OPTN/UNOS Thoracic Organ Transplantation Committee
Meeting Minutes
August 23, 2018
Conference Call

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

Introduction

The Thoracic Organ Transplantation Committee met via Citrix GoToTraining teleconference on 08/23/2018 to discuss the following agenda items:

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

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

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

Lung Allocation

UNOS staff asked the Committee if they wanted to discuss changes to lung allocation. The Committee members agreed to focus on heart allocation and continue to monitor the recent changes to the lung policies.

Review of Allocation Tables

UNOS staff provided examples of how the proposed distances for heart allocation would look in the allocation tables. UNOS staff noted that the tables are condensed versions used to illustrate the ordering if DSA is replaced through the first 13-14 classifications.

The proposed distances to replace DSA include:

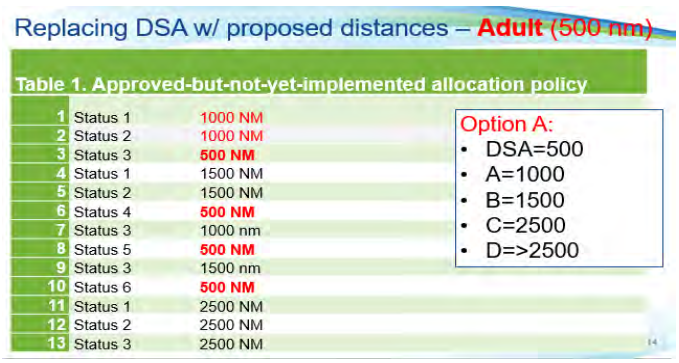
- 150 nautical miles – This does not change the broader sharing for adult Status 1 and 2 as well as pediatric Status 1A, this simply replaces DSA with 150 nautical miles (nm).
- 250 nautical miles – Same ordering as 150 nm.

UNOS staff presented three options for replacing DSA with 500 nm:

<u>Option A:</u>

In order to maintain broader sharing for adult Status 1 and 2, there would need to be a different distance for classifications 1 and 2 (Adult Status 1 and 2) as shown below in **Figure 1**:

Figure 1



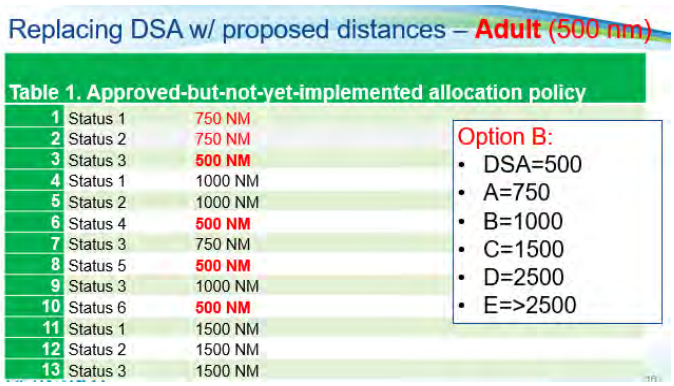
For pediatrics, the broader sharing for Status 1A would be 1000 nm, then 500 nm would replace DSA as shown below in **Figure 2**:

Figure 2

Option B:

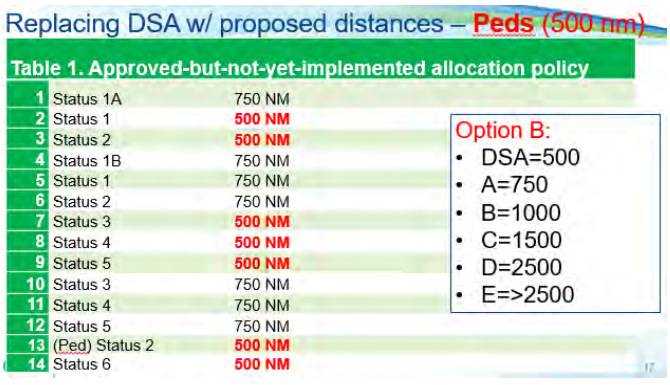
This option provides broader sharing for adult hearts out to 750 nm instead of 1000 nm, then replaces DSA with 500 nm as shown below in **Figure 3**:

Figure 3



For pediatric hearts, the broader sharing for Status 1A would be 750 nm, replace DSA with 500 nm and Zone A would be 750 nm as shown below in **Figure 4**.

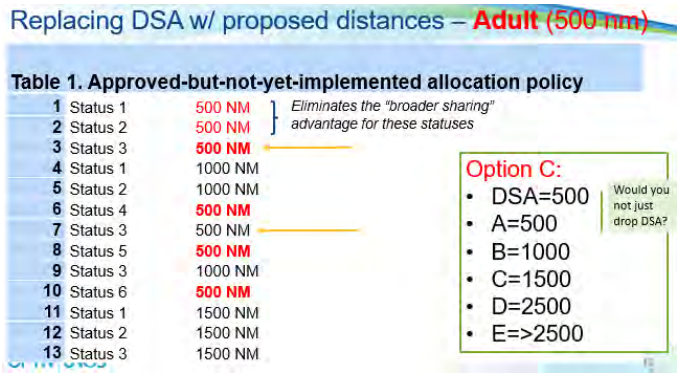
Figure 4



Option C:

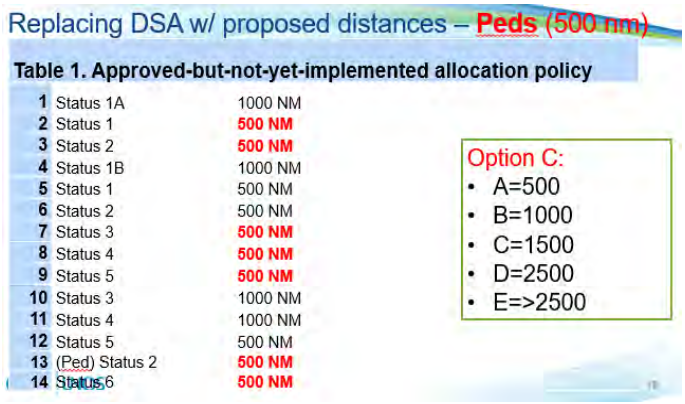
This option does not provide an advantage for adult Status 1 and 2 because the distance is the same for Status 3 candidates as shown below in **Figure 5**.

