

OPTN Policy Oversight Committee

Meeting Summary

August 10, 2023

Conference Call

Jennifer Prinz, BSN, MPH, Chair

Erika Lease, MD, FCCP, Vice Chair

Introduction

The OPTN Policy Oversight Committee met via Citrix GoToMeeting teleconference on 08/10/2023 to discuss the following agenda items:

1. New Project: Standardize the Patient Safety Contact Notification Process and Duplicate Reporting
2. New Project: Establish Exception Criteria for Liver Cancer Diagnoses
3. New Project: Clarifying Requirements for Pronouncement of DCD Donor Death
4. Post-Implementation Memos

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

1. New Project: Standardize the Patient Safety Contact Notification Process and Duplicate Reporting

A representative for the Disease Transmission Advisory Committee (DTAC) presented their new project to the Policy Oversight Committee (POC).

Data summary:

The purpose of the project is to improve the functionality of the patient safety contact and infectious disease reporting process. Inconsistencies in this process have been noticed across transplant programs and Organ Procurement Organizations (OPOs) which lead to an increased difficulty and time spent contacting the patient safety contact or receiving affirmation of successful notification. Additionally, this project will address duplicate reporting of malignant and infectious disease results, as there are currently two policies addressing this topic and this can create unnecessary burden on centers during their reporting process.

The pre-meeting review of the project indicated a cost benefit analysis of low cost/low benefit as the project is projected to require 860 IT implementation hours and would not affect a large proportion of the waiting list population.

Summary of discussion:

Votes: 14 yes, 0 no, 0 abstain

This project will move forward to the Executive Committee for approval.

A member suggested that this project could include a review of the patient safety form itself, ensuring it is up to date and asking the necessary questions. They added that an additional metric for evaluation would be to review instances when a contact is unreachable, as this information is already collected. Additionally, they asked, relating to duplicate reporting, whether there are data on how many patient safety events continue after triage and whether a subset of the DTAC is looking into those numbers as

they could be relevant for infectious and malignant disease reporting. The DTAC representative clarified that there is other work being done on closing the loop on responses with patient safety contact notifications and confirming receipt of information. They also explained reviewing only higher-level disease reports doesn't give an accurate account of how many cases might be coming through the door, so while they want to reduce the data collection burden, they also want to ensure all events are accounted for.

The Vice-Chair of the POC sought clarification on whether this would standardize communication between transplant programs and OPOs and what is shared. The DTAC representative explained that it is important to make sure the lines of communication are clear, but it is hard to generalize given the variation in what needs to be communicated in specific cases.

Next steps:

The POC approved moving this project forward to the Executive Committee.

2. New Project: Establish Exception Criteria for Liver Cancer Diagnoses

The Vice-Chair of the Liver and Intestine Committee (LIC) presented their new project to the POC.

Data summary:

The purpose of the project is to update the National Liver Review Board (NLRB) guidance to align with emerging literature that shows transplant benefits for certain oncological diagnoses. The guidance would create avenues for patients with such diagnoses to be granted certain MELD exception points. This is all in an effort to increase equity in transplant.

The pre-meeting review of this project indicated that it is low cost/low benefit as the project is expected to require 500 IT technical implementation hours.

Summary of discussion:

Votes: 11 yes, 1 no, 0 abstain

This project will move forward to the Executive Committee for approval.

A member highlighted the increased desire for information but expressed uncertainty regarding the size of the patient population in question. They inquired about potential methods to obtain a more precise estimate of this number. The Vice-Chair of LIC clarified that it is enigmatic in nature, attributing that to the highly selective criteria for the patients involved. However, they noted that existing literature indicated a rising trend in the number of these patients. The discussion shifted toward the importance of determining the denominator, emphasizing the potential for policy changes to stimulate more patients to seek access to this type of transplant, consequently increasing its value.

A member posed a question regarding any controversies or variations in the understanding of the timing of transplants for these patients and the potential exceptions that this policy change might create. Specifically, they wanted to know if the proposed guidance would elevate these patients to the top of the transplant list and whether this approach was appropriate. The response from the Vice-Chair focused on the paramount consideration of understanding the biology of the cancer in these patients. They mentioned that protocols at their own center included waiting periods, but they also cited survival data from the literature. This data suggested that these patients should not automatically be given top priority on the waitlist. Instead, an anecdotal MELD score range of 15-20 might be more appropriate based on the available data.

