OPTN Pediatric Transplantation Committee
Meeting Summary
October 20, 2021
Conference Call

Evelyn Hsu, MD, Chair
Emily Perito, MD, Vice Chair

Introduction

The OPTN Pediatric Transplantation Committee (the Committee) met via Citrix GoToMeeting teleconference on 10/20/2021 to discuss the following agenda items:

1. Pediatric Bylaws: 6-month Monitoring Report
2. Multi-Organ Transplantation (MOT) Committee Discussion

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

1. Pediatric Bylaws: 6-month Monitoring Report

The Committee reviewed the Pediatric Bylaws 6-month monitoring report, which highlights the main results from these changes.

On December 15, 2020, the established requirements were updated for pediatric components and minimum qualifications for primary pediatric transplant surgeons and physicians for the following transplant programs: kidney, liver, pancreas, heart, and lung.

The following are the results from the monitoring report:

Total number of programs

- Number of kidney programs with approved pediatric component = 105 (Region 11 had the most)
- Number of liver programs with approved pediatric component = 55 (Region 11 had the most)
- Number of pancreas programs with approved pediatric component = 27 (Region 5, 9, and 10 had the most)
- Number of heart programs with approved pediatric component = 59 (Region 3 and 5 had the most)
- Number of lung programs with approved pediatric component = 39 (Region 10 had the most)

Change in transplant volume

- Majority of centers have remained consistent or seen an increase in transplants from pre to post-implementation era, except for lung.

Waitlist additions

- Majority of centers have remained consistent or seen an increase in waitlist additions from pre to post-implementation era, except for lung.

Waitlist Removal Reasons

- For all organs, transplant was the majority reason for removal from the waitlist in both pre and post-implementation eras.

- For heart, kidney, and liver, removal due to death or too sick to transplant remained similar from pre to post-implementation.

Summary of discussion:

A member noted that the percentage of pancreas and lung waitlist removals due to "death or too sick for transplant" increased after these bylaws were implemented and inquired if this may have been caused by some change in the program. A member stated that the number of waitlist removals for lung is very small, so there will only need to be a difference of 1 or 2 patients in order for the percent to increase.

A member inquired about the specific goal of the new pediatric component criteria, especially since the waitlist removals and transplant volume stayed consistent pre and post-implementation. Staff stated that this was monitoring to make sure that these changes didn't significantly disrupt the system. A member stated the goal of the pediatric bylaws was to increase the standards for pediatric programs without decreasing access for pediatric candidates, and that that potential change in access wasn't changing things such as waitlist additions, removals, or deaths.

A member inquired if the Committee will look at this data again. Staff stated that the Committee will see a monitoring report in March or April 2022 for one year post-implementation and again for two years post-implementation.

A member inquired about the cohort dates for pre and post-implementation. Staff explained that pre-implementation was 6/15/2020 to 12/15/2020 and post-implementation was 12/15/2020 to 6/15/2021.

A member inquired if there is any outcomes data that should be included in the monitoring report that might be influenced by the change in the pediatric bylaws and the additional pediatric programs. Staff stated that outcomes data wasn't requested in the monitoring report, but could be included in the additional reports. A member inquired about other outcomes that would be of interest to the Committee. A member stated that post-transplant survival would be an outcome they would want to monitor. Staff stated that it's possible to add post-transplant survival to a report; however, the Committee may need to wait for the one year report.

A member mentioned that they'd like to include the utilization of the emergency exception pathway for heart and liver programs in the one year monitoring report. Staff stated that the 6 month report only showed one liver and one heart case where the program attempted to use the pathway but didn't enter the data correctly, so it hasn't been much of an issue.

A member stated they are fully in support of these pediatric bylaws, but are concerned that programs may feel like this was a lot of paperwork without any reason to have an approved pediatric component. A member stated that a number of programs didn't reapply for the pediatric component and it would be interesting to see that total number stratified by organ type.

A member emphasized that the centers that remained pediatric centers aren't going to affect access, instead it will be the centers that only did a few pediatric transplants and didn't reapply. So, the data should either show that centers with a pediatric component are getting busier due to pediatric candidates being routed through those centers or that pediatric candidates just aren't getting transplanted. The member stated they weren't sure whether the Committee can determine that with the data presented in this monitoring report.

A member stated that it appears there was one unapproved pediatric heart program that added pediatric candidates post-implementation and inquired about what happened to those candidates. Staff

explained that the Member Quality department monitors the use of the emergency exception pathway weekly and this case was caught and addressed.

A member suggested considering the number of programs with a pediatric component pre and post-implementation and the number of transplants pre and post-implementation in order to determine whether some pediatric candidates were lost. The member added that this may be helpful due to the regional referral nature of the smaller programs.

A member inquired if there is any way to capture whether pediatric candidates were lost or needed to travel more due to the decrease in programs with a pediatric component. Staff noted this it's important to consider the historical timeline of this project and what was occurring in parallel with the project. Staff explained that the change to the pediatric bylaws was approved by the Board of Directors in December 2015. Then, these changes needed to go through Office of Management and Budget (OMB) approval and programs were given time to prepare for implementation; so, in many ways the pre-implementation cohort is a group of programs that already implemented these changes since they knew they were coming. Staff continued by stating that every organ type included in the changes to the pediatric bylaws had also gone through significant allocation changes over the last five years that impact things such as post-transplant mortality and waitlist additions.

