OPTN Lung Transplantation Committee Meeting Summary November 12, 2020 Conference Call

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Introduction

The Lung Transplantation Committee met via Citrix GoTo teleconference on 11/12/2020 to discuss the following agenda items:

- 1. Recap Tools Available to the Committee
- 2. Placement Efficiency Rating Scale

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

1. Recap Tools Available to the Committee

UNOS staff provided an overview of the tools and resources available to the Committee and how they were used to support development of the continuous distribution framework.

Summary of discussion:

- Analytic Hierarchy Process (AHP): Elicit preferences on complex relationships between goals
- Revealed preference analysis: Express the current system as a score-based system
- Exchange rates: Evaluate the goals relative to one another and provide context
- Rating scales: Determine how to award points within attributes
- Sensitivity tool: Visualize the impact of different changes on the match run
- Data requests: Provide relevant data to aid decision making

UNOS staff introduced an additional Excel tool to help visualize changes to the placement efficiency rating scale. Members did not have any questions or comments.

2. Placement Efficiency Rating Scale

The Committee discussed how to develop a placement efficiency rating scale that better reflects how decisions about organ offers change as distance from the donor hospital increases.

Summary of discussion:

Background

The Committee previously developed two rating scales related to placement efficiency. The first rating scale was based on data regarding organ transportation costs. The second rating scale was a linear rating scale intended to account for other proximity-related inefficiencies, where maximum points would be awarded for being located at the donor hospital, and zero points would be awarded for the maximum distance, which is 5,181 nautical miles (nm). The Committee expressed interest in exploring different options for this latter rating scale, including a S-shaped curve.

The Final Rule states that allocation policies shall promote the efficient management of organ placement.¹ In 2018, the OPTN Board adopted recommendations from the Ad Hoc Geography Committee identifying appropriate reasons for constraining the geographic distribution of organs, including to increase efficiencies of donation and transplant system resources.² This is the primary justification for incorporating the S-shaped placement efficiency rating scale into the continuous distribution allocation system.

Developing the S-Shaped Curve

Since the OPTN does not have detailed data to determine the shape of a curve for placement efficiency, the Committee could instead use available data and clinical expertise to define the inflection points at which there are significant changes in efficiency. The Committee discussed four inputs for this curve:

- 1. Leaving the donor hospital
- 2. Switching from driving to flying
- 3. The midpoint of an infeasibility curve
- 4. The slope of the infeasibility curve

For example, the slope of the driving curve might be flat, if there is not much difference in efficiency between driving five miles or ten miles to procure an organ. There might be a steep slope for the transition from driving to flying to reflect logistical issues and coordination costs, and a shallow slope to represent flying to transplant candidates within a feasible distance. At some point, there may be a steep drop to indicate the point of infeasibility, based on high projected cold ischemic time and distances beyond current practice where there is a high likelihood that organ offers would be refused. The Committee could define the point of infeasibility by choosing the midpoint and the slope of this curve.

UNOS staff noted that the Committee should be careful not to double count any attributes. Since organ transportation costs are incorporated into the other rating scale, this S-shaped curve should not account for those costs. This S-shaped rating scale should account for other inefficiencies, like the potential loss of organ due to distance or ischemic time; the potential for slowing down the allocation process by offering organs to those who are unlikely to accept; and risks associated with flying to procure organs.

A member asked how SRTR data was used to determine that the inflection point for the transition from driving to flying is at 45 nm. UNOS staff said that SRTR used projected travel times for driving versus flying based on the location of the donor hospital and the location of the transplant center during actual lung transplants. The Committee previously said that as a rule of thumb, if the drive is over 60 minutes, then a flight will be chosen,³ and a 60-minute drive was estimated to be a distance of 45 nm on average.

