the OPTN website and thanked the Board and the presenters for their participation.

Upcoming Meetings

- October 7th, 2021
- December 6th, 2021

Attendance

- **Board Members**
 - Matthew Cooper
 - Jerry McCauley
 - David Mulligan
 - Ed Hollinger
 - Laurel Avery
 - James Sharrock
 - Amishi Desai
 - Jan Finn
 - Joe Ferriera
 - Marian Michaels
 - Adam Frank
 - R. Patrick Wood
 - Annette Jackson
 - Cliff Miles
 - David Gerber
 - Jeff Orlovski
 - Maryjane Farr
 - Brad Kornfeld
 - Jonathan Fridell
 - Andrea Tietjen
 - Mindy Dison
 - Leway Chen
 - Merry Smith
 - Celeste Williams
 - William Hildebrand
 - Patrick Healey
 - Melissa McQueen
- **HRSA Representatives**
 - Chris McLaughlin
 - Frank Holloman
 - Shannon Dunne
- **SRTR Staff**
 - Jon Snyder
 - Ajay Israni
- **UNOS Staff**
 - Susie Sprinson
 - Susan Tlusty
- **Other Attendees**
 - Paulo Martins
 - Chris Curran
 - Martha Pavlakis
 - Ian Jamieson
 - Erika Lease