

**OPTN Policy Oversight Committee
Meeting Summary
December 5, 2024
Teleconference
Jennifer Prinz, BSN, MPH, Chair
Erika Lease, MD, Vice Chair**

Introduction

The OPTN Policy Oversight Committee (POC) met via teleconference on 12/05/2024 to discuss the following agenda item:

1. New Project Review: *Require West Nile Virus Seasonal Testing for Donors*
2. Project Prioritization Discussion Continued
3. January 2025 Public Comment Preview and Next Steps

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

1. New Project Review: Require West Nile Virus Seasonal Testing for Donors

The Committee reviewed the following project: *Require West Nile Virus Seasonal Testing for Donors*.

Presentation Summary:

The intended changes proposed by the OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) include reducing unintended transmission of West Nile Virus (WNV) through solid organ transplantation by requiring WNV seasonal testing (June- October) for all donors (deceased and living). The Committee will consider the type of test that should be used (Minipool, ID NAT, etc.) and the limitations of these tests (i.e. is one test more sensitive than the other). The Committee will also consider the feasibility of obtaining a test, and the timing of test results. Changes to policy and existing guidance on donor screening and testing for WNV will also be considered. Additionally, the Committee will discuss changes to data fields in the OPTN Computer System. WNV NAT and WNV antibody fields currently exist in the OPTN Computer System. Changes requiring discussion include the removal of WNV antibody field, due to it being duplicative to the WNV NAT field, and the addition of WNV NAT testing field to the living donor TIEDI form since that is not currently collected on living donors which also has reporting implications. Proposed WNV testing requirements would require updates to OPTN Policies 2.9: *Required Deceased Donor Infectious Disease Testing* and 14.4: *Medical Evaluation Requirements for Living Donors*.

Summary of Discussion:

Staff reviewed the benefit score applied to the project based on information provided in the project form. A member commented that the project could have a positive impact on vulnerable populations since some of those populations could be adversely affected by WNV (ex. pediatric, highly sensitized, etc.). A member advised that the entire solid organ transplant population is considered vulnerable. It is not limited to specific subgroups like children but includes all recipients, as they are immunosuppressed and at high risk of complications from WNV. Members highlighted that they should be considering the vulnerable population question positively. One member highlighted how pediatric populations, due to their susceptibility, should be weighted within the broader scoring of population impacts. The Committee agreed to adjust the benefit score to reflect a positive impact on vulnerable populations,

resulting in a benefit score of 53. Another member advised that testing could protect recipients from WNV exposure, which is currently a gap in the process. A member raised a question on practical aspects like whether all Organ Procurement Organizations (OPOs) can conduct testing, turnaround times, and implications of positive results. For instance, a WNV-positive donor might lead to shutting down an organ donation. The Vice Chair of the Living Donor Committee provided clarification of testing processes, including antibody testing and platform consistency, is crucial, as confusion exists around interpreting WNV-positive results. Another member highlighted that the policy would provide much-needed guidance for OPOs and labs, standardizing responses to WNV-positive donors and mitigating risks. Another member advised that the project is a low-cost, high-benefit initiative that complements broader screening and data collection efforts.

Vote:

Does the Committee recommend approval of the new project to Executive Committee?

14 yes, 0 no, 0 abstain

Next Steps:

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

2. Project Prioritization Discussion Continued

The OPTN contractor staff presented on prioritization of projects and continued to discuss potential approaches.

Presentation Summary:

The benefit score is a scoring framework used to evaluate the potential impact of a project, assigning points based on several criteria, with a maximum score of 100. The scoring framework assesses alignment with strategic plan goals, impact on vulnerable populations, breadth and percentage of population impacted, and project measurability.

Summary of Discussion:

The Committee discussed potential adjustments to the existing benefit score framework. The Vice Chair emphasized the importance of considering the risks of not doing a project, such as patient safety or organizational risks, alongside other scoring components. The Chair suggested quantifying risk levels (e.g., no risk, mild, severe) to weigh them effectively in scoring decisions. One member raised concerns about the binary nature of scoring (30 points for alignment, 0 for no alignment) and suggested introducing a middle tier for partial alignment with less weight than full alignment. However, the Committee did not have immediate solutions. Regarding population impact scoring, the Chair proposed researching the history of these figures for clarity in future discussions.

Next Steps:

The Committee will continue discussions on a project prioritization approach during an upcoming meeting.

3. January 2025 Public Comment Preview and Next Steps

The OPTN contractor staff presented the January 2025 Public Comment slate and advised of next steps.

Presentation Summary:

The POC conducts an initial review of public comment items. This process focuses on assessing whether projects are prepared for public feedback rather than critiquing their content. It emphasizes identifying

and addressing challenges related to demonstrating the problem or accumulating evidence before public consideration. Any feedback or concerns from this review are relayed to the sponsoring committee for response or modification prior to the public comment period. While all projects receive a brief review, those needing deeper evaluation can be flagged for in-depth discussion. This step ensures that public comment items are well-prepared and evidence-based before being released.

Next Steps:

At the January 15 meeting, the POC will conduct a full review of public comment proposals to evaluate their readiness and provide recommendations to the Executive Committee for approval. POC members will be assigned specific proposals for review, with assignments distributed by the end of December. Members are expected to thoroughly review their assigned items, provide relevant feedback, and actively participate in focused discussions during the meeting to ensure proposals are prepared for public comment.

Upcoming Meeting(s)

- January 15, 2025 - Teleconference

Attendance

- **Committee Members**
 - Erika Lease
 - Cynthia Foreland
 - Heather Bastardi
 - Hannah Copeland
 - Dennis Lyu
 - Kelley Hitchman
 - Jennifer Prinz
 - Lisa Stocks
 - Lisa McElroy
 - Lori Markham
 - Lorrinda Gray-Davis
 - Oscar Serrano
 - Macey Levan
 - Paige Porrett
 - Ty Dunn
 - Rachel Miller
- **HRSA Representatives**
 - Ray Lynch
 - Shannon Dunne
- **SRTR Staff**
 - Allyson Hart
- **UNOS Staff**
 - Lindsay Larkin
 - Kaitlin Swanner
 - Tamika Watkins
 - Susan Tlusty
 - Darby Harris
 - Cole Fox
 - Kimberly Uccellini
 - Rebecca Goff
 - Viktoria Filatova