

## **OPTN Pediatric Transplantation Committee**

### **Meeting Summary**

**March 30, 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 3/30/2021 to discuss the following agenda items:

1. Active Collaborations
2. Review of Committee's Past Projects
3. Pediatric Bylaws Update
4. One-Year Impact of Acuity Circles on Pediatrics
5. Review of Liver Committee's Median MELD at Transplant (MMaT) Pediatric Data Request
6. Continuous Distribution Update
7. Review of Recent Kidney & Pancreas Changes

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

### **1. Active Collaborations**

The Committee reviewed the following projects that members are currently participating on:

- Continuous Distribution
  - Use of age at the time of registration for pediatric definition in continuous distribution
- Kidney-Pancreas Continuous Distribution
- Liver PELD/Status 1B Criteria Workgroup
- Heart ABOi Workgroup

#### Summary of discussion:

A member noted that the Kidney-Pancreas Continuous Distribution (CD) Workgroup is still in the planning phase, but is hoping to put a concept paper out for the summer 2021 public comment cycle. Members that participate on the Kidney-Pancreas CD Workgroup agreed that pediatric priority continues to be an area of focus.

### **2. Review of Committee's Past Projects**

The Committee reviewed previous projects that they have worked on and abstracts that have been published and presented at conferences.

#### *Past Initiatives*

- Acuity Circles
  - Pediatric donors for pediatric liver waitlist candidates
- Pediatric National Liver Review Board (NLRB)
- Changes in Heart Allocation

- Kidney Sequence C work

#### *Previous Projects*

- Pediatric Transition and Transfer Guidance Document (8/2018)
- Revise pediatric emergency membership exception pathway (7/2017)
- Establish pediatric training and experience (8/2015)

#### *Conference Presentations*

- Presented at American Transplant Congress (ATC) 2020
  - Poster: Four Years of KAS: A Pediatric Specific Report (Manuscript in progress)
  - Oral Presentation: Pediatric National Liver Review Board: Impact on Children on the Waitlist
- To be presented at ATC 2021
  - Rapid Fire Oral Presentation: The Pediatric National Liver Review Board: What Happens to Waitlist Registrations with Denied Exception Forms?
- To be presented at Pediatric Academic Societies 2021
  - Platform Presentation: Effect of Multi-Organ Allocation Priority on Pediatric Kidney Candidates

#### Summary of discussion:

The Chair suggested that the progress of abstracts and presentations that the Committee is working on should be a standing agenda item so members can stay updated and help where needed.

### **3. Pediatric Bylaws Update**

The Committee received an update on the Pediatric Bylaws, which were implemented on 12/8/2020. The Committee will receive the 6-month policy monitoring report during summer 2021.

There are a total of 283 active programs with a pediatric component as of 3/29/2021. As of 3/19/2021, zero pediatric candidates were registered at a program without a pediatric component.

#### Summary of discussion:

The Chair stated that updates on the pediatric bylaws implementation will be helpful during future in-person committee meetings. The Chair also inquired if any members have heard frustrations in the community regarding these bylaws.

A member stated that these bylaws have been very helpful in the nephrology community as part of forming the basis for a more rigorous transplant curriculum.

### **4. One-Year Acuity Circles Data Preview**

The Committee received a data preview on the impact acuity circles has had on pediatrics. The One-Year monitoring report was not finalized, so the members were encouraged to provide feedback if there was some data of importance missing in the preview.

The full one-year report will be available on the OPTN website in the upcoming weeks.

#### Data summary:

- Waitlist (WL) additions consistent in characteristics, decrease overall
- Decrease in WL dropout rates, increase in WL transplant rates
- Decrease in Status 1A/1B deceased donor liver transplant (DDLTL)
- Increase in non-exception DDLTL

- Increase in DDLT from pediatric donors
- Increase in adolescent DDLT (67%)
- Increase in national share donors (60% national)
  - Increase in DDLT from 250 – 500 nautical miles
- Slight increase in cold ischemic time

Summary of discussion:

The Chair stated that it's interesting the liver-alone waitlist mortality rate seems to increase for the 0-11 age group with MELD/PELD 37+. Staff stated that this does seem to be an increase; however, it isn't statistically significant. A member questioned if the decrease of the waitlist mortality rate is statistically significant for the 12-17 age group with MELD/PELD 37+. Staff stated that it is marginally significant.

