

## **OPTN Policy Oversight Committee**

### **Meeting Summary**

**August 12, 2020**

**Conference Call**

**Alexandra Glazier, JD, Chair**

**Nicole Turgeon, MD, Vice Chair**

### **Introduction**

The Policy Oversight Committee (POC) met via Citrix GoTo teleconference on 08/12/2020 to discuss the following agenda items:

1. Workgroup Updates
2. New Project
3. OPTN Strategic Plan Discussion

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

#### **1. Workgroup Updates**

The POC received updates on the progress of three workgroups sponsored by the POC: Local Recovery, Biopsy Standards, and Provisional Yes. The workgroups were asked to develop recommendations for project ideas (either short term or long term) on these topics, and these updates included preliminary recommendations under consideration.

#### Summary of discussion:

##### *Local Recovery*

The Local Recovery Workgroup is considering the following recommendations:

- Communication Enhancements in DonorNet® to better facilitate local recovery
- OPTN policy that considers the role of local procurement in expedited placement projects (i.e. what happens when an organ is turned down by a recovering surgeon)
  - Guidance to promote consistent practices in local organ recovery process
  - Guidance addressing best practices in local organ recovery process

A member asked if this group is taking into account the economics of local recovery. The Vice Chair said that the workgroup is focused more broadly on developing project ideas that will promote efficiency in the system, so the workgroup is not looking at economic aspects at this time. However, when the recommended approaches are handed over to committees for further work, then those committees could consider economic aspects of local recovery.

##### *Biopsy Standards*

The Biopsy Standards Workgroup is considering the following recommendations:

- Minimum set of donor kidney criteria for biopsy
- Minimum set of criteria for pre-recovery liver biopsy
- Project aimed to maximize the use of image sharing
- Recommendations on type of pathological readings which can be performed with each tissue

- Recommendations on samples for pathology in clinical assessments of the donor suitability as well as other non-organ pathological assessments

A member expressed support for these recommendations, and said that this topic is especially important for kidney since the community has been doing pre-transplant biopsies for a long time without any standardization.

### *Provisional Yes*

The Provisional Yes Workgroup is considering the following recommendations:

- Top recommendations:
  - Dynamic match run (as donor conditions may change that would alter provisional yes)
  - Conditional yes option
  - Increased offer filters (system implementation)
- Additional ideas that may be considered based on the results of a pending data request:
  - Slowing the escalation pattern
  - Limiting the number of offers, including provisional yes, that are sent by organ procurement organizations (OPOs)
  - Consequences or regulation for centers that accept provisional yes but then turn down once primary

The workgroup submitted a data request to UNOS regarding provisional yes behavior and will be reviewing the results of that data request on September 1<sup>st</sup>.

A member said that this is a really important issue, particularly with broader sharing, since transplant programs are getting more organ offers. The member said that provisional yes can create a jam as OPOs make offers on the match run and programs decline, and if this issue is not resolved, it could result in organ discard because of the time it takes to allocate an organ. The member said that increased use of offer filters will be critical since they can be customized for each candidate. The member asked for more information on the conditional yes and dynamic match run approaches.

The Provisional Yes Workgroup Chair (PY Chair) explained that the conditional yes approach would allow transplant programs to indicate the conditions under which they would accept an offer, and if the organ does not meet those conditions, then the transplant program would be bypassed and no further action would be required. For the dynamic match run, the idea is that the filters for the match run could change as characteristics of the donor organ change to screen off candidates for whom transplant programs would not accept the organ.

The member said that if the Workgroup recommends pursuing consequences or regulations for programs using provisional yes inappropriately, then the Membership and Professional Standards Committee (MPSC) should be involved in that effort since it potentially involves monitoring and adverse actions. The PY Chair agreed and said that this approach would be intended to impact only those programs showing a significant, consistent pattern of this behavior.

The member offered a suggestion for an additional approach: using artificial intelligence to better match donors and recipients using real-time data, including how long the candidate has been on the waiting list, and how long the candidate is likely to remain on the waiting list if the offer is turned down. The PY Chair said this was an excellent suggestion and that the workgroup will be reviewing more information from UNOS related to technological capability.

A member said that all three of these projects would be enhanced with standardized photo documentation for both organ procurement and pathology, and perhaps even video for donor hearts.

The member said that if he has laboratory studies and images of a liver, he can decide whether or not to accept the liver. Similarly, heart surgeons often just need to take a look at a heart and see how it is beating to know whether or not they want to accept it. If there were a standardized way to take pictures and upload them to UNet<sup>SM</sup>, perhaps even using smart phones with microscope attachments, that would help these efforts.

