

OPTN Policy Oversight Committee
Meeting Summary
May 9, 2024
Teleconference
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Introduction

The OPTN Policy Oversight Committee met via teleconference on 05/09/2024 to discuss the following agenda items:

1. Expeditious Task Force Update
2. New Project: Promote Efficiency of Lung Donor Testing
3. Health and Human Services (HHS) Directive Update
4. New Project: Updates to National Liver Review Board Guidance and Further Alignment with LI-RADS

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

1. Expeditious Task Force Update

The Committee received updates provided by Expeditious Task Force members.

Presentation Summary:

There is a "Late Declines Discovery Project" that kicked off on April 17, focused on understanding reasons for late declines of organ offers. A "Non-use Workgroup" is advising on research studies and data products related to non-use of organs. The "Rescue Pathways Workgroup" is developing a protocol, with the aim of sending a draft to the Executive Committee for review on May 21.

The draft "Rescue Pathways" protocol outlines criteria for expedited placement of kidneys with KDPI greater than or equal to 75 percent, including eligible candidates and transplant programs with history of accepting high KDPI kidneys. There are plans to pilot this expedited placement protocol with up to five organ procurement organizations (OPOs) initially.

Patient education efforts are underway regarding high KDPI kidney transplants. There are upcoming events/collaborations related to this initiative in Utah (April 12) and New Jersey (May 31). Lastly, there is an effort to better utilize and expedite placement of higher-risk kidney organs that may otherwise be discarded or experience prolonged cold ischemic times before acceptance.

Summary of Discussion:

Members advised there is a distinction between transplant programs being willing to accept higher KDPI kidneys versus individual candidates. The consent process currently focuses on candidates explicitly consenting to accept kidneys over 85 percent KDPI. Multiple members questioned whether the explicit consent process for greater than 85 percent KDPI kidneys should be maintained, modified (e.g. lowering threshold to 75 percent), or eliminated entirely. Some members felt eliminating the requirement could create risks or disparities for patients. One member commented that eliminating the consent process altogether could make the organ allocation process less efficient by requiring all candidates to be offered all kidney offers regardless of KDPI.

2. New Project: Promote Efficiency of Lung Donor Testing

The Committee reviewed the following project: *Promote Efficiency of Lung Donor Testing*.

Presentation Summary:

Organ offer patterns have changed with the implementation of continuous distribution of lungs. Members have expressed concerns about the quality of organ offers. The donor data available at the time they are expected to review and respond to offers are outdated or incomplete. The project's purpose is to promote efficiency of lung allocation by considering changes to lung donor testing in OPTN *Policy 2.11.D: Required Information for Deceased Lung Donors* and creating guidance on requested deceased donor information.

The proposal has two parts - one focused on changes to deceased donor testing/information requirements (proposed for public comment in Summer 2024), and another on changing specific data fields like bronchoscopy, smoking history, lung capacity calculation (proposed for Winter 2025 public comment). The rationale driving the proposal is that since the implementation of continuous distribution for lungs in March 2023, there has been an increase in preliminary acceptances but also more offers being reviewed before final acceptance. More comprehensive donor data submission is aimed at reducing the number of offer refusals due to missing data. Specific metrics being tracked include percentage of declines due to missing organ-specific test data, sequence number of final accepting center, and allocation time from first notification to acceptance.

Summary of Discussion:

Some potential areas of concern were noted by members, specifically the proposal requiring CT scans and bronchoscopies on all donors, which may be challenging especially for DCD donors. However, it was expected these issues would be addressed during public comment. There were suggestions to collaborate with the Organ Procurement Organization Committee on this project given their role in data collection/submission. Disease Transmission Advisory Committee (DTAC) involvement was recommended if guidance around fungal cultures is pursued, since that could impact DTAC's work. The OPTN Operations and Safety Committee is also planning to review donor testing requirements more broadly, presenting an opportunity for alignment across committees.

Overall, while some operational challenges were noted, there seemed to be general support to move forward with the project, with opportunities identified for cross-committee collaboration given the proposal's wide-ranging impacts.

Vote:

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

15 yes, 0 no, 0 abstention

Next Steps:

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

3. Health and Human Services (HHS) Directive Update

The Committee reviewed and discussed the HHS Directive Update.

Presentation Summary:

The OPTN received an HHS Secretarial Directive on February 2, 2024, to collect new data. This includes the ventilated referral notification form and the referral evaluation registration form.

