

**OPTN Liver and Intestinal Organ Transplantation Committee**  
**Meeting Minutes**  
**December 7, 2018**  
**Conference Call**

**Julie Heimbach, MD, Chair**  
**James Trotter, MD, Vice Chair**

**Introduction**

The Liver and Intestinal Organ Transplantation (Liver) Committee met via teleconference on 12/7/2018 to discuss the following agenda items:

1. Split Liver Variance
2. Board Update

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

**1. Split Liver Variance**

In an existing variance in region eight, transplant centers can choose to split a liver and utilize either the anatomic right lobe or the anatomic right tri-segment in the patient that the liver was allocated to and then use the anatomic left lobe or the anatomic left lateral segment for another candidate at their center that appeared on the same match run, or a candidate at an affiliated pediatric center who appeared on the same match run. Transplant hospitals and Organ Procurement Organizations (OPOs) in region eight unanimously agreed to request a new variance for the transplantation of split livers that would expand the parameters of their current variance. The variance as proposed by region eight would permit a transplant hospital in region eight to split a liver and use any segment of the liver in the patient that the liver was allocated to and then use the remaining segment for another candidate at their center or an affiliated center if it was not accepted by candidates at Status 1 or with a model for end-stage liver disease (MELD) or pediatric end-stage liver disease (PELD) score of 33 or higher at liver transplant programs within 500 nautical miles (NM) of the donor hospital.

At the December 3, 2018 OPTN Board of Directors (Board) meeting, an amendment to the policy to *Eliminate the use of DSAs and Regions in Liver Allocation* was offered by a member of the Board. The amendment would have created a variance modeled after the one requested by region eight, except it would not have been limited to just region eight. Like the variance requested by region eight, the amendment would have created a variance that allowed any participating liver transplant hospital to split an allocated liver, and transplant the first liver segment into the candidate to whom the organ was allocated, while transplanting the second liver segment into a candidate registered at the same transplant program. After some discussion by the Board, the amendment was voluntarily withdrawn by the sponsor with a request that the Liver committee consider broadening the concept of a variance for region eight to permit any region to join.

Summary of discussion:

The chair reminded the committee of the new split liver variance that was requested by region eight. In this variance, livers transplanted in region eight (no matter where they were recovered) can be split and the second segment can be kept at the same program or an affiliated program, after first offering the segment to Status 1 candidates within 500NM of the donor hospital and then to candidates with MELD/PELD of 34 or higher within 250NM of the donor hospital. When this variance was discussed it was within the context of the Broader-2-Circles (B2C) allocation

model. Additionally, the variance applied to any type of split liver and it required transplant hospital to document refusals.

The chair informed the committee that a member of the Board presented the variance as an amendment to the policy to *Eliminate the use of DSAs and Regions in Liver Allocation* at the Board meeting on December 3, 2018. The sponsor of the amendment wanted the variance to be open to all transplant hospitals, not just those located in region eight. Ultimately, the Board member withdrew the amendment, but asked the committee to consider opening the variance to allow other regions to participate. The committee must decide whether they want the variance to be open, opt-in/opt-out, or closed in the public comment proposal.

The chair also asked if the committee wanted the distribution threshold for the liver segment not being used for the primary recipient to be Status 1 candidates within 500NM and then MELD/PELD 37-40 or MELD/PELD 33-40 within 500NM of the donor hospital. Some of these waitlist candidates would have already seen the original offer unless it was an offer from a pediatric donor, which would have been allocated to a pediatric candidate first. The intent of this threshold would be to make the allocation sequence more closely imitate that of the Acuity Circles (AC) Model.

The other question for the committee was whether the candidate for the second liver segment must appear on the same match run as the candidate for whom the liver was originally accepted. It is unlikely that the candidate for the second segment would not appear on the original match run. The chair asked the committee for input on these topics.

A committee member noted that the variance being discussed is a variation of the existing split liver variance, wherein a transplant program can elect to split a liver and utilize either the anatomic right lobe or the anatomic right tri-segment in the patient that the liver was allocated to and then use the anatomic left lobe or the anatomic left lateral segment for another candidate at their program that appeared on the same match run, or a candidate at an affiliated pediatric center who appeared on the same match run. Because there is an existing variance, there is precedent for having a split liver variance and the committee member supported opening the variance to transplant programs outside of region eight.

Another committee member noted that programs without a pediatric component will take the left lateral segment and keep the right tri-segment, which could disadvantage pediatric patients who might otherwise be candidates for the left lateral segment. The chairs stated that the variance might not work for all regions, which is why they can make the variance optional. The chair further clarified that the variance would be a three-year demonstration project.

