

**OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
Meeting Minutes
October, 10 2017
Chicago, IL**

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Introduction

The OPTN/UNOS Liver and Intestinal Organ Transplantation Committee met in Chicago, Illinois on 10/10/2017 to discuss the following agenda items:

1. Recap of Last 6 Months
2. Overview of Data
3. Recap of Public Comment
4. Details of Proposal with Consensus in Public Comment
5. Details of Current Proposal
6. Other Committee Efforts

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

1. Recap of Last 6 Months

Committee leadership provided a summary of the efforts by the Committee since they last met in Chicago in May 2017.

Summary of discussion:

Committee leadership discussed that following the Committee's last meeting in Chicago in May 2017, the Committee continued to discuss the 500-mile circle and "neighborhoods" models. In May, members of the Committee expressed concern with these models due to travel and logistical issues of broader sharing, however the group continued to discuss these two concepts. At the OPTN/UNOS Board of Directors meeting in June, Committee leadership provided an update on the liver redistribution project, and the Board reiterated their support for the project and the continued effort by the Committee to have a proposal for public comment in July of 2017.

Committee leadership continued to discuss that shortly after the Board of Directors meeting, the Committee began discussing a previous concept that utilized a 150 mile circle. This concept, similar to other circle models showed a decrease in geographic disparity, but with significantly less impact on travel. These discussions led the Committee to support the current proposal to be issued for public comment in July 2017.

Committee leadership outlined the agenda for today's meeting. It was stated that during today's meeting, the Committee would address the specific details of the proposal in light of the public comment received by the community. A committee member asked for clarification on the original data that was issued with the public comment proposal. The data showed a decrease in the amount of livers flown for transplant, and the committee member asked why the new modeling showed an increase in flying, for practically the same model. A committee member replied that it was their understanding that this was due to the original data not having a sharing threshold. SRTR staff commented that the threshold may have been the major factor on the increase in flying with the current model, however, there have also been other changes to liver program activity that could affect the percentage of organs flown. Another committee member asked how the modeling identifies whether an organ was flown. SRTR staff

commented that the modeling utilizes the amount of driving time for an organ to travel to predict whether it would be flown. A committee member reiterated the idea behind the percent flying metric is to capture the change in travel and costs for a program with a proposal that broadens distribution.

A committee member asked how the practice of moving donors to a recovery center is captured in this proposal and how that affects flying. A committee member reiterated that this was important because the number of recovery centers is expected to increase in the future. It was stated that the practice of recovery centers is important for later discussion when the Committee decides whether proximity points should be provided to candidates in the Donor Service Area (DSA) in addition to the proximity circle.

2. Overview of Data

Committee leadership provided a summary of the LSAM data to date and the Committee discussed the results.

Summary of Discussion:

Committee leadership introduced the data by describing that there is nothing new to share and that the results reviewed data have been shared with the Committee and community during public comment. Overall, it was stated that the modeling showed a decrease in variance in median MELD at transplant, one of the metrics identified by the Committee to assess geographic disparity. Additionally, waitlist mortality decreased slightly nationwide in the modeling. In terms of travel, it was stated that the distance organs travel and the percentage of organs flown increased with the modeled concepts, including the concept issued for public comment. It was stated that the transplant rate of non-exception candidates is expected to increase, whereas exception candidates are modeled to have a decrease in transplant rate.

It was stated that the percent of organs flown increases slightly from 50% in the current system, to 55% in the proposal with a MELD/PELD sharing threshold of 29. It was reiterated that this is considerably less flying compared to the increase seen with 500 mile circles, “neighborhoods”, and the 8-district proposal. A committee member reiterated that the variance in median MELD at transplant is decreased from the current system, but not to the level seen with previous concepts that distributed livers over significantly larger geographic areas.

It was stated that the modeling was favorable for the pediatric population. The transplant rate and overall transplant count is predicted to increase for the pediatric population. Further subgroup analyses of the modeling included new metrics the Committee had not previously requested in prior modeling requests over the last 5 years. These included analyses on the impact of the proposal on candidates based on their type of insurance, level of education, and the candidates’ place of residence (metropolitan or rural). Committee leadership stated that these results have been previously shared not only with the Committee, but broadly with the community and made available on the OPTN website. It was stated that the results showed a lack of strong evidence that the proposal disproportionately impacts any of these subgroups compared to the effects seen in the nationwide population. Committee leadership stated that there was a pending data request that was not complete prior to the meeting in Chicago, but would be available to the Committee and the board of directors in the coming weeks. This data request includes additional analyses related to the effect of the proposal on metropolitan or rural populations.

