OPTN/UNOS Organ Procurement Organization Committee Meeting Minutes December 10, 2018 Conference Call

Jennifer Prinz, RN, BSN, MPH, CPTC, Chair Diane Brockmeier, RN, BSN, MHA, Vice Chair

Introduction

The Organ Procurement Organization (OPO) Committee met via teleconference on December 10, 2018 to discuss the following agenda item:

1. Review and Approve Policy Language

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

1. Review and Approve Policy Language

The Committee Chair noted that the goal of the meeting was to review the draft expedited placement policy language and vote to move the proposal forward to public comment.

Summary of discussion:

The Committee Chair provided an overview of the work of the expedited placement work group. The draft that was presented was the final language as agreed upon by the work group. The Committee Chair reminded members that this proposal is focused on liver allocation.

The work group agreed to require all transplant hospitals that wish to receive expedited liver offers to submit candidate level acceptance criteria. The liver acceptance criteria includes the following:

- Minimum and maximum age
- Maximum body mass index (BMI)
- Maximum distance from the donor hospital
- Minimum and maximum height
- Percentage of macrosteatosis
- Minimum and maximum weight

The work group recognized that age, weight, and BMI are currently included as liver donor acceptance criteria. However, they agreed that this information, as well as the other proposed criteria, should be required for expedited offers and be entered for both DBD (donation after brain death) and DCD (donation after circulatory death), depending on which type of donor the candidate and transplant hospital are willing to accept offers from.

The work group members agreed that the transplant hospitals should be required to enter the percentage of macrosteatosis in case the liver biopsy information is available at the time of the offer. The work group discussed the use of the term macrosteatosis and agreed it was the best term to use if there was a biopsy available. A member asked if there was any discussion about adding bridging fibrosis for any reason. The Committee Chair stated that there was some discussion about this but there was no agreement from the transplant center representative to add it. She added that this might be an issue that comes up during public comment.

The Committee discussed the next section of the draft policy that outlines the expedited offer process. The work group agreed that two conditions must be met for an OPO to be able to make expedited placement offers:

- The donor has entered the operating room or in the case of a DCD donor, withdrawal of life sustaining medical support has been initiated, whichever occurs first
- The host OPO or Organ Center is notified that the primary potential transplant recipient will no longer accept the liver

The Committee Chair reminded members that if both of the conditions are met, the OPO would be permitted but not required to make expedited liver offers. The Committee Chair reiterated that the reason for giving OPOs the flexibility to decide whether or not to initiate expedited placement is to allow OPOs to utilize the backup offer for the liver.

The Committee Chair provided an overview of the next section of policy that outlines the reporting requirements for OPOs. The OPO will be required to provide the following information prior to sending electronic expedited liver offers:

- Date and time donor entered the operating room or withdrawal of life sustaining medical support was initiated, whichever occurs first
- Date and time host OPO was notified by the primary transplant hospital that they will no longer accept the liver offer for the primary potential transplant recipient
- Reason for organ offer refusal by the primary potential transplant recipient

Once expedited liver offers have been sent, transplant will have 20 minutes to accept the offer in order to be eligible to receive the liver. If they do not respond within 20 minutes, it will be considered a refusal and the transplant hospital will not be eligible to receive the expedited liver offer for that candidate. At the end of the 20 minutes, the candidate that appears highest on the list will receive the liver. The work group spent a considerable amount of time discussing the timeframe for making a decision on expedited offers. The transplant hospital representatives on the work group supported the 20 minute time limit in order to expedite the process. The thought being that the liver donors are already in the operating room and time is critical if the liver is turned down late in the process.

A member asked if documenting the date and time of being notified that the primary center was turning down the offer should be entered into the donor highlights section in DonorNet[®] since there currently isn't a field for this information. UNOS staff stated that this would be part of programming and those fields would be added so they would be available for members. The Committee Chair stated that the idea is to be able to do this in the match run with ease while in the operating room, recognizing that there would be limited time. UNOS staff stated that as this proposal moves forward, especially following Board approval, committee members will be asked to provide input on the programming.

Another member asked for clarification on if there is a primary center with two back ups, would the primary center not be required to offer to any provisional yes before going to expedited placement. The Committee Chair stated that if you have a primary center and patient two and three backed up at different centers and center 1 declines while the primary center is in the OR, the primary center would be permitted to go to the second patient and the third patient without initiating expedited placement.

