

OPTN Heart Transplantation Committee

Meeting Summary

September 8, 2020

Conference Call

Shelley Hall, MD, Chair

Richard Daly, MD, Vice Chair

Introduction

The OPTN Heart Transplantation Committee met via Citrix GoToMeeting teleconference on 09/08/2020 to discuss the following agenda items:

1. OPTN Engagement Opportunities
2. Incorporating COVID-19-related Organ Failure in Candidate Listings
3. COVID-19 Emergency Policies and Data Collection
4. Align OPTN Policy with U.S. Public Health Service Guideline, 2020

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

1. OPTN Engagement Opportunities

Sara Rose Well, UNOS Transplant Community Administrator, shared additional ways to engage with the OPTN as volunteers.

Summary of discussion:

Board of Directors and Committee nominations are open through September 30th for terms that begin in July 2021. Descriptions of these openings are posted on OPTN website. The Board of Directors is seeking members with heart and lung experience.

A member mentioned that they were having issues logging into to the website to apply for volunteer positions. UNOS staff is following up to help troubleshoot.

The Chair asked if volunteers are able to serve on two committees. Since volunteer opportunities are limited and the goal is to share these roles with as many community members as possible, volunteers are encouraged to only participate on one committee at a time. The Committee was encouraged to share these openings with their colleagues and to apply if their terms are ending and they would like to continue volunteering.

Public comment is open until October 1. The Committee is encouraged to submit comments as individuals and reach out to colleagues to make them aware of the proposals put forward.

The Committee members were also encouraged to attend the upcoming regional meetings. The Committee was informed that they could attend any of the virtual regional meetings, even those outside of their region. Information about each regional meeting is posted on the OPTN website.

The Committee was invited to participate in the Continuous Distribution prioritization exercise by October 1. The Committee will receive an email with instructions. The Chair noted that this exercise is important so members can become more aware of this process prior to doing a similar exercise for heart when heart allocation moves to Continuous Distribution. Anyone can be invited to participate in this exercise regardless of their transplant knowledge or experience.

A member asked if committee members can be allowed access to UNetSM in order to view data collection forms. UNOS staff offered to send this member STAR File documentation so they can review the data fields.

The OPTN is evaluating the structure, processes, performance, and effectiveness of its regional structure. Committee members were encouraged to submit feedback on the regional structure by visiting the OPTN website.

2. Incorporating COVID-19-related Organ Failure in Candidate Listings

Elizabeth Miller, UNOS Policy Analyst, provided an overview on the *Incorporating COVID-19-related Organ Failure in Candidate Listings* proposal sponsored by the Lung Transplantation Committee that is currently out for special public comment.

Summary of discussion:

The Lung Committee has a proposal out to incorporate two new COVID-19 diagnoses options to Group D of the lung allocation score (LAS). These diagnoses are “COVID-19: Pulmonary Fibrosis” and “COVID-19: Acute Respiratory Distress Syndrome.”

Several lung transplants have occurred due to COVID-19 requiring a need to track these specific cases. These diagnoses will be added to UNetSM on an expedited timeline. Public comment will end on October 1st and the proposal will go to the OPTN Board of Directors for approval on October 8th. If approved, these changes will be implemented in October.

Members agreed that there is a need to collect COVID-19 data for heart candidates, specifically for COVID-19 related myocarditis. The Chair agreed that the heart COVID-19 diagnoses should be included with the existing proposal in order to expedite implementation. A member raised a question about separating patients who have primary and secondary diagnoses relating to COVID-19 in order to assist in retrospective analysis. The members of the Heart Committee were told that it would be best to keep lung candidates that have an existing disease that was exacerbated by COVID-19 under their initial diagnoses listing.

The Chair noted that it may be important to also track a patient’s history of COVID-19 in order to evaluate how outcomes may be affected in the future. A member asked about policies relating to when a person with COVID-19 should be transplanted. A member responded that they had successful outcomes transplanting a patient who previously had COVID-19.

A member asked what other members are using to assess when a candidate may be ready for transplant following COVID-19 diagnosis. The Chair responded that their program was following inflammatory markers to assess patient readiness for both transplants and implanting ventricular assist devices (VADs).

The members discussed adding the following diagnoses:

- COVID-19: Myocarditis
- COVID-19: “other” with free form text
- Acute, fulminant heart failure with confirmed or highly suspected COVID-19
- Active myocarditis with confirmed or highly suspected COVID-19
- Chronic dilated cardiomyopathy due to/significantly exacerbated by COVID-19 related myocardial disease including coronary artery involvement from COVID-19-Associated Multisystem Inflammatory syndrome
- Chronic dilated cardiomyopathy with a history of COVID-19 infection but no documented COVID-19 related myocardial disease

A member suggested pulling COVID-19 data into the risk-stratification dataset.

