

OPTN Liver and Intestinal Organ Transplantation Committee

Meeting Summary

October 22, 2019

Chicago, Illinois

James Trotter, MD, Chair

James Pomposelli MD, PhD, Vice Chair

Introduction

The OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) met in Chicago, Illinois on 10/22/2019 to discuss the following agenda items:

1. Committee Charge Review
2. Policy Oversight Committee (POC) Report
3. Public Comment Update
4. Lawsuit Update
5. NLRB Four-Month Report
6. NLRB Subcommittee Report
7. Hawaii and Puerto Rico Subcommittee Report
8. OPOM Presentation
9. Open Session

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

1. Committee Charge Review

All OPTN Committees are being asked to review their current charges and update if necessary. The Committee reviewed their charge.

Summary of discussion:

The Chair presented the Committee's charge for review. A Committee member suggested that the charge give the Committee purview over liver disease patients, not just transplant candidates. The Committee unanimously supported the suggested change to the charge, but ultimately determined it was too broad of a change. The Committee decided to recommend approval of the following charge:

"The Liver and Intestine Transplantation Committee considers medical, scientific, and ethical aspects related to liver and intestine organ procurement, distribution, and allocation. The committee considers both the broad implications and the specific members' situations of these liver or intestinal issues or policies. The goal of the Committee's work is to develop evidence-based policies aimed at reducing the burden of liver disease in transplant patients (candidates and recipients), increasing liver utilization, improving access to liver transplantation, and improving the health outcomes of liver transplant recipients."

A formal vote was taken regarding: do you support sending the charge to the Board of Directors for approval?

Results were as follows: 14 (88%) Yes; 1 (6%) Abstain; 1 (6%) No

Next steps:

The charge will be sent to the BOD for final approval during their December meeting.

2. Policy Oversight Committee (POC) Report

The Vice Chair provided an update on the work of the POC.

Summary of discussion:

The Vice Chair provided an overview on the strategic policy priorities that have been developed by the POC. The Committee discussed how the POC prioritizes projects and it is expected to take a more active role in project approval. The Committee agreed to discuss potential project ideas that align with the strategic policy priorities during the open session portion of the agenda.

Next steps:

The Committee will discuss new project ideas later in the agenda.

3. Public Comment Update

The Committee discussed their public comment proposal to clarify the definition of pre-existing liver disease and their special public comment proposal on the units of distribution used in the closed split liver variance.

Summary of discussion:

The Chair presented an overview of the public comment submitted on the pre-existing liver disease proposal. A Committee member noted that the clarification is beneficial to patients, as they should not be disadvantaged by having received a prior liver transplant. The Committee discussed the rationale for using 56 days as the cutoff for onset of hepatic encephalopathy (HE). The Committee noted that this cutoff is based on the clinically-agreed upon definition. The Committee discussed if the clarification could have any unintended consequences such as including patients with chronic rejection as Status 1A. The Committee continued to discuss clinical aspects of the clarification, particularly regarding what conditions constitute fulminant hepatic failure. The Committee noted that children often have fulminant hepatic failure without HE or without HE that can be measured. This makes fulminant hepatic failure harder to define in children. The Committee agreed that there may be additional changes to consider in the future in order to improve the requirements for pediatric candidates. The Committee discussed the best way to word the policy language. Committee members suggested changes to the proposed language.

A formal vote was taken regarding: do you approve sending the modified policy language to the BOD for approval?

Results were as follows: 16 (100%) Yes; 0 (0%) Abstain; 0 (0%) No

The Committee then discussed the responses received to date on the special public comment proposal to align the units of distribution used in the split liver variance with the units of distribution used in the allocation of deceased donor livers. A Committee member asked if there are other policies, specifically increased pediatric priority, that could be implemented while the Acuity Circles policy is tied up in litigation. UNOS staff clarified that the pediatric priority is linked to Acuity Circles in such a way that it cannot be implemented without Acuity Circles.

Next steps:

The clarification of pre-existing liver disease and the proposal to align the units of distribution used in the split liver variance will both be considered by the BOD at their December meeting.

4. Lawsuit Update

The Committee received an update on the ongoing litigation regarding the Acuity Circles policy.

Summary of discussion:

Committee members asked about the timeline for implementation of the Acuity Circles policy if the decision is made by the courts that Acuity Circles can be implemented. The Committee was informed that there will be at least 14 days of notice given to the transplant community prior to the implementation of the Acuity Circles policy. Committee members asked for additional communication for the general public. UNOS staff noted that the UNOS website contains information regarding the litigation.

Next steps:

The Committee will remain updated on the implementation status of Acuity Circles.

5. NLRB Four-Month Report

The Committee reviewed the results of the four-month National Liver Review Board (NLRB) Report.

