

**OPTN Policy Oversight Committee
Meeting Summary
September 9, 2020
Conference Call**

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

Introduction

The Policy Oversight Committee (POC) met via Citrix GoTo teleconference on 09/09/2020 to discuss the following agenda items:

1. Public Comment Update
2. New Projects
3. Operations and Safety Committee Broader Distribution Data Collection Project Update
4. Workgroup Recommendations
5. Reminders

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

1. Public Comment Update

The Vice Chair of the Disease Transmission Advisory Committee (DTAC VC) presented an update on feedback received to date on the proposal *Align OPTN Policy with U.S. Public Health Service Guideline, 2020*. The Vice Chair of the Liver and Intestine Committee (Liver VC) presented an update on feedback received to date on the proposal *Further Enhancements to the National Liver Review Board*. The Chair explained that this information was being shared for awareness so there was no action required from the POC unless they had specific questions or concerns.

Summary of discussion:

The DTAC VC shared that the proposal *Align OPTN Policy with U.S. Public Health Service Guideline, 2020* has received consistent feedback regarding suggested improvements. Suggestions include modifying the living donor specimen storage requirement to less than ten years; reconsidering universal post-transplant testing; allowing more than 96 hours for repeat testing; allowing for more than a 24-hour window for donor sample storage; and clarifying the new "informed consent" process. POC members did not have additional feedback.

The Liver VC shared that the proposal *Further Enhancements to the National Liver Review Board* has received a significant number of comments related to candidates with primary sclerosing cholangitis (PSC). Candidates with PSC typically have low calculated Model for End-stage Liver Disease (MELD) scores and poor quality of life, but historically low waiting list mortality. Current guidance for PSC is restricted to candidates with higher mortality risk, and the comments advocate for higher priority for PSC candidates based on poor quality of life factors. The proposal currently out for public comment does not include changes to PSC guidance, but the Liver & Intestine Committee has submitted a data request and plans to consider changes to PSC guidance as part of an upcoming project.

Next steps:

Public comment will remain open until October 1, 2020.

2. New Projects

The POC reviewed two new projects: *Updating National Liver Review Board Guidance and Policy Clarifications*, sponsored by the Liver & Intestine Committee, and *Transplant Program Performance Monitoring Enhancement*, sponsored by the Membership & Professional Standards Committee (MPSC).

Summary of discussion:

Updating National Liver Review Board Guidance and Policy Clarifications

The Liver VC explained that the purpose of this project is to update guidance documents for the National Liver Review Board (NLRB) to better reflect current clinical practice and experience with the NLRB. Changes to guidance for the Pediatric specialty board would address clinical problems associated with pediatric patients that are not necessarily reflected in PELD (Pediatric End-stage Liver Disease), including complications of portal hypertension, including ascites and gastrointestinal bleeding; growth failure/nutritional insufficiency; metabolic liver disease; and other situations not currently addressed. The policy change would address standardized criteria for cholangiocarcinoma (CCA) exceptions. The Liver & Intestine Committee would also review guidance for candidates with PSC as part of this project based on the recent public comment feedback.

The POC considered the impact of this project relative to the strategic plan, the strategic policy priorities, and the committee's current workload. The Liver & Intestine Committee plans to collaborate with the Patient Affairs Committee and the Pediatrics Committee on this project.

Discussion

The Chair asked the POC for any feedback on the timing and sequencing of this project, and for any additional feedback to improve alignment across projects. The Liver VC explained that the committee is proposing this project now in response to feedback from members currently serving on the NLRB. The Vice Chair of the Pediatrics Committee (Pediatrics VC) said that this project complements an ongoing project related to pediatric liver candidates, since this project will address issues impacting pediatric liver candidates not covered by the other project.

The Vice Chair of the Kidney Committee (Kidney VC) noted that the Kidney Committee is also doing a pediatric workgroup to consider how to make sequence C kidneys from pediatric donors available for pediatric candidates. The Kidney VC was not sure if there are synergies between these two projects or if there needs to be more coordination or communication across these two projects. The Pediatrics VC said that the Pediatrics Committee has been following developments in these two projects, and that the NLRB updates are mostly disease-specific and may not be directly applicable to the kidney project. The Chair affirmed that the POC is a great place for these conversations to take place to coordinate work across committees.

Transplant Program Performance Monitoring Enhancement

UNOS staff explained that the purpose of this project is to develop a balanced scorecard to achieve a more holistic approach to evaluating transplant program performance. The MPSC currently only uses a single metric to identify transplant programs for assistance with performance improvement: one-year post-transplant graft and patient survival. The project would also evaluate new ways to monitor, collaborate with, and provide assistance to OPTN members.

Strategic Plan Alignment

This project is aligned with the strategic goal to improve waitlisted patient, living donor, and transplant recipient outcomes. The Chair said that if the goal of the measurement is performance improvement, that could ultimately result in increasing transplantation. In other words, broadening the scope of what

the MPSC might consider beyond patient outcomes to process performance points could increase the number of transplants. UNOS staff noted that the MPSC has discussed selecting metrics that will help increase the number of transplants rather than introducing disincentives to pursue certain organs.

