OPTN Heart Transplantation Committee
Status Extension Review Subcommittee
Meeting Summary
January 20, 2021
Conference Call

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

Introduction

The Status Extension Review Subcommittee met via Citrix GoToMeeting teleconference on 1/20/2021 to discuss the following agenda items:

1. Results of Data Requests Addressing Status Extensions Requests
2. Review revisions of Policy 6.1.C.iv: Mechanical circulatory support device (MCSD) with Pump Thrombosis
3. Discuss extension criteria for identified policies

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

1. Results of Data Requests Addressing Status Extensions Requests

UNOS Research staff reviewed the findings of the Subcommittee's data request.

Summary of discussion:

To guide their work, the Subcommittee requested data on the number of adult heart candidates who were ever-waiting at as well as the number of extension forms submitted for the following statuses and criteria between 10/18/2018 and 1/01/2021:

- Policy 6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Bi-ventricular Support Device *(valid 14 days)*
- Policy 6.1.B.ii: Ventricular Tachycardia (TF) or Ventricular Fibrillation (VF) *(valid 14 days)*
- Policy 6.1.C.iv: MCSD with Pump Thrombosis *(valid 14 days)*
- Policy 6.1.C.v: MCSD with Right Heart Failure *(valid 14 days)*
- Policy 6.1.C.vi: MCSD with Device Infection *(valid 14 days)*
    - MCSD with device infection – Erythema *(valid 14 days)*
    - MCSD with device infection – Debridement *(valid 14 days)*
    - MCSD with device infection – Bacteremia *(valid 42 days)*
    - MCSD with device infection - Recurrent bacteremia (valid 90 days)
    - MCSD with device infection - Positive culture (valid 90 days)

The members also requested information on the non-consecutive and consecutive time candidates spent at the statuses and criteria of interest listed above.

There were 777 candidates ever-waiting at one of the status/criteria of interest between October 18, 2018, when the new adult heart allocation changes went into effect, and December 31, 2020. Just over 50% of the 777 ever-waiting at one of the criteria of interest waited under at least one extension to the criteria of interest.

UNOS staff encouraged the members to review the ratio of extensions to candidates ever waiting, rather than the number of extensions alone. The most extension forms were submitted for Status 3 MCSD with pump thrombosis followed by MCSD with device infection and MCSD with right heart failure. MCSD with pump thrombosis has a ratio of 10.38, MCSD with device infection has a ratio of 4.76, and MCSD with right heart failure has a ratio of 4.49.

The candidates that submitted extensions do not appear to be jumping between statuses as the longest consecutive sequence of extensions and total number of extensions are similar for all criteria. This supports the Subcommittee's concern about candidates being parked at a specific status and crtieria. Overall, there appears to be evidence that candidates are submitting a large number of extension forms and spending a significant amount of time at certain criteria of interest under an extension, the most significant being MCSD with pump thrombosis. On average, 12 extensions are submitted under MCSD with pump thrombosis resulting in the candidate remaining at this status an average of 171 days. However, when considering this average, one candidate had 51 extensions under this criterion.

A member asked for data relating to the number of these candidates that received transplants. UNOS staff will add this information to the report and noted that candidates at Status 1 receive transplants sooner, which reduces the need for extension. The Chair wants outcomes (transplanted, death, removal from waiting list) added to report.

UNOS staff asked if there is a medical reason for needing many extensions under MCSD with pump thrombosis. The Vice Chair responded that the patient could be sensitized or have other factors that make them difficult to transplant.

A member asked why the pump thrombosis criterion is the outlier of the other Status 3 criteria. The Chair commented that the pump thrombosis policy is nebulous and less clear than the other Status 3 criteria. The Vice Chair commented that once a patient gets pump thrombosis, it never goes away and clinical teams are more cautious with these patients because they are at risk for stroke or bad hemolysis. A member commented that since there is no requirement for requalifying for criteria it is easy to maintain this status. These candidates can be put on intravenous Heparin and wait at this status since they have already met the pump thrombosis criteria.

A member asked if pump thrombosis needs to be redefined in order to not consider it as a lifelong condition. The Chair and Vice Chair commented that the definition should be made clearer and additional criteria needs to be added in order for candidates to qualify for extensions.

