

**OPTN Executive Committee
Meeting Summary
August 14, 2023
Webex**

Dianne LaPointe Rudow, ANP-BC, DNP, FAAN, Chair

Introduction

The OPTN Executive Committee met via Webex on 08/14/2023 to discuss the following agenda items:

1. Welcome and Announcements
2. New Policy Projects from the Policy Oversight Committee*
3. Whistleblower Protection Policy
4. OPTN Task Force on Efficiency
5. OPTN Strategic Planning
6. Performance Summary Process Overview

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

1. Welcome and Announcements

The committee was welcomed to the meeting and reviewed the agenda.

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

Jennifer Prinz, Chair of the Policy Oversight Committee (POC), presented three new projects on behalf of the committee. Ms. Prinz presented a new project from the ad hoc Disease Transmission Advisory Committee (DTAC) to Standardize the Patient Safety Contact Notification Process and Duplicate Reporting. The purpose of the project is to improve the functionality of the patient safety contact and infectious disease reporting processes. Ms. Prinz explained that currently, there are duplicate reporting efforts of infectious disease and malignancy results in OPTN Policy 15.4.B and 15.5.B. The strategic plan alignment of the project is to promote living donor and transplant recipient safety. The POC discussed potential challenges in standardizing communication between OPO and transplant centers and unanimously approved to send the project to the Executive Committee for review.

Ms. Prinz then presented a new project from the Liver and Intestinal Organ Transplantation Committee to Establish Exception Criteria for Liver Cancer Diagnoses. The purpose of the project is to update NLRB guidance to align with emerging literature. The Liver and Intestinal Organ Transplantation Committee noted that transplant benefit for certain oncological diagnoses has been shown in research, however calculated MELD scores remain low, resulting in a potential lack of access. The committee proposes to develop guidance for multiple diagnoses including unresectable colorectal liver metastases, unresectable intrahepatic cholangiocarcinoma less than two centimeters, and unresectable downstaged intrahepatic cholangiocarcinoma. The committee noted that research has shown that contrast enhanced ultrasound (CEUS) is a technology that can accurately diagnosis hepatocellular carcinoma (HCC), thus the committee proposes to update HCC policy and guidance language to incorporate CEUS as an acceptable imaging tool for HCC diagnosis in addition to dynamic-enhanced CT and MRI. The project aligns with the strategic plan goal to increase equity in access to transplants. The POC discussed the difficulty in identifying the number of patients this could impact. During discussion, it was clarified that there would be strict timing protocols in the guidance so that medically urgent candidates would not be

disadvantaged by inclusion of these patients. The POC voted in approval to send the project to the Executive Committee for review.

The Organ Procurement Organization (OPO) Committee has proposed a new project on Clarifying Requirements for Pronouncement of DCD Donor Death. The purpose of the project is to review and revise Policies 2.14 and 2.15, if necessary, to clearly outline permissible and prohibited behavior by individuals that may be employed at a donor hospital and by the OPO in the context of donor pronouncement of death. Ms. Prinz shared that the project is a referral from the MPSC based on an issue identified through its monitoring activities. The project aligns with the strategic plan goal to increase the number of transplants. During the POC's discussion, they recommended adding the Ethics Committee as a collaborating committee to the project. The committee voted in unanimous approval to send the project to the Executive Committee.

Summary of discussion:

There were no questions or comments from the committee.

Vote:

The Executive Committee approved the initiation of the projects from the Policy Oversight Committee (POC):

- Standardize the Patient Safety Contact Notification Process and Duplicate Reporting (DTAC)
- Establish Exception Criteria for Liver Cancer Diagnoses (Liver)
- Clarifying Requirements for Pronouncement of DCD Donor Death (OPO)

3. Whistleblower Protection Policy

Jason Livingston, General Counsel, presented on the draft whistleblower protection policy. Mr. Livingston recapped the June 25 meeting in which the then Executive Committee discussed creating a whistleblower protection measure, including implementing a policy. Based on feedback from the June 25 meeting, Mr. Livingston compiled a draft and provided it to the committee before today's call. Mr. Livingston asked the committee for feedback on the draft and if there were any areas they would like to edit ahead of voting on a final draft.

