OPTN Executive Committee
Meeting Summary
December 3, 2023
St. Louis, MO and Virtual

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

Introduction

The OPTN Executive Committee met in St. Louis, Missouri on 12/03/2023 to discuss the following agenda item:

1. Offer Filters Implementation Timeline*
2. Letter from UNOS Xenotransplantation Work Group
3. Whistleblower Protection*
4. Expeditious Task Force Updates

1. Offer Filters Implementation Timeline*

Dianne LaPointe Rudow, Chair of the Executive Committee, presented an update on the offer filters implementation timeline. She reviewed that the purpose of offer filters is to allow transplant programs to apply program specific, multi-factorial filters to avoid donor offers that they do not want to receive. Dr. LaPointe Rudow presented the current timeline and the new proposed timeline. Dr. LaPointe Rudow explained that the committee is asked to consider an alternate timeline based on feedback from heart and liver programs wanting to utilize the filters, and due to efforts currently underway to increase the usage of kidney offer filters.

Dr. LaPointe Rudow then explained potential impacts of changing the offer filters timeline. She explained that this change would delay the implementation of the Board approved Operations and Safety Committee (OSC) policy proposal "Optimizing Usage of Kidney Offer Filters" by approximately 4 months, which would be outside of the 12-month Board delivery commitment. Dr. LaPointe Rudow also shared feedback provided by OSC leadership on the change in timeline. She noted that OSC leadership agreed in having filter abilities for all organs, and raised some concern about delaying default filters for kidneys. Dr. LaPointe Rudow asked the committee to share their ideas on potentially changing the implementation timeline for organ offer filters.

Summary of Discussion:

A committee member suggested the OPTN have more education available to the community on offer filters. A committee member commented that they supported prioritizing heart and liver offer filters to ensure all organs are able to utilize filters. They also commented that they thought it was reasonable to delay the default kidney filters. The committee member asked if there is data available on centers that are not utilizing the offer filters but are routinely declining offers. Dr. LaPointe Rudow shared that contractor staff is providing one-on-one coaching for programs that are not currently using filters and how they may be able to utilize the filters for their programs. She commented that this coaching could also continue if the committee chooses to delay implementation.

A committee member stated that from an OPO perspective, if there are heart and lung offer filters, then this might mean that programs are able to work through renal offers faster, and possibly get to the

operating room faster. They commented that the plan to alter the implementation timeline was reasonable.

A representative from HRSA asked about the evidence that centers are unable to get through their offers without filters in place. A committee member commented that because the use of offer filters has greatly reduced the overall denominator for centers by filtering out offers they would never accept, this function would be well utilized in filtering offers for heart and lung offers as well. Another committee member commented that there have been multiple requests from the community to implement offer filters for heart and lung.

Dr. LaPointe Rudow asked for patients' perspectives on delaying the Board approved policy. A patient committee member commented that although they were skeptical of delaying the implementation timeline at first, they agree that this is something that needs to be done, especially when heart and liver programs are asking for these filters. They also commented that programs should not be denied the use of offer filters when they are being evaluated on their acceptance rate. Another patient committee member stated that providing more tools to the greater community will be well received by the patient community.

A committee member stated that heart and liver programs need the use of offer filters sooner. A committee member asked about mandating the use of kidney offer filters. Dr. LaPointe Rudow stated that this is the intention of the policy, and they are discussing a delay for three months. A committee member commented that even when the default filters are implemented, centers can still turn the filters off. They commented that there is no mandate for centers to use the filters.

A committee member stated that based on the presentation, the use of offer filters steadily increased for kidney, and so offer filters for heart and liver should be implemented now so there is more synergy among the usage of offer filters across organ types. A committee member stated their support for modifying the timeline, and stated that from an OPO perspective, it would greatly aid their efficiency measures.

