Introduction

The Pediatric Transplantation Committee met via teleconference on March 21, 2018 to discuss the following agenda items:

1. National Pediatric Transplant Week
2. Update on Newly Approved Projects
3. Public Comment - Modifications to the Distribution of Deceased Donor Lungs
4. Public Comment - Clarify Informed Consent of Transmittable Conditions

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

1. National Pediatric Transplant Week

Committee members and invited guests profiled an initiative developed with DonateLife America to feature pediatric transplantation during National Donate Life Month

Summary of discussion:

During planning for National Donate Life Month, there was an awareness to highlight the need of children waiting for organ transplantation. Featuring National Pediatric Transplant Week [April 23-27, 2018] was seen as a mechanism to engage transplant professionals to share their powerful stories, and honor the families of pediatric organ donors. To support these efforts, a toolkit was developed to share data, social media content, frequently asked questions (FAQs), and pediatric stories of hope.

New artwork was shared with the Committee and the content was very positively received by the members. There was substantial interest sharing the information at members’ hospitals.

Next steps:

Members will receive this information and toolkit electronically.

2. Update on Newly Approved Projects

UNOS staff provided a brief update on projects approved by the Executive Committee.

Summary of discussion:

The Executive Committee met recently on February 26, 2018 to consider two new projects of interest to the Committee. These projects include 1) an effort by the Kidney Transplantation Committee to examine what modifications could be made to the Kidney Allocation System (KAS), with a focus area of the project on pediatric kidney transplantation, and 2) a Committee-lead effort to reduce pediatric liver waitlist mortality. Both of these projects were approved for future work. UNOS staff reported that working groups would be formed in the coming month.

During discussions, the Executive Committee was aware of the substantial interest in each project by two to three OPTN committees. They asked the Policy Oversight Committee (POC) to examine what role, if any, project co-sponsoring would play in the two aforementioned projects.
Next steps:
An in-depth update on both projects will follow during the April 19, 2018 in-person meeting in Chicago, IL.

3. Public Comment - Modifications to the Distribution of Deceased Donor

UNOS staff profiled a proposal from the Thoracic Committee that is out for public comment.

Summary of discussion:

Emergency changes to lung allocation policy were implemented in November by the Executive Committee. These changes came as the result of a “critical comment” by a lung transplant candidate to the Secretary of Health and Human Services (HHS) requesting that the Secretary set aside lung allocation policy that distributed lungs to all candidates in the donation service area (DSA) before distributing lungs to Zone A (which at the time was a 500 nautical mile circle around the donor hospital). As a result of this critical comment and motions filed in federal court, the Secretary directed the OPTN to review current policy to determine whether the use of DSA in lung allocation policy was consistent with the Final Rule, and whether distributing to a 500 nautical mile circle was more consistent with the Final Rule than distributing first to the DSA.

The Executive Committee determined that it is permissible to consider the benefits of distributing organs more geographically proximate to the donor, the DSA is not an appropriate substitute for geographic proximity because DSAs are not consistent in terms of size, shape, and population. The Executive Committee found that DSAs as used in lung allocation policy are not rational or consistent, and result in inequities.

The scope of the proposal includes three focus areas:

1. DSA as a unit of distribution in lung allocation policy
2. Impact of changes on heart-lung allocation policy
3. Impact of changes on sensitized lung transplant candidates

DSA as a unit of distribution in lung allocation policy

Without the time to perform detailed analyses regarding the impact of distributing lungs more broadly, the Executive Committee was hesitant to adopt a policy distributing lungs initially to all candidates within 500 nautical miles of the donor. It reviewed OPTN data that showed that most lungs are transplanted within 250 nautical miles of the donor. On November 24, 2017 the Executive Committee, with HRSA’s permission, immediately changed policy to distribute lungs to a 250 nautical mile zone before distributing to a 500 nautical mile zone. Because these changes were adopted on an emergency basis, they will only be in effect for one year (until November 24, 2018) unless the Board takes action to either make the changes permanent, to modify them, or to terminate them. The Thoracic Committee is also required to retrospectively distribute the change for public comment.

After the change, the Thoracic Committee requested thoracic simulation allocation modeling (TSAM) from the SRTR to compare the potential effect of distributing to the DSA first as compared with a 250 nautical mile zone first and compared to a 500 nautical mile zone first. Overall:

- The DSA and 250 nautical mile waitlist mortality rates were similar.
- Transplant rates in the DSA and 250 NM simulations differed slightly or not at all; however, in the 500 NM simulation average rate declined.
- One-year post-transplant mortality rates are not impacted dramatically by any of the modeled distances.
**Impact of changes on heart-lung allocation policy**

The removal of the DSA impacted other parts of lung policy, specifically heart-lung allocation. The approved heart-lung allocation policy explicitly mentions the DSA. It also heavily relies on the distances for sharing hearts and for sharing lungs to be equal, which is no longer the case with the 250 nautical mile sharing. And, putting aside the changes to geographic sharing, the approved heart-lung policy will still be difficult for OPOs to follow, because it inadvertently suggests that the OPO must skip over certain heart candidates. Given these complications, the Thoracic Committee looked at approved heart-policy to figure out how to clarify the intent and provide very precise language for OPOs to follow. In short, if the OPO follows the heart match, the heart will always pull the lungs. But, if an OPO follows the lung match, the lungs will pull the heart unless there is an urgent heart candidate within a certain geographical distance that needs the heart.

After reviewing available data, the Thoracic Committee proposed granting priority to heart or heart-lung candidates in heart classifications 1-4 for heart-lung offers prior to allocating heart-lungs to lung or heart-lung candidates in lung classifications 1-12 for offers from adult donors. We also include a similar construct for allocation of heart-lungs from pediatric donors in the proposal.

