OPTN Pediatric Transplantation Committee
Meeting Summary
September 23, 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 9/23/2021 to discuss the following agenda items:

1. Needs Assessment: Pediatric Priority in Organ Allocation
2. Ad Hoc Disease Transmission Advisory Committee (DTAC) – Pediatric Public Health Services Guidelines Blood Draw Policy Update
3. Public Comment Presentation: Continuous Distribution of Kidneys and Pancreata Concept Paper, Kidney and Pancreas Committees
4. Public Comment Presentation: Ethical Considerations of Continuous Distribution in Organ Allocation, Ethics Committee

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

1. Needs Assessment: Pediatric Priority in Organ Allocation

Committee members discussed current challenges and opportunities in pediatric heart, liver, lung, and kidney allocation.

The following were presented as opportunities in pediatric allocation:

Heart

- Status exceptions handled by Regional Review Boards
- Establishment of Pediatric National Heart Review Board (active 6/15/2021)
- Expand access to ABO-incompatible (ABOi) heart transplantation
- Address need for increased granularity in highest urgency group (Status 1A) with continuous distribution
- Reconsider whether highest degree of HLA sensitization should have a role in prioritization under continuous distribution

Liver

- Increase pediatric priority above adults for organs from donors who are less than 40 years old
    - Raise blood type priority for O to A, AB for children from pediatric donors
    - By new calculated score – age-adjusted mortality
    - Change allocation order for organs and consider multi-organ
    - By exception score (blocked by NLRB)
- Make split liver transplantation mandatory
- Consider pediatric access to living donation and domino transplantations

Lung

- Adolescents on the transplant list are often not the size of adolescents – these adolescent candidates compete for lungs from adults when they need lungs from children and the wait can be long
    - See how this is handled with the transition to continuous distribution of lungs

Kidney

- Definition of pediatric – age at time of listing versus (vs.) at time of match run vs. at time of disease onset
- Use of kidney donor profile index (KDPI) in continuous distribution and the appropriateness of using KDPI for pediatrics
- Incorporation of multi-organ allocation into continuous distribution

Summary of discussion:

The following is a summary of the Committee's discussion:

Heart

The Chair inquired how long a candidate waits at Status 1A. A member stated that it varies based on size, organ availability, and location, but infants have a longer waiting time that is typically around 4-5 months. A member noted that older pediatric patients are benefiting from an idiosyncrasy in the adult heart criteria, where adult-sized pediatric patients are quickly offered hearts from adult donors since those pediatric patients are congruent to Status 1 adults.

The Chair stated that it seems there are ordering changes in heart allocation that could take place that would benefit the sickest patients.

A member inquired if there are any metrics regarding how long pediatric patients are on ventricular assistant devices (VAD). A member stated that some of that data could be collected from the OPTN, but most of the data is going to come from organizations that are specifically focused on VAD utilization. The member noted that the use of devices has evolved and is still evolving, so while there isn't a Food and Drug Administration labeling for destination therapy, more centers are willing to use destination therapy.

Liver

A member stated that they participated in the Regional Review Board and National Liver Review Board (NLRB) and inquired if there has been a review of the three exception request denials in order to better understand why the requests weren't approved. The Chair stated that they aren't sure whether there has been a review, but, from their understanding, the NLRB continues to be inconsistent in the way that they are judging scores. The member stated that it may be important to review these cases and determine what contributed to the request denial. It was noted that the members on the review boards typically don't have much experience with pediatrics and aren't involved in the pre-transplant medical management of the pediatric patients. A member stated that there should be a separate pediatric review board or an appeals review board.

A member stated that the use of living donors and split liver deceased donors, from the surgical standpoint, would have a large effect on children since a lot of centers currently don't have the expertise to perform split liver transplants, which requires a high level of expertise. It was noted that there isn't a requirement for surgeons at pediatric programs to have experience with split liver transplants or technical variant grafts. The Chair also stated that infrastructure, such as number of

operating rooms available or practitioners willing to travel, is limiting for smaller centers as well. A member mentioned that, if experience were a requirement for pediatric surgeons, there may be a decrease in the number of approved pediatric programs.

A member emphasized the fact that, in France, transplant centers clear their list because of the wide use of split liver transplant and inquired if there were any worse outcomes that had been reported. The Chair stated that worse outcomes have not been reported. The member inquired why split liver transplant isn't used more broadly in the United States. The Chair noted the issues of lack of expertise, access, and infrastructure mentioned above.

A member suggested that, to achieve increasing the use of split liver transplant, there may need to be a reworking of who performs the transplants – for example, is there an additional fellowship training that pediatric surgeons need. The member proposed that this would be a great topic to have a workgroup or task force discuss.

A member inquired if there has been research or modeling done to determine the impact of access a mandatory split liver policy would have. The Chair stated that currently it is all theoretical; however, looking at that data or modeling would be an interesting study.

