OPTN/UNOS Liver and Intestine Transplantation Committee
Meeting Minutes
October 30, 2018
Conference Call

Julie Heimbach, M.D., Chair
James Trotter, M.D., Vice Chair

Introduction

The Liver and Intestine Transplantation (Liver) Committee met via teleconference on 10/30/2018 to discuss the following agenda items:

1. Public Comment Summary
2. Geography Committee Update
3. Other Significant Items

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

1. Public Comment Summary

The Liver Committee is currently receiving public comment on the proposal titled, "Liver and Intestine Distribution Using Distance from Donor Hospital." The special public comment period closes on November 1 at 5:00 PM Eastern.

The Liver Committee will meet in-person on November 2, where they will review the public comment again.

Summary of discussion:

The Chair reminded the Committee of the Organ Procurement and Transplantation Network's (OPTN) commitment to the Health Resources and Services Administration (HRSA) regarding the requirement to eliminate the use of Donation Service Areas (DSAs) and Regions in liver allocation. The Committee must be able to explain and justify the decisions that are made at the in-person meeting on November 2. The Chair also reminded the Committee that their goal is not just to make a policy that is consistent with the Final Rule but also to reduce disparity in access to transplants.

The Chair presented data on the public comments received to date. There have been 696 comments thus far, with many coming from Texas, California, New York, transplant hospitals, and the general public.

UNOS staff identified common themes that were discussed during regional meetings and in public comment. Common themes for the Broader 2 Circle (B2C) model include:

- B2C is closer to the current allocation system so it would involve less change and therefore fewer unintended consequences.
- Because B2C distributes over less broad of an area, there would likely be less logistical difficulty.
- B2C is less of a disadvantage to areas with high incidence of liver disease, although it is difficult to know how the policy will impact patients that are not on the waitlist.
- Some comments stated that B2C disadvantages non-exception patients. The Chair noted that this concern is not isolated to just B2C and the National Liver Review Board (NLRB) should help alleviate this issue.
- Other comments questioned whether the B2C model satisfied the Final Rule.

Common themes for the Acuity Circles (AC) model include:

- According to SRTR modeling, the AC model will result in lower mortality. The Patient Affairs Committee asked why the AC model was not preferable to B2C given the fact that it is modelled to save more lives.
- AC model has a larger impact on reducing variance.
- ACs would be a larger change from the current allocation system than B2C. Some comments supported the idea that more change is preferable over less change.
- There is concern that ACs will lead to an increase in discards due to more travelling.

Common themes about circle size include:

- Circles around cities on the coast and borders will cover areas without people. The Chair noted that the population density of these areas addresses this concern.
- Some of the larger DSAs expressed concern that the B2C model would actually reduce distribution. The Chair expressed the opinion that there might be a way to alter the B2C model to alleviate this concern.
- Other committees asked why the Liver Committee was not considering a population-based model.
- The committee needs to have a specific plan for Alaska.

Common themes about the sharing threshold include:

- Majority of comments seemed to support the 29 threshold. There were also requests for either no threshold or a threshold lower than 29.

Other themes identified in the public comments were:

- The allocation model should be as close as possible to the continuous distribution model currently being proposed by the Geography Committee
- General support for the changes to pediatric allocation
- Mixed feedback on blood type variance for Puerto Rico

The Chair then presented the feedback from each of the OPTN Regions. The Chair reminded the committee that many of the voting members in the regions are not affiliated with a liver program and, therefore, may not have voted on the proposal. Also, many of the vote counts showed mixed results. The regional feedback is shown below:

<u>Region 2:</u>

- Split on B2C
- Support MELD 35 threshold
- Prefer smaller circles
- Some support for ACs

<u>Region 3:</u>

- Oppose both B2C and ACs
- Support MELD 35 threshold
- Prefer circles to remain the same size

<u>Region 5:</u>

- Generally oppose B2C
- Prefer lower threshold and larger circles
- Support ACs

Region 7:

- Split on B2C
- Support MELD 32 threshold
- Prefer circles to remain the same size
- Some support for ACs

Region 8:

- Support B2C
- Support MELD 35 threshold
- Oppose ACs

Region 10:

- Support B2C
- Prefer MELD threshold of 32 or 35
- Split between keeping circles the same size or making them larger
- Oppose ACs

Region 11:

- Split on B2C
- Mixed support for MELD threshold
- Prefer circle sizes to remain the same size
- Strongly oppose ACs

The litigants in *Cruz et al v. U.S. Dept. of Health and Human Services, (S.D.N.Y 18-CV-06371)* submitted a letter to the committee as a public comment. The Chair previously shared this letter with committee members and OPTN leadership. The Chair asked the committee to consider the letter prior to the meeting on November 2. In the letter, the litigants stated that they believe B2C does not meet the requirements of the Final Rule, but AC model does. The Chair stated that the letter will be discussed more at the meeting on November 2.

HRSA has provided the committee with a number of questions that must be answered as part of the policy making process. HRSA is asking the committee to provide objective evidence or medical criteria for each policy decision. The Chair expressed the difficulty of finding such evidence and asked committee members to think about possible answers to the questions prior to the meeting on November 2.

