

**OPTN Executive Committee
Meeting Summary
June 25, 2023
Richmond, Virginia and Webex**

Jerry McCauley, MD, MPH, FACP, Chair

Introduction

The OPTN Executive Committee met via Webex Meetings teleconference and in Richmond, Virginia on 06/25/2023 to discuss the following agenda items:

1. Welcome & Announcements
2. New Projects from the Policy Oversight Committee*
3. Patient Information Letter*
4. Strategic Planning Process Preview
5. Strengthening Whistleblower Protections
6. Closed Session

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

1. Welcome and Announcements

Jerry McCauley, OPTN President, welcomed the Executive Committee to the meeting and shared the agenda.

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

Cole Fox, Senior Policy Analyst for the Policy Oversight Committee (POC), presented two new proposed projects on behalf of the committee. Cole Fox presented a new project from the Minority Affairs Committee (MAC) to Refit KDPI without Race and HCV, and a new project from the Lung Transplantation Committee to Promote Efficiency of Lung Allocation.

The proposal to Refit KDPI without Race and HCV from the MAC looks to remove race and HCV from KDPI by refitting the calculation without these coefficients. Removing race aims to better reflect the quality and post-transplant survival of kidneys from deceased donors who identify as African American and Black. Removing HCV aims to better reflect the quality and post-transplant survival from deceased donors who are HCV positive. The MAC considers the project to be an important effort to increase equity in access to transplants and expects the project to take approximately 1,900 implementation hours for a June 2024 technical implementation Board cycle. The POC assigned the project a high cost, high benefit score, which received an overall benefit score of 90. The POC voted to recommend for approval to the Executive Committee.

The Lung Transplantation Committee proposed a project to Promote Efficiency of Lung Allocation to promote efficiency of lung allocation by considering the creation of offer filters for lungs and to make updates to OPO offer notification limits, donor acceptance criteria, and required lung donor testing. The goal of the project is to quickly advance solutions that do not require changes to policy or data collection, and to develop a proposal for solutions that require policy or data collection changes.

Cole Fox shared the background of the project to highlight that lung continuous distribution was implemented on March 9, 2023, and early monitoring metrics show upward trends in the median

number of transplant programs receiving offers before lungs are accepted, median offer number of acceptance, and the median number of transplant programs that received an offer notification. The number of lung transplants are around the same, however they may be trending upwards.

The project proposal aligns with the strategic plan goal to increase the number of transplants and the POC assigned the project a benefit score of 61.

During the POC's review of the project, they discussed the impact the project could have on all organ types and discussed expanding the approach to all organs. It was decided that organ offer challenges would be similar across allocation systems and so these changes may be worth performing systematically instead of piecemeal. The POC unanimously recommended the project to the Executive Committee.

Summary of discussion:

During the presentation on the new project proposal from the MAC, a committee member commented that the project is a high priority for the broader community. Another committee member commented on the importance of the project and highlighted the importance of including Hepatitis C.

During the presentation to Promote Efficiency of Lung Allocation, a committee member asked if the POC was able to provide a range on the technical implementation hours and costs. Support staff for the Lung Transplantation Committee explained that the committee does not have a range but that they plan to bring the project back to the Executive Committee when they have a clearer idea of the number of implementation hours. They noted a range is difficult to provide because implementation will depend on the direction the committee chooses to take the project. A committee member asked to clarify that this is not an absolute project approval, but instead this is approval for the Lung Committee to continue their discussion on efficiency. In the near future, the project will come back to the POC for review and will be presented to the Executive Committee again.

A committee member asked if there was a timeline for the project to Promote Efficiency of Lung Allocation. Lung Support Staff shared that the project form lists January 2024 as a tentative public comment date. They explained that the goal of the committee is to evaluate the project further and to bring the project back to the POC and Executive Committee with a clearer timeline and resource estimate. Lung Support Staff expects the committee to have an update on the project by January 2024, if not sooner. A committee member asked the Lung Committee to analyze the distance between donor and transplant center and to see whether logistical variables have been programmed appropriately.

Vote:

The Executive Committee approved the project proposal to Refit KDPI without Race and HCV from the Minority Affairs Committee. The Executive Committee approved the project proposal to Promote Efficiency of Lung Allocation from the Lung Transplantation Committee.

