

OPTN Board of Directors

Meeting Summary

August 8th, 2022

Conference Call

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Introduction

The Board of Directors met via Webex on 08/08/2022 to discuss the following agenda items and public comment items:

1. Welcome
2. Strategic Policy Priority Updates and Concept Papers Case Review
3. Modify Heart Policy to Address Patient Safety Following Device Recall
4. Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations
5. Update Data Collection for Lung Mortality Models
6. Enhancements to OPTN Donor Data and Matching System Clinical Data Collection
7. Transparency in Program Selection

The following is a summary of the Board of Directors discussions.

1. Welcome

Board Manager, Susie Sprinson, started the meeting with multiple announcements to the board. New Board Liaison, Morgan Jupe, was introduced to the board, board members were reminded that public comment opened on Wednesday, August 3rd, and the board was reminded when regional meetings are and how they can sign up. Next steps for Board Member engagement were presented. A list of non-discussion items going out for Summer 2022 Public Comment were shared with the board.

2. Strategic Policy Priority Updates and Concept Papers Case Review

Nicole Turgeon, Chair of the Policy Oversight Committee (POC), presented the strategic policy priority updates on behalf of the POC. Dr. Turgeon spoke on the importance of the three strategic policy priorities and how some of this cycles public proposals and concept papers support these priorities.

Summary of discussion:

Dr. Turgeon shared the upcoming timeline related to continuous distribution and the progress across different organs, specifically focusing on lungs, kidney and pancreata, and liver and intestines.

Dr. Turgeon discussed the Redefining Provisional Yes and the Approach to Organ Offers proposal, with the purpose of increasing efficiency in organ offers and to reduce overall allocation time. The proposal is based on a three-tiered framework for programs to follow and the responsibilities within each tier.

The Optimizing Usage of Kidney Offer Filters concept paper was presented next. The purpose of the concept paper is to provide an update about the ongoing work on kidney offer filters, increase awareness on the benefit of such filters, and to seek feedback from the community. The overall goal of the proposal is to work on the efficiency of the organ offer filter system.

A board member asked what impact this policy would have on KDPI patients on the waitlist. They asked about the timing of receiving kidney offers once they have gone through offers to multiple other patients. Another board member asked about the terms of filtering and if for example, a program has a filter because there are some surgeries they never perform, does this mean they will never be able to do these types of operations. Dr. Turgeon expressed that these are areas where the committee is searching for feedback from the community. Mr. Shepard explained that because this topic is still a concept paper, now is the critical time for board members to express their concerns and comments about the paper, before the paper becomes a proposal. A board member commented that the IT requirements should be discussed so that the Finance Committee can prioritize the needs of committees. A board member commented that it should be made clear to transplant programs that the goal of offer filters is for organizations to improve their offer filter system. A board member asked if there is going to be a timeline on programs implementing these changes, to which Dr. Turgeon explained that the proposal asks for feedback on what people believe an appropriate timeline would be.

3. Modify Heart Policy to Address Patient Safety Following Device Recall

The board heard from JonDavid Menteer from the Heart Committee, about their recent emergency policy implementation addressing recent device recalls. The Heart Committee is seeking retrospective feedback during the Summer 2022 Public Comment cycle.

The reason for the emergency implementation was to quickly address patient safety risk associated with the recall and the risk of product recall, following multiple FDA VAD recalls in 2021 and 2022. The policy seeks to address the question of patient status when it comes to device recall. The committee worked to make the policy broad to allow other devices recalled in the future to follow this policy.

4. Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations

The Board of Directors heard from Alejandro Diez, the Vice Chair of the Minority Affairs Committee (MAC), about the MAC proposal for Summer 2022 Public Comment. The purpose of the proposal is to address waiting time modifications for registered Black kidney candidates affected by race-neutral eGFR calculations and to provide a pathway for affected candidates to regain time lost due to use of race-inclusive eGFR calculations.

Summary of discussion:

The key concepts of the proposal are to restore wait times to Black candidates and to increase equity in access to transplants. This would provide an opportunity for hospitals to apply race-neutral calculations to candidates that are already registered on the waitlist. The goal is to provide a solution that increases equity to a historically disadvantaged population. Programs will be responsible for their own calculations and will not be required to submit their modifications.

During discussion, a board member asked what the timeframe for these changes are and they also asked for a clarification on who these modifications are going to affect, to which Dr. Diez explained that this will only affect patients moving forward. Many members commented that they believed these changes in calculations should be mandatory, so the policy holds more weight. Another board member raised the discussion of when these changes are to be made – is it once a patient is referred or can they go back further in time to edit these calculations, to which MAC Leadership responded that this too is a question the committee is looking for feedback about.

