OPTN/UNOS Organ Procurement Organization (OPO) Committee Meeting Minutes February 27, 2019 Conference Call

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Introduction

The Organ Procurement Organization (OPO) Committee met via teleconference on February 27, 2019 to discuss the following agenda items:

- 1. Expedited Placement Proposal Update
- 2. Broader Organ Distribution Proposals
- 3. Guidance on Effective Practices in Broader Distribution
- 4. Split Liver Proposal
- 5. Modify HOPE Act Variance to Include Other Organs

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

1. Expedited Placement Proposal Update

UNOS staff provided an update on the public comment responses received so far on the expedited placement proposal

Summary of discussion:

UNOS staff noted that the proposal has passed in all regions except for Region 7. Overall, there is support for this proposal. There have not been a lot of individual comments on the website yet but there were several from OPOs voicing opposition on the proposal. The common themes among the comments made so far were shared with members. Members were reminded that the majority of the comments tend to come in during the last week of the public comment cycle. At the end of public comment, UNOS staff will work with Committee leadership to identify the themes and develop a strategy for making policy modifications that might need to be made in response to public comment. This will be discussed in further detail during the in-person committee meeting in April.

UNOS staff asked the Committee members if they had received any feedback on the proposal. The Committee Chair noted that she has received feedback within the community where there has been support but several suggested modifications. A member agreed and stated that during the Region 2 meeting discussion, there was a suggestion made that a report should be done before putting out an expedited offer. There was uncertainty of how this would work as there would not be much information to report at the time before the OR. There were a couple of OPOs who were strongly against the proposal but it was not the majority within Region 2.

Another member stated that people have also made comments that they would like to utilize the process they currently use and not be held accountable for a new policy.

The Vice Chair stated that part of the opposition deals with backing up the timeframe and being allowed to run expedited placement before the OR with the concern so that when in the OR, it will effectively impact and minimize the number of discards. Another comment made was around wanting to ensure that if transplant centers opted-in for expedited placement, they should have the resources in place to back this up.

The Vice Chair noted that during a presentation to the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, there was a question concerning how long OPOs should be required to wait before cross clamp to ensure that the liver will be placed by the expedited center. There was also concern voiced on how it would be "enforced" that the recovery team in the OR will actually stay and recover the organ. These are all legitimate concerns and there was some discussion about this with the work group with the expectation being that these teams would stay; however, the concern was if the OPOs have the authority to require them to stay and if so, for how long.

The Chair agreed that these comments were similar to a Membership and Professional Standards Committee (MPSC) presentation of this proposal and it was suggested that there should be something in policy requiring the team that is present to stay for the recovery of the organ.

UNOS staff shared with members the remaining regional meeting dates. UNOS staff will follow up with members assigned to present at their designated meetings to help with preparing for their presentations.

Next Steps:

• UNOS staff will follow up with members assigned to present at the remaining regional meetings to provide support in preparation for their presentations on the Expedited Placement proposal.

2. Broader Organ Distribution Proposals

UNOS staff provided an overview of the proposed allocation changes specific to thoracic, Vascularized Composite Allograft (VCA), and kidney-pancreas.

Summary of discussion:

UNOS staff provided an overview of the proposed allocation changes specific to thoracic, VCA, and kidney-pancreas. Members were asked to provide their perspective of how these broader distribution proposals would impact OPOs.

The Vice Chair commented that a concern would be the cost impact as well as transportation methods (recovery teams being required to fly vs. the utilization of local recovery teams). A member commented that as case times are increasing there will be an impact on donor hospitals. Another member stated that they are observing an increase in the number of imports that require them to send a recovery teams. She noted that a year ago there was an average of three flights a week in sending a plane to recover a heart, liver, or lung. They are now over five flights a week, and can see this continuing to grow with changes to liver allocation. This creates challenges for their local cases due to transportation resources such as planes not being available.

