OPTN Heart Transplantation Committee
Status Extension Review Subcommittee
Meeting Summary
December 1, 2020
Conference Call

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

Introduction

The Status Extension Review Subcommittee met via Citrix GoToMeeting teleconference on 12/1/2020 to discuss the following agenda items:

1. Project overview
2. Discuss project form

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

1. Project overview

The Chair and UNOS staff provided an overview of the background and problem statement of the *Review of Extension Requirements in Adult Heart Allocation Policy* project.

Summary of discussion:

The Chair commented that this Subcommittee is charged with continuing the work from the previous year. The Committee previously identified gaps and inconsistencies in Heart allocation policies. The Subcommittee will address the remaining items that were not included in the proposal from the last public comment cycle. UNOS staff commented that the policy modifications being addressed by the Subcommittee are likely to be more controversial in public comment and will need additional supporting evidence to justify the needed changes.

This project is intended to address concerns around "parking" candidates at certain statuses and issues relating to the lack of criteria required to extend statuses.

2. Discuss project form

The member reviewed and discussed previously drafted policy modification language.

Summary of discussion:

The Committee identified the following policies to review and potentially modify:

- *Policy 6.1.A.ii: Non-dischargeable, Surgically implanted, Non-Endovascular Biventricular Support Device*
- *Policy 6.1.B.vi: Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF)*
- *Policy 6.1.C.iv: Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis*
- *Policy 6.1.C.vi: Mechanical Circulatory Support Device (MCSD) with Device Infection*
- *Policy 6.1.C.v: Mechanical Circulatory Support Device (MCSD) with Right Heart Failure*

UNOS staff noted that these potential changes may be require more intensive IT support and programming.

Policy 6.1.C.iv: Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis

The Subcommittee reviewed a proposed revision of *Policy 6.1.C.iv: Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis* written previously by the Committee. The Chair commented that the Committee chose to address this policy because, as written, it is vague and does not provide timeframes. Theoretically, a candidate applying for a status may have experienced a symptom such as a stroke years prior and still meet criteria for a pump thrombosis. The potential policy modification would increase granularity and establish a temporal relationship between symptoms and form submission. The Chair noted that paracorporeals are rarely used but remain in the revised policy in case they resurge in use. Pump parameters are also defined in the suggested revision.

A member suggested combining *6.1.C.iii Mechanical Circulatory Support Device (MCSD) with Hemolysis* with *Policy 6.1.C.iv: Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis.* Both policies provide criteria for Status 3 and hemolysis is often thought to be caused by pump thrombosis. Hemolysis could be considered a subcategory of pump thrombosis. UNOS staff commented that combining policies would affect forms, related programming, and research data. This impact needs to be explored to determine feasibility.

A member suggested increasing the granularity of the inotrope support information in the proposed language relating to the presence of left-sided heart failure in order to be more consistent with the level of detail required in the other criteria. They also noted more detailed inotrope information is required in policy *6.1.C.v Mechanical Circulatory Support Device (MCSD) with Right Heart Failure*. The Chair commented that this was debated when the criteria was drafted but the sentiment was that committing a ventricular assist device (VAD) patient to an indwelling line indicates that their condition is severe, regardless of the inotrope dosing.

Members discussed how many criterions need to be met to be eligible for the Status 3 under this policy. A member commented that other conditions can cause systemic thromboembolism unrelated to a left ventricle assist device (LVAD). A member commented that the first three criteria listed in the drafted language for suspected pump thrombosis describe symptoms, while the fourth criterion describes treatments. The member suggested at least one criteria describing symptoms and the criteria describing treatments should be met to qualify for Status 3 under this policy.

The members agreed that if a patient is experiencing pump thrombosis and is seeking a transplant, rather than having their pump replaced, hospitalization is an appropriate requirement. The Chair noted that most Status 3 policies require hospitalization.

Members agreed to keep the proposed paracorporeal language although these devices are less common. They chose to reorder the proposed language so that the suspected pump thrombosis in an implanted LVAD section is first.

