OPTN Continuous Distribution of Lungs Meeting Summary November 20, 2019 Conference Call

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Introduction

The Continuous Distribution of Lungs Workgroup met via Citrix GoTo on 11/20/2019 to discuss the following agenda items:

1. Continuous Distribution of Lungs: Blood type, multi-organ, candidate size

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

1. Continuous Distribution of Lungs: Blood type, multi-organ, candidate size

The Workgroup continued their discussion regarding continuous distribution, and possible factors to be included in the composite allocation score.

Summary of discussion:

Blood Type

The Workgroup discussed blood type earlier this year and stated that blood type is most relevant for patient access, as opposed to post-transplant outcomes. Based on previous discussions, the Workgroup considered the following approaches for ABO:

1. A potential rating scale based upon the ratio of ABO compatible or identical lung donors to lung candidates, by candidate blood type.

2. A matrix of points that is different dependent upon the donor. For example, a candidate with blood type A might receive X points for an O donor but Y points for an A donor.

One Workgroup member stated that historically, the OPTN had prioritized identical over compatible because of a theoretical assumption of post-transplant outcomes and that blood type O had less access to transplant. Some members supported the first option, and stated that this would not be sending out offers for incompatible blood types. Also, another member supported the first option provided that it is based on LAS and not just on the blood type. Clarification was provided that blood type AB does not need as much priority because they can match with every blood type; in this way, points might be equally given to blood type A and B so that everyone has equal access to receiving an offer. Also, the continuous distribution system probably would give more points for medical urgency over blood type, but certain blood types would still give some boost points. Workgroup members supported the recommendation to build a ratings scale for candidate blood type using one year of historical data on the volume of lung candidates by blood type and lung donors by blood type. The ratings scale will be based on the ratio of ABO compatible (or identical) lung donors to lung candidates by candidate blood type. The system and the ratings scale will assign points based on candidate blood type, not the level of compatibility with the donor. One Workgroup member vocalized their support because option 1 would maintain fairness for blood type O group, while recognizing that a there are a large number of blood

type A, and still maintaining availability for the other blood types. Similarly, this would be one way of a compromise that has seemed to work for heart allocation (similar also to the inverse ratio for cPRA).

<u>Multi-organ</u>

During public comment, a question was raised regarding multi-organ candidates and 1) what changes will be necessary for heart/lung and other existing multi-organ policies and 2) whether multi-organ candidates should receive priority in the composite allocation score for lungs. The Workgroup discussed whether to add priority points for multi-organ candidates.

During the discussion, several members agreed that they must understand the interaction between different organ lists and the different prioritizations between different lists. One suggestion was to possibly build in a priority system whereby candidates who wait longer get greater priority (such as multi-organ) because this would support the goal of equity. Another member stated that a candidate's priority depends on severity of illness of the other organ. For example, the necessity to pull a kidney may not be as high as the need for the heart. In this way, giving points in isolation is difficult without knowing severity of organs, and might therefore make the current multi-organ situation worse. One member also mentioned that without data, whatever the Workgroup picks for priority points will be "random".

A Workgroup member supported the Policy Oversight Committee clarifying and overhauling the entire multi-organ policy. Particularly, under the current allocation system multi-organ candidates are disadvantaged because they are limited only to donors within the boundaries of their OPO. This thereby decreases the candidate's access. Furthermore, there was a concern that OPOs also have different practices when allocating multi-organs, such as a liver and lung. Similar thresholds for allocating multi-organs should be sought (similar to the simultaneous liver/ kidney policy), particularly for lung/liver and lung/kidney, in order to ensure candidates are listed appropriately.

Though members did not support adding multi-organ into the composite score at this time due to a lack of data, members agreed that multi-organ combinations with lungs needed to be monitored, including waiting list time and waiting list mortality. Workgroup deferred on modifying heart/lung policy at this time as well, however this will be discussed on another call for continuous distribution.

The Workgroup requested to analyze outcomes for multi-organ lung candidates (waiting list mortality and waiting time). The analysis will examine the impact of removing DSA from allocation on patients listed for multi-organs (including heart/lung). One Workgroup member opined that if there was been an increase in waiting list mortality or waiting time, then the Workgroup should take multi-organ into consideration now. The data analysis proposed will be included in the 18 month monitoring report (removal of DSA) for pre and post comparison.

Candidate Size

During the October 17 in-person meeting, the Workgroup discussed size matching. At that meeting, the Workgroup agreed that while size matching holds promise for the future, they would not include size matching at this time. However, the Workgroup may want include priority points dependent upon the size of candidates (the theory is that smaller candidates are harder to match therefore need priority for smaller donors).

During the discussion, members stated that recent publications used candidate height as a measure for lung size. A member noted that height is the simplest measure and that surgeons really look at the height in terms of what is acceptable and not (first they screen the candidate, then they set height parameters in UNet, followed by fine tuning the offers with gender and age). However, this brought up a concern from one member who stated surgeons want to cast a broad net, instead of a narrower match

run. The Workgroup agreed that this discussion would not be intended to modify the donor acceptance criteria but rather about giving priority points for smaller size candidates in order to improve access.

There was some discussion regarding the need to need to take into consideration a candidate's underlying condition as well as candidate's height. One member commented that it's not just short stature idiopathic pulmonary fibrosis (IPF) candidates that are disadvantaged, but also short stature women with cystic fibrosis and COPD. Though another member stated that their center does not have issues with getting offers for COPD candidates, other Workgroup members argued that all short stature candidates have access issues compared to other taller candidates and that there may be regional variation in which diagnoses groups are disadvantaged.

In terms of data, a member stated that the Workgroup won't know the extent of disadvantage for short stature candidates until data is analyzed. A member suggested looking at the number of donors that would be available to certain candidates (such as a female with COPD). Another member stated that they should look at height distribution of donor pool and then determine whether the donor pool disadvantages certain candidates at a certain height. The Workgroup agreed to look at the distribution of donor heights by core diagnosis group, including all deceased lung donors.

Briefly, the Workgroup discussed surgical techniques in reducing lung volume. One member stated that an issue is how to determine how to volume reduce lungs (anatomic reduction vs. wedge reduction). Also, there have been several pleural effusion issues post-transplant. Though surgical techniques are changing, the Workgroup agreed to include candidate height for now, and then to possibly modify it once more data becomes available.

Next steps:

The data requests will be written and distributed to Committee leadership for approval. The Workgroup will continue their discussion on candidate size at the next meeting.

Upcoming Meeting

• November 21, 2019