A member asked if the Committee had any patients who had COVID-19 related Cardiomyopathy and needed transplant. Members have not seen this yet. Another member asked if the Committee had experienced adult patients with coronary enlargement or thrombotic complications that could be secondarily related to COVID-19. The Chair noted they had seen multiple patients with thromboembolic complications. These patients may need transplant in the future.

The Committee agreed that COVID-19 does cause myocarditis and tracking this information would continue help inform venoarterial extracorporeal membrane oxygenation (VA-ECMO) practices going forward.

The Chair commented that if patient previously had cardiomyopathy, they may have devices and therefore are unlikely to receive MRIs which will be a challenge.

A member mentioned a patient listed for lung and heart. Their heart condition is secondary to COVID-19 lung issues. They questioned how this could best be coded or categorized.

Next steps:

UNOS Lung Committee staff will circle back for specific diagnoses by email.

3. COVID-19 Emergency Policies and Data Collection

Chelsea Haynes, UNOS Board & Government Relations Manager, provided a presentation on the *COVID-19 Emergency Policies and Data Collection* proposal.

Summary of discussion:

The *COVID-19 Emergency Policies and Data Collection* proposal outlines the actions taken in March and April in response to the COVID-19 pandemic. These initial decisions were the result of many committees' input and was sponsored by the Executive Committee.

Comparing 2020 to 2019, the number of deceased donor transplants performed in 2020 year to date is greater.

It is uncommon for the Executive Committee to take emergency actions. Bylaw 11.7 outlines when emergency actions are warranted. These actions have been continuously evaluated and monitored since implementation. The Committee is being asked to provide feedback on the action outlined below.

The overall goals of these actions were to increase patient safety by reducing candidate, recipient, and living donor exposure to COVID-19, reduce burden on transplant hospital staff, prevent disadvantaging candidates who are unable to safely access the hospital for pre-transplant lab testing, and provide organ procurement organizations (OPOs) and transplant hospitals efficient communication of COVID-19 testing status and results.

Action 1: Updates to Candidate Data During 2020 COVID-19 Emergency

This action allows programs to use a candidate's most recently submitted lab data to maintain medical urgent allocation priority. Programs must document that they are using this emergency policy for tracking purposes. There has been nearly no utilization of this action by heart transplant programs.

Action 2: Relax Data Submission Requirements for Follow-Up Forms

Amnesty for the submission of Transplant Recipient Follow-Up (TRF), Living Donor Follow-Up (LDF), and Post-Transplant Malignancy (PTM) forms began on April 13, 2020. Programs are encouraged to complete and submit these forms retrospectively when able. This action also extends the timeline to

report recipient graft failure or death from 14 to 30 days. Approximately 30% of TRF forms are in amnesty status each week.

Action 3: Modify Wait Time Initiation for Non-Dialysis Kidney Candidates

This action allows programs to request the initiation of waiting time for non-dialysis kidney candidates to be backdated to the date the program intended to list the candidate for transplant with the intention of keeping these candidates from being disadvantaged if they are delayed when completing their required labs for registration. This modification request form was implemented on April 10, 2020. Kidney waitlist additions are increasing but remain lower in volume over last year.

Action 4: Incorporate COVID-19 Infectious Disease Testing into DonorNet®

An optional field was added to DonorNet® to allow reporting on COVID-19 testing, test type, specimen type, and the result. This was implemented on April 20, 2020. Entering this data as well as performing testing is not mandatory. 100% of recovered deceased donors have been tested for COVID-19 between April 21, 2020 and August 4, 2020, although only about 75% used the discrete infectious testing fields.

The Committee was invited to provide input through public comment.

A member asked about how these efforts are being coordinated with SRTR. UNOS staff responded that SRTR representatives attend the Executive Committee meetings and receive all monitoring reports. UNOS staff will look into other ways to coordinate best communication. The member noted that the form submission amnesty will impact SRTR's modeling.

The Chair raised a concern about the implementation timeline for Action 1 and suggested this action expire in December rather than March. They expressed that the heart community is dependent on data and not requiring submission could open up opportunities for gaming. A member agreed that data collection is important and programs should continue to submit forms.

4. Align OPTN Policy with U.S. Public Health Service Guideline, 2020

Dr. Ricardo La Hoz, Chair of the Ad Hoc Disease Transmission Advisory Committee (DTAC), shared a presentation on the proposal *Align OPTN Policy with U.S. Public Health Service Guideline, 2020*.

Summary of discussion:

On June 26, 2020, PHS published an updated Guideline for assessing solid organ donors and monitoring transplant recipients for human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) infection. The Final Rule requires that OPTN policies are consistent with the Guideline. The intent of the proposal is to increase the use of organs with a low risk of unexpected disease transmission as well as allow for more contextualization when discussing the risks and benefits of accepting or declining organs from donors with specific risk factors. In addition, it provides a safety back up that promotes early identification of HIV, HBV, and HCV if transmission unexpectedly occurs by focusing on prompt implementation of therapy to minimize allograft damage and mortality.