The members edited the proposed language to read:

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by a Mechanical Circulatory Support Device (MCSD), is admitted to the hospital, and meets either of the following criteria:

- *Suspected pump thrombosis in an implanted LVAD:*
  *Must have **one** of the following:*
  1. *Transient Ischemic Attach (TIA) (as observed by symptoms such as, but not limited to unilateral facial weakness, vision problems, and/or slurred speech, lasting less than 24 hours), Cerebrovascular Accident (CVA) or peripheral thromboembolic event in the absence of intracardiac thrombus or significant carotid artery disease, or*

2. *Presence of left-sided heart failure not explained by structural heart disease, such as AI, and requiring inotropic support, or*
3. *Abnormal pump parameters, such as significant and persistent increase in pump power and low flow despite good blood pressure control;*

And *have one of the following treatments:*

4. *Need for treatment intravenous anticoagulation (eg. Heparin), intravenous thrombolytics (e.g. tPA), or intravenous antiplatelet therapy (e.g. eptifibatide or tirofiban) in the hospital*

- *Suspected pump thrombosis in a dischargeable paracorporeal device:*

1. *Visually detected thrombus in a paracorporeal ventricular device (LVAD), and*
2. *TIA (as observed by symptoms such as, but not limited to unilateral facial weakness, vision problems, and/or slurred speech, lasting less than 24 hours), ischemic Cerebrovascular Accident (CVA), or peripheral thromboembolic event in the absence of intracardiac thrombus or significant carotid artery disease.*

This status is valid for up to 30 days from submission for the Heart Status 3 Justification Form. After the initial 30 days, this status can be extended by the transplant program every 84 days by submission of another Heart Status 3 Justification Form.

Members agreed that adding wedge greater than 15 and mean arterial pressure (MAP) less than 90 may be appropriate to include in the criteria describing left heart failure.

The Chair commented that previously, the Committee was told it would take too much time to make the use of the terms MCSD, LVAD, VAD, percutaneous, etc. consistent across policies. UNOS staff mentioned that this could be addressed.

The members discussed if the paracorporeal criteria should be formatted to have symptoms and treatments similar to the LVAD criteria. They agreed that since there needs to be evidence of the clot, this formatting is unnecessary. Members chose to leave the criteria as written.

Members agreed if the candidate stays hospitalized, 30 days is appropriate.

Members discussed if specific definitions should be included to describe pump parameters. The Chair commented that different devices would have varied pump powers. A member asked if a chemical biomarker such as lactate could be included in the criteria to indicate perfusion issues. The member commented that a candidate may have low pressure but excellent evidence of perfusion. Members commented that making the criteria too specific by incorporating values may lead to more exception requests, but if left too vague, may not indicate pump thrombosis. The members considered removing the proposed pump parameter criteria.

Members agreed that there need to be a temporal relationship between meeting criteria and status requests. Seven days may be too short for a program to assess that transplant is the best option rather than a pump replacement or other treatment. Members agreed that 14 days is appropriate. Members discussed cases in which a candidate has a stroke and may not be ready for transplant for more than a month. A member suggested that the hospitalization requirement could include that the candidate is admitted for pump thrombosis. The members ultimately decided that the hospitalization requirement is adequate and a timeframe is not needed.

Members questioned the proposed language that allows status extension at 84 days. A member commented that it is unlikely that a patient is experiencing pump thrombosis would still be alive in the hospital after 84 days unless the thrombosis was resolved.

The members discussed if there should be criteria required for status extensions. This could be similar to the requirements for Status 1 or 2 where evidence is needed to exhibit the candidate cannot be removed from inotropic support. Other extension criteria suggested were evidence of recurrent embolic events and contraindication to pump exchange. A member suggested requiring that the candidate meet the initial criteria for the status in order to extend.

The members discussed if the Review Board would need to review extension requests that indicate a contraindication to pump exchange in the same way the Review Board reviews Status 2 contraindications to VADs for Status 2 balloon pump candidates.

UNOS staff will circle back with the members to further clarify some of the clinical criteria to ensure the policy is widely understandable.

The Chair asked if they should review all policy to identify where there are gaps for extension criteria. UNOS staff will arrange a meeting to discuss.

Next steps:

The Chair will draft language for extensions requirements to review with the Subcommittee. UNOS staff will add more detail send the presentation to the members.

Upcoming Meeting

- December 18, 2020

Attendance

- **Subcommittee Members**
  - Arun Krishnamoorthy
  - Cindy Martin
  - Greg Ewald
  - Jonah Odim
  - Rachel White
  - Rocky Daly
  - Shelley Hall
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Vanessa Arriola
- **SRTR Staff**
  - Andrew Wey
  - Katie Audette
  - Yoon Son Ahn
- **UNOS Staff**
  - Eric Messick
  - Janis Rosenberg
  - Julia Chipko
  - Keighly Bradbrook
  - Leah Slife
  - Michelle Rabold
  - Sara Rose Wells
  - Sarah Konigsburg
  - Susan Tlusty