

OPTN Transplant Administrators Committee

Meeting Summary

September 10, 2021

Conference Call

Nancy Metzler, Chair

Susan Zylicz, MHA, BSN, RN, CCTC, Vice Chair

Introduction

The OPTN Transplant Administrators Committee (TAC) met via Citrix GoToMeeting teleconference on 09/10/2021 to discuss the following agenda items:

1. Update on Disease Transmission Advisory Committee (DTAC) Data Request
2. Public Comment Proposal: Update Data Collection to Align with US Public Health Service Guideline 2020 (DTAC)
3. Public Comment Proposal: Establish Continuous Distribution of Lungs (Lung Committee)
4. Update on Continuous Distribution of Kidneys and Pancreata
5. National Living Donor Advisory Group – TAC Recommendations
6. Public Comment Proposal: Data Collection to Evaluate Organ Logistics and Allocation (Operations and Safety Committee – OSC)
7. Other Significant Items

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

1. Update on Disease Transmission Advisory Committee (DTAC) Data Request

UNOS staff presented an update on a data request submitted by DTAC relating to specimen storage requirements.

Data summary:

A previous DTAC project, *Align OPTN Policy with U.S. Public Health Service Guideline, 2020*,¹ added a requirement to store living donor specimens for 10 years, consistent with the 2020 Public Health Service (PHS) Guideline issued by the Centers for Disease Control and Prevention (CDC) and the 10-year storage requirement for deceased donor specimens. This data request was prepared upon request of the OPTN Executive Committee to review data on the time from donor recovery to case reporting of potential donor-derived transmission events. The data request reviewed 2,774 potential donor-derived disease transmission events reported to the OPTN from 2008 through 2019, and found that almost 90% of all cases were reported within a year of transplant. Ten cases were reported over 10 years after transplant, and the longest time from donor recovery to case reporting was 17.5 years. Overall, DTAC felt that the data support the 10-year storage requirement for both living and deceased donor specimens.

Summary of discussion:

The Chair expressed concern about the cost to transplant hospitals to process, store, and track living donor storage specimens for 10 years, particularly for hospitals that perform upwards of 200 living

¹ "Align OPTN Policy with U.S. Public Health Service Guideline, 2020," OPTN, accessed September 10, 2021, <https://optn.transplant.hrsa.gov/governance/public-comment/align-optn-policy-with-u-s-public-health-service-guideline-2020/>.

donations per year. A member asked for the mean or median time to reporting. UNOS staff explained that the data were broken out based on whether the cases were led by the CDC or not, and for CDC-led cases, it was 88 days, and for all other cases, it was 19 days. A member agreed with the Chair that 10 years is a very extended period and asked for clarification on the origin of the 10-year living donor specimen storage requirement. UNOS staff said DTAC recognizes that the requirement imposes additional costs to members and that most cases are reported within a shorter time period, but there are events that occur beyond that mean or median time for both deceased and living donors. Accordingly, DTAC felt that keeping the existing policy is appropriate. CDC representatives also highlighted the importance of keeping the 10-year requirement to investigate reports. The purpose of the requirement is to identify if a transmission occurred so that the recipient can receive appropriate medications. The Chair asked if DTAC had been given information from the OPTN Fiscal Impact Group (FIG) about the national cost of fulfilling the 10-year requirement. UNOS staff affirmed that the FIG considers the implications of all proposals and that information was included in the briefing paper for the OPTN Board of Directors. UNOS staff noted that the changes were incorporated in an effort to align OPTN policies with the PHS Guideline provided by the CDC. The Chair acknowledged the need to align with CDC but suggested that the cost of the extended storage is not worth the benefit when all other factors are considered. The Chair said the feasibility of unfunded mandates like this requirement should be weighed against the potential positive impact on the system, and this requirement does not seem like it will have a significant impact. Members agreed. UNOS staff shared the fiscal impact analysis included in the briefing paper,² and said that from a cost-benefit standpoint, even though these events are rare, they are very significant so it is important to act quickly and be able to identify if a transmission occurred. A member noted that the cost of storing deceased donor specimens is managed by the organ procurement organizations (OPOs) and reimbursed by Medicare, whereas transplant hospitals have to cover the costs of the living donor specimen storage.

2. Public Comment Proposal: Update Data Collection to Align with US Public Health Service Guideline 2020 (DTAC)

The Vice Chair of DTAC presented the committee's public comment proposal *Update Data Collection to Align with US Public Health Service Guideline 2020*.³

Summary of discussion:

Members expressed support for this proposal and said that it is straightforward. A member asked whether there is a time-frame associated with data collection where there had been donor incarceration for 72 or more consecutive hours. For example, should it be reported if the incarceration occurred five years ago? The DTAC Vice Chair explained that risk criteria are only reported if they occurred within the month prior to donation.