5. Update Data Collection for Lung Mortality Models

The Board of Directors heard from Marie Budev, the Chair of the Lung Transplantation Committee, about one of the committee's proposals going out for public comment this summer. The proposal is to update data collection on disease severity of lung candidates.

Summary of discussion:

Dr. Budev presented the key concepts and goals of the proposal, while also presenting questions to the board on which the Lung Committee desire feedback about. The committee hopes that updating data collection will determine whether new criteria should be included in the models. These data additions would be based on clinical literature and expertise. Dr. Budev also highlighted the updates that will need to be implemented in the OPTN Waitlist if this policy were to take effect.

A board member asked how long it would take for the committee to collect meaningful data to update models based on these data elements, to which Dr. Budev responded one to two years of data collection. This board member also asked whether there have been discussions about analyzing data retrospectively, to which Dr. Budev agreed to take this comment back to the committee but that it is not easy to retrieve this kind of digital data and this data is not easy to look at retrospectively. A board member commented that they believed this proposal was a reasonable first step and is interested to receive feedback from the public about whether there would need to be more data collection first.

6. Enhancement to OPTN Donor Data and Matching System Clinical Data Collection

The Board of Directors heard from Kurt Shutterly, Chair of the Organ Procurement Organizations (OPO) Committee, about their proposal going out for public comment this summer. The proposal seeks to streamline communication of donation after circulatory death (DCD) donor information and to provide easily accessible DCD information.

Summary of discussion:

The OPO Committee would like to streamline this information because this data is not currently collected in the OPTN Donor Data and Matching System and this will help to reduce risk, reduce undue communication, and improve organ placement efficiency along with many other benefits. Mr. Shutterly discussed the IT implementation efforts that would be necessary in updating the OPTN Donor Data and Matching System as well. The OPO Committee wishes to receive feedback on whether or not these changes would be burdensome for OPOs to report.

A board member suggested that programs and OPOs are made aware of this upcoming proposal and ensure they are aware of the update needs. A board member emphasized the importance of highlighting ERP and to ensure that the data fields include this data as they believe ERP is going to change DCD practices soon. Mr. Shutterly agrees with the suggestion and believes the OPO Committee is going to focus on this aspect in the second phase.

7. Transparency in Program Selection

The Board of Directors heard from Laura Schmitt, Ethics Committee Liaison, and Andy Flescher, Vice Chair of the Ethics Committee, about the committee's white paper. They explained that the paper is patient focused, with the purpose of focusing on the ethical principles that necessitate the availability of transparency and the information presented to patients when pursuing transplant evaluation.

Summary of discussion:

The theme of the paper is to increase transparency to patients about transplant centers, to provide patients with information in an accessible and patient-centered manner. The Ethics Committee hopes to

ensure patient autonomy and shared decision-making throughout the transplant process. Multiple board members were pleased to hear about the paper and value the visibility the project creates. A board member asked about the role that SRTR has played in this paper, to which Dr. Flescher explained there has been a conscious effort to make this a patient driven focus.

Upcoming Meeting

- September 21st, 2022

Attendance

- **Board Members**
 - Adam Frank
 - Andrea Tietjan
 - Annette Jackson
 - Barry Massa
 - Bradley Kornfeld
 - Christopher Woody
 - Clifford Miles
 - Dianne LaPointe Rudow
 - Earnest Davis
 - Edward Hollinger
 - Evelyn Hsu
 - Irene Kim
 - Jan Finn
 - Jeff Orłowski
 - Jim Sharrock
 - Jonathan Fridell
 - Laurel Avery
 - Linda Cendales
 - Lloyd Ratner
 - Manish Ghandi
 - Matt Cooper
 - Mark Barr
 - Meg Rogers
 - Melissa McQueen
 - Nicole Hayde
 - Richard Formica
 - Robert Goodman
 - Stuart Sweet
 - Valinda Jones
 - Wendy Garrison
 - Willscott Naugler
- **HRSA Representatives**
 - Andriana Martinez
 - Adrienne Goodrich-Doctor
 - Christopher McLaughlin
- **UNOS Staff**
 - Brian Shepard
 - Maureen McBride
 - Morgan Jupe
 - Susie Sprinson
- **Other Attendees**
 - Alejandro Diez
 - Andy Flescher
 - JonDavid Menteer
 - Marie Budev

- Nicole Turgeon