3. Recap of Public Comment

Committee leadership presented an overview and analysis of the public comment received on the proposal. The Committee subsequently discussed public comment.

Summary of Discussion

Committee leadership introduced the public comment received on the proposal by detailing the magnitude of the amount of public comment, and the need for the Committee to review the themes in public comment and their impact on the Committee's decision making. It was stated that the public comment encompassed a variety of perspectives including physicians, recipients, professional societies, OPTN Committees, regional comments, and members of the general public. Additionally, it was stated that the data showed an increase in public comments from specific parts of the country, demonstrating the fact that the public comment is not an equal representation of every state. A committee member asked if there had ever been so much public comment that included transplant professionals. It was stated that there have been other OPTN proposals with considerable comment by members of the community. It was stated that the level of engagement by the community has been beneficial to the project in order to build consensus on a change to the current system.

The public comment by the professional societies and advocacy groups was presented followed by the public comment of each regional meeting. The official comments from the regional meetings was mixed with some regions supporting the proposal and providing comments, supporting the proposal with amendments (with additional comments), and not supporting the proposal (with additional comments). It was stated that a detailed breakdown of how the regions felt about specific details of the proposal would be shared and discussed later in the day when the Committee begins to make decisions on a final proposal. The feedback from the OPTN Committees and general public comment were also shared.

A committee member stated that there was considerable public comment about the need to not rush this process and leadership agreed that this was discussed in public comment. A committee member stated that when the Committee discusses underserved and/or vulnerable populations, that the focus not only be on individuals in rural areas. It was emphasized that there are underserved and/or vulnerable populations in metropolitan areas. It was stated that several of the themes in the public comment of the 8-district proposal were absent in the recent public comment of the current proposal. It was reiterated that this potentially shows progress in responding to some of the previous concerns related to this project.

A committee member stated that the concerns about travel and its modeled impact would not be felt uniformly by all programs. An example was given that a 5% increase in travel for a large program has less impact than a 5% increase on a smaller program, and this impact needs to be considered. A committee member discussed the public comment against using MELD score at transplant as a measure of disparity, and emphasized that mortality represented by MELD and actual mortality on the waiting list were two different things. This committee member further stated that the exception scores for candidates play a large part in the median MELD score of a DSA. Committee leadership reiterated that the National Liver Review Board (NLRB) and its corresponding changes to exception practices, will be in place prior to the implementation of the current liver distribution proposal.

The topic of metrics and the use of variance in median MELD at transplant as a metric of geographic disparity was discussed. It was emphasized by several committee members that the variance in median MELD at transplant should not be the primary metric for the Committee moving forward. A committee member stated that a key metric for the Committee pending implementation of this proposal would be the number of offers for patients at the highest

calculated MELD scores. Committee members reiterated that it will be important for the Board of Directors to understand that the variance in median MELD at transplant was not the primary metric of disparity, but one metric along with several others. UNOS staff stated that the monitoring plan in the briefing paper is traditionally changed based on public comment and feedback by the Committee, therefore this sentiment can be expressed in the briefing paper.

A committee member stated that the fact that the proposal is focused on median MELD at transplant is a concern due to the limitations of MELD in allocating livers. To this concern, a committee member stated that from their perspective this proposal is a relatively small change. They stressed the importance of the appropriate metrics in defining disparity, and for use in post-implementation monitoring, but to not allow these issues distract from the details of the current proposal.

A committee member suggested that there is a fear that the current proposal could be easily expanded following the initial implementation. UNOS staff and OPTN leadership spoke to the necessary steps, including official public comment, for any subsequent changes proposed by the Committee. Speaking back regarding the monitoring plan, a committee member emphasized that it will be difficult to monitor what change is affecting the outcome due to the fact that NLRB, and potentially this proposal, will be implemented fairly close to one another. It was reiterated that the NLRB will be in place prior to the implementation of the current proposal.

The Committee discussed the role of their position on the committee and the need to “sell” this proposal to their respective regions. It was emphasized that there were many members of the transplant community that do not approve of a change, and that it was important to message any change made today to the broader community. A committee member stated that it had less to do with “selling” the proposal, and more to do with gaining trust from the community that the Committee is the group that is making decisions in the best interest of all viewpoints.

