

**OPTN/UNOS Operations and Safety Committee
Meeting Minutes
February 28, 2019
Conference Call**

**Michael Marvin, MD, Chair
Christopher Curran, CPTC, CPTBS, CTOP, Vice Chair**

Introduction

The Operations and Safety Committee (OSC) met via teleconference on February 28, 2019 to discuss the following agenda items:

1. Update and Discussion: Guidance Document
2. Public Comment Proposal Review: Expedited Placement of Livers
3. Project Updates: ABO, DonorNet[®] Functionality, Human Leukocyte Antigen (HLA) Interface, Post Recovery Test Results Sharing Project

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

1. Update and Discussion: Guidance Document

UNOS staff provided an update on the public comments received on this proposal.

Summary of discussion:

UNOS staff discussed the comments received during the first six regional meetings. There has been overall support among the regions with consistent concerns about the financial and billing sections of the document.

The Committee Chair shared that in presenting the proposal to the Transplant Administrators Committee (TAC) and the Liver and Intestinal Organ Transplantation Committee, there was support for the proposal but opposition to the financial sections. The argument was that UNOS should not be discussing fair market value for organ recoveries. The Committee Chair suggested that the tone could be changed in these sections of the document. The goal of this section was to recommend that members think about this topic, as it is not within the Committee's purview to create policies on these issues.

The Vice Chair agreed that the comments have been similar regarding the finance sections and billing practices with OPOs. The Vice Chair presented to the Organ Procurement Organization (OPO) Committee and the feedback centered on the variability of billing practices among OPOs and there should not be language in a document addressing how you determine fair market value. It was recommended to modify the language in this section. The Vice Chair noted that the intent of the guidance document was not to determine the fair market value or who should be paid and when, but instead to encourage transparency about these practices between transplant programs and OPOs. The Committee Chair asked members if there was any additional feedback being heard from the community.

A member stated that there has been general concern from previous instances where the language from guidance documents were used to put standards in place that could eventually lead to policies. The Chair agreed that this concern was raised and believes it would be reasonable to modify the language. The goal of the document is to ensure that members are having the conversations and being transparent. Committee members agreed that this message could still be conveyed by using different language.

The Vice Chair has begun drafting a general version of this section, which will be discussed during the in-person meeting in March. The Committee Chair stated that the key points should be that surgeons and OPOs are encouraged to discuss the options for what happens when surgeons are going out on their own behalf and when surgeons are going out on behalf of the OPO.

A member asked for information about how best to address the proposal and the concerns raised for the upcoming regional meetings. The Committee Chair replied by stating that the best approach is to start off the presentation with information about why the guidance document was taken off the consent agenda which was due to concerns about the finance and billing sections and let the audience know that these sections are being re-evaluated.

UNOS staff agreed to resend the regional meeting information to the regional representatives to help with preparation for the upcoming regional meetings. The Committee Vice Chair volunteered to help with the meeting prep and discussion points for members to include in their presentations for the regional meetings.

Next Steps:

- The Vice Chair will redraft the finance and billing sections of the document which will be recirculated to members for feedback and discussed more thoroughly during the in-person meeting on March 28, 2019.
- UNOS staff will resend regional meeting information to the Committee regional representatives to help with preparation of their presentations. The Committee Vice Chair is available to help with regional meeting preparation.

2. Public Comment Proposal Review: Expedited Placement of Livers

The Committee Vice Chair of the Organ Procurement Organization (OPO) Committee provided an overview of the committee's Expedited Placement of Livers to members.

Summary of discussion:

The Vice Chair of the Organ Procurement Organization (OPO) Committee provided an overview of the expedited placement of livers proposal.

The OSC Vice Chair asked for clarification related to the language addressing the criteria for when OPOs can initiate expedited liver offers. He noted that there can be difficulty placing donation after cardiac death (DCD) donor livers. He asked if there was any discussion allowing DCD expedited liver offers within the hour of the expected withdrawal of support? In this case, it would allow transplant programs that are considering these DCD livers to have more time to prepare.

The Vice Chair also noted that the criteria in this proposal assumes that there was placement for a liver. It does not address the scenario where a liver hasn't been placed when the donor enters the operating room (OR). The Vice Chair suggested that language could be added stating that if there is not a primary program acceptance when the donor is entering the OR, expedited placement can be initiated. The OPO Committee Vice Chair stated that this was not previously discussed by the work group and that the recommendation will be taken back to the committee for further discussion.

