

OPTN/UNOS Pediatric Transplantation Committee
Meeting Minutes
February 20, 2019
Conference Call

George Mazariegos, MD, Chair
Evelyn Hsu, MD, Vice-Chair

Introduction

The Pediatric Transplantation Committee (the Committee) met via teleconference on 02/20/2019 to discuss the following agenda items:

1. Update on Pediatric Program Bylaw Implementation
2. Thoracic Committee Proposal
3. Ethics Committee White Paper
4. Update from Regional Meeting Presentations

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

1. Update on Pediatric Program Bylaw Implementation

The OPTN Board of Directors approved new pediatric transplant program Bylaws in 2015. Program applications in accordance with the new Bylaws are slated to be distributed during the summer of 2019.

Summary of discussion:

UNOS staff presented an update on the status of the upcoming pediatric program Bylaws. UNOS staff are going to create a toolkit on the OPTN website to help educate members on the Bylaws. The toolkit will contain:

- A frequently asked question (FAQ) document
- A link to current primary personnel applications. When programs apply for the pediatric component, they will also have to meet the requirements outlined in the primary personnel requirements.
- A link to educational offerings in UNOS Connect
- An implementation timeline with narration

The Chair stated that it would be helpful to have as much detailed information included in the narrated timeline as possible. UNOS staff asked if there were any other educational resources that should be included in the toolkit. The Vice-Chair asked if someone is already approved as a primary personnel, would they need to re-submit an application. The Chair was concerned that they would need to reapply.

A Committee member asked what the timeline is for implementation of the new Bylaws. UNOS staff stated that the timeline is not finalized because the new forms have not been approved by the Office of Management and Budget (OMB). Once the forms are approved and the applications are sent out to the programs, then the timeline starts. UNOS staff stated that applications will be due 90 days after the application is received by the program. However, most applications are not complete on the first submission and the UNOS Member Quality Department will work with programs to complete their application during the 18 month review process. This review will happen on a rolling basis.

A Committee member stated that some programs in his or her region were concerned that they would not be able to provide adequate documentation of certain aspects of the new requirements because they completed the requirements long ago. UNOS staff stated that the new Bylaws require a date of procurement and donor ID for verification of a procurement. Another Committee member mentioned that the organ procurement organization (OPO) that assisted on the recovery may have this documentation.

UNOS staff informed the Committee that the UNOS Member Quality Department are available to answer any specific questions. Committee members can send any questions to UNOS staff, who will get answers and present them on a future call. The Chair asked for more clarity surrounding the 18-month application review period and turnaround times.

Next steps:

Committee members are encouraged to send any questions about the new Bylaws to UNOS staff.

2. Thoracic Committee Proposal

The OPTN Thoracic Organ Transplantation Committee (Thoracic Committee) has a policy proposal titled, "Eliminate the Use of Donation Service Areas (DSAs) in Thoracic Distribution" out for public comment. The Chair of the Thoracic Committee presented the policy proposal to the Committee.

Summary of Discussion:

The policy proposal will ensure that heart allocation policy is compliant with the Final Rule by removing the use of donation service area (DSA). Adult heart allocation policy was recently changed in October 2018, so the Thoracic Committee wanted to make minimal changes. They decided to replace DSA with a fixed distance circle around the donor hospital. The Thoracic Committee considered four different versions of a fixed distance circle allocation model before deciding on a 250 nautical mile (NM) circle. The proposal also removes policy language that permits prioritization of sensitized heart candidates, which became impractical without DSA, and it removes the term "zone" from OPTN policy and replaces it with actual distances.

The Thoracic Committee was mindful to use supporting evidence per the Final Rule. The proposed policy:

- Is based in sound medical judgement
- Seeks to achieve the best use of donated organs and promote patient access to transplantation
- Promotes the efficient management of organ placement

The Thoracic Committee strongly considered a 150 NM circle, but ultimately decided on 250 NM because this distance best balances broader sharing and travel time. The expected effect of the proposed policy on the pediatric population is the same as it is on adults. The change to adult heart allocation in October 2018 has resulted in an increased opportunity for transplant for pediatric recipients from adult donors. The current policy proposal is not expected to have a dramatic effect on outcomes for the pediatric population. Expected outcomes for the pediatric population were similar across the different models. The Thoracic Committee looked at many other subgroups in their policy development. Overall, programs with more sick candidates are less disadvantaged as a result of broader sharing. Transplant programs will be getting more offers from further away and transplant teams may need to travel more to procure organs, which may lead to higher costs. OPOs will also have to allocate organs to candidates that are further away from the donor hospital, so match runs will be longer.

The policy proposal will go before the OPTN Board of Directors at their June 2019 meeting. The Thoracic Committee is asking for specific feedback on the 250 NM circle and if they should propose a different distance.

