

OPTN Heart Transplantation Committee

Meeting Summary

September 15, 2020

Conference Call

Shelley Hall, MD, Chair

Richard Daly, MD, Vice Chair

Introduction

The Committee met via Citrix GoToMeeting teleconference on 09/15/2020 to discuss the following agenda items:

1. Introductory Remarks
2. Review Public Comments
3. Primary Graft Dysfunction (PGD) Data Elements

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

1. Introductory Remarks

The Committee was reminded of upcoming regional and committee meeting dates. The October 20th Committee meeting is cancelled.

2. Review Public Comments

UNOS staff reviewed public comments received on both Heart Transplantation Committee proposals.

Summary of discussion:

Guidance and Policy Addressing Adult Heart Allocation

This proposal has received majority support during the regional meetings conducted so far. There is support for the Status 2 exception request template to increase consistency as well as the proposed timeframe for patients on inotropes.

Some criticisms were raised about the reduction to seven days for extensions under the proposed changes to Policy 6.1.A.ii due to the perception that these patients are likely to remain at the same level of medical urgency beyond seven days. There was also a concern about patients' conditions slipping as a result of less frequent hemodynamic monitoring regarding the proposed changes to Policy 6.1.D.ii that extends the requirement to 180 days from 90 days.

The Chair noted that these criticisms are small in percentage compared to the support received. In regard to the decrease in extension time for Status 1, it is generally agreed that these patients are more medically urgent and should be required to submit justifications more frequently. In regard to the extension to 180 days for hemodynamic monitoring, this change was at the request of transplant programs.

The Chair responded to the public comment suggestion to address the weaning of mechanical circulatory support (MCS) criteria in the guidance document by commenting that this is an interesting suggestion and if repeated, could be addressed in future guidance.

Other comments received in response to the appropriate timeframes for Policy 6.1.A.ii, beyond sentiment that the patients' condition will not improve in seven days, included a comment that decreasing the timeframe may be impractical because of the appeals process. UNOS staff reminded the Committee that the appeals are reviewed retrospectively.

For Policy 6.1.D.ii, a comment was submitted in support of the timeframe for patients on inotropes and the creation of the criteria for Status 2 patients.

In response to a feedback question about the usefulness of the guidance, a comment was received suggesting a standard format of data required for submission of a Status 2 exception to make the data provided consistent for reviewer, specifically in regard to pre and post intra-aortic balloon pump (IABP) hemodynamic data as well as the reason for exception. The Chair questioned whether this is already addressed in the regional review board extensions. UNOS staff will attempt to reach out to the commenter for clarity.

UNOS staff asked the Committee to submit feedback on the comments received so far for inclusion in the briefing document.

Guidance Addressing Pediatric Heart Exception Requests

This guidance proposal has received majority support in sentiment voting from 6 regions. Positive feedback received so far include that this guidance is timely, it will assist in increasing the consistency of review, and agreement that reviewers should have pediatric experience.

Criticisms include that there needs to be more clarity in some of the criteria and formatting, the guidance needs to match best practices and not further promote inequity in the system, the guidance should be revised based on broader pediatric heart transplant consensus, and there needs to a root cause analysis for exception requests prior to Continuous Distribution.

The Chair commented that Continuous Distribution is only for lung. UNOS staff commented that they believe the commenter was forward thinking to when heart moves to Continuous Distribution.

A member questioned the criticism about the need for more consensus noting that feedback was solicited and incorporated from the Advanced Cardiac Therapies Improving Outcomes Network (ACTION) as well as other pediatric transplant groups when drafting the proposal. A member questioned if this comment was in response to the criteria relating to inotrope support as there may be a conflict between what is included in the guidance and what is performed clinically at various programs. Another member commented that the biggest contention issue is the deliberate exclusion of inotrope drip dependent dilated cardiomyopathy (DCM) patients from Status 1A following the latest policy change. Some programs feel that there are very few patients who cannot have ventricular assist devices (VADs) and cannot be successfully bridged to transplant until they have mechanical respiratory or cardiac support. These programs may agree that these patients should remain at 1B. The thresholds put forward in the guidance proposal may continue to have issues when seeking consensus.

Dilated Cardiomyopathy (DCM)

Comments received regarding the DCM category included a request for more details on what is considered a VAD contraindication for patients who are in the 5-10 kg range and a suggestion to remove "feeding intolerance" from the criteria satisfying the evidence of poor systemic perfusion. Several comments received were in regard to the inotrope dosing criteria which was considered by some to be too low to indicate increased medical urgency.

A member commented that the 0.5 mcg/kg-min milrinone is standard care for pediatric patients with Congenital Heart Disease (CHD). A member agreed that this dosing is standard care.

A member agreed with removing the “feeding intolerance” criteria as they perceive that this may be abused. They also agreed that the inotrope support requirements could be increased.

The Chair asked if it was fair to require higher dosing of inotropes than what is currently required for adult Status 3.

A member commented that this inotrope dosing criteria is the same as Status 1A pediatric patients with CHD. The goal is likely to remain consistent between these two patient populations.

