OPTN Policy Oversight Committee
Meeting Summary
March 18, 2024
In-Person Meeting
Jennifer Prinz, BSN, MPH, Chair
Erika Lease, MD, Vice Chair

Introduction

The OPTN Policy Oversight Committee (The Committee) met in-person in Richmond, Virginia on 03/18/2024 to discuss the following agenda items:

1. Follow-Up: Strategic Plan Discussion
2. Efficiency Efforts
3. Breakout Group Discussion of Policy Ideas
4. Policy Prioritization Workgroup Update
5. New Project Review: Requirements for Communicating Post-Transplant Disease
6. Post-Implementation Subcommittee Update

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

1. Follow-Up: Strategic Plan Discussion

The Committee revisited discussion on the Executive Committee's *2024-2027 OPTN Strategic Plan* proposal*.*

Presentation Summary:

The Chair reviewed the Executive Committee's 2024-2027 OPTN Strategic Plan proposed three goals: Improve Offer Acceptance Rate: Increase opportunities for transplants for patients in need by enhancing offer acceptance, Optimize Organ Use: Maximize the use of organs for transplantation for waitlisted patients, while maintaining or improving upon past equity gains, and Enhance OPTN Efficiency: Increase the efficiency of the OPTN through improvement and innovation to serve the greatest number of patients.

Recognizing the need to prioritize and manage work differently, a Board workgroup was launched in early 2024 to refine the project prioritization and approval processes. This plan will be managed by the Board and Executive Committee through regular reviews of strategic plan metric results, review of OPTN resource allocation, and discussion of community needs. This plan is intentionally structured to provide flexibility and latitude to the Board to be responsive to the needs of the community. Specific initiatives or projects are not included in the plan, but rather will be selected and approved by the Board or Executive Committee.

Summary of discussion:

Members commented that the proposed strategic plan and its goals are too narrow in scope, appear to be tactical in nature, and may be overlooking other important areas such as equity, safety, living donation, long-term outcomes, and ongoing critical projects like continuous distribution and multi-organ transplant. The Committee feels this plan is an abrupt shift in OPTN focus and does not build on past strategic plan gains, nor does it incorporate context of ongoing projects. The Committee suggests broadening the strategic goals to explicitly include living donation, equity, safety, and ability to

incorporate new data elements (ex. NRP). In response to the Executive Committee's question "What organs are at the greatest risk of non-use?" members commented this question should be answered with available data vs. community input. Members expressed concern for the metrics outlined in the plan causing unintended consequences to other areas important to the community not outlined in the proposed goals. Members commented that the added transparency for patients is a welcome addition to the strategic plan, however there is concern for patient safety and equity not being explicit within the plan's goals.

Members expressed concern that potentially deprioritizing current projects may lead to disengagement from the community and committee volunteers. Long-term, ongoing projects such as continuous distribution have been a significant investment of community time and effort. Deprioritizing this work may give the impression that it is no longer important. The POC supports maintaining the strategic policy priorities in progress to allow these projects to continue to completion. The POC requests clarity on the Executive Committee's vision for current committee projects and strategic policy priorities.

Members expressed concern regarding the future role of the POC in the proposed strategic plan and potential changes to the policy prioritization process. The POC requests clarity from the Executive Committee on how projects that are not clearly aligned with strategic plan goals should be evaluated, prioritized, and resourced. POC members encourage a stronger partnership between the POC, Executive Committee, and Board of Directors in evaluating committee work, prioritizing, and resourcing.

Next steps:

The Committee will submit a formal public comment on the Executive Committee's *2024-2027 OPTN Strategic Plan* proposal.

2. Efficiency Efforts

The Committee received an update on the Expeditious Task Force efforts.

Presentation Summary:

The OPTN Expeditious Task Force was created in 2023 to determine pathways to increase the number of successful transplants and improve organ allocation efficiency. Organ Transplantation is at a critical inflection point. There is an opportunity to modernize the transplant system, drastically increase the number of successful transplants annually, and give more patients a second chance at life with gifts from donors and their families. The Expeditious Pillars of focus will be targeting growth, efficiency, as well as use/utilization.

Central to the work is aligning exploration with improvement to patient experiences. It's important to have a patient-centered approach. The Task Force mission is to drive transformation, growth, and create opportunity across the transplant industry and beyond. The Task Force currently represents partners from across the transplant community and the work will require aligning an ever-growing network of collaborators to be successful.