The POC considered the impact of this project relative to the strategic policy priorities and the committee's current workload. MPSC expects to collaborate with DAC, the Ethics Committee, the Organ Procurement Organization (OPO) Committee, the Minority Affairs Committee (MAC), the Transplant Administrators Committee (TAC), and the Transplant Coordinators Committee (TCC), primarily by soliciting feedback prior to public comment to inform the MPSC's proposal.

Discussion

The Chair said that development of a better metric is really important, especially if it will hit on process points, which are the focus of the strategic policy priority related to efficiency. The Chair said that this project should move forward right away. The Vice Chair agreed that this project is really needed, and asked if there is any thought that there might need to be different metrics for different organs, which would change the landscape for how this project develops. UNOS staff affirmed that the MPSC has been discussing whether there should be variations in the scorecards based on organ type.

The POC approved both projects (17 – yes, 0 – no, 0 – abstain).

Next steps:

The projects will go to the Executive Committee for approval during their meeting on 9/18/2020.

3. Operations and Safety Committee Broader Distribution Data Collection Project Update

UNOS staff presented an update on the Operations and Safety Committee's (OSC) project on broader distribution data collection.

Summary of discussion:

The goal of this project is to develop data collection for evaluating the logistical impact of broader distribution, following allocation policy changes across organs that have expanded the range of organ distribution. This project was approved by POC on 5/10/2019. A request for feedback was released for public comment in Fall 2019, during which time the transplant community expressed support for data collection to evaluate the logistical impact of broader distribution, specifically "mode of transportation." A report on this feedback was delivered to the OPTN Board of Directors in December 2019, and a data collection proposal is currently in development. The project is co-sponsored by DAC. The scope of the project has expanded to evaluate current data related to travel, like perfusion and cold ischemic time.

The POC considered the impact of this project relative to the strategic plan, the strategic policy priorities, and the committee's current workload. OSC will be collaborating with members of DAC, OPO, TCC, and TAC for this project.

Discussion

The Chair said it is important that the workgroup includes members from DAC since it is a data collection project. In terms of alignment with the strategic policy priorities, the project does align with the efficient matching priority because it could support other work in that area, as well as the ongoing continuous distribution work. The Chair asked if there has been an evaluation of how this project needs to be coordinated with other work to support the efficient matching projects. One example is the ongoing review of the Deceased Donor Registration (DDR) sponsored by the OPO Committee. The OSC originally suggested collecting some of this data on the DDR, so there will be some overlap with that effort. The UNOS support teams will coordinate to avoid duplication of efforts. An attendee asked if this project will

also tie into an ongoing UNOS Labs project looking at transportation. UNOS staff said they have been coordinating with the UNOS Labs team as well.

The Chair asked when the OSC expects to have a proposal to release for public comment. The goal is August 2021. Since this project will involve a more extensive review of the data and the workgroup intends to look at data across multiple data collection instruments, that will take some time. The Chair noted that will be about two years from the time of project approval to getting something out for public comment, and almost three years until anything comes out, which is a fairly long time. The Chair asked if this project will still deliver value, since things have changed so much since 2019 when this project was first reviewed and there are other ongoing related projects.

The OSC Chair said that unless the OPTN starts to identify the data that needs to be collected, then two years from now, members will wish that the OPTN had started gathering this data. The timeline is long, but it is important to have time for stakeholders to weigh in so as not to overburden anyone with data collection. The OSC Chair said that the workgroup can evaluate whether it is possible to accelerate the timeline or if the original plan is appropriate to identify the data needed to assess the impact of broader sharing. The Vice Chair said this topic comes up often in regional meetings, and the focus of this particular project gives the issue the visibility it needs outside of related efforts. The Chair asked the OSC Chair to check in with other projects that might want to use this data in various ways to make sure that the proposal meets the needs of those projects.

A member asked if there are milestones with this project that should be aligned with milestones of other related projects. The Chair said it is difficult to do that until there is a better understanding of what data would be collected. The DAC VC said that a lot of these projects take far too long to get to a conclusion and get them out to public comment.

The UNOS CEO said there may be some data in this area that should be collected from everybody for a long time. There may also be a need for a study that involves a handful of willing participants from different regions and different operational statuses that could deliver answers faster, and then the OPTN could decide if that data needs to be collected forever. The OSC Chair agreed that it will be important to work in conjunction with the UNOS Labs project.

Next steps:

OSC will develop a proposal with the goal of releasing it for public comment by August 2021.

4. Workgroup Recommendations

The Workgroup Chairs presented the recommendations from their workgroups.