A member stated that that's an important point and helps explain why there isn't a huge change in the 6 month monitoring from pre to post-implementation of the pediatric bylaws changes.

2. Multi-Organ Transplantation (MOT) Committee Discussion

The Committee reviewed the background and future efforts of the multi-organ transplantation (MOT) work.

In 2019, the Policy Oversight Committee (POC) identified MOT as a strategic policy priority and, in 2021, the OPTN Board of Directors approved clarification to general MOT policy, which was medical criteria for heart and lung candidates to receive offers for either a kidney or liver if they were listed for a second organ.

The following are the future efforts for the MOT Committee:

- Eligibility Criteria (short term)
    - Qualifying criteria for the second organ
- Allocation threshold (short term)
    - Qualifying candidate criteria related to the primary organ
- Safety net (short term)
    - For candidates that receive a single organ, but qualify shortly after transplant
- Match run prioritization (long term)
    - Policy directing organ procurement organizations (OPOs) to allocate certain single organ or MOT allocations in a particular order
    - Not specifically addressed in current policy

The MOT Committee is currently working on a project regarding eligibility criteria for heart-kidney and lung-kidney candidates (which will go out during January 2022 public comment cycle) and decided that all pediatric candidates registered for both organs should be eligible to receive both organs.

<u>Summary of discussion:</u>

A member inquired if the proposed eligibility criteria for heart-kidney and lung-kidney applied to either adult and pediatric candidates or just adults. Staff explained that the criteria only applied to adults – if a

pediatric candidate was registered for both organs, then they would be eligible for a heart-kidney or lung-kidney.

A member noted that the pediatric candidates who would be eligible for heart-kidney and lung-kidney transplants, in the proposed criteria, are less than 12 years old. The member expressed concern that this doesn't account for all pediatric candidates (12-17 years old). Staff explained that those 12-17 year old candidates would have to meet the criteria in order to be eligible for a heart-kidney or lung-kidney transplant.

A member inquired if that age range is reasonable from the lung perspective, especially since the Committee has been working on standardizing the pediatric definition across all organs so that it encompasses all candidates less than 18 years old. A member noted that continuous distribution of lungs will grant additional points to candidates who are less than 18 years old. The member also mentioned that, from their understanding, most patients under the age of 12 who are listed for lung currently tend to have a lung allocation score (LAS) greater than 30, so they think this issue may be balanced out in continuous distribution.

A member emphasized the importance for the Committee to see data on how many adolescents this policy could be affecting. The member stated that typically, if it's such a small number, the Committee advocates for adolescents to be included in pediatrics as opposed to subjecting them to adult criteria, which may not apply as well to them. A member agreed that these numbers are going to be very small, especially for lung-liver.

A member inquired if there's any reason the MOT Committee would not agree to make this criteria "less than 18 years old" instead of "less than 12 years old". A member noted that there has only ever been one teenager who has received a lung-kidney transplant.

A member inquired if "any pediatric status" for a heart includes all candidates less than 18 years old. Members confirmed that pediatric status for heart is all candidates who are less than 18 years old; however, pediatric status is based on age at the time of listing. So, a candidate could be listed at 17 years old and not receive an offer until they're 21 years old, but they would still be considered pediatric.

A member inquired if this policy gives direction to OPOs on what organ match run to allocate from first. Staff explained that MOT policy is being approached in phases and match run prioritization, which gives more instruction to OPOs on what organ match run to allocate from first when they have multiple organs, multiple match runs, and MOT candidates, will be addressed later in the project timeline.

A member emphasized that the Committee appreciates the attention the MOT Committee has given to pediatric multi-organ candidates; however, the Committee also has a concern in regards to the impact that adult MOT candidates may have on the pediatric single organ candidates when it comes to priority for the second organ, especially for kidney-pancreas. Staff stated that that's an excellent point and the MOT Committee will be discussing that during the next part of their project. Staff explained that this policy solely deals with eligibility criteria for heart-kidney and lung-kidney and doesn't address how they will be prioritized in the allocation scheme.

A member inquired if there are any proposed policies for the heart-kidney and lung-kidney safety net criteria or if that still pending. Staff explained that the MOT Committee is currently working on the safety net policy and it will be almost identical to what is established for the simultaneous liver-kidney (SLK) safety net criteria. A member noted that the SLK safety net policy prioritizes safety net kidney candidates behind pediatric candidates in the kidney prioritization, so there isn't really an impact on pediatric patients.

Upcoming Meetings.

- November 17, 2021 (Virtual)

Attendance

- **Committee Members**
  - Emily Perito
  - Abigail Martin
  - Brian Feingold
  - Caitlin Peterson
  - Geoffrey Kurland
  - Jennifer Lau
  - Kara Ventura
  - Rachel Engen
  - Regino Gonzalez-Peralta
  - Shellie Mason
  - Warren Zuckerman
  - William Dreyer
- **HRSA Representatives**
  - Jim Bowman
  - Raelene Skerda
- **SRTR Staff**
  - Christian Folken
  - Jodi Smith
  - Simon Horslen
- **UNOS Staff**
  - Rebecca Brookman
  - Matt Cafarella
  - Betsy Gans
  - Eric Messick
  - Katrina Gauntt
  - Laura Schmitt
  - Leah Slife
  - Matt Prentice
- **Other Attendees**
  - Melissa McQueen