Vote:

The Executive Committee approved the following resolution:

> **RESOLVED**, that the OPTN Contractor is released from the 12-month Service Level Agreement with the OPTN Board of Directors regarding the implementation of *Optimizing Usage of Offer Filters* proposal, adopted by the OPTN Board of Directors on June 26, 2023, in order to prioritize the implementation of the *Enable Liver Offer Filters* project and the *Enable Heart Offer Filters* project.

2. Letter from UNOS Xenotransplantation Work Group

Dianne LaPointe Rudow, Chair of the Executive Committee, presented a letter Board Leadership received on the practice of xenotransplantation from a UNOS Xenotransplantation Work Group. Dr. LaPointe Rudow explained that the letter from the work group identified questions that need to be answered by the time xenotransplantation becomes a common therapy for organ failure. The work group identified appropriate authorities to answer these questions, completed a question prioritization survey to identify which questions need to be answered in the short-, medium-, or long-term future, and the work group categorized the questions. Dr. LaPointe Rudow shared that Board leadership requested the Executive Committee to discuss the potential implications and considerations for the OPTN.

Dr. LaPointe Rudow asked the committee to discuss how the OPTN should prepare to respond to emerging developments in xenotransplantation.

Summary of Discussion:

The Chair of the UNOS Xenotransplantation Work Group spoke to the Executive Committee and explained that the work group would like their work to be proactive to the coming advances associated with xenotransplantation, not reactive. They commented how important the OPTN's involvement in xenotransplantation will be and that it is important for the OPTN to start to consider how this form of transplantation may affect transplantation as a whole. A committee member commented that it is important for the OPTN to act proactively and consider how xenotransplantation recipients will interact with the Waitlist. The committee member commented that the OPTN cannot act on any xenotransplantation work until there is a directive from HRSA to do so.

A committee member commented that it would be helpful for the OPTN to create guidelines for xenotransplantation, such as what testing may need to be performed for xenotransplantation candidates. The Chair of the Executive Committee stated that this cannot be pursued until the OPTN receives instructions from HRSA. A committee member recommended that a histocompatibility representative be included in the conversations on xenotransplantation moving forward.

A committee member noted that they were pleased with the list of potential federal partners listed in the letter. They stated that having an active working group within the OPTN with the noted federal partners is an important next step. A committee member noted that it is important for the OPTN, as the expert on transplantation in the country, to act on xenotransplantation and do something now, rather than waiting until xenotransplantation is more prevalent. A committee member noted that it is important to get ahead of this topic, and that it could be helpful to form a committee to prioritize this work.

A representative from HRSA stated that although HRSA is supportive of innovation and being proactive about xenotransplantation, NOTA does not identify non-human organs as something within the authority of the OPTN, therefore there needs to be a statement from HRSA that would allow the OPTN authority to discuss xenotransplantation. A committee member commented that the focus is how the OPTN will interact with patients who have received a xenotransplantation and then are placed on the allotransplantation waiting list. They commented that the interaction between the two is what the OPTN must consider. A representative from HRSA commented that they agree and understand the request from the OPTN.

It was summarized that the OPTN has authority over the impact of the use of a non-human organ on the allotransplant waiting list. Contractor staff suggested that the committee define what the scope of the OPTN will be and what the OPTN should prioritize and focus on when it comes to xenotransplantation. A committee member commented that a directive from HRSA will help to ensure that there is support throughout the OPTN for innovation in the transplant space. The committee member also noted that because there are going to be more technologies in the future of transplantation, the OPTN could create a framework when adopting new technologies, that can be used in the future for new innovations.

3. Whistleblower Protection*

Rebecca Murdock, Senior Policy Counsel, presented on potential whistleblower protection principles for the OPTN. Ms. Murdock shared a timeline of the whistleblower protection plan since the beginning of the concept in June 2023. She shared that in June 2023, the Executive Committee approved the project with the goals of including a strong statement encouraging different viewpoints and no retaliation will be permitted for the expression of those viewpoints, and codify existing process for concerns about suspected violations of law or ethics into OPTN policy. In August, the committee reviewed the draft policy language, and in September the committee approved the policy for implementation.