Summary of discussion:

Biopsy Standards and Practices

The OSC Chair presented the recommendations of the Biopsy Standards & Practices Workgroup:

- Develop a minimum set of donor kidney criteria appropriate for biopsy
 - Timeframe: Short term
 - Priority: High
 - Proposed sponsor: Kidney Committee, possible workgroup with OPO Committee
- Develop guidance to maximize the use of image sharing technology across the entire network
 - Timeframe: Short term
 - Priority: High
 - Proposed sponsor: Network Oversight and Operations Committee or OSC

- Develop a form that pathologists would complete during biopsy readings to allow for consistent analysis across OPOs and transplant programs
 - Timeframe: Short term
 - Priority: High
 - Proposed sponsor: Workgroup consisting of Kidney, Liver & Intestine, and Data Advisory committee members
- Develop a minimum set of donor criteria appropriate for bedside liver biopsy
 - Timeframe: Short term
 - Priority: Moderate
 - Proposed sponsor: Liver & Intestine Committee, possibly with OPO Committee participation

The OPO VC said that the American Society of Transplantation (AST) just put out some guidance on this. The OPO VC volunteered to help evaluate how the guidance aligns with the recommendations of the workgroup. The Liver VC asked why the recommendations did not include adding photo documentation for liver and lung, and video documentation for heart. The OSC Chair agreed that available imaging tools should be utilized more frequently. The Chair said that the POC can provide some of this feedback directionally when the POC pushes work to committees. The Vice Chair said that the local recovery workgroup recommendations also touch on image sharing.

Local Recovery

The Local Recovery Workgroup Chair (LR Chair) presented the recommendations of the Local Recovery Workgroup:

- Consider expanding expedited placement policy to all organs as a method of promoting local recovery
 - Timeframe: Long term
 - Priority: High
 - Proposed sponsor: OPO Committee
- Streamline communications in DonorNet® to allow OPOs the ability to update status of donors and send push notifications before, during, and after allocation
 - Timeframe: Long term
 - Priority: High
 - Proposed sponsor: OSC in collaboration with current UNOS programming efforts
- Guidance on consistent practices for the organ recovery process to provide transplant programs with considerations when deciding whether or not to use a local recovery team
 - Timeframe: Short term
 - Priority: Low
 - Proposed sponsor: OSC with workgroup including OPO, Kidney, Pancreas, Heart, and Liver & Intestine committees
- Guidance on best practices for the organ recovery process, including ethical implications of certain practices observed currently
 - Timeframe: Short term
 - Priority: Low
 - Proposed sponsor: Ethics Committee

With regard to the last recommendation, the LR Chair gave examples of surgeons evaluating a heart or liver, declining the organ, and walking out, instead of waiting to see if another program would consider using that organ. The LR Chair suggested collaborating with professional societies to develop this

guidance. The Chair said that it did not seem necessary for the Ethics Committee to state that a surgeon should not walk out when there is a surgery that could be done to save a patient's life. The Chair said this should not be separate from a best practices document so the last two recommendations could be combined in one effort. Members did not have additional comments or questions.

Next steps:

For the next POC meeting, POC leadership will sort the recommendations from the three workgroups. POC leadership will facilitate a conversation with the POC about which recommendations should be sent immediately to committees to start work; which recommendations should be delayed for future work; and which recommendations may require further information before the POC can make a decision.

5. Reminders

UNOS staff presented the following reminders:

- Board and Committee nominations are open through 9/30/2020
- Public comment is open through 10/1/2020
- Virtual regional meetings are ongoing, and members are encouraged to attend
- Members are encouraged to participate in the prioritization exercise associated with the continuous distribution project
- Members are encouraged to submit their feedback regarding the OPTN Regional Review through 10/1/2020
- Information on all of these reminders are available on the OPTN website

Upcoming Meetings

- October 14, 2020
- November 5, 2020

Attendance

- **Committee Members**
 - Alexandra Glazier, Chair
 - Nicole Turgeon, Vice Chair
 - Sandra Amaral
 - Marie Budev
 - Rocky Daly
 - Lara Danziger-Isakov
 - Garrett Erdle
 - Andrew Flescher
 - Rachel Forbes
 - John Lunz
 - Stacy McKean
 - Sumit Mohan
 - Martha Pavlakis
 - Emily Perito
 - Jim Pomposelli
 - Kurt Shutterly
 - Susan Zylicz
- **HRSA Representatives**
 - Marilyn Levi
 - Shannon Taitt
- **SRTR Staff**
 - Katie Audette
 - Jon Snyder
- **UNOS Staff**
 - Brian Shepard, CEO
 - James Alcorn
 - Sally Aungier
 - Rebecca Brookman
 - Matt Cafarella
 - Laura Cartwright
 - Julia Chipko
 - Craig Connors
 - Robert Hunter
 - Sarah Konigsburg
 - Lindsay Larkin
 - Meghan McDermott
 - Elizabeth Miller
 - Rebecca Murdock
 - Matt Prentice
 - Sharon Shepherd
 - Leah Slife
 - Kiana Steward
 - Kaitlin Swanner
 - Kim Uccellini
 - Emily Ward

- Joann White
- **Other Attendees**
 - Chris Curran
 - Michael Marvin
 - Kim Rallis