The Committee discussed the idea of forming an official statement about their intentions with this proposal moving forward. The idea of the statement is to provide a united statement from the Committee regarding monitoring the success of a proposal. A committee member stated that it was important to include a comment about the role of DSA performance moving forward. There was additional comment about emphasizing the role of transplant centers, and OPOs, when discussing DSA performance. A committee member stated that from a patient perspective, all that a patient wants to know is that they have a fair opportunity for a transplant along with every other patient in the country. Committee leadership stated that the group will revisit the idea of a formal statement later if time allows. Committee leadership then asked for volunteers for a formal subcommittee that will be tasked with developing post-implementation metrics and monitoring any post-implementation data analyses.

4. Details of Proposal with Consensus in Public Comment

The Committee discussed elements of the current proposal with broad consensus in the community.

Summary of Discussion

Committee leadership introduced the idea of only providing proximity points to candidates with a MELD/PELD of at least 15. It was stated that this was overwhelmingly supported during the regional meetings. A committee member stated that the intent of the policy was never to increase access to transplant to candidates with a MELD/PELD less than 15, those individuals with the lowest risk of mortality on the waiting list. This was supported by the Committee for inclusion in a final board proposal.

Committee leadership introduced the idea of removing the cap on MELD 40 for candidates receiving proximity points. This adjustment would allow candidates in the MELD 35-40 population to maintain differentiation by MELD (with five proximity points). Otherwise a MELD 35 candidate, and a MELD 39 candidate would both be at a MELD 40 with the addition of proximity points. The comment in opposition of this proposed that all candidates can be at a MELD of 40 and not to un-cap. The Committee stated that there is evidence to support a clinical difference between the MELD 35-40 population that would encourage uncapping the scores. It was emphasized that the policy would not uncap MELD 40 to candidates that do not qualify for proximity points. This was supported by the Committee for inclusion in a final board proposal.

Committee leadership introduced the previous discussion by the liver distribution subcommittee concerning adult Hepatic Artery Thrombosis (HAT) candidates. Currently, these candidates are provided a MELD of 40 with an approved exception due to their high risk of mortality. However, they may have calculated MELD scores that would exclude them from the initial broader sharing classification. The sentiment of the subcommittee was to allocate to these candidates based on their approved exception score. All other adult candidates are allocated to based on their calculated MELD score in the initial broader sharing classification. This was supported by the Committee for inclusion in a final board proposal.

Committee leadership introduced the separate liver allocation for DCD donors or donors at least 70 years old. The public comment proposal prioritizes the DSA for this subset of donors. A committee member stated that this was widely supported, both due to current data that shows the majority of these organs are transplanted in the DSA, and the idea that this will incentivize DSAs to utilize these organs. This was supported by the Committee for inclusion in a final board proposal.

There was a motion to vote on the current public comment proposal in its entirety. That vote was 1-support, 19-oppose, and 1-abstention. This motion is not approved and the public comment proposal and its specific details will not move forward. The Committee will discuss the necessary changes during the discussion in the afternoon.

A committee member commented that the group should vote now on the previously discussed details that received support by the community and the Committee. A committee member made a motion to support the four previously discussed concepts: 1) Providing points to candidates with a MELD/PELD of 15, specifically a calculated MELD of 15 for adult candidates and an allocation MELD or PELD for pediatric candidates 2) Uncapping MELD 40 for adult candidates that receive proximity points, 3) Allocating to HAT candidates based on their exception score, and 4) Separate allocation for DCD or age at least 70 years old donors. The vote was 20-support, 0-oppose, and 0-abstentions in favor that these parts will be included in a final board proposal.

5. Details of Current Proposal

The Committee discussed the more significant details of the current liver distribution proposal that received the majority of public comment.

Summary of Discussion

Committee leadership introduced the feedback received on the concept of a 150-nautical mile radius circle around the donor hospital that includes candidates outside of the region. A committee member stated that there was likely very little change that could be made on the circle without further modeling and/or another round of public comment. Committee leadership stated that there was public comment on 1) a larger circle, 2) a smaller circle, 3) keeping the same sized circle, or 4) a circle who's sized was based on population density. A committee member stated that a larger circle was necessary to address geographic disparity in the western

part of the country. A committee member asked why population density was never modeled and another committee member replied that the concern with population density is that certain areas of the country would have much larger circles compared to the more metropolitan areas and that population density would not treat all areas as equally as a standard 150 mile circle.

