

**OPTN/UNOS Pediatric Transplantation Committee**  
**Meeting Minutes**  
**January 16, 2019**  
**Conference Call**

**George Mazariegos, MD, Chair**  
**Evelyn Hsu, MD, Vice Chair**

**Introduction**

The Pediatric Transplantation Committee (the Committee) met via teleconference on 01/16/2019 to discuss the following agenda items:

1. Public Comment – Split Liver Variance
2. Public Comment – Eliminate the Use of DSAs and regions from kidney and pancreas distribution

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

**1. Public Comment – Split Liver Variance**

As part of the spring 2019 public comment cycle, the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee is sponsoring a public comment proposal titled, “Split Liver Variance.” The intent of this proposal is to create a variance that would make it easier for participating programs to split a liver and allocate the second segment to another candidate listed at their program. The chair of the Liver Committee presented the proposal to the Committee and responded to questions and comments.<sup>1</sup>

Summary of discussion:

The original variance was proposed by Region 8, but the current proposal asks for public input on whether the variance should be restricted to Region 8 or if it should be open to other regions.

The variance attempts to address the fact that there are insufficient livers available by making it easier for programs to split livers into two segments that can be transplanted into multiple candidates. There are logistical issues under the current system that make it difficult to split livers for use at separate programs. There is an existing national split liver variance but it is not used often.

The proposal would create a new variance aimed at making splits happen more often. The variance would be in effect for three years, at which point it will be evaluated and reassessed. In the proposed variance, a participating transplant program can transplant one portion of a liver into the candidate to whom it was allocated and keep the second portion for another candidate at the same or an affiliated program. The second segment must first be offered to candidates that are listed as Status 1 or with MELD/PELD > 32 who are within 500 NM miles before being kept at the original program.

In current policy, if a program transplants the left lateral segment of a liver, the right side is then re-allocated according to the match run. Additionally, in the existing national variance, if the program transplants the right hemiliver or trisegment first, then they can keep the left segment.

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<sup>1</sup> The presentation of the “Split Liver Variance” proposal to the Pediatric Committee took place prior to the beginning of public comment. Before being approved for public comment, the OPTN/UNOS Executive Committee updated the proposal so that any interested program would be able to participate, instead of entire regions.

In this proposed variance, the transplanting program has the opportunity to keep either segment of the liver no matter which portion is transplanted first.

The chair of the Liver Committee noted that the OPTN/UNOS Board of Directors (the Board) supported this variance being open to all regions. The chair of the Liver Committee reiterated that this is a time-bound, demonstration project that will be reevaluated after three years. The Liver Committee chair then asked for questions and comments.

The chair of the Committee asked if the variance would apply to right lobe/left lobe splits or trisegment/lateral segment splits and whether a liver from an adult donor allocated to a pediatric candidate would be included. The Liver Committee chair clarified that the variance applies to any type of split and that pediatric donors will first be allocated to a pediatric candidate, but the recipient of the second segment could be an adult.

A Committee member suggested that any program should be able to participate, regardless of the region.

A Committee member asked if there is an incentive for a primary adult program to split a right trisegment. The chair of the Liver Committee stated that the incentive would be that the program can now keep both sides of the liver so they should be more willing to encourage an adult candidate to accept a split liver, allowing them to transplant the second segment into another candidate. The chair of the Liver Committee reiterated that this is a demonstration project and not a policy change. There could be unexpected outcomes and it is necessary to evaluate the impact of the proposal on all populations.

A Committee member asked how many adult programs are affiliated with a pediatric program. The chair of the Liver Committee did not have a specific number but noted that it is common.

The vice-chair of the Committee asked if Region 8 had any issues with the requirement to offer the second portion of the liver to high-urgency candidates within 500 NM because it reduces some of the incentive. The chair of the Liver Committee stated that this trade-off was included because the donor may not originate in the region to which the liver was allocated so it was important to offer the second segment to the most urgent candidates at a large distance. Additionally, it is not likely that programs will accept a split liver for their Status 1 or high MELD candidates so the second segment will often remain under the control of the original program.

A Committee member asked if the primary purpose of the variance is to benefit pediatric patients or to benefit all patients. The chair of the Liver Committee stated that the goal of the variance is to increase split livers which would be beneficial to all patients. Pediatric patients and small adults, in particular, should see a benefit.

A Committee member asked if it would be beneficial to target programs with a pediatric component for the variance. The chair of the Liver Committee stated that there is not an option to just target one type of program.

A Committee member asked how the variance would work with the new allocation system where region is no longer used for allocation. The chair of the Liver Committee stated that this would be the first time that a variance is implemented under the new allocation system but it is still feasible. The Committee member supported opening the variance to any program.

A Committee member asked about the outcomes of split livers. There is limited data on split livers for adults but outcomes are good for children.

#### Next steps:

The Pediatric Committee will submit a formal public comment based on the discussion.

## **2. Public Comment - Eliminate the Use of DSAs and regions from kidney and pancreas distribution**

As part of the spring public comment cycle, the OPTN/UNOS Kidney Transplantation and OPTN/UNOS Pancreas Transplantation Committees are sponsoring a public comment proposal titled, "Eliminate the use of DSAs and regions from kidney and pancreas distribution." This document is a concept paper (not a policy proposal) that explains a number of distribution models to replace the use of DSA and region in kidney and pancreas allocation. The drafting of the concept paper was led by a workgroup of representatives from a number of committees including the Kidney, Pancreas, and Pediatric Committees.

