

**OPTN Lung Continuous Distribution Workgroup
Meeting Minutes
July 11, 2019
Conference Call**

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Introduction

The Lung Continuous Distribution Workgroup met via Citrix GoTo teleconference on 07/11/2019 to discuss the following agenda items:

1. Monitoring of the Modification to the Pediatric Lung Allocation Policy
2. Continuous Distribution of Lungs: Concept Paper Feedback and Regional Meetings

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

1. Monitoring of the Modification to the Pediatric Lung Allocation Policy

UNOS staff presented a monitoring report on the Pediatric Lung Allocation policy that was implemented on March 30, 2017.

Data summary:

In studying the modifications to the pediatric lung allocation policy that were implemented on March 30, 2017, it can be seen that there have been impacts on pediatric lung candidates. Most significantly has been the increase in offers to pediatric patients listed between the ages of 12-17 years old. This reflects policy which states pediatric donor lungs are being allocated to pediatric candidates first. So far, 8 candidates under 2 years old have indicated they are willing to receive an ABOi lung and 1 ABOi lung transplant has been performed for a candidate under 2 years old. However, this sample size and population is small and will be continued to be monitored.

Summary of discussion:

Overall, Workgroup members viewed this report's conclusions favorably, and viewed the changes to this policy as meeting the intended objectives (which was to expand pediatric access to pediatric donor lungs). One Workgroup member asked whether pediatric donor lungs (less than 18 years of age) were being accepted by adults (18 years or older). UNOS staff clarified that "organ offer" refers to a candidate that receives an offer and could have accepted the organ (e.g. up to the final organ acceptance). That being stated, there were still pediatric donor lungs being accepted by adults. Another Workgroup member asked how often LAS exception requests for pediatric candidates less than 12 years old are reported and how many of these candidates are transplanted. A Workgroup member responded that according to their data, there were not many adolescent exception requests.

2. Continuous Distribution of Lungs: Paper Feedback and Regional Meetings

UNOS staff opened up discussion regarding the continuous distribution of lungs concept paper. Specifically, UNOS staff asked whether the concept paper was understandable, if the conclusions were supported by evidence, and whether the paper contained an appropriate level of detail regarding methodologies and age.

Summary of discussion:

Though Workgroup members generally expressed favorable opinions of the concept paper there were some points that members thought needed to be modified or clarified. For example, a few Workgroup members stated that the paper was extremely dense, and needed to be reduced or a more robust executive summary written. Another Workgroup member questioned why the paper did not mention how success would be measured or which metrics would be used to judge success under a continuous distribution framework. This member was also concerned that the concept paper lacked clear guidance as to what UNOS staff wanted regarding community feedback, and that this could in turn lead to a lack of feedback received. The Workgroup member suggested that the community should be asked about which metrics to use when judging the success of the new allocation system, and including such questions in the concept paper. UNOS staff stated that they want feedback from the community regarding whether the processes for developing a continuous distribution system outlined in the paper are sensible for all organs, not just for lungs. Furthermore, there is a clear intention for the paper to connect new policies to NOTA and the OPTN Final Rule when justifying why certain choices are made in developing the new allocation system. As for how the new system will be measured, UNOS staff will consider this discussion point more, and possibly incorporate it into the paper.

Speaking to the OPTN Final Rule, another Workgroup member stated that the community is not as concerned about meeting the legal obligations under such legislation, but rather they are more concerned about the effects the policy could have on their patients. There was general concern from Workgroup members that the paper focused too heavily on legal aspects, and that this would not be viewed well by the public. UNOS staff agreed to include more case reviews in the paper, which may help exemplify the issues under the current allocation system. Workgroup members supported including more examples such as these, but also stressed that the paper should not emphasize the issue of geography so heavily above all the other factors.

Another Workgroup member opined that UNOS staff and other Workgroup members should anticipate negative reactions about this paper. This member stated that the Workgroup should focus on how to present the paper during the public comment cycle, and how best to address questions during regional meetings. This member also went on to state that there was not enough information given about the pediatric population, and how they will be prioritized under a continuous distribution system. For example, some of the examples seem to suggest that age is a slippery slope and that pediatric candidates may lose priority when “cliffs” are eliminated. Furthermore, the Workgroup member stated that not only did the paper make it seem like pediatric candidates might be de-prioritized, but that certain centers might also be disadvantaged if they are located in rural areas (flying versus driving). All of these concerns may in turn be asked about during regional meetings. In response, UNOS staff agreed to include more information about not wanting to disadvantage certain centers based on geography, and to weave more discussion about age into the paper. There was general agreement that the various methodologies talked about in the paper should not be the primary focus at regional meetings.

In terms of other topics to include in the paper, a Workgroup member suggested including more background on past research and policies that have been done, because this may not be clear to the community. The member suggested to look at previous research done in comparing certain regions and donor availability (e.g. regional waitlist outcomes, regional outcomes etc.) when developing metrics. Furthermore, UNOS staff might want to state that the Workgroup will examine continuous distribution policy by comparing the new system to what has been implemented in the past. This member also stated that though many of the examples were useful, they were more “extreme” and did not accurately represent the smaller differences in LAS that may prove to be more difficult. Other Workgroup members

agreed, and indicated that it may be useful to include an example in the paper that shows how a currently disadvantaged patient could benefit (less obvious example). Another member was grateful that the example of a lung composite allocation score (Figure 3) had been re-worked so that travel mode was not weighted the most. However, the member was concerned that ischemic time was too big a component in the scoring and may be picked out during public comment. Other Workgroup members echoed this concern, citing strong issues with how travel time was being aligned with ischemic time in Figure 3. UNOS staff agreed to re-work Figure 3 so that ischemic time is not as heavily weighted, and also agreed to create more nuanced and less extreme examples to include in the paper.

Lastly, a Workgroup member suggested that the paper be clearer that the LAS score is akin to the “medical priority score” and that they should be separated the first time they’re mentioned in the concept paper.

Next steps:

UNOS staff will compile the feedback from the Workgroup and make the suggested edits to the concept paper.

Upcoming Meetings

- July 18th
- August 8th
- August 15th