

OPTN Policy Oversight Committee

Meeting Summary

June 13, 2022

Conference Call

Nicole Turgeon, MD, FACS, Chair

Jennifer Prinz, RN, BSN, MPH, CPTC, Vice-Chair

Introduction

The Policy Oversight Committee (the Committee) met via Microsoft Teams teleconference on 06/13/2022 to discuss the following agenda items:

1. Project Benefit
2. New Project Review

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

1. Project Benefit

Staff provided a review of the scores from the benefit exercise, as well as an overview of the scores for the current portfolio.

Data summary:

- Strategic Plan Alignment (23%) – Does this project fit within one of the four OPTN Strategic Plan Goals? (Y/N)
- Strategic Policy Priority Alignment (23%) – Is this project a key initiative in one of the strategic policy priorities? (Y/N)
- Vulnerable Populations (23%) – Does this project positively impact any vulnerable populations? (Y/N)
- Size of Population Impacted
 - Number of patients impacted (9%)
 - Percent of patients in target population impacted (9%)
- Measurable Impact (13%) – Is this project measurable based on its key metric? (Y/N)

Summary of discussion:

A member inquired why the proposal to revise the OPTN Charter had any score within question on vulnerable populations. The Chair suggested that it could have received score because it technically impacts all populations, which include vulnerable ones. They added that this was a good focus for discussion, as they did not feel that projects which impact all populations should receive the same benefit as those specifically targeting vulnerable ones. Another member also noted difficulty in scoring the project to revise the OPTN charter, as its focus was significantly different than some of the other proposals. They stated that the Committee needed to consider how they would be scoring projects to revise the charter or bylaws.

A member proposed having the list of vulnerable populations present next to the question on their survey to remind reviewers which populations they were considering when scoring. This was supported by the Chair.

A second member noted that, when they scored the Modify Living Donor Exclusion Criteria project, they scored it based off of the vulnerable population of ethnic minorities that the project is addressing, rather than living donors. They wondered if thought should be given to the implications of projects, even if they don't explicitly call out their impact on vulnerable populations. The Chair replied that the score was not intended to be a substitute for discussions surrounding the projects.

It was noted by a member that measurable impact should be closely tracked in all of the Committee's discussions, since that is what provides the feedback loop to inform efficacy.

The Chair and a member voiced support for the overall project benefit scoring, only commenting that there was not much separation between scores in the middle. The member added that any metric that provided the same score to each project reviewed was not highly discriminatory and its use should be considered.

Next steps:

Staff will start considering cost in conjunction with benefit in the metric. The Committee will begin to utilize the benefit scoring in new project reviews.

2. New Project Review

The Committee reviewed two new projects seeking approval.

Data summary:

Review of Liver Variances in OPTN Policy (OPTN Liver Committee)

- There are currently four variances in liver policy (ABO blood type, HI/PR access for urgent candidates, region 8 split liver, Open split liver)
- This project will set the end date for all variances to be upon implementation of continuous distribution

Ethical Considerations of Normothermic Regional Perfusion (OPTN Ethics Committee)

- This project will evaluate the ethical implications of Normothermic Regional Perfusion (NRP) as a surgical technique in deceased organ recovery

Summary of discussion:

Review of Liver Variances in OPTN Policy

A member questioned how monitoring could take place for this project, as the project is to end an existing structure. The representative from the Liver Committee responded that their plan was to continue monitoring the effectiveness of the former variances in the new structure. With no further discussion, the Committee unanimously recommended approval of this as a new project (12 yes, 0 no, 0 abstain).

Ethical Considerations of Normothermic Regional Perfusion

The Vice-Chair emphasized that the project should be careful with language surrounding authorization and informed consent. They also suggested including the transplant administrator perspective in the discussion workgroup. The Vice-Chair from the Ethics Committee noted that all instances of the word consent had been removed from their draft documents based on initial feedback.

The discussion lead contributed that there had been transplant societies who had both voiced concern and support for the usage of NRP. They added that there had been comments which called into question whether this went against the concept of nonmaleficence. The Ethics Vice-Chair responded that the

discussion of nonmaleficence would be incorporated into their larger discussion of “killing versus letting die”. With no further discussion, the Committee recommended approval of this as a new project (10 yes, 0 no, 1 abstain)

Next steps:

The approved projects’ sponsoring committees will update the Committee with their progress as they progress.

Upcoming Meeting

- July 11, 2022
- July 27, 2022

Attendance

- **Committee Members**
 - Nicole Turgeon
 - Jennifer Prinz
 - Sandra Amaral
 - Richard Daly
 - Alden Doyle
 - Andrew Flescher
 - Valinda Jones
 - Jim Kim
 - John Lunz
 - Oyedolamu Olaitan
 - Natalie Santiago Blackwell
 - Zoe Stewart Lewis
 - Susan Zylicz
- **HRSA Representatives**
 - James Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Ryo Hirose
 - Ajay Israni
- **UNOS Staff**
 - James Alcorn
 - Matt Cafarella
 - Michael Ferguson
 - Cole Fox
 - Rebecca Goff
 - Darby Harris
 - Nadine Hoffman
 - Kristina Hogan
 - Courtney Jett
 - Lindsay Larkin
 - Krissy Laurie
 - Taylor Livelli
 - Lauren Mauk
 - Maureen McBride
 - Eric Messick
 - Rebecca Murdock
 - Kelley Poff
 - Tina Rhoades
 - Liz Robbins
 - Janis Rosenberg
 - Sharon Shepherd
 - Laura Schmitt
 - Susie Sprinson
 - Kaitlin Swanner
 - Kayla Temple

- Kimberly Uccellini
- Stryker-Ann Vosteen
- Joann White