Leaving the Donor Hospital

UNOS staff asked if there is an efficiency benefit, besides travel cost, that would justify giving a small boost to candidates located at the same hospital as the donor, relative to other candidates within driving distance. UNOS staff suggested two options for discussion: (1) having a 0% drop between candidates located at the donor hospital and other candidates within close proximity (i.e. no boost for candidates at the same hospital), or (2) having a 5% drop (a small boost) between candidates located at the donor hospital and other candidates within nearby driving distance. An attendee noted that sometimes donors are transported to an organ procurement organization (OPO), so even if the system

¹ 42 CFR §121.8(a)(5)

 ² "OPTN/UNOS Board adopts principles of geographic organ distribution," OPTN, June 10, 2018. Accessed November 30, 2020: <u>https://optn.transplant.hrsa.gov/news/optnunos-board-adopts-principles-of-geographic-organ-distribution/</u>
³ OPTN Thoracic Committee Continuous Distribution of Lungs Workgroup Meeting Minutes, May 16, 2019. Accessed November 30, 2020: <u>https://optn.transplant.hrsa.gov/media/3086/20190516_lungworkgroup_summary.pdf</u>

shows that a candidate is located at the same hospital as the donor, those efficiencies may not exist if the donor was transported. A member asked about a situation in which there are three or four transplant programs located very close together, like in Boston or Philadelphia. The member was not sure that it would make sense to distinguish between patients located at those hospitals, if otherwise their allocation scores would be very similar. UNOS staff shared that the Ad Hoc Geography Committee was concerned that this approach would create a perception issue of unfairly prioritizing candidates who happen to be located at a high volume donor center.

The Committee took an informal poll. Seven members voted for 0% and six members voted for 5%.

Committee leadership noted that this is a rare occurrence for lung transplants. The Chair did not think there was a need to add a boost for candidates located at the donor hospital but was interested in more feedback from the Committee. A member said that it is technically more efficient to be co-located, but when there are multiple transplant programs in the same city, it does not make sense to distinguish between them from an efficiency standpoint. A member said that transplant hospital staff experience the gain in efficiency, since they can essentially handle the procedure with one team instead of sending another team to handle procurement. It is rare, but when it happens, it is a discrete benefit. A member said that some centers have a separate procurement team, so this probably varies a lot by program in terms of the staff that are involved and whether or not there is an efficiency benefit.

Switching from Driving to Flying

UNOS staff presented three different options to represent the transition from driving to flying, including a 10% drop, a 30% drop, and a 50% drop. A member asked if there is any data to help the Committee to understand how these different options would impact a small transplant program, in terms of how organs would be redistributed, since small programs fly for all of their organs and never drive. UNOS staff said that information could be provided by simulation modeling down the road. An attendee said the assumption is that the logistical and cost issues are agnostic to geographic variation in population. UNOS staff said it could be possible to create separate curves for different areas of the country, but that would add more complexity. The attendee asked if the variability of population density is going to create some inherent biases in how this curve treats different programs across the country. If so, then the Committee should not place a lot of weight on this rating scale. UNOS staff said the Committee does not need to lock into all of these decisions prior to modeling. The Committee can select some different options for the modeling request to understand how they impact allocation. The attendee recommended identifying the populations of patients that might be impacted by various decisions so that the Committee can review those impacts in the modeling.

The Committee took an informal poll. Seven members voted for a 10% drop; three members voted for something in between 10% and 30%; three members voted for 30%; and zero members voted for 50%.

Infeasibility Midpoint and Slope

UNOS staff explained that there is a point of infeasibility at which candidates are unlikely to accept offers; the cold ischemic time is too long; and/or centers are unwilling to travel. There are two parts to this component: the midpoint, since the "point" of infeasibility will be a range depending on other factors; and the slope or steepness, based on whether the biggest change occurs over a small area, or if the change is more gradual across distance. UNOS staff shared data showing that it is rare to see offers past 1,500 nm, but that is due in part to the current system that offers lungs in zones. The most common maximum acceptable distance entered for lung candidates on the waiting list is 1,500 nm.

A member was not sure that there is an infeasibility point in the continental U.S. In the current system, the quality of the organs is marginal once offers are being made out to 2,000 nm, but once the system

allows for offering higher quality organs at that distance, there are probably not a lot of limitations or points of clinical infeasibility. A member agreed that current OPTN data on distance is confounded by the current allocation system, and how a program determines feasibility is also influenced by the medical urgency of their candidates. UNOS staff noted that the Committee will also have to consider how much weight should be placed on placement efficiency relative to medical urgency.

A member noted that normothermic ex vivo lung perfusion modalities are available and programs are traveling farther and claiming that there are no issues with outcomes. A member did not think that factors into the discussion. Anecdotally, the member's program accepts donation after cardiac death (DCD) organs from California, which is thousands of miles away, with ischemic time over 9 to 10 hours, and it is not necessary to have continuous normothermic perfusion devices to consider going those distances. The distance that programs are willing to travel is strongly influenced by the medical urgency of their candidate. There are lot of programs that do not use continuous warm perfusion devices but will still use cold static storage for prolonged transports. A member said it was surprising that 1,500 nm is the most common acceptance criteria, and said that there is significant variability across programs.