3. Patient Information Letter*

Justin Wilkerson, member of the Patient Affairs Committee (PAC), presented on the updated patient information letter on behalf of the committee. OPTN Policy 3.5 Patient Notification requires transplant hospitals to provide the OPTN Patient Information Letter to patients when: they are registered on the waiting list, evaluation is complete and a patient is not registered on the waiting list, and when patients are removed from the waiting list for reasons other than transplant or death.

The timeline of the updates to the letter were shared to highlight that the Executive Committee Patient Engagement Workgroup recommended an update to the letter in April 2022. In June 2022, the Executive

Committee asked the PAC to update the letter. Then from September 2022 until May 2023, the PAC reviewed and edited the patient notification letter.

Changes made to the letter include lowering the reading level from 13.2 to 8.8 to ensure readability. Mr. Wilkerson shared that the committee discussed whether patients would understand the letter when they received it and what the best time is for patients to receive this letter. The changes also clarified and further highlighted information about the Patient Services Line that is available to patients.

The implementation plan of the letter was discussed to share during summer 2023 regional meetings, to post the letter on the OPTN website, and to then have members start using the letter by October 3, 2023.

Summary of discussion:

A committee member asked if the PAC had any conversations about what happens to patients when they are put on hold. Mr. Wilkerson explained that the committee did not specifically discuss this, but they did discuss what happens when patients come off the waitlist for various reasons and that patients should always receive the letter. The PAC discussed how members determine that patients are to receive these letters, but they did not discuss patients on hold.

A committee member asked if the letters would be available to patients in more than one language. Mr. Wilkerson responded that the committee did not discuss this specifically. Another committee member commented that the letter is only available in English and Spanish. The committee member stated that there should be an effort to have the letter translated into many more common languages. Dr. Maureen McBride, OPTN Executive Director, explained that if patients call the Patient Services Line, there are translation services available but that the OPTN could consider translating the letter into more languages.

A committee member asked if the PAC had any conversation on when the letter is sent to patients. Another committee member noted that when patients receive the letter, they may be more concerned about their health than reading the letter. Mr. Wilkerson commented that during the PAC's time working on the letter, he called the Patient Services Line listed in the letter and found the service to be very helpful.

A committee member voiced their appreciation of the PAC's work on the project and how much more work there can be done to provide information to patients. The committee member commented that the PAC holds a unique position to help ensure the information is relayed to patients and encouraged the PAC to continue their work on the patient letter and patient communication.

Vote:

The Executive Committee approved the updated patient notification letter from the Patient Affairs Committee.

4. Strategic Planning Process Preview

Ryan Ehrensberger, Chief Strategy Officer, presented a preview on the strategic planning process and the breakout sessions planned for the June 2023 Board meeting. Dr. Ehrensberger explained that the current OPTN Strategic Plan has approximately one year remaining and it is time to begin conversations on the next OPTN Strategic Plan. Dr. Ehrensberger explained that because of the amount of community input the plan receives and because the plan goes through the public comment process, it is important to begin the work now.

Dr. Ehrensberger shared the steps of the strategic planning process. The first step will take place at the June 2023 Board meeting (the following day) during a brainstorming session amongst attendees. Dr. Ehrensberger explained that the Executive Committee will be the committee to compile and discuss the initial ideas received during these sessions. The committee is asked to consider what the OPTN should achieve over the next three years and what the main anchors should be for the OPTN in the years to come. Summer 2023 regional meetings will also hold discussions around strategic planning so the larger community may share their input. The Executive Committee will be working on a regular basis to refine the input the OPTN receives during these sessions, and to determine the most important topics to include in the next strategic plan. Dr. Ehrensberger explained that the Executive Committee will finalize the draft plan and will submit the draft for winter 2024 public comment. After public comment, the Executive Committee will review public comment feedback, before submitting the strategic plan to the Board during the June 2024 Board meeting. If the Board approves the plan, then it will go into effect later that calendar year.

Summary of discussion:

There were no questions or comments from the committee.

5. Strengthening Whistleblower Protections

Jason Livingston, General Counsel, presented on the opportunity to strengthen the organization's whistleblower protections. Mr. Livingston explained that the OPTN has received allegations regarding retaliation against whistleblowers and thus recommends the OPTN, in a deliberate and appropriate manner, acknowledge the current state of the OPTN's Bylaws and existing protections. Mr. Livingston noted that not every complaint or concern constitutes whistleblowing, and a response does not legally qualify as retaliation, and is therefore not actionable.

