

OPTN Policy Oversight Committee

Meeting Summary

January 8, 2021

Conference Call

Alexandra Glazier, JD, Chair

Nicole Turgeon, MD, Vice Chair

Introduction

The Policy Oversight Committee (POC) met via Citrix GoTo teleconference on 01/08/2021 to discuss the following agenda items:

1. Winter 2021 Public Comment Review
2. New Projects

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

1. Winter 2021 Public Comment Review

The POC reviewed and voted to recommend approval of ten public comment items. Vice Chairs (VCs) presented updates on each public comment item as well as a key metric for evaluating each proposal.

Summary of discussion:

The POC reviewed the following public comment items:

- Revise General Considerations in Assessment for Transplant Candidacy (Ethics Committee)
- 2021-2024 OPTN Strategic Plan (Executive Committee)
- Develop Measures for Primary Graft Dysfunction in Hearts (Heart Committee)
- Require Notification of Human Leukocyte Antigen (HLA) Typing Changes (Histocompatibility Committee)
- Calculate Median MELD at Transplant Around the Donor Hospital and Update Sorting Within Liver Allocation (Liver & Intestine Committee)
- Update National Liver Review Board Guidance Documents and Policy Clarification (Liver & Intestine Committee)
- Update Membership Requirements and Application and Review Process (Membership and Professional Standards Committee (MPSC))
- Update Transplant Program Key Personnel Training and Experience Requirements (MPSC)
- Clarify Multi-Organ Allocation Policy (Organ Procurement Organizations (OPO) Committee)
- Modify the Deceased Donor Registration (DDR) Form (OPO Committee)

Revise General Considerations in Assessment for Transplant Candidacy

The Chair was surprised that the paper does not include any discussion of financial considerations. The Ethics VC said that the Ethics Committee discussed financial considerations at the outset but did not see how they could address this without talking about overhauling the whole health care payment system. The committee chose to take a narrower view on psychosocial criteria and how they are applied in assessing candidates for transplant. The committee plans to update the paper to explain why this was not considered. The Chair agreed with this approach so that the topic is not entirely absent. The Chair

noted that there is no access to transplant for patients who do not get listed, so this is a huge component to ensure that patients in need get access. While this was not addressed in the paper, the Chair recommended that it go forward to public comment.

HRSA staff said that the authority falls within Ethics Committee to give generalized advice to the OPTN body, which means all members of the OPTN, and therefore the committee can make guidance for the OPTN body about what should be included in listing criteria. HRSA staff said that this is different from giving guidance directly to OPTN members, since members are still in control of determining whether they use that information. The Chair said that this is not a policy proposal or a guidance document; it is a white paper so that all members can understand the ethical considerations of this work. The Ethics VC said that the Ethics Committee is sensitive to the comments raised by HRSA staff, and aims to focus on descriptive, rather than prescriptive, work. The Chair said the POC should keep in mind when reviewing white papers that while more descriptive papers may raise fewer concerns, they may also be less valuable. Rather than just describing experiences of transplant professionals, the white papers should map experiences to the ethical considerations, which can be done in a way that is not dictated or required by policy, but is more than descriptive because it is analytical.

2021-2024 OPTN Strategic Plan

UNOS staff presented updates to the OPTN strategic plan proposal, noting that the goal to promote the efficiency of the OPTN was rolled into the goal to increase the number of transplants. The idea is that while efficiency is still important to the OPTN, the OPTN should not be focused on efficiencies that do not increase the number of transplants. The Executive Committee also proposes increasing resource allocation for this goal. The committee added an initiative to increase the number of donation after cardiac death (DCD) donor organs that are recovered and transplanted. The committee also added an initiative to examine differences in access to transplant, as part of a government-sponsored innovation study to look at social determinants of health and access to the waitlist. The Chair noted that the POC's strategic policy priority focused on efficient matching is intended to increase the number of transplants, so that proposed change to the strategic plan is consistent with the discussions held with the POC.

Require Notification of Human Leukocyte Antigen (HLA) Typing Changes

The Histocompatibility (Histo) Committee originally thought it was optimal to implement electronic notifications of HLA typing changes, but the committee is not sure if this would be a substantial benefit relative to the resources required for IT implementation effort. The committee will seek feedback during public comment as to whether electronic notifications would be valuable. The key metric will determine whether requiring immediate reporting results in earlier correction of certain discrepancies. The proposal considers both donor and recipient typing, and timelines for reporting. The committee is also seeking feedback as to whether the OPTN should mandate re-executing the match run following a change in HLA typing.