The Chair stated that from their perspective, the import offers have been increasing 30-40% for the last two years and the trend seems to be continuing for the third year in a row. In addition to this, there are challenges with staffing because of the increase in workload.

A member stated that there are multiple flights and different teams being used in these processes. When OPOs are accustomed to working with a certain surgeons, the increase in distance will require a learning curve and adjustment to working with new teams.

Another member stated that the donor family perspective also needs to be considered. Longer donor case times have an impact on donor families. The longer donor families have to wait due to the logistics of broader distribution can be difficult during this difficult time. There is also the

concern that it will increase the risk that an organ will not be utilized due to these longer case times.

The Chair stated that in looking at these broader distribution proposals, OPOs are calling for increasing efficiencies in the system. This could help reduce case times and make sure the right organs go to the right center in the most timely and efficient manner.

Another member stated that when it comes to cost, each OPO has different practices regarding surgical recovery fees. This will become confusing and will be an additional cost if current practices are maintained. Standardizing the recovery practices and having local recovery teams or recovery teams in the OR performing the recoveries will need to be the standard in order to make this work. One member noted that in addressing the timing of cases, OPOs and transplant hospitals will need to work together to modify their processes and practices in order to adjust to these changes. The Vice Chair agreed with this and added that the other intangible piece will be around relationships. This adds another layer of complexity to this issue as practices vary.

A member stated that another issue being observed is the use of third party screeners reviewing offers before the transplant surgeons. There are a lot of requests before the offer goes to the surgeon, adding unnecessary tests and a level of frustration when there is a decline of an organ for size 12 hours later.

Another member noted that when organs are placed an OR time is set. This is typically four to six hours with the goal to prevent the increased wait for the donor family and also the increased cost at the donor hospital. If the wait time increases, it can create difficulties in the process for the next donor. There should be accountability during these processes and a solid back up if necessary. Transplant hospitals could potentially have two offers and chose to go with the one that is closer if the OR is delayed. There is the potential for this to happen more when the liver allocation changes are implemented.

A member voiced concern regarding the kidney allocation. With broader distribution if the kidney is shipped then a positive cross match result comes back, the timing will be such where it does not make any sense to bring it back. This would result in the organ being placed using local import backups and create an opportunity for this process to be manipulated. The Committee Chair reiterated that there should be implementation and monitoring of the data to evaluate how often the kidney is not being used for the original intended candidate

UNOS staff noted that a draft summary of the comments will be provided to Committee leadership for review prior to be provided to the sponsoring committees and posting on the OPTN website.

Below are the votes on the specific organ allocation proposals.

Thoracic:

- What is your opinion of this proposal to eliminate the use of DSAs in thoracic distribution?
 - Vote: 1 Strongly Support, 11 Support, 2 Oppose

Kidney/Pancreas:

- Which framework do you prefer?
 - Vote: 9 Hybrid, 5 Fixed Concentric Circles
- Within the framework you selected, which circle size(s) do you prefer? Check one or two.
 - Vote: 2 (150nm), 7 (250nm), 1 (300nm), 3 (500nm)

- Should there be different systems for kidney and pancreas organs?
 - Vote: 7 Yes, 5 No

VCA:

- What is your opinion of this proposal?
 - Vote: 11 Support, 1 Neutral/Abstain
- Do you recommend an alternative distance for VCA distribution other than 750nm outlined in this proposal?
 - Vote: 5 Yes, 7 No

3. Operations and Safety Committee (OSC) Guidance on Effective Practices in Broader Distribution

The Operations and Safety Committee (OSC) provided an overview of this proposal.

Summary of discussion:

The OSC Vice Chair provided an overview of the guidance document. He acknowledged the concerns being expressed regarding the billing, financial, and fair market value sections of the document. The OSC is aware of the concerns and plan to revise these sections based on the feedback received from OPOs and colleagues across the country.

