

**OPTN/UNOS Policy Oversight Committee
Meeting Minutes
June 15, 2018
Conference Call**

**Ms. Jennifer Milton, BSN, CCTC, MBA, Chair
Dr. Elizabeth Pomfret, MD, PhD, Vice Chair**

Introduction

The Policy Oversight Committee (POC) met via teleconference on June 15, 2018 to discuss a letter received by the Secretary of the U.S. Department of Health and Human Services (HHS) on May 30, 2018, and the subsequent letter from Health Resources and Services Administration (HRSA) to the OPTN on June 8, 2018, that asked for a review of the liver policy, specifically four questions about the use of DSA and regional boundaries. The purpose of this call was to review the Liver Committee's response and to provide feedback to the Executive Committee, who will then approve the final response to HRSA regarding the issue.

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

1. Discussion of Liver Committee's Proposed Response to Letters

The Committee began the discussion by reviewing the Liver Committee Response to the letters. The Liver Committee provide four items in response:

- There is general support of the current proposal of regional share 32 with proximity circles and DSA priority for DCD and donors > 70.
- The committee recognizes that DSA is a non-optimal geographic boundary for allocation
- Need to begin modeling changes to the new system such as lower threshold or larger circle, or linking adjacent DSA's, which are focused on the areas most divergent in access to transplantation (summer of 2018 - now).
- The committee is unwilling to endorse broad changes in this policy which would then undermine the logic of the whole process (over the past several years) and would therefore not represent the views of the liver community which we recognize as divided.

The Liver Committee Vice Chair began the discussion by presenting and overview of the issue and this draft response, and also pointing out that the December 2017 proposal approved by the Board is a step in the right direction since it broadens sharing with the proximity circles around the donor hospital that often extend beyond the regions.

After the Liver Committee Vice Chair presented, the POC further discussed the response. The comments included these points and specific questions:

- A POC member asked if they had data about how often organs are shared more broadly after being offered locally? What percent of the time?
Response from Liver Committee Vice Chair: Currently when an organ comes from a Dallas OPO, 62 percent of the time it will go locally, and 38 percent of the time it will go regionally or nationally. And so this policy will probably bump it up another 5 or 10 percent to regionally.
- My immediate response is that the first bullet makes sense since we are allowed to use medical criteria/clinical decision making if it's not arbitrary.
- Why do we have the MELD 32 cutoff? Why not say all livers are shared regionally?
Response from Liver Committee Vice Chair: Logistical problems and higher costs. It would be more difficult to place marginal organs. There's agreed upon medical criteria to keep

those marginal organs close. Regional sharing at 32 was based on modelling that shows the travel time would increase significantly after that and discards would increase. There was an agreement between all regions on the 32 cutoff.

- I appreciated the comment that broader sharing could increase organs wasted. Will that be listed in the comments to HRSA?
- The logistical concerns are as important as the need to share more broadly.
- It could be better spelled out that 32 is the cutoff because beyond that there would be too much organ wastage.
- The Liver Committee is charged with finding consensus within the community... that was 32 for the redistribution proposal.
- I understand the challenges of trying to get consensus in the community, but the lawsuit (letter) is basically saying “we don’t like DSAs, we don’t like regions, because these are constructs of convenience and history”. Maybe there are reasons, but the question is can we get completely away from DSAs and Regions and use some circles, some shape, or some algorithm that does not go back to DSA or Regions?. Because that’s the core right now, and right now the law firm is saying “these are constructs of convenience.”
- And if I may add very quickly that at that point that they will go right at the DSA priority and DCD donors over 70. I don’t think DSA should be a priority when some (DSAs) are very small and some are very large.

Response from Liver Committee Vice Chair: Historically this is based on the relationship between the centers and the OPOs within the DSA. They can just place these marginal organs more quickly. So in that regard, it’s not arbitrary. If we were to dissolve that relationship with these marginal organs, which are largely responsible, by the way, for the surge in donation in the past few years, we would decrease the number of transplants. Some people do not believe that would occur, but that’s the logic.

- Some DSAs have a greater than 2-hour radius. So “local” is a relative term.
- There’s not argument here. But if we don’t respond to this in some way, we will lose all control of this.
- We need an evidence-based approach, we need more data and time to get that.
- If we put DSA in bullet number one, we are asking for this to be taken over by the courts. You are not even saying we are going to begin exploring eradicating these arbitrary boundaries.

