OPTN Pediatric Transplantation Committee
Meeting Summary
March 3, 2022
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 3/3/2022 to discuss the following agenda items:

1. Public Comment Presentation: Improving Liver Allocation: MELD, PELD, Status 1A and Status 1B (OPTN Liver Committee)
2. Public Comment Discussion: Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation (OPTN Multi-Organ Transplantation Committee)
3. Public Comment Discussion: Continuous Distribution of Kidneys & Pancreata Request for Feedback (OPTN Kidney & Pancreas Committees)
4. One-Year Pediatric Bylaws Monitoring Report
5. Review of Scientific Registry for Transplant Recipients (SRTR) Mortality Data
6. Idea Generation

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

1. Public Comment Presentation: Improving Liver Allocation: MELD, PELD, Status 1A and Status 1B (OPTN Liver Committee)

The Committee reviewed the OPTN Liver Committee's *Improving Liver Allocation: MELD, PELD, Status 1A and Status 1B* proposal. The Committee provided feedback on the proposal to be included in Winter 2022 public comment responses.

Summary of discussion:

A member stated that they believe this proposal is reasonable. The member mentioned that they supported adolescents using the Pediatric End-Stage Liver Disease (PELD) score since it is hard to know how much they have been disadvantaged from circle-based allocation.

A member highlighted that they thought age-adjusted mortality was going to be standardized and aligned with the Model for End-Stage Liver Disease (MELD) score in this proposal. The Chair stated that that was correct and the charter of the workgroup was to eliminate waitlist mortality. The Chair further explained that the OPTN Liver Committee had modeled adding more points to age-adjusted mortality and found that it was more likely to have a greater impact on eliminating mortality; however, that wasn't something they felt comfortable doing in this proposal.

A member noted that age-adjusted mortality aims to equalize mortality if everyone on the adult waitlist was 18 years old, but still relative to other patients with end-stage liver disease in need of a transplant. The member also mentioned that using age-adjust mortality allows adjustments to the PELD score overtime without having to redo the entire equation.

A member expressed appreciation for the inclusion of creatinine in the proposed PELD score and noted that a normal level of creatinine is going to vary significantly between a baby and a twelve year old. The member highlighted that there didn't seem to be an interaction between creatinine and age or size in the calculation and inquired if this could disadvantage pediatric patients with growth failure.

A member stated that the OPTN Liver Committee had looked at using estimated glomerular filtration rate (eGFR) to account for growth failure but, since eGFR already includes height, they didn't see a significant difference. The member also mentioned that the points awarded for creatinine only vary within a particular range and, above that range, patients will receive the maximum number of points for creatinine.

A member inquired if using cystatin C instead of creatinine had been discussed. The Chair explained that there wasn't a way to collect information on cystatin C and, thus, no way to retrospectively look at its impact.

A member inquired if the long-term goal of this proposal is to decrease the number of exception requests or exception points given. The Chair stated that increasing the efficiency of the system and decreasing the arbitrary nature of the approval and submission of exceptions scores was one of the goals of this proposal, along with eliminating pediatric waitlist mortality.

A member stated that, when looking at pediatric liver patients, there's a decent minority of whom are pediatric oncology patients, which is the reason they are in need of a transplant. The member inquired if Status 1B scores are added onto the PELD score or if the Status 1B scores are just within the Status 1B group of patients. The Chair explained that Status 1B scores are being given to patients who have already qualified for Status 1B, it's not adding any points to patients' scores who are not Status 1B. The Chair further explained that the Status 1B score is used to sort within that status.

A member expressed concern for pediatric oncology patients because most of these patients have very little waitlist mortality, but there's a risk if they have to wait longer for a transplant. The member stated that the risk for these patients is having to have extra rounds of chemotherapy, which more and more data is showing has a lot of very deleterious long-term side effects for these children.

The Chair stated that that was a concern from the Status 1B perspective – would the chronic liver disease patients in Status 1B take over and not allow other patients in the status receive transplants? The Chair mentioned that it was about 40 patients per year who were listed as having chronic liver disease and listed as Status 1B, but the number of Status 1B patients at any one time is low. So, with the small number of chronic liver disease patients being prioritized ahead of other Status 1B patients, it shouldn't be a problem but it does provide an opportunity for the Committee to be included in the monitoring plan of this proposal.

