OPTN Executive Committee Meeting Summary October 10, 2023 Houston, TX and Webex

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

Introduction

The OPTN Executive Committee met in Houston, Texas and via Webex on 10/10/2023 to discuss the following agenda items:

- 1. Welcome and Announcements
- 2. Strategic Planning
- 3. Expeditious: Organ Usage Through Placement Efficiency
- 4. Predictive Analytics
- 5. Closed Session

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

1. Welcome and Announcements

Dianne LaPointe Rudow, Chair of the Executive Committee, welcomed the committee to the meeting and presented the agenda.

2. Strategic Planning

Contractor staff presented the requirements of the strategic plan and reviewed the decisions the committee has made thus far. Contractor staff presented the objectives of the meeting and decision points the committee should focus on. The committee decided to analyze three goals for the next strategic plan and to develop objectives and metrics for these goals. The three goals the committee analyzed are:

- Increase organ acceptance
- Decrease organ non-utilization
- Increase efficiency and improve allocation

Contractor staff presented that strategic objectives should be more specific and focused than strategic goals, should break goals into measurable outcomes that can be achieved with a defined timeframe, should provide a clear focus on what needs to be accomplished to realize the overarching vision, and should be relatively stable to provide a consistent direction. Contractor staff suggested the committee consider relevance, feasibility, measurability, alignment and authority, and prioritization when considering potential objectives.

The committee was broken into three different groups to each analyze one of the three goals of the strategic plan. Committee members discussed objectives for each goal and reported their findings back to the group. The committee agreed on ten objectives at the time of conversation, subject to additional refinement in subsequent meetings. The objectives presented for each goal were:

- Goal 1: Increase organ acceptance
 - o Redefine what an offer is

- o Member resources and capacity planning
- System level transportation resource and capacity planning
- o Education for patients and transplant programs
- Goal 2: Decrease organ non-utilization
 - Understand the root cause of non-utilization
 - Evaluate alternative allocation for non-utilized organs
 - o Increasing transparency of best practices for all stakeholders
- Goal 3: Increase efficiency and improve allocation
 - o Review policy development and implementation process
 - o Analyze OPTN data to ensure we are measuring the right things
 - o Increase innovation

Next, the committee identified potential metrics to help measure the objectives of each goal. Contractor staff shared that metrics are to provide actionable insights on each strategic goal. They encouraged the committee to choose metrics that offer a clear and meaningful picture of how the OPTN is progressing towards the strategic objective. Contractor staff suggested the committee consider relevance, feasibility, measurability, balance, data availability, and alignment when considering potential metrics. The committee was broken back up into groups and were asked to consider potential metrics for their strategic objectives. Each group reported back on the draft metrics for each goal and the committee held discussion on each goal's proposed metrics, subject to refinement in future meetings. The metrics presented were:

- Goal 1: Increase organ acceptance
 - Capacity planning for membership organizations
 - Maximize transportation efficiency
- Goal 2: Decrease organ non-utilization
 - Reduce avoidable non-utilization: differentiate between recovered and not transplanted versus not recovered at all
 - Reducing non-utilization variation by OPOs and transplant hospital
 - o Identify and prioritize top three barriers by stakeholder for allocations out of sequence
 - Expand methodology of organ filters
- Goal 3: Increase efficiency and improve allocation
 - Measure member satisfaction with the policy development process now and in three years
 - Gap analysis in data collection to understand what data is being used and which data needs to be added
 - Balance innovation and patient safety

The committee then considered alignment and integration of how the strategic goals, objectives, and metrics all work together. The committee reviewed the plan they had composed throughout the activities and contractor staff shared they would compile the information discussed to share with the committee before their next meeting. The refined goals and objectives for the strategic plan were:

- Goal 1: Increase organ acceptance
 - Education both patient and for transplant programs regarding metrics
 - Redefine an offer
 - Capacity planning for member organizations include a work plan with suggested metrics
 - Transportation ensuring there are sufficient transportation resources available and to incorporate transportation in the modernization contract

- Goal 2: Decrease organ non-utilization
 - o Evaluate root cause
 - Transparency in best practices
 - o Evaluate alternative allocation for organs at high risk of non-utilization
- Goal 3: Increase efficiency and improve allocation
 - Review policy development and implementation process to improve efficiency and increase member and patient outcomes
 - Increase innovation, partnerships, and solutions for members to enhance relationships and increase member satisfaction
 - Evaluate OPTN data to ensure we are measuring "the right things" to support expedited placement, decrease costs

Summary of Discussion:

When discussing non-utilization, the committee discussed the concept of alternative allocation pathways and the impact they could have on organ non-utilization. The committee discussed potentially naming one of the objectives to be more user friendly to say "the right organ, to the right patient, and the right time". The committee discussed if becoming more organ-centric was the right solution to decrease organ non-utilization.

