

OPTN/UNOS Thoracic Organ Transplantation Committee
Meeting Minutes
August 30, 2018
Conference Call

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Introduction

The Thoracic Committee met via teleconference on 08/30/2018 to discuss the following agenda items:

1. OPTN Operations and Safety Committee – Update on Broader Distribution Guidance Document
2. Ad Hoc Committee on Geography Update
3. Modifications to the Adult Heart Allocation System -- Status 4 Inotropes without Hemodynamic Monitoring Transition
4. Eliminate the Use of Donation Service Areas (DSAs) in Thoracic Distribution

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

1. OPTN Operations and Safety Committee – Update on Broader Distribution Guidance Document

This effort was initiated to support committee members, OPOs, transplant programs, and other organ-specific committees by creating a guidance document to support operations surrounding broader organ distribution.

The Operations and Safety Committee formed two separate subgroups to work on this project with the goal of have a document ready for public comment by Spring of 2019. The first group is putting together a questionnaire for 58 OPOs and transplant programs that arrange air transportation to gather organ-specific information regarding flight/aircraft availability or limitations, stumbling blocks, and cost of travel. One Committee member noted that since lung allocation has changed there has been a lot more flying versus driving. This information will be collected through interviews conducted by each Committee member.

The Operations and Safety Committee is also exploring the following topics to include in the guidance document:

- Building relationships to optimize operations
- Organ allocation procedures
- Staffing
- Streamlining communications
- Metrics to evaluate issues/monitor the system
- Setting OR times
- Specimen sharing and crossmatching

One Committee member asked how many transplant hospitals were being surveyed. The Operations and Safety Committee representative noted that the questionnaire will focus on all 58 OPOs as well as any transplant centers that arrange their own transportation. He also clarified that the information gathered from the questionnaire will be used to develop the guidance document and is not designed to become new policy.

2. Ad Hoc Committee on Geography Update

The Committee was provided with a summary of the Ad Hoc Geography Committee conference call held on 08/20/2018. Each organ-specific committee provided an update on the distances being considered for the modeling requests that will be submitted to the SRTR. During this meeting, the Ad Hoc Geography Committee focused on the rationale for the distances and to make sure there is consistent approaches to developing proposals to eliminate DSA and Regions. There were limited questions about the progress of the heart allocation modeling request.

The main focus of the call was a discussion about the geographically isolated areas such as Alaska, Hawaii and Puerto Rico. Committee members were reminded that Hawaii and Puerto Rico have liver and kidney programs while Alaska does not. Therefore, Alaska would have no local organ distribution. The options considered were to do nothing, have a circle that is large enough to cover them, or have a circle large enough to cover them but only use it for organs offered to and from these locations. The Ad Hoc Geography Committee took a vote and decided to leave the process as it currently exists.

One Committee member asked what will ultimately happen with the three allocation frameworks being proposed by the Ad Hoc Geography Committee. One Committee member stated that it is his understanding that there would ultimately be one organ allocation framework across all organ systems. Another Committee noted that the fixed distance framework is one that could be implemented quickly while another framework such as continuous distribution would be better as a long-term goal.

3. Modifications to the Adult Heart Allocation System -- Status 4 Inotropes without Hemodynamic Monitoring Transition

UNOS staff noted that the new allocation system will be implemented on Oct. 18, 2018. Policy states that a program can assign candidates to the status if the candidate is supported by continuous infusion of a positive inotropic agent and meet all of the following criteria:

- Cardiac index less than 2.2 within 7 days prior to submission of the form
- Pulmonary capillary wedge pressure greater than 15
- At least one of the following intravenous inotropes:
 - Dobutamine greater than or equal to 3 mcg/kg/min
 - Milrinone greater than or equal to 0.25 mcg/kg/min
 - Epinephrine greater than or equal to 0.01 mcg/kg/min
 - Dopamine greater than or equal to 3 mcg/kg/min

One Committee member noted that the problem with the current criterion is that if patients are stable on inotropes at home, programs would have to wean inotropes and do a repeat right heart catheterization. Several Committee members believed that this will only be a transition problem and not an ongoing problem and the focus should be on creating a safe transition. One Committee member noted that programs could possibly register candidates for any other status for which they may qualify for; bring in the candidate for hemodynamic testing if clinically appropriate; or request a status 4 exception which is the only exception where candidates do not have to be hospitalized.

After discussion with leadership and UNOS staff, there was agreement that the most feasible option would be to request an exception to get the candidates into status 4. A memo will be drafted to give Review Boards a heads up about a potential increase in exception requests. Committee leadership will work with UNOS staff to identify data elements to encourage programs to standardize the requests. UNOS will send out a general communication about transition options in the September communication.

Another Committee member was concerned that 1B requests might not be approved by the Review Boards. Committee leadership noted that there will be a standard set of criteria that, if met, will allow the exceptions to be approved. One Committee member suggested simplifying the process further by implementing a checkbox that indicates the patient meets all the criteria. Another Committee member noted that patients will have an active status for pending approval of their exception, so it is highly unlikely that anyone who has initiated inotropes will not have hemodynamic information available.

The Committee briefly discussed the possibility of developing a guidance document. UNOS staff noted that a formal guidance document would be subject to the same policy development process and would not be able to meet the timeline for the implementation of the new system. Committee leadership noted that the exception request guidance would actually be more like a memo with a few bullet points.

One Committee member asked when a patient who is listed for heart/kidney changes status (because of complication and requirement for ECMO for instance) and the heart becomes available, if the kidney would automatically go to that recipient. UNOS staff noted there is another policy that addresses the allocation of the second required organ from the same donor.

4. Eliminate the Use of Donation Service Areas (DSAs) in Thoracic Distribution

Leadership and UNOS staff will work with SRTR staff to finalize the modeling request that will be submitted on August 31, 2018. The request will include the following distances as well as the outcomes/metrics agreed upon during the August 23, 2018 conference call:

- 150 nautical miles
- 250 nautical miles
- 500 nautical miles, options A and C.

Upcoming Meetings

- September 13, 2018
- September 27, 2018
- October 11, 2018
- October 18, 2018
- October 25, 2018
- November 1, 2018, in-person meeting
- November 15, 2018
- November 29, 2018
- December 15, 2018