The Chair emphasized that the impact of this proposal was never modeled and there are concerns about accuracy. The Chair suggested that there needs to be adequate representation of pediatrics on the OPTN Liver Committee and throughout the evaluation of this proposal.

There was no further discussion.

2. Public Comment Discussion: Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation (OPTN Multi-Organ Transplantation Committee)

The Committee reviewed the OPTN Multi-Organ Transplantation (MOT) Committee's *Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation* proposal. The Committee provided feedback on the proposal to be included in Winter 2022 public comment responses.

Summary of discussion:

A member inquired if there is an estimate for how many patients this proposal would affect and if there is an idea of the types of donors for these heart-kidneys and lung-kidneys. The member noted that, if these tend to be from younger donors, the kidney donor profile index (KDPI) is not a good gauge for what is a good quality kidney and there are some implications of lower quality kidneys going to multi-organ transplant (MOT) candidates instead of age-matched candidates.

Staff stated that there were 219 heart-kidney transplants and 11 lung-kidney transplant in 2019, so the populations of these MOTs are quite small. Staff also mentioned that they are starting to look at data on heart candidates that would no longer be covered under required shares as part of this proposal.

Staff also mentioned that the distribution of eGFR for recipients who have received simultaneous transplants is expected to stay consistent with this proposal. With the eligibility criteria in place, those candidates who are beyond the eGFR of 30 threshold will be less likely to receive a simultaneous transplant, since the organ procurement organizations (OPOs) will not be required to offer both organs to those candidates.

A member highlighted that, in Sequence A and Sequence B in kidney allocation, pediatrics have higher priority than safety net patients so this should not impact pediatric allocation for the kidneys. The Chair stated that this should be used to establish a precedent.

The Chair expressed the importance of the OPTN MOT Committee considering the downstream effects of MOT policy on pediatrics, especially when discussing MOT versus single organ transplant. Staff explained that there will be opportunities in the future to delve into these potential downstream effects on pediatrics, especially with the OPTN MOT Committee discussing recommendations for kidney and pancreas continuous distribution. Staff also mentioned that there has been some feedback in regards to liver allocation, so the OPTN MOT Committee hopes to contribute to the liver continuous distribution project as well.

A member mentioned that one of the downstream effects is that, when a pediatric kidney candidate is on the match run with a MOT candidate, the kidney is typically not allocated until much later. This causes centers to not have enough time to bring the pediatric kidney candidate in to get a crossmatch, so the kidney has to be turned down. The member noted that this is difficult to measure because it simply looks like the kidney was offered to a center and they declined; however, it's more of an operational work flow issue.

There was no further discussion.

3. Public Comment Discussion: Continuous Distribution of Kidneys & Pancreata Request for Feedback (OPTN Kidney & Pancreas Committees)

The Committee reviewed the OPTN Kidney and Pancreas Transplantation Committees' *Continuous Distribution of Kidneys and Pancreata* Request for Feedback. The Committee provided feedback on the proposal to be included in Winter 2022 public comment responses.

The Committee also reviewed data regarding the following effects of prioritizing kidney-pancreas candidates over pediatric kidney-alone candidates:

- Adult kidney-pancreas candidates typically receive low KDPI/high quality kidneys
    - Pediatric candidates only have priority for kidneys with KDPI <35%
- Adult kidney-pancreas candidates have shorter active waiting times than pediatric kidney candidates
- Additional wait time for pediatric kidney candidates once the kidney is allocated to a kidney-pancreas candidate

- About an additional four months

Summary of discussion:

A member encouraged the Committee to participate in the analytic hierarchy process (AHP) exercise, even if their expertise is outside of kidney and pancreas. The member stated it's important for the OPTN to hear what the transplant community thinks of pediatric priority in general.

A member mentioned that having two separate exercises didn't allow people to show whether they preferred prioritizing a kidney-pancreas candidate over a pediatric kidney alone candidate or vice versa. The member noted that this has been a concern of the Committee and pediatric transplant community and inquired if there is an opportunity to include this feedback in the AHP exercise. A member explained that there should be an opportunity to share this feedback in the exercise, if just in the comments.