When discussing metrics, a committee member commented that it is important to consider both the positives and negatives associated with each metric. When discussing metrics for goal 1, the group stated that they thought it was important for HRSA to consider the importance of transportation and encourage incorporation of transportation into the OPTN modernization contract. The group discussed other metrics to potentially include in goal 1, including education for patients and providers. It was noted that the OPTN could provide learning modules to have a target of 20% of waitlisted patients complete the module by the end of the strategic plan period. The committee discussed how outreach would be performed to patients to complete the module. The committee noted that the metric for goal 1 could be the organ offer acceptance ratio. The group assigned to discuss goal 1 also noted the potential metric of redefining what an offer is. The group discussed analyzing cold time and how to decrease cold time, as this is the highest refusal code reason.

The committee discussed the best way to measure non-utilization. For example, the committee discussed whether this should be analyzed looking at areas of the country, organ type, DCD versus brain death, or member type.

When discussing metrics for increasing efficiency and improving allocation, the group discussed improving the policy development and implementation process. The group reported back that identifying areas of improvement in the policy development and implementation process could be the first step in understanding how to improve the process. The group also stated that if efficiency increases, the community could see a decrease in implementation time. When discussing increasing efficiency in data collection, the group noted that collaboration is necessary between multiple different bodies. The group considered ways to speed up this process and make this collaboration more efficient. The group expressed that it is important to focus on decreasing member burden. A representative from HRSA commented that it is necessary to notify the public of the burden of data collection. When discussing goal 3, the group shared that this metric could be measured by identifying and building relationships with stakeholders.

When the committee analyzed the plan holistically to see how the goals and objectives aligned with one another, it was noted that there is nothing about living donation in the draft strategic plan at the time of

their review. The committee discussed if the plan was flexible enough to also support living donation efforts and how living donation could be supported by increasing patient safety.

Next Steps:

Contractor staff will share a summary of the conversations during the meeting. Contractor staff will edit the strategic plan based on today's conversations, and the committee will consider a draft for public comment. The committee will vote whether to send the proposed strategic plan to winter 2024 public comment.

3. Expeditious: Organ Usage Through Placement Efficiency

Contractor staff presented an update on the Expeditious Task Force. Staff presented the objective of the discussion: to consider task force appointments, provide an update on the most recent town hall, consider future communications plans, and consider feedback received on the Plan-Do-Study-Act (PDSA) variance framework.

Contractor staff provided an update on the composition and appointment of individuals to the Task Force. The Task Force considered recommendations from the community, committees, and selfnominations. They shared that Board leadership will serve as advisors to the Task Force and the SRTR will advise and support the Task Force. Contractor staff shared the composition of the Task Force based on member's primary affiliation, OPTN volunteer status, and region.

Contractor staff shared a summary from the most recent town hall on the Task Force. They shared that Dennis Wagner and Accenture will co-facilitate the Task Force workshops, which will focus on identifying bold aims, securing commitments, and agreeing on a decision-making model to help prioritize projects aimed at sharing effective practices and system improvements. They shared that Accenture will assist with the project for at least the next six months.

Contractor staff presented the communication plan for the Task Force. They shared that the current communication plan currently includes town halls and webinars, website FAQs, written updates, and emails to the community. Contractor staff shared that the OPTN Board of Directors or the OPTN Executive Committee traditionally approve communications sent on behalf of the OPTN prior to distribution. They shared that to ensure communication is sent in a timely manner, the Expeditious co-chairs request the Executive Committee delegate to the Task Force the authority to communicate via email and other methods about Expeditious activities. They noted that all Expeditious communications will be reviewed by the Expeditious co-chairs, Board leadership, and HRSA prior to distribution.

Contractor staff then presented how the OPTN Expeditious Task Force will likely recommend a Plan-Do-Study-Act (PDSA) or a similar quality improvement initiative, especially regarding allocations out of sequence. The conversation was framed in the context of hard-to-place organs and the different ways to implement changes around hard to place organs. Contractor staff noted that the Final Rule 42 CFR 121.8(g) permitted the OPTN to develop experimental policies to improve organ allocation through a variance process. Contractor staff also noted language detailing the use of variances in OPTN Policy 1.3.D and in OPTN Policy 1.3.B. Contract staff explained that variances help promote clarity, transparency, and compliance with the Final Rule and OPTN policies and bylaws. Variances are meant to test allocation approaches before enacting these practices into policy.