**Impact of changes on sensitized lung transplant candidates**

The final problem is that current sensitization policy for lung candidates allows all transplant programs and the OPO in the DSA agree to allow the OPO to offer lungs out of sequence to a candidate they’ve agreed is highly sensitized. The removal of DSA-first sharing means that if this policy were to stay as written, not everyone with the potential to be “skipped” would have the opportunity to agree to it. The Committee considered multiple options, including:

- Allowing all parties within any area in which the candidate could be in zone A to agree,
- Allow for sensitized candidates to apply to the LRB for an exception, or
- Striking the policy altogether.

Ultimately, the Thoracic Committee decided to propose striking it altogether, because it is rarely, if ever used. UNOS staff closed by summarizing the questions the Thoracic Committee is seeking feedback on the following:

- Do you think 250 nautical miles from the donor hospital is the ideal scheme for lung distribution and should become permanent policy?
- Are the proposed changes to heart-lung allocation policy clear?
- Which of the options the Committee considered for sensitized candidates do you prefer?
  - Removing the policy altogether (proposed)
  - Allowing application to the LRB
  - Allowing all parties within any area in which the candidate could be in zone A to agree
  - Other

The Chair thanked UNOS staff for the presentation, and opened the floor for discussion. Several members offered feedback on the proposal, including:

- The 250 mile distance does not pose a challenge for pediatric lung transplantation. Pediatric lung transplant programs routinely travel farther distances for lung procurements. One member verbalized that a 250 mile zone for lung transplant programs in coastal areas do not have the same population density as those lung transplant programs that have land within the entire 250 mile zone. Population density may be a more appropriate scheme in organ allocation, rather than a concentric circle.
• The volume of pediatric heart/lung transplants performed annually is low. [Based on OPTN data there were only 2 pediatric heart-lung transplants performed over a two year period, 2016-2017] The proposed changes are clear, and pediatric heart/lung candidates do not appear to be disadvantaged by the proposal.
• General agreement with the approach to remove the policy language for highly sensitized lung candidates. One member noted that an alternative could include some role for the review boards for highly sensitized candidates.
• The Committee recommends inclusion of the following metric for post-implementation monitoring:
  o Number of pediatric lung transplants performed involving donors > 18 years old.

Next steps:
UNOS staff will prepare a draft response and share with the Chair and Vice Chair. Once approved, the response will be posted on the OPTN website.

4. Public Comment - Clarify Informed Consent of Transmittable Conditions
The Vice-Chair of the Ad-hoc Disease Transmission Advisory Committee (DTAC) profiled a proposal that is out for public comment.

Summary of discussion:
The OPTN/UNOS Membership and Professional Standards Committee (MPSC) sent a memo to the DTAC asking for clarification on OPTN Policy 15.3 (Informed Consent of Transmissible Disease Risk). The MPSC expressed concerns that a broad interpretation of current policy implies the need to get individual consent for any and every positive result including Epstein Barr Virus (EBV) and Cytomegalovirus (CMV) results or positive donor cultures. Implementing that in practice might not be reasonable and cause an undue burden for programs. In addition, it is very difficult, if not impossible, to monitor and enforce. DTAC never intended for common organisms such as EBV and CMV to be broadly included as part of this policy and felt that some changes to the policy could help to remove the ambiguity.

The speaker shared the policy changes were the product of a work group with members from the American Society for Transplantation (AST) and the American Society for Transplant Surgeons (ASTS). The policy language was rearranged to emphasize the general discussion and education requirement of potential transplant candidates that occurs at the time of listing a candidate. The proposal also adds a clause to this general discussion at the time of wait listing to have transplant hospitals highlight that donor results can affect post-transplant care and management. The work group had deliberation to what recognized transmissible conditions should be included in policy. They concluded to tie the specific consent process to conditions that candidates are screened for in UNetSM according to OPTN Policy 5.3.B (Infectious Disease Screening Criteria). DTAC feels the modifications proposed provides for a clear and enforceable policy as requested by MPSC.

The speaker noted this proposal is a minimum standard and transplant hospitals can do more based on their local practices. It should be noted that other informed consent requirements at transplant such as when using donor organs that from U.S. Public Health Service (PHS) increased risk donors do exist. The proposed policy would apply to recipients receiving organs from all donor types (living and deceased). The proposed policy is not intended to prescribe or modify how transplant programs obtain or document informed consent.

The speaker shared that conversations in the past several weeks with transplant colleagues noted incredible diversity of understanding and practices on the requirements of OPTN Policy 15.3. She then closed by thanking the Committee and asking two specific feedback questions.
a. Should OPTN policy specify patient signature, or is documentation of discussion between the provider and the recipient (or next of kin) sufficient?
b. Are conditions named in policy for candidate screening and re-executing the match run still applicable and complete?

The Chair thanked the speaker for the presentation and opened the floor for questions. Several members offered feedback on the proposal, including:

- The critical component is that the informed consent process is done diligently and correctly. There did not appear to be value-added for a policy requirement of a patient/patient representative signature for informed consent.
- As written, the proposal intends to require informed consent for accepting a CMV positive intestine for transplantation. Feedback from the regions and the Liver Committee has been against the inclusion of CMV. Members agreed with this sentiment to not include a policy requirement for informed consent in the setting of a positive CMV test result in the donor.

Next steps:
UNOS staff will prepare a draft response and share with the Chair and Vice Chair. Once approved, the response will be posted on the OPTN website.

With no more business to discuss, the conference call was adjourned.

Upcoming Meetings
- April 19, 2018 9-3 Central (Chicago, IL)
- May 16, 2018 4-5 PM Eastern (full committee conference call)
- June 20, 2018 4-5 PM Eastern (full committee conference call)