Ms. Murdock explained that after the committee approved the policy in September, HRSA notified the OPTN that *Policy 1.6: Whistleblower Protection Policy* has member burden implications and needs public comment. Ms. Murdock noted that the goal of the Executive Committee in creating this policy was to codify the existing reporting process and share in a manner transparent and available to the community, not just to members subject to OPTN policies.

Ms. Murdock shared that the topic is being brought back to the Executive Committee for them to consider reframing the proposal from a policy to whistleblower protection principles. She shared that the proposed principles are a model used in other organizations, and the principles and contain many of the same themes included in the original policy proposal.

Ms. Murdock asked the committee to consider whether they would like to move the from the policy proposal to a broader principles document that would live on the OPTN website and could be changed without going to public comment.

Summary of Discussion:

A committee member confirmed that if the committee decided to incorporate these ideas into principles, that this will not preclude these ideas from becoming policy in the future. Ms. Murdock confirmed that this was correct, and that the committee would need to vote to rescind the action that the committee made in September. Ms. Murdock explained that the ideas were originally framed in policy because policy is a place to show members how the OPTN performs a specific practice. However, because there are no member actions within this policy and the policy mostly highlights actions for the OPTN to take, it is not the same as other OPTN policies.

A representative from HRSA commented that any proposal like this, should be an OPTN Policy or Bylaw, and should be subject to OPTN public comment. The representative from HRSA stated that voting on a resolution by the committee and status of this resolution is unclear to them because there is no reference to resolutions in the OPTN Final Rule or NOTA. They commented that having these ideas as a list of principles would not provide clarity on the weight of these principles. The representative from HRSA asked if OPTN Bylaws would require that whistleblower complaints submitted to the OPTN be sent to the Secretary of HHS. The representative from HRSA commented that it would be less complicated, from HRSA's perspective, for the whistleblower protections to be formatted as a policy, submitted for public comment, and approved as an official requirement of the OPTN. The Chair of the Executive Committee asked why this would have to be submitted for public comment. The Chair stated that this would not impact allocation and it would act as a principle on how the OPTN will handle whistleblowers. A representative from HRSA asked if there were concerns about submitting the proposal for public comment. A committee member stated that it is important the OPTN put these principles into practice sooner rather than later and submitting the policy to public comment would be a lengthy process. Ms. Murdock explained that these principles would act as an administrative governance piece of information, and would not have any impact on membership. She explained that if in the future, if the committee wanted to consider holding members accountable when complaints are submitted, then this would need to be put into policy. Contractor staff explained that these principles provide information to the transplant community on how the OPTN would handle whistleblowers and the process in place for such complaints.

A committee member commented that they do not believe submitting the whistleblower protections for public comment would be a negative thing. They commented that erring on the side of transparency is important. Other committee members agreed with this rationale. Contractor staff agreed but noted that they were not sure policy is the appropriate place for these protections to live.

A committee member suggested that the whistleblower protections include a preamble ahead of the principles that states that the OPTN welcomes active debate and conversation around policies and actions of the OPTN. Contractor staff suggested this be included in a code of conduct.

A committee member commented that there should be a whistleblower policy as well as a code of conduct in place. A representative from HRSA noted that putting a draft policy out for public comment could show that the OPTN took action and is aiming to achieve the input of the entire transplant community.

Dr. LaPointe Rudow summarized that based on conversation, the Executive Committee would like to develop a whistleblower policy and a code of conduct and to put them both out for public comment. A committee member asked if the whistleblower policy and code of conduct could be implemented as an emergency action and then have a retrospective public comment period, however another committee member stated that it is important to save emergency policy actions for true emergent situations.

