OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

OPTN Pediatric Transplantation Committee
Meeting Minutes
May 15, 2019
Conference Call

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

Introduction

The Pediatric Transplantation Committee (the Committee) met via teleconference on 05/15/2019 to discuss the following agenda items:

1. Update on Final KAS Data Request
2. Update on Pediatric Committee Collaborative Improvement Project
3. Review Committee Projects
4. Update on Pediatric Bylaws Implementation

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

1. Update on Final KAS Data Request

At the Committee's last meeting, they requested additional data on pediatric outcomes under the Kidney Allocation System (KAS). UNOS staff wrote a data request to capture the Committee's discussion. UNOS staff presented the data request to the Committee to make sure that all the necessary information was included.

Summary of discussion:

UNOS staff presented the Committee's data request. Once the Committee approves the request, UNOS staff will submit the request to the Health Resources and Services Administration (HRSA).

The Committee requested four-year KAS data on the following metrics:

- Mortality rates stratified by age
- Delayed graft function (DGF) stratified by age
- Transplant rates stratified by age
- Transplant rates in highly sensitizes children (98-100% Calculated Panel Reactive Antibodies (CPRA))
- Number and proportion of DR matching/mismatching
- Graft survival for DR matching/mismatching
- Kidney Donor Profile Index (KDPI) distribution of pediatric kidney donors by age
- Characteristics of recipients of KDPI >35 kidneys from pediatric donors (age, CPRA, etc.)

The age groups for stratification are 0-5, 6-10, and 11-17. Committee members had no additional comments.

Next steps:

UNOS staff will submit the data request to HRSA and present the data at an upcoming Committee meeting.

2. Update on Pediatric Committee Collaborative Improvement Project

The Committee has previously discussed participating in a collaborative improvement (CI) project. The Committee came up with four CI project ideas during their last meeting. UNOS staff presented information on the process for selecting a final topic for a CI project.

Summary of Discussion:

The Committee previously agreed upon the four following topics as potential CI projects:

- Increase utilization of Public Health Service (PHS) increased risk organs
- Evaluate organ offer turn-down/acceptance
- Increase recipient follow-up efficiency/improve follow-up
- Increase living donation

The Chair noted that the Committee previously discussed potential data points to measure the impact or current state of the first two project ideas. The Chair then stated that for increasing living donation, they could look at the variation in living donation for livers and kidneys across centers, matched with waitlist mortality and outcomes.

UNOS staff noted that they are working on creating problem statements, gathering high-level data, and conducting a literature search for each of the potential projects. This information will be presented to a subcommittee in the next few weeks, who will then have one week to review the information. Once the subcommittee approves, the UNOS CI team will package the data, literature reviews, and problem statements into a Value Factor Analysis (VFA) in SurveyMonkey for leadership to review. The VFA in SurveyMonkey will then be sent to the entire Committee for voting, and the subsequent results will be shared on a future Committee call. The Committee will then move forward with the project selected.

A Committee member asked if increasing utilization of PHS increase risk organs would build upon the guidance from the Disease Transmission Advisory Committee (DTAC) in 2017 and if there could be an educational component as a result of the project. The Committee member stated that transplant candidate parents may not be aware that increased risk organs are a viable option. UNOS staff stated that they would consider the DTAC recommendation and could consider creating an educational component if that project was selected.

The Chair asked what data points they could examine for increasing recipient follow-up efficiency. UNOS staff stated that they previously created a report on this topic and can use that as a reference.

A Committee member stated that they should look at the percent of kidney offer turn-downs that are PHS increased risk organs and what their KDPI's were. The Committee member commented that programs may be turning down high-quality kidneys, only because they are PHS increased risk.

The Chair stated that they should evaluate acceptance practices for pediatric candidates for split liver grafts versus whole livers. The Vice Chair stated that there has been recent literature published on this topic. The Vice Chair stated that they should look at instances where a program turned down a liver offer for a pediatric candidate, and then the organ was accepted by a different program and transplanted into another pediatric recipient. This would may show how program behavior differs.

A Committee member asked if it would be possible to see if a pediatric program turned down a whole liver that could have been split, and the organ was then accepted by an adult program and transplanted as a whole organ. UNOS staff stated that they could look at this. The Chair noted that they could use the split liver criteria to define this analysis.

Another Committee member asked if it would be possible to look at the impact of the degree of antigen matching between donors and recipients on organ offer acceptance.

A Committee member asked how the Committee could get programs to split more livers if the data shows that they are being underutilized. The Chair stated that the data would help the Committee choose which CI project to pursue. Depending on the project chosen, there could be multiple ways that the Committee works to change behavior.

Another Committee member asked if it is possible to see why an organ was labeled as PHS increased risk, not just that it was PHS increased risk. UNOS staff stated that this is difficult because this information is stored in the donor text, not a discrete data field. UNOS staff also noted that OPTN policy does not require that programs report why organs are PHS increased risk, just that they are PHS increased risk. However, the data does show if the donor was hemodiluted.

