**OPTN Policy Oversight Committee
Meeting Summary
November 14, 2022
Conference Call**

**Nicole Turgeon, MD, FACS, Chair
Jennifer Prinz, RN, BSN, MPH, CPTC, Vice-Chair**

Introduction

The Policy Oversight Committee ("Committee") met via Citrix GoToMeeting teleconference on 11/14/2022 to discuss the following agenda items:

1. Budget Update & NRP Follow Up
2. New Project Review
3. Recap and Next Steps

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

1. Budget Update & NRP Follow Up

OPTN Staff provided an update on the OPTN budget approval process for fiscal year 2023. The POC voted in favor of the budget in their June 2022 meeting. Staff also provided an update on the normothermic regional perfusion (NRP) discussion that was held at the previous meeting.

Data summary:

Budget Update

- On 9/16/2022, the Health Resources and Services Administration (HRSA) notified the OPTN that the proposed fiscal year 2023 budget was not approved
- The OPTN will continue collecting the fiscal year 2022 OPTN fee until a new budget is approved

NRP Follow Up

- Following the Committee's recommendation from their previous call, the OPTN Ethics committee affirmed their need for more time to discuss the ethical implications of NRP
- The Ethics Committee still intends to complete this white paper during 2023

Summary of discussion:

The visiting board member on the Committee added that the issues HRSA identified were notably in-person meeting costs and overall workload costs. They stated that HRSA requested a clearer indication that a larger IT budget was necessary to complete all the projects undertaken by the OPTN.

The Vice-Chair of the Ethics Committee contributed that the Workgroup analyzing NRP is making progress, but the extra time will be beneficial to reviewing each individual's perspective.

Next steps:

Staff will provide any updates to the Committee as necessary surrounding the OPTN budget or NRP.

2. New Project Review

The Committee reviewed two new projects seeking POC approval: *OPTN KPD Blood Type Alignments* and *Improving Access to Transplant for Multivisceral Candidates.* These projects were presented by the OPTN KPD Workgroup Chair and Liver & Intestine committee staff.

Data summary:

OPTN KPD Blood Type Alignments

- This proposal seeks to align OPTN kidney paired donation pilot project (KPDPP) matching policy for blood groups A, non-A1, AB, and non A1B with that in kidney policy
- It will also require annual reevaluation of donors in the KPDPP, including medical, psychological, and informed consent requirements

Improving Access to Transplant for Multivisceral Candidates

- This guidance document seeks to ensure multivisceral candidates are provided appropriate access to transplant by creating National Liver Review Board (NLRB) guidance to allow for more consistency in the approval of MELD exceptions for this population

Summary of discussion:

OPTN KPD Blood Type Alignments

The discussion lead for this proposal noted that, after reviewing the resources available for June 2023, they would be hesitant to add an additional project to that cycle. Staff responded that there were technical implementation hours available as the OPTN Operations and Safety committee would not be pursuing their proposal on redefining provisional yes for that Board of Directors cycle.

A second member added that the alignment aspect seemed like "low-hanging fruit" while also being impactful and necessary; they were supportive of the project.

With no further discussion, the Committee approved the project *OPTN KPD Blood Type Alignments* (16 yes, 0 abstain, 0 no).

Improving Access to Transplant for Multivisceral Candidates

The Chair inquired if this project would slow down the implementation of continuous distribution. The Liver chair replied that this would likely not, due to the low level of effort required to develop this policy. The discussion lead also asked if this should be sequenced ahead of continuous distribution because of the low number of patients impacted; however, they did acknowledge that, if this was a low resource investment, there would be no adverse effect to sequencing it ahead of continuous distribution.

Staff clarified that the area this guidance document targets would specifically impact the adult multivisceral population. The pediatric population did not see a significant change in mortality following the implementation of acuity circles.

The Vice-chair of the Multi-organ Transplant (MOT) committee requested the MOT committee be included as a stakeholder among the collaborating committees listed. Both the Chair and the Liver Chair were supportive of this suggestion.

With no further discussion, the Committee approved the project *Improving Access to Transplant for Multivisceral Candidates* (16 yes, 0 abstain, 0 no).

Next steps:

The sponsoring committees will provide the Committee any update when necessary.

