

**OPTN Heart Transplantation Committee
Status Extension Review Subcommittee
Meeting Summary
December 18, 2020
Conference Call**

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

Introduction

The Status Extension Review Subcommittee met via Citrix GoToMeeting teleconference on 12/18/2020 to discuss the following agenda items:

1. Overview of data collection principles
2. Review project form

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

1. Overview of data collection principles

UNOS staff provided an overview of the OPTN Data Collection Principles and the role of the Data Advisory Committee (DAC).

Summary of discussion:

The OPTN Data Collection Principles were approved by the Board of Directors in 2006. The DAC is charged with ensuring data collection projects are in alignment with the principles. During the life data collection projects, there are several check ins with the DAC. The first check in for the *Review of Extension Requirements in Adult Heart Allocation Policy* project was on December 14th. The DAC members raised considerations around ensuring the value of the data is balanced with the additional administrative burden that may be associated with modifying the extension requests

The *Review of Extension Requirements in Adult Heart Allocation Policy* project aligns with the OPTN Data Collection Principle of develop transplant, donation, and allocation policies. Before the next check in with the DAC in February, the Subcommittee members will assess any proposed data elements against the DAC Standard of Review Checklist.

2. Review project form

The members reviewed and provided edits to the project form.

Summary of discussion:

The Chair requested that the sentence in the problem statement describing a candidate who experienced a stroke should be revised so this situation is called out as an example.

The members discussed the table that displays counts of waitlist additions and transplants of individuals at status by extension for policies being considered for modification by the Subcommittee. The Chair emphasized the importance of including that those who transition into more urgent statuses are not captured in the counts provided in the table. Transplant candidates may be initially listed at Status 4 but then are upgraded to Status 3 due to ventricular assist device (VAD) complications. A member

recommended including information on this patient population to help the reader better interpret the numbers provided in the table. Another member recommended including proportions in the table to show the percentage of those on the waiting list at each status and criteria included in the table. UNOS staff will add the percentages to see if it adds value and is easy to understand.

The members agreed to add the status numbers (i.e. 1,2,3) to the table to help the reader understand how the counts are grouped in following paragraph.

A member suggested including information about how many candidates are transplanted at a status extension for the policies the Subcommittee is addressing compared to the number of candidates transplanted at status by extension under other policies in order to highlight any outliers.

A member suggested including information on the number of days permitted by extensions for each policy. UNOS staff will consider adding this information to the table.

The Chair commented that policy modifications do not need to be guided by volume of candidates, but rather striving to ensure the appropriate candidates have access to the appropriate status.

When asked what data or information would most help support this project, the Chair requested data about candidates that transition from Status 4 to Status 3. If unavailable, this limitation needs to be addressed in the proposal.

A member suggested including a bulleted list that synthesizes the problem statement at the beginning of the project form in order to provide a brief summary. The Chair suggested these two points to summarize the problem statement:

- Inconsistency in extension requirements between statuses
- Variability in duration of extensions

UNOS staff asked about the specific data that would be useful to describe the volume of patients associated with the selected criteria being considered for modification, the number of extensions at that status and criteria, and number of days under extension. The members discussed the value of examining consecutive time as compared to nonconsecutive time at a status and status extension. A member suggested looking at the average number of extensions to determine if candidates are staying at certain criteria significantly longer than other criteria.

The members discussed the value of looking at both candidate's time consecutively and nonconsecutively at a status. The Chair noted that changes in statuses can range from issues managing a patient to deactivating a patient for a couple of days if they will be unavailable for transplant due to travel or other reason. The members agreed that both nonconsecutive time and consecutive time at a status would be helpful to review to assist in assessing if the changing status is due to fluctuation of the candidate's condition or if the candidate is being parked at a status.

The Chair commented that this project is intended to make the criteria fairer and not to make it more difficult for candidates to be listed at Status 3. A member agreed that the focus should be on improving consistency across the criteria and extension requirements and also increasing the consistency of the level of granularity provided in the criteria.

The members discussed the potential unintended consequences of these policy modifications. These modifications may result in increased exception requests if the candidate is no longer able to meet an extension based on the established criteria.

UNOS Research staff shared the process for submitting a data request. The first step requires the Subcommittee to come to a consensus about the data they would like to review. UNOS staff then drafts

the request, then the request is reviewed by Heart Committee leadership to ensure accuracy and finalize any details, and then is submitted for approval by HRSA. Calculating the timeframes will be more time intensive.

The members reviewed the *Proposed Solution* section of the project form. The Chair suggested an edit to describe the criteria as “appropriate” rather than “additional.”

The members agreed that information relating to *Policy 6.3: Status Updates* should be included in this section. A member commented that individuals may interpret this policy differently. Including this information will help remind programs that the policy requires "if a heart transplant candidate's medical condition changes and the criteria used to justify the candidate's status is no longer accurate, then the transplant program must update the candidate's status and report the new information to the OPTN within 24 hours of the change in medical condition." The members agreed that it is necessary for programs to confirm their patients are still meeting the status criteria they are listed at. Patients that become stabilized may no longer be eligible for the higher statuses which should be reserved for those with the most medical urgency.

A member suggested including bullet points to summarize the *Proposed Solution* section.

The members agreed to the list of stakeholders to involve in the project and suggested adding American Society for Apheresis (ASFA) and the Society for Cardiovascular Angiography and Intervention (SCAI). A member suggested reaching out to ASAIO (formerly known as the American Society for Artificial Internal Organs). The members noted that many members of the smaller organizations are likely also members of the larger organizations such as American Society of Transplant (AST) or the International Society for Heart and Lung Transplant (ISHLT).

Next steps:

UNOS staff will update the project form based on the feedback received and send an updated version to Heart Committee leadership prior to sending to the Policy Oversight Committee on December 23.

Upcoming Meetings

- January 20, 2021

Attendance

- **Subcommittee Members**
 - Cindy Martin
 - Greg Ewald
 - Jonah Odum
 - Rocky Daly
 - Shelley Hall
- **HRSA Representatives**
 - Adriana Martinez
 - Jim Bowman
- **SRTR Staff**
 - Katie Audette
 - Yoon Son Ahn
- **UNOS Staff**
 - Eric Messick
 - Janis Rosenberg
 - Keighly Bradbrook
 - Leah Slife
 - Michelle Rabold
 - Sara Rose Wells
 - Sarah Konigsburg