A member asked if some form of notification other than electronic might suffice. The Histo VC said the committee believes that electronic notification would be the most efficient option, but there are a lot of questions about how to do that, depending on the phase of allocation and who should get notified. For this reason, the committee wanted to gauge the community's interest in electronic notifications before working out the details of how to do that.

Calculate Median MELD at Transplant Around the Donor Hospital and Update Sorting Within Liver Allocation

The Chair noted that the POC has previously discussed the Liver & Intestine Committee's interest in completing this project prior to continuous distribution to even out geographic disparities that previous

policies have attempted to address. The committee will review public comment feedback and decide what they want to present to the Board. The VC of the Pediatrics Committee asked if this proposal still includes ranking calculated model for end-stage liver disease (MELD) and pediatric end-stage liver disease (PELD) candidates above exception candidates. The Liver VC said this would include ranking the non-exception candidates over the exception candidates for the same MELD score. This proposal would not impact the PELD calculation. The Pediatrics Committee has been worried that if this proposal includes PELD and adolescents with a MELD score, this could reverse some of the increases in equity that were just made in the last update to liver allocation. The Liver VC said the committee is sensitive to those concerns and does not think that there will be an impact on those candidates.

Update National Liver Review Board Guidance Documents and Policy Clarification

The Liver and Intestine Committee updated this proposal to include less restrictive guidance for candidates with primary sclerosing cholangitis or secondary sclerosing cholangitis.

Update Membership Requirements and Application and Review Process

This proposal includes revisions to membership requirements for transplant programs and organ procurement organizations (OPOs). Revisions to membership requirements for histocompatibility laboratories will be delayed until August 2021 for public comment.

Vote

Members did not have questions or comments on the remaining items. The POC voted to approve these proposals for public comment (20 – yes, 0 – no, 0 abstain).

Next steps:

The Executive Committee will vote on approval of the public comment items on 01/13/2021.

2. New Projects

The POC reviewed and voted to recommend approval of four new projects.

Summary of discussion:

The POC reviewed the following projects:

- Review of Extension Requirements in Adult Heart Allocation Policy (Heart Committee)
- Improving the MELD Calculation (Liver & Intestine Committee)
- Establish Membership Requirements for Genitourinary Organ Transplant Programs (Vascularized Composite Allograft (VCA) Committee)
- Ethical Considerations of Continuous Distribution in Organ Allocation (Ethics Committee)

Review of Extension Requirements in Adult Heart Allocation Policy

This project is part of a broader effort to clarify heart allocation policy, and this piece will focus on extension requirements for candidates at any given status. The key metric for evaluating this project is the number of consecutive days that candidates spend at particular statuses under an extension. The Heart Committee wants to ensure that there is consistency in how long candidates stay at a status if they no longer meet the qualifying criteria.

The Chair noted that this project falls into an over-allocated goal – increase equity in access to transplants – but the OPTN has several projects in queue that will fall into the category to increase the number of transplants. This is described as a large project but the Heart Committee has the bandwidth to do this work. The Heart VC explained that this project is focused on clarifying policy to answer questions that have been asked of the committee, so it should be straightforward.

Improving the MELD Calculation

This project will address disparities in how MELD is calculated for female candidates and small-statured adults. This project aligns with the strategic plan goal to increase equity in access to transplants. The key metric is to reduce the disparity in liver transplant rate and waitlist removal due to death. The Liver and Intestine Committee has several ongoing projects but this project is not expected to be a huge lift as there is a lot of research to inform how to adjust MELD to address this issue. This project is sequenced to address this disparity prior to the shift to continuous distribution.

A member asked if the committee has considered addressing this in simultaneous liver-kidney allocation, since there is the same muscle mass problem that could result in underestimating or overestimating glomerular filtration rate (GFR). It may be worth considering other equity concerns as part of this project, like whether people should be considered for living donor organs while undergoing a liver transplant, or liver-kidney while undergoing a kidney transplant, instead of evaluating these issues in a piecemeal fashion. The Liver VC said that the proposed solution is to give female candidates 1.3 or 1.4 more MELD points, and these are candidates with liver failure, so it would not really impact the other situations described. This approach would not address candidate size disparities, but the main goal is to give female candidates a few more MELD points. A member noted that there was a recent paper from Jayme Locke on this issue,¹ and asked if there has been any discussion at an international level. The Liver VC was not aware of any international discussion but said that this problem has been discussed for several years, and now there is better data to confirm that there is a problem.

