

**OPTN Executive Committee
Meeting Summary
December 4, 2022
St. Louis, Missouri and Webex**

Jerry McCauley, MD, MPH, FACP, Chair

Introduction

The OPTN Executive Committee met in St. Louis, Missouri and via Webex on 12/04/2022 to discuss the following agenda items:

1. New Projects from the Policy Oversight Committee (POC)*
2. Network Operations Oversight Committee (NOOC) Bylaw Enhancement Project Preview
3. MPSC Communication to the Community*
4. Predictive Analytics
5. Lung Continuous Distribution Update*

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

1. New Projects from the Policy Oversight Committee (POC)*

Dr. Nicole Turgeon, Chair of the Policy Oversight Committee (POC), presented two new projects from the POC. The first project was OPTN KPD Blood Type Policy Alignments and Donor Re-Evaluations Efficiency Requirements. This project would remove the specific titer requirements and require transplant programs to establish their own protocols for transplant non-A1B kidneys into blood types O and B candidates. The project would also require annual donor re-evaluation in the OPTN KPDP. The project aligns with the strategic goal to increase the number of transplants by improving efficiency by ensuring donor information is up to date.

Dr. Turgeon also presented the project on Improving Access to Transplant for Multivisceral (MVT) Candidates. The purpose of the project is to ensure MVT candidates are provided appropriate access to transplant by creating National Liver Review Board (NLRB) guidance to allow for more consistent and equitable approval of MELD exceptions for this population. This project aligns with the strategic goal to provide equity in access to transplants.

Summary of discussion:

During the discussion on the KPD Blood Type Policy Alignments and Donor Re-Evaluations Efficiency Requirements, a committee member urged the group to broaden the discussion around KPD and discuss how much the OPTN is going to invest in KPD. Dr. Turgeon reminded the committee member that there is an OPTN KPD Workgroup that can address this topic, and noted that this project is one step in the right direction towards expanding KPD. Another committee member agreed that this is the type of project that could be discussed at a higher level to determine the amount of resources the OPTN wants to devote. Another committee member agreed with the need to expand the work of KPD and to discuss what the goals of KPD should be. Dr. Maureen McBride, OPTN Executive Director, reminded the group that operating the KPD program is a requirement of the OPTN Contract and that the OPTN can work with HRSA to better understand the priorities of the workgroup and KPD in general.

Vote:

The Executive Committee unanimously approved the initiation of the two new projects from the Policy Oversight Committee.

2. Network Operations Oversight Committee (NOOC) Bylaw Enhancement Project Preview

Edward Hollinger, Chair of the Network Operations Oversight Committee (NOOC), presented the committee's project to enhance existing bylaws to strengthen the security of the OPTN Computer System. The recommendations of the revisions to the bylaws would be to require members to follow the OPTN Contractor's terms of use when using the OPTN Computer System, clarify which membership types included access to the OPTN Computer System, define baseline security requirements for all OPTN Members, and to require notice to the OPTN if an incident occurs at an OPTN member institution that accesses the OPTN Computer System or with software that exchanges data with the OPTN Computer System. Dr. Hollinger spoke on some of the challenges involved when adopting an enhanced OPTN Security Policy. The next steps for the committee's work are to define baseline security requirements for all OPTN Members and Non-Members and plan to submit a proposal for January 2023 public comment.

Summary of Discussion:

A representative from HRSA started the discussion portion by noting HRSA's support of bolstering cybersecurity policies around member institutions. They commented how important this project was to HRSA and commended the work that the NOOC is doing. A member of the Executive Committee encouraged the NOOC to review what requirements other entities require from OPOs, transplant centers, and laboratories and noted that different regulatory agencies have varied requirements. They also encouraged the NOOC to evaluate the impact of the environment of the different member types and their operations. Dr. Hollinger informed the group that the NOOC is working to make the framework flexible enough for members to implement but not so flexible that the requirements are not adhered to. Dr. Hollinger also agreed that the scope across the different member entities looks vastly different from each other and NOOC is working to identify the potential risks and benefits with each. The committee is also working to identify what the biggest gaps are in the operations to identify any issues different member types may experience.

A committee member acknowledged the varied systems members may use and the costs associated with each and asked if the NOOC has determined how much something like this may cost for different member institutions. They also asked if the OPTN could lose members because of their inability to meet the standards set by the policy. Dr. Hollinger informed the member that the NOOC met with the Fiscal Impact Group (FIG) the week before and are working with the group to determine what the different costs may be for different member types. Dr. Hollinger said that the NOOC hopes to receive more clarity about different member entities' security during public comment.

A committee member asked what an OPO would do if a lab they collaborate with is struggling to meet the member requirements. Dr. Hollinger said that the level of access is critical to this question. The level that some of the smaller members interact with the OPTN Computer System is a little lower and the framework the NOOC is developing is not going to be a one size fits all type framework. They understand that there are different security needs and parameters for different member institutions.

3. MPSC Communication to the Community

Zoe Stewart Lewis, Chair of the Membership and Professional Standards Committee (MPSC) presented an action item for the committee to vote on pertaining to the committee's communication with the community. The MPSC hopes to increase communication with the community to help promote safety and compliance and increase transparency. The committee hopes to make resources and

communications available on the OPTN website for public access. The MPSC is asking the Executive Committee for authority to communicate with members of the community about potential safety events and MSPC activities.