Contractor staff suggested another option for the committee to consider, noting that the committee could submit the principles for public comment, while they are in place. They stated that submitting them as principles does not necessitate public comment, however principles can be submitted for public comment. A representative from HRSA commented that HRSA does not believe a resolution has standing in the OPTN and that HRSA is unsure on the standing of principles. Contractor staff commented that in the past, principles have been voted on and adhered to.

A representative from HRSA stated that if the whistleblower principles were implemented as a bylaw, then there would be standing for action to be taken if the principles are violated. Contractor staff noted that there are no actions noted in the principles as they currently stand, so this would not be a concern. They noted that the whistleblower principles are a statement of position and are in place to protect whistleblowers. A committee member commented that although the resolution of the principles may be imperfect, is it still valuable for the OPTN to note the whistleblower principles in place.

Vote:

The Chair made a motion that the principles be formatted into a policy and to create a code of conduct that the committee can submit for public comment. The committee unanimously approved the motion.

Next Steps:

The committee chair proposed submitting the whistleblower protection policy and code of conduct for public comment. The Chair proposed the Executive Committee vote on principles at a future meeting to submit for public comment.

4. Expeditious Task Force Updates

Dr. LaPointe Rudow presented an update on the Expeditious Task Force workshop, presented feedback on the three variance framework questions, and discussed OPTN performance metrics with the Executive Committee.

Dr. LaPointe Rudow first shared an update on the bold aims that the task force has been working to develop. She shared that the three areas the bold aims will focus on are growth, utilization, and efficiency. Dr. LaPointe Rudow noted that the task force needed to secure the bold aim of growth before developing the metrics for the rest of the bold aims. She shared that the task force considered three aims for next steps in terms of growth, she asked for the committee's feedback on the growth aim, and ultimately asked for the committee's approval to allow the task force to pursue the aim. Dr. LaPointe Rudow shared that once the task force has refined this aim, then the task force will look to refine the

other two bold aims. She shared that the Task Force will focus their aims on growth throughout the OPTN.

Dr. LaPointe Rudow shared that the Task Force has also been reviewing allocations out of sequence (AOOS) data. She shared that an update from the MPSC showed that allocations out of sequence, during any month, can range from 15-20% in each organ group. She noted that in November alone, the MPSC reviewed 1,500 cases of allocations out of sequence. Dr. LaPointe Rudow shared that the Task Force has proposed that the MPSC review a random sample of allocations out of sequence and to review PDSAs (Plan, Do, Study, Act) to expedite placement. Dr. LaPointe Rudow asked if the Executive Committee would support designating the MPSC to review allocations out of sequence to develop a process and to analyze what it may look like if the OPTN paused outcome measurements for a period of time. The committee then took a vote on to designate the MSPC to review allocations of out sequence and to analyze what would happen if outcomes measurements were not collected for a period of time. The committee unanimously approved the motion.

Dr. LaPointe Rudow shared the project options the Task Force will review and anticipated next steps for the group. She shared that the Task Force has been analyzing the bold aims and now the Task Force will focus on what the projects may be. She shared that these projects will include communication efforts, process improvement projects, PDSAs, potential pilots, potential collaboratives, policy enhancement or monitoring changes. She noted that the Task Force will also analyze education tools, webinars, and individual outreach, and technology enhancements.

Dr. LaPointe Rudow shared anticipated next steps for the Task Force. She shared that these next steps are to enhance the project and communications plans to incorporate recently prioritized activities, developing a plan for messaging and outreach to hospital leaders and other stakeholders. She also stated the Task Force could consider submitting abstracts, begin a process to create PDSAs or pilot variances, and consider other ways to engage the community.