A member stated that there are times, due to geography (especially in Alaska), where there may not be time to exhaust the match run before going to the OR and begin expedited placement before going to the operating room. The member asked to clarify that this proposal is in reference to expedited placement once the donor has entered the OR. The Committee Chair stated that this policy proposal is only addressing when the donor is in the OR. In hoping that this phase of the policy is approved and goes into place, there would be a second phase to determine the expedited placement process pre-OR. Another member asked if there would be any sort of monitoring of centers accepting expedited placements. UNOS staff stated that this was something that would be put in the evaluation and monitoring plan. There were a lot of concerns, even from the work group members about how this was going to work, how it would be monitored, and how transplant centers and OPOs would be held accountable for certain things. This will be outlined as well in the public comment proposal. The Committee Chair provided the member with further explanation on utilization rates – how many times the transplant centers are offered an organ and turn it down – and being able to track that and share this information. The surgeons from the work group think that being able to share this data would be important to avoid the system being bogged down.

The Committee Chair summarized that the utilization rates are part of the monitoring that will be put forward with the proposal. One of the things that makes this more challenging for the transplant center is that each of the criteria points would need to be filled out on each recipient that the center wants to list for expedited offers. Depending on the volume, the centers are going to have to start to discern which patients get listed.

A member asked how the list would be generated – will it be local, regional or national? When running the expedited list, will there be out of region centers appearing or if it would go to local first. The Committee Chair stated that this would be working down the list as it is initially generated and then there would be an electronic switch or the capability to push a button to go to expedited placement. The patients who are not listed to receive those offers will be screened off the list. There were no further questions or comments by members in regards to this portion of the proposal.

The next part of the discussion focused on modifications to current policies. The first modification was made to the definition of organ offer acceptance where a sentence was added that outlines acceptance under the expedited process. UNOS staff explained that throughout the process all current policies were reviewed to ensure that the new policies being proposed did not conflict with current policies. UNOS staff identified the following policies that require modifications:

- Policy 5.3.D: Liver Acceptance Criteria
- Policy 5.4.C: Liver Offers
- Policy 5.6.B: Time Limit for Review and Acceptance of Organ Offers

The Committee Chair opened the floor for additional questions and comments before the committee voted on the proposal. The Chair reminded members of the intent of the proposal due to four issues the committee identified and discussed early on in the process that:

- Lack of transparency within the current system
- Lack of guidance for OPOs and transplant hospitals to manage the expedited placement process
- Lack of consistent practices across the U.S.
- Inconsistent access to organs for the candidates in need of transplant

A member stated that essentially expedited placement would be permitted and members would not receive letters from the MPSC, however there are some circumstances where expedited placement are done in pre-OR cases. There would obviously be MPSC letters for those circumstances but there would be no change in how they would react to that. The Committee Chair stated that there is uncertainty in saying how the MPSC would react to those cases, but that there would not be a letter sent for expedited placement once in the OR and if the OPOs follow the new policy. The MPSC would still look at all out of sequence and out of policy allocations so the pre-OR expedited cases would still be reviewed and would require a response. A member asked for clarification if the issue of pre-OR cases needing to do expedited placement would at some point be addressed in the future. The Committee Chair stated that as a work group, both pre-OR and post-OR expedited placement was discussed. The work group determined that it would be easier to address the in-OR allocation changes first. While the work group worked to identify the donor profiles that would need to be considered for pre-OR, it was proving to be challenging. Additionally, one of the key components of the pre-OR system is identifying transplant hospitals that are willing to accept marginal organs.

The Committee Chair then moved for the committee to vote on whether or not they approve the policy language and recommend it be distributed for public comment. There were fifteen voting members on the call to cast a vote.

<u>Vote:</u> The committee unanimously voted to support the proposal to be moved forward to public comment.

UNOS staff provided next steps to members. UNOS staff will work with committee leadership to finalize the public comment document. The draft is due on December 14, 2018. An e-mail will be sent to members to set up regional meeting prep calls for the regional reps once a few dates are proposed. UNOS staff will draft slides over the next few weeks to aid in the discussion/prep during those meetings.

UNOS staff and the Committee Chair thanked the work group and members for all of their hard work on the proposal.

Next Steps:

- UNOS Staff will working with the Committee Chair to finalize the public comment document.
- The draft will be submitted on Friday, December 14, 2018
- Members will receive an e-mail to set up regional prep calls for regional reps

Upcoming Meeting

• TBD