The Biopsy Standards Workgroup Chair asked if the PY Workgroup has considered updating OPTN policy to provide a more robust description of what it means to be a backup offer. The PY Chair said the workgroup has not discussed that specifically since they have been more focused on project ideas rather than specific policy changes. The PY Chair said that workgroup discussions have included a lot of anecdotes, so the workgroup is looking forward to the results of the data request to have a better idea of the scope of the problem. Since there are different incentives for each situation, especially depending on the quality of the organ, the data may help tease out those occurrences. The Biopsy Standards Workgroup Chair suggested adding a recommendation to add structure to the policy language around backup offers to help prevent organ discards.

A member said that these recommendations were going down the right path, especially with their focus on the match run. From an OPO perspective, the member said that something has to change in response to broader sharing because it is taking too long to place organs. OPOs and transplant programs need to find consensus on a better way to allocate organs. The member said that transplant programs should take backup offers seriously and review the information rather than simply selecting provisional yes.

Another member expressed support for this effort, saying that the number of offers has gotten out of hand. The member said it is common to be offered a lung while #130 on the list, even though there are 50 to 70 provisional yeses ahead, so there is not a lot of incentive to spend time reviewing that offer. The member said it is helpful when transplant programs are notified that they are the next backup.

Next steps:

The Local Recovery Workgroup and the Biopsy Standards Workgroup will present their final recommendations to the POC by September 9<sup>th</sup>. The Provisional Yes Workgroup will present their final recommendations to the POC by October 14<sup>th</sup>.

**2. New Project**

The POC considered a new project entitled “Tracking Candidate Listings for COVID-19 Related Organ Failure,” sponsored by the Lung Committee.

Summary of discussion:

The Vice Chair of the Lung Committee noted that these candidates would be assigned a diagnosis code under Group D since candidates with COVID-19 related lung failure are currently being listed using diagnoses in this group. Adding the new diagnosis codes, which distinguish between acute and chronic lung disease caused by COVID-19, will provide the OPTN with more granular data. The Lung Committee is pursuing expedited approval in order to start this process quickly and would come back to the POC later this month with a full proposal. The POC voted to approve this project (16-yes, 0-no, 0-abstain).

Next steps:

The POC will review the public comment proposal associated with this project on August 24<sup>th</sup>. The Executive Committee will review the project and proposal for approval at the end of August.

### 3. OPTN Strategic Plan Discussion

The UNOS CEO provided an overview of the strategic planning process and ideas raised by the OPTN Board and committee chairs. The CEO asked for feedback from the POC, noting that it is important for the POC to be involved in the early stages so that the plan aligns with committee work moving forward.

#### Summary of discussion:

The CEO outlined the major strategic plan goal categories, consistent with the existing strategic plan:

- Increase transplants
- Equity in access
- Waitlisted patient, living donor and transplant recipient outcomes
- Living donor and transplant recipient safety
- Efficiency in donation and transplant

The CEO shared additional ideas aligned with the POC's strategic policy priorities:

- Ideas currently underway aligned with POC's existing strategic policy priorities:
  - Improve equity in transplant opportunities for multi-organ and single organ candidates (Multi-Organ)
  - Reduce geographic disparity in access to transplant (Continuous Distribution)
  - Measure and improve organ allocation efficiency (Efficient Matching)
- Ideas outside of current work but aligned with POC's existing strategic policy priorities:
  - Improve logistics, safety, and transportation of organs
  - Improve efficiency in the policy development and implementation process
  - Increase seamless data exchange between members and UNet

The Chair noted that the POC now has the opportunity to align the strategic policy priorities with the broader OPTN strategic plan. The Chair asked the POC if there is anything listed that should not be a high priority because it will not have a big impact across the system, or if there is anything missing that should be a high priority because it would deliver a bit impact across the system. The Chair emphasized that removing something from the strategic plan does not mean that it is not important work, just that the OPTN does not need to place strategic focus on this work. The Chair encouraged members to think about the information they will need as they become the chairs of their committees in order to align their committee work with the strategic plan. The Chair asked members to consider the ideas listed above that are outside of current work but aligned with POC's strategic policy priorities, and asked whether any of these ideas should be added to the strategic plan as a goal.

A member said that efficiency is a reasonable goal for the OPTN. The member noted that the OPTN is in the process of moving towards continuous distribution, and increasing efficiency is supposed to be part of that effort. The member said there is some overlap between the proposed ideas and ongoing work.