The Chair noted that the maximum cold ischemic time for pediatric DDLT doesn't seem to be increasing post-policy. Staff stated that that's correct and the distribution of cold ischemic time isn't that different between pre-policy and post-policy.

A member inquired about what can be done to help the children that have higher MELD/PELD scores, because it seems the offers post-policy are concentrated in the lower MELD/PELD scores, especially MELD/PELD <15. The member stated that it seems like the policy is shifting the donors the wrong way. Staff pointed out that pediatric candidates with MELD/PELD 37+ and Status 1 are still getting 2.5 times as many offers and the pediatric candidates with MELD/PELD 33-36 are getting 3 times as many offers compared to the pre-policy era. Staff explained that some of the big increases in offers for pediatric candidates with lower MELD/PELD scores could be attributed to broader distribution.

A member inquired if this is specifically compared candidates' offer rates pre-policy. The member explained that if it's a pre and post-policy comparison within the MELD/PELD score groups, then lower MELD/PELD pediatric candidates may not be receiving more offers than higher MELD/PELD pediatric candidates – these rates are just showing the increase in offers post-implementation for each MELD/PELD score group.

A member inquired if this data only includes offers that could be utilized because, in their experience, they've received offers for a MELD/PELD 15 candidate while the candidate was number 350 on the waitlist. The Chair seconded this question. Staff explained that this is using OPTN match run data, so it depends on specifically how this was run. Staff stated that this data likely includes all the offers received until the organ was accepted.

A member inquired if the increase in adolescents being transplanted could be due to more adolescents being listed for transplant. Staff explained that this data is looking at total counts and they don't have an inference behind what's causing this, but they did notice this pattern as well.

The Chair expressed confusion regarding why listings would have decreased in the last year post-implementation of the policy. The Chair stated the only reason they could come up with is access to care that was affected by the COVID-19 pandemic. A member stated that they have seen the same pattern, especially in pediatric candidates with metabolic disease, and have seen a lot fewer kids referred for metabolic diseases partly because of COVID-19 (kids were indoors, not catching viral diseases and going into crisis) and partly because some of the families are waiting for new gene therapies. The Chair stated that that would possibly account for the decrease in Status 1B listings.. Staff explained that, in the one-year report, data will be broken down by specific COVID-19 eras – COVID-19 onset and COVID-19 stabilization.

A member stated that, even though the Pediatric Bylaws Implementation wasn't implemented until December 2020, there may be a chance programs were preparing for that transition and this data may

be missing a subset of children who might have been transplanted at a center that wasn't able to become a pediatric center. Staff explained that the Committee may be able to determine this when the 6-month monitoring report for the Pediatric Bylaws is presented in the summer.

The Chair stated that the plan to release this one-year acuity circles report on the OPTN website is a good start and inquired if there would be a pediatric-specific report in regards to acuity circles or if there has been discussion about the publishing plan for a manuscript from the Liver & Intestine Committee. Staff explained that there will be a pediatric section of this report, but there isn't a specific plan for a manuscript publication yet. The Chair suggested that discussing the post-implementation acuity circle data and publishing the report, or just the pediatric section, as a contribution to the current science and literature would be very helpful.

The Chair inquired if members have seen a palpable change in the number of offers they are receiving, the number of transplants they are doing, the distance they are travelling for offers, or the quality of their offers. A member stated that their first impression would be no; however, that may be particular to how the member's organ procurement organization (OPO) deals with offers. If an offer is coming outside of the member's OPO area, the OPO takes the call instead of the transplant center and the OPO would only call the center if the candidate was close to receiving the organ.

A member stated that it was expected most surgeons would travel a significant distance and, although the mileage flown is consistent with the member's past experience, centers are now getting offers from larger distances for Status 1B and high PELD candidates. The offers from a wider area has increased and has improved availability of organs for the sick Status 1B or high PELD candidates.

The Chair inquired if there has been an increase in splitting livers since the implementation of acuity circles. A member stated that they think there has been an increase. The member stated that, from the implementation of acuity circles, more patients at their center have been transplanted and 80% of those transplants were split livers. A member stated that, being on the east coast, it's hard for them to know because they were having to split so many livers pre-policy.