Summary of discussion:

After reviewing the results of the report, the Committee discussed the results for the pediatric population specifically. A Committee member noted that there has been a decrease in the number of pediatric transplants after the implementation of the NLRB. The Committee also noted that the percent of approved forms for pediatric exceptions has decreased. The Committee suggested looking at data more specific to the pediatric population and that breaks out pediatric end-stage liver disease (PELD) scores from model for end-stage liver disease (MELD) scores. The Committee was informed that the Pediatric Committee is already working on a data request for this and it will be shared with the Committee when complete.

Another Committee member commented that the number of denied forms may seem high because forms are being denied at one score and then approved at a lower score. A Committee member also asked for more data on the number of exceptions by region, as the number of exception in some regions has increased substantially.

Next steps:

The Committee will continue to monitor the results of the NLRB and will review the pediatric data request when it becomes available. The Committee will also receive an updated report after the policy has been in effect for at least 6 months.

6. NLRB Subcommittee Report

The NLRB Subcommittee Chair provided an update on the work NLRB Subcommittee. The Committee is slated to have a public comment proposal to update the NLRB Guidelines, NLRB Guidance, and policy language in the spring public comment cycle.

Summary of discussion:

The Committee discussed the proposed changes to the NLRB Guidelines, NLRB Guidance, and policy language.

Guidelines:

The Committee discussed adding an explanation to the guidelines on what reviewer decisions should be based upon, especially when there is no clear guidance or policy. A Committee member suggested

adding language to the guidelines saying that reviewers should consider comparable conditions in such instances. The Committee also decided to make small, stylistic changes to the proposed language.

The Committee discussed changing the threshold for removing inactive reviewers from the NLRB. The Committee agreed to change the language regarding the removal of inactive reviewers to have a threshold based on the percent of cases missed that were assigned. They also agreed to change the requirement to remove inactive reviewers so that removal is done at the discretion of the NLRB Chair, instead of mandatory removal. The Committee then agreed to add language outlining what counts as a failure to vote.

The NLRB Subcommittee chair presented the clarification to the guidelines outlining that final appeals will be heard by the NLRB Subcommittee as opposed to the full Committee. The Committee agreed with this clarification.

Guidance:

The Committee discussed updating the guidance for hepatocellular carcinoma (HCC), specifically that the requirement for HCC candidates to have met T2 criteria within the last two years only applies for the initial request and not extensions. The Committee agreed that the current guidance is confusing and it should be clarified.

The NLRB Subcommittee Chair presented the recommendation to add adult metabolic disease to the guidance. The NLRB Subcommittee Chair noted that there had not previously been any guidance for metabolic disease and that they will monitor the metabolic disease cases to see if it should eventually be added to policy so that these cases are auto-approved. A Committee member suggested not including a prescriptive exception score for adult metabolic disease to better align with the guidance for other conditions.

The NLRB Subcommittee Chair presented the Subcommittee's recommendation to add language to the section in guidance for polycystic liver disease (PLD) to consider giving patients also requiring a kidney transplant a score equal to MMaT. The Committee discussed adding guidance related to the presence of certain comorbidities for PLD as well. The Committee agreed to keep discussing this section of the guidance. A Committee member again suggested that there not be prescriptive MELD exception scores in guidance.

The NLRB Chair presented the subcommittee's recommendations for changes to the guidance for primary cholangitis to also include secondary cholangitis. The Committee had no comment.

Policy:

The NLRB Subcommittee Chair presented the Subcommittees recommendations for reducing the number of HCC cases going to the review board. The NLRB Chair noted that the Subcommittee suggested language to allow automatic extensions of HCC candidates as long as they meet the regular extension criteria, even if they were not initially auto-approved. This would reduce the number of cases being reviewed by the HCC review board. The Chair stated that there should be a template to make it clearer when programs should submit an exception to the HCC review board or the Adult Other review board. The NLRB Subcommittee Chair then presented the proposal to clarify the language for updating the median MELD at transplant (MMaT) scores. The Committee had no comments.

Upcoming Work:

The NLRB Chair then presented some of the upcoming work of the NLRB Subcommittee. The Committee discussed ways to review the reviewers to ensure that they are providing consistent comments. The NLRB Subcommittee Chair noted that the Society for Pediatric Liver Transplantation (SPLIT) completed a

survey about the NLRB and had some suggestions for updating the pediatric guidance document. The NLRB Subcommittee Chair stated that the Subcommittee will consider this feedback during the next round of public comment. Also, the Committee has submitted a data request to get more insight on HCC auto-approval turn down reasons. The NLRB Subcommittee Chair informed the Committee that after they review the one-year data report, they will then consider if any of the diagnoses in guidance could move into policy. The NLRB Subcommittee Chair stated that the Subcommittee has discussed creating a template for submitting exception cases to help members submit more structured forms. The NLRB Subcommittee Chair presented the possibilities of creating a pediatric specific Appeals Review Team (ART) and adding a Committee member to each ART. The NLRB Chair also suggested providing more education to ART participants and to the liver transplant community generally. The NLRB Chair then asked the Committee if there should be a way for the MMaT for the area of distribution to be seen when reviewing PELD requests. A Committee member noted that this may not be helpful.