The Vice Chair of the Data Advisory Committee (DAC VC) said that one thing that is missing is that data almost invariably becomes an afterthought. The DAC VC said that the strategic plan does not reflect that if the OPTN wants to change things, there needs to be a better way to acquire the data for the things that the OPTN wants to measure, but the OPTN also needs to be aligned on what the OPTN wants to measure. The DAC VC said that OPTN members are generally aligned on the goals of achieving a more efficient allocation system and better outcomes, but the question then becomes how the OPTN measures those goals and what that system looks like. When the data is an afterthought, then the OPTN does not have the data to develop good measures and feedback loops.

A member said that one thing that is missing in terms of equity is equity of the sexes, since women and other adults of small stature are disadvantaged by the current MELD (Model for End-stage Liver Disease) system for liver. A member said that another ongoing equity challenge is pediatric prioritization and how it fits in with these concepts of efficiency and utility. For example, there has been a lot of literature recently regarding KDPI (Kidney Donor Profile Index) and its inadequacy for pediatric candidates. Conceptually, the concern is that focusing solely on efficiency and increasing the number of transplants is not really hitting the target. The OPTN must balance the rationing of organs in a way that is effective and efficient. If everyone gets a transplant but everyone dies, that is not a good outcome, so it is about counterbalancing these competing priorities in diverse populations.

The Vice Chair of the Ethics Committee (Ethics VC) said the Ethics Committee has discussed that three of the strategic plan goals represent utility, whereas there is only one strategic plan goal that represents equity. The Ethics VC said that sometimes there is a perception problem because there is a reality problem. Particularly given the current situation in our country, there has been some discussion that the OPTN should make equity a priority in terms of who recipients are, in general.

The CEO said that the strategic plan will be a governing document and a prioritization document, and in the end it is about making specific, actionable decisions over a defined period time. The CEO said that the POC should not get caught up in trying to decide whether something is inherently valuable, but focus more on the things that the OPTN should do right now. The CEO said that the OPTN has a big focus on equity, though there may be more projects that the OPTN can do on this topic. While brainstorming, the OPTN tends to default to changing allocation. In order to do more transplant type of projects, OPTN members need to push themselves to move beyond the tendency to make changes to allocation. The goal is to push OPTN policymakers out of that comfort zone to make sure all bases are covered.

The Chair asked if members identified any possible new strategic policy priorities when they were reviewing the strategic plan document. Members did not have any suggestions.

#### Next steps:

The Chair will consolidate feedback to share with the OPTN Board, including the POC's support for maintaining the same general categories in the strategic plan, and the feedback on addressing racial inequities and inequities based on sex. The Chair encouraged members to email her with any additional feedback on the strategic plan.

#### **Upcoming Meetings**

- August 24, 2020
- September 9, 2020
- October 14, 2020

## Attendance

- **Committee Members**
  - Alexandra Glazier, Chair
  - Nicole Turgeon, Vice Chair
  - Sandra Amaral
  - Marie Budev
  - Rocky Daly
  - Garrett Erdle
  - Andrew Flescher
  - Rachel Forbes
  - Hueng Bae Kim
  - John Lunz
  - Paulo Martins
  - Stacy McKean
  - Sumit Mohan
  - Martha Pavlakis
  - James Pomposelli
  - Kurt Shutterly
  - Titte Srinivas
- **HRSA Representatives**
  - Vanessa Arriola
  - Marilyn Levi
  - Arjun Naik
  - Raelene Skerda
  - Shannon Taitt
  - Robert Walsh
- **SRTR Staff**
  - Katie Audette
- **UNOS Staff**
  - Brian Shepard, UNOS CEO
  - James Alcorn
  - Kristine Althaus
  - Nicole Benjamin
  - Rebecca Brookman
  - Matt Cafarella
  - Laura Cartwright
  - Scott Castro
  - Julia Chipko
  - Craig Connors
  - Shannon Edwards
  - Chelsea Haynes
  - Sarah Konigsburg
  - Maureen McBride
  - Meghan McDermott
  - Eric Messick
  - Elizabeth Miller
  - Kelley Poff

- Matt Prentice
- Tina Rhoades
- Leah Slife
- Peter Sokol
- Susie Sprinson
- Kiana Stewart
- Kaitlin Swanner
- Ross Walton
- Sara Rose Wells
- Joann White
- **Other Attendees**
  - Chris Curran
  - Kim Rallis
  - Craig Van De Walker