To guide the work, The Task Force created a Bold Aim. The first Bold Aim is to achieve 60,000 annual successful deceased donor organ transplants by the end of 2026. This Bold Aim defines success and will drive progress, growth, and efficiency in organ transplantation. To provide clarification, the number of deceased donor transplants, not number of organs transplanted from deceased donors.

Some Task Force suggestions included the following: Consider a separate, patient-focused event. Hospital C-Suite targeted sessions on growth and financials. Align metrics/incentives. Invite payors.

Efforts to disseminate effective practices and standardize donor and allocation processes, including but not limited to communication, required donor testing, donor management, biopsy reads, and virtual crossmatching.

Summary of discussion:

A member suggested that if variances (exceptions to standard policies) are allowed, they must have strict timelines and be expanded to larger groups quickly to avoid inconsistencies. The member also commented they are against eliminating consent for high KDPI organs entirely. A member also commented there are regional variances and opportunities to utilize high KDPI kidneys better. The Vice Chair suggested informing patients about the use of higher risk organs and giving waiting time credit for accepting them. Another member cautioned high KDPI consent policies can make placing hard-to-place organs even harder. Finally, a member suggested facilitating partnerships between HRSA and CMS to better adjudicate data on graft loss risk.

Next steps:

 The Committee will continue to receive updates on the Expeditious Task Force's progress.

3. Breakout Group Discussion of Policy Ideas

The Committee discussed policy ideas targeting Non-use of organs, Organ procurement organization (OPO) efficiency, and transplant program efficiency.

Presentation Summary:

The Expeditious Task Force has been soliciting ideas for policies that may need revising to promote system efficiency. The themes for policy ideas included Non-use of organs, OPO efficiency, and Transplant program efficiency. The Committee was then split into three breakout groups to discuss those policy ideas as it pertains to what priority, feasibility, conflicting projects/policies, impact, efficiency goals, quick wins vs. longer-term projects, project benefit, proposed strategic plan, what committees are best to sponsor vs. be engaged in potential project, and other policy ideas/solutions to promote efficiency.

Summary of discussion:

Non-use of organs**:** There is a strong emphasis on the critical need for accurate and comprehensive data collection to identify barriers, justify policy changes, and understand variances in organ acceptance/turndowns. Challenges are noted around data collection costs, changing practices like machine perfusion creating a "moving target", and the potential for observed behavior changes. Members highlighted needing better data to include late organ turndowns and high KDPI kidney utilization patterns. The Committee expressed that there is broad support for revising or replacing the KDPI metric to better reflect true graft quality and outcomes for kidneys currently labeled as "high risk". Some high KDPI kidneys may have reasonable outcomes but face negative perceptions. However, maintaining consent processes for higher risk KDPI kidneys is still supported. Exploring a "safety net" pathway for placing high risk organs is suggested, potentially expanding beyond just kidneys. The overarching themes are improving data transparency, revising risk metrics, increasing appropriate utilization of viable organs currently stigmatized as "high risk", and incorporating living donation pathways - all aimed at increasing overall transplant rates.

OPO Efficiency: As it pertains to organ offer filters there is strong support for eliminating the requirement to use the Organ Center (OC) for national kidney offers, and instead having mandatory offer filters that OPOs/centers can apply directly. Prioritizing development of improved, patient/center-specific offer filters across all organ types, not just stepwise by organ. Providing more data, education,

and incentives (e.g. showing impact on offer volume) to drive adoption of offer filters by centers were also suggested. Virtual crossmatching was discussed amongst the group as well as Clinical Laboratory Improvement Amendments (CLIA) has approved removing physical crossmatch requirements. Members commented that it was important to work on policies to incentivize entering unacceptable antigens for better virtual crossmatching. A member commented there should be a requirement for donor human leukocyte antigens (HLA) typing for match runs. When it comes to unblind matching, members suggested unblinding centers (not candidates) during match runs to drive competition/efficiency.

The group discussed biopsy processes and digitizing slides for more seamless remote readings as well as evaluating centralized reading services. Lastly, the group discussed donor testing updates and that reviewing testing protocols was of importance. Overall, there was a drive to empower OPOs/centers with better tools and data to make efficient decisions, while increasing standardization, and utilizing trials/variances to rapidly test new processes - with a goal of increasing organ utilization and transplant volumes.

Transplant Program Efficiency: The Committee discussed key challenges and tradeoffs in organ allocation policies, especially balancing the goals of increasing transplant numbers/efficiency while maintaining equity, safety, and optimized organ placements.

Next steps:

The Committee's feedback will be summarized and referred to the Expeditious Task Force for consideration.