Figure 5



For pediatric hearts, the broader sharing for Status 1A would be 1000 nm with DSA being replaced with 500 nm as shown below in **Figure 6**.

Figure 6



UNOS staff noted that the Committee should consider prioritizing the three 500 nm options in order to keep the number of modeling requests at four. Several Committee members noted that option C for adults might be the most difficult to propose because it doesn't offer a distance advantage for Status 1 and 2 candidates. One Committee member noted that it still prioritized the sickest patients without proposing the longer distances that might impact travel and cold ischemia time (CIT).

The Committee members agreed that the 500 nm, option B (incorporating 750 nm) was the most arbitrary distance but noted it was proposed as an alternative to 1000 nm. One Committee member noted that one issue is not that 1000 nm is too far to travel but that the offers have already been accepted. Another Committee member commented that there might be a disadvantage for the smaller centers because the larger centers can absorb more risk. Finally, one Committee member noted that if some centers are unable to maintain an adequate volume of transplant, then patients could lose access if they don't have the means to travel and be listed at another transplant center.

One Committee member asked for clarification that the first classification for adult donors will still include adult Status 1 or pediatric 1A candidates. UNOS staff confirmed that both are

included and will remain in the first classification regardless of the distance. The Committee Chair noted that there is a clear advantage for pediatrics in the approved not yet implemented policies which was the intent based on the smaller number of pediatric candidates. Another Committee member noted that pediatric programs (heart and lung) have been successful traveling greater distances because CIT has less of an impact on pediatric organs.

The Committee discussed narrowing the modeling requests down to four distances. SRTR staff noted that as the distances increase, the relationship is quite linear. Therefore, if the Committee chooses to model 500 nm and 1000 nm as the first units of allocation, then the Committee could evaluate 750 nm by inference instead of running the TSAM for that particular distance. The Committee members expressed support for this approach.

One Committee asked if the pediatric modeling was incorporated into the adult modeling. SRTR staff noted that a set of rules used for the modeling is similar to how the match runs operate. For example, when an organ donor becomes available, a set of rules is applied based on the donor's age and those include the allocation of both adult organs and pediatric organs.

The Committee members agreed to model the following distances:

- 150 nm
- 250 nm
- 500 nm, options A and C.

Outcomes Metrics

The Committee reviewed the following list of outcomes metrics to include in the modeling request:

- Waitlist death counts and waitlist mortality rates
- Transplant counts and transplant rates
- 1 year post-transplant counts and mortality rates
- Center volume
- Geography:
    - Candidates: urban v rural
    - State
    - East/West of Mississippi
- In addition…
    - Subgroup analyses of specific diagnosis groups, OPTN regions, ethnicities, age groups, or blood types…other vulnerable populations?

One Committee member asked how a new system would impact the number of LVADs implanted region by region since there is currently a lot of variability. The Committee Chair noted that there is really not a good way to analyze the impact of mechanical assist devices.

One Committee members asked if the transplant counts and transplant rates are the same as waitlist time. The Committee Chair noted that the transplant rate is the number of transplants divided by the number of days waiting for an organ. One Committee member asked if it made sense to add waiting time. SRTR staff noted that they do not look at waiting time on its own, instead they look at the number of transplants and the transplant rate which does incorporate time. They noted that they could potentially separate the components of the rate data but it would be difficult to interpret the data.

One Committee member asked about the average distance traveled. SRTR staff noted that the distance data does not exist until the donor and recipient pair is identified. Once they have the

simulated transplant data then they can determine how many transplants were performed at distances X, Y, and Z. Another Committee member asked if the distances could be separated into quartiles. SRTR staff noted that they can break it down by whatever distances the Committee would like to evaluate, they just can't have the important waitlist metrics by distance. The Committee Chair suggested the Committee evaluate 150 nm since that is the distance identified as the transition point from driving to flying. The Committee can evaluate whether or not there is a sudden increase in the number of transplants that involve flying. One Committee member noted that the Committee had previously looked at distance presented as distribution. SRTR staff noted that UNOS Research staff had previously presented data in the observed lung data. SRTR staff noted that they have a lot of code set up to do these analyses so anything that gets changed will add time to do the analysis.

One Committee member asked if the TSAM (Thoracic Simulation Allocation Modeling) results show what position on the match run each of the offers were accepted. This would provide information about how many additional offers the OPOs need to make in order to place the organs. For example, does the match position of the offer end at sequence number 20 instead of sequence number 5. SRTR staff noted that they weren't sure how accessible that data is and whether the information is in the output files but they agreed to look into whether that is a possibility.

One Committee member asked about including CIT and SRTR staff noted that it is not an available measure because it is based on a number of factors and it's an observed data point that would need to be predicted.

Finally, one Committee member asked if the TSAM modeling would be using contemporary data. The SRTR staff noted that the data has not been updated due to the number of geography projects. They noted that while the numbers might not be the same, the relationships between the different sets of rules are not going to substantially change.

Next steps

- Submit modeling request to SRTR
- Geography Committee meetings debrief

Upcoming Meeting

- August 30, 2018 (Conference call)