OPTN/UNOS Operations and Safety Committee
Meeting Minutes
December 13, 2018
Conference Call

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

Introduction

The Operations and Safety Committee (OSC) met via teleconference on December 13, 2018 to discuss the following agenda items:

1. Review and Approve Effective Practices in Broader Distribution Guidance Document
2. UNOS Update on ABO Notification

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

1. Review and Approve Effective Practices in Broader Distribution Guidance Document

The Committee Vice Chair provided an overview of the final draft of the guidance document with the goal of the meeting to vote on moving the document forward to public comment.

Summary of discussion:

The Committee reviewed each section of the document.

Introduction – This section provides a brief summary of what the guidance document is intending to do and its purpose.

Building relationships to optimize operations - This section came from the concept that some parts of the country were already forming work groups/collaboratives to build relationships with members in neighboring donation service areas, transplant programs, and OPOs. The section further explains the importance of building these relationships and improving communications.

Transportation resources - The Vice Chair noted that the hope was the SRTR could provide some data showing the impact that broader liver distribution will have on the net gains and losses from each donation service area so that OPOs could have some idea what additional resources would be needed to support broader distribution. The Committee was unable to get this data before the deadline for the guidance document so this section was kept general by noting that OPOs and transplant programs that are involved in transportation logistics might need to expand aviation resources to meet the needs with broader distribution.

The Committee Chair inquired if the results from the questionnaire could be added to the document as an appendix. UNOS staff stated that the questionnaire was included as an appendix in the liver proposal and it could also be added as an appendix to the guidance document. The Vice Chair stated that a brief paragraph could be added to summarize the questionnaire data in the appendix of the document.

The Vice Chair asked if there was an opportunity to make changes to the document following public comment. UNOS staff stated that as long as an issue was brought up during public comment, it would be appropriate to add additional language to the document. A committee member clarified that the committee could ask for feedback during public comment by adding a question to the public comment document. The Vice Chair suggested that the committee add a recommendation that OPOs performing a critical analysis of their aviation resources. In reference to the pilot shortage document that was provided to the committee by the subject

matter expert, the Vice Chair suggested that the committee add a reference to this document and recommend that OPOs develop systems to support broader distribution.

Streamlining communications – This section includes recommendations to make enhancements to DonorNet® and also highlights a current functionality that allows members to "follow a donor" with regards to the operating room time. This section also addresses the benefits of sharing images, including diagnostic studies, CTs, bronchoscopies, other video imaging files. The Committee included a reference to a previous guidance document that was developed in 2012 that gave guidance on organ photos and the importance of sharing organ photos with transplant programs that were considering organs. The last paragraph of this section provides a recommendation to have the module in DonorNet for the sharing of post-recovery donor information so there is a consistency in the reporting of information to transplant programs.

Histocompatibility considerations - This section of the document was developed with collaboration from the Histocompatibility Committee. There was an issue raised by Member Quality on item 3 of the transplant center section. The concern raised was that there may be confusion between the unacceptable antigens in the wait list screening patients off match runs and the concept of virtual cross match. UNOS staff clarified that the concern voiced by Member Quality (MQ) was that it is not trying to imply that the antigen data entered in the candidate record serves as a virtual crossmatch with the donor when the match is generated. This is due to the fact that the match run is in no way intended to serve as the virtual crossmatch. The Vice Chair asked if there was any proposal from MQ on alternative language to this. UNOS staff stated that there was no alternative language proposed; they only wanted to bring this concern to the committee's attention. The Vice Chair agreed with MQ's sentiment that the match run and the screening process is not a virtual crossmatch, but when candidates are screened off matches because of unacceptable antigens, it essentially is doing a virtual crossmatch or excluding candidates based on unacceptable antigens that a transplant program has deemed unacceptable. What this particular statement is trying to say is to add the antigens thoughtfully because it may have unintended consequences of screening someone off a list. The Vice Chair asked for thoughts on the need to add anything additional to clarify this point.

UNOS staff proposed the use of a link referencing a Transplant Pro article providing more information on pre-transplant crossmatch requirements. The Vice Chair asked if this information was put up by the Histocompatibility Committee. UNOS staff stated that the article was created in conjunction with a number of committees. The Vice Chair stated that this resource would be great to use in the document as a reference. The committee agreed not to change the guidance document because what the document is trying to address is that some centers do not want to enter unacceptable and instead want to "see them all" but yet they are not really practicing this way because they are filtering them out after the match run.

The Vice Chair stated that when having this discussion with the Histocompatibility Committee, it was determined that the recommendation on if all unacceptable were entered should come from the Histocompatibility Committee, rather than the Operations and Safety Committee. It was clarified that the recommendation in this section does not say the match run is doing the virtual crossmatch.

Organ allocation procedures - This section addresses effective wait list management and continues on to discuss data validation of donor information. UNOS staff solicited information from the Organ Center about their experience. When the Organ Center is asked to perform organ allocation they perform a validation of the data. They discovered that 3% of the time they find data that is inaccurate that results in the need for rerunning a match run. This demonstrates that inaccurate donor information could disadvantage patients and should therefore be a process for making sure that data is accurate so that there are accurate lists.