4. **Policy Prioritization Workgroup Update**

The Committee received an update on the Policy Prioritization Workgroup (the Workgroup).

Presentation Summary:

In early 2024, a Board workgroup was created to refine project prioritization and approval processes. The workgroup is comprised of 10 members representing the Board of Directors and the Policy Oversight Committee. To provide effective oversight and resource management, the Board requires greater understanding of the OPTN's body of work and its impact. The current OPTN process does not include active reprioritization of the work or full transparency into current prioritization processes. With the implementation of a more focused strategic plan, the establishment of the Expeditious Task Force, and the finite capacity and resources of the OPTN, a process must be defined to:

- Ensure key priorities of the transplant community are resourced with impactful initiatives
- Ensure the OPTN's resources are allocated in a way most beneficial to the transplant community (both in alignment to the strategic plan and outside of the plan)
- Provide clarity to roles and responsibilities within the oversight and prioritization process

The scope for this group was to define a process to prioritize, approve, decline, and request refinement of work in support of the OPTN Strategic Plan, Task Force, and other critical work for the transplant community. Define a process to manage the OPTN portfolio of work (resources). As well as provide clarification of roles, responsibilities, and needed information to execute the defined process.

The Workgroup goals are to share a recommended prioritization and approval process including implementation considerations for the new process at the June 2024 Board meeting. The proposed process should address key pain points, address problem statements, and achieve key measures of success.

Summary of discussion:

A member raised concern for a lack of understanding around how policy ideas are currently prioritized. It was noted they are supposed to align with the strategic plan. The member commented there is already Board and community involvement in this process. The Vice Chair acknowledged there is a lack of transparency in the current "ideas phase" across committees and an opportunity for more standardization and education. Another member raised concern that requiring every idea to go through an extensive prioritization before any analysis can slow down the policy process too much. This can be seen as a shift away from subject matter experts driving what is most relevant towards more of a broad "spit-balling" approach. The Vice Chair clarified the intent is not to remove subject matter expertise input, but to bring more standardization and consistency to the initiation and prioritization process across committees. The Committee supported more transparency but raised concerns around resource constraints already faced by the OPTN.

While supporting the need for more transparency and standardization in the idea generation and prioritization process, the Committee raised concerns about overengineering the process to the point of stifling ideas before analysis, resource constraints, and maintaining committee subject matter expertise input. Improving data analysis capabilities was also highlighted as a need.

Next steps:

The Workgroup is currently discussing ideas focused on early prioritization and strategic plan alignment. The Workgroup will then focus on project idea generation and clarity of roles. A progress update to Committee Chairs and the Executive Committee is tentatively planned for March/April.

5. New Project Review: Requirements for Communicating Post-Transplant Disease

The Disease Transmission Advisory Committee (DTAC) presented to the Committee their new project: Requirements for Communicating Post- Transplant Disease.

Presentation Summary:

The purpose of this project is to update and clarify transplant program requirements for reporting and communicating recipient diseases (Phase 1). Improve the structure and efficiency of the 45-day follow-up process for reporting potential disease transmission events (PDTE) (Phase 2).

Strategic Goal: Promote living donor and transplant recipient safety. In addition to promoting transplant recipient safety, this project includes efficient efforts by updating and clarifying reporting requirements and improving existing data collection: project also aligns with proposed 2024-2027 Strategic Plan. Key Metric for Phase 1: Aim for a 10 percent reduction in the proportion of canceled events due to improper reporting. To demonstrate increased efficiency by reducing the current cancellation rate of 32 percent in 2023, out of 708 events reported, 288 of those cases were canceled. Events in these categories could be reduced with clarified policy language.

Committee members were surveyed ahead of the meeting and the project benefit score showed a 58 with a low cost/benefit for Phase 1 of the project.

Summary of discussion:

There was initial agreement that reducing the number of canceled transplant events due to reporting issues makes sense as a measurable goal. A member noted the Lung Transplantation Committee's insight would be valuable for this project as it relates to lung procurement airway cultures and reporting requirements. A member commented that the focus should be on improving processes around unexpected disease transmissions, rather than expected ones where the risk was known pre-transplant.

There were questions around how "expectedness" of a transmission event would be determined and by whom. The Chair of DTAC clarified the first phase would not involve changes to donor testing requirements, but rather would provide clarity on what events require reporting or not. Multiple members pointed out that simply reducing canceled events by 10 percent seems like a modest impact, and clearer policies/guidance could have a bigger effect.

The Committee noted the first phase seems important, but cautioned the potential second phase efforts could become expansive quickly. Members also commented that the planned second phase of the project could have a higher benefit to the system.