Mr. Livingston noted that in every state there are laws that protect against whistleblowing, along with laws in the federal government to offer protections. These laws protect individuals who raise claims of wrongdoing from retaliation and is not limited to an employment context. Mr. Livingston highlighted the critical comment process in the OPTN Final Rule (42 CFR 121.4) that is typically used for broad disagreements about policy and noted that it is included in the Final Rule to analyze how the OPTN is adhering to its responsibilities and how the OPTN Contractor is serving the OPTN's needs. 42 CFR 121.4 of the OPTN Final Rule contains a high-level description of the process. Mr. Livingston emphasized that the process is well defined and has been in regulation for over twenty years.

Available resources for volunteers, staff, or other community members to report incidents of potential retaliation were discussed. Mr. Livingston explained that the OPTN Contractor maintains a patient services line that is targeted to patients and acts as an avenue for the OPTN to receive concerns from stakeholders. The OPTN Contractor also maintains a portal throughout the OPTN Website to improve patient safety, which is a resource targeted more towards professionals. The Contractor also maintains an Ethics Hotline which is a resource for internal employees of the OPTN Contractor to report any concerns anonymously. The Contractor also has internal policies that prohibit retaliation and harassment. Although there are many different mechanisms to report information, there are opportunities to increase transparency.

Mr. Livingston presented potential options on how to strengthen whistleblower protections throughout the OPTN. The four options that were offered to the committee were: a bylaw modification, a policy modification, a board-approved statement, and a communications effort from the OPTN. A bylaw modification would involve embedding a process in the OPTN Bylaws and include a detailed statement on the OPTN's nontolerance for retaliation against whistleblowers. With this modification, the OPTN could offer a process for a high-level internal review on how complaints are compiled. Benefits in taking

this approach include that the OPTN Bylaws stay with the OPTN regardless of the contractor and OPTN Bylaws are transparent to the community. Conversely, a possible hardship in this approach would be that bylaws are difficult to change, and it would require more procedural steps if implemented.

Another option presented to the committee would involve a policy modification. A policy modification would make similar changes proposed in a bylaw modification; however, a policy modification is slightly easier to amend. A policy modification would not have to go to public comment and could be approved by the Executive Committee, instead of the entire Board. The statement in a policy modification would be largely similar to the proposed bylaw modification statement. The third option presented to the committee is slightly less formal, but the Board could compose and publish a statement detailing nontolerance for retaliation against whistleblowers. This option would not have the force that a bylaw or policy modification would have but could be administered to the public in a quicker fashion. This option would also not provide any additional protections or processes. The last option presented to the committee was a proposed communications effort to direct the organization to publicize some of the existing methods that already exist and coalesce them; however, communications efforts are not always as visible to the general public as say a bylaw or policy modification.

Summary of discussion:

A committee member asked what happens if someone declares themselves to be a whistleblower and what constitutes retaliation. They also asked what happens after someone declares themselves to be a whistleblower and what this means for the organization. Mr. Livingston responded that this goes back to the question of what a whistleblower truly is. Mr. Livingston explained that a true whistleblower must allege a wrongdoing, and the wrongdoing must be material. Mr. Livingston also explained that because the organization deals primarily with volunteers, the OPTN is not in the position to retaliate against anyone absent a formal action of the organization.

A committee member commented that the OPTN could put forth a policy statement on retaliation. They continued that a bylaw statement seems as though it will take more time, so in the interim they could issue a policy statement.

A committee member asked how the OPTN makes new members, new OPTN Contractor staff, and new volunteers aware of OPTN policy on retaliation and current reporting mechanisms. Mr. Livingston stated that this is an identified weakness in the OPTN's process. Mr. Livingston continued that the internal process for new OPTN Contractor staff is solid, however there could be a more conscious effort when onboarding volunteers. Mr. Livingston stated that there needs to be a more definitive process in place, and it needs to be better communicated to volunteers. The committee member then asked how often this training is offered to OPTN Contractor staff. Mr. Livingston explained that the OPTN contractor performs this training on an annual basis. The committee member asked how vendors, that are not internal OPTN Contractor staff nor volunteers, would know how to report an incident and how information is communicated to these individuals. Mr. Livingston responded that the information is posted within the OPTN Contractor's building. A committee member stated that a policy modification is likely necessary, along with an increase in communication to volunteers. Another committee member commented that they think a bylaw statement would be a better route for the OPTN to state how to direct the Executive Committee or OPTN contractor staff to create a detailed policy and action plan.