A committee member stated that the 150 mile proximity circle was originally designed to be the area of distribution for proximity points, and a larger concentric circle outside of the 150 mile circle (250 or 500 mile) would actually be the extent of the area of distribution. So it was emphasized that the 150 mile proximity circle, may not always be the extent of the area of distribution. A committee member stated that it was difficult to support the 150 mile circle without also considering the other details of the proposal.

The Committee discussed the idea of providing proximity points, both the geographic area that points are provided to candidates within, and the specific number of points. Regarding the geographic area to provide points to, the public comment proposal provided points to candidates in the circle. However, there was extensive discussion during public comment concerning providing proximity points to candidates in the circle and the OPO's DSA. A committee member stated that there is no negative implications of providing points to candidates in the DSA in addition to the circle. This was met with agreement by the Committee. There was a request to take a straw poll on providing points to candidates in the DSA and the circle. That straw poll was 14-support, 0-oppose, and 6-abstentions. This was a non-binding vote.

The Committee then discussed the number of points to be provided to candidates. The public comment proposal included 5 MELD or PELD proximity points. A committee member stated that the difference in each increasing MELD or PELD point was significant when you looked at the difference between 5 points and fewer points, for example 3 points. A committee member reiterated that 5 MELD or PELD points does not consider the biology of the disease, and 5 MELD points is a significant inflation to a patient's MELD or PELD score based purely on being within close proximity of the donor hospital. The Committee agreed to revisit the points in relation to their next topic, the sharing threshold.

The public comment proposal included a MELD or PELD sharing threshold of 29 for inclusion in the initial broader sharing classification. Committee leadership stated that there was significant public comment on the appropriate sharing threshold. A committee member stated that the current threshold of 29, or lower, will have a significant impact on the amount of travel in the western United States. It was reiterated that the sharing threshold is the most significant decision for the Committee to make. The Committee reviewed previous modeling results on the effect of different thresholds. A committee member stated that it does not appear that a change of a few MELD/PELD points impacts the results very greatly. However, a committee member responded that it's hard to draw comparisons between the modeling results for the 8-district model and the current proposal.

A committee member stated that a threshold of 32 was proposed in several regions and represents an incremental change that the community can come together on. Another committee member stated that a threshold of 32 provided support for fewer proximity points, however staying at a threshold of 29 may influence them to support 5 proximity points. A committee member stated that they have concern that a sharing threshold of 32 will not go far enough in addressing the current problem. A committee member replied that incremental change was much more achievable than radical change to current liver distribution. There was a question raised about not having modeling of a 32 threshold. A committee member replied that there has been extensive modeling of different thresholds and these results can predict the relative movement in change. However, it was stated that making an incremental change is the

only way to see the actual effect of a policy change. A committee member brought up the fact that the modeling does not include the changes to the NLRB, which would lead them to support an incremental change and a threshold of 32. A committee member replied that if there was very little difference between 29 and 32, then a threshold of 32 is beneficial if it builds more support in the community of a change. Committee members responded that a threshold of 32 will certainly be more supported in their respective regions.

A committee member stated that with the recent discussion of a sharing threshold of 32, they would like to revisit the conversation of 3 versus 5 proximity points. Committee leadership emphasized the importance of looking at how the threshold and proximity points interact with one another. Due to the biological difference with 5 MELD/PELD points a committee member stated that they would not support 5 proximity points regardless of the sharing threshold. A committee member asked if a threshold of 32 and 3 proximity points was required to go back out for public comment again. UNOS staff stated that this decision was ultimately left to the Board of Directors and the Committee should consider whether this change represents a change that the members of the community would have expected during public comment. It was stated that the details being discussed were all concepts that represent permissible post-public comment changes.

The Committee discussed the urgency for sending a proposal for Board consideration in December 2017. Attendees first discussed the need to first decide on a final proposal before addressing whether additional public comment is necessary. OPTN leadership reiterated that it's less about a specific deadline, and more about maintaining the OPTN's ability to retain its decision-making abilities. OPTN leadership emphasized that the controversy will not completely go away regardless of the outcome of the project; however, coming to a solution sooner rather than later, allows the Committee and community to move on to address other topics in liver and intestinal transplantation. Others discussed whether additional time and public comment would change the final proposal or increase consensus in the community; attendees were split on the later issue. UNOS staff clarified to the Committee that whether the Committee decides for additional public comment, or the Board of Directors decides for additional public comment, it would not affect the timing of the next round of public comment on this proposal.