The Chair inquired if there's a thought to look a split livers in this report and whether or not there's an increase in them. Staff stated that that data can be included. A member noted that it's important to also look at whether the other part of the liver is being transplanted in another patient or not.

A member noted the increase in DDLT from pediatric donors could impact split livers because they typically originate from adult donors. The member also worried about what that would mean for pediatric recipients, especially now that there are less pediatric donors – does that mean that pediatric recipients aren't being offered the adult livers? At first one could think that a pediatric donor to a pediatric recipient is a good thing, but could it actually decrease what is available to pediatric recipients. The Chair stated that the trend of pediatric donors is decreasing over time. These implementation rules have resulted in a decreased number of adult donors, which are most likely to be split, to pediatric recipients. The Chair stated that it's only the children who have the highest MELD/PELD scores that account for almost all of the adult donors that are allocated to kids. The Chair inquired how, whether these livers are split in situ or split in the cold, is the acuity circles policy encouraging increasing the number of splits.

A member stated that another component in the data looking at the number of splits is that, currently, the number of trauma deaths have decreased. So now, potential donors are older and their livers are not suitable for split liver transplantation. The trauma data has overall carried through nationally, so if there is a decline in splits it may be factorial due to everything that's happened with COVID-19.

A member stated that, presumably, a lot of these splits are larger livers from adults that have been offered to pediatric candidates and the pediatric candidate accepts, but says they only need the left lateral segment and is willing to put the right tri-seg back into the pool. The member inquired if there is any way to look to see if livers are being split the other way around – splits from an offer that was to an adult and the center said they could split it and was willing to give a piece to a pediatric candidate. Staff stated that there has been a split liver variance report looking at the type of split liver transplants and that can be sent to members.

##### **5. Review of Liver Committee's Median MELD at Transplant (MMaT) Pediatric Data Request**

The Committee reviewed the Liver Committee's Median MELD at Transplant (MMaT) Pediatric data request and was asked to provide feedback and consensus on the post-public comment change options to this proposal.

###### Summary of discussion:

A member inquired about what happens to hepatocellular carcinoma (HCC) adult patients who have gotten exception points – are they ranked below the lab MELD adult candidates, are they categorized the same way as lab MELD adult candidates, or are they ranked with the pediatric group? Staff explained that for an adult donor offer, candidates with a lab MELD/PELD 27, for example, will be ranked before candidates with an exception MELD/PELD 27. The HCC candidates would be in the second group because they have an exception score. Staff continued by stating that there's no distinction based on age, instead it's lab score versus (vs.) exception score at the same MELD/PELD score. The Chair stated that the Committee's major concern is that, if there are such a large proportion of pediatric candidates that have exception scores because PELD doesn't adequately predict their mortality on the waitlist, then the children who are most likely to receive organs from adult donors will suffer some decline in their access to those donors.

The Chair mentioned that, looking at the number of children who are listed, the vast majority of the children with an exception are in the MELD/PELD 29+ category. Although the proportion of the adults with no exception are not significant compared to the number adults on the waitlist, the numbers are enough to displace the majority or all of the children who are listed in those categories by exception. The Chair emphasized that it's not significant to make this change relative to adults, but it is significant to make this change relative to children when comparing the same MELD/PELD groups.

A member noted that the MELD/PELD 33+ group, looking at the exceptions, there are 46 patients in the 0-11 years old category and 11 patients in the adults category. The member mentioned that there's a 4:1 ratio of pediatric patients to adults at those high exception scores and organs that are offered to the lower MELD/PELD scores will be predominately offered to pediatric patients. A member brought up another issue, which is that 83% of organs going to the 0-11 year old patients are coming from pediatric donors and currently only 3% of adults are being transplanted with pediatric organs. There's not very much competition for the organs at the high MELD/PELD scores. The Chair emphasized that the concern was that the adult candidates with no exceptions are going to be ranked ahead of smaller children with exceptions, who constitute the majority of the children listed between 0-11 years old.

The Chair stated that there's fewer pediatric lab candidates than pediatric exception candidates, so it would make sense to rank in the following order, after MELD/PELD and blood type, to stay consistent: pediatric lab candidates, pediatric exception candidates, adult lab candidates, adult exception candidates. The Chair emphasized that it would be more favorable to be consistent across the rankings of lab vs exceptions for adult and pediatric candidates and putting pediatric candidates ahead of adult candidates at a given score would alleviate the majority of concerns that have been raised during public comment.

