

OPTN Board of Directors

Meeting Summary

March 31, 2022

Conference Call

Matthew Cooper, MD, Chair
Jerry McCauley, MD, Vice Chair

Introduction

The OPTN Board of Directors met via conference call on 03/31/2022 to discuss the following agenda items:

1. Welcome
2. Announcements & Board Member Engagement
3. Overview of Winter 2022 Public Comment Items
4. Establish OPTN Requirement for Race-Neutral eGFR Calculations
5. Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation
6. Continuous Distribution of Kidneys & Pancreata Request for Feedback
7. Establish Minimum Kidney Donor Criteria to Require Biopsy & Standardize Kidney Biopsy Reporting and Data Collection
8. Redesign Map of OPTN Regions

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

1. Welcome

Matthew Cooper, Board President, opened with the explanation that this meeting is to go over the Winter 2022 Post-Public Comment.

2. Announcements & Board Member Engagement

Board Liaison, Susie Sprinson, went over the next steps for board member engagement. Following the Post-Public Comment discussion the board will meet in Board Policy Groups to discuss the policies and then the Board Meeting will take place in June.

Include specific assignments for specific people (Research will collect ## data as requested, UNOS Staff will determine whether ## is a realistic policy expectation, etc.)

3. Overview of Winter 2022 Public Comment Items

A member of the UNOS Policy and Communications staff, Lauren Mauk, reviewed the 8 proposals that were out for Winter Public Comment that were less controversial or had less comments.

The Liver Intestine Committee has two projects the first is to create more equitable and efficient liver allocation by updating MELD and PELD scores and policy for status 1A and 1B. The second project from the Liver Intesting Committee is the review the NLRB Policy and Guidance the purpose of this proposal is to ensure that the guidance and policy used by NLRB remains clear and aligned with current research so that appropriate candidates receive MELD and PELD exceptions.

The next proposal was the Living Donor Committee's modification of the living donor exclusion criteria that would broaden individuals' opportunities to become living organ donors.

The Histocompatibility Committee proposed revisions to CPRA calculation which will increase access to transplant of highly sensitized and minority candidates. There was supportive feedback in the comments only one question on transition.

The DTAC & Pediatric Committees co-sponsored the Pediatric Candidate Pre-Transplant HIV, HBV, HCV Testing. This proposal states that candidates younger than 11 years old would not be required to receive HIV, HBV and HCV during their hospital admission. Instead they could have this test completed between their waitlist and transplantation. Comments were supportive but did question the age, should it be 12 instead of 11, and questions about a weight threshold.

The VCA Committee's proposal on VCA Graft Failure Definition. This proposal would removed a planned removal from being categorized as a graft failure. This change would improve data quality and update the waiting time policy. This has also received support, one comment was that it should be clarified that this is only for uterous planned removal.

The Executive Committee had two projects the OPTN Charter to clarify the relationship between the OPTN and OPTN Contractor. The other is the Reinstatement of Updates to Candidate Data During COVID-19 which is expected to expire in April.

Summary of discussion

There was no discussion on these proposals.

4. Establish OPTN Requirement for Race-Neutral eGFR Calculations

A representative of the Minority Affairs and Kidney Transplantation Committee presented the proposal for race neutral eGFR calculations. This proposal would prohibit the use of eGFR calculations that include race-based variable in OPTN policy. The policy is intended to increase equity in access to transplantation for Black kidney candidates by more accurately estimating their GFR values. The overall public comment was supportive of the proposal. The concerns that were raised where that there needed more educational resources to assist in a smooth transition to race-neutral calculations. Another was that prohibited use of race in eGFR calculations may reduce the number of qualified Black living donors.

Summary of discussion

A comment from a board member regarding the lowering the GFR on donors; you can run other tests that are more accurate, there shouldn't be concerns of lowering living donors based on this test.

A board member mentioned that in a comment from the public someone asked whether this is being considered for KDPI. The committee member replied that this was not part of the conversation.

No additional questions or comments were raised.

5. Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation

A Multi Organ Transplantation committee member presented the proposal Establishing Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation. The purpose of the proposal is to set eligibility criteria and safety net for heart-kidney and lung-kidney allocation based on kidney function. This proposal would require OPOs to offer kidney with heart or lung if a candidate meets

medical criteria for simultaneous transplant. It also creates a safety net for heart and lung recipients with poor kidney function to receive some priority in kidney allocation. Public comment sentiment showed majority support with some concern mainly from the heart community. These concerns were about the exclusion of status 4/5 heart candidates, concern about the proposed GFR threshold for heart-kidney criteria and concerns that OPOs would be penalized for late turndowns. Post public comment the committee is considering adding status 4 and 5 heart candidates to eligibility criteria. The committee will finalize the board proposal to go forth to the Board.

