OPTN Pediatric Transplantation Committee
Meeting Summary
October 6, 2022
O'Hare Hilton, Chicago, Illinois, Paris Ballroom

Emily Perito, MD, Chair
Rachel Engen, MD, Vice Chair

Introduction

The OPTN Pediatric Transplantation Committee (the Committee) met in Chicago, Illinois, on 10/06/2022 to discuss the following agenda items:

1. Demystifying Continuous Distribution
2. Post-implementation Evaluation of Pediatric Emergency Exception Proposal
3. Liver: Acuity Circles 2-Year Monitoring Report
4. Kidney: 1-Year Monitoring Report
5. NASEM Report and the OPTN Response
6. Working Lunch Report Out
7. Multi-Organ Transplant (MOT) Committee Road Map
8. Heart ABOi Project Update
9. Year In Review and Goals For Upcoming Year

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

1. Demystifying Continuous Distribution

The Committee heard a presentation on Continuous Distribution.

Summary of discussion:

A committee member asked if there is a way to establish a threshold when prioritizing candidates so that candidates at high risk of waitlist mortality, such as pediatric candidates, are not inadvertently deprioritized. The presenter replied that the Massachusetts Institute of Technology (MIT) can help the OPTN use mathematical optimization techniques to determine thresholds, so that specific candidates retain increased access to transplants while continuing to incorporate other attributes that align with the OPTN Final Rule.

Another member asked where estimated glomerular filtration rate (eGFR) and social determinants that might disadvantage non-English speakers fit into continuous distribution. The speaker replied that eGFR is a criteria used in OPTN policy; it is not a specific attribute of continuous distribution. The speaker added that incorporating the social determinants of health (SDoH) into allocation has been discussed by other Committees. However, there is currently no consensus on how to incorporate SDoH into allocation. The presenter noted that this topic needs additional cross-committee consideration and will be part of a larger OPTN discussion.

Another member asked if the use of kidney donor profile index (KDPI) as a weight modifier is to allow for more efficient organ allocation. The member asked the presenter to elaborate on the goal of differential prioritization.

The presenter responded that in KDPI, there are four match runs in the OPTN policy for kidney allocation, and pediatric candidates are prioritized in the first two match runs. In kidney transplantation, there is a pediatric attribute for three out of four match runs in the example. A center is more likely to accept a higher quality organ for a pediatric since they are given priority. The goal of KDPI is more than efficiency; it is also about ensuring equitable access to transplants. The presenter stated that differential prioritization is based on various reasons, which is part of the discussion that the Committees have when deciding how to modify KDPI.

The Chair asked if the weight modifiers are the primary way donor characteristics will be incorporated into the composite allocation score or if other donor characteristics may be considered. The presenter replied that the example provided is the framework used to bring in donor characteristics. In this case, the donor characteristic is KDPI, but other donor characteristics, such as age or body mass index (BMI), can be used.

A member asked whether pediatrics and adult donors will be entered as weight modifiers in the kidney continuous distribution. The presenter replied that there would be one overall allocation algorithm for each organ within continuous distribution, but there would be donor weight modifiers to incorporate different donor characteristics. These donor weight modifiers will be used to incorporate the different donor factors.

Regarding kidney weight modifiers for KDPI, a member explained that pediatric candidates get priority for the KDPI 0-85% kidneys in the current system. Pediatric candidates do not get priority for KDPI 86-100% because they are less likely to accept marginal kidney donors. A Committee member noted that it is essential to consider the burden that increased organ offers have on personnel from OPOs and transplant programs, especially for pediatric programs, which tend to be smaller. Giving pediatric candidates increased priority for organ offers they are unlikely to accept will exacerbate the burden on staff members responsible for evaluating and responding to organ offers.

A member asked how offer filters would be applied. The presenter replied that offering filters would be a separate tool. As the OPTN moves forward with changes to allocation, there needs to be better minimum acceptance criteria tools for members to use. These tools will be ready when kidney and pancreas shift to a continuous distribution framework.