A Committee member asked if it would be within the scope of this project to require the reason for why an organ was categorized as PHS increased risk to be included in data collection. UNOs staff stated that this would require a policy change.

Another Committee member asked if it would be possible to look at the date that the nucleic acid amplification testing (NAT) was sent in relation to the time of procurement. The Committee member stated that sometimes the NAT testing is within three days of procurement, but it becomes more reliable at five days. UNOS staff stated that they could look at this as part of the PHS increased risk project.

A Committee member asked if it would be possible to analyze other data points that may show why the donor organ was classified as PHS increased risk. UNOS staff stated that they would look into these data points.

Next Steps:

UNOS staff will incorporate the Committee's feedback. They will draft problem statements, gather relevant data, and conduct literature reviews for each of the projects.

3. Review Committee Projects

The Committee previously completed a survey prioritizing which projects they would like to pursue next. The four CI projects listed above came out of this survey. The Committee is still considering other potential projects, beyond the CI effort explained above. The Committee discussed each project and assigned it a priority level (low, medium, high) so that they can focus their future efforts.

Summary of Discussion:

The Chair presented each of the projects included in the survey. Projects were reviewed by organ system. The results of the Committee discussion are provided below:

- **All Organ Projects**:
    - *Encourage Use of PHS Increased Risk Organs*: Project is being considered as a CI project, so not applicable.
    - *Promote Care Plane Adherence for Pediatric Recipients*: Low priority
    - *Risk Tolerance in Pediatric Transplant*: High priority
    - *Evaluate Organ Turn-Downs*: Project is being considered as a CI project, so not applicable.
    - *Guidance on Late Graft Dysfunction Surveillance to Promote Long-Term Recipient/Graft Survival*: High priority

- *Establish OPTN policy Requirement on Transition/Transfer Protocols*: Part of CI data request, so not applicable.
- *Guidance on Suicide Risk Identification/Reduction*: High priority. The Committee agreed that this was an important project, but was unsure if reliable data on the prevalence of the issue is available.
- *Update Recipient Follow-up Data Collection*: Low priority

- **Heart Projects**:
  - *Assess Disadvantaged Patients in the Heart Allocation System:* High priority, specifically highly-sensitized candidates. This also could be broadened to look at all organ systems.
  - *Review Urgent Status Criteria for Pediatric Heart Candidates:* High priority
  - *Transplant Outcomes for Pediatric Congenital Heart Disease:* Low priority
  - *Development of a Scoring System to Weigh Accepting a Heart Offer versus Continuing to Remain on the Waiting List:* Low priority

- **Liver Projects**:
  - *Review Urgent Status Criteria for Pediatric Liver Candidates:* High priority. This could also look at which candidates are disadvantaged in the allocation system. The Vice Chair also stated that they should look at overall waitlist mortality for pediatric candidates. A Committee member asked if there is the potential to examine the pediatric end-stage liver disease (PELD) score. The Chair said that this could be an option, but it will be a difficult project. A Committee member stated that re-evaluating PELD could follow this project.

- **Kidney Projects:**
  - *Review Trends in Pediatric Kidney Transplantation*: High priority
  - *Increase Participation of Pediatric Kidney Programs in kidney paired donation (KPD)*: High priority. Committee members noted that there is large area for improvement in KPD participation among pediatric programs.
  - *Criteria for Pediatric simultaneous liver kidney (SLK)*: Low priority

Next Steps:

UNOS staff will organize the Committee's feedback and log the project ideas.

4. Update on Pediatric Bylaws Implementation

New bylaws for pediatric components are slated to be released soon. The Committee has submitted a number of questions to UNOS staff related to the bylaws and their implementation.

Summary of Discussion:

UNOS staff stated that the OPTN will not be able to provide application information from previous primary applications. Also, there is no alternative pathway or letter of attestation in the current version of the bylaws.

The Chair and Vice Chair came up with the idea to work with a small group of individuals to test the application process. UNOS staff will reach out to individual committee members to do so.

UNOS staff also noted that the Committee does have the option to change the bylaws, but it would entail new project approval, public comment, and OPTN Board of Directors approval. UNOS staff informed the Committee that OPTN Membership Analysts are anticipating an increase in work with the implementation of the bylaws and will be the main point of contact to

answer any questions. UNOS staff also reminded the Committee of the toolkit posted on the OPTN website.

A Committee member asked when the application would be active. UNOS staff stated that the application is still waiting on Office of Management and Budget (OMB) approval, so the exact timeline is not certain. After the application is approved by OMB, there will be a 30-day notice after which the application will be active for 90 days. HRSA staff stated that they are working on getting the application approved as quickly as possible.

A Committee member asked what applicants should do if they are not able to get a letter from a previous supervisor or programs director. Another Committee member asked if there was a procurement requirement for a pediatric heart physician. UNOS staff will get answers and respond to the full Committee.

Next Steps:

UNOS staff will keep the Committee informed of any developments in the application approval process. UNOS staff will also provide answers to the Committee's questions.

Upcoming Meeting

- June 19, 2019 – Teleconference
- July 17, 2019 - Teleconference