There was a motion for a final board proposal that includes:

- Adult candidates who have a calculated MELD score of 32 or higher, as well as pediatric candidates younger than age 18 with an allocation MELD or PELD score of 32 or higher, would be prioritized for organ offers within the region plus the circle. This is the "sharing threshold".
- Additional transplant priority (equivalent to 3 MELD or PELD points) would be awarded to liver candidates with a MELD or PELD of at least 15, and who are either within the same donor service area (DSA) as a liver donor or are within 150 nautical miles of the donor hospital but in a different DSA or region. Specifically, these points are added to the calculated MELD of adult candidates (at least 18 years old) and the allocation MELD or PELD for pediatric candidates.
- For the purpose of calculating this additional transplant priority, MELD would not be capped at 40. For example, an adult candidate with a calculated (lab) MELD of 38 would receive a score of 41 for offers within the DSA or circle; one with a calculated MELD of 40 would receive a score of 43 for DSA/circle organ offers.
- Adult candidates with early hepatic artery thrombosis currently receive a standard MELD exception score of 40, unless they meet specific additional criteria that make them

eligible for status 1A. Under the current proposal, these candidates are the only ones who would receive immediate prioritization within the region and circle based on an exception score as opposed to a calculated score. They will retain their exception score of 40 for this purpose.

- Livers from deceased donors who are age 70 or older, or who are DCD donors, have a separate allocation that prioritizes the DSA before broader distribution to the region or circle. Livers from donors with these medical characteristics are most often used within close proximity of the donor location, according to the medical judgment of transplant professionals.

This motion was seconded. A committee member asked a point of clarification regarding the recent changes to the SLK proposal. UNOS staff replied that the current proposal does not affect the new policy language implemented as part of the SLK proposal. It was reiterated that the Kidney and Liver Committees will certainly discuss potential future changes to align these separate efforts. A committee member discussed the current motion and reemphasized that a threshold of 29 represents a more substantial change and is preferable than the current motion. A committee member responded that it is important the current motion if approved, is allowed to continue long enough post-implementation to ensure an appropriate amount of data has been collected to address the effect, before making subsequent changes. Committee leadership reiterated the previous discussion about the importance of a monitoring plan and the effort to develop a new subcommittee that works on post-implementation data analyses.

The motion was reread to the Committee and the corresponding policy language that represents this proposal was shared to the Committee. The Committee subsequently voted on the motion 13-support, 6-oppose, 1-abstention. The motion and final board proposal outlined above was approved.

A committee member made a motion that the Committee make a recommendation to the OPTN/UNOS Board of Directors that the previously approved proposal is issued for public comment again. This motion was seconded and a committee member expressed concerns that the remaining modeling using the *Community Health Score* was important to see and share with the community. A committee member stated their opposition to this motion, and explained that a recommendation was not necessary, and that it was important to allow the Board of Directors the ability to make a decision on their own. A committee member reiterated that this was a significant change to the public comment proposal and that another round of public comment would be beneficial to the community. However, another committee member replied that this is a very small change and additional public comment delays a future implementation of proposal and subsequently delays implementing a solution to address geographic disparity in access to a liver transplant. A committee member asked for clarification on what would happen if the Board of Directors decided for it to go out for public comment again. UNOS staff replied that the Committee would discuss any decision the Board of Directors makes and determine the next steps.

The Committee voted on the motion to make a recommendation to the OPTN/UNOS Board of Directors that the proposal is issued for public comment again, 7-support, 12-oppose, and 1-abstention. This motion was not supported by the Committee.

Committee leadership brought back to the group the suggestion that a new subcommittee is formed to discuss the monitoring plan pending board approval. The Committee agreed to identify volunteers for this subcommittee.

6. Other Committee Efforts

The Committee briefly discussed the efforts of the Pediatric Committee to address the allocation of livers for pediatric candidates.

Summary of Discussion

Committee leadership provided a brief overview of the current data and efforts of the Pediatric Committee related to pediatric liver allocation. The Committee will be providing volunteers in the future to work with the Pediatric Committee on this project.

Upcoming Meetings

- November 2nd, 2017 – Conference Call
- December 21st, 2017 – Conference Call