

**OPTN Policy Oversight Committee
Meeting Summary
February 10, 2021
Conference Call**

**Alexandra Glazier, JD, Chair
Nicole Turgeon, MD, Vice Chair**

Introduction

The Policy Oversight Committee (POC) met via Citrix GoTo teleconference on 02/10/2021 to discuss the following agenda items:

1. Public Comment Update
2. Public Comment Presentation: *2021-2024 OPTN Strategic Plan*
3. Contract Requirements and POC
4. New Project
5. Other Business

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

1. Public Comment Update

The Chair presented a public comment update. There were no questions or comments. Public comment will close on 3/23/2021.

2. Public Comment Presentation: *2021-2024 OPTN Strategic Plan*

UNOS staff presented the public comment proposal, *2021-2024 OPTN Strategic Plan*, on behalf of the Executive Committee.

Summary of discussion:

The Chair noted that the three strategic policy priorities (SPPs) previously identified by the POC – efficient matching, continuous distribution, and multi-organ transplantation – align with goals in the strategic plan. The Chair said it makes sense to roll the goal to promote the efficiency of the OPTN into the goal to increase the number of transplants, since the goal of promoting efficiency is ultimately to increase the number of transplants. The Ethics Vice Chair (VC) agreed and said that combining these goals will help the Ethics Committee to think about their projects within that framework.

The Ethics VC asked why increasing the number of donation after cardiac death (DCD) organs is mentioned specifically in the strategic plan, and why living donation is not identified as just as important an initiative for procurement. The Chair noted that the goal to increase transplants does include a goal to increase the effectiveness of paired living donation programs. The Ethics VC suggested that there is nothing more important in the long-term than increasing living donation, and asked why there seems to be an implicit bias against it. The Chair suggested that the strategic plan places an emphasis on deceased donation instead of a bias against living donation, which may be warranted since deceased donation serves all patients waiting for transplant, whereas living donation primarily applies to kidney; to a lesser extent, to liver; and to a very small extent, to lung. The OPTN's ability to promote living donation via policy is more limited than the OPTN's ability to increase deceased donation. However, the Chair agreed that living donation is a key piece to increasing the number of transplants overall, and asked if

the initiative to increase the effectiveness of paired living donation programs is insufficient, and if so, what feedback could be provided to the Board to broaden that initiative. The Ethics VC was in favor of broadening the focus to all living donation. The Ethics VC noted that kidney candidates are the biggest population of patients on the waiting list, so in terms of evaluating whether deceased donor or living donor procurement serves more patients, it really depends on how it is framed.

The VC of the Vascularized Composite Allograft (VCA) Committee said this point was illustrated by the Share 35 policy for pediatric kidney candidates.¹ The number of transplants increased but there was public consternation that it reduced the incentives for living donation. That policy only applied to the small pool of children, but increasing the number of transplants in of itself might not be the right goal if it serves to dampen living donation, as it could reduce quality and access for the population as a whole. In this sense, living donation can be thought of as a counterbalance to deceased donation, and if deceased donation increases, the OPTN should look at how it impacts living donation. The Ethics VC suggested that if more people visited dialysis centers, there would be an overall increase in transplants due to empathy. The Ethics VC said there should be more emphasis on living donation as a means to increase the number of transplants. The Chair summarized that the POC feels that living donation is a key piece of how the OPTN can increase the number of transplants, particularly kidney transplants.

The UNOS CEO said the goal of the strategic plan is to give OPTN committees guidance on the direction of their policy development work, and that increasing living donation sounds more like a hope than a goal. Increasing the effectiveness of paired donation programs was included because the OPTN runs one of these programs, so it is a more actionable initiative. The UNOS CEO asked for any feedback on other mechanisms to increase living donation that would provide more detailed guidance to committees. The Chair agreed that the strategic plan needs to be focused on what is within the purview of the OPTN.

The VC of the Data Advisory Committee (DAC) said the advantage of naming efficiency as a separate goal is that it allows efficiency to be recognized as a significant problem in the current allocation system. The Chair said that the downside with the current strategic plan is that most of the policy projects to increase transplants have actually been categorized under efficiency. This makes it look like the OPTN is not dedicating enough resources to increasing the number of transplants, even though resources are being allocated in that area, so that was one of the arguments for combining these two goals.