The plan for the whistleblower policy would be to create a new Policy 1.6. Key aspects that the committee identified to be included in the policy were to include a clear statement that the OPTN opposed and will not tolerate retaliation, and that there is a process in place for handling reports. Policy 1.6 would outline a separate path for accounting or audit matters, which include referral to the Finance Committee and the Treasurer, depending on the timing of the concern. Policy 1.6 will also include a clear statement that the whistleblower will maintain their confidentiality and that the OPTN will maintain the confidentiality to the extent possible. The policy will also include a statement that the whistleblower must act in "good faith".

Mr. Livingston asked the committee if they think the policy achieves the intended goal and if there is anything missing from the current draft that should be included in the final policy.

Summary of discussion:

A committee member asked about reports regarding the Executive Director. Mr. Livingston responded that if this situation arises, the report could go to the OPTN President.

A committee member commented that many people do not understand the definition of what a whistleblower is and that this policy may not solve that problem. They expressed concern that people may allege retaliation against whistleblowing, when what they reported does not constitute

whistleblowing. Mr. Livingston explained that a whistleblower is someone who is on the inside of an organization where the organization has a power differential and the organization can retaliate against that person for stating a negative opinion. A typical scenario would be when this occurs in the workplace. Mr. Livingston also explained that the critical comment process may better fit the situation that the committee member is describing. The critical comment process is included in the Final Rule, and notes that members of the public can submit a concern about the way the OPTN is operating and conducting business. Those complaints would go directly to the Secretary of the Department of Health and Human Services (HHS). Mr. Livingston explained that the OPTN also has the patient safety reporting process to ensure that concerns that go through the whistleblower process that deal with a patient safety concern are handled differently. The committee member asked how in this process they could emphasize the difference between operational complaints, versus complaints that are opined criticism of the organization. Mr. Livingston responded that there are potential gaps in reporting, but someone in this situation could employ the critical comment pathway in the Final Rule.

A committee member asked if there is a mechanism for a whistleblower to report a concern and have the initial review of the report conducted outside of the OPTN. Mr. Livingston explained that the critical comment process in the Final Rule provides this pathway for reports to be handled outside of the organization. Policy 1.6 is to provide a clear statement from the organization that whistleblowers will not be retaliated against, because within its nature a whistleblower complaint comes from within the organization.

Next Steps:

The policy change is an administrative matter and would not need to be submitted for public comment. Mr. Livingston will incorporate any feedback or suggested edits to the draft, and the final draft will be shared with the Executive Committee to vote on during the September 8 meeting. If the committee approves the policy, it will be implemented immediately. Communication efforts will be sent out to let the community know that the policy has been approved and implemented.

4. OPTN Task Force on Efficiency

Dr. LaPointe Rudow introduced the idea of creating an OPTN Task Force on Efficiency to address some of the topics that the Board discussed during the June 2023 Board Meeting. Ann-Marie Leary, Assistant Director of Member Quality, provided an update to the committee on the conversations and discussions that have gone into the creation of developing a task force to address efficiency throughout the community. The presentation was framed as an introduction to the topic, and that the committee will discuss the topic in greater depth during their next meeting on August 18.

The thought behind creating the task force was to develop methods for continuous improvement throughout transplant, utilizing the current resources that are available. In order to further increase transplantation, the community might consider standardizing processes throughout the system.

The group will look to prioritize, coordinate, and facilitate efficiency-related work, with approximately twenty members on the task force, which is inclusive of members of the Board of Directors along with other stakeholders. Suggested areas of focus the task force might include an alternative allocation process for hard-to-place kidneys, standardization of aspects of donor management, allocation and offer evaluation process, and programming and tools, such as expanded availability of offer filters for all organ groups.

The Task Force will evaluate recommendations already provided in the National Academies of Sciences, Engineering, and Medicine (NAEM) report, the Systems Performance Committee report, and at OPTN Board/Committee meetings and professional conferences. The goal is to have the Task Force evaluate

recommendations that have already been made by the community. The Task Force will also utilize collaborative methods that have been effective, including the Organ Donation Breakthrough Collaborative, Systems Performance Committee, COIIN, and Offer Acceptance Collaboratives. The task force is to act as an additional group to support the work of the OPTN Committees. The Task Force will also perform interviews with members of the community, and hold webinars, conferences, meetings and surveys to ensure members of the community are able to provide input. The Task Force is intended to be an additional group to help support the policy making committees with the goal of focusing committee's on efficiency work.

