Introduction

The OPTN Ethics Committee met via teleconference on August 15, 2019 to discuss the following agenda items:

1. Thoracic Public Comment Proposal: Continuous Lung Concept Paper
2. Pancreas Public Comment Proposal: Remove DSA and Region from Allocation

The following is a summary of the OPTN Ethics Committee’s discussions.

1. **Thoracic Public Comment Proposal: Continuous Lung Concept Paper**

The Thoracic Committee Vice Chair provided members with an overview of the Thoracic Committee’s Continuous Lung Concept Paper.

**Summary of discussion:**

Members were asked to provide feedback on whether they feel the concept proposal is the correct strategy and approach for this project.

A member asked for clarification regarding the various weighted factors and whether these factors had diminishing or increasing utility in part of the calculation. The member added that it is ethically difficult to weigh various factors against each other such as waiting time and asked how this would be measured.

The Thoracic Committee Vice Chair stated that there were a few frameworks the Thoracic Committee had been reviewing, but no decisions have been made as the Thoracic Committee wanted to make sure they were taking the right approach before moving further with the project.

Another member asked for clarification on what is meant by the term “system efficiency”.

The Thoracic Committee Vice Chair provided an example that with broader distribution, the Committee heard anecdotally that a number of programs began to see an increase in flying for organs. In one circumstance, a program reported that their costs for travel tripled. The intent is to be more efficient and considerate of the good for the system as a whole, not just the individual programs.

UNOS staff added that with system efficiency, it is not a description of just costs. There are also other factors that need to be considered. Part of the concept paper is getting feedback from the community on what other efficiency considerations should be taken into account for this project.

A member stated that the concept paper was very interesting and asked if the Thoracic Committee considered how this would affect candidates who are listed at multiple centers. The Thoracic Committee
Vice Chair stated that this was a valid point and that the Thoracic Committee had not discussed this topic directly.

Another member asked if prior history of being a living donor is considered with this concept. The Thoracic Committee Vice Chair stated that living donation was not something done in the lung transplant community but that for other organs, there may be other issues that need to be accounted for in the system. This would be a good point for liver and kidney allocations as they move forward with this process. The member clarified that if ever a living donor needed a different organ, would they have priority? The Thoracic Committee Vice Chair stated that this could be taken into consideration but had not been brought up until now.

The Committee Chair asked that in regards to page 14 of the concept paper, there was mention about waiting time being given little weight and asked for clarification on why this would be the case. The Thoracic Committee Vice Chair stated that from the lung standpoint, wait time is something that may be incorporated to some degree, but would probably not have a large emphasis because there is quite a difference in lung patients in terms of their progression of disease.

The Committee Chair continued by stating that by giving all of the variables (medical urgency, placement efficiency, patient access) equal weight, this would ultimately reinforce the same type of geographic disparities that were originally intended to be addressed by removing the DSAs. The Committee Chair asked if this has come up before and what discussion has taken place to address this issue.

The Thoracic Committee Vice Chair stated that in the Committee’s discussions, there has been an assessment of which variables would have more emphasis than others. It is not anticipated that all of the variables would have equal weight. The Committee Chair added that the Thoracic Committee should be mindful that the purpose is to give greater weight to patient access.

The Vice Chair asked if the concept paper has any bearing on some of the issues in pediatrics. The Thoracic Vice Chair stated that this is one of the factors that would be considered and there have already been discussions on how to incorporate pediatrics into the new system. No conclusions have yet been made. The Vice Chair asked to clarify if public comment on this proposal would be separate from any future proposals for pediatrics. The Thoracic Committee Vice Chair confirmed that this was the case and added that the purpose of this concept paper is to make sure the community feels that the way the Thoracic Committee is thinking about the issue is the right way and receive suggestions particularly regarding the different components and determining how they will fit into the new system.

UNOS staff called for a vote from the Committee members to demonstrate their sentiment of the Thoracic Committee’s Continuous Distribution of Lungs Concept Paper.

