

OPTN Heart Transplantation Committee

Meeting Summary

October 6, 2021

Conference Call

Shelley Hall, MD, Chair

Richard Daly, MD, Vice Chair

Introduction

The OPTN Heart Transplantation Committee met via Citrix GoToMeeting teleconference on 10/06/2021 to discuss the following agenda items:

1. Amend Status Extension Requirements in Adult Heart Allocation Policy
2. Report Primary Graft Dysfunction in Heart Transplant Recipients
3. Potential emergency policy actions to address transplant hospital capacity?
4. Discuss Eligibility and Safety Net Criteria in Potential Simultaneous Heart-Kidney Transplant Policy
5. Update on status of ABOi Offers Project
6. Clarification of data definitions in UNetSM
7. Other Committee Business and Closing Remarks

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

1. Amend Status Extension Requirements in Adult Heart Allocation Policy

The Committee reviewed the proposal, the public comment feedback, and revised the policy as necessary.

Summary of discussion:

Policy 6.1.A.iii: MCSD with Life Threatening Ventricular Arrhythmia

Committee members were supportive of requiring extension reapplications at seven days in order to be consistent with the status 1 policy, especially since most patients are transplanted in under 7 days. Members discussed the negative repercussions if a patient is listed at the wrong status, such as blood type making it more difficult to receive an organ after at a higher status.

A member suggested defining panel-reactive antibodies (PRA) and specifying what an elevated PRA is to create consistency across centers. The chair clarified that PRA cannot be included in policy because there is not a set definition of PRA and this policy would not be the appropriate place to define PRAs since it has already gone out for public comment. Additionally, the Chair noted that the OPTN Histocompatibility Committee has considered this but has been unable to reach a consensus on developing a proposal.

In terms of the ventricular arrhythmia, a member asked if there is a formal definition of electrical cardioversion? The Chair confirmed that antitachycardia pacing (ATP) has been included as a cardioversion in the counts for shock utilization. The Chair suggested adding '(external, internal, or ATP)' next to 'required electro cardioversion' but the group agreed that ATPs inclusion is a general accepted fact in the community and did not require specification. Members countered that centers could be underutilizing the status if they thought ATP did not make patients eligible or submit exception requests

when they thought a patient was no longer eligible. However, members ultimately decided that this distinction could be thoroughly made in the policy education and was not necessary in the policy itself.

When discussing the 7-day extension timeframe, a member inquired if the transplant staff would need to resubmit the initial form or if there would be a specific 'extension' form and UNOS staff clarified that there is an automated extension form. The Committee suggested adding language to line 80 that 'if the candidate remains hospitalized on continuous IV and continues to have qualifying arrhythmic events.'

UNOS staff informed the Committee that if a patient qualifies for a status by the eligibility criteria then the status applies for 7 days but if they qualify through an exception then the status applies for 14 days, therefore providing an advantage for qualifying by exception criteria as opposed to eligibility criteria. A member responded that the average response time for an exception request is 5-7 days and since the transplant center is unlikely to transplant the patient while the exception request is pending there likely will not be any added time benefit for qualifying in that way.

UNOS staff confirmed that a comment will be added to life threatening ventricular arrhythmia and extracorporeal membrane oxygenation (ECMO) clarifying that the candidate has experienced the problem again, whether since their initial qualification or an extension.

When discussing whether the status 2 or 3 was the appropriate transition for this population, it was felt that the policy had to remain at status 3 because that is what is indicated in Policy 6.1.A.i addressing ECMO. One member was concerned that this policy would lead to more exception requests for centers wanting their patient to be at status 2, but a member countered that status 3 is correct because the patient is no longer experiencing episodes.

Policy 6.1.C.iv: MCSD with Pump Thrombosis

The Committee discussed if language was needed to specify that the patient is still experiencing the conditions that originally qualified them for the status. A member requested that the consensus of this policy should be reflected in the Right Ventricular (RV) failure policy in order to be consistent across similar diagnosis and treatments.

Members discussed the role intravenous (IV) heparin, and similar anticoagulants, plays in determining the status and level of care necessary for these patients. Additionally, the use of extensions for this Status criterion is high, averaging 13 per patient during the period analyzed. The Committee felt it was appropriate to require hospitalization and continuous IV anticoagulant with an extension request every 90 days for this group of patients.

Consideration of Potentially Disadvantaged Groups and Transition Procedures

Members decided how to transition all patients to the new status requirements the policy is implemented. For *Policy 6.1.C.iv: MCSD with Pump Thrombosis* the Committee decided to allow patients to retain their status until the next extension. For *Policy 6.1.A.iii: MCSD with Life Threatening Ventricular Arrhythmia* the Committee decided to allow patients to retain their status until the next extension.