Dr. LaPointe Rudow noted that the objective in sharing this with the committee was to provide them with an update on the conversations taking place and the direction the work may be going. During these discussions, it was weighed whether the OPTN should carry on with the current work it has planned, or to examine how the OPTN can support the system in performing more efficiently.

Summary of discussion:

A representative from HRSA asked about the documentation that would be submitted on the work that the OPTN plans to pause. Ms. Leary explained that the first step will include a high-level assessment by staff so there is a general understanding of the projects that align with efficiency work and which projects may not. The committee discussed adjusting the timeline of existing project work, and whether this decision was best for the Executive Committee or Board of Directors.

A committee member commented that this work is important to address now instead of proceeding with current policy, in order to address the issue of non-utilization throughout the community. Another committee member agreed that with the escalating non-utilization rate it is important that the Task Force is created sooner rather than later. They stressed the importance of devoting all resources and efforts into determining where the disconnect is and what is leading to the increase in non-utilization. Dr. LaPointe Rudow explained that the Task Force will likely be a three-year project, and that the Task Force will first look at existing research and then explore opportunities and solutions. The committee member stated that additional data collection may be necessary.

A committee member asked how the patient voice will be represented throughout the process. Dr. LaPointe Rudow responded that patients will be part of the Task Force and the expectation is that all stakeholders will be represented. Committee members asked how the work by the Task Force is being prioritized compared to the other ongoing initiatives the OPTN has underway. Dr. LaPointe Rudow explained that the request to focus on increasing organ utilization and decreasing organ non-use came out of discussions from the June Board meeting. The idea of the Task Force has been positively received by the community at regional meetings thus far.

A committee member commented that although the planned work is important, the community has made it clear that efficiency and organ non-utilization are efforts they would like to focus on. They noted that there is a need to streamline some of this work, and this includes being flexible to adapt with the changes in the community. They continued that efficiency is a main concern with the professional community as well as those outside the community and this work should be prioritized. Dale Smith, Chief Financial Officer, explained that it is important for the committee to consider which work they are prioritizing and the financial limits of the work.

Next Steps:

The committee will present the plan for the Task Force on Efficiency to the full OPTN Board at their next meeting. Committee members commented the importance in understanding the full Board's thoughts on the Task Force before proceeding. At the next Executive Committee meeting, the committee will

analyze current work across the OPTN and evaluate how current work aligns with efficiency and which project timelines should be reconsidered.

5. OPTN Strategic Planning

Dianne LaPointe Rudow, OPTN President, presented an update on the 2024-2027 strategic planning process. The goal of the conversation was for the committee to define success of goals and to discuss what data the committee needs in order to create metrics for each identified goal. The timeline of the work to date was shared with the committee, along with next steps and what the committee can expect throughout the rest of the strategic planning development process. Currently, community feedback discussions are taking place at each regional meeting in order to receive input from the community on what goals they feel are important to include in the next strategic plan.

Prior to the meeting, the committee was asked to complete a survey by ranking the five goals and noting whether there are any other goals the committee should consider. Based on the survey, the committee ranked “increase transplants” as their highest priority. The theme of increasing transplants includes focusing on increasing organ acceptance, minimizing organ non-use, and increasing efficiency and improving allocation. The second highest ranked theme was “increase donors and available organs for use”. This theme includes focusing on minimizing organ non-use, increasing donation with an emphasis on living donation, and a focus on OPO metrics and data driven improvement. The third highest ranked theme was “improve allocation efficiency”, which would include reducing non-utilization of organs, decreasing allocation time, and minimizing transportation. The fourth highest ranked theme was “maximize value of organs/increase post-transplant quality of life” which would include defining quality of life, publishing information and data, and increasing recipient survival and years of organ usefulness. The fifth ranked theme was “patient engagement, education, and transparency” that would focus on patient education, tools, and surveys.

Dr. LaPointe Rudow shared additional feedback the committee provided in the survey, including potential themes to add to the strategic plan and potential themes to remove or alter. Some potential themes to add included decrease transplantation waiting time, increase communication, expedite policy, agility of the OPTN to work with one or more contractors, increase education and transparency for physicians and providers, and to increase use of marginal organs. Some themes the committee suggested removing or changing included: for all goals to focus on increasing transplants, to consider removing this as a separate goal, to remove quality of life, and to add patient engagement as a component of all goals.

