

**OPTN/UNOS Executive Committee  
Meeting Minutes  
October 5, 2018  
Conference Call**

**Sue Dunn, RN, BSN, MBA, Chair  
Maryl R. Johnson, MD, FACC, Vice Chair**

**Introduction**

The Executive Committee (EC) met teleconference on 10/05/2018 to discuss the following agenda items:

1. Welcome and Overview of Agenda
2. New Project Approvals
3. Special Public Comment Proposal

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

**1. Welcome and Overview of Agenda**

Meeting attendees were welcomed and the agenda for today's meeting was reviewed.

**2. New Project Approvals**

Data summary:

The Policy Oversight Committee (POC) recommends the following three projects to move forward:

- **Clarifications on Reporting Maintenance Dialysis - Living Donor Committee (LDC).** The first is a simple project tied to clarification on reporting maintenance dialysis. There needed to become clarity in the language because of "being on dialysis" versus "maintenance dialysis" later in the document. The LDC asked for approval to work on the project to make sure language is appropriately inclusive and applicable to all organs. LDC and POC agreed it would affect a small population, but it was felt to be quite important.
- **Effective Practices for Broader Organ Sharing (Guidance) - Operations and Safety Committee (OSC).** For the second is a project, there was a sense of critical timeliness given the other projects on broader geographic allocation, so POC voted to move this project forward. POC did provide feedback to OSC to clarify language, especially around the goals of the policy, which they took back and took to heart. They also recommended adding additional collaboration from the key stakeholders during development of the project.
- **Region 8 Split Liver Variance - Liver and Intestinal Transplantation Committee.** The POC unanimously voted to support this project, as it is a very timely project for the region that has had an established practice. It will not present a major change for Region 8; they just wanted to make sure a variance for split livers is established. There were some questions raised as to whether the liver allocation changes should be completed before addressing variances, but overall there was 100% support for this to drive increased utilization of donated livers. To clarify, this is a new project, not part of the public proposal going out which will be discussed later in this meeting.

Summary of discussion:

A motion to approve was made and seconded to approve the three projects to move forward. After hearing no questions from any Committee members, a verbal vote was taken on all three project proposals. Results were as follows: 100% yes; 0% no; 0% abstained.

### 3. Special Public Comment Proposal

#### Data summary:

The Chair of the Liver and Intestine Committee (LIC) presented on their project: Eliminate the use of DSA and Regions in Liver Distribution.

Last December the LIC passed the policy of broader distribution through the Board of Directors, followed by critical comment in May and subsequently a lawsuit in July. As a result, EC and HRSA directed the LIC to come up with a new proposal that is in alignment with the Final Rule.

The LIC proposed two circle-based models. The liver distribution models are circles of two different sizes around the donor hospital. In addition, a change was made to NLRB passed by the Board in June 2017, but one component of that related to the Median MELD at Transplant (MMaT) for area of distribution, which was primarily the DSA. Because DSA had to be removed, the NLRB also had to be revised. The proposal therefore includes a different message to calculate MMaT, which is a circle-based model of 250 nm around the recipient hospital. For the NLRB, it is evaluation what the recipient is being exposed to in terms of what score is needed to access transplant.

Intestine and SLK policies were also addressed. The proposal for intestine was a large circle around the donor hospital (due to small numbers of intestine) of 500 nm. The SLK policy previously relied on the requirement that a kidney be shared with the liver for candidates with a score of 35 and above throughout the region. Since the region is being eliminated, the proposal is to change the threshold to a MELD score of 32 and a circle of 250 nm around the donor hospital. For candidates under 32, sharing would be at 150 nm around the donor hospital.

The pediatric population was also addressed. Pediatric donor livers will be offered to children nationally before being offered to adult recipients.

Existing variances were addressed. The Region 9 variance ended because it is not part of the current distribution model, but will keep the Hawaii variance and blood group O livers can be offered to blood group A recipients before going to broader sharing. For policy clarification, O livers will be allocated to B candidates before A and AB candidates; allocation of livers for other methods of hepatic support and MELD less than 6 was simplified; removal of references to local, DSA and region; clarification to exception criteria.