Next steps:

UNOS staff will send out updated language and the Committee will vote on what to send to public comment during their next meeting.

7. Hawaii and Puerto Rico Subcommittee Report

Candidates with high MELD/PELD scores or listed as Status 1 have access to regionally-shared organs under the current allocation system. However, there will no longer be regions under the Acuity Circles policy. A Work Group has been meeting to come up with potential solutions to allow high MELD/PELD and Status 1 candidates listed in Hawaii and Puerto Rico to maintain sufficient access to donor organs in the short period of time in which candidates of such medical urgency would need access.

Summary of discussion:

The Chair presented the concerns raised for candidates listed in Hawaii and Puerto Rico. The Chair then presented the options being considered to address the concerns. The options considered were:

- Creating a large circle around Hawaii and Puerto Rico to give candidates listed in these areas access to donors in the contiguous US
- Create an alternate virtual location for the candidates at Seattle-Tacoma Airport (Sea-Tac) and Miami International Airport
- Allow OPOs who are willing to opt in to a variance to give additional access to Hawaii and Puerto Rico

A Committee member commented that the timeline for coming up with a solution is important because if the Acuity Circles policy goes into effect without a solution, then candidates in Hawaii and Puerto Rico could potentially be disadvantaged. The Committee member suggested that the implementation of the solution align with implementation of Acuity Circles. The Chair noted that the proposed solutions involve uni-directional allocation.

A Committee member noted that Hawaii currently receives regional shares from Region 6 and they would prefer to maintain a similar relationship. The Chair asked how they could justify a system that would approximate the current relationship between Hawaii and Region 6. The Committee member noted that there is also low organ availability in Region 6 so it makes sense to group them with Hawaii so they can distribute organs together.

The Committee then discussed the timeline for implementation of a potential solution. A Committee member reiterated that the solution should be implemented as close to the implementation of Acuity Circles as possible. The Committee considered that creating a variance could be the quickest way to get

a solution implemented. A Committee member noted that there are other variances for Hawaii that are based on its geographic isolation. A Committee member was unsure that OPOs would volunteer to participate in a variance with uni-directional sharing so the Committee would need to be more prescriptive. The Committee reviewed data on weekly donor availability by DSA.

The Committee continued to discuss the virtual-listing solution. A Committee member noted that there are airports closer to Hawaii than Seattle, so it would be difficult to justify using Sea-Tac as a location for virtually-listing candidates in Hawaii. The Committee was informed that this solution would be the most difficult to operationalize from an IT perspective. A Committee member noted that the Hawaii OPO may not perform as well as other OPOs so it could be better to improve donation in Hawaii than make a variance for one part of the country that is different than the rest of the system.

The Committee was informed that this project could potentially go out for special public comment but that it would still require time to implement. The Committee discussed the variance solution and that it would be outside of the system so could be a short-term fix until something is implemented in the system. The Committee took an unofficial vote to gauge sentiment and the majority of Committee members supported virtual-listing.

Next steps:

The Committee agreed that there is urgency to figure out a solution to this problem and agreed to discuss more at their next meeting.

8. OPOM Presentation

The Committee heard a presentation on the optimized prediction of mortality (OPOM), a score developed as a potential alternative to the use of MELD.

Summary of discussion:

The researchers who developed the OPOM score presented their research to the Committee for their feedback. Committee members provided substantial feedback on OPOM and ultimately agreed that the results were encouraging.

Next steps:

The Committee will remain updated on the development of the OPOM score.

9. Open Session

Committee members discussed new project ideas and other items.

Summary of discussion:

A Committee member commented that there is a need to look critically at pediatric organ allocation. The member suggested creating an ad hoc committee to develop principles or a framework for pediatric allocation across the organ systems.

The Committee then discussed continuous distribution. The POC will be determining the sequencing of continuous distribution at their next meeting. On the topic of multi-organ equity, the Committee noted that many multi-organ combinations are not explicitly addressed in policy. A Committee member asked if there have been any discussions about inequity in transplant for females. A Committee member noted that the closed split liver variance should help with this. Another Committee member commented that a more scientific method, such as surface area, could be used to match organs. A Committee member suggested that the Committee consider a project looking at organ utilization practices.

Next steps:

The Committee will continue to discuss future projects at upcoming meetings.

Upcoming Meetings

- November 19, 2019 – Teleconference
- December 6, 2019 - Teleconference