A member stated that there currently is criteria that mandates which donor livers should be considered for split liver transplants, so there would be a way to analyze how many livers met that criteria compared to how many livers actually ended up being split and transplanted into two candidates. The Chair stated that it's about 3% of livers that meet the criteria to be split.

Lung

There was no discussion.

Kidney

A member inquired why kidney-pancreas transplants have the highest impact on pediatric candidates compared to other multi-organ combinations. A member stated that it could be due to the difference in how the next sequential candidate was defined in the OPTN dataset and that the data may not have captured the correct population due to the type of study used.

2. Ad Hoc Disease Transmission Advisory Committee (DTAC) – Pediatric Public Health Services (PHS) Guidelines Blood Draw Policy Update

The Committee reviewed the proposed changes to Policy 15.2, which address the concerns regarding the amount of blood needed from small children for HIV, HBV, and HCV testing during admission for transplant.

The following summarizes the changes:

- Since it is current practice for candidates to be tested during evaluation (creating a baseline), it would be acceptable for candidates 10 years old or less at the time of transplant to not be required re-testing upon admission for transplant
    - Policy exception for candidates 10 years old and less – while HIV, HBV, and HCV testing is still required, there is no timeframe attached

Summary of discussion:

A member inquired if there was any discussion about changing the requirement for testing after transplant. The Chair stated that it was not part of this discussion, but if this continues to be an issue

then it may come up in the future. Staff stated that there is a time frame for getting the post-transplant testing done; however, there is a significantly shorter timeline for pre-transplant testing.

3. Public Comment Presentation: Continuous Distribution of Kidneys and Pancreata Concept Paper, Kidney and Pancreas Committees

The Committee reviewed a presentation from the Kidney and Pancreas Committees on their Continuous Distribution concept paper, which summarized the attributes the Kidney and Pancreas Committees are considering in their continuous distribution framework.

Summary of discussion:

The Committee expressed the importance of engaging the community in a community-wide exercise, like the Lung Committee did, to help prioritize attributes against each other.

The Committee expressed concern about the use of kidney donor profile index (KDPI) as a predictor for outcomes in pediatric patients. There's evidence that KDPI has an age related inflection point among late teenage donors, which means that pediatric candidates aren't getting access to kidneys from high quality pediatric donors. A member posed the question whether KDPI should be used for pediatric candidates and whether the cut off at 35% should be the same for pediatric recipients.

The Committee suggested considering alternatives to KDPI or analyze whether an alternative may be achievable based on existing data. A member noted an equation had been developed for pediatric donor kidneys, which included weight percentiles, height percentiles, and whether the kidneys were being used as en bloc. Data showed that this equation out predicted KDPI in terms of outcomes.

The Committee also suggested focusing on en bloc kidneys as an area to improve access for pediatric candidates.

4. Public Comment Presentation: Ethical Considerations of Continuous Distribution in Organ Allocation, Ethics Committee

The Committee reviewed Ethical Considerations of Continuous Distribution in Organ Allocation white paper from the OPTN Ethics Committee.

The following is the rationale for the white paper:

- Current allocation system creates edge cases, whereby some candidate may not be treated similarly because they fall into different classifications
    - Examples of classification criteria include: compatible vs. identical blood type

Summary of discussion:

The Committee emphasized the importance of calling out the pediatric population in Ethics Committee white papers as a vulnerable population, especially since there continues to be discussion regarding the cut off age for the pediatric definition. In this country, there is an obligation to protect minors and these discussions erode this protection.

A member noted that an ethical consideration for the pediatric definition in continuous distribution should be age at disease onset instead of the age at listing for transplant, which would eliminate some of these hard boundaries.

A member suggested that age could be assigned value in a continuous, but declining fashion, based on the potential benefit from an organ transplant. A member noted that, in order to do this, it would need to be discussed whether the one-year, limited, post-transplant survival outcomes are appropriate to determine utility.

The Committee suggested citing the Ethics Committee's previous white paper on the Ethical Principles of Pediatric Prioritization to show that both of these white papers are related.

Upcoming Meetings

- October 20, 2021 (Virtual)

Attendance

- **Committee Members**
  - Evelyn Hsu
  - Emily Perito
  - Abigail Martin
  - Brian Feingold
  - Caitlin Peterson
  - Caitlin Shearer
  - Geoffrey Kurland
  - Kara Ventura
  - Johanna Mishra
  - Rachel Engen
  - Regino Gonzalez-Peralta
  - Shellie Mason
  - Warren Zuckerman
- **HRSA Representatives**
  - Jim Bowman
  - Raelene Skerda
- **SRTR Staff**
  - Jodi Smith
- **UNOS Staff**
  - Rebecca Brookman
  - Matt Cafarella
  - Betsy Gans
  - Abigail Fox
  - Elizabeth Miller
  - Katrina Gauntt
  - Leah Slife
  - Laura Schmitt
  - Matthew Prentice
- **Other Attendees**
  - Melissa McQueen
  - Keren Ladin
  - Jim Kim