One committee member asked if increased flying was associated with an increase in discards. The Chair was not sure this is the case and stated that there were not increased discards with Share 35.

HRSA is asking the committee to provide evidence that more flying of organs cannot happen. The committee and community members have repeatedly stated that the percentage of organs flown is an important consideration in the policy proposal. In order to defend any decision that cites this concern, the committee must provide evidence showing the point at which there is too much travel. A committee member pointed out that the two issues associated with increased flying are higher costs and increased risk to procurement teams. The same committee member expressed skepticism that the committee will be able to quantify the flying capacity of the private jet fleet in the United States.

The Operations and Safety Committee put out a questionnaire to organ procurement organizations (OPOs) about travelling for procurement. The data from the questionnaire will provide insight on current practices regarding air transport for organs and some information

regarding flying versus driving. UNOS staff committed to sending this data to the committee and it will be presented at the meeting on November 2.

A committee member stated that the major issue with ACs is the logistical difficulty and increased costs due to more flying. The committee member stated that when lung allocation went to a 250 nautical mile (nm) circle, the median organ acquisition cost went from $30,000 to $75,000 and the percent of organs flown went from 30% to 70%.

A HRSA representative provided some clarification on the intent of their questions. The representative stated that HRSA is looking for an answer to why the 150 nm circle was chosen, given the factors of efficiency and medical urgency that must also be considered.

A committee member stated that it is difficult to predict how many of the small liver programs will sink if they are required to fly more. The American Society of Transplant Surgeons (ASTS) is starting to research the issue of safety and travel, which is currently a black box. A committee member asked to see more information on who voted at the regional meetings. UNOS staff will provide more information once public comment closes, but will not provide information at the transplant hospital level.

A committee member mentioned that in his/her region, pilots can only be on duty for approximately six hours. So if a pilot flies three hours to a procurement, which then takes two or three hours, that pilot cannot then fly the procurement team back.

One committee member attended the Chair's presentation to the Patient Affairs Committee, and noted that the issues of cost and safety are not intuitive issues to the patient population. The general public will likely weigh variance and mortality more than cost and safety. What seems intuitive to healthcare providers is not necessarily intuitive to the general public.

A committee member noted that while pilots can time out of their shifts, his/her region routinely transports organs from distances farther than 250 nm, so this may not be a universal constraint.

Next steps:

The Chair stated that she would be reaching out to individual members for help in preparation of the meeting on November 2. UNOS staff committed to providing complete analysis of the public comment, results of the Operations and Safety Committee questionnaire, and any other significant items at the meeting on November 2.

2. Geography Committee Update

The state-based organ allocation model was previously presented in full to the Geography Committee. The Chair of the Geography Committee presented a summary of this discussion and the Geography Committee's feedback to the Liver Committee.

Summary of Discussion:

In the state-based allocation model, each state and the halo of states around the state would serve as a distribution area for the most urgent patients. If the organ is not allocated at this level, then it would be allocated within the state and then across the nation. There are a number of logistical challenges to this model including the fact that many states do not have a liver program and many states do not have a halo of states around them.

Members of the Geography Committee felt that this is not a viable framework because it is a variation of DSAs and Regions. Lawyers that participated in the presentation to the Geography Committee stated that the model would not meet the requirements of the Final Rule. There was no support for the model within the Geography Committee.

A member of the Liver Committee stated that the state-based allocation system could be an operational model. However, The Chair of the Geography Committee and UNOS staff reiterated the conclusion that the model would not meet the requirements of the Final Rule.

Next Steps:

No next steps were discussed.

3. Other Significant Items

The Committee further discussed the AC and B2C models, as well as the process for the meeting on November 2.

Summary of Discussion:

A member of the Liver Committee asked how ACs are considered legal, while B2C is not. UNOS staff stated that B2C is legally defensible if the committee is able to answer the questions from HRSA that were previously discussed. A committee member asked if it would be legally viable to justify the model by stating that the model is agile and can be changed once the effects of implementation are clearer. The Chair reiterated the fact that regardless of what model they choose, they must provide justification for the decisions made.

The Chair reminded the committee of some of the decisions they will need to make on November 2, including which model to recommend and the sharing threshold. UNOS Staff will prepare more detailed analysis of public comment for the meeting.

A committee member discussed the idea of changing the MELD/PELD threshold to allow for broader sharing and potentially less travel. The Chair stated that there will be the opportunity to tweak either B2C or ACs at the meeting on November 2.

Another member of the committee commented that he did not think regional members knew that they would be voting on the proposal during the regional webinars. This could make analysis of the regional votes more complicated. UNOS staff reminded the committee that there are many public comments submitted on the OPTN website, so there will be plenty of public input available to guide the meeting on November 2.

A committee member asked how much weight the Board of Directors will place on the recommendation of the Liver Committee. Another committee member stated the belief that it is the duty of the committee to put forth what they believe is the best policy, regardless of pending litigation.

Next steps:

The Chair stated that she would be reaching out to individual members for help in preparation of the meeting on November 2. UNOS Staff committed to providing complete analysis of the public comment, results of the Operations and Safety Committee questionnaire, and any other significant items at the meeting on November 2.

Upcoming Meeting

- In-person meeting on Friday, November 2, 2018 in Chicago.