Another member asked if artificial intelligence (AI) modeling or public comment will be required before these proposed policy changes are approved and implemented. The presenter replied that the National Organ Transplantation Act (NOTA) requires all changes to organ allocation to be released for public comment.

Another member expressed that the Committee had the opportunity to have multiple Continuous Distribution presentations and discussions. The member asked the Committee what they had been hearing about continuous distribution from people in their communities.

A member asked if a specific population is continuously disadvantaged in the statistical modeling's composite allocation score (CAS). It would be interesting to see if the statistical modeling can predict which population will always have a low CAS score. The presenter replied that while looking at the distribution scores and how individuals are impacted, heart-lung patients consistently scored too low in lung transplantation to get a heart-lung offer. Clinical characteristics could change, and they would be able to rise in priority.

Another member commented that for the last decade, there had been discussions about the allocation system in the U.S and how it compares to allocation systems in other countries. The member noted that,

like other countries, there needs to be more focus on pediatric candidates and ensure that pediatric access does not worsen. However, there has been a continued effort to improve pediatric access.

Another member stated that educating the community about continuous distribution is crucial. It is essential to understand where educational resources are located and how accessible they are to the community. Some community members don't know how to make a public comment. Pediatric families and parents are encouraged to voice their concerns or bring up areas of opportunity. There should be a better way to educate them on the topic. The presenter agreed that engaging patients in continuous distribution is important. Patients have the opportunity to engage in the continuous distribution prioritization exercise. There has been discussion about more opportunities and tools for the public to provide input on the value-weighted decisions. These tools would help explain the weights' meaning and how the rating scales work.

Another member asked about the level of transparency when deciding on the weight modifiers and if they would be publicly available. The presenter confirmed that they would be publicly posted.

A member noted that statistical modeling can be faulty. The modeling system is not built for pediatrics, and there's been data to show that LSAM modeling is not accurate when applied to pediatric candidates. The member suggested that if children receive priority, there should be guardrails to ensure their priority does not go away.

A member mentioned that organ allocation is complex, and many providers may not understand the nuances of the continuous distribution allocation policy. The member further explained that if healthcare providers are confused about allocation policy, candidate families are also likely to be confused. There should be some effort to find a way to make the allocation process more understandable.

2. Post-implementation Evaluation of Pediatric Emergency Exception Proposal

The Committee heard an update on the results of the Membership and Professional Standards Committee's (MPSC) review of the pediatric emergency exception proposal from December 2020 – August 2022.

Summary of discussion:

The report included information about programs that want to list candidates under 18 years old who must meet the pediatric component membership bylaws implemented in December 2020. From December 2020- August 2022, five candidates under 18 were listed at programs that did not have an approved pediatric component. Of the five instances, one under-18 candidate registered at a program that did not have a pediatric component and met the criteria under the emergency exception bylaws.

The presenter showed data on the emergency exception pathways. A member asked about the difference between the one-heart candidate and the five candidates on the graph pertaining to the emergency exception pathway data. The presenter replied that one heart candidate met the liver emergency exception criteria listed in the OPTN bylaws. The presenter further explained that five pediatric transplant candidates listed at an adult center did not meet the specific exception criteria in the bylaws.

A member clarified that the OPTN emergency exception bylaws were implemented, and two programs listed and transplanted a pediatric candidate without meeting the pediatric criteria. The member asked why they didn't meet the criteria. The presenter responded that one of the liver situations had not been reviewed by the MPSC yet, but will be on the agenda for the next MPSC meeting. That situation involved

a pediatric candidate with several clinical issues that the pediatric hospital did not feel would receive better care at an adult hospital.

The presenter clarified that the purpose of the update is to report back to the Committee on the findings based on the monitoring plan and ask the Committee to determine whether there should be changes to the emergency exception criteria.

A member asked what happens when an adult center without a pediatric component tries to list a pediatric candidate. The presenter replied that when a program is attempting to list a candidate under the age of 18, there's a pop-up box that requires them to enter additional information stating that the candidate meets the specific emergency exception criteria.

3. Liver and Intestine: Acuity Circles 2-Year Monitoring Report

The Committee heard an update on Acuity Circles 2-year monitoring report.