Response from Liver Committee Vice Chair: Consider that these were put together like 28 minutes ago... need to be word-smithed still.

- This is good feedback ... the feedback from the POC is that this would not address the concern and that we need to be cautious on the use of “DSA” in our response. That could be the response from POC.
- Has anybody looked at the donor quality, ischemic time, and acceptability of these organs. Instead of these broad categories like DCD? Donor quality should be in the metric. It should all be based on ischemic time, or mileage-based, ischemic time-based system that includes concentric circles. That’s just my personal opinion.
- DSA/Regional is just asking for a lawsuit. These are just buzzwords that we’re digging in our heels, and I think we need to say we are going to dismantle this. We can’t say that we are going to keep doing this because “It’s the way we do it, or it’s the way it’s always been.”

The POC Chair agreed that POC will recommend that these terms/words are avoided. She asked for other input about the Liver Committee’s response.

- I’d like to see more methodical decision making play a role. I don’t want to do this quickly. We don’t want to increase discard rates. I think any system that ignores discard rates would

be discounted. I'd like to see this be a focus. Bullet point one should be medical-decision making as being important.

- If we just say... if we just say DSA is not the right way to go we will have to have an immediate fix. It seems to me that, when we look at lung, the cost of a lung transplant has gone up significantly since we went to concentric circles. I think if we can justify why DSA is not the worst thing in the world and why it is consistent with the Final Rule (costs), and that we are looking for better options and we want to get rid of DSA, but we have to do it thoughtfully. Costs and other issues are important... risks of traveling for transplant team. It needs to be rationally based, and it is rational to use DSA in the short term as we work to get away from it.
- I think we need to make it clear that there are a lot of medical decisions that are beyond the DSA issues, quality of the donor, cold ischemic time...again, we need to make that clear when we move forward.
- There's a concern that if we don't double down on this we will lose the medical factors/input and a judge (non-medical) will make a decision. There is great concern that this will happen very quickly and we'll have a system that doesn't consider medical issues.
- I think that the issue is that organs should be traveling further. They are just saying that "local" needs some other definition... just redefining what local means. Right now it just means DSA.

The Chair then asked for any other specific comments about the Liver Committee's response. These comments followed:

- In bullets one and two we want to say we need to deemphasize DSA and emphasize medical concerns... particularly keeping in mind discards.
- Already touched on it, in bullet 4, we need to emphasize the unintended consequences in a wholesale change in policy, and that we would not be willing to support a rushed decision that would not consider the clinical/medical issues and organ/donor quality, and discard rates.
- I think there are real unintended consequences in not having any idea of what the impact would be, no real analysis of the costs of this, the real costs of this. So it is a very important thing... this will hurt small programs with small margins. This really needs to be in the mix, in a formal way. We need to have the data.

Response from Liver Committee Vice Chair: In the redistribution proposal (December 2017), we looked at that, and it was thought that transplanting patients sooner would help decrease or overcome some of those costs, but as you point out, those are different pots.

- Need to emphasize that organ placement is a complex interaction between donor quality/availability and recipient variables, of which geography is just one small part. So to revamp the entire system based on geography and to do it quickly, would not be the best decision.

Based on these comments, the POC presented this response to the Executive Committee at their June 18, 2018 call.

- For #1: De-emphasize DSA in the response, and emphasize need for medical decision-making and the goal to minimize discards.
- For #2: The POC agrees that DSA is not an optimal boundary for geography, but also believes that it is important to take into consideration marginal donors and discard rates. (Any discussion that ignores discard rates is not in the best interest of patients.)
- For #3: The POC agrees with this.
- For #4: The POC agrees that we should emphasize that there would likely be unintended consequences from broad changes made quickly, but also that the focus on geography

discounts the complex variations in donor quality/recipient needs and therefore would not be in the best decision. It is vitally important to get medical/expertise input for any proposed changes.

Upcoming Meetings

- Tuesday, July 31, 2018, 1:00 PM ET, public comment review
- Friday, November 2, 2018, 8:30 AM CT, In-person, Chicago, IL