### Summary of Discussion:

The chair of the Kidney Committee presented the concept paper. The intent of the document is to remove the use of DSA and region in kidney, kidney-pancreas (KP), and pancreas allocation. This would better align allocation policies with the Final Rule and would help move kidney, KP, and pancreas allocation towards the single, unified allocation framework as directed by the Board.

The solutions in the document do not represent a definitive list of policy options, but simply provide some potential frameworks. The workgroup has not made any formal decisions about a particular framework. Most importantly, the workgroup is seeking input on framework type and variation of policy option characteristics such as circle size and proximity endpoints.

The concept paper included five different proposed solutions:

- A fixed concentric circle framework with a 150 NM small circle and a 300 NM large circle
- A fixed concentric circle framework with a 250 NM small circle and a 500 NM large circle
- A fixed concentric circle framework with a single 500 NM circle
- A hybrid framework with a single 500 NM circle that utilizes a small (shallow) number of proximity points inside and outside the circle
- A hybrid framework with a single 500 NM circle that utilizes a large (steep) number of proximity points inside and outside of the circle

The chair of the Kidney Committee noted that none of these solutions are perfect, but they are useful to compare to each other and to give multiple variations from which to choose. In the hybrid models, proximity points would be awarded to candidates according to the distance from the donor hospital to the transplant program at which the candidate is listed. In the shallow hybrid model, candidates inside the 500 NM circle are awarded up to one proximity point and candidates between the 500 NM and 2500 NM circles are awarded up to two proximity points. In the steep hybrid model, candidates inside the 500 NM circle are awarded up to two proximity points and candidates between the 500 NM and 2500 NM circles are awarded up to four proximity points.

The workgroup received modeling on organ travel distance for each of the models. There is not much difference in organ travel distance between the shallow and steep hybrid models. There is a slight difference between the fixed concentric circle models.

The workgroup also looked at transplant rates and counts. It is difficult for the Scientific Registry of Transplant Recipients (SRTR) to model these metrics because the data comes from the DSA-based allocation system. Nonetheless, transplant rates and counts were predicted to decrease with each of the models. This is a concern of the workgroup. However, pediatric transplantation was not negatively impacted by any of the models.

The workgroup is asking for feedback on which of the variations is a better replacement than current policy. Feedback should be grounded in evidence tied to the Final Rule. The workgroup

is also asking the transplant community to indicate their preference between the fixed concentric circle model and the hybrid model. And finally, the workgroup is asking for feedback on if pancreas and kidney allocation systems should be changed separately.

The chair of the Kidney Committee then asked for questions. A Committee member asked why the workgroup did not propose a fully continuous distribution model. The chair of the Kidney Committee stated that this is because the workgroup did not have time to do this and the hybrid model is the closest to continuous distribution.

The chair of the Committee asked if it would be possible to include assigning points to candidates based on certain clinical characteristics in the new distribution system. The chair of the Kidney Committee stated that this is something that could be looked at in the future but the workgroup was focused on assigning points based on distance from donor hospital at this time. The idea of assigning proximity points was to assign some local priority but also to not have organs travelling long distances for similar candidates. The chair of the Kidney Committee noted that the workgroup was conservative in their point values, and they may need to be increased to have a significant impact. Also, the steep hybrid model will keep organs more locally, as opposed to the shallow model.

A Committee member commented that any new policy should not cause longer cold ischemia times or reduced access for pediatric candidates who are getting pre-emptive transplants. The chair of the Kidney Committee stated that the workgroup was given permission to change the kidney allocation system (KAS) while working on the current project and the Kidney Committee unanimously voted to move pediatric candidates up in the allocation scheme so that they are behind the 100% CPRA candidates but in front of the 99% and 98% CPRA candidates. The chair of the Kidney Committee then noted that broader sharing does create the potential for longer cold ischemia times for all populations, but programs can choose not to accept offers that travel long distances.

A Committee member was concerned that all of the models will decrease transplant rates and counts. Additionally, the Committee member felt that allocation changes to kidneys and pancreata should be done separately due to the differences in cold ischemia time that each can handle. The Committee member also commented that there should be some consideration given to ensuring that pediatric candidates maintain access to low KDPI kidneys and they are not overly-allocated to multi-organ transplant (MOT) candidates. The chair of the Kidney Committee stated that the modeling is not perfect, which is a known limitation. Second, the modeling did show positive results for vulnerable populations, including pediatrics. And finally, the chair of the Kidney Committee stated that they would like to address MOT transplantation but this would involve many other committees and is outside of the scope of their current work.

A Committee member asked if there was any discussion about moving pediatric candidates to the same place in Sequence C as they are in Sequences A and B. Many of the pediatric donors in Sequence C are allocated to adults, but there are pediatric candidates who could utilize these kidneys. The chair of the Liver Committee stated that the new dual and en bloc policies could help this issue. However, this may be something that the Kidney Committee could look into in the future.

#### Next Steps:

The Pediatric Committee will submit a formal public comment based on the discussion.

#### **Upcoming Meeting**

- February 20, 2019 teleconference