A member stated that the AHP exercise was easy to participate in, but they worry that the precedent that could be set for pediatric priority in kidney allocation will be used in liver and heart allocation as well.

A member highlighted the importance to know the difference between KDPI and estimated post-transplant survival (EPTS).

- KDPI is a score that is assigned to the kidney donor and is supposed to be an estimation of how long the kidney is expected to survive after transplant.
- EPTS is a score assigned to candidates and is supposed to be an estimation of how long candidates will experience graft function with high-longevity kidneys.
    - Not given to pediatric candidates

The member stated that these two scores have unintended consequences for the pediatric population because potential pediatric recipients don't receive an EPTS score and the KDPI for pediatric donors is not really accurate. In the current system, if a candidate has a good EPTS score and the donor has a good KDPI then the candidate receives priority and, typically, those candidates are adults.

A member stated that it seems pediatric priority is only included in the kidney and pancreas continuous distribution framework through the pediatric variable. The member suggested that, when deciding eventual weights of attributes, it needs to be clear that EPTS does not apply to pediatrics.

The Chair noted that the OPTN Kidney and Pancreas Transplantation Committees need to either be wary of assigning a lot of weight to attributes that don't apply to pediatrics or determine the attributes that will apply to all patients and equalize them in a way that will include pediatrics.

A member mentioned that they had trouble accessing the AHP exercise and suggested reconsidering the registration process since it could be a barrier to receiving feedback.

There was no further discussion.

4. One-Year Pediatric Bylaws Monitoring Report

The Committee reviewed the one-year monitoring report on the Pediatric Bylaws, which established requirements for pediatric components and minimum qualifications for primary pediatric transplant surgeons and physicians for kidney, liver, pancreas, heart, and lung transplant programs.

Data Summary:

- The number of kidney, liver, pancreas, heart, and lung transplant programs with an approved pediatric component have remained consistent with the results from the 6-month monitoring

report – the number of programs with a pediatric component have either increased or decreased by one.
- For each organ program with the exception of lung, the majority of centers have remained consistent or seen an increase in transplants from pre- to post- era.
- Similar to transplants, for each organ program the majority of centers have remained consistent or seen an increase in waitlist additions from pre- to post- era

Summary of discussion:

A member inquired if there are other data elements that the Committee would want to include in the next monitoring report. The member suggested considering long-term care or long-term graft survival at centers with approved pediatric components.

A member inquired how many centers were performing pediatric transplants during the pre-policy era and then did not apply for an approved pediatric component. The member suggested that the Committee should look at the implications of that, especially in regards to patients travelling further and cold ischemic time.

A member inquired how the Committee is capturing patients that might die because they can't get to a transplant center in the data. A member explained that this is not in the data because there is no way to know which patients don't get listed. Another member mentioned that some kidney centers look at something from the Centers for Medicare and Medicaid Services (CMS) that tracks patients through to listing.

A member inquired if the emergency exception pathway had been used. Staff explained that no one has used the pathway yet – two heart programs and one other program tried to use the pathway but they did not enter the correct data. The member questioned if programs aren't using the pathway because they don't need it or because they don't know how.

A member inquired about the parent perspective on travelling far distances due to programs not applying for an approved pediatric component. One member mentioned that they hadn't heard anything regarding that since lung patient families are few and far between. The Chair mentioned that they heard it wasn't a distance issue since the programs that were closing were close to other programs.

A member stated that, in the development of the pediatric bylaws, it was the patient families that were shocked there were no requirements for pediatric programs. The member mentioned that there was pushback about access, distance travelled, and delay in reaching a center. It was mentioned that there were centers that didn't want to apply for the approved pediatric component, but they also felt there were centers around them that could care for the pediatric patients.

A member pointed out that, if they were a parent of a lung candidate, it would be a major concern that five of the 40 pediatric lung programs were doing the majority of lung transplants. Another member stated that parents are always going to want to go to the five centers with the highest volume – it's always a quality over quantity issue no matter the distance. A member also mentioned that the Committee should keep in mind the families that don't have the means to go to the centers with the highest volumes.

A member suggested sharing the maps of the programs with the approved pediatric components with those working on the *Redesign Map of OPTN Regions* proposal, since it may be helpful to see the distribution of pediatric programs.