Dr. LaPointe Rudow summarized the conversation from the Executive Committee's October 10 meeting to discuss allocation PDSAs and pilot variances. She shared that the Executive Committee was supportive of developing a singular framework for allocation PDSAs and pilots, and the Executive Committee was supportive of these following a special public comment period to obtain feedback quickly. She shared that the Executive Committee had asked for contractor staff to draft a framework and to bring this information to a future meeting for further discussion. Dr. LaPointe Rudow shared anticipated next steps, including hosting town halls to introduce the initiative, finalizing and releasing the variance framework proposal for special public comment, and asking the community to submit existing protocols and results of completed PDSAs and pilots. She shared that the task force will create a process to evaluate and prioritize possible PSDAs and pilots, and that the task force intends to recommend PDSAs by the time a variance framework is approved and ready to be implemented. She shared that the purpose of this conversation was for the Executive Committee to provide additional feedback on the proposed framework for the special public comment proposal.

Dr. LaPointe Rudow asked the committee to consider three questions:

- Does the OPTN want to structure the pilot to include all organs or just kidney?
- Does the OPTN want to structure the framework to allow open and closed variances?
- Which group will have authority to approve protocols?

Summary of Discussion:

When discussing the bold aim of growth, a task force member on the Executive Committee commended the work of the task force and agreed that developing metrics and measurable outcomes are important

for the success of the task force. A committee member, representing the patient community, commented that they believe the OPTN is too conservative and need to give patients the opportunity to be transplanted at lower success rates if available. Another committee member representing the patient community asked how patient safety would be measured. A committee member commented that they were impressed by the conversations had during the Task Force meeting on projects that will help enhance transparency with patients.

A committee member asked if the Task Force has discussed stakeholder engagement. Dr. LaPointe Rudow shared that there were multiple conversations about stakeholder engagement and that Board Leadership plans to engage with HRSA to arrange a meeting with Centers for Medicare & Medicaid Services (CMS). The committee member commented that sharing the vision of the Task Force with the payer groups would be beneficial so they can visualize what the end point of the Task Force will be and the data that support this. A representative from HRSA commented that they are optimistic about conversations with payers.

A committee member asked how these changes have been perceived by transplant surgeons. Dr. LaPointe Rudow commented that there are transplant surgeons apart of the Task Force and adding their input to represent this group. She stated that surgeons on the Task Force are supportive of the changes but want to ensure their hospital leadership is supportive of these changes. The committee vice chair commented that these changes are not about one group within the transplant community but are about how the system can work better.

After the committee unanimously agreed to designate the MPSC to review allocations out of sequence and to pause measurement outcomes, HRSA asked what members of the OPTN would be involved in this study. Dr. LaPointe Rudow explained that the MPSC would have the discretion to advise the Task Force on which members should be included. She explained that the details are still unknown as PDSAs have still not been developed at the time of the meeting.

A committee member shared that based on feedback they have heard, the community believes the Task Force is heavy in OPO representation and they would recommend that granting the Executive Committee the authority to approve protocols would be the appropriate recommendation.

A representative from HRSA commented that the proposed frameworks for variances should be approved by the Executive Committee and be shared with the full Board as well. Maureen McBride, OPTN Executive Director, shared that the variance framework would be sponsored by the Executive Committee and would be submitted for special public comment, and then the framework would be approved by the Board.

The committee agreed with the recommendation for the Executive Committee to review and approve proposals from the Task Force, including the applicable communications and analysis plans. Multiple committee members agreed that the policy framework should be written so it is applicable to allow PDSAs involving any organs and not specifically just kidney. The committee discussed what the purpose of a closed variance was and discussed whether the framework of the variances would be applicable to alternative adaptations per the Final Rule.

Next Steps:

Contractor staff will draft language for a public comment proposal incorporating the framework feedback discussed by the committee.

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**
  - Adrienne Goodrich-Doctor
  - Christopher McLaughlin
  - Suma Nair
- **UNOS Staff**
  - Anna Messmer
  - Dale Smith
  - James Alcorn
  - Julie Nolan
  - Liz Robbins Callahan
  - Maureen McBride
  - Morgan Jupe
  - Rebecca Murdock
  - Ryan Ehrensberger
  - Susie Sprinson
  - Tony Ponsiglione