The OSC Chair stated that there was concern about the 20 minute timeframe being proposed. The OPO Committee Vice Chair replied that there have been several recommendations to expand the timeframe from 20 minutes to 30 minutes. The OPO Committee has discussed this and are not opposed to such a change. The goal of the shorter time frame was to reiterate the urgency of this placement, but also making sure the practicality of keeping a team to recover the liver is foremost in the minds of the OPOs and transplant programs in the surgical suite. As the public commentary moves forward, the OPO Committee will evaluate and take all feedback into

consideration. It is possible the timeframe could be modified if there is strong consensus of changing the proposed 20 minute time frame to 30 minutes.

A member asked that if there is a primary with backups in place with provisional acceptances, where does this fall into the expedited placement process? If the backup declines, does it then go to expedited placement? UNOS staff clarified that the expedited placement process was not intended to interfere with the current back up offer process, but is instead intended to ensure that people are not bypassed on the match run. Two of the goals of this proposal are to provide transparency and equitable access to liver offers. The member asked for clarification that expedited placement is an option but that if there are backups in place, they can be used. Both UNOS staff and the OPO Vice Chair confirmed that this was correct. The OPO Vice Chair added that the traditional backups are still following the initial match run list.

The Vice Chair asked if the refusals from the initial list are carried over to the expedited placement list. UNOS staff clarified that while drafting the policy language, IT evaluated how the programming might work. It was decided that the offers will not go back to those transplant centers who have refused the offer on the original match run. The rationale was that if it was refused by a transplant hospital on the initial match run, it would most likely not be accepted on the expedited list.

The OSC Chair moved for a vote on this proposal.

Vote:

- What is your opinion of the Expedited Placement of Livers proposal?
 - **Vote: 6 Strongly Support, 4 Support, 1 Neutral/Abstain, 0 Opposed, 0 Strongly Opposed.**

3. Project Updates: ABO, DonorNet[®] Functionality, Human Leukocyte Antigen (HLA) Interface, Post Recovery Test Results Sharing Project

Summary of Discussion:

UNOS staff and Committee Leadership provided members with an update on the Committee's current projects: ABO, DonorNet[®] Functionality, Human Leukocyte Antigen (HLA) Interface, and Post Recovery Test Results Sharing Project.

ABO project:

The Vice Chair provided members with background information on recent ABO events. Upon the direction of UNOS leadership, the Committee was asked to develop a project to address ABO issues. A project plan was developed and submitted to the Policy Oversight Committee (POC) for review. The POC recommended that the project be re-evaluated by the Committee to determine what specifically needs to be addressed and what course of action is being proposed. The Vice Chair stated that the POC agreed with the Committee's plan to form a work group and hold a kickoff meeting with subject matter experts (SMEs) to gather more information and provide a clear plan and set of objectives for this project. UNOS staff agreed with this plan and noted that the POC's decision does not interfere with the timeline for this project. If the OSC decides to address this issue through education or communication, it would be exempt from POC approval. However, a guidance document or policy proposal would need to be brought back to the POC for approval. UNOS staff noted that the work group has been formed and will be meeting on March 7, 2019 to develop a course of action in addressing this issue.

DonorNet[®] Functionality:

The Chair and Vice Chair met with the UNOS Customer Council group and discussed the DonorNet® Functionality project. The Chair summarized that the Customer Council team seemed to be in support of this idea. This initiative would improve communication between transplant centers and OPOs because the information would be updated in real time within an app. The next steps were decided that this would go back to IT. Another meeting has been scheduled for March to help move this project forward.

HLA Initiative:

UNOS staff provided members with an update on the committee's HLA Typing Errors proposal, which was passed by the Board in December 2108. This proposal is currently scheduled for implementation in the fourth quarter of 2019.

UNOS staff noted that an IT service request has been submitted. The next steps would be to include Histocompatibility Committee Leadership on an OSC leadership call to discuss how the Committees envision this working in order to provide IT with more information in order to determine the level of effort for this work.

The Committee Chair agreed with this and stated that this would be a big IT project because it would involve development of interfaces between software.

Post Recovery Test Results:

The Vice Chair noted that the post recovery test results project will create a system in DonorNet® for notifying transplant programs of donor test results that come in after organ recovery and organ transplantation. It is an electronic automated notification from DonorNet® to transplant programs. There are five OPOs involved in the pilot scheduled to begin on March 12, 2019.

Upcoming Meeting

- March 28, 2019 (In-person)