Establish Membership Requirements for Genitourinary Organ Transplant Programs

This project will establish requirements for genitourinary organ transplant programs, particularly for uterus. While uterus has become the most highly sought VCA transplant, current membership requirements do not reflect the expertise needed for these transplants, like obstetrics and gynecology. This aligns with the strategic plan goal to promote living donor and transplant recipient safety, and the key metric is the number of patient safety reports relative to the volume of approved genitourinary organ transplant programs. This is a medium-sized project and the POC agreed that the timing and sequencing of the project is appropriate.

Ethical Considerations of Continuous Distribution in Organ Allocation

This project will develop a white paper addressing ethical considerations of continuous distribution, including selection of attributes for the framework and ethical principles to help guide future discussions. The Ethics Committee does not plan to weigh in on whether continuous distribution is a good idea or ethically justified. Instead, this project would present ethical analyses examining:

- How a continuous distribution framework balances ethical principles, including justice and utility
- Implications of removing hard barriers/boundaries
- Who will be advantaged and disadvantaged, even if temporarily, by this framework
- Representation of stakeholders in the framework and processes by which they have been included in framework development
- Potential for transparent and effective communication of the algorithm to potential candidates
- Process for revising and updating the composite allocation score in light of new data

This project aligns with the strategic plan goal to promote the efficient management of the OPTN and the strategic policy priority on continuous distribution. It is a small project and the Ethics Committee has

¹ Saulat S. Sheikh and Jayme E. Locke, "Leveraging Frailty to Mitigate Sex-Based Disparities in Access to Liver Transplant: Justice in Allocation," *JAMA Surgery*, published online December 30, 2020, doi:10.1001/jamasurg.2020.5675.

the bandwidth to work on this. The timing of this work is important since continuous distribution is well underway for lung and has commenced for kidney and pancreas.

The Chair said that her understanding is that the project is about how the OPTN understands and articulates the ethical principles for continuous distribution, so there will be a consistent ethical framework across all organs. The Chair asked whether looking at groups who might be advantaged or disadvantaged fits into this scope of the project, or if it should be more focused on unpacking the ethical principles for allocation in this framework. The Ethics VC said that the committee considered exploring who might be advantaged or disadvantaged because a member suggested that the community would be interested in that answer, but the Ethics VC agreed to share the feedback with the committee. The Chair said it sounds like the project really is an ethical evaluation of the framework itself rather than how the OPTN can use the framework in the most ethically consistent way. Otherwise, it would be beyond the scope of the work to evaluate who might be advantaged or disadvantaged, based on the work that is already underway. The Chair asked if HRSA staff had any immediate concerns or comments. HRSA staff said they will review the project and provide any feedback within the next week or so.

Vote and Discussion

The POC voted to approve these projects (15 – yes, 0 – no, 0 abstain).

A member noted that a lot of the project sequencing depends on UNOS IT bandwidth, and suggested that the POC should decide which IT projects go first. UNOS staff noted that the IT team has a lot of expertise about the different systems that informs how to sequence this work, but said that it is an interesting idea that can be discussed further.

Next steps:

The Executive Committee will review the projects for approval on 01/13/2021.

Upcoming Meetings

- February 10, 2021
- March 10, 2021

Attendance

- **Committee Members**
 - Alexandra Glazier, Chair
 - Nicole Turgeon, Vice Chair
 - Sandra Amaral
 - Marie Budev
 - Rocky Daly
 - Lara Danziger-Isakov
 - Alden Doyle
 - Garrett Erdle
 - Andrew Flescher
 - Heung Bae Kim
 - John Lunz
 - Paulo Martins
 - Stacy McKean
 - Sumit Mohan
 - Martha Pavlakis
 - Emily Perito
 - James Pomposelli
 - Kurt Shutterly
 - Titte Srinivas
 - Susan Zylicz
- **HRSA Representatives**
 - Vanessa Arriola
 - Marilyn Levi
 - Chris McLaughlin
 - Shannon Taitt
- **SRTR Staff**
 - Jon Snyder
- **UNOS Staff**
 - James Alcorn
 - Kristine Althaus
 - Nicole Benjamin
 - Roger Brown
 - Matt Cafarella
 - Laura Cartwright
 - Julia Chipko
 - Craig Connors
 - Shannon Edwards
 - Betsy Gans
 - Chelsea Haynes
 - Robert Hunter
 - Sarah Konigsburg
 - Lindsay Larkin
 - Jason Livingston
 - Lauren Mauk
 - Meghan McDermott

- Eric Messick
- Elizabeth Miller
- Rebecca Murdock
- Kelley Poff
- Matt Prentice
- Tina Rhoades
- Sharon Shepherd
- Leah Slife
- Peter Sokol
- Kaitlin Swanner
- Kayla Temple
- Susan Tlusty
- Kim Uccellini
- Ross Walton
- Sara Rose Wells