Next steps:

The POC will have the opportunity moving forward to develop new SPPs aligned with the strategic plan. The Executive Committee will review public comment feedback before finalizing the proposed 2021-2024 strategic plan to be submitted to the OPTN Board of Directors for approval in June.

3. Contract Requirements and POC

UNOS staff presented on OPTN contract requirements and how they relate to the POC's work.

Summary of discussion

UNOS staff presented metrics included in the contract deliverable for policy development, as well as some additional proposed metrics to aid the POC in monitoring policy development. The Chair explained that POC leadership and UNOS staff proposed these metrics as an effort to track delays late in project development so that the POC can evaluate how to address those issues earlier in the process.

¹ Sandra Amaral et al., "Racial Disparities in Access to Pediatric Kidney Transplantation Since Share 35," *Journal of the American Society of Nephrology* no. 23 (June 2012):1069-1077, <https://doi.org/10.1681/ASN.2011121145>

The VC of the Membership and Professional Standards Committee (MPSC) said these metrics would be a very valuable addition, because it is painful to have a proposal pulled right at the end of the policy development process. The VC of the Kidney Committee agreed and said that that it is similar a transplant center in that if you are trying to figure out where something went wrong, it is helpful to have more data to understand what happened.

HRSA staff thanked UNOS staff for their work on this effort. HRSA staff said they were open to feedback, and the goal of the contract requirements and associated metrics is to make sure everyone is on the same page in terms of authority and compliance.

The Chair thanked HRSA and expressed support for alignment between POC, UNOS, and HRSA to ensure the policy development process moves as smoothly as possible. The Ethics VC supported this approach and said he takes it as a commitment from HRSA to avoid late surprises as long as the committees and UNOS staff have been working with HRSA throughout the process to meet these requirements.

Next steps:

UNOS staff will track progress and periodically report to POC on the metrics required by the contract, as well as the additional metrics identified for POC review.

4. New Project

The POC reviewed one new project, *Non-Citizen/Non-Resident Guidance Document*, sponsored by the Ad Hoc International Relations Committee (AHIRC).

Summary of discussion:

The AHIRC VC explained that the purpose of the guidance document is to educate transplant centers on the differences between non-citizen/non-resident (NCNR) candidates traveling to the U.S. for transplant versus NCNR candidates traveling to the U.S. for reasons other than transplant. The document would:

- Assist programs in their understanding of evaluation, waitlist, transplant, and post-transplant follow-up of NCNR candidates to improve accuracy of reported NCNR recipient follow-up
- Help transplant centers identify resources available in NCNR candidates' home countries for post-transplant follow-up
- Explain how to accurately categorize a candidate as NCNR versus non-U.S. citizen/resident on the Transplant Candidate Registration (TCR)

AHIRC felt it was important to pursue this project due to findings from an information request regarding transplant program level of knowledge around NCNR practices, and lower completion rates of follow-up data collection for NCNR recipients relative to non-NCNR recipients.

POC reviewed the strategic plan alignment and committee bandwidth. The key metrics for the proposal would monitor whether the guidance document effectively explained how to categorize NCNR candidates, and whether the guidance document increased reported follow-up care for NCNR recipients. This project is not aligned with the strategic policy priorities and requires a small amount of resources.

The Chair asked how the goal to increase reporting on follow-up care for NCNR recipients ties into what seems to be the primary goal, which is to ensure that NCNR candidates are categorized correctly. The AHIRC Chair said that AHIRC wants to be good stewards of the organs available in the U.S., and more data will help inform provider decision-making. The Chair asked if AHIRC believes that the low number of form submission indicates that the programs don't know how to fill out the forms, or that follow-up care is inadequate. The AHIRC VC said the committee believes that both issues are contributing factors. The Chair said it makes sense to clarify how to categorize these candidates but was not sure how this

guidance will address concerns about follow-up since centers outside of the U.S. may be responsible for providing that patient care. The AHIRC Chair said patients receive education when they come to the U.S. for transplant, so that is the best opportunity to explain the importance of follow-up care after transplant. This guidance document will provide recommendations for that process.

