

**OPTN Heart Transplantation Committee
Meeting Summary
July 21, 2020
Conference Call**

**Shelley Hall, MD, Chair
Richard Daly, MD, Vice Chair**

Introduction

The OPTN Heart Transplantation Committee met via Citrix GoToMeeting teleconference on 07/21/2020 to discuss the following agenda items:

1. Committee SharePoint site
2. Regional meetings update
3. Committee meeting schedule
4. Continue discussion of potential project ideas

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

As the first official OPTN Heart Transplantation Committee meeting, the Chair welcomed new attendees as well as the returning members of the OPTN Thoracic Committee and invited them to introduce themselves.

1. Committee SharePoint site

UNOS staff gave an overview of the Heart Committee SharePoint site.

Summary of discussion:

The Heart Committee SharePoint has information on meeting and other important dates, orientation slides, and links to resources. Public comment documents, OPTN policies, and the Committee Project dashboard are linked at the bottom of the page. The OPTN Materials page provides agendas and other meeting materials by meeting date. Several members commented that they still need assistance to gain access. UNOS staff will request assistance from volunteer@unos.org. The Chair commented that the site is helpful because it hosts all of the meeting documents and suggested also saving emails from UNOS in a folder to reference.

2. Regional meetings update

UNOS staff shared that all upcoming Regional Meetings will be held virtually and gave an overview of the schedule as well as resources for members who have not attended in the past.

Summary of discussion:

Regional meeting dates will be included in all slide sets for the next upcoming meetings through September. These dates can also be found on the OPTN website. Prep calls are generally scheduled with the Regional Representatives to review the policy proposal presentations a week or so prior to their region's meeting. The Chair suggested logging into the earlier Regional Meetings to hear the presentation given by other Committee Regional Representatives as a way to prepare. The Chair commented that UNOS staff will provide the Regional Representatives with slides, speaking points, and

notes. The Chair requested that the Regional Representatives review the meeting dates and contact the UNOS support staff if they are unable to attend.

UNOS staff gave an overview of the resources available on the OPTN Regional Meeting site. This site includes meeting dates, webinars of previous proposals, and the public comment documents. There is also an overview about what to expect at a Regional Meeting and an overview on how voting occurs.

Next steps:

Committee members were requested to review the Regional Meeting schedule and contact UNOS staff if they are unable to attend. Meetings to prepare Regional Representatives to give presentations will be scheduled throughout August.

3. Committee meeting schedule

UNOS staff presented the Committee with a list of all upcoming meetings.

Summary of discussion:

OPTN Heart Transplantation Committee meetings occur on the third Tuesday of each month from 5:00-6:00 ET. The date for the April in-person meeting is still pending.

4. Continue discussion of potential project ideas

UNOS staff and the Chair lead a discussion on potential project ideas that the Committee will pursue this upcoming year. The Committee members were asked to provide comment on the topics as well as how they are prioritized.

Summary of discussion:

UNOS staff provided a framework for considering each project, asking the Committee to consider the following:

- How does idea address National Organ Transplantation Act and Final Rule?
- Does evidence suggest policy action or other solution will address the problem?
- What data collection, analyses, or modeling is needed to address the issue?
- Does it address a Strategic Policy Priority as established by the Policy Oversight Committee (POC)?
 - Continuous Distribution
 - Multi-organ
 - Efficient donor and recipient matching
- Priority-level of idea?
- Timeframe needed to address the idea?
- Idea's impact transplant programs, Organ Procurement Organizations (OPOs), and histocompatibility labs?
- How does the idea impact the OPTN?

UNOS staff gave an overview of the policy development process, stating that the projects being considered are in the Idea and Problem Analysis stages. Project forms that outline the problem statement, the potential solution, as well as the target population and other key information will be created for the projects that are selected to pursue. These project forms will be reviewed by POC and the Executive Committee.

The Chair shared that the Vice Chair is the Heart Transplantation Committee's representative on POC and will present the project ideas for approval. The Chair noted that the policy development process

takes time. All proposals including guidance must go through the public comment process for discussion and feedback.

The Chair shared that all existing project ideas were considered by Committee leadership. Similar project ideas were merged and obsolete or completed ideas were closed. These ideas were condensed into a prioritized list that was presented to the Committee.

One project, the *Continuous Distribution of Hearts*, is scheduled to begin in December 2022. Continuous distribution of Lungs is the first organ moving to this allocation model and uses the Lung Allocation Score (LAS). Continuous Distribution of Lungs will be presented during this upcoming public comment period. Heart will be the last solid organ moving to the continuous distribution model because there is no established Heart Allocation Score.

The Chair asked the members for input on the projects as well as how they are prioritized.

