

**OPTN Lung Transplantation Committee
Meeting Summary
September 17, 2020
Conference Call**

**Erika Lease, MD, Chair
Marie Budev, DO, Vice Chair**

Introduction

The Lung Transplantation Committee met via Citrix GoTo teleconference on 09/17/2020 to discuss the following agenda items:

1. Public Comment Proposal: *Align OPTN Policy with U.S. Public Health Service Guideline, 2020*
2. Lung Committee Analytical Hierarchy Process (AHP) Exercise Results

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

1. Public Comment Proposal: *Align OPTN Policy with U.S. Public Health Service Guideline, 2020*

The Chair of the Disease Transmission Advisory Committee (DTAC) presented the public comment proposal *Align OPTN Policy with U.S. Public Health Service Guideline, 2020*.

Summary of discussion:

The Vice Chair asked whether the requirement to draw testing specimens for deceased donors within 96 hours of procurement applies to donation after cardiac death (DCD). The DTAC Chair affirmed the requirement applies to all deceased donors. The Chair asked whether the documentation of hepatitis B (HBV) vaccination would be collected after transplant, since some candidates complete the vaccination series prior to transplant and some do not. The Chair also asked how transplant programs would document candidates that have received one or more HBV vaccine series but have not responded, and how this information will be collected without adding too many questions on the data collection instruments. The DTAC Chair explained that the proposed policy would require transplant programs to conduct HBV surface antibody testing on candidates following hospital admission but prior to transplant to assess whether the candidate responded to vaccination. DTAC does not have a final proposal for how to collect this information but the DTAC Chair agreed that the form submitted at the time of transplant may be the most appropriate form to capture whether the candidate was vaccinated and the number of doses received. The Chair said the OPTN should be mindful about not adding too much data collection while ensuring that the collected data is both usable and useful.

A member asked about the 10-year living donor specimen requirement and how it aligns with current policy requirements for deceased donor specimens. The DTAC Chair explained that organ procurement organizations (OPOs) are required by current policy to store a pre-procurement sample for all deceased donors for 10 years. The specimens are used for investigation of donor-derived disease transmission events. In the same way that deceased donor samples are currently stored for 10 years, the proposal would impose the same requirement for living donor samples to enable the same investigations. Currently, there are no requirements to store samples for living donors.

A member asked how one should refer to a higher risk donor, and if it is recommended to document a discussion of risk with the patient since informed consent is no longer required. The DTAC Chair

explained that the policy would remove the label of “increased risk donor.” DTAC considered changing the label but all of the ideas considered had negative connotation. Removing the label makes it more difficult to describe to patients, but it is DTAC’s intent that the conversation will shift to a more personalized discussion with the transplant candidate about:

- their risk of mortality on the waitlist,
- the additive mortality risk of declining an organ from a donor with risk factors,
- the actual risk of transmission for subpopulations of donors,
- the testing performed after transplant, and
- whether there is an impact on allograft or patient survival if disease is transmitted.

Although formal informed consent would no longer be required in policy, transplant programs are welcome to develop a separate consent process. However, studies found that the formal informed consent process was one of the reasons that organs have been discarded from donors currently described as increased risk.

An attendee asked where to find the policy requirements for the OPO to preserve specimens for 10 years, since *OPTN Policy 4.8 Preservation of Excess Specimens* only requires histocompatibility laboratories to retain specimens for additional testing for five years. UNOS staff explained that the requirement for OPOs is in *OPTN Policy 2.2 OPO Responsibilities*.

The Committee conducted a sentiment vote on the proposal: 3 strongly support, 9 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose.

Next steps:

The Committee’s feedback and sentiment vote will be posted on the OPTN website.

2. Lung Committee Analytical Hierarchy Process (AHP) Exercise Results

UNOS staff reviewed the Committee’s AHP exercise results to prepare the Committee for a more in-depth discussion of the community AHP results following public comment.

Summary of discussion:

UNOS staff explained that the Committee will review areas of disagreement or outliers in the AHP results to ensure all relevant voices are heard and considered, as well as areas of agreement, to ensure there are not any hidden or repugnant biases. The Committee will be able to compare their results against current policy, legal requirements, and the community AHP results.