Next steps:

UNOS staff will make the changes discussed during today's meeting and circulate the revised policy for Committee review. The formal vote on the proposal will occur during the Committee meeting on Tuesday, October 19 at 5:00 pm ET.

2. Report Primary Graft Dysfunction in Heart Transplant Recipients

The Committee reviewed the proposal, the public comment feedback, discussed the data collection language and revised the policy as necessary.

Summary of discussion:

PGD – Feedback about Potential Increased Data Burden/Workload for Coordinators

Members discussed that there will be a learning curve with the new data requirements but after the implementation, the time it takes to complete the forms will be reduced. The Chair also clarified that the data does not need to be submitted at the 24-hour mark, but instead the data is just from 24 hours. Throughout the Committee's discussions, they emphasized having the data definitions and flow of information be as clear and concise as possible to not increase the burden for coordinators.

Data Collection Language

A member suggested adding a text box to the question 'Is Primary Graft Dysfunction (PGD) present?' UNOS Research staff informed the Committee that text boxes required additional analysis that can cause delays and potential for the data to be unusable down the line. UNOS staff also predicted some pushback from the OPTN Data Advisory Committee (DAC) on the use of text boxes. Members hoped to gain a better understanding if PGD was determined based on the clinician's understanding or if the data indicated PGD was present. This would provide a better understanding of how mild PGD is determined since it can be challenging to identify.

The Chair clarified that this is just the first step in gathering information and addressing PGD. Members discussed whether PGD should be identified as moderate or severe or just remain a binary yes or no answer choice. Ultimately, members decided to limit the answer choices to yes or no and allow centers to identify what is unusual for them. If the transplant staff enters 'no' then the PGD specific questions will gray out. If the transplant center enters 'yes' then they will be asked follow up questions. The follow up questions are being revised from 'Left Ventricular Dysfunction' to 'Left Ventricular Primary Graft Dysfunction' and from 'Right Ventricular Dysfunction' to 'Right Ventricular Primary Graft Dysfunction.'

The Chair asked the Committee to clarify what timeframe is required to submit the echocardiogram (ECHO) and which to send for a patient who has multiple. A member suggested the ECHO taken closest to the patient's arrival in the intensive care unit (ICU) should be used for the 24-hour mark, which a member noted that sometimes the ECHO taken in the operating room (OR) is the only one taken in the first 24 hours. A member suggested indicating this in the policy, or subsequent education, so additional ECHOs are not ordered unnecessarily. The Chair suggested 'lowest ejection fraction (EF) from final OR time to 24 hours after arrival to ICU and lowest EF between 24 and 72 hours (plus or minus 4 hours) after arrival to ICU if available.' The Committee agreed to proceed with this timeframe.

A member expressed concern that not all EFs will provide a percentage, some will just indicate if the results are normal function or mildly depressed. The Committee decided on including categories low, moderate, and severe and provided percentages that correspond with each category. A member was concerned that clarification is needed explaining that the EF scores are measured when the recipient does not have mechanical support. However, another member countered that the lowest EF score should occur prior to mechanical support.

Members discussed if the medication collection information is relevant to identify PGD, and decided that the information in the proposal is pertinent, and should not be reduced.

Inotrope and Vasopressor Ranges

Additionally, the Committee elected to use both (mcg/kg/min) and (mcg/min) to accommodate the different ways transplant programs report the dosages and suggested using a base weight of 80 kg to calculate the ranges. The Committee elected to categorize the scores as low, moderate, and severe. When discussing inotropes, the Vice Chair brought up that isoproterenol was not included on the list.

The Committee determined that this medication was not necessary because it was not used to treat PGD. The Committee agreed that the medication dosages and hemodynamics reported should all be from the same data collection and time point to be more consistent.

Pediatric Considerations

A member suggested including “Left Atrial Pressure” with the “Pulmonary Capillary Wedge Pressure” data element to better accommodate pediatric candidates by allow transplant programs to report left atrial pressure instead. Some transplant programs measure left atrial pressure directly, and the consensus of the Committee was that these directly measured values are acceptable for capturing information about pediatric patients.

Members agreed to modify the pulmonary artery pressure data element so pediatric programs can submit an estimate of the pulmonary artery systolic pressure as a substitute for a direct measurement. The estimate can be obtained by using an echocardiogram-determined tricuspid valve regurgitant jet gradient added to the right atrial pressure measurement. A member emphasized the importance of indicating if the calculation is measured or calculated to provide stronger data. Members discussed if it was necessary to be more specific in what was measured by stating ‘catheter’ instead but others had concern that it could outdate the information as technology progresses. Members decided on using two checkboxes where coordinators indicate either ‘PA or other catheter’ or ‘non-invasive estimate.’