Another committee member mentioned that in the AC model, organ distribution goes beyond regional boundaries so it may be unfair for some regions to adopt the variance and be able to split livers while others do not participate. The committee member suggested making the variance open to everyone.

A committee member noted that in many areas of the country, the right tri-segment goes down the match run and is allocated fine. Pediatric centers would likely support the variance, but adult centers without an affiliated pediatric centers might not support the proposal.

The chair stated that when the proposal is put out for public comment, the committee can ask if the variance should allow for any type of split. There is already a national split liver policy where if a center uses the left side of the liver, they can keep the right side. A committee member noted that splits where the first candidate receives the left segment are not commonly done. Under the current policy, if a center does a split and uses the right side for the adult that the liver was allocated to, the center can keep the left side of the liver. However, if the program gives the left side to the adult that the liver was allocated to, then they cannot keep the right side of the

liver. The committee member noted that being able to keep the right side would be appealing to adult programs. A left lateral segment/right tri-segment split is done for many pediatric candidates regardless.

Another committee member stated that splitting is not done often enough because optimal splitting is done *in situ* and transplant programs are not traveling to do split livers. Another issue is deciding on the division of the vessels. The committee member also noted that transplant programs will fly out to procure an organ, take it back to their transplant center to split the organ, and then offer the right tri-segment, which adds cold ischemic time to the right tri-segment. The committee member thought that the variance should be a demonstration project in region eight that will be evaluated in three years.

Another committee member brought up the idea of fairness and stated that livers will still be allocated to the number one candidate in the sequence, and the liver program can decide to split. No one is being disadvantaged by this. The committee member supported the idea of being able to keep either segment.

The chair again asked the committee to consider whether the variance should be offered to any region that wants to participate and if they should ask in public comment if the variance should apply to any type of split. The chair suggested that both of these questions be put out for public comment and reminded the committee that the Board supported not limiting the variance to region eight.

A committee member stated that the variance would be controversial in his/her region. The committee member asked to see data on how often segments are discarded.

The chair suggested asking in public comment if each region would want to participate in the variance. The committee member who stated that the variance would be controversial was satisfied with this idea. The chair noted that there are regions that will not want to participate, but there are regions beyond region eight that would want to participate.

Another committee member asked how a demonstration project such as this variance would take place within the AC model. When the variance was first discussed, it was limited to livers that were recovered and allocated in region eight. Regions still exist as administrative units, just not for the purposes of liver allocation. The original variance was updated to include any liver that was allocated to region eight, no matter where the liver was recovered.

A committee member noted that regions adjacent to the regions that elect to participate in the variance may be disadvantaged. For example, if a liver is recovered in one region and allocated to a region participating in the variance, the participating region can then split the liver and keep both segments, bypassing candidates in the region where the liver was recovered for the second segment. The committee member supported the notion of a demonstration project and mentioned the idea of allocating each liver that could be split to pediatric candidates over a certain MELD/PELD in the future.

Another committee member mentioned that the concern about allocation of the second segment is not valid because the second segment will be offered to Status 1 candidates and then candidates above a certain MELD/PELD within 500NM of the donor hospital. The committee member who brought up the concern about allocation of the second segment thought that the allocation sequence previously described would make the variance more acceptable.

A committee member from region eight stated that the variance would increase splitting and efficiency, but the committee member noted that the variance is not universally popular and it should be opt-in. The committee member also anticipated controversy due to the 500NM sharing. The chair stated that the purpose of public comment is to identify potential

controversies and understand what the country is comfortable with doing. The public may suggest that the variance be limited to only livers recovered in participating regions. The chair asked if the committee member wanted to include limiting the variance to livers recovered in participating regions as a question in public comment. The committee member thought that this would be a good question to ask in public comment and suggested not asking about which types of splits should be included in the variance.

Another committee member, who is a pediatric hepatologist, stated his/her support for any split liver strategy. The committee member stated that other regions should be able to opt in/out because the variance will affect many regions due to broader distribution. More regions participating would also allow for quicker learning.

The chair asked the committee for their opinions on the need for transplant hospitals to document refusals. She asked if the documentation would just be the turn-down codes or if more documentation was needed. A committee member from region eight stated that they were intending to just use the turn-down codes. There was no objection to this.

The chair asked the committee if there should be a built-in outcomes review after three years and which metrics should be tracked as part of this review. The chair recommended patient/graft survival, number of split livers performed, age (adult vs. pediatric) and gender of recipients. A committee member suggested tracking the number of cut-downs in the regions that elected not to participate in the variance. Another committee member suggested tracking the number of right tri-segments used, the number of right tri-segments discarded, and the MELD/PELD score of the candidates allocated the right tri-segment. The committee member was interested in seeing if the right tri-segments are being allocated to a candidate group that is traditionally disadvantaged such as women or smaller adults.