Continued Policy Refinements

Continued Policy Refinements is considered a high priority by Committee leadership. This project entails continuing work that began last year to address the major areas of policies that are met with complaints or requests for clarification. The areas of policy that may need to be addressed include *Policy 6.1.C.vii: Mechanical Circulatory Support Device (MCSD) with Mucosal Bleeding*, *Policy 6.1.C.vi: MCSD with Device Infection*, and *Policy 6.1.C.iv: MCSD with Pump Thrombosis*.

A member commented that this would require a small effort to add more information similar to the guidance document and is not necessarily a project in itself. The Chair responded that this is an ongoing task of the Committee and is considered a project by nature that the Committee is working on it. UNOS staff commented that modifications to policy requires identification of the core problem, numbers of those affected, and evidence to support the suggested changes put forth by the Committee in order to make a strong public comment document which takes time.

The Chair suggested discussing member questions on MCSD policies at the November Committee meeting and using the next three meetings to discuss PGD. These MCSD policy modifications were initially left off of the policy modification going to public comment in August because of the complexity of what is required from a programming perspective.

Accommodating New Technologies in Heart Allocation Policy

Accommodating New Technologies in Heart Allocation Policy is considered a high priority by Committee leadership. New devices such as NuPulse, as well as potential future devices do not fit into the categories included in existing policy: dischargeable ventricular devices (VAD), non-dischargeable VADs, percutaneous devices, and total artificial hearts. NuPulse is currently being considered a balloon pump and candidates with this criteria are assigned as Status 2 if inpatient and Status 3 if outpatient. NuPulse is still in the research phase and not yet FDA approved. Members will need to determine to accommodate NuPulse by adding a new category or modify policy to accommodate new devices in general by another approach.

The Chair asked if any members had an update on when NuPulse would be approved by the FDA. A member responded that the trial has been put on hold due to COVID-19 and NuPulses are not currently being implanted. The Chair suggested moving this project down in priority and replacing with *Hemodynamic Monitoring Equivalence* project.

A member commented on the cost effectiveness and utility of these new technologies and questioned how these will become increasingly recommended by oversight bodies and how that will factor into allocation. The Chair said that it is not UNOS' purview to decrease cost of transplant for hospitals. The

member responded that they raised the question because Congress has asked the National Academy of Sciences to find out if the OPTN can factor these issues into the allocation process with regard to equity and fairness.

Hemodynamic Monitoring Equivalence

Hemodynamic Monitoring Equivalence is considered a high priority by Committee leadership. Transplant hospitals have questions about using equivalent technologies such as continuous output pulse oximetry or CardioMEMs to approximate cardiac output. Equivalent technology for obtaining hemodynamic information could be defined by the Committee.

A member commented that hemodynamic monitoring and new technologies could be handled by exceptions. The Chair responded that the Committee strives to reduce exception requests and guide regional review boards on topics that appear frequently in exception requests.

A member commented that there is no good way to noninvasively measure cardiac output. There is a device called Starling manufactured by Baxter that measures impedance but it is expensive and not commonly used. CardioMEMs measures pulmonary artery diastolic (PAD) but not pulmonary capillary wedge pressure (PCWP). There is no adequate technology currently available to measure hemodynamic information.

A member agreed that this is a high priority item because of the number of exception requests that are received because of this occasionally trivial requirement. Patients should be monitored to determine how medically urgent their status is and not placed on monitors to gain a higher status.

National Heart Review Board

National Heart Review Board is considered a medium priority by Committee leadership. There is a Lung Review Board and National Liver Review Board already established. The National Heart Review Board for Pediatrics was recently approved and is pending implementation. The Committee would determine the structure for this review board if deemed that it is a project that should be pursued.

A member commented that this project would be good initiative.

Define and Collect Data of Primary Graft Dysfunction

Define and Collect Data of Primary Graft Dysfunction (PGD) is considered a medium priority by Committee leadership. There was a request submitted to define PGD. This definition may help better track outcomes of sicker recipients.

A member commented that PGD is a big problem. Both OPTN and ISHLT data do not have categories that adequately capture occurrences of PGD. Data is needed to determine the frequency and severity of PGD as it may be increasing in prevalence.

The Chair agreed with the member about moving this project to high priority. UNOS staff noted that there will be a data collection element to this project which will extend the timeline needed to prepare a proposal for public comment. A member agreed that work should begin on this project as it will likely take longer to get the data.

A member commented that this work may help inform a Heart Allocation Score. Defining diseases rather than the way they are treated furthers the mission of the Committee.