A committee member asked if the OPTN Contractor believes the current bylaws in place are deficient, and if they do not, then they would not necessarily support another bylaw change, but instead support promoting current policy and pathways in place. It was noted that the pathways are not deficient, but instead the issue is whether volunteers are aware of how to issue a complaint; and the committee

member concluded that they attribute this to be more of a communications issue than a bylaw or policy issue.

A committee member suggested that retaliation and whistleblower training be included in the annual training that is required of volunteers. They stated that this would take care of how the OPTN onboards new volunteers, and address how volunteers are informed of the policies and practices in place. Another committee member agreed and added that information on what happens when an issue is received should also be included. A committee member asked how the Board or Executive Committee are notified if an incident has occurred and what these communications efforts look like. Mr. Livingston explained that this topic has also been raised in the context of the OPTN Membership and Professional Standards Committee (MPSC). Mr. Livingston suggested there be a screening process in place to verify whether complaints are substantial. When addressing the question of notifying the Board of complaints, Mr. Livingston asked what level of detail the Board would be interested in receiving and how staff could determine what information is appropriate and relevant to relay. The committee member suggested tracking any complaints that come to the OPTN and if there is a trend in complaints, then this could help them to determine if certain complaints truly meet the definition of whistleblowing. Dr. McBride summarized that additional communication efforts on the process currently in place are needed. A representative from HRSA commented that although the OPTN Contractor may have an internal process, the OPTN does not have a process in place, and this may require a bylaw change. They commented that what practices are currently in place for the OPTN do not appear to be formal processes, and they asked what actions need to be taken to create a process for the OPTN.

A committee member stated that including this process in the OPTN Bylaws is important to manage the governance of the OPTN. They believe modifying current OPTN Bylaws is important to show the OPTN's commitment to protect whistleblowers. A committee member suggested the OPTN include the process in policy in the immediate future because it is a quicker process, but to also consider including the process in OPTN Bylaws in the future.

A representative from HRSA asked if the processes in place are enacted by the OPTN Contractor or through the OPTN itself. They continued that the processes in place are from the OPTN Contractor and not the OPTN itself, which causes an organizational issue for the OPTN, noting that that the practices should be part of the organization's bylaws.

A committee member suggested that in the interim, the Board publish a statement that they do not condone whistleblowing. Another committee member agreed that this could be an important first step to make. They noted the importance of issuing a statement from the Board that they have investigated and looked into the claims, but it is important to distinguish whistleblowers from those who may disagree. The committee member suggested the Board make a statement that although there have been no substantiated reports of retaliation against whistleblowers, it is important to the Board that something like this does not occur in the future. Mr. Livingston stated that to their knowledge, no one has ever submitted a report of whistleblowing or an allegation of retaliation against the OPTN or the OPTN Contractor.

A committee member suggested that when the bylaw modification is drafted, that the legal definitions of a whistleblower and retaliation be included in documentation.

Next Steps:

Staff will put together a statement, and develop a policy or bylaw proposal, for the Executive Committee's review at a future meeting.

6. Closed Session

The Executive Committee met in a closed session.

Attendance

- **Committee Members**
 - Bradley Kornfeld
 - Dianne LaPointe Rudow
 - Irene Kim
 - Jeffrey Orłowski
 - Jerry McCauley
 - Jim Sharrock
 - Linda Cendales
 - Lloyd Ratner
 - Matt Cooper
 - Valinda Jones
- **HRSA Representatives**
 - Adrienne Goodrich-Doctor
 - Christopher McLaughlin
 - Frank Holloman
 - Shannon Taitt
 - Suma Nair
- **UNOS Staff**
 - Anna Messmer
 - Cole Fox
 - Dale Smith
 - Jason Livingston
 - Julie Nolan
 - Kaitlin Swanner
 - Linwood Butler
 - Liz Robbins Callahan
 - Maureen McBride
 - Michael Ghaffari
 - Morgan Jupe
 - Ryan Ehrensberger
 - Susie Sprinson
 - Tiwan Nicholson
- **Other Attendees**
 - Justin Wilkerson