

**OPTN/UNOS Operations and Safety Committee
Meeting Minutes
January 25, 2018
Conference Call**

**David Marshman, CPTC, BS, Chair
Michael Marvin, MD, FACS, Vice Chair**

Introduction

The Operations and Safety Committee (Committee) met via Citrix GoToTraining teleconference on 1/25/2018 to discuss the following agenda items: Project Name

1. Public Comment Proposal: Change Waiting Time Criteria for Kidney-Pancreas Candidates (Pancreas Transplantation Committee)
2. Public Comment Proposal: Broader Distribution of Adult Donor Lungs (Thoracic Transplantation Committee)
3. Other Significant Items

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

1. Public Comment Proposal: Change Waiting Time Criteria for Kidney-Pancreas Candidates (Pancreas Transplantation Committee)

The Committee heard the public comment proposal to "Change Waiting Time Criteria for Kidney-Pancreas Candidates" presented by the Pancreas Committee Vice-Chair. The Operations and Safety Committee members discussed the evaluation questions below, following the presentation.

- i. Have regional variations been examined? One Committee member does have concerns that they might see a large increase of higher BMI pancreas-kidney candidates in their region which could in turn have other consequences for other kidney candidates.
Although regional variations have not been examined, the Pancreas Committee chair thought that this was a good questions and plans to pursue getting this data that could be sent back to Operations and Safety for review. It was shared that the overall numbers of both Type 2 (Diabetic) Simultaneous Pancreas-Kidney (SPK) candidates and transplants have been stable and relatively small for the past ten years.
- ii. Would there be any anticipated increase in cold ischemic time (CIT)?
The Pancreas Committee does not anticipate change in transplant program behavior due to the proposed changes and therefore does not believe CIT will change.
- iii. Could infection rates be examined due to possibility that operating on higher BMI candidates, and potentially greater surgical risks, might result in greater infection rates?
The data to answer this question will not exists in a central place as it was acknowledged that UNOS/OPTN does not currently collect this type of outcome data outside of overall graft and patient survival rates.
- iv. Will the Pancreas Committee evaluate potential impacts on kidney-alone candidates?
The Pancreas Committee will first examine impacts on kidney-pancreas candidates. If that data shows a significant change then the Committee would look at kidney-alone candidates, however, the Pancreas Committee believes that overall impact will be minimal.

The Committee expressed appreciation for the answers and plans to support this proposal.

2. Proposal 2: Thoracic Committee: Broader Distribution of Adult Donor Lungs

The Committee heard the public comment proposal on “Broader Distribution of Adult Donor Lungs” presented by the Thoracic Organ Transplantation Committee Chair. The Operations and Safety Committee members had several comments and questions as outlined below. The responses from the Thoracic chair are also included.

- i. The Committee suggests analyzing the impact of changes in distance when the donor hospital is not the same as the recovery hospital. This situation will impact allocation and could have an impact on the overall objectives.

The Thoracic Committee is aware of the need for this data analysis and will be working to answer this question during public comment.

- ii. Due to the complexities of running simultaneous match runs and knowing when to follow which match and then when to switch to another match, the Operations and Safety Committee strongly suggests that prompts and alerts similar to what exists for liver-intestine/multi-visceral matches be added in UNetSM for heart-lung allocation. Multi-organ allocation can be very confusing and knowing when to switch match runs might be challenging. Having a “smart” system will assist procurement staff to operationalize the proposed policy in a reliable, consistent and equitable fashion.

Although IT programming is not currently part of this proposal, the Thoracic Committee agrees that this is a good idea and will explore the feasibility of adding some electronic instructional assistance similar to existing prompts.

- iii. When taking away the highly sensitized option there might be unintended consequences.

The sensitization policy for heart candidates and lung candidates is currently the same. It is used more frequently for hearts than for lungs (there are no known instances of the lung policy being used). So, the Committee felt removing the sensitization policy for lung candidates only was not too risky.

- iv. There are concerns that heart candidates with congenital heart disease (CHD) will be disadvantaged by the proposed heart-lung policy, because if the OPO allocates the heart-lungs off the lung side, the lung can pull the heart unless there is a status 1 or 2 adult heart candidate or pediatric status 1A candidate in the first few classifications that needs the heart. CHD candidates in the new allocation system for hearts may not qualify for status 1 and 2, so lung candidates may pull hearts away from those heart candidates.

The Thoracic Committee will further explore this concern. There is specific guidance out for CHD candidates, as well as restrictive and hypertrophic cardiomyopathy candidates that can assist partially with this concern by guiding review boards on when to grant exceptions into the higher statuses for those candidates even if they don't qualify under policy. Additionally, there are relatively few heart-lung transplants each year (28-35) so this “disadvantage” would rarely occur. However, the Thoracic Committee will take this comment into consideration to make sure the proposed heart-lung policy is not creating an unintended impact on CHD patients.

- v. Having two different distances for first-level zones (heart = 500 nautical miles; lung = 250 nautical miles) might cause further confusion.

The Thoracic Committee recognizes the potential for confusion and explained that this is the reason heart-lung policy needs amending. They explained that they are proposing changes based on classification versus zones to address the issue.

Next steps:

The Committee will submit formal public comments on the OPTN website after individual members weigh in on specific feedback questions and approve a formal response.

3. Other Significant Items

The Committee did not have time for the OPO Committee's presentation on their public comment proposal "Guidance on Requested Deceased Donor Information". The Committee will defer their discussion to a later date.

Upcoming Meeting

- February 22, 2018 Teleconference