AHIRC indicated that there would be no collaborating committees on this project. The Chair asked if DAC should be a partner on this project since it touches on the quality of data collection. The AHIRC Chair said they do plan to work with DAC on this effort. The Ethics VC said that the Ethics Committee does not need to be involved right now but could be involved in the future, based on the intersection of the goals to categorize the patients correctly and to promote follow-up data collection.

The VC of the Pediatrics Committee asked for more information on these patients to evaluate if any other committees should be collaborators. The AHIRC Chair said that kidney is the most common transplant for these patients, followed by liver, and occasionally heart or lung. Travel for international patients decreased during the pandemic, but AHIRC believes that this education is extremely important, especially since one program notified AHIRC that they have been categorizing candidates incorrectly when they responded to the information request. The Pediatrics VC said that collecting data on long-term outcomes for pediatric candidates is particularly important, so if there are a sizable number of pediatric NCNR patients, then the Pediatrics Committee should collaborate on this effort. These data may also feed into efforts in continuous distribution to incorporate estimates of post-transplant survival into allocation to a greater degree.

The VCA VC said that her center performs a number of living donations for NCNR patients who go back to their home countries after transplant. The VCA VC recommended that the guidance document consider telehealth as an opportunity for longer-term follow-up on these patients. The VCA VC also recommended that AHIRC consider embassies as stakeholders in this area, because the transplant hospital typically has to negotiate with the embassy regarding conditions for the transplant, and how long the patient can stay in the U.S. The Chair recommended that AHIRC keep in mind the limits of what can go into an OPTN guidance document. Clarifying OPTN data collection would certainly be in scope but guidance on negotiating with embassies may not be in scope.

The Ethics VC said that if the guidance document is restricted to the accuracy of the data, then the Ethics Committee does not need to be involved, but if the document involves the responsibility of following up with people who are vulnerable, then the Ethics Committee would likely have a role and it would be important to tie the accuracy of data to a primary objective like outcomes or safety.

POC voted to approve the project with the recommendation that AHIRC clarify the scope of the proposal and identify additional collaborators as needed (15-yes, 0-no, 0-abstain).

Next steps:

The Executive Committee will review the project for approval on 03/01/2021.

5. Other Business

The Chair welcomed Jennifer Prinz as the incoming Vice Chair of POC, beginning 07/01/2021.

Upcoming Meetings

- March 10, 2021
- April 12, 2021

Attendance

- **Committee Members**
 - Alexandra Glazier, Chair
 - Nicole Turgeon, Vice Chair
 - Sandra Amaral
 - Pramod Bonde
 - Marie Budev
 - Rocky Daly
 - Andrew Flescher
 - Rachel Forbes
 - Heung Bae Kim
 - John Lunz
 - Stacy McKean
 - Sumit Mohan
 - Martha Pavlakis
 - Emily Perito
 - Kurt Shutterly
 - Susan Zylicz
- **HRSA Representatives**
 - Vanessa Arriola
 - Marilyn Levi
 - Shannon Taitt
- **SRTR Staff**
 - Ajay Israni
 - Bert Kasiske
- **UNOS Staff**
 - Brian Shepard, UNOS CEO
 - James Alcorn
 - Sally Aungier
 - Nicole Benjamin
 - Rebecca Brookman
 - Roger Brown
 - Matt Cafarella
 - Liz Robbins Callahan
 - Laura Cartwright
 - Julia Chipko
 - Chelsea Haynes
 - Robert Hunter
 - Sarah Konigsburg
 - Lindsay Larkin
 - Ann-Marie Leary
 - Lauren Mauk
 - Maureen McBride
 - Meghan McDermott
 - Elizabeth Miller
 - Rebecca Murdock
 - Matt Prentice

- Laura Schmitt
- Sharon Shepherd
- Leah Slife
- Susie Sprinson
- Kaitlin Swanner
- Susan Tlusty
- Joann White
- **Other Attendees**
 - Alejandro Diez
 - Barry Friedman
 - PJ Geraghty
 - Zoe Stewart Lewis
 - Dolamu Olaitan
 - Jennifer Prinz