Next steps:

UNOS Research staff will add outcome data to the report.

2. Review revisions of Policy 6.1.C.iv: MCSD with Pump Thrombosis

The members reviewed the draft revision of MCSD with Pump Thrombosis policy and continued their discussion from the previous meeting.

Summary of discussion:

The members discussed including both Transient Ischemic Attack (TIA) and Reversible Ischemic Neurologic Deficit (RIND) as required criteria. The members agreed to include the following as a criterion for identifying pump thrombosis:

"Transient Ischemic Attack (TIA) lasting less than 24 hours or Reversible Ischemic Neurologic Deficit (RIND) lasting less than 72 hours (as observed by symptoms such as, but not limited to unilateral facial weakness, vision problems, and/or slurred speech), Cerebrovascular Accident (CVA), or peripheral thromboembolic event in the absence of intracardiac thrombus or significant carotid artery disease."

The Chair noted that if symptoms of RIND last more than 72 hours, it would be considered a stroke.

The members discussed if "significant carotid artery disease" needs further definition. The members agreed to add the example "ulcerated greater than 50% plaque." The Vice Chair commented that if the patient had severe carotid artery disease, they would likely not be candidates for transplant. The Chair suggested revisiting this after reviewing relevant literature. UNOS staff commented feedback on this item can also be solicited during public comment.

Where this policy mentions Aortic Insufficiency (AI), the members agreed to add a reference to policy 6.1.C.vii MCSD with AI.

The members discussed whether there needs to be a defined timeframe for symptoms required to qualify for the criteria in addition to the requirement for hospitalization and need for continued intravenous therapy. A member asked how many patients experiencing pump thrombosis are treated as outpatient. The Chair commented that this is rare. The Chair suggested adding language to require that the patient's hospitalization is due to pump thrombosis. A member commented that the other status criteria include temporal relationships and suggested adding a timeframe for consistency. The Chair suggested including this as a question during public comment. The members will address this again in a future discussion.

3. Discuss extension criteria for identified policies

The members discussed the extension requirements for MCSD with Pump Thrombosis.

Summary of discussion:

The members discussed the number of days extensions for this status should be valid. A member commented that the extensions for 6.1.C.vii MCSD with Mucosal Bleeding is 90 days. The Chair and members agreed with making the extension for pump thrombosis 90 days for consistency. UNOS staff commented that the initial justification for MCSD with Pump Thrombosis has been extended from the current 14 days to the proposed 30 and the extension from 14 to 90. The Chair commented that this increase in days could create a good balance with the proposed narrowing of qualifying criteria.

The members discussed the criteria that needs to be met in order to extend at this criteria. The members suggested including language that would require the candidate to continue to meet the criteria listed in order to be eligible for an extension. A member raised a concern that this requirement could be confusing if the program believes they need to recertify that the patient still has the initial clinical values such as increased pulmonary capillary wedge pressure or mean arterial pressure, and commented that the Subcommittee is primarily asking if the patient is still hospitalized and needs continued intravenous therapy. The members agreed with this idea, commenting that otherwise the programs may believe they need to do another right heart catheter or that the patient needs to experience another TIA in order to extend. The members agreed extensions should require that the patient is hospitalized and requiring intravenous therapy.

The members suggested adding a need for intravenous anticoagulation to the paracorporeal criteria. A member commented that there may be instances that a program chooses to not anticoagulate a paracorporeal patient, but these rare cases could be handled by exception. The following was added to the suspected pump thrombosis in a dischargeable paracorporeal device section of the criteria: "Need for treatment intravenous anticoagulation (e.g. heparin), intravenous thrombolytics (e.g. tPA), or intravenous antiplatelet therapy (e.g. eptifibatide or tirofiban) in the hospital"

The members discussed which of the paracorporeal criteria need to be required to qualify when the thrombus is visually detected. The members determined that if the thrombus is visually detected, the other two criteria are not required. If not visually detected, the two other criteria must be met.

UNOS staff asked if regional review should be required. The Chair commented that these revisions are prescriptive enough and would not need Regional Review Board involvement.

Next steps:

UNOS staff will send the revised document and discussion questions for the Subcommittee members to review.

Upcoming Meeting

- February 10, 2021

Attendance

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