OPTN/UNOS Thoracic Organ Transplantation Committee Meeting Minutes July 26, 2018 Conference Call

Ryan Davies, MD, Chair Erika Lease, MD, Vice Chair

Introduction

The Thoracic Organ Transplantation Committee met via Citrix GoToTraining teleconference on 07/26/2018 to discuss the following agenda items:

- 1. Geography Resources
- 2. Donor Hospital Location Project Update
- 3. Eliminate the Use of DSAs in Thoracic Distribution

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

1. Geography Resources

UNOS staff informed the Committee about the geography resources now available on Transplant Pro¹.

2. Donor Hospital Location Project Update

UNOS IT staff provided an update on this project. Historically, we have had only city, state and zip code information for each donor hospital. Therefore, the physical location of a hospital was only as precise as the data we collected, which means the center point of the zip code is used as the approximation of the hospital location. This project undertook the daunting task of mapping all active donor hospital in the system (over 6000) to a physical street address location. UNOS worked with the OPOs to collect these data and do the mapping.

- Collect Street Addresses for every hospital
- Recalculate Latitude and Longitude
- Match Precision Improvements this might have a minor impact on the zones
- Zones in Heart and Lung
- Distance Screening for all organs but kidney

The Committee members did not have any questions.

3. Eliminate the Use of DSAs in Thoracic Distribution

UNOS staff noted that the goal of the discussion is to assess various policy options for removing DSA from allocation and provide clinical and scientific advice to the OPTN/UNOS Board of Directors as to which is the best option that can feasibly be ready for public comment in January 2019.

Assumptions

• Complete analysis of extensive changes to policy is not possible within the allotted time frame.

¹ https://transplantpro.org/policy/organ-distribution/

- There is insufficient time to adequately model and assess the impact of large-scale changes to the allocation system (which is not even implemented yet)
- The use of concentric circles to replace DSA is the only feasible alternative within that time frame.

<u>Tasks</u>

- Identify distances that we would like SRTR to model as replacements for DSA this is the task for today.
- Determine rational tests we are going to use to assess the results of these modeling outcomes, including waitlists. How much are people flying, cost increases
- Submit distances and tests to SRTR for modeling
- Consider how to make zones consistent between heart and lung, and revise policy for sensitized candidates
- Review modeling results
- Submit final policy draft for public comment

The Committee chair provided a quick overview of the current allocation algorithm and provided an example of how the replacement of DSA might look, for example replacing DSA with 250 nautical miles. Questions for the Committee include:

- Should there be a distance that acknowledges increased risk from flying?
- Other considerations

He noted that the Committee needs to be consistent with the geographic organ distribution principles and provide a rationale for recommending a particular distance.

One Committee member commented that a distance less than 250 nautical miles will be more palatable and something that will "bridge the gap" until the Committee can perform a more rigorous evaluation. Another Committee member noted that smaller concentric circles does not meet the spirit of what we are trying to accomplish by eliminating DSAs. She commented that anything less than 100 nautical miles would not be acceptable.

One Committee member noted that the goal is just to determine what needs to be modeled to better inform the Committee's decisions. There was a question raised about how many models the SRTR can perform at one time. SRTR staff noted that it's not necessarily the number of models but the complexity of the requests. He noted that, in general, the recommendation is to limit the requests to 3-4 data sets.

The Committee discussed additional distances besides 250 nautical miles. One Committee member recommended 150 miles to be consistent with the liver requests, even though thoracic organs are quite different. The Committee chair noted that it might be beneficial to model a shorter distance for the "driving to flying" transition which could serve as a justification for that distance. He recommended 100 miles as more realistic, maybe even 50 miles. He also noted as an example, in Texas there could be a 50 mile drive just to get to the airport.

One Committee recommended modeling 150 miles for the driving/flying metric, 250 miles to align with lung, and also 500 miles. UNOS staff noted that not many hearts are accepted out to 500 miles.

One Committee member suggested that part of the Committee's statement should be that not enough time was provided to evaluate costs and in the end it could go against the Final Rule by decreasing access to organs. Another Committee member commented that as all the organ systems are evaluating farther distances, there is the potential for multi-organ centers to "break" and potentially decrease access to organs. Additionally, surgeons might be gone longer to procure organs and unable to accept additional offers. Finally, with an increase in flying there might be less planes available.

The Committee Chair noted that costs are an important consideration even though there isn't much data collected to analyze it. The Committee member agreed that the driving to flying data is a starting point.

One Committee member asked if there was a potential for lawsuits from the perspective of increased distances. Another Committee member responded that the Committee needs to worry about the clinical decisions and not potential lawsuits.

The question was raised about how long it will take to run the data based on distances. UNOS staff noted that for liver it was estimated at 10 weeks. SRTR staff noted that it might take longer for the thoracic models since the processes are not as refined as the liver models. They will be able to provide a better estimate once they see the final data request from the Committee. He noted that in addition to running the data, there is additional time needed to analyze the results and prepare presentations to the Committee.

In summary, the Committee members were supportive of modeling 250 and 500 nautical miles as well as a shorter distance such as 100-150 nautical miles.

Next steps

During the next conference call, the Committee will start discussing the outcomes they want to measure. These will be considered within the context of the distribution principles:

- Reduce inherent differences in the ratio of donor supply and demand across the country
- Reduce travel time expected to have a clinically significant effect on ischemic time and organ quality
- Increase organ utilization and prevent organ wastage
- Increase efficiencies of donation and transplant system resources

Upcoming Meeting

• August 9, 2018 (Conference call)

Attendance

• Committee Members

- o Ryan Davies, MD
- Erika Lease, MD
- Rocky Daly, MD
- Monica Colvin, MD
- o Deana Clapper, RN
- o Mike McMullan, MD
- o Masina Scavuzzo, RN
- Nirav Raval, MD
- o Shelley Hall, MD
- o Donna Mancini, MD
- Jeffrey Goldstein
- Tania Sherrod, RN
- Maria Budev, MD

HRSA Representatives

- o Marilyn Levi
- Jim Bowman
- SRTR Staff
 - Katie Audette
 - o Josh Pyke
 - Bert Kasiske, MD

OPTN/UNOS Staff

- Kim Uccellini, MS, MPH
- Robert Hunter
- o Betsy Gans
- Bonnie Felice
- Rebecca Lehman, PhD
- Leah Slife
- o Shyni Mohan