The Vice Chair commented that the 0.5 dosage was the standard previously. The workgroup did not discuss altering this criterion but agreed that this could be addressed based on the feedback received. The inclusion of “feeding intolerance” was to keep from setting the bar too high for these patients. These criteria can be reviewed again if there is consensus that these need to be readdressed.

UNOS staff asked if there is evidence available that would contradict or support these decisions. A member commented that this is a small patient population and supported leaving the guidance broad and then reevaluating in a year. Another member disagreed that this is not a small population that the inotrope requirement change for Status 1A impacted pediatric heart transplant programs. One benefit of the policy change is that there are less patients at Status 1A and waiting time for these patients has decreased. A disadvantage is that there may be patients on various supports that qualify for Status 1B but need to remain in the hospital. The member voiced concern that the guidance may make the new policy looser, negating the intention of the policy change.

CAV and Retransplantation

One criticism for the *CAV and Retransplantation* category included a request for more clarity about the hospitalization requirements. Another commenter questioned the ability to diagnose triple vessel disease. Other comments included that the criteria may incentivize programs to measure hemodynamics under suboptimal conditions in order to qualify patient for an exception and that the criteria could be improved by including diastolic heart failure with frequent admissions for therapy.

A member commented that outside of a VAD, hospitalization is required in order to qualify for 1A status exception. UNOS staff commented that they believe that the commenter would prefer to have this requirement listed more explicitly in the guidance language.

Single Ventricle

A commenter supported the inclusion of this Single Ventricle since this population does not respond as effectively to inotropic support or mechanical circulatory support (MCS) as DCM patients.

Restrictive and Hypertrophic Cardiomyopathy

A commenter suggested providing a timeframe for episodes of sudden death, arrhythmia, or syncopal events and exception request submission for Restrictive and Hypertrophic Cardiomyopathy patients.

UNOS staff commented that this Pediatric Guidance will be presented to the Pediatric Committee and their feedback will be reviewed by the Pediatric Heart Workgroup.

Next steps:

UNOS staff commented that this Pediatric Guidance will be presented to the Pediatric Committee. All feedback received will be reviewed by the Pediatric Heart Workgroup at their next meeting on September 22nd.

3. Primary Graft Dysfunction (PGD) Data Elements

The Committee discussed the *Reporting Immediate Graft Dysfunction in Heart Transplant Recipients* project's progress to date and discussed potential data elements to include in data collection.

Summary of discussion:

UNOS staff defined in-scope and out of scope activities for the Committee's PGD project. Primarily, the Committee is being asked to focus on identifying data elements that will eventually help monitor and develop policy concerning PGD. The goal is to choose data elements that provide a comprehensive view of PGD and will be useable in analysis three to four years in the future. The Committee was asked to consider how this data may resolve PGD related issues as well as how this data could be used to monitor policy impacts. The Committee was also asked to consider if the data elements selected are already collected by another organization.

During the discussion, the Committee was asked to consider developing a problem statement, a potential solution, identify a target population as well as populations that may be impacted, and identify potential controversy or barriers.

UNOS staff commented that the goal is not to rewrite the International Society for Heart and Lung Transplantation (ISHLT) consensus definition of PGD or create a new data collection form.

The Lung Transplant Recipient Registration (TRR) was presented as an example of how data is collected using components of ISHLT's definition of PGD for lung. The definition of severity scale for PGD was also presented. This informed the mock up that the committee reviewed. The Committee was asked to respond to the data elements included in the mock up.

The Chair commented that the goal is not to define PGD but rather develop something concrete and simple to collect data elements for all transplants with PGD, unless these data points are available elsewhere. This data will be used to analyze the occurrence of PGD in relation to the patients' pre-transplant status and survival, and potentially used in a future heart allocation score (HAS).

The Chair asked if, similar to lung, 72 hours is an appropriate timeframe and suggested 72-96 hours. ISHLT suggests a 24 hour timeframe for identifying PGD. The Committee discussed whether the data should be collected at a specific time or within a specific amount time.

A member commented that 24 hours is consistent with ISHLT's definition but there is an issue that PGD is not always identified in first 24 hours. It occasionally takes longer to see that ventricular function is not performing as it should be. Another member commented that most patients come out of surgery on inotropes so 24 hours is too wide of a net to cast as most patients would qualify as PGD under these criteria.

The Chair suggested using the term "within" when establishing a timeframe for data collection to accommodate instances in which patients go into surgery with an elective VAD transplant and come out on ECMO. In these type of cases, PGD can be identified before but within 72 hours.

A member agreed with using "within" in regard to patients with MCS support. If a patient needs a newly placed device within 72 hours, this would indicate PGD. It's important to wait the 72 hours for the use of inotropes to allow the dust to settle post-transplant.

A member commented that there needs wiggle room to identify when the 72 hours begin, whether it be when cross clamp comes off, when the patient leaves the operating room (OR), or when they go back to the OR for re-bleeding. The transplant staff entering the data on the form later will need to understand

the timeline. The Chair suggested having the start time as when the patient arrives to the intensive care unit (ICU).