Donation after Cardiac Death (DCD)

There were a lot of questions about DCD data but unfortunately it is not within the scope of this project to address. Alternatively, it was suggested that the Heart Committee develop a project proposal to create a DCD donor data collection form. Member discussed the importance of pursuing this project, specifically with the OPTN Organ Procurement Organization (OPO) Committee, but also do not want to pursue a project that may eventually fade out in favor of a system wide DCD protocol. Ultimately, the Committee did agree that this is an extremely relevant project for them to pursue and would like to collaborate to develop a more harmonious approach.

Next steps:

UNOS staff will make the changes discussed during today’s meeting and circulate the revised policy for Committee review. The formal vote on the proposal will occur during the Committee meeting on Tuesday, October 19 at 5:00 pm ET.

3. Potential emergency policy actions to address transplant hospital capacity?

UNOS staff inquired if the Committee is interested in pursuing an emergency policy action to address the high inpatient occupancy rates many transplant hospitals appear to be experiencing in the midst of the COVID-19 health emergency.

Data summary:

Percentage of transplant hospitals with a heart transplant program that experienced inpatient bed utilization rates of 65% or greater during weeks of 8/15/2021 through 9/05/2021 (197 hospitals reported data for all 4 weeks):

- 65% or greater – 149 of 197 (76%)
- 75% or greater – 105 of 197 (53%)
- 85% or greater – 48 of 197 (24%)
- 95% or greater – 12 of 197 (6%)

Summary of discussion:

A member asked if any transplant hospitals had requested exceptions due to this issue and was told it has occurred. It was suggested that hospitals in the region could work together to combine resources and fill gaps in care when other centers have reached capacity.

A member noted that COVID is not going away any time soon so the policy would need provide a sense of flexibility and fluidity that would allow for changes as needed. UNOS staff clarified that emergency policies have limited effective dates and are regularly reviewed by the Executive Committee to determine if it should be extended or sunsetted.

A member inquired about the origin of the existing policy and why it is required for the patient to be in-patient at the transplant hospital as opposed to being in-patient at any hospital. The Chair responded that when the adult heart policies were being revised, some of the primary considerations for requiring hospital admission were if the transplant team could follow up with the patient at a different hospital, does that hospital have an operating room (OR), and can the hospital provide the same access to care for the transplant patient? Members agreed that the accessibility of the transplant team to the patient is essential and can be very challenging if they are admitted at a different hospital.

A member asked if the severity of the situation hospitals are experiencing were worth an emergency policy, especially since the majority of transplant care teams would not have ease of access to their patients if they were not at the same hospital. It was suggested that programs experiencing issues could describe their circumstances using the COVID-19 reporting site found in UNetSM. This practice would not be ideal, however, an emergency policy should be considered if it would decrease the quantity of exception requests being submitted.

The Vice Chair noted that since heart patients cannot be listed at multiple centers if hospital admission is required, if the hospitals were administratively linked then it would be in the best interest of the patient to be admitted at the alternative location. The Chair clarified that a caveat would be needed that allows this practice only when there is no availability at the primary hospital. Members were concerned that once a loophole was opened it would be difficult to close and suggested adding a caveat that as soon as there is availability at the primary hospital the patient must be relocated.

A member asked if these scenarios are not occurring very often and when they do occur, they are being resolved with exception requests, then why does there need to be an emergency policy? The Chair recognized the validity of this question and stated that centers could be proactive if they experience this issue. A member noted that the community has placed an emphasis on having patients at the transplant hospital and it is important to recognize that and not open a door with emergency policy before it is necessary.

The Chair suggested sending a short survey to hospital administrators to gauge if they are experiencing this issue and if they have another hospital in close proximity that could accommodate the patient and transplant care team.

A member highlighted the importance of the Committee having these discussions and being proactive to address any potentially significant issues for the community. With that being said, the Committee came to the consensus that transplant centers should continue to submit information to the COVID-19 portal in UNetSM when availability issues arise and not proceed with developing an emergency policy at this time.

Next steps:

UNOS staff will monitor the quantity of these exception requests coming in. If conditions change in the future, then the Committee will reevaluate this decision as needed.

4. Discuss Eligibility and Safety Net Criteria in Potential Simultaneous Heart-Kidney Transplant Policy

UNOS staff reviewed the Simultaneous Heart-Kidney (SHK) eligibility criteria and safety net in the policy proposal by the Ad Hoc Multi-Organ Transplantation (MOT) Committee, which is slated to go out for public comment in January 2022. The MOT Committee has opted for a policy that reflects the eligibility criteria and safety net in the Simultaneous Liver-Kidney (SLK) policy. UNOS staff asked the Committee to consider what types of questions they would like to ask the community during public comment.

Summary of discussion:

The Chair enquired if the eligibility for status 1-3, from the OPO proposal, would remain when the new MOT policy is implemented. The Chair's concern is that if dialysis is a requirement for eligibility then there are heart patients on dialysis who are not in status 1-3 that would be eligible.