Next steps:

UNOS staff will summarize TAC feedback and post it as a public comment on the OPTN website.

² "Align OPTN Policy with U.S. Public Health Service Guideline, 2020," Briefing Paper, OPTN, accessed September 15, 2021, https://optn.transplant.hrsa.gov/media/4225/bp_202012_align_2020_phs_guideline.pdf.

³ "Update Data Collection to Align with US Public Health Service Guideline 2020," OPTN, accessed September 10, 2021, <https://optn.transplant.hrsa.gov/governance/public-comment/update-data-collection-to-align-with-us-public-health-service-guideline-2020/>.

3. Public Comment Proposal: Establish Continuous Distribution of Lungs (Lung Committee)

The Chair of the Lung Committee presented the committee's public comment proposal *Establish Continuous Distribution of Lungs*⁴ and requested feedback on various aspects of the proposal, including the proposed changes to multi-organ allocation.

Summary of discussion:

The Chair expressed support for anything that makes multi-organ allocation easier to follow, including decreasing the discretion that OPOs have in multi-organ allocation because it leads to inconsistency in practice and frustration between transplant centers and OPOs. The Lung Chair agreed and said the Lung Committee wanted to make sure there are no concerns with eliminating some of the discretion that OPOs have today. A member supported increased clarity regarding multi-organ allocation and said their transplant hospital's lung team feels like this proposal is moving the community forward. Their hospital has done two heart-lung transplants recently and recognizes that heart-lung allocation is challenging for OPOs. The Lung Chair agreed and said their transplant program has had similar experiences with heart-lung allocation and that the OPTN can continue to improve heart-lung allocation when heart shifts to a continuous distribution allocation framework.

A member asked if the composite allocation score is similar to the kidney estimated post-transplant survival (EPTS) score. The Lung Chair said they were not as familiar with kidney allocation but explained that the current Lung Allocation Score (LAS) accounts for waitlist mortality and post-transplant survival, whereas the composite allocation score includes a number of other factors, including proximity efficiency, some of which will be consistent across match runs and some of which will vary by match run. A member asked whether there will be changes to data that need to be reported for lung candidates. The Lung Chair said all of the elements currently used in the LAS will continue to be collected since they feed into the composite allocation score. However, the Lung Committee has moved into a separate phase of work to evaluate additional data that the OPTN should collect to better estimate waitlist mortality for lung candidates.

A member expressed appreciation for the detailed explanation of how the composite allocation score was developed since it helps with educating team members. The Lung Chair said they hope it will also help with explaining the new system to patients.

With regard to the proposed changes to the exceptions process, a member said that five days is sufficient time to allow reviewers to vote on exception applications.

Next steps:

UNOS staff will summarize TAC feedback and post it as a public comment on the OPTN website.

4. Update on Continuous Distribution of Kidneys and Pancreata

UNOS staff and the Vice Chair of the Pancreas Committee presented the committee's concept paper, developed in collaboration with the Kidney Committee, entitled *Update on Continuous Distribution of Kidneys and Pancreata*.⁵

⁴ "Establish Continuous Distribution of Lungs," OPTN, accessed September 10, 2021, <https://optn.transplant.hrsa.gov/governance/public-comment/establish-continuous-distribution-of-lungs/>.

⁵ "Update on Continuous Distribution of Kidneys and Pancreata," OPTN, accessed September 10, 2021, <https://optn.transplant.hrsa.gov/governance/public-comment/update-on-continuous-distribution-of-kidneys-and-pancreata/>.

Summary of discussion:

A member thanked the committees for their work on this complicated subject. Another member noted that dialysis start date and waiting time play a huge role in kidney allocation. The member asked if the proposed system would convert these factors into attributes that would be considered in addition to other factors, so that allocation would not hinge as much on dialysis and waiting time as it does today. The member said it is hard to comprehend how the composite allocation score will work for kidney because kidney candidates are not necessarily facing the same time constraints as a heart, liver, or lung candidates. UNOS staff affirmed that waiting time will be one of the attributes in the proposed system but the committees have not yet established how much weight each attribute will have. The committees used the factors currently used in kidney and pancreas allocation as a starting point for identifying the attributes that will be included in the continuous distribution allocation framework. Dialysis and dialysis time are not distinct attributes in the proposed system but the committees are considering how dialysis will factor into the composite allocation score, including how time on dialysis impacts individual patients.

Regarding the medical urgency attribute, a member asked if the committees are considering the administrative burden of tracking and entering relevant data. UNOS staff said the administrative burden of potential data collection has not been discussed yet, but the Kidney Committee proposes including an attribute related to medical urgency based on the recently approved medical urgency policy.⁶ The Vice Chair of the Pancreas Committee affirmed that the committees are in an early phase of this project so any feedback on how to define the proposed attributes is appreciated.

Next steps:

UNOS staff will summarize TAC feedback and post it as a public comment on the OPTN website.