Contractor staff noted that if variances have to undergo a regular public comment timeline and approval process, this may add significant time to the PDSA process, and some policy requirements are not applicable for variances that are part of short PDSA cycles. Contractor staff also noted that variances follow the policy development cycle and follow the traditional public comment cycle, unless noted as expedited.

Contractor staff asked the committee to consider the maximum and minimum time each PDSA should run, how quickly the committee would want to receive feedback on the effect of the PDSA, and whether there were any other reporting requirements or metrics the committee would like to incorporate into the study evaluation plan.

Summary of Discussion:

The committee discussed the process of keeping the Board informed throughout the work of the Task Force. A representative from HRSA suggested outlining a process on how the Task Force will operate on behalf of the Board of Directors. The committee discussed how the Board will continue to receive updates on the Task Force's work. It was noted that members of the Board of Directors on the Task Force can help provide routine updates to the Board. The committee also discussed that the Task Force will coordinate their initiatives through the Executive Committee or the Board of Directors.

The committee discussed the public comment cycle with variances and whether the current public comment process is appropriate for variances. Contractor staff noted that some of the variances would not last as long as the public comment cycle, so it begged the question of whether the traditional public comment cycle was applicable to PDSAs. Contractor staff noted that public comment would serve as an opportunity to update to the community on the variances the Task Force is pursuing. General Counsel noted that there is not currently an alternative pathway for variances when it comes to public comment. Members of the committee agreed that there should be a different timeline for variances or the work of the Task Force will be slowed tremendously. A committee member thought it was important for the Task Force to note when a variance would not follow the typical timeline within policy.

After discussion, the committee decided that the OPTN should distribute a singular framework for public comment that all PDSAs will use.

Vote:

The Executive Committee unanimously approved delegating authority to the Expeditious Task Force cochairs to communicate with the community about Expeditious via reports, emails, and other methods necessary.

4. Predictive Analytics

Michael Ghaffari, Senior Director of Technology Development, provided an update on predictive analytics. Mr. Ghaffari explained that predictive analytics can predict time to next offer (TTNO) and waitlist mortality (WLM).

Mr. Ghaffari shared the national rollout plan for predictive analytics. He shared that predictive analytics was presented at every winter 2023 regional meeting, the offer acceptance collaborative, and at multiple community events and conferences.

Mr. Ghaffari shared the upcoming accessibility enhancements to predictive analytics. He noted that predictive analytics is coming to the OPTN Donor Data and Matching System Desktop this year and program-specific reporting on all predictions will be available. He explained that TTNO and WLM will both be updated with more recent data, and TTNO will be updated with new methodologies. Mr. Ghaffari noted that modeling improvements are underway to address geographic inadequacies in transplant indicators, and to address competing risk of waitlist removal.

Summary of Discussion:

The committee discussed whether predictive analytics could measure and study center specific data and. The committee also discussed that the OPTN is looking to integrate predictive analytics into the

OPTN Donor Data and Matching System Desktop. It was noted that having predictive analytics available on OPTN Donor Data and Matching System Desktop will also allow OPOs the opportunity to utilize its capabilities.

The committee discussed how many providers are utilizing predictive analytics in real time. A committee member also asked if there were any disclaimers included within predictive analytics. The disclaimer is included to remind users what the tool is for, but not a substitute for. The committee continued to discuss the data that is included in the predictive analytics tool.

5. Closed Session

The committee met in a closed session.

The meeting adjourned.

Upcoming Meetings

• November 6, 2023

Attendance

• Committee Members

- o Andrea Tietjen
- o Dianne LaPointe Rudow
- o Ginny McBride
- o Jerry McCauley
- o Jim Sharrock
- o Linda Cendales
- o Manish Gandhi
- o Melissa McQueen
- o Richard Formica
- o Silas Norman
- o Valinda Jones
- Wendy Garrison

• HRSA Representatives

- Adrienne Goodrich-Doctor
- o Christopher McLaughlin
- o Daniel Thompson

UNOS Staff

- o Ann-Marie Leary
- o Anna Messmer
- o Dale Smith
- o Jacqui O'Keefe
- o James Alcorn
- o Julie Nolan
- o Lauren Mauk
- o Liz Robbins Callahan
- o Maureen McBride
- Micheal Ghaffari
- o Morgan Jupe
- o Roger Brown
- o Ryan Ehrensberger
- o Samantha Noreen
- o Tiwan Nicholson
- o Tony Ponsiglione
- o Trish Jasion