

**OPTN Policy Oversight Committee
Meeting Summary
May 8, 2023
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 05/08/2023 to discuss the following agenda items:

1. Follow-up on Efficiency Conversation
2. Pre-Public Comment Check-in
3. New Projects

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

1. Follow-up on Efficiency Conversation

At the previous meeting, the Committee examined possible updates to the “Efficient Matching” policy priority. The Committee also discussed using a portion of the technical implementation budget to support system enhancements.

Data summary:

The proposed non-policy enhancements are based off recommendations from the OPTN Operations & Safety Committee’s Workgroup on Redefining Provisional Yes. System enhancements and improved workflows were identified as a method to improve the efficiency of the overall allocation system.

The proposal from the Workgroup did not proceed after feedback from their concept paper, but the recommendations were considered by the Committee as relevant to the efficient matching policy priority.

The proposed enhancements are:

- Improve the Transplant Center organ offer console display
- Update the find candidate and multi-candidate refusal options
- Easier navigation between multi-organ match runs
- Ability to see donor information and potential recipient info in one view

Summary of discussion:

A member asked if any potential controversies had been identified by either staff or the Operations and Safety Committee in pursuing these enhancements. Staff replied that they were being shown to the Committee for awareness and to understand if they were relevant to the members’ clinical opinion.

The Vice-chair of the Operations & Safety Committee noted that their committee had discussed and approved of the enhancements package.

There were no further comments on approving the enhancements package for Board approval during their June 2023 meeting.

Next steps:

The enhancements package will be presented to the Board of Directors at their June 2023 meeting.

2. Pre-Public Comment Check-in

The Committee reviewed the projects being submitted for public comment during the fall 2023 public comment cycle. This is the first of two public comment presentations to provide the Committee with an opportunity to share feedback with the sponsoring committee. The Committee is not voting at this point to release the proposals for public comment.

Data summary:

Kidney/Pancreas Continuous Distribution

- Due to modeling request delays, this proposal will be submitted as a request for feedback rather than an approval for Kidney/Pancreas Continuous Distribution
- The Kidney and Pancreas committees are considering Board of Directors approval at their June 2024 meeting
- Because of its delay, there is a budget gap identified in the cycle
 - This is anticipated to be filled by three smaller projects to use the implementation hours that had been allocated to continuous distribution

Ethical Considerations of Normothermic Regional Perfusion

- The Committee initially heard this proposal during their public comment preview for the January 2023 public comment release
 - During that discussion, it was recommended that this proposal delay to the next cycle to refine the opinions presented in the paper
- This paper examines the complex ethics of using normothermic regional perfusion (NRP), its interaction with the Dead Donor Rule, and gives guidance related to the authorization of NRP donors

Summary of discussion:

Kidney/Pancreas Continuous Distribution

A member asked what the specific issues encountered were that delayed the proposal. The Kidney Committee Vice-chair replied that there were certain areas of allocation, such as dual kidney and exception review boards, that required more attention than the sponsoring committees felt they had time for. Staff added that there were operational challenges, such as the above, as well as en-bloc and released organ policy, for example, that were complex efficiency issues.

Ethical Considerations of Normothermic Regional Perfusion

A member asked what OPTN Committee have been involved in the discussions. The presenter responded that they did not know the exact number, but there has been a year-long Workgroup with representation from many OPTN committees, as well as interested stakeholder organizations, who have met consistently to determine the format of the analysis.

The presenter also noted that, following the Committee's recommendation from their previous meeting, the paper includes recommendations, but still provides the reader space to draw their own conclusions with the evidence presented.

Next steps:

3. New Projects

The Committee reviewed two new projects seeking POC approval.

Data summary:

Amend Adult Heart Status 2 Mechanical Device Requirements

- This policy proposal will require certain proof of inotropic failure within 7 days prior to the use of an intra-aortic balloon pump (IABP) in order to gain status 2. This would also apply to other percutaneous circulatory mechanical devices within status 2.
- Analysis of IABP candidates indicate their mortality rate more closely aligns with status 3 rather than status 2 candidates

HLA Tables Update 2023

- Perform updates to the OPTN Policy HLA equivalency tables in order to maintain currency with HLA typing capabilities. The updates are:
 - Add 365 typing options at the p-group level
 - Add HLA matching tables for the A, B, and DR loci
- These updates would increase the utility of API development currently being done for labs

Summary of discussion:

Amend Adult Heart Status 2 Mechanical Device Requirements

A member asked what drove the practice of implanting IABPs in candidates in order to gain status 2 priority. The Vice-Chair of the Heart Committee replied that it is a policy loophole to allow otherwise non-qualifying candidates to achieve status 2. The Heart Committee has heard from a variety of sources that it is an issue. They added that, based on the data they had most recently reviewed, two-thirds to three-quarters of all status 2 candidates would no longer qualify if the updated guidelines were approved (300-500 heart candidates being transplanted at status 2). The member requested that the numbers be included in the proposal to give scope to the urgency for this policy change. The Chair also supported including that information.

A member asked why this policy had such a high implementation cost if the onus of the proposal was to add a small amount of justification with the status 2 form. Staff noted that part of the implementation cost was modifying the submission system to account for the new information.

A member asked whether the implantation of an IABP could be considered a violation of patient safety if it was done in order to gain status 2 priority. They also wondered if there were center-specific trends of some programs using this loophole much more than others. The Heart Vice-Chair replied that they offhand felt that there was a wide disparity in programs using the loophole, but that data had not been given to them. They supported an investigation into if there were specific centers that were using the loophole more than others.

With no further discussion, the Committee voted to approve the project (17 yes, 0 no, 1 abstain)

HLA Tables Update 2023

A member noted that they felt it was appropriate given the budget gap and supported its approval. They did note that some labs may need to update their software to utilize the API.

With no further discussion, the Committee voted to approve the project (17 yes, 0 no, 0 abstain)

Next steps:

Upcoming Meeting

- June 12, 2023

Attendance

- **Committee Members**
 - Nicole Turgeon
 - Jennifer Prinz
 - Andy Flescher
 - Gerald Morris
 - Jesse Schold
 - Peter Stock
 - Scott Lindberg
 - Jason Huff
 - PJ Geraghty
 - Rachel Engen
 - Stevan Gonzalez
 - JD Menteer
 - Jim Kim
 - Kimberly Koontz
 - Natalie Blackwell
 - Stephanie Pouch
 - Scott Biggins
- **HRSA Representatives**
 - Vanessa Arriola
- **SRTR Staff**
 - Ajay Israni
 - Jon Snyder
- **UNOS Staff**
 - Cole Fox
 - James Alcorn
 - Kayla Temple
 - Lauren Mauk
 - Alex Carmack
 - Darby Harris
 - Joann White
 - Kaitlin Swanner
 - Laura Schmitt
 - Lloyd Board
 - Meghan McDermott
 - Sara Rose Wells
 - Sharon Shepherd
 - Susan Tlusty
 - Taylor Livelli
 - Tamika Qualls
 - Stryker-Ann Vosteen
 - Roger Brown
 - Matt Cafarella
 - Lindsay Larkin
 - Keiran McMahon
 - Eric Messick

- Amber Fritz
- Isaac Hager