5. National Living Donor Advisory Group – TAC Recommendations

UNOS staff presented an overview of the National Living Donor Advisory Group and the Chair asked TAC members to recommend three individuals who should serve on this group.

Summary of discussion:

A member said they are passionate about this issue and would be interested in pursuing this opportunity. The Chair thanked the member and asked if anyone else was interested. UNOS staff asked interested members to submit their resume via email. The Vice Chair noted that the nominees do not need to be currently serving on TAC and asked TAC members to consider other transplant administrators who may be a good fit for this opportunity.

Next steps:

UNOS staff will share the TAC recommendations with the National Living Donor Advisory Group.

6. Public Comment Proposal: Data Collection to Evaluate Organ Logistics and Allocation (Operations and Safety Committee – OSC)

UNOS staff presented the committee's public comment proposal *Data Collection to Evaluate Organ Logistics and Allocation*.⁷

⁶ "Addressing Medically Urgent Candidates in New Kidney Allocation Policy," OPTN, accessed September 15, 2021, <https://optn.transplant.hrsa.gov/governance/public-comment/addressing-medically-urgent-candidates-in-new-kidney-allocation-policy/>.

⁷ "Data Collection to Evaluate Organ Logistics and Allocation," OPTN, accessed September 10, 2021, <https://optn.transplant.hrsa.gov/governance/public-comment/data-collection-to-evaluate-organ-logistics-and-allocation/>.

Summary of discussion:

A member suggested using the term “organ arrival” rather than “organ check-in time” in the data definition because organ check-in, as defined in OPTN policy, involves a number of steps.

A member asked if the time of first anastomosis would need to be submitted in WaitlistSM at the time that the patient is removed from the waiting list. UNOS staff affirmed that the committee thought that would be the most efficient approach. A member said that approach should not be a problem for hospitals who have that data available in their electronic medical records, but some hospitals still use paper records. It might be hard for staff to locate those paper records with the time of first anastomosis when removing the candidate from the waiting list. The Chair agreed and noted that the operating room staff who record the time of first anastomosis do not have access to Waitlist, and that information has to be entered by a transplant coordinator within 24 hours, so that may require a lot of back-and-forth between these staff members at hospitals using paper records. A member said this back-and-forth might also result in confusion about whether a time should be recorded as AM or PM. A member recommended clearly defining the time of anastomosis, for example, to refer to the first stitch of the first anastomosis.

A member asked if the OPTN accommodates data collection related to normothermic regional perfusion (NRP) now that it has become a more common perfusion method. UNOS staff said the OSC is deferring to Heart and Liver Committees on that issue and that those committees may consider future data collection on perfusion in future projects. The OPTN is aware of clinical trials on NRP and is waiting to see what data are collected through those trials and what would be most applicable to the OPTN.

A member suggested collecting data via the Transplant Recipient Registration (TRR) forms instead of Waitlist because transplant programs may be able to utilize Phoenix import/export functionality for the data and avoid human error in data entry. The Chair agreed it might be helpful for transplant programs to have more time to share this information between team members. The Chair said there is so much going on in the operating room during transplant that just adding one small requirement like this can be a burden. A member agreed that it might be better for the data to be collected in TIEDI[®] instead of Waitlist since their hospital does not have someone available 24/7 to enter these data. The Chair agreed that having more time might improve data quality so that hospital staff are not rushing to submit this information within 24 hours.

Next steps:

UNOS staff will summarize TAC feedback and post it as a public comment on the OPTN website.

7. Other Significant Items

UNOS staff asked for volunteers who would be interested in participating in a workgroup sponsored by the Operations and Safety Committee focused on mandating the use of offer filters based on criteria identified in policy. A member who is also involved in a project on provisional yes said they would be interested in serving on the workgroup since there seems to be synergy between the two projects. Another member expressed interest as well.

Upcoming Meetings

- September 22, 2021
- October 27, 2021

Attendance

- **Committee Members**
 - Nancy Metzler, Chair
 - Susan Zylicz, Vice Chair
 - Megan Fairbank
 - Joshua Gossett
 - Rachel Hatmon
 - Jason Huff
 - Michelle James
 - Deb Maurer
 - Deonna Moore
 - Denise Neal
 - Laura O'Melia
 - Melissa Porter
 - Melissa Roberts
 - Brian Roe
 - Erica Seasor
 - Scott Wansley
- **HRSA Representatives**
 - Vanessa Arriola
- **UNOS Staff**
 - Sarah Booker
 - Angel Carroll
 - Abigail Fox
 - Kristina Hogan
 - Lindsay Larkin
 - Krissy Laurie
 - Kaitlin Swanner
 - Susan Tlusty
 - Joann White
- **Other Attendees**
 - Lara Danziger-Isakov
 - Erika Lease
 - Oyedolamu Olaitan