This section also recommends that OPOs wait to run lists until they are ready to allocate so that the most current information will ensure appropriate identification of candidates based on their status or medical urgency.

The Vice Chaired moved on to the next part of this section, which discussed back up offers. A recent policy change now requires a response within an hour from the time of notification. Transplant centers are encouraged to respond for multiple candidates rather than just the one candidate they are being offered the organ for. It has been found that when sending out an offer to a transplant program, they will enter a provisional yes for one patient and then they are sent another notification. The provisional yes has morphed into a placeholder and it should be used if actually considering an organ at a transplant program. A member stated that they were unsure of how this section would come across in public comment because it addresses a matter of controversy that does exist. Another member stated that this section accurately reflects the discussions the committee had on this topic. The Committee Chair stated that the wording of the comment may be too strong and proposed to soften the wording so that it will read that the provisional yes “at times” may have devolved into a placeholder when the offer is for a backup candidate”

A member proposed using the provisional yes definition provided by OPTN policy. The Committee reviewed the current definition and the Vice Chair proposed the committee recommend that the definition is made more specific. Another member stated that sometimes as a transplant center receives an offer, the yes really is provisional because there is not enough information given at the time to make a decision. The Vice Chair stated that the intent of this section is to address that if there is an instance where this is a backup and the organ would go to this offer if the primary declines the offer, there should be some effort to determine if the transplant program is interested for that candidate. The Vice Chair proposed to leave the language in this section as is and move on to the other sections of the document to review. The committee had no additional comments for this section.

Establishing the time of organ recovery - The focus on this section is to encourage OPOs to collaborate with transplant programs during the allocation process. The section goes on to encourage setting the time for recovery of organs being an open and collaborative discussion between the OPO and all parties that may be accepting of organs. The committee had no additional comments to add to this section.

Organ procurement surgeon models - This section discussed the various surgeon models that are used, which was discussed in depth during the last committee call. The Vice Chair briefly reviewed new items that were added to this section that discussed OPOs and transplant programs considering, when possible, relying on colleagues in local areas to provide procurement services. The Committee Chair stated that this was an important and great addition to this section, as this proposed process could save time and resources. The committee had no additional comments to add to this section.

Organ procurement-related billing - This section explained the billing procedures and recommended that OPOs should inform teams arriving from outside their DSA of the process for submitting invoices for organ procurement. The committee had no additional comments to add to this section.

Data metrics - The Vice Chair provided a brief overview of this section which addresses data metrics and how this should be monitored post-implementation of any allocation policy changes. This section also discussed potential transplant recipient (PTR) codes and the recommendation to change them to capture better data in the refusals. The committee had no additional comments to add to this section.

The Vice Chair opened the floor for any comments on the guidance document. A member stated that the document will create a lot of discussion among the community. The committee agreed and had no additional comments to add to the document.

UNOS staff reminded the Vice Chair about a section provided by the Ad Hoc Disease Transmission Advisory Committee (DTAC) that addresses seasonal and geographic endemic infections. The Vice Chair stated that this section should be included and asked for feedback on this section. It was agreed to include the section into the document which was placed after the organ allocation section.

The Vice Chair then proposed to move to a vote on the guidance document moving to public comment. There were twelve voting members on the call to cast a vote.

Vote: The Committee unanimously voted to approve the guidance document be moved forward to public comment.

2. UNOS Update on ABO Notification

UNOS staff provided an update on a UNOS notification that was sent out to members.

Summary of discussion:

UNOS staff reviewed the UNOS notification that was sent out on November 30, 2018 reminding members to use pre-transfusion red blood cell samples whenever possible. There will be further review of policies around this issue. There was informal guidance provided in the notification that whenever possible, OPOs should use pre-red blood cell samples to determine primary blood type, and if they do not exist, to consult blood bank or other experts and follow the protocol for resolving conflicting types. The notification also stated that if the deceased donor has recently received blood products, there may need to be consideration in reconfirming the donor's blood type.

UNOS staff reminded members that there are policies requiring OPOs, recovery hospitals and transplant hospitals to establish and follow protocols to address conflicting results for primary blood type. In 2014, the Committee performed a Failure Modes and Effects Analysis (FMEA), where all stages of ABO testing were extensively reviewed which led to ABO policy changes based on this analysis. At the time, when there was no pre-transfusion specimen available for testing, the Committee's response was to put in the requirement to have a protocol. Moving forward, the Committee will be revisiting this issue and reviewing those results to determine if any other recommendations or guidance is needed. UNOS staff stated that it is likely there will be more discussions to come and this would also be a time to review all potential situations. There have been more questions over the years about cord blood, neonates, and molecular testing. There was also a suggestion from the public as well as the Histocompatibility Committee Chair about educating the community about the use of buccal swabs (DNA based type of test), where preliminary information suggest that the turnaround time would be shorter.

Upcoming Meeting

- January 3, 2019 (Teleconference)