Summary of discussion:

A committee member stated that the most important thing the community will do over the next three years will be to participate in the new system that HRSA creates and adapt to any changes throughout the system. They believed that the goals of the strategic plan will flow from the changes that come with the HRSA modernization initiative.

A committee member commented that they were upset to see the theme around patient engagement, education, and transparency ranked fifth and that it is important for the committee to focus on improving engagement with the patient community. Dr. LaPointe Rudow agreed that this was notable and that patient engagement and education should be included in all the goals that are in the strategic plan. They wondered if including patients in each goal provided a stronger message to the community. A committee member commented that it is important to include metrics with a goal of patient education. The committee member suggested engaging patient representatives on the Board in reviewing the metrics to ensure the metrics are serving their intended goal. A committee member suggested engaging with HRSA to redefine the role that patients play in the community to have a more meaningful impact.

Other committee members agreed that the role of patients throughout the OPTN could be reevaluated. A committee member commented that when they completed the survey, they saw patients fitting into every goal and that the patient voice is important to include in each goal.

Next steps:

The ideas shared in the survey will be compiled and discussed further in an upcoming meeting.

6. Performance Summary Process Overview

Tony Ponsiglione, Chief People Officer, presented on the Executive Director performance summary. He explained what the Executive Director's performance summary entails, noting that it is completed on an annual basis, led by the immediate past OPTN President. Committee members are encouraged to identify potential goals throughout the year for future years, or to amend current goals if appropriate.

The performance summary includes multiple different inputs. The immediate past OPTN President would gather information on the Executive Director's performance and compare them to the Executive Director's goals. The immediate past president may also utilize other sources for feedback including the Contractor's Senior Leadership Team, past and current Executive Committee members, HRSA staff, and other members of the community as deemed appropriate.

Mr. Ponsiglione explained that the timeline runs from August 14 until September 30, when the Executive Director's performance summary is due to HRSA. The timeline includes the Executive Committee receiving an overview of the OPTN Executive Director review process and timeline, and a review of the goal setting process and timeline for the upcoming year. Next, the immediate past president will solicit input and will then draft a performance summary. The Executive Committee will then meet to provide input for the 2023 performance summary. Finally, the immediate past president will finalize and deliver the OPTN Executive Director's performance summary.

Summary of discussion:

A representative from HRSA asked what the Executive Committee thought about soliciting feedback from the entire Board of Directors. A committee member commented that it makes sense that the Executive Committee leads this process because they may have more frequent interaction with the Executive Director, but it is important to still engage the entire Board of Directors. They commented that it is important to gather feedback and for the entire Board of Directors to be part of the process. The committee member suggested administering a survey to the entire Board to receive their input.

A committee member suggested that the group consider creating a position description for the Executive Director so in the future, the committee may evaluate the Executive Director with the description in mind.

A committee member suggested a metric be included in the Executive Director's performance summary to measure their level of patient engagement. They suggested starting with the patient representatives on the Board, and then branching out to patient representatives on OPTN policymaking committees.

Next Steps:

The committee will receive a list of the performance indicators that were used to evaluate the Executive Director over the past year for their review prior to their next conversation on September 22.

A survey will be sent to the entire Board to provide feedback on the OPTN Executive Director's performance over the past year. The survey will be compiled and used by the immediate past president during their drafting of the performance summary.

Upcoming Meetings

- August 18, 2023
- September 8, 2023
- September 22, 2023
- October 10, 2023
- November 6, 2023

Attendance

- **Committee Members**
 - Andrea Tietjen
 - Dianne LaPointe Rudow
 - Ginny McBride
 - Jim Sharrock
 - Linda Cendales
 - Manish Gandhi
 - Melissa McQueen
 - Richard Formica
 - Silas Norman
 - Valinda Jones
 - Wendy Garrison
- **HRSA Representatives**
 - Christopher McLaughlin
 - Daniel Thompson
 - Frank Holloman
- **UNOS Staff**
 - Ann-Marie Leary
 - Anna Messmer
 - Dale Smith
 - Jacqui O'Keefe
 - Jason Livingston
 - Julie Nolan
 - Krissy Laurie
 - Liz Robbins Callahan
 - Maureen McBride
 - Michael Ghaffari
 - Morgan Jupe
 - Roger Brown
 - Stryker-Ann Vosteen
 - Susie Sprinson
 - Tiwan Nicholson
 - Tony Ponsiglione
 - Tynisha Smith
- **Other Attendees**
 - Jennifer Prinz