A member suggested using multiple time markers with criteria such as needing an IABP at 24 hours in order to identify earlier cases of PGD. The Vice Chair commented that this would be captured by using “within” to describe the timeframe. There needs to be more thought around defining the inotrope criteria. The Chair commented that newly placed devices within a specific amount of time would be a simple way of identifying PGD. A challenge with using hemodynamic data is that it is dependent on the type of support the patient is receiving.

A member suggested collecting lowest left ventricular ejection fraction (LVEF), lowest right ventricular ejection fraction (RVEF), highest right atrial pressure (RAP), highest pulmonary capillary wedge pressure (PCWP), and lowest cardiac index (CI) values. The highest combination of inotrope support should also be captured, although these are hard to measure and report on because the formula to calculate is difficult. A member also noted that finding the highest and lowest values is also labor intensive for the staff entering data. A member raised a concern about using highest and lowest values because of the way this data is recorded and the manual process that would be required of the person needing to identify the lowest or highest value when reviewing a patient’s records.

A member raised a concern about there being a cut off for identifying PGD at 72 hours. The Chair suggested adding another data element that collects when inotropes stop being administered to allow for a calculation of time between the transplant date and the inotrope stop date. This information can be used to assess if there is any correlation between this length of time and outcomes as well as pre-transplant status. The member supported this idea. A member offered to send a list of inotropes that should be included in this data collection.

A member asked if data should be collected on how the heart was preserved. Currently, information on the preservation fluid and amount of fluid is collected on donor forms. A member commented that there may be value in collecting information on what Organ Care System (OCS) was used to preserve the heart. The Chair suggested adding a field that collects whether or not an OCS was used. A member suggested only collecting “warm preservation” or “cold preservation.” UNOS staff commented that data is collect on whether the organ is perfused on the Deceased Donor Registration (DDR).

A member commented that right ventricular ejection fraction (RVEF) should also be collected through echocardiography. A member commented that the data collected needs to be simple enough to allow staff to enter valid, useable data. If the form requires too much time to complete or requires too complicated of data, the data received is more likely to be unusable.

A member suggested only including the following data elements:

- Need for IABP within 72 hours (yes/no)
- Need for RVAD within 72 hours (yes/no)
- Type of support at 72 hours (LVAD, RVAD, BIVAD, ECMO, percutaneous LVAD, pick list)
- Date off inotropes

This member also commented that collecting cardiac index (CI), right atrial pressure (RAP), and transpulmonary pressure gradient (TGP) may not be helpful. The question asked should be if the patient has PGD or pulmonary hypertension or pulmonary vascular disease. This could be asked directly. The Chair noted that the additional questions will only appear if they answer “yes” to PGD.

A member asked if the goal of the data is sensitivity or specificity. If only identifying severe PGD requiring retransplant, the data collection can remain simple. If more specific than that, especially as

warm perfusion increases, then more information is required. The member asked what the use of the data will be four years down the line. They noted that depending on the data required, this could take the coordinators a lot of time.

A member suggested asking the programs to diagnose the severity of PGD using the definition already developed. They suggested removing ejection fraction, RAP, PCWP, TGP, pulmonary artery systolic pressure (PASP), and CI from the mock up presented. The only field they suggested to add was a question about the duration of inotropes. A member disagreed, stating that ejection fraction and CI need to be included in order to be consistent with ISHLT's definition and to be able to capture moderate and severe cases. Another member agreed.

A member suggested collecting whether or not the patient is on a VAD and last day of inotrope support at 72 hours. Another member commented that some of the data elements need to be used from the ISHLT definition as that is what is currently established and are markers that programs are currently following. Pulmonary artery pressure, RAP, and CI are regularly collected and should all be available at 72 hours.

A member asked if this project would address pediatric and adult recipients. They noted that the same registration and follow up forms are used for both populations. A member agreed that the best approach may to address both populations simultaneously.

Next steps:

The Chair will work with UNOS staff to create new mockups based on the discussion as well as learn more about what is collected at procurement that may be useful prior to the Committee's next discussion at the in-person meeting on October 29.

Upcoming Meeting

- October 29, 2020

Attendance

- **Committee Members**
 - Adam Schneider
 - Arun Krishnamoorthy
 - Cindy Martin
 - David Baran
 - Donna Mancini
 - Hannah Byford
 - Hannah Copeland
 - J.D. Menteer
 - Joh Hammond
 - Jonah Odim
 - Jose Garcia
 - Kelly Newlin
 - Laura DePiero
 - Michael Kwan
 - Mike McMullan
 - Rachel White
 - Rocky Daly
 - Shelley Hall
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Katie Audette
 - Monica Colvin
 - Yoon Son Ahn
- **UNOS Staff**
 - Eric Messick
 - Julia Chipko
 - Keighly Bradbrook
 - Lauren Mauk
 - Sarah Konigsburg
 - Sara Rose Wells
 - Susan Tlusty