A member expressed concern because there is no way for them to capture when a patient is unable to be listed for a heart transplant because their kidneys are too damaged. A member was supportive of a more liberal eligibility criterion, as opposed to safety net, because the patients are already so sick when they go in for their second transplant surgery. The Chair proposed asking the community 'Is a GFR less than 30 the appropriate cut off for a heart-kidney transplant?'

Next steps:

If members think of specific questions to include in the public comment proposal please send them to UNOS staff and the Committee will continue this discussion during later Committee meetings.

5. Clarification of data definitions in UNetSM

UNOS Research staff discussed the data definitions for Machine Perfusion on the Deceased Donor Registration (DDR) Form to accurately reflect Normothermic Machine Perfusion and Normothermic Regional Perfusion. This revised data definition will go through internal review then external review but does not need to go out for public comment.

Data summary:

Heart machine perfusion: If there was machine used in preservation of the heart, select **Yes**. If not, select **No**. This field is **required**.

Coronary Artery Disease (CAD): If the recipient has been diagnosed with coronary artery disease in a transplant heart, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is **required**.

Summary of discussion:

Heart Machine Perfusion

Members highlighted the importance of making the distinction of in vivo and ex vivo because different methods are used depending if the donor is DCD or brain dead. A member shared that in most cases machine perfusion is ex vivo, but it can still occur in vivo. The Chair suggested having a different DCD and Donation after Brain Death (DBD) form so that there would be more clarity on practices used in each procurement surgery. The UNOS Research Staff agreed, but making this data definition change would be the quickest way to resolve this without going through the full policy cycle.

A member suggested wording the question to ask 'was there mechanical perfusion of the organ after removal of the donor's body?' The group agreed that this definition would be clear and sufficient.

Coronary Artery Disease

The Committee was asked what specific criteria should be used to diagnose Coronary Artery Disease in a transplanted heart. The Chair suggested changing the name of the form from CAD to CAV, meaning Coronary Artery Vasculopathy, which would allow more flexibility in how the center identifies CAV. Other members countered that there should be a form for CAD and CAV, while others stated that the Committee still needs to establish a definition for the new form so the issue is not solved. UNOS Research staff informed the committee that they could not change the title from 'disease' to 'vasculopathy'.

A member stated that a definition cannot be established without determining what the intent of the form is. A member suggested their best effort may be spent clarifying what the Committee believes people are doing when they fill out this form. A member suggested sending a survey out to centers to gain a better understanding of how they are presently filling out these forms. The Committee came to the consensus that by changing the definition, they will not be able to compare the existing data to the new data and therefore would rather revise the form as a whole.

Next steps:

UNOS staff will draft the revised Heart Machine Perfusion definition and circulate them to the Committee for feedback. UNOS staff will connect with data governance to discuss possible next steps for reviewing the Coronary Artery Disease form.

6. Update on status of ABOi Offers Project

Rocky Daly, the Vice Chair, provided an update on the ABOi Offer project that the Committee is collaborating with the OPTN Pediatrics Committee on. The purpose of the project is to update policy to align with current research findings related to ABOi pediatric heart transplant to increase donor pool and reduce wait time. This project considers modifications to *Policy 6.6.B.: Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Hearts*. The workgroup is currently waiting for a data analysis before continuing with its work.

7. Other Committee Business and Closing Remarks

UNOS staff provided an overview of the Vice Chair appointment process. The Committee will vote on the final policy proposals during the October 19 meeting so please let UNOS staff know if you will be unable to attend the meeting to ensure quorum is reached.

Upcoming Meetings

- October 19, 2021
- November 16, 2021
- December 21, 2021
- January 18, 2022
- February 15, 2022
- March 15, 2022
- April 19, 2022
- May 17, 2022
- June 21, 2022

Attendance

- **Committee Members**
 - Adam Schneider
 - Amrut Ambardekar
 - Arun Krishnamoorthy
 - Cindy Martin
 - Cristy Smith
 - David Baran
 - Hannah Copeland
 - J.D. Menteer
 - Jennifer Carapellucci
 - Jonah Odum
 - Jose Garcia
 - Kelly Newlin
 - Michael Kwan
 - Richard Daly
 - Shelley Hall
 - Steve Kelban
- **HRSA Representatives**
 - Jim Bowman
 - Raelene Skerda
- **SRTR Staff**
 - Katie Audette
 - Monica Colvin
 - Yoon Son Ahn
- **UNOS Staff**
 - Eric Messick
 - Keighly Bradbrook
 - Krissy Laurie
 - Laura Schmitt
 - Lauren Mauk
 - Leah Slife
 - Nicole Benjamin
 - Sara Rose Wells
 - Susan Tlusty