

OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
Meeting Minutes
February 21, 2019
Conference Call

Julie Heimbach, MD, Chair
James Trotter, MD, Vice Chair

Introduction

The Liver and Intestinal Organ Transplantation Committee (the Committee) met via teleconference on 02/21/2019 to discuss the following agenda items:

1. Effective Practices in Broader Organ Sharing
2. Ethical Implications of Multi-Organ Transplants (MOT)
3. Expedited Organ Placement
4. Split Liver Variance
5. NLRB Transition

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

1. Effective Practices in Broader Organ Sharing

The OPTN Operations and Safety Committee (OSC) has a guidance document titled, "Effective Practices in Broader Organ Sharing" out for public comment. The OSC Chair presented the guidance document to the Committee.

Summary of discussion:

The guidance document was created in response to a recommendation from the Ad Hoc Geography Committee to address logistical challenges in broader distribution. The guidance document includes ideas on best practices for broader sharing and recommendations on how to handle the overall changes to the allocation system.

To develop the guidance document, the OSC distributed a questionnaire on transportation practices to 58 organ procurement organizations (OPOs) and 10 transplant centers. The results of this questionnaire were provided to the Committee and the Board of Directors. In a parallel effort, the OSC started developing the guidance document by identifying key topics and having work groups develop content.

The guidance document addressed the following topics:

- Building relationships to optimize operations
- Transportation resources
- Streamlining communications and information distribution
- Histocompatibility considerations with broader geographic organ distribution
- Organ allocation procedures
- Recognizing seasonal and geographic endemic infection in organ donors
- Establishing the time of organ recovery
- Organ procurement surgeon models
- Procurement team staffing models
- Organ procurement-related billing
- Establishing fair market value for organ procurement activity
- Organ procurement malpractice coverage considerations

- Data metrics

The OSC Chair noted that the OPO Committee voiced concern for the document's discussion of fair market value for organ procurement activity. The OSC is open to editing this portion of the document.

The OSC is specifically asking the transplant community for feedback on if there should be additional data collection necessary for OPTN Committees to evaluate the logistical impact of broader distribution.

A Committee member stated that the financial issues discussed in the document are not under the purview of the OPTN and establishing fair market value for organ procurement activities involves factors that are donation service area (DSA) specific. The Committee member stated that these topics should be addressed in another arena. The OSC Chair reiterated that the OSC intends to rework these parts of the document.

The Committee voted on: What is your opinion of Guidance on Effective Practices in Broader Distribution?

Results were as follows: 0 Strongly Support; 0 Support; 5 Neutral/Abstain; 0 Oppose; 1 Strongly Oppose

Next steps:

UNOS staff will submit a public comment on the guidance document on behalf of the Committee.

2. Ethical Implications of Multi-Organ Transplants (MOT)

The OPTN Ethics Committee has a white paper titled, "Ethical Implications of Multiple Organ Transplant" out for public comment. A representative of the Ethics Committee presented the white paper to the Committee.

Summary of Discussion:

The current allocation system for MOT has developed over time and is not standardized across organ types. This has generated confusion in the transplant community and a lack of consistency that could create inequity in access to transplant. Additionally, the amount of MOT has approximately doubled since 2012. Because of this, the Ethics Committee felt it was important to create a white paper to guide the other OPTN Committees as MOT policies are reevaluated.

In the white paper, the Ethics Committee discussed twelve different ethical dilemmas that could arise in MOT. One ethical dilemma described in the white paper is organ quality. Organs used in MOT tend to be of higher quality than organs used during single organ transplantation. This disadvantages single organ transplant candidates who lose access to these high quality organs. The committees that oversee the distribution of these organs must make sure that the allocation of high quality organs to MOT candidates is ethically justified.

Another ethical dilemma addressed in the white paper is relative futility. The mortality risk of MOT is greater than single organ transplantation and when an MOT recipient dies, they are taking more organs out of circulation. So, higher quality organs are going to patients with a lower likelihood of survival. The benefit of high-risk MOT must be weighed against the disadvantage to single-organ candidates.

The Ethics Committee provided recommendations for each dilemma identified in the white paper. One recommendation is to establish data reporting for MOT outcomes. The majority of MOT outcomes data is not publicly reported so by making this data more available, there will be

a greater ability to evaluate outcomes. More so, because MOT outcomes are not reported, programs may convert high-risk single-organ candidates into MOT candidates so that the poor outcomes are not reported.

The Ethics Committee also recommended that there should be minimum requirements for MOT that would include prioritization of medically-urgent candidates.

The Ethics Committee recommended the creation of additional “safety net” policies for MOT combinations so that patients who go through single organ transplantation can still be prioritized for a second organ as needed.

And finally, the Ethics Committee recommended that Committees minimize harm to subgroups that are already disadvantaged in access to transplants, such as children, minority populations, and highly sensitized patients.

The Committee did not have any questions or comments.

The Committee voted on: What is your opinion of Ethical Implications of Multi-Organ Transplant?

Results were as follows: 0 Strongly Support; 2 Support; 2 Neutral/Abstain; 1 Oppose; 0 Strongly Oppose

Next Steps:

UNOS staff will submit a public comment on the white paper on behalf of the Committee.

3. Expedited Organ Placement

The OPTN Organ Procurement Organization (OPO) Committee (OPO Committee) has a policy proposal titled “Expedited Placement of Livers” out for public comment. The Vice Chair of the OPO Committee presented the policy proposal to the Committee.