3. Other Significant Items

The Committee reviewed the progress of the Benefit Scoring Subcommittee and the Post-Implementation Monitoring Subcommittee. These were presented by the chairs of the subcommittee.

Data summary:

Staff provided clarity on the difference between the OPTN Strategic Plan and the POC Strategic Policy Priorities

- OPTN Strategic Plan
    - Increase Transplants
    - Provide Equity in Access to Transplant
    - Improve Outcomes
    - Promote Safety
- POC Strategic Policy Priorities
    - Continuous Distribution
    - More Efficient Donor/Recipient Matching to Increase Utilization
    - Improve Equity for Multi-Organ and Single Organ Candidates

The following ideas were proposed at the previous meeting:

- Add elements to the benefit score (feasibility, numeric size of the population)
- Clarify benefit elements (population size, impact)
- Threshold score for projects moving forward (minimum score required to be achieved)

The Chair of the Post-Implementation Monitoring Subcommittee compared the function of post-implementation monitoring akin to that of a data safety monitoring board. They added that the function should not be for the Committee to perform the analysis but to draw inferences from the analyses. The core processes would be to:

- Periodically review and evaluate projects
- Define what would trigger review
- Determine what the review is evaluating
- What recommendations are available to be made
- Identify reviewers

Summary of discussion:

Benefit Scoring Subcommittee

Staff noted that there was an extremely high rate (~99%) of projects scored by the committee that received full score for aligning with OPTN Strategic Plan. The Workgroup chair added that many of the scored projects were receiving very high scores, which likely did not accurately gauge the nuances between projects.

A member suggested that technical implementation effort required should be considered for benefit scoring. The Chair replied that the technical implementation effort was not something that required the Committee to estimate and should be provided as a static score; in addition, it may need to be considered outside of the context of benefit when reviewing a project.

The Chair wondered if projects should receive any points for aligning with strategic plan and policy priority, noting that there would be benefit to promoting projects that align with both of these. A member proposed that projects would gain points only if they aligned with an under-allocated policy priority.

A second member suggested that the POC should focus on the areas in which there was not an objective value in order to be able to quantify the subjective areas to provide an aggregate score of objective and subjective values. Once that score was produced, it could be weighed against the overall cost of the project. As an aside, they supported adding a policy priority on whether a proposal will increase access to the waiting list.

The Workgroup chair concluded by noting that the process could be updated by having the sponsoring committee provide responses to the Committee for review, rather than having the Committee members answer the questions.

Post-Implementation Monitoring Subcommittee

The Chair of Post-Implementation Monitoring Subcommittee emphasized that this should be an iterative process, but members should be considering what the initial design of the Committee's review looks like.

<u>Next steps:</u>

The chairs will provide report outs following their next subcommittee meetings.

Upcoming Meeting

- December 12, 2022

Attendance

- **Committee Members**
  - Nicole Turgeon
  - Jennifer Prinz
  - Andy Flescher
  - Brad Kornfeld
  - Alejandro Diez
  - Dolamu Olaitan
  - Gerald Morris
  - Jason Huff
  - Jesse Schold
  - Jim Kim
  - Jondavid Menteer
  - Lisa Stocks
  - Peter Stock
  - Natalie Blackwell
  - Rachel Engen
  - Scott Lindberg
  - Stephanie Pouch
  - Kimberly Koontz
- **HRSA Representatives**
  - Amond Uwadineke
  - Marilyn Levi
  - Vanessa Arriola
- **SRTR Staff**
  - Marian Charlton
  - Ryo Hirose
- **UNOS Staff**
  - Amber Fritz
  - Anna Wall
  - Chelsea Haynes
  - Cole Fox
  - Courtney Jett
  - Darby Harris
  - Isaac Hager
  - Kaitlin Swanner
  - Kayla Temple
  - Kelley Poff
  - Kieran McMahon
  - Krissy Laurie
  - Lauren Mauk
  - Liz Robbins Callahan
  - Matt Belton
  - Matt Caffarella
  - Roger Brown
  - Ruthanne Leishman
  - Sharon Shepherd

- o Susie Sprinson
- o Tamika Qualls
- o Taylor Livelli
- o Tina Rhoades
- o Morgan Jupe
- **Other Attendees**
  - o James Pomposelli