A Committee member asked if there is any plan for a review board to address access for highly sensitized candidates. The Thoracic Committee discussed this idea but the current policy for highly sensitized candidates is not used very often and it is not practical within the proposed policy. However, the Thoracic Committee does want to collect more data on sensitized candidates in the future.

The Chair of the Pediatric Committee asked if it would be beneficial for pediatric allocation to have a larger circle than the 250 NM that is proposed. The Chair of the Thoracic Committee stated that pediatric donor allocation already goes out to 500 NM circle for pediatric candidates that are Status 1A. There are a couple places in the country where pediatric candidates may lose some access to adult donors, but for most locations, pediatric candidates will have greater access to transplantation.

The Committee voted on: Do you recommend an alternative distance for thoracic distribution other than 250 NNM outlined in this proposal?

Results were as follows: 0 Yes; 7 No

The Committee voted on: What is your opinion of Eliminate the Use of Donation Service Areas (DSAs) in Thoracic Distribution?

Results were as follows: 3 Strongly Support; 3 Support; 1 Neutral/Abstain; 0 Oppose; 0 Strongly Oppose

Next Steps:

UNOS staff will distribute a survey for the Committee Members to submit feedback on the presentations from the previous meeting. UNOS staff will draft and submit a public comment on the policy proposal based on these discussions on behalf of the Committee.

3. Ethics Committee White Paper

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

Summary of Discussion:

The multi-organ transplantation (MOT) system is not standardized across organ systems which has led to some confusion, a lack of consistency, and possibly inequity in the way that these organs are distributed. MOT rates have approximately doubled over the past six years and the Ethics Committee felt that there should be more guidance and clarity around MOT.

The Ethics Committee identified twelve ethical dilemmas that could exist in MOT and addressed each of these dilemmas in the white paper. For each dilemma, the Ethics Committee provided recommendations for other committees to use when they are developing MOT policies.

One of the ethical dilemmas addressed 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. 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, which may be disadvantaging single organ transplant recipients. This may be ethically justified, but it is something that the individual committees must decide.

The Ethics Committee provided a number of recommendations in the white paper as well. 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. 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 Chair of the Pediatric Committee asked how data was used to create the analysis and recommendations in the white paper, specifically if waitlist outcomes of the pediatric population were considered independently. The Ethics Committee member stated that they were only trying to use enough data to show where disparities may exist, but not why they exist. The Ethics Committee did look at the pediatric population, but ultimately felt that detailed data analysis would be better left up to the individual committees.

A Committee member asked if MOT includes kidney-pancreas (KP) transplants. The Ethics Committee representative stated that KP transplants were not included in the white paper for a number of reasons. First, KP transplants are relatively common in comparison to other MOT combinations, so the Ethics Committee felt that KP would overshadow other organ combinations. And second, KP transplants treat the same disease, so while they may be two organs, the Ethics committee considered them one transplant. The Committee member stated that KP transplants tend to take high quality organs from pediatric candidates and recommended that this be discussed in the paper. The Ethics Committee representative stated that the paper does not focus on pediatrics, which should be its own paper.

A Committee member stated that it is important that the prioritization of KP candidates over pediatric kidney candidates is discussed in the paper because it is a prevalent issue. It could be included in a separate paper, but the Pediatric Committee must be able to provide input on this issue. It should not be left up to individual committees because there is not always strong pediatric representation on the committees. The Chair stated that a project to address some of the MOT issues specific to the pediatric population could be an opportunity for collaboration across OPTN committees.

Another Committee member asked if the paper provided any recommendations on how to address inequity for disadvantaged populations. The Ethics Committee representative stated that this data would need to be better analyzed before making any policy changes.

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

Results were as follows: 0 Strongly Support; 5 Support; 1 Neutral/Abstain; 2 Oppose; 0 Strongly Oppose

Next Steps:

UNOS staff will draft and submit a public comment on the white paper based on the meeting discussion on behalf of the Committee.

4. Update from Regional Meeting Presentations

UNOS staff provided an update on the Committee presentations at the regional meetings.

Summary of Discussion:

Three of the regions had no comments. One region reiterated that programs should start getting ready for the implementation of the new Bylaws. One region recommended that the Committee look at the disproportionate number of liver patients transplanted with an exception score and re-evaluate the pediatric end-stage liver disease (PELD) score. Another region raised a concern about how surgeons who fulfilled their procurement requirements prior to documenting the cases would comply with the new Bylaws. This requirement is consistent with other Bylaws which requires the procurement to be documented in a log that includes the date of procurement and the donor ID.

Next Steps:

The Chair asked Committee members to send any agenda items for the next meeting.

Upcoming Meeting

- April 16, 2019 – Richmond, Virginia