Summary of discussion:

Expedited placement of organs has long been a useful way for OPOs to place organs quickly. However, there is no OPTN policy that addresses expedited placement. This absence of policy has created a lack of transparency about how expedited placement currently works. Additionally, OPOs and transplant hospitals have no formal guidance on expedited placement, so it is performed inconsistently and candidates have inconsistent access to organs.

Therefore, the OPO Committee is putting forth a proposal to create a system for the expedited placement of livers. Initially, this system would only be used following “in operating room (OR)” turn downs.

In order for a transplant program to “opt-in”, they must agree to allow any procurement team to recover the liver and must enter the different criteria for each type of donor from which the transplant program would be willing to accept an expedited offer.

In order for an OPO to initiate an expedited placement, both of the following criteria must be met:

1. The donor has entered the operating room or in the case of a donation after cardiac death (DCD) donor, withdrawal of life sustaining medical support has been initiated, whichever occurs first.
2. The host OPO or Organ Center is notified by the primary transplant hospital that the primary potential recipient will no longer accept the liver.

The proposed policy outlines the additional information that OPOs must enter before sending the expedited offer. Additionally, it requires that the expedited offers must be made using the expedited match run. Transplant programs must accept the expedited offer within 20 minutes in order to be eligible to receive the offer. At the end of the 20 minutes, the liver will be placed with the candidate with an acceptance for the offer that appears highest on the match run.

To implement the proposal, OPO staff should be able to explain the conditions appropriate to initiate an expedited liver placement and educate their staff on the newly required information. Transplant programs will need to enter acceptance criteria on a candidate-by-candidate basis in order to receive the expedited liver offers and develop processes that allow quick review of expedited offers within the allotted 20 minutes. The OPTN will need to make system programming changes.

A Committee member asked if the workgroup considered the advantage that the policy gives to the program that is present at the procurement and that this may incentivize late turn-downs. The OPO Committee Vice Chair stated that this was discussed and the program that is present in the OR would be eligible for the expedited offer for another candidate at their center. The Committee member suggested that late turn-downs be tracked and trigger a review. The OPO Vice Chair stated that the workgroup did discuss accountability metrics and intends to capture this data in a more accurate way.

A Committee member asked if there is any guidance for how long the procurement team will wait in the OR for logistical arrangements to be made after organ acceptance. This was not discussed specifically, but it is expected that the procurement team already present in the OR will stay and procure the organ. The Committee member suggested that the workgroup talk to OPOs about this issue.

Another Committee member noted that the procurement team should be willing to wait for logistics to be set up prior to cross clamp, and that a policy mandating a certain length of time is unnecessary.

The Committee voted on: What is your opinion of Expedited Placement of Livers?

Results were as follows: 1 Strongly Support; 4 Support; 1 Neutral/Abstain; 0 Oppose; 1 Strongly Oppose

Next Steps:

UNOS staff will submit a public comment on the policy proposal on behalf of the Committee.

4. Split Liver Variance

UNOS staff provided an update on public comment feedback on the Split Liver Variance.

Summary of Discussion:

Public comment feedback has been mixed. Five of the seven individual comments supported the variance being open to any program that wants to participate. Region 10 supported an amendment to have the variance only apply to hemiliver splits at adult programs.

A Committee member commented that the policy should not apply to a left lateral/right tri-seg split. All candidates should have access to these organs. Instead, the policy should only apply to left/right hemiliver splits for adults.

The themes identified in public comment thus far are:

- Concerns about variance benefitting only pediatric or only adult programs
- Discussion around limiting to certain types of splits

- Concerns about the impact on nearby non-participating centers and decreased sharing
- Concerns that the required sharing with the high MELD/PELD candidates will make the variance less effective
- Questions about how OPOs will know if a center is participating in the variance

UNOS staff asked Committee members to start thinking about what barriers to participation might exist if individual centers are allowed to participate and if there is any additional data they would like to see.

A Committee member asked how the variance would be implemented if it cannot involve the use of regions and stated that most programs would just opt in if it is an open variance. The Committee member felt that the variance should either be open to all programs or none.

A Committee member supported the idea to limit the variance to left/right hemiliver splits for adults.

Next Steps:

The Committee will discuss the proposal more during their next call.

5. NLRB Transition

UNOS staff provided an update on public comment feedback on the National Liver Review Board (NLRB) Transition proposal.

Summary of Discussion:

The feedback for this proposal has been mixed, but slightly more positive than negative. Region 10 supported an amendment to require the review of all non-standard exceptions during the one month transition period.

The themes identified in public comment thus far are:

- Preference for either a three month transition or simultaneous implementation
- Recommendation to use median model for end-stage liver disease (MELD) at transplant (MMaT) for the transplant center
- Request for the MMaT scores by DSA
- Recommendation to convert scores or have NLRB review all scores before Acuity Circles is implemented
- General concerns about MMaT system
- Preference for 500 nautical mile (NM) circles (instead of 250NM)
- Preference for national MMaT
- Recommendation to include nourishment in MELD calculation

The NLRB subcommittee will be convening soon to discuss the options. A Committee member noted that the transplant community is confused about the NLRB transition situation and why two similar exception patients in the same circle can have different scores.

Next Steps:

The NLRB subcommittee will meet to discuss the transition options. The full Committee will discuss this more during their next meeting.

Upcoming Meeting

- March 21, 2019 1:00 PM EDT, Richmond, VA