UNOS staff shared how the Committee ranked the attributes overall:

1. Medical urgency: Prioritize sickest candidate first to reduce waiting list mortality (27.67%)
2. Patient access: Increase access for patients under the age of 18 (25.59%)
3. Candidate biology: Increase transplant opportunities for patients who are medically harder to match (19.7%)
4. Post- transplant survival: Prioritize candidates who are expected to survive for at least one year after receiving a transplant (9.95%)
5. Patient access: Increase access for prior living donor (9.01%)
6. Placement efficiency: Improve placement efficiency (8.62%)

These results are largely consistent with the Committee’s results from February 2020.

UNOS staff showed the balance between equity and utility in the Committee's results, where utility includes medical urgency, post-transplant survival, and placement efficiency, and equity includes patient access (access for patients under the age of 18 and for prior living donors) and candidate biology. In the Committee's results, utility and equity were roughly balanced, with equity weighted at slightly higher than 50% and utility weighted slightly lower than 50%.

UNOS staff showed how the level of agreement varied across the 16 pairwise comparisons. For example, over 90% of the members agreed that candidate biology should be prioritized relative to placement efficiency, but there was only 50% agreement on how to prioritize post-transplant survival relative to increasing access for prior living donors. When discussing the community results, the Committee will review each pairwise comparison to discuss how much weight should be assigned to each attribute, and the justification for how the weights are assigned. UNOS staff asked the Committee to be prepared to discuss how they made their decisions when completing the exercise.

UNOS staff showed that there are outliers in some of the pairwise comparisons. For example, most members agreed that prioritizing the sickest candidate first should be prioritized over placement efficiency, but a few members thought that placement efficiency should take priority. In these situations, it will be important for outliers to explain their point of view to ensure that all perspectives are considered before the Committee makes their final decisions.

UNOS staff explained that the Committee will be asked to complete the exercise one more time after discussing the community results. At that point, the Committee's results will hopefully be drawing towards consensus. The Committee will talk through the results to resolve any lingering differences of opinion, or to choose to send multiple options to SRTT for modeling. Members will be provided with an interactive sensitivity tool to help them envision what the match run will look like with various weights.

HRSA staff asked UNOS staff to explain how UNOS will address responses that are skewed by uneven response rates from different demographics, for example, if the majority of the respondents are from transplant programs, or if patients are underrepresented, or if there are geographic anomalies in participation. HRSA staff asked how UNOS staff will be drilling down into the aggregate results by stakeholder groups. UNOS staff explained that UNOS has been collecting demographic data throughout the process so that the Committee will be able to see how different respondents prioritized the attributes. UNOS staff shared feedback from the OPTN Ethics Committee that if there are particular groups that are not in agreement with the broader results, then UNOS should conduct outreach to better understand those perspectives and why those groups voted the way they did.

Members asked to see their individual results by pairwise comparison instead of in aggregate to understand where their perspectives fall among the group.

Next steps:

UNOS staff will send committee members their individual pairwise comparison results. Following public comment, UNOS staff will send the community AHP results to the Committee.

Upcoming Meetings

- October 7, 2020 – Lung Committee
- October 8, 2020 – Lung Committee
- October 15, 2020 – Lung Committee

Attendance

- **Committee Members**
 - Erika Lease, Committee Chair
 - Marie Budev, Committee Vice Chair
 - Alan Betensley
 - Whitney Brown
 - Deana Clapper
 - Ryan Davies
 - June Delisle
 - Cynthia Gries
 - Julia Klesney-Tait
 - Jasleen Kukreja
 - Dennis Lyu
 - Daniel McCarthy
 - Kenneth McCurry
 - John Reynolds
 - Marc Schechter
 - Kelly Willenberg
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Yoon Son Ahn
 - Katie Audette
 - Melissa Skeans
 - Maryam Valapour
- **UNOS Staff**
 - James Alcorn
 - Julia Chipko
 - Craig Connors
 - Rebecca Goff
 - Elizabeth Miller
 - Amanda Robinson
 - Darren Stewart
 - Kaitlin Swanner
 - Susan Tlusty
 - Emily Ward
 - Sara Rose Wells
 - Karen Williams
- **Other Attendees**
 - Matthew Hartwig
 - Ricardo La Hoz
 - Masina Scavuzzo
 - Jennifer Schiller
 - Stuart Sweet