Summary of discussion:

A member asked if the report is based on a post-COVID period. The presenter replied that the report includes the peak of covid, and the post covid period data is broken out a little more specifically. After the post-COVID -period, the data is grouped within the 2-year report. A member asked if pediatric candidates are categorized by allocation score at waitlist removal. The presenter replied that their allocation score categorizes them, but their score can change over time.

Another member noted that pediatric candidates are getting transplanted at lower model end-stage liver disease/ pediatric end-stage liver disease (MELD/PELD) scores, but fewer of them need to get to the high MELD/PELD scores to get transplanted. A member asked if patient families have access to a calculator where they can enter their data and determine their MELD/PELD score. The presenter replied that they would soon; currently, they have access to the lung allocation score (LAS) calculator.

The presenter noted a decrease in pediatric deceased donor liver-alone transplants amongst 0-2 years old. During the pre-acuity circle implementation, there were 472, 0–2-year-old pediatrics deceased donor liver alone transplants and 377, 0-2-year-old pediatric transplant recipients post acuity circle policy. A member stated that candidates under two years old could often be transplanted with a split liver segment. The member asked if controlled for the change in the number of recipients that are 0-2 years old, is this still a decrease in how many pediatric transplants? The presenter replied that if you look at the proportion of liver transplants, they have decreased from 25% to 22%. The decrease in transplants has been in the smallest children.

Another member commented that the increase in distance between transplant programs and donor hospitals could have potentially contributed to the decrease in the number of split liver transplants because a split liver procurement is more complicated and requires more surgical staff. The member continued by saying that programs are less likely to accept a split liver graft that was procured by an outside surgeon than a graft procured by a surgeon at that program.

A member noted that the acuity circles 2- Year monitoring report does not highlight some of the concerns of the Committee. The member expressed that it is important to highlight that 0-2-year-old pediatric candidates are not seeing the benefit that would be expected for pediatric candidates to see from the allocation changes. The member suggested that having the 0-2-year-old pediatric data fleshed out more in future reports would be helpful.

4. Kidney: 1- Year Monitoring Report

The Committee heard an update on the kidney 1 -year monitoring report.

Summary of discussion:

A member inquired about the accuracy of the report. During covid, there was no vaccine, and many centers stopped doing transplants. The report concludes that there were more transplants within one year. It seems like there would be fewer transplants after implementing acuity circles. The member suggested that reviewing a two-year data report may be more helpful or looking at data from 2019.

5. NASEM Report and the OPTN Response

The Committee heard an update on the NASEM report and the OPTN responses.

Summary of discussion:

A member noted that there had been concerns raised about data security and asked if they had been data on data security breaches. The presenter replied yes- they have had various amounts of attacks they have been able to fend off that didn't get through. Information technology (IT) has been doing a good job. Their systems never come down for security risk, and now they're working on strengthening the system.

A member asked if UNOS made a statement in the Washington Post or New York Times. The presenter replied that there was a response, but it had not been published yet.

A member noted that there is mistrust in the community regarding transplantation. When a hearing such as this occurs, there needs to be an immediate response, so the community knows what is true and what is not. The longer the delayed response, the more confusion, debates, and fear. In addition to a statement, there needs to be action behind the statement to show the community that they can trust UNOS and transplantation stakeholders.

A member asked about the difference between UNOS and OPTN. The presenter replied that UNOS is a non-profit organization and could theoretically exist without the OPTN. The OPTN is a body established in regulation and law. It is a non-profit entity with its own rules and governance structure separate from UNOS.

A member asked if the topic of pediatrics came up in the NASEM report. The presenter replied that pediatrics was recognized as a vulnerable population, but very little specific information was included in the report. We should consider equity and access implications specifically to pediatrics.

6. Working Lunch Report Out

The Committee split into small groups to discuss opportunities to develop projects in alignment with the NASEM recommendations.

Summary of discussion:

Group 1:

A member recommended customizable dashboards for accepting offers. There should be a texting component in donor net to ask questions and receive instant answers and feedback. Additionally, there should be more agile decision-making when multiple committees make decisions. When a donor offer is declined, there should be an automatic update for what happens to the donor if the recipient declines to increase utilization. There should be patient-facing dashboards to help increase transparency in patient status and information. The dashboard would help give patients additional information and insight into offers and acceptances.

