

**OPTN Thoracic Heart Subcommittee
Meeting Minutes
June 27, 2019
Conference Call**

Shelley Hall, MD, Subcommittee Chair

Introduction

The Thoracic Heart Subcommittee met via Citrix GoTo teleconference on 06/27/2019 to discuss the following agenda items:

1. Modifications to Pediatric Heart Allocation Policy
2. Adult Heart Exception Review
3. Substantive Clarifications to Adult Heart Allocation Policy

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

1. Modifications to Pediatric Heart Allocation Policy

UNOS staff gave a brief overview of the pediatric heart status project, including approval by the Executive Committee (ExComm) on 06/25/2019, and project next steps.

Summary of discussion:

There were no questions or discussion from Subcommittee members.

Next steps:

UNOS staff will begin working with Committee leadership to schedule Workgroup meetings for this project.

2. Adult Heart Exception Review

UNOS staff gave a brief overview of the adult heart exception review project, including potential barriers and next steps.

Summary of discussion:

UNOS staff have begun to store the redacted exception cases since implementation, but previous exception requests have not gone through this process. Due to time constraints and to more efficiently use the members' time, Committee leadership would need to identify certain heart statuses to analyze requests for, and then analyze it. One Subcommittee member stated it would be helpful to know which status has the most exception requests. UNOS staff clarified that this data was released in the first heart monitoring report, but only by status and not by criteria.

Another Subcommittee member mentioned that this redaction process is similar to a previous process done 6 years ago when developing the new adult heart policy. UNOS staff clarified that previously the narratives had been de-identified, but not all narratives underwent this process (approximately 100-200 cases were completed in an Excel document). However, Subcommittee members were frustrated that this process seemed to make something more difficult than it really needed to be. UNOS staff reiterated that this approach would standardize processes and that the sample size would be representative of the larger population. One Subcommittee member opined that status 2 exceptions should be analyzed first because there is a perception that status 3 and status 4 candidates are not getting transplanted at high enough rates. Other Subcommittee members supported analyzing status 2 or status 3 first as well.

Another Subcommittee member opined that if the information will be de-identified, then other members besides leadership be included in the review process. UNOS staff stated that it might be more efficient for leadership to categorize the exception cases and then show the results to the full Subcommittee.

Next steps:

UNOS staff will begin to prioritize the heart projects and determine the timelines for each. Once this is done, then UNOS staff will begin to work on the projects.

3. Substantive Clarifications to Adult Heart Allocation Policy

UNOS staff gave a brief overview of the project, including previously identified policy language issues and how best to address them.

Summary of discussion:

UNOS staff discussed heart policy language issues that might be included under this project, or that might be approved by ExComm (such as status 4 inotrope policy language that could qualify as a patient safety issue). UNOS staff asked Subcommittee members whether the Fall 2016 Public Comment language for status 4 inotropes was still relevant and accurate (see below)

Cardiac index of <2.2 L/min/m² for candidates without inotropic or mechanical support within 7 days prior to inotrope administration.

One Subcommittee member asked if a candidate would qualify if the cardiac index was done 3 months prior to inotrope administration? Subcommittee members replied no, they would not qualify. However in follow-up, this member asked whether a candidate would have to be taken off of an inotrope to meet this criteria if they have already been on the inotrope for a period of time. One Subcommittee member commented that such cases are usually put as exception requests, but would need to double check. Furthermore, in order to account for this particular scenario, new policy language would have to be developed and approved through public comment. Another question was about how candidates are currently extending under status 4 if they are on inotropes (e.g. 90 days). A suggestion was to use the extension language for this status and apply it to candidates who are inotrope-dependent and have been on inotropes for a while. However, the Subcommittee Chair stated that this would still require new policies to be developed and can be addressed at a future time. However, one Subcommittee member stated that the above policy language does not “clean-up” or address the problem. It was clarified that the issue being discussed right now is regarding the short timeframe (7 days) in which a candidate must be evaluated, treated and listed for status 4. Specifically, this policy language would switch “7 days prior to submission of status justification form” to “7 days prior inotrope administration”. The current policy is being interpreted as requiring candidates be re-catherized to obtain new hemodynamic values, such as cardiac index. UNOS staff clarified that the only reason this policy language would not go out for public comment was because the language already went through public comment.

The next problem identified were inconsistent definitions of extension criteria (some are very specific or some are generalized). One Subcommittee member stated that the solution may be policy revisions and not necessarily policy clarifications, because as it is right now, members are extending differently (some allowing patients to decompensate). Subcommittee members stated that each status and criteria must be looked at individually and to get as much done under clarifications. UNOS staff clarified that any other policy changes (except for the status 4 inotropes) would need to go through public comment. One Subcommittee member stated the extension language is being interpreted in many ways, and which are not aligned with the original intent. In effect, Subcommittee members stated that this project would

only be modifying language to what the original intent was to begin with. For example, it was not the intent of the Subcommittee at the time to merely allow a form submission without any new clinical data being provided for extending. Subcommittee members were frustrated and asked for more clarity surrounding how policy is being interpreted, what the original intent was, and how best to address the language issues. There was also frustration that no work has been done in identifying policy language problems since October 2018. UNOS staff suggested that they put together how staff are interpreting the language, the intent of the language and a summary of the criteria. Subcommittee members agreed to this approach.

In terms of the member questions received, one Subcommittee member questioned whether UNOS staff and Thoracic Committee leadership knew the specific questions that the community has been asking since post-policy implementation. Subcommittee leadership replied that they know the questions, and UNOS staff has kept documentation of the questions received.

In terms of the project form fields, Subcommittee members stated that the target population is the entire population of candidates on the heart Waitlist. The impact is time to transplantation and patient safety because there are centers destabilizing candidates in order to prove that they are still sick enough to extend. Another problem is how policy is being interpreted differently than the Committee had originally intended. Subcommittee members stated that this project deals with equity (due to differences in policy interpretation) and patient safety. For stakeholders, Subcommittee members did not voice any opinions on who needs to weigh in. Subcommittee members did not see a need to include other OPTN Committees in the process.

Next steps:

UNOS staff will clarify whether the status 4 inotrope language can be approved by ExComm. Committee leadership may work with UNOS staff to develop a document detailing the original intent of the policy and how it is currently being interpreted.

Upcoming Meetings

- July 25th
- August 24th
- September 26
- October 17th (in-person)