Another member expressed support for the idea of standardizing access for these patients but voiced concerns about the potential repercussions on organ allocation for other patients due to increased access. The Vice-Chair acknowledged this concern and assured POC that the LIC would consider it.

Next steps:

The POC approved moving this project forward to the Executive Committee.

3. New Project: Clarifying Requirements for Pronouncement of DCD Donor Death

A presenter for the Organ Procurement Organization (OPO) Committee introduced their new project to the POC.

Data summary:

The project was recommended to the OPO Committee by the Membership and Professional Standards Committee (MPSC). The project aims to provide clarity on who may conduct a DCD pronouncement of death as many OPOs employ or contract with physicians to provide the on-call medical director services, when not on call for the OPO, as part of the donor hospital's care team. OPTN Policy 2.15.G language is not currently adequate to ascertain whether policy is being violated and requires review.

The pre-meeting review of this project indicated it was low cost/low benefit and there are currently 0 IT technical implementation hours associated with this project.

Summary of discussion:

Votes: 12 yes, 0 no, 0 abstain

This project will move forward to the Executive Committee for approval. Additionally, they recommend that the Ethics Committee be included to work on this project.

A member asked for more clarification on the project and whether the Ethics Committee was going to be involved in this as they perceived a number of ethical issues could arise from allowing individuals employed by OPOs to pronounce death at the donor hospital. The presenter for the OPO Committee offered clarity on the conversation, giving an example situation: OPOs often contract or employ physicians to do on-call medical director work, additionally these physicians also work as an intensivist or something related at a donor hospital. In this event the physician is not currently working for the OPO but at their own hospital and is involved in the pronouncement of death. This policy seeks to clarify language around whether it is permissible for this physician to conduct the pronouncement of death when not employed by the OPO at that time.

Another member provided further context as this situation, as their center employs such a physician for one week a month, assisting in screening potential donors and answering questions on donor management. The rest of the month they work as an intensivist, and so the member's center was seeking guidance on how this physician could conduct their work as a medical practitioner and also protect themselves.

Another member agreed that the Ethics Committee should be involved in the discussion of this project. The Vice-Chair of the MPSC added that the policy language needed to be clarified, as the integrity of the system should be maintained as well as the integrity of those who work in the system.

Next steps:

The POC approved moving this project forward to the Executive Committee.

4. Post-Implementation Memos

UNOS staff presented to the Committee the memos that were drafted for the Kidney and Pancreas DSA and Region Removal policy change post-implementation reviews. Committee members had the opportunity to review prior to the meeting and were invited to offer additional feedback or commentary. The Chair of the Post-Implementation Monitoring Subcommittee added that the objective of these documents and the Subcommittee itself is to provide a more wholistic perspective on the outcome of a policy change, ensuring that key metrics are met and outcomes, intended or unexpected, are given due consideration. There was no concern about the memos noted, and these will be sent to the respective committees for consideration.

Upcoming Meetings

- September 14, 2023
- October 20, 2023 (in-person)

Attendance

- **Committee Members**
 - Arpita Basu
 - Christine Brenner
 - Erika Lease
 - Jason Huff
 - Jennifer Prinz
 - Jesse Schold
 - Lisa Stocks
 - Nicole Turgeon
 - Peter Stock
 - Rachel Engen
 - Sanjay Kulkarni
 - Stevan Gonzalez
 - Kim Koontz
 - Scott Lindberg
 - Shimul Shah
- **HRSA Representatives**
 - Shelley Grant
- **SRTR Staff**
 - Ajay Israni
 - Jon Snyder
- **UNOS Staff**
 - Cole Fox
 - James Alcorn
 - Kaitlin Swanner
 - Kayla Balfour
 - Krissy Laurie
 - Matt Cafarella
 - Meghan McDermott
 - Stryker-Ann Vosteen
 - Taylor Livelli
- **Other Attendees**
 - Lara Danzinger-Isakov
 - Ginny McBride (Board Member)