The two proposed liver distribution models are referred to as the B2C or ladder model and the acuity circles model. Both models use sizes of 150, 250 and 500 nm around donor hospital; have sharing thresholds at certain MELD/PELD scores, have capped standard exception scores; prioritize pediatric candidates for pediatric donors; DCD and donors at least 70 years old are allocated to 150 nm circle first.

- **Acuity Circles Model.** A table was shown to illustrate the acuity circles regular adult (not DCD or over 70) allocation sequence for liver. The first circle is 500 nm for status 1A and 1B around donor hospital. Then there would be a smaller 150 nm circle for the sickest patients MELD 37-40, a 250 nm circle for MELD 37-40, and then 500 nm circle for MELD 37-40. This would serve as a surrogate for population-based circle so the liver would only go to the larger circle if there were no patients MELD 37-40 and would only travel if it has to. Then the circle would go down by bands 33-36, with the same idea of smaller, bigger and then biggest circle. Then down to 29 in the same way, 150, 250 and

500 nm circle. Then there is a broad group of patients from 15 to 28 where it is 150, 250, 500 nm and then national.

- **B2C (Ladder) Model.** Again, a table was shown to illustrate the B2C adult allocation sequence for liver. The first circle is 500 nm for status 1A and 1B around donor hospital, followed by 250 nm circle at threshold of MELD 35/32/maybe 29, followed by 150 nm from MELD 15-28/31/34 depending on previous MELD. Then it goes to 250 nm, 500 nm, and then national.

The modeling data that the LIC reviewed shows the variance in MMaT in current model is 9.97 and in the Board-approved model from 2017 was 7.41. The acuity circle 250/500 model performs the best at 4.33 and 300/600 was 4.07. The broader two-circle model at MELD 32 or 35 also improved the variance over the 2017 liver policy.

Median transport times in hours for livers are similar for the Board-approved model and the current model, and will increase slightly for each of the circle-based models. Median transport distances in miles and percent of organs flown again increase with all the circle-based models.

After reviewing the data, the LIC went back and forth between the two models and different thresholds. A slim majority (received 10 votes) supported sending out the broader two-circle model at MELD of 32 for public comment, but would still like feedback on the acuity circles model (received 8 votes). The broader two-circle at MELD of 29 has not yet been modeled, but is still worth considering.

#### Summary of discussion:

HRSA reviewed the draft proposal. They felt the LIC was able to put together a very comprehensive proposal under heavy scrutiny and heavy time constraint. They did have a couple of edits to strengthen the proposal against legal challenges.

HRSA suggested edits include:

- The supporting evidence needs to be further elaborated explaining why variance/time/distance factors overrule clinical factors and result in choosing a different option and it is not just Committee opinion.
- Justification for MELD 32 is difficult, given that the proposal identifies 29 as a point of inflection for clinical value of the proposal, which will need to be addressed in some way. There may need to be additional SRTR modeling.
- Include all relevant previously-modeled options that meet the requirements of removing DSA and region. This will provide greater flexibility to the Board of Directors when making their decision about alternatives. If everything is put out for public comment again, there will be no question about the Board choosing one of those options.

One member asked what further elaboration of the supporting evidence needs to look like. The HRSA representative stated that OPTN Board and EC are responsible for determining sufficient evidence, but HRSA would look at it. The requirement from July was that there needs to be a written rationale and evidence to support why one geographic boundary would be chosen over another. The LIC Chair asked how best to frame the evidence, as she feels they tried to consider the numbers when coming up with the proposal. However, there is only slight difference between MELD 32 and MELD 29, which is why they would like feedback from the community.

For clarification, HRSA does not feel further data analysis, nor a major rewrite of the proposal is necessarily. What is needed is language to connect the data points and explain what the

evidence is saying. What does the difference between 60.8 and 71.4 actually mean and why does that justify choosing 6.54 over 4.33?

The POC reviewed the proposal and had comments. POC members asked for cost for members to implement broader distribution, asked for clarity about the overall goal eliminating DSAs and regions as the basis for the change, and there was a particular concern about addressing broader sharing and shifting resources from more vulnerable populations into other areas. They wondered if upon more modeling of lower MELDs, the trends would go down further or if the curves would flatten; however, there is not enough time to do further modeling. Therefore, the POC recommended that it be released for public comment.

A motion was made and seconded to move the proposal forward. Discussion was then open to Executive Committee members.