A member asked if there was a prospective list of data points that are going to be collected. The OSC Vice Chair replied that the Committee is requesting feedback on specific data points that should be collected routinely and relate to the logistics of broader organ distribution. The member replied that it would be good to come up with data points ahead of time rather than looking back retrospectively.

The Committee Chair asked for clarification that the vote would be on the guidance document as written. UNOS staff stated that the vote taken will be contingent on the OSC making the recommended changes to the billing and financial sections.

Vote:

What is your opinion of Guidance on Effective Practices in Broader Distribution?
• Vote: 3 Strongly Support, 6 Support, 1 Oppose

The voting reflects the Committee's support of the guidance document based on recommendations to adjust the billing and financial sections.

4. Split Liver Variance Proposal

The Liver and Intestinal Organ Transplantation Committee provided an overview of their Split Liver Variance Proposal.

Summary of discussion:

UNOS staff provided an overview of the Liver and Intestinal Organ Transplantation Committee's Split Liver Variance proposal.

A member asked why this proposal would be restricted to a region if allocation policies were moving away from using regions and DSAs. UNOS staff noted that this is the reason why it is being proposed as an open variance where anyone can join. Additionally, regions will still exist as administrative units and could theoretically exist as a regional variance if a group of transplant centers want to work together to test and evaluate this variance in order to determine if it could be applied as national policy.

A member stated that there was a concern that this proposal would reward Region 8 and would provide disadvantages to other regions. Another member agreed with this sentiment and expressed concern about bypassing patients. The Committee Chair stated that the OPTN already has a policy in place for split livers and that this proposal pertains to splitting the organ in a different way and has the potential to increasing the number of splits livers. The existing variance allows anyone in the country to participate. The difference in this variance would be that it can start with either the left or right liver segment. The second segment would first need to be offered out through MELD 32 candidates within 500 nautical miles using the same match run.

The Committee Chair asked UNOS staff to clarify that this did not change the way the current policy is written. The proposal focuses on the split process and ensures that high MELD candidates get offered the other lobe. Current policy is written this way as well. There is no change in the allocation process in split liver – it just allows for the other segment to be the primary. UNOS staff stated that this was correct.

UNOS staff summarized that if a center accepts a liver offer and agrees to split the liver and kept the left trisegment, the right trisegment is still offered to status 1 and MELD 32 or higher candidates all the way up to 500 nautical miles. After that, if no offer is accepted, the center would be allowed to keep the right trisegment for one of their candidates.

The Committee Chair clarified to members that this has not yet been implemented in Region 8. It has been moved to public comment to obtain feedback on whether this should be piloted in Region 8 or expanded to all regions. A member voiced support for this proposal to increase splitting but is concerned about bypassing candidates on the waiting list due to distance.

There were no additional comments. The Committee Chair moved for a vote on Liver and Intestinal Organ Transplantation Committee's Split Liver Variance proposal.

Vote:

- What is your opinion of Split Liver Variance?
 - Vote: 2 strongly support, 1 support, 3 oppose
- Should this variance only be available to Region 8 or should it be available to other members (i.e., open variance)?
 - Vote: The Committee unanimously voted in support that this variance should permit other members to participate

5. Modify HOPE Act Variance to Include Other Organs

The Ad Hoc Disease Transmission Advisory Committee (DTAC) provided an overview of their Modify HOPE Act Variance to Include Other Organs proposal to members.

Summary of discussion:

The OPO Committee had no comments or questions. The Committee Chair moved for a vote on the Ad Hoc Disease Transmission Advisory Committee's Modify HOPE Act Variance to Include Other Organs proposal.

Vote:

- What is your opinion of this proposal?
 - Vote: 6 Strongly Support, 2 Support

No additional comments or updates were presented. The meeting was adjourned.

Next Steps:

UNOS staff will draft and send the comments made on each presented proposal to the Committee Chair and Vice Chair for their review. Once finalized and approved, the Committee's vote and comments will be posted for public comment.

Upcoming Meetings

- March 14, 2019 (Teleconference)
- April 16, 2019 (In-person)