**Vote: 36% Strongly Support, 43% Support, 21% Neutral/Abstain, 0% Oppose, 0% Strongly Oppose**

The Committee Chair voiced concern on the percentage of neutral/abstain votes and asked for discussion among the members to better understand if there were any concerns that lead to this vote.

A member stated that due to the proposal being a concept and lacking specific details and decision on the weights given to criteria in a new system, it is difficult to have an opinion on the ethical dilemmas associated with a hypothetical system.

Another member agreed with this and added that they wavered between support and neutral/abstain and ended on voting neutral/abstain in terms of uncertainty of where the Thoracic Committee will land.
in specificity in weighing the different aspects altogether. Perhaps in a future draft or more formalized proposal may show which way the Committee will lean on this.

The Committee Chair stated that usually, a policy proposal provides a more robust justification and rationalization of the Committee’s perspective. The Committee Chair asked UNOS staff on the distinction between the concept paper and a policy proposal.

UNOS Staff clarified that the intent of the concept paper is to show the community the idea of what continuous distribution might look like as a policy in concept form. There still needs to be a determination of what weight needs to be given to certain factors that make up a patient’s score. These factors vary by organ and how they are currently allocated, which will eventually go into the composite allocation score. The feedback provided by the Committee will be helpful in getting the Thoracic Committee the information needed specifically for lungs and what will go into that score.

Next steps:
The comments received by the Committee will be synthesized into a formal statement that will be submitted for public comment.

2. Pancreas Public Comment Proposal: Remove DSA and Region from Allocation

UNOS staff provided the Committee with an overview of the Pancreas Committee’s public comment policy proposal.

Summary of discussion:
The Committee Chair asked if there was some type of reciprocity system related to facilitated placement. UNOS staff stated that in facilitated placement, it is not reciprocal. The way the policy was originally devised, was an opt-in system for any pancreas program that wanted to receive expedited offers that the OPOs could contact the transplant programs to send those offers three hours out from the operating room. It was revealed that a lot of the transplant programs did not actually accept these offers. The Pancreas Committee decided to change the opt-in criteria to transplant programs that accepted five imported transplants from outside their DSAs in the past two years in an attempt to limit this to programs that are actually doing these expedited transplants. The number of imported pancreata is used as an indicator that the program is likely to accept an offer in the future.

The Committee Chair asked why any limitations are necessary and if these limitations could potentially obstruct organ flow, which seems to be an issue for transplant programs rather than a matter of increasing patient’s access to the organ.

UNOS staff replied that the purpose of this process is to avoid organ discard. The Pancreas Committee is proposing to make the programs more flexible, where a program only has to import two pancreata in the past two years, which is less stringent than the original policy.

A member asked how this new allocation system would affect the pediatric population and if there was any modeling that could be done to look at data to see how this solution may impact waste, whether there would truly be a benefit, or if it was theoretical.

UNOS staff stated that the Pancreas Committee is looking into doing a project on creating pediatric priority in pancreas allocation because it does not currently exist. The Pancreas Committee will be getting an update on this potential project during their next Pancreas Committee call and upcoming in-person meeting. At that point, they will have a more in-depth discussion leading to a data request for further analysis. The Pancreas Committee did initially look at data that indicated that there are some
pancreas alone pediatric candidates that could be disadvantaged by the current system and will be addressing this in a separate project.

In regards to modeling organ waste or discard, the SRTR modeling is not capable of doing this. The Pancreas Committee discussed this issue because pancreas is different from other organs. The Pancreas Committee felt that with the steep proximity points, it may avoid certain discards by keeping more organs closer to the donor hospital while having a bigger circle would allow those programs that are more aggressive to still accept those offers from farther away than they would be able to do otherwise which could impact utilization.

UNOS staff called for a vote on the Pancreas Committee’s proposal.

**Vote: 0% Strongly Support, 58% Support, 42% Neutral/Abstain, 0% Oppose, 0% Strongly Oppose**

There were no additional comments or questions. The meeting was adjourned.

**Next steps:**

The comments received by the Committee will be synthesized into a formal statement that will be submitted for public comment.

**Upcoming Meetings**
- September 19, 2019 (Teleconference)
- October 15, 2019 (In-person)