OPTN Heart Transplantation Committee
Status Extension Review Subcommittee
Meeting Summary
March 9, 2021
Conference Call

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

Introduction

The Status Extension Review Subcommittee met via Citrix GoToMeeting teleconference on 3/9/2021 to discuss the following agenda items:

1. Request project modification: Adding collection of transplant program email addresses on adult and pediatric justification forms
2. Considering opportunities to improve consistency of extension criteria in adult heart policy

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

1. Request project modification: Adding collection of transplant program email addresses on adult and pediatric justification forms

UNOS staff shared a request to add email fields to adult and pediatric status justification forms. Having these email addresses readily available helps the Heart Review Board team reach out to appropriate points of contacts when necessary.

Summary of discussion:

The Chair asked if there are any downsides for including this component as part of the Status Extension Review project. UNOS staff shared that the only negative attribute is the time associated with entering an email address on justification forms. Collecting email addresses of the appropriate transplant program staff contacts allows for UNOS staff to communicate form denials more efficiently. A member suggested collecting multiple email addresses to ensure that emails are not missed if specific program staff are out of the office. UNOS staff commented that the plan is to collect three emails.

The Committee agreed to add data elements for the collection of email addresses to the Status Extension Review project.

2. Considering opportunities to improve consistency of extension criteria in adult heart policy

The Subcommittee reviewed previously proposed policy revisions.

Summary of discussion:

Policy 6.1.B.vi: Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF)

UNOS staff asked if the members agree that the candidate should be required to remain hospitalized on continuous intravenous antiarrhythmic therapies in order to be eligible to extend at this status and criterion. The Chair commented that this should be consistent with other VT or VF candidates and raised a concern about not requiring hospitalization for Status 2 candidates. The members agreed with the proposed revision as presented.

The Chair commented that the required information collected for this status and criterion should match policy *6.1.A.iii Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia.* She noted that the requirements should not be more onerous for Status 2 than Status 1 and that the required source documentation is adequate in ensuring the candidate meets criteria.

Policy 6.1.C.v: MCSD with Right Heart Failure

UNOS staff shared that the members previously determined that this status and criterion can be extended once and have a timeframe of 90 days. This increases the timeframe from the current 14 days.

A member asked if after the 90-day extension expires, the candidate will need to stop inotropes to prove they meet the initial criteria again. The member commented that, as written, the hemodynamic information would need to be collected prior to inotrope initiation. She asked if there are other medical criteria or hemodynamic data that would prove eligibility for this status without removing the patient from inotropic support.

The Chair commented that the goal is not to remove the patient from inotropic support. She asked if documenting that the patient is still on the listed therapies is all that should be required in which case, the candidate should be permitted to extend every 90 days. UNOS staff commented that the initial consideration around limiting extensions was relating to the medical urgency of candidates at this status. Candidates who are eligible for this status are unlikely to be supported for long lengths of time without receiving a transplant. The Chair confirmed that candidates with persistent RV failure requiring inotropes are unlikely to recover. These candidates either receive a transplant or palliative inotropes. The Chair commented that she has managed patients with RV failure on palliative inotropes for lengths of time longer than a year.

The Chair suggested that it should be required to document if the candidate is still on the therapies in order to extend. Updated hemodynamic information could be required for a second extension.

The members discussed how this status and criterion could be made consistent with *6.1.D.ii Inotropes without Hemodynamic Monitoring*, recently extended to have a timeframe of 180 days. The Vice Chair commented that the spirit of the discussion was to not require a right catheter every 90 days, but require ongoing inotropes. At 180 days, a new right heart catheter would be required in order to submit updated information. A member suggested mirroring the language in *6.1.D.ii Inotropes without Hemodynamic Monitoring.*

A member commented that data collected from the right heart catheter may not indicate RV failure since the candidate is stabilized on inotropes and questioned the purpose for collecting this data.

A member asked what the median time to transplant is for a Status 3, blood type O candidate. Members commented that their blood type O candidates typically have longer wait times. UNOS staff commented that data specific to blood type is not readily available on the monitoring report.

A member asked if there are any objective data that could support eligibility for this status. A member commented that the measures will be patient specific. UNOS staff shared that the median time to transplant for all candidates at this status is 63 days, which falls within the proposed 90-day extension.

The members discussed whether requiring the candidate to remain on the therapies listed in the policy is adequate. A member commented that it may be useful to track how a candidate's treatments change over a period of time, noting that a candidate may begin on multiple inotropes and then drop down to only one to retain the status.

The Chair commented that keeping an indwelling arterial catheter line in a candidate with a ventricular assist device (VAD) is a risk for infection. The Vice Chair added that managing a pump is also difficult. The members agreed that this level of support indicates medical urgency.

The Vice Chair suggested changing policy language to include candidates that meet the eligibility criteria 7 days prior to the initiation or while on any of the therapies listed. This would eliminate the need to repeat a right heart catheter. Currently, the extension form requires the inotrope, dosage, and date of initiation. UNOS staff suggested breaking the "7 days prior to the initiation or while on any of the therapies above" language suggested into two criteria by adding a third criterion that applies to candidates currently on the listed therapies to in order to better align with validation rules programmed in UNet^{sm}.