Group 2:

Members discussed that in current pediatric policy, if an individual develops end-stage disease before turning 18 years old. Still, because of access to care, or the location where they live, they did not get on the waitlist until after they turned 18, and they don't get pediatric priority. It's unclear how often this is happening, but it impacts pediatrics. The members considered taking a closer look into this concern.

Regarding Kidney-Pancreas transplants, there were concerns about disparities for children who age into the adult system and need a second transplant. The group also discussed transitioning from the donation service area (DSA) to allocation circles. DSA size was based on population density; now, it is based purely on geographic nautical miles. This is a concern because this means something very different if you are in Utah compared to living in New York City. The group also discussed HLA matching and utilizing UNOS and SRTR data. The group suggested working on a white paper to better understand the direction of OPTN monitoring and specific pediatric data the Committee would like to see from the monitoring reports. In terms of equity ad SDoH, the member stated that UNOS has not looked at the pre-transplant phase and how candidates get on the waitlist.

Group 3:

A member mentioned a better way to educate patients and parents, such as videos, infographics, etc. The Committee should understand the barriers and how to incentivize programs in terms of split liver. More surgical representation input on how to define and prioritize accepting a split liver. We need a productive way that incentivizes split liver transplants. This group was also interested in seeing data on DCD kidneys for pediatrics, lowering discard rates, and increasing our allocation process as we move into the continuous distribution framework.

Group 4:

A member mentioned that there is information on distance from centers and suggested the Committee look at how outcomes are different by distance because we can't address a problem unless we know there is an issue. The group indicated including the preferred language in the data that is collected. The group discussed other topics, such as for-profit dialysis centers and ensuring pediatric centers are not disadvantaged by adult centers. Members mentioned that there should be shared communication amongst transplantation professionals about what is happening at the centers. Lastly, there is a need for standardized pediatric monitoring for policy implementation.

Group 5:

A member stated increasing transparency and ensuring patients and families know the program's size. The group also discussed prioritizing multi-organ transplant patients over pediatric patients and how this impacts pediatrics. Also, concerns about not receiving wait time unless a patient is on dialysis and the impact of that on pediatrics.

7. Multi-Organ Transplant (MOT) Committee Road Map

The Committee heard an overview of the Committee roadmap and upcoming projects from the Multi-Organ Transplant Committee Chair.

Summary of discussion:

A member noted that there are challenges around how to come up with a medical urgency score for pancreas. A member suggested asking for more data. For example, more data on the mortality rate for an individual that needs a Kidney-pancreas versus just a kidney, and what is the priority, how much more points they would get. A member suggested stratifying how sick a kidney transplant patient is.

A member noted that sometimes people get listed for a liver and kidney when they have kidney disease that will resolve once they get a functioning liver in place—having a safety net so that a program will only transplant a liver and give the liver a chance to see if the kidney disease will improve. The patient will get a little extra point if their condition doesn't improve because they took the chance. Overall, ensuring a safety net for other organs is essential, and the member suggested the MOT Committee look at it.

8. Heart ABOi Project Update

The Committee heard an update on the heart ABOi project.

Summary of discussion:

A member asked when the proposal go out for public comment. The presenter replied that it would go out for public comment in January 2023.

Upcoming Meeting

- November 16, 2022

Attendance

- **Committee Members**
  - Abigail Martin
  - Caitlin Peterson
  - Kara Ventura
  - Neha Bansal
- **HRSA Representatives**
  - Marilyn Levi
- **SRTR Staff**
  - Jodi Smith
- **UNOS Staff**
  - Tamika Watkins
  - Matt Cafarella
  - Betsy Gans
  - Eric Messick
  - James Alcorn
  - Julia Foutz
  - Kaitlin Swanner
  - Keighly Bradbrook
  - Krissy Laurie
  - Lindsay Larkin
  - Samantha Weiss
- **Other Attendees**
  - Katie Siegert
  - Lisa Stocks