The rates of donors recovered who were classified as an "increased risk donor" in a given year increased from a low of 7.5% in 2007 to over 27% by 2018 and 2019. Currently, accepting offers from these donors requires a separate informed consent from the potential recipient.

The proposal includes the following:

- Remove label "increased risk donor"
- Shorten timeframe for donor risk criteria assessment from 12 months to one month
- Remove hemodilution as infectious disease risk criteria in policy

- Require deceased donor testing specimens drawn within 96 hours of procurement
- Require living donor recovery hospitals to arrange storage of pre-transplant samples for 10 years
 - This matches current policy for deceased donor samples
- Remove requirement for a separate informed consent when donors meet risk criteria
- Require assessment of need for HBV vaccination during candidate medical evaluation and report vaccination status
- Add required testing:
 - Candidate pre-transplant for HIV, HBV, and HCV during transplant hospital admission but before transplant occurs
 - Universal NAT for HIV, HBV, HCV on all transplant recipients 4-8 weeks after transplant
 - Liver recipient testing between 11-13 months post-transplant for HBV NAT

From an Organ Procurement Organization (OPO) standpoint, the proposal will require the modification of the donor screening assessment for identifying donor risk criteria and repeat tests if procurement does not occur within 96 hours of when infectious disease samples are first drawn.

Transplant hospitals will be required to:

- Complete additional testing for living donors, candidates, and recipients
- Update candidate evaluations to include assessment for HBV vaccination need
- Report reasons HBV vaccination cannot be initiated or completed prior to transplant
- Arrange for living donor specimen storage

The Chair of DTAC noted that the policy reinforces that the need for transplant supersedes the need for vaccination and the candidate's vaccination status should not be a barrier to transplant. DTAC is seeking feedback during public comment from committees and regional meeting attendees.

A member asked if it is possible to leave notation of hemodilution in the donor chart. The Chair of DTAC responded that this information will remain as the data may be important for other reasons but will no longer be used to assess risk of transmission.

A member commented that HBV vaccine is typically administered over 6 months and many patients do not have this amount of time. The Chair of DTAC restated that the patient's acuity and need for transplantation will supersede the need for a vaccine. Information will need to be recorded about whether vaccination was attempted as well as what the barriers were, including if the patient was transplanted.

A member raised a concern about potential delays that could be associated with the 96 hour timeframe for testing deceased donors. The Chair of DTAC commented that this concern has been raised by others and this feedback is being considered.

The Chair commented that the policy proposal has already been adapted based on feedback received, specifically around the HBV vaccination requirement. The Chair of DTAC agreed saying that vaccination is considered a best practice, although it is not in the purview of the OPTN to mandate a vaccine. However, tracking this data is important as HBV is a common disease that is unintentionally transmitted. UNOS staff commented that this policy only focuses on reducing the risk of unintentional transmission.

A member asked if there is a requirement for HBV titer information post-transplant. HBV surface antibodies will be collected.

The Chair commented that they support removing the "increased-risk" label but has a concern about how to educate a potential recipient on risks associated with specific organs. Educational materials are

being developed. Personalized conversations will be held with candidates that assess all risk factors more comprehensively.

A member asked how these risk conversations will be documented. The Chair of DTAC responded that documentation will be required but a formal consent process will not be required. A member commented that there will not be a separate consent for “increased-risk” donors but these risk factors can be addressed during a singular consent process.

The Chair raised a concern about risks associated with the unintentional transmissions being transferring to transplant program rather than the OPTN. The Vice Chair commented that the “increased-risk” label has scared candidates from accepting organs when their bigger risk may be not getting a transplant.

A HRSA representative commented that the intention of the proposal is for the risks to be included in the initial consent, as opposed to a separate consent. Recipients can choose to decline any organ for any risk factor they choose. Regarding the 96 hour timeframe for donor testing, the HRSA representative said that if PCR labs are still pending, transplant will move forward without results.

Upcoming Meetings

- September 15, 2020
- October 29, 2020

Attendance

- **Committee Members**
 - Adam Schneider
 - Donna Mancini
 - Jose Garcia
 - Greg Ewald
 - Jondavid Menteer
 - Jonah Odim
 - Michael Kwan
 - Mike McMullan
 - Kelly Newlin
 - Rachel White
 - Richard Daly
 - Ryan Davies
 - Shelley Hall
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Melissa Skeans
- **UNOS Staff**
 - Chelsea Haynes
 - Courtney Jett
 - Elizabeth Miller
 - Eric Messick
 - Janis Rosenberg
 - Julia Chipko
 - Kaitlin Swanner
 - Keighly Bradbrook
 - Rebecca Goff
 - Sara Rose Wells
 - Sarah Konigsburg
 - Sarah Taranto
 - Susan Tlusty
- **Other Attendees**
 - Hannah Byford
 - Ricardo La Hoz