There will be two projects forthcoming to the Policy Oversight Committee with a target of late summer of 2024. The two projects are Ventilated Patient Data Collection from the Organ Procurement Organization Committee and Pre-Waitlist data collection from transplant programs.

Currently the projects are in the analysis and design phase. Solutions will be reviewed with HRSA in the coming months when decisions on development plans will be finalized.

Data collection requirements will be posted for public comment as part of the Office of Management and Budget (OMB) federal process (60-day and 30-day postings targeted in 2024). HRSA intends to revise the February 5, 2024 Directive to include additional direction on submission timelines, start dates and changes to existing forms that result from this new data collection.

Summary of Discussion:

A committee member spoke about the proposal's aims to collect more data on patients between referral for transplant and being listed on the waitlist. Currently there is a gap in understanding the composition, timelines, and processes for this pre-waitlist population. While this data will not capture all potential transplant candidates who were never referred, it will provide more insight into barriers and opportunities to improve access to getting listed for transplantation.

The same member confirmed that there is no current intent to use this data for center performance evaluation or quality measures. The primary goal is to gain a better national understanding of these pre-waitlist populations. There was careful consideration given to balance the need for data with avoiding excessive burden on OPOs/centers during the process of determining which data elements to include initially. The data collection is proposed to occur at two main phases: a) At time of referral for transplant evaluation (smaller dataset) b) At time of selection committee review determining waitlist viability (more detailed dataset) Iterative refinement of the data collection is expected over time, but this represents an important first wave of data elements identified as high priority.

The full details on the specific proposed data elements are available for review on the OPTN website. In summary, while being cognizant of data collection burden, the proposal aims to fill a key knowledge gap to better understand and improve accessibility to getting listed for transplant.

4. New Project: Updates to National Liver Review Board Guidance and Further Alignment with LI-RADS

The Committee reviewed the following project: *Updates to National Liver Review Board Guidance and Further Alignment with LI-RADS*.

Presentation Summary:

The purpose for the project is to:

- Ensure consistency in non-standard exception applications and reviews by updating Adult MELD Exception Review guidance document to revise content based on new literature as well as adding associated score recommendations
- Provide access to standard HCC exception pathways for liver candidates who are receiving care from transplant programs utilizing contrast-enhanced ultrasound by updating HCC policy and guidance to add contrast-enhanced ultrasound as an acceptable adjunct diagnostic tool for HCC
- Promote efficiency by updating HCC imaging classification criteria to align with LIRADS-5 terminology

This project is separate but aligned with the recent *NLRB Updates Related to Transplant Oncology* proposal which deals with HCC and adds guidance for other tumor diagnoses. The goal is to first update

HCC components separately through this project, before potentially incorporating Transplant Oncology guidance later. Updating exception scoring guidance through this project is prudent and may help inform how to prioritize exceptions appropriately within continuous distribution of liver allografts.

Summary of Discussion:

A member noted that aligning HCC imaging classification criteria with the latest LI-RADS terminology will simplify and improve the policy language around imaging criteria for HCC. Including associated score recommendations in the MELD exception review guidance is aimed at reducing variation in how exceptions are scored/prioritized. Allowing contrast-enhanced ultrasound for HCC diagnosis improves equity of access to HCC exception pathways for candidates at centers utilizing this imaging modality.

Vote:

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

11 yes, 0 no, 1 abstention

Next steps:

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

Upcoming Meeting

- June 13, 2024

Attendance

- **Committee Members**
 - Jennifer Prinz
 - Lisa Stocks
 - Rachel Engen
 - Kim Koontz
 - Nicole Turgeon
 - Christine Brenner
 - Scott Lindberg
 - JD Menteer
 - Lori Markham
 - Stevan Gonzalez
 - Ty Dunn
 - Peter Stock
 - Jesse Schold
 - Sanjay Kulkarni Shimul Shah
 - Erika Lease
 - Oscar K. Serrano
 - Stephanie Pouch
 - Matthew Hartwig

- **HRSA Representatives**
 - Shannon Dunne
 - Aite Aigbe

- **UNOS Staff**
 - Kaitlin Swanner
 - Jamie Panko
 - Susan Tlusty
 - Robert Hunter
 - Viktoria Filatova
 - Laura Schmitt
 - Courtney Jett
 - Roger Brown
 - Lloyd Board
 - Holly Sobczak
 - Eric Messick
 - Meghan McDermott
 - Rebecca Goff
 - Nadine Rogers
 - Morgan Jupe
 - Houlder Hudgins

- **Other**
 - Neil Devendra Shah
 - Shelley Tims Grant