One comment was that it would be helpful if HRSA could indicate exactly what data is needed, so if there is a real concern, that it will be addressed. Guidance around the vulnerable populations would be especially helpful. The HRSA representative will look into providing more clear guidance.

There was agreement with HRSA on putting previous liver models and previous options out for public comment as well. One question was regarding the expedited timeline and whether it remains the same. HRSA confirmed that the timeline still holds in place to allow time for public comment before consideration by the Board of Directors.

There was also agreement with putting out both MELD of 29 and 32 for public comment. One comment was that additional data was needed for 29. There was agreement that there would be benefit to modeling for MELD 29.

For clarification, to be included with the proposals for public comment will be background information describing the different frameworks the LIC looked at in the last couple of months so people can read more about those. In the public comment tool itself, more targeted feedback, rather than more general feedback, will be requested on the proposals. The public will be asked to rank the 6 models that SRTR simulated (including 8-district model and neighborhoods model). OPTN will make the decision on what to include and whether to rank models or not.

The EC's task today is to approve what is before them with the LIC, but the public comment would go out with the other models mentioned above.

One comment was that another congressional letter went up to the HHS Secretary asking for a delay. HRSA did receive the letter and it is currently under review.

One member asked if there was consideration for skipping the 150 nm circle and moving straight to 250 and then 500 in the models. This was not considered by the LIC. There is a higher volume of liver transplants than thoracic, so as a matter of volume and allocation, they wanted to have a limited area.

One suggestion was given related to cost. The reason that miles and percentages of organs flown is important is because of increases in cost per transplant due to jet fuel. Not achieving more transplants due to this is troublesome. If the data exists, it might be useful to estimate costs into dollar amounts with the increase or decrease in transplants.

One comment was that HRSA has suggested putting out all previous modeling for public comment, but previous modeling has already gone through public comment in the past and the community has already weighed in on the prior models. Another member agreed with the above and suggested putting out only what the LIC has now, unless HRSA comes out with a letter with a strong statement saying previous models should be included. When the LIC looked at this issue over the last several years, everything looked at has been compliant with the Final

Rule, specifically Section 8, but there was significant concern that the other sections were ignored.

For clarification, HRSA is not suggesting all the models that have ever been considered be re-released. The suggestion is for only the models that meet the requirements of removing DSA and region for distribution be released, which is likely just a few. HRSA does not have a preferred outcome; it is up to OPTN to make the decision.

One member suggested not using "DSA" in the language at all since that is what they are trying to move away from. Including comments about DSA might be confusing for people trying to sort through the options that have been presented. However, as an administrative unit, DSAs are not going away and will still be used by OPOs. A review was done of distribution policies for use of DSA, so this proposal cleans those up so that the references to DSA will be only administrative in nature. Changes were not made to other areas of policy or bylaws (other than in allocation).

The EC Chair agreed with getting information on MELD 29 versus 32, expanding rationale around cost, and getting something from HRSA regarding vulnerable populations to add clarity to the discussion.

UNOS staff then described the actual public comment document itself. There is a section that starts off with liver allocation frameworks, listing 4 or 5 frameworks that the Committee considered over the last couple of years. UNOS added in sentences stating that the Board and the Committee will have the discretion to consider any of the models that previously modeled by SRTR and meet the requirements of removing DSAs and regions, as well as decreasing variations in geographic disparity across the country. Secondly, paragraphs were added describing the three geographic framework proposals with links on where to find more information about those.

Other specific questions include what the MELD sharing threshold should be, as well as recommendations for fixed distance circles and whether they should be smaller, larger, or remain the same. A question will also ask for public opinion on the proposal in the form of support, oppose or neutral. A large text box at the end will be provided for feedback on the overall proposal.

The LIC Chair brought up a final concern. If there are too many options, it will be more difficult to get a consensus. Presentation decisions will be worked out by the Liver Committee leadership to make the questions clearer.

The Executive Committee then voted on approving the Liver and Intestine Committee proposal for "Eliminating the use of DSAs and regions in liver and intestine distribution" as described today.

Results were 100% yes; 0% no; 0% abstained.

### **Upcoming Meetings**

- November 14<sup>th</sup>, 2018
- December 3, 2018 (@ Dallas)
- January 15, 2018