A member commented that there may be data to collect outside of UNOS. A member responded that the Committee will need to determine the data they want. The member agreed and commented that the project would require discussion up front to build consensus around what data they want to collect and then there would be a lag while the data forms are approved and implemented.

The Chair requested that the members send PGD articles to UNOS staff to collect. These articles will be shared for the Committee to review prior to discussion. PGD will be a discussion item for the next upcoming Committee meetings. A member asked if they should send some suggested variables. The Chair recommended starting with literature. The Committee will develop an outline, gathering input via email, refine the outline, and then the robust outline will be written as policy by UNOS staff.

Utilization of High Risk Donors

Utilization of High Risk Donors is considered a medium priority by Committee leadership. Transplant hospitals have voiced concern around utilizing high risk donors and being penalized for associated outcomes. The Committee would assess a way to increase to utilization of these donors without impact to the program's statistics. Current monitoring practices may impede the aggressiveness of a program.

Access for Sensitized Heart Patients

Access for Sensitized Heart Patients is considered a low priority by Committee leadership. Initially, the Histocompatibility Committee discussed this project idea with the Committee. Ultimately, the Histocompatibility and Heart Committee chose to not pursue this project at this time due to challenges relating to HLA data.

Heart Allocation Score

Heart Allocation Score (HAS) is considered a low priority by the Committee leadership. This project will eventually be pursued when more data is collected and may be worked on in tandem with creating the continuous distribution model in 2022.

A member asked why PGD and DCD are not being considered as components of HAS. The data would need to be collected simultaneously. They noted that all other organs have a score. The medical urgency of candidates will play a significant role in continuous distribution allocation. The member shared that the Institute of Medicine and National Academies have received funding from Congress to look at these issues to ensure compliance with NOTA and the Final Rule regarding equity and fairness. The member raised concerns about delaying the start of this project. The Chair agreed that this project has high priority and responded that the expectation for HAS to go live is five to ten years. The Committee will begin work on HAS in 2022 when there is an adequate amount of data to analyze.

A member asked where the data for PGD, DCD, and HAS will come from. The Chair responded that data will come from the OPTN and the scientific community. The Committee will define the data needed, develop policy, and then the data will be collected by the OPTN.

A SRTR representative commented that if the new heart allocation statuses are to be included in HAS, there will need to be a couple of years' worth of candidate data and a year or two of follow up data if modeled similar to the Lung Allocation Score (LAS) which uses waitlist severity and post-transplant severity components. The new allocation policy is collecting a lot of data to get at some issues that were not collected previously. A member asked how this relates to variables that will need to be collected for PGD or DCD. A member responded that the barrier to PGD is not a data absence in terms of predictive indicators like donor or recipient factors but rather that there is no data field in the OPTN dataset that indicates that the patient had PGD unless they died within 24 hours of transplant or were retransplanted. Otherwise, there is no data field that includes the use of mechanical support within 24 hours. The Committee will need to define what needs to be collected to identify which patients had PGD rather than assess the risk factors already collected.

Donation after Circulatory Death (DCD)

Donation after Circulatory Death (DCD) is considered a low priority by the Committee leadership. There are trials going on currently. Policy will need to be created once approved. Similar to utilizing high risk donors, there may be questions around including these donors in monitoring and outcomes data. This is lower priority due to still being in the trial and research phase.

A member commented DCD is going to be approved sooner than anticipated. The Committee should begin looking at how to assess donors and outcomes. A member asked how DCD outcomes are reported on and monitored currently. A member responded that DCD recipient outcomes are monitored in the same way as other recipients.

The Chair noted that a goal is that each Committee meeting is productive by having enough projects to work on while being considerate of UNOS staff bandwidth and the time needed to collect the data required for public comment. Projects will be prioritized, resourced, and then timelines will be established based on needs of the Committee. The Chair said that another goal is to have a proposal ready for each public comment period.

Next steps:

The Committee agreed to begin having discussions to define and determine variables for PGD and finish the policy refinements that were started last year. New technologies will be addressed later due to NuPulse being delayed and will be moved to medium priority. Hemodynamic monitoring will be the third project that the Committee will address.

The next Committee meeting will be used to discuss the policy refinements and start discussion on PGD. The Committee member were asked to send articles on PGD to UNOS staff for the Committee to review 2 weeks prior to the upcoming meeting.

Upcoming Meetings

- July 21, 2020
- August 18, 2020
- September 15, 2020
- October 20, 2020
- October 29, 2020: Committee In-person meeting, Chicago, IL
- November 17, 2020
- January 19, 2021
- February 16, 2021
- March 16, 2021
- April 20, 2021
- April 2021: Committee In-person meeting, Chicago, IL – TBD
- May 18, 2021
- June 15, 2021