Another committee member noted that the variance still disadvantages adult-only programs with small women candidates. These candidates are not getting access to the same livers. The chair agreed with this concern.

In the existing split liver variance, representatives from participating regions agreed to meet after the first ten segmental liver transplants performed as a result of the variance, and each ten thereafter, to review outcomes. The chair asked the committee for feedback on this aspect of the variance. UNOS staff supported the idea of representatives discussing results but stated that the interventional oversight of the variance should be left to the Membership and Professional Standards Committee (MPSC).

A committee member asked if the variance will allow programs to not fly out to split a liver but instead bring the entire liver back to the transplant program and split it there. A committee member from region eight stated that the variance was appealing because it would allow for more splitting for small women. A committee member again asked if the variance would increase pediatric splitting because it would not be necessary to send a team out to do an *in situ* split. A committee member stated that some centers might do this as a gaming mechanism to take the entire liver, but that would probably occur less under the variance. A committee member suggested tracking whether livers that are taken back to a transplant center are actually split or if they are re-allocated after being brought back to the transplant program. Another committee member reiterated that the liver is still allocated to the first person on the match run. The chair agreed to monitor late re-allocation as requested by the committee.

The chair stated that it seems like the committee has come to the conclusion to ask each region if they would want to participate instead of making it a closed variance. A committee member again suggested not asking about the specific types of splits that should be included in the variance during public comment. The committee member stated that asking for this information

would add an unnecessary level of complexity to public comment. The committee decided to not specifically ask about this but will still consider any feedback that is submitted. The committee will specifically ask if each region would like to participate.

The chair asked the committee again about whether the MELD/PELD threshold should be MELD/PELD 37-40 or MELD/PELD 33-40 at 500NM. The first level of distribution in the AC model is MELD/PELD 37-40 and the second level goes down to MELD/PELD 33. The chair stated that a threshold of MELD/PELD 33 at 500NM seemed reasonable. No one objected to a threshold at MELD/PELD 33-40 at 500NM.

UNOS staff asked the committee to clarify if the variance will be open. The chair stated that it will not be a fully open variance but it will be a variance that applies to regions that opt-in.

A committee member asked for the definition of an affiliated pediatric institution. Some programs have an affiliated adult institution, as well. The chair stated that they could change the policy language to say “affiliated institution,” instead of “affiliated pediatric institution.” A committee member asked if the two affiliated institutions would need to be under the same center code. There are affiliated adult and pediatric centers that have different codes so it cannot be mandatory that they are the same code. Another committee member asked if each pediatric center can have only one affiliated adult program. A committee member suggested that each pediatric program designate one affiliated adult program. A committee member mentioned remembering that affiliated pediatric programs either had the same name or were geographically close to the adult program in order to be considered affiliated. The chair asked if it was suitable to require each pediatric program to declare their affiliated adult program. Another committee member suggested changing the policy language from “affiliated” to “affiliated or partnered,” because some programs can be partners but not directly affiliated. A committee member asked if it is possible to affiliate with more than one program. The chair said that it might be possible if there is an adult program, a pediatric program, and a Veteran’s Affairs (VA) program. This is something that the committee could review if it occurs. There will also be pediatric programs that are not affiliated with any adult program. The committee agreed on making the programs that apply for the variance declare any affiliated programs as the solution.

UNOS staff presented the proposed policy language. Language on monitoring and the process to participate in the variance will be in the public comment proposal and evaluation plan. The chair asked the committee if the potential recipient for the second segment must be on the same match run used to allocate the liver. If they had to execute a new match run, there could be new candidates on the match run which would complicate the process. Adults are on match runs for pediatric donors and ABO incompatible candidates are on each match run.

A formal vote was taken regarding: send the split liver variance out for public comment?

Results were as follows: 8 (80%) Yes; 1 (10%) No; 1 (10%) Abstain

#### Next steps:

UNOS staff will draft a public comment proposal for the variance as voted on by the committee. The proposal will go out for public comment from January 22, 2019 to March 22, 2019.

## **2. Board Update**

#### Summary of Discussion:

The committee did not have time to discuss the outcomes of the Board meeting on December 3, 2018. However, the chair did state that the Board adopted the AC model. The National Liver Review Board (NLRB) webinar for the community will be on December 13. At their next call, the committee will discuss the concerns with the AC model which were distributed prior to the meeting as part of the slide deck.

Next Steps:

The chair asked committee members to think about the concerns about the AC model and be ready to discuss them at their next meeting.

**Upcoming Meeting**

- January 17, 2019