Summary of discussion

There was some consensus between heart and abdominal surgeons on the status 4 patients. The status 5 heart transplant candidate, is any patient that needs a dual organ who is somewhat sicker than a status 6. Some of the challenges in the Multi organ committee hear these concerns and want it to be uniform policy throughout. The allowing of status 4 or 5 heart seems inconsistent with other organs. The committee is very comfortable with how the safety net is working and the committee talked to the heart committee

There were a few members who questioned the data for candidates that are liver transplant recipients and how they do with a kidney transplant. The committee has the data to support the safety net, survival of the graft and survival rate of recipients. The President asked that this data could be shared for Board Policy Group review.

The OPO community has concerns about late turn down. UNOS employee Kaitlin Swanner, as long as the OPO still offers the single organ to the multi organ candidate it should not be an issue with the allocation. That was followed up with a request for language being put together to clarify the policy for OPOs.

6. Continuous Distribution of Kidneys & Pancreata Request for Feedback

The purpose of this project was to solicit feedback on the continuous distribution of kidneys and pancreata. The requested feedback was on the rating scales and weights and attributes such as HLA matching, EPTS/KDPI longevity matching blood type prioritization, etc. The exercise weighted the priorities of different demographic groups. The general themes that came up were the support for patients, prioritization of living donors and pediatric candidates. Potential disadvantages included the effect on pediatric patients, low socioeconomic status or rural areas. The workgroup and committee will finalize the rating scale for each attribute, determine weight for each attribute, build a framework and submit modeling request and continue to update the community on progress.

Summary of discussion

One member mentioned that the pancreas continuous distribution due to the prior living donor prioritization is a non entity, it would be so rare that this scenario would play out. The president mentioned that if there are important questions that should be asked, get them to the committee so those other variables can be considered.

Another member commented that they were surprised at how similar the responses were between kidney and pancreas. The president commented that maybe the survey questions were not clear to accurately reflect the response.

7. Establish Minimum Kidney Donor Criteria to Require Biopsy & Standardize Kidney Biopsy Reporting and Data Collection

The purpose of the Establishing of Donor Criteria to Biopsy is to set a minimum donor criteria to biopsy kidneys. There was good support for this proposal but there was opposition from OPO and stakeholder

organizations. The concerns were how biopsies are collected, prepared, read and reported. The validity of correlation between biopsy and graft outcomes. There was also concern that this could delay allocation while waiting on biopsy.

The standardizing biopsy reporting would require certain data when reporting biopsy results. There would be a new form to standardize the report. There was general support for this proposal some opposition was from the OPOs. The supported stated that this would streamline communication between OPOs and transplant hospitals. Concerns were access to pathology services. Following Public Comment the committee is considering changes to eliminate the expanded criteria donor definition from Minimum Criteria, expanding criteria to account for additional acute kidney injury indicators.

Summary of discussion

A member asked if it is the intention to biopsy every DCD kidney? It was not the intention of the proposal to require biopsy for DCD.

There is a concern that this criteria is too broad. More biopsy would lead to higher discard. It is also beyond the scope of OPOs to require pathologist to fill out this form. There are concern that this would be impractical to apply.

A member said that he generally supports the minimum biopsy but he doesn't feel like the system is ready for it. The concerns is the discard rate due to delays. Is there an exception clause if the hospital is ready to accept the organ? The committee member stated that if that hospital then passes on it and it is reallocated and the new hospital wants a biopsy it extends the cold time.

8. Redesign Map of OPTN Regions

The purpose of the concept paper was to gather feedback on the options for updating the map of the OPTN Regions to be more balanced by population. In public feedback it was asked which metric should the OPTN consider for redesigning the regions what map would best serve the OPTN or should the map be left the same?

There was broad support for the current structure for the historic collaboration and because there is no value in changing the regions. There was some support for 11 more equal regions to provide more equal representation. There was concern that fewer, larger regions would reduce representation and others questioned the timing and purpose of changing regions.

Summary of discussion

The board expressed their relief that the majority was supportive of keeping the regions the way they currently are structured.

Upcoming Meetings

- Board Policy Groups
May 23, 24, 25

Board Preview Calls
June 20, 21

Board of Directors Meeting
June 26, 27

Attendance

- **Committee Members**
- **HRSA Representatives**
 - Chris McLaughlin
 - Frank Holloman
 - Shannon Taitt
- **SRTR Staff**
 - Jon Snyder
- **UNOS Staff**
 - Alex Tulchinsky
 - Betsy Gans
 - Brian Shepard
 - Carrie Caumont
 - Cole Fox
 - Courtney Jett
 - David Klassen
 - Eric Messick
 - Isaac Hager
 - Jacqui O'Keefe
 - James Alcorn
 - Jason Livingston
 - Kaitlin Swanner
 - Kelley Poff
 - Kim Uccellini
 - Krissy Laurie
 - Kristina Hogan
 - Lauren Mauk
 - Lindsay Larkin
 - Liz Robins Callahan
 - Matt Cafarella
 - Maureen McBride
 - Meghan McDermott
 - Rebecca Brookman
 - Roger Brown
 - Sara Rose Wells
 - Steve Harms
 - Susan Tlusty
 - Susie Sprinson
 - Tina Rhoades
- **Other Attendees**
 - Nicole Turgeon

- Oyedolamu K Olaitan
- Jim Kim