A member inquired that there's no reason to think that the mortality risk from a lab PELD 29 is different than an exception PELD 29. The Chair stated that that is correct and, when looking at this data, there are 4 pediatric candidates that are at a lab PELD score above 29 and a larger number of pediatric candidates are at an exception. The Chair emphasized that they would be willing to put the lab ahead of the exceptions scores because the impact upon the pediatric list would be minimal.

A member inquired if there's any data that shows the potential impact on how this change will impact small adults or women. The presenter stated that there wasn't any data that demonstrates this; however, the concept is that if there are small adults on the list and small pediatric candidates are given priority, then there will be a disadvantage to the small women or men. A member concluded that the pros of the suggested change are definite from the data and the cons are conceptual, so the Committee may need to get more information about this to understand the potential disadvantage to the small adult population.

A HRSA representative inquired if this sorting occurs after waiting time on the wait list or if this sorting occurs first and then waiting time is used as a tiebreaker. Staff clarified that one of the necessary changes, as a result of the change in the MMaT calculation, is that the waiting time calculation for exception candidates will now be different than it is for lab candidates. For exception candidates, it will be time since submission of the earliest approved exception. For the lab candidates, it will be time at score or higher. Because these waiting times will be different, it doesn't make sense to compare the two categories and try to sort them by waiting times. Therefore, prior to sorting on those waiting times, the lab vs. exception candidates would be sorted separately and candidates would subsequently be sorted based on waiting time. The HRSA representative pointed out that if there isn't a great deal of difference between waitlist mortality for adult lab vs. exception candidates or pediatric lab vs. exception candidates then absolutely prioritizing each group first could lead to odd disparities in waiting time within each group. The presenter stated that, at least in adults, the lab scores tend to vary frequently and the exception scores tend to be more fixed.

The presenter stated that another argument that has been made is that if there's concern about the pediatric patients with exception scores being disadvantaged then the pediatricians could ask for higher exception scores. However, that feeds into another problem which is that exception scores will just continue to increase. The Chair stated that that's exactly right, especially when it's been messaged to not ask for those higher exception scores after the implementation of the National Liver Review Board (NLRB).

The Chair inquired about the next steps for this feedback. The presenter stated that this has been very helpful and the suggested change has some appeal because it would keep the ranking of pediatric and adult candidates the same. Staff explained that the Liver & Intestine Committee will meet and have discussions regarding the Committee's sentiment and will vote on whether to implement these changes on 4/14/2021. A member inquired if the Liver & Intestine Committee plans on voting with all four options because then there could be a plurality, but that wouldn't accurately capture the sentiment from the Committee. The presenter stated that the Liver & Intestine Committee will have a similar discussion as the Committee had today and then they will vote on two options.

Committee members agreed that the Liver & Intestine Committee should discuss no change to the proposed policy vs. sorting in the following order: pediatric lab, pediatric exception, adult lab, and adult exception.

## **6. Continuous Distribution Update**

The Committee received an update on the progress of the continuous distribution project as it pertains to lung, kidney, and pancreas.

## Summary of discussion:

### Lung

The Chair pointed out that, when talking about the simulated allocation modeling in regards to pediatrics, the term favorable means that the modeling shows favorable results and the term artifact means that the modeling shows negative results. The Chair also inquired if the percent of patients that died by 2 years post-transplant could be including some deaths from the waitlist because it's not death per transplant, it's death overall. Staff mentioned that they would have to defer to their SRTR colleagues on the second question, but in regards to the first point they are definitely aware of it. Staff explained that when they received the results there were really only a few things that were concerning and the increase in post-transplant death was one of them, so this has been discussed.

A member inquired if there's increased death rates in teenagers and if one of the reasons for this may be allowing older organs to be used in this young population. The member continued by stating that excluding those older organs might make the death rate better, but it may also reduce the transplant rate that was a positive from this modeling. Staff said that this is a philosophical question of what is trying to be equalized. Is continuous distribution trying to equalize the number of transplants per candidate year? Number of offers? Staff explained that the Lung Committee didn't come to a conclusion on what they are trying to equalize, but what this data showed them is that the pediatric population is getting more offers allowing them to be more selective, and in turn that would hopefully decrease the post-transplant death rate.