The Chair and members questioned the pulmonary capillary wedge (PCW) and central venous pressure (CVP) values included in the policy. A member raised a concern that these do not adequately indicate RV failure. Some candidates may meet this criterion by being volume overloaded but not have RV failure. RV failure may need to be identified through cardiac index and cardiac output values. The Chair asked if the second criteria including the CVP and PCW values should be removed. She commented that creating a PCW/ CVP ratio of 1 may be excessive and suggested including a PCW value of less than 15. A member suggested requiring the candidate to meet 2 or 3 criteria to allow some wiggle room with the expectation is that the patient has RV failure.

The Chair will follow up with parameters that would better identify RV failure. UNOS staff will look up how many candidates are assigned to this status in the 18-month monitoring report.

Policy 6.1.C.vi: MCSD with Device Infection

The members reviewed the policy revisions drafted at the previous meeting. UNOS staff asked if intravenous (IV) antibiotics need to be specified for each row in the table. The members agreed to add IV antibiotics to all criteria. UNOS staff asked if there is potential to disadvantage patients who are prescribed oral antibiotics. The members agreed that if the candidates are able to be cured with oral antibiotics, they should be at a lower status. A member agreed that bacteremia is serious and needs IV antibiotics. A member commented that if there are contraindications to IV antibiotics for any reason, an exception request would be appropriate.

UNOS staff asked if the criteria "a culture-positive fluid collection between the driveline site and the device" should include a requirement of "within the last 14 days" to create consistency with the positive bacterial or fungal culture criterion. The Chair considered an example of a destination therapy (DT) patient with device infection who is on antibiotics for 3-5 weeks and is then listed for transplant. When this patient is listed, the original culture could be from two months ago. A member commented that if the patient is on IV antibiotics, they should be eligible for this status. The members agreed to not include a timeframe for this criteria.

Status 1 criteria timeframes

The members discussed if all Status 1 criteria should have the same timeframes for both the initial justification and extensions. The Chair shared that the intent for Status 1 criteria having a timeframe of 7 days was to limit opportunities for people to overuse this status. A member supported having all of Status 1 renew every 7 days and commented that this status needs to be reserved for the most medically urgent candidates and there should be a requirement to continually prove the candidate's urgency. Members agreed that all Status 1 criteria should have a timeframe of 7 days.

The members supported changing the timeframe for *6.1.A.iii Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia* from 14 to 7 days. The requirements will need to be revised to ensure that the specified events have occurred within 7 days of form submission. A member agreed that if the candidate has not had an event in 7 days, they may not be urgent enough to be eligible for Status 1.

A member asked if a patient with MCSD and arrhythmia would downgrade to a Status 2 or 3. UNOS staff commented that downgrade language is not included in every Status 1 criteria. The Chair asked if downgrade language should be included for each criteria in Status 1. A member asked what status those who are denied under *6.1.A.iii Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia* would be eligible for. The member raised a concern about patients being treated with anti-arrhythmic therapies not being eligible due to being stabilized and are thereby not experiencing episodes of ventricular fibrillation or ventricular tachycardia within the proposed 7-day timeframe. The Chair commented that Status 3 would be appropriate if denied by the review board or due to form expiration. The members agreed to add language that would permit a downgrade to Status 3 if these candidates' forms expires, rather than automatically downgrading them to Status 5 or 6 as is done currently.

A member commented that since the extensions for 6.1.A.iii are not reviewed, if they meet criteria, they will stay at this status. If they do not meet criteria, the renewal cannot be completed and will likely seek an exception.

UNOS staff asked if the extension criteria for *6.1.A.ii Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device* needs any revision. The Chair and members commented that the current extension requirements are adequate.

The Chair shared that candidates who are assigned Status 1 under *6.1.A.i Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)* previously were downgraded to Status 6 if their forms expired. This was modified so these candidates would be downgraded to Status 3 as a protection. The Vice Chair commented that candidates could be resuscitated with ECMO, become eligible for this status and criterion, and then be weaned. He commented that candidates assigned to Status 1 under *6.1.A.ii Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device* are less likely to be weaned from their support.

Next steps:

The Chair will provide suggested RV failure parameters for the subcommittee to consider.

UNOS staff will provide the number of patients who are downgraded to Status 5 or 6 due to form expiration. This information will be used to assess if the issue is significant enough to address with policy modifications to create safety nets.

Upcoming Meeting

- TBD

Attendance

- **Subcommittee Members**
  - Arun Krishnamoorthy
  - Cindy Martin
  - Greg Ewald
  - Jonah Odim
  - Jose Garcia
  - Rocky Daly
  - Shelley Hall
- **HRSA Representatives**
  - Adriana Martinez
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Katie Audette
  - Yoon Son Ahn
- **UNOS Staff**
  - Eric Messick
  - Janis Rosenberg
  - Keighly Bradbrook
  - Leah Slife
  - Nicole Benjamin
  - Sara Rose Wells
  - Sarah Konigsburg