UNOS staff showed a table of nine different options with varying infeasibility midpoints and slopes, noting that the Excel tool can help the Committee to get a sense of the differences between these curves. UNOS staff suggested that the Committee think about the steepness or slope in terms of the width of the transition zone, and whether that is 1,000 nm or 3,000 nm.

A member said that from a biologic standpoint, these curves could be pushed out to the right, but the purpose of this curve is to address inefficiency, and that will vary a lot between programs. For example, the staff who handle procurement varies between programs, since some hospitals use faculty whereas others send fellows or junior faculty. Programs that send more junior personnel to handle procurement experience less impact on efficiency based on distance than programs that send faculty members, who would have to cancel elective cases to go do a procurement.

An attendee was curious whether this strategy will exacerbate the issues with the current system that make it difficult for programs that want to go a long way to get organs. The attendee suggested a strategy relying on transplant programs to be honest in terms of how far they are willing to go. UNOS staff said that based on the weight for proximity in the AHP results, that impact will be incremental. Zones are going away so a patient with really high medical urgency will get offers at a far distance, so the question is really how much distance should play a role. The Committee's preferred option can be added to the sensitivity tool so the Committee can feel out what weight makes sense relative to medical urgency. Centers can use screening criteria today, so perhaps there should be education moving forward about the importance of truth in listing with respect to screening criteria.

A member asked if there is data showing how often programs are taking advantage of offers at longer distances, like 1,500 or 2,000 nm. If centers say they want all offers but never travel beyond 2,000 nm, that would be cause for feedback. UNOS staff said that offers beyond 1,500 nm or 2,000 nm are rare, but that is influenced by current policy. The member asked if it is possible to get center-specific data to be able to provide that feedback to the centers, since the solution to this issue is more responsibility in the transplant centers. UNOS staff said this has been an ongoing effort with kidney for years, and the current offer filters project is intended to reinforce that. The member asked if there is a way to factor in center density within a prescribed radius. For example, by the time a program gets an offer from 4,000 miles away, there are often quality issues so it is not a desirable organ. However, if a program travels 4,000 nm west to Hawaii, where there are no intervening centers, quality is not an issue. Programs would not want to wade through all of those offers within 4,000 nm, but depending on the geography, it might be reasonable to look for offers at longer distances.

The Committee took an informal poll to indicate their preferences across the nine different curves.

- 1 attendee voted for option 4 (midpoint at 1,500 nm; 2.0 steepness)
- 3 attendees voted for option 7 (midpoint at 2,000 nm; 2.0 steepness)
- 2 attendees voted for option 7 or 8
- 3 attendees voted for option 8 (midpoint at 2,000 nm; 3.0 steepness)

Next steps:

Overall, the Committee expressed a preference for an S-shaped curve with a 0% drop between candidates at the donor hospital and other candidates within driving distance; a 10% drop for the transition from driving to flying; an infeasibility midpoint at 2,000 nm; and a steepness between 2 and 3 for the infeasibility curve. Using this feedback, the Committee will finalize their modeling request for SRTR on 11/19/2020.

Upcoming Meeting

• November 19, 2020

Attendance

• Committee Members

- Nirmal Sharma
- Kenneth McCurry
- o Erika Lease
- o John Reynolds
- Kelly Willenberg
- Julia Klesney-Tait
- o Dennis Lyu
- o Dan McCarthy
- o Marie Budev
- o Alan Betensley
- o Mindy Dison
- o Whitney Brown
- Marc Schecter

HRSA Representatives

- o Jim Bowman
- o Adriana Martinez
- SRTR Staff
 - o Yoon Son Ahn
 - o Katie Audette
 - o Maryam Valapour

UNOS Staff

- Kaitlin Swanner
- o Amanda Robinson
- Craig Connors
- o Darren Stewart
- o James Alcorn
- Janis Rosenberg
- o Julia Chipko
- Karen Williams
- o Leah Slife
- Rebecca Goff
- Sara Rose Wells
- Susan Tlusty
- o Elizabeth Miller

• Other Attendees

- Stuart Sweet
- Masina Scavuzzo
- Samantha Taylor
- Jarrod Dalton