Overall, while the general concept had support, there seemed to be a desire for more specific details and discussions before full evaluation, as well as managing scope for avoiding significant expansion in future phases. Clear determination of "unexpected" events and improved reporting guidance were highlighted as priorities.

The Committee unanimously approved the project for referral to the Executive Committee: 18 yes, 0 no, 0 abstention.

Next steps:

The project will be reviewed by the Executive Committee for approval.

6. Post-Implementation Subcommittee Update

The Chair of the Policy Oversight Committee Post-Implementation Subcommittee (the Subcommittee) presented on the Subcommittee's proposed process.

Presentation Summary:

The Policy Oversight Committee (POC) has been reviewing projects after implementation and review (as per its charge), but the process has not been well defined. The POC created a Post-Implementation Subcommittee to better define and bring consistency and clarity to the process.

The Subcommittee met 2022-2023 and helped identify:

- When the POC engages with post-implementation review
- What the ask is of committees to provide for the Policy Oversight Committee at final post-implementation review
- A process for formalizing POC review of committee feedback and providing a memo back to the sponsoring committee

For most projects, post-implementation review may occur at six-months, one year and two-year post-implementation. The POC Post-implementation Review Process occurs at the end of the monitoring period. The POC engages when the committee reviews the final monitoring report, whenever that is, but most typically at two years out from implementation. This allows the POC to receive the full picture in terms of the impact of the project, and accounts for limited POC bandwidth since it is not feasible for the POC to review all monitoring reports.

The expectations for committees are to conduct a final post-implementation review where they should discuss and identify whether the project was successful according to a key metric(s), any unintended consequences, and any mitigating factors or limitations in the monitoring analysis. Committee vice-chairs would then present to the POC the final report and their committee's discussions. Following POC discussion, a summary of feedback will be sent via memo to the sponsoring committee for their review and consideration.

The expectations for POC members are to review takeaways from the final monitoring report and the conclusions/feedback from the committee about success, unintended consequences, and limitations. With its membership including vice-chairs from all the committees, the POC can provide feedback to the committee regarding:

- Implications on other projects or priorities within the policy portfolio
- Any gaps or opportunities for improvement in the committee review process
- Identification of further project ideas that may be implied by the analysis

The Post-Implementation Subcommittee accomplished what it set out to do. Given the improved structure and clarity of process, the Subcommittee is disbanded.

Summary of discussion:

A member commented that when data is provided to support new policy proposals or ideas, it often lacks clear statistical analysis and measures of significance/confidence intervals. The data may show differences between groups, but without robust statistical evaluation, it's unclear if those differences are meaningful or just random variation. The Subcommittee Chair agreed that policy development projects should be grounded in objective, rigorous, and testable data analysis upfront. Suggesting variance models could potentially fit well into this proposed framework of upfront rigor.

The overarching themes from discussion are a push for more statistically rigorous data analysis, objective measurable goals, and potentially third-party evaluations - all applied early in the policy development lifecycle. This is aimed at ensuring policy initiatives are grounded in sound evidence and tangible measurable impacts, rather than subjective assertions.

Next Steps:

The Committee will implement the new post-implementation review process with upcoming final monitoring reports. The process will be revisited and adjusted as needed.

Upcoming Meeting(s)

- April 11, 2024 – Teleconference
- May 9, 2024 - Teleconference

Attendance

- **Committee Members**
  - Jennifer Prinz
  - Lisa Stocks
  - Rachel Engen
  - Stephanie Pouch
  - Kim Koontz
  - Erika Lease
  - Gerald Morris
  - Nicole Turgeon
  - Christine Brenner
  - Scott Lindberg
  - Arpita Basu
  - JD Menteer
  - Lori Markham
  - Matt Hargrove
  - Stevan Gonzalez
  - Ty Dunn
  - Vijay Gorantla
  - Peter Stock
  - Jesse Schold
- **HRSA Representatives**
  - Marilyn Levi
  - Shelley Grant
  - Vanessa Arriola
- **SRTR Representatives**
  - Ajay Israni
- **UNOS Staff**
  - James Alcorn
  - Kaitlin Swanner
  - Lindsay Larkin
  - Stryker-Ann Vosteen
  - Viktoria Filatova
  - Cole Fox
  - Rebecca Goff
  - Kim Uccellini
  - Houlder Hudgins
  - Kieran McMahon
  - Krissy Laurie
  - Trish Jasion
  - Tamika Watkins
  - Roger Brown