Summary of Discussion:

A committee member offered some considerations to the committee such as identifying the difference in the two types of NRP and the different conversations each one receives. They encouraged the MPSC to not combine NRP into one term and to bifurcate them instead. Another committee member encouraged the MPSC to ensure their messaging to members is different than the other emails members receive from the OPTN so they do not get lost amongst other correspondence. A committee member thought that the MPSC should work with the OPTN Operations and Safety Committee and the OPO Committee to pull in multiple other organizations to ensure this is successful. A committee member offered their view that although standards are important, they do not want the MPSC to get ahead of themselves and start regulating something before they have figured out what works best. They also said that being able to distribute information about lessons learned is extremely important. A committee member emphasized how important it is for the lessons learned through the MPSC to be shared with the greater public and the lessons that could be learned from them. They also emphasized the importance of anonymity and confidentiality when it comes to self-reporting, so members feel comfortable when reporting. Dr. Stewart Lewis emphasized the importance of anonymity and confidentiality for members to self-report. She noted that MPSC is aware that if confidentiality were ignored then members may hold back with self-reporting or redact information to the point where the MPSC cannot fully understand the situation. A committee member said that providing insight to members about the types of incidents that have occurred will help members understand situations and be proactive with their own programs and evaluating their own risk.

Vote:

The committee unanimously approved the proposal from the MPSC to delegate authority to the MPSC to communicate with the community about potential safety issues and the work of the MPSC via reports, emails, and other methods necessary.

4. Predictive Analytics

Alex Tulchinsky, Chief Technology Officer, and Laura Cartwright, Manager of Research Science, presented an update to the committee on predictive analytics. Mr. Tulchinsky presented on the collaboration between the OPTN and Accenture on the project, the phases of the project, the feedback from beta testing, and the purpose of the pilot program. The committee was briefed on the monitoring and measurement of the pilot project to monitor offer decision making, gather user feedback, and the monitoring of the models. The modeling updates presented to the committee detailed that monitoring results are consistent with previous reports, the modeling team is continuing to improve methodology, and the Human-Centered Design team is working to refine the user display. Mr. Tulchinsky detailed the continuing cycle of feedback the team has utilized for the national rollout. The goal is to gather feedback to analyze what actions to take and following up with the users of the system to see where improvements may be made. He highlighted the disclaimer on the page was created due to feedback from the advisory group. The disclaimer says that the information shown is to help someone make decisions, the engine is not meant to make the decisions for them.

Summary of Discussion:

A committee member commended the group's work and how extraordinary this will be for the transplant community. A committee member suggested the group provide the information about what

one's chances of survival is when they receive a higher KDPI offer versus receiving a significantly better offer. They continued that offers are not static and wondered if cold ischemic time is built into this model yet. Mr. Tulchinsky and Dr. Cartwright confirmed that it was not. Dr. Cartwright continued that one of the most challenging parts of the work has been to determine what the next best offer may be. The committee member encouraged them to include the time that the offer is given, in terms of cold ischemic time. They also suggested they include the estimated time of arrival of the organ.

A committee member asked to confirm that the group is going to track the results of the predictions, and Dr. Cartwright explained that the group will track what the predictions originally were and what the real outcomes were and how they differ from one another. The team will continue to update the modeling from this information. A committee member said that this could possibly provide an opportunity for shared decision making between patients and physicians depending on how the data is presented to the patient.

5. Lung Continuous Distribution Update

Erika Lease, Immediate Past Chair of the Lung Transplantation Committee, presented an action item to the Executive Committee on lung continuous distribution. Dr. Lease presented that lung continuous distribution is scheduled for implementation on January 31st, 2023, but the committee is looking to move implementation to March 2nd, 2023, to give members more time to prepare following the holidays. The Lung Committee and staff have increased outreach efforts to prepare the community for the changes but feel that the community still needs more time to prepare.

Summary of Discussion:

A committee member asked if Dr. Lease knew what impact continuous distribution is going to have on the number of organ offers that a center is likely to receive and how that may impact workload. Dr. Lease responded that the lung community generally doesn't use filters and the workload of lung transplants is very different than kidney transplants. Dr. Lease said that she would like to encourage members to use filters but it is more difficult for lungs. A committee member commented that members should share information on continuous distribution with their colleagues.

Vote:

The committee unanimously approved to move the implementation date of lung continuous distribution from January 31st, 2023, to March 2nd, 2023.

Attendance

- **Committee Members**
 - Brad Kornfeld
 - Dianne LaPointe Rudow
 - Gail Stendahl
 - Jeff Orlovski
 - Jerry McCauley
 - Jim Sharrock
 - Linda Cendales
 - Lloyd Ratner
 - Matt Cooper
- **HRSA Representatives**
 - Adrienne Goodrich-Doctor
 - Christopher McLaughlin
 - Frank Holloman
 - Marilyn Levi
 - Shannon Taitt
 - Suma Nair
- **SRTR Staff**
 - Jon Snyder
 - Ajay Israni
- **UNOS Staff**
 - Alex Tulchinsky
 - Ann-Marie Leary
 - Anna Messmer
 - Cole Fox
 - James Alcorn
 - Kaitlin Swanner
 - Laura Cartwright
 - Morgan Jupe
 - Susie Sprinson
- **Other Attendees**
 - Ed Hollinger
 - Erika Lease
 - Nicole Turgeon
 - Zoe Stewart Lewis