There was no further discussion.

5. Review of Scientific Registry of Transplant Recipients (SRTR) Mortality Data

The Committee reviewed Scientific Registry of Transplant Recipients (SRTR) data describing pre-transplant mortality among pediatric transplant candidates stratified by age, race, disease severity, and geography.

Data Summary:

- Overall improvement in pre-transplant mortality across organ types over time
- Higher risk subgroups within each organ type persist
- Potential to utilize these data to target policy and practice changes

Summary of discussion:

A member inquired if there's some way to include a comparison of mortality between adults and children. A SRTR representative agreed that it's important to see the difference between adults and children; however, even if the adult mortality is higher, one wouldn't want to underestimate the importance of the pediatric mortality. The SRTR representative also mentioned that there will be pediatric-specific section for each organ in the SRTR Annual Report and they will elicit the Committee's feedback regarding what should be featured.

The Chair inquired about the possibility of a pediatric-specific report, in addition to the SRTR Annual Report, that could be used as a guide for the Committee and their work. The SRTR representative mentioned that that is what is being worked towards because pediatric issues need to be highlighted not only to those with pediatric expertise, but also those without.

There was no further discussion.

6. Idea Generation

The Committee was encouraged to discuss issues or ideas that they would like to work on as new projects.

Summary of discussion:

The following is a list of ideas that the Committee discussed:

- Encouraging split liver transplantation
    - Include in Continuous Distribution of Liver?
        - Staff explained it's on the list for Continuous Distribution of Liver, but it's not guaranteed that the OPTN Liver Committee will want to include it in their framework
    - Concerns:
        - Most adults are willing to accept split livers but none of them receive them
        - Expertise required to perform split liver transplants – will receive pushback from centers that don't have the expertise
            - A member noted that a program must have two surgeons for split liver transplants from living donors and inquired about the number of surgeons needed for split liver transplants from deceased donors.
                - Only need one surgeon for split liver transplant from a deceased donor
            - Not necessarily something a program with a pediatric component can control – adult surgeons will need to perform the split liver transplants since most of the living donors are adults

        - Scrutiny around waitlist and post-transplant outcomes
        - Extra time it requires – possibly sending a team out to perform the split, determining who gets what part of what vessels
    - Want to offer priority and distinguish between who should be performing split liver transplants and who is willing to perform them
        - Would not want to decrease the utilization of organs just because not everyone can perform a split liver transplant
- Assess whether programs are struggling to find the required expertise for an approved pediatric component
- Incorporation of kidney donor profile index (KDPI) in Continuous Distribution of Kidneys and Pancreata
    - Concerns:
        - Have not looked at outcomes in pediatric recipients; however, KDPI is being used to limit which kidneys pediatric candidates can receive
        - Pediatric kidneys will not be offered to pediatric recipients - majority being transplanted into adult recipients
        - Data showing KDPI doesn't predict outcomes in pediatrics the same way it does in adult recipients
        - Vessel size and very small pediatric candidates
            - School age kids (5-10 years old) almost always have a high KDPI and those kidneys are being allocated to adults rather than being offered to pediatric candidates
- Heart Status 1A downgrades
    - Is this really a problem?
    - Could be a pretty quick fix – maybe just an email reminder that the patient is going to downgrade

There was no further discussion.

The meeting was adjourned.

Upcoming Meetings.

- April 20, 2022 (Virtual)

Attendance

- **Committee Members**
  - Evelyn Hsu
  - Emily Perito
  - Abigail Martin
  - Brian Feingold
  - Caitlin Peterson
  - Caitlin Shearer
  - Dan Carratturo
  - Douglas Mogul
  - Jennifer Lau
  - Johanna Mishra
  - Shellie Mason
  - Rachel Engen
  - Walter Andrews
  - Warren Zuckerman
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Christian Folken
  - Simon Horslen
  - Jodi Smith
- **UNOS Staff**
  - Rebecca Brookman
  - Matt Cafarella
  - Joann White
  - Kaitlin Swanner
  - Katrina Gauntt
  - Lauren Guerra
  - Lauren Mauk
  - Leah Slife
  - Lindsay Larkin
  - Rebecca Goff
  - Samantha Weiss
- **Other Attendees**
  - Melissa McQueen