The Chair clarified that the interactive online tool shows what percentage the pediatric priority would need to be weighted in order to effectively put all children ahead on the list. Staff explained that that's correct, and the graph shows that if pediatric priority is weighted 20% then that put kids effectively at the top of the list.

The Chair inquired if the express interest of the Committee is to eliminate pediatric waitlist mortality, then what would that look like with this modeling. Staff explained that pediatric waitlist mortality probably wouldn't get to 0, at least not for lung, but this modeling hasn't been done for other organs. Staff mentioned that it might be possible, but the graph would need to be stretched out in order to see what that level looks like.

The following are considerations for the Committee when analyzing the Lung Committee's modeling:

- Transplants for adolescents increase dramatically under all scenarios
- Post-transplant deaths appear to increase for all under 18 in all scenarios, but the sample size is small, and there is less confidence in this finding
- All metrics among pediatrics were similar whether using 31% or 20% weight for pediatrics
- Few gains in mortality and transplants for pediatrics above 10-15%

The Chair inquired if this was going to be an iterative process where data is evaluated every so many years to see if the weights of attributes are still accurate, or will data just be looked at closely within the first couple of years after implementation to see if weights have to change. Staff explained that the monitoring report for continuous distribution, especially for the first few years, will be a very robust reports since it's such an abrupt change in methodology for allocation. It hasn't yet been decided what the frequency should be in terms of relooking at the weights between the organs. Staff also emphasized that the weights of attributes don't need to be the same between the organs, and they don't think that would be appropriate in this first iteration of continuous distribution.

The Chair stated that the principles that the organs are currently following for pediatrics could be applied, if not the exact weighting. Staff stated that principle of pediatric priority points will be seen

across all of the organs, since most organs already give some type of priority to pediatric candidates and those that don't have already expressed interest in including the priority in their model.

#### *Kidney-Pancreas*

There were no questions or comments.

### **7. Review of Recent Kidney & Pancreas Changes**

The Committee was provided on update on the implementation delay of the recent kidney and pancreas allocation changes, which eliminated the use of DSA and region in pancreas and kidney allocation policy.

The following policies were implemented on 3/15/2021:

- Eliminate the use of DSA and Region in Pancreas Allocation Policy
- Eliminate the use of DSA and Region in Kidney Allocation Policy
  - Increased priority for pediatric and prior living donor candidates within 250 nautical miles (NM) of the donor hospital
- Addressing Medically Urgent Candidates in New Kidney Allocation Policy
  - Medical urgency data collection period opened one week prior to implementation
- Distribution of Kidneys and Pancreas from Alaska
- Modifications to Released Kidney and Pancreas Allocation

#### Summary of discussion:

The Chair inquired about the main concerns that Health & Human Services (HHS) expressed in order to delay the implementation of these policies. The presenter stated that they believed it was felt that there were some issues with losing local organs. Staff explained that the HHS response and the critical comment is posted on the OPTN website and they will provide the link to members.

The presenter noted that, from their own centers experience, it seems that there are more pediatric offers going out, so that's very good news for pediatric patients in this new system.

#### **Upcoming Meetings**

- April 21, 2021 (Teleconference)



## Attendance

- **Committee Members**
  - Evelyn Hsu
  - George Mazariegos
  - Abigail Martin
  - Andrew Bonham
  - Caitlin Shearer
  - Douglas Mogul
  - Jennifer Lau
  - Johanna Mishra
  - John Barcia
  - Kara Ventura
  - Meghan Potis
  - Regino Gonzalez-Peralta
  - Samantha Endicott
  - Shellie Mason
  - Walter Andrews
  - Warren Zuckerman
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Raelene Skerda
- **SRTR Staff**
  - Chris Folken
  - Jodi Smith
- **UNOS Staff**
  - Rebecca Brookman
  - Matt Cafarella
  - Betsy Gans
  - James Alcorn
  - Joann White
  - Julia Foutz
  - Leah Slife
  - Lindsay Larkin
  - Matt Prentice
  - Nicole Benjamin
  - Tina Rhoades
- **Other Attendees**
  - Rachel Forbes
  - James Trotter
  - Joseph Hillenburg