

## **OPTN Pediatric Transplantation Committee**

### **Meeting Summary**

**May 19, 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 5/19/2021 to discuss the following agenda items:

1. Letter to OPTN Blood Draw Policy
2. Ad Hoc Multi-Organ Workgroup/Continuous Distribution
3. OPTN Pediatric Liver Collaborative Update
4. Current Progress of Abstracts/Presentations
5. Continuous Distribution Update
6. Heart ABOi Project Update
7. National Heart Review Board Suggestion

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

#### **1. Letter to OPTN Blood Draw Policy**

The Committee reviewed a letter sent to them and the OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) expressing concerns with OPTN Policy 15.2: *Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements*. The specific concern was that the volume of blood required for the tests was excessive and dangerous for pediatric candidates below a certain weight threshold.

#### Summary of discussion:

A DTAC representative stated that the maximum amount of blood mentioned in the letter is the maximum amount of blood that can be drawn in a child, not the amount of blood it takes for these three tests. The Chair inquired about the amount of blood required for these tests and if it's variable across institutions. A DTAC representative mentioned that it may be variable because at their institution they could do these tests with under 5 cubic centimeters (cc's) of blood. It was noted that, for a very small child, this could still be a problem.

Another DTAC representative mentioned that it takes less than 5 cc's of blood at their institution as well.

A member stated that it would be helpful if DTAC could provide guidance on what the minimum volume of blood is on certain machines. A DTAC representative stated that they aren't sure how easy that would be, given the number of different machines used and each lab having its own threshold. A member inquired if there are some common thresholds for volume of blood or examples that are widely accepted. DTAC representatives stated that they could do some research into this.

The Chair inquired if the DTAC representatives had thoughts on whether these tests need to be repeated at admission. A DTAC representative stated that, if a patient is listed, gets tested, and is a child

under 10 years old, then the probability of disease transmission is so remote that they question the need to repeat this testing at hospital admission.

A member mentioned that the policy states that this testing needs to be completed at transplant admission; however, the majority of babies receiving heart transplants are typically admitted for their whole listing time, so if the tests were done during the patient's evaluation then they aren't being repeated.

A member noted that every potential heart transplant recipient also gets a transfusion at the time of their transplant, so they don't see how this is an issue if the blood is drawn immediately before going to the operating room. A DTAC representative stated that the cardiac children aren't as big of an issue, other than the fact that they are of small size. The DTAC representative mentioned that it's probably not necessary to do repeat tests on the pediatric liver and kidney population under 10 years of age who go home to wait for 6 months to a year.

A member supported the previous statement – it's unnecessary to repeat these tests when the results will rarely, if ever, be positive.

A DTAC representative mentioned that, while this population with extraordinarily low risk still need to be tested, testing them more than once in 6 months could also increase false positive results.

A DTAC representative inquired how, since this policy is the result of aligning with the recommendations from the Centers for Disease Control (CDC), members see the pathway forward in order to have the CDC modify the recommendations and reach a consensus. Staff stated that the path forward, based on recommendations from the Committee and DTAC, will need to be evaluated more in depth since the options aren't clear. Staff will need to follow up on next steps in terms of alignment with the CDC.

The Chair suggested a multi-pronged approach – one approach is adjusting the CDC guidelines and the other is to ask for a change to the wording that reflects practices of pediatric centers. Staff inquired if the Chair meant changing the wording in OPTN policy. The Chair stated they meant changing the wording in OPTN policy as it pertains to children under the age of 10 years old who have already had their blood drawn.

Staff explained that there was a strong effort to align OPTN policy with the CDC guidelines, but summarized that the Committee wants to look into the option of changing OPTN policy alone.

A DTAC representative inquired if this is an opportunity to capture the information about the number of transmissions in the pediatric population, previously in the early post-transplant period, related to these specific pathogens in order to demonstrate that the risk profile of this population is different than what it is in adults and support a modification. Another DTAC representative agreed with that idea and suggested also gathering data on how many times, during registration, it's discovered that a child below a certain age has Hepatitis C, Hepatitis B, or HIV. The DTAC representative explained that the intent of completing the labs at transplant admission was to establish a baseline for a potential investigation of a donor derived event at that age, which the likelihood is pretty low. However, it's also unlikely that these pediatric patients will be infected with any of these viruses, so by combining all of this information, it could be used as rationale for not requiring the additional blood draw.

A member emphasized that the policy mainly affects those children that go home after they're listed and return for transplant because if the blood is drawn once during the transplant admission then that satisfies the criteria.

A DTAC representative stated that small pediatric heart candidates usually stay in the hospital and inquired if small liver candidates, who would have an issue with this volume of blood being drawn, are

staying in the hospital. Members stated that a quarter of them are metabolic or have cancer and come in already fairly anemic, so then this would be an added risk. A DTAC representative stated that there have been zero Hepatitis C, Hepatitis C, and HIV transmissions in the pediatric liver population. However, it was also noted that split liver transplants are occurring more frequently so the pediatric liver candidates are sometimes receiving an organ from an adult.

A DTAC representative inquired, if the pre-test probability of transmission is pretty low as a rationale for not repeating the testing, why the testing couldn't just be done at the time of listing and, if the vast majority of pediatric candidates are going to stay in the hospital, then that satisfies the requirement.

A member stated that, from a policy perspective, just changing the language to say "can be drawn prior to the time of transplant" would practically achieve what the Committee wants. A DTAC representative stated that that eliminates a baseline for adult patients because it doesn't adjudicate for adult patients who are going home, waiting, and potentially participating in certain risk behaviors before they are readmitted.

A member suggested using the previously suggested language change and specifying that it's for a certain age population.

A member emphasized that most of these infants will get evaluated and then the vast majority will be outpatient – the idea that they will be staying in the hospital until transplant is the minority of the time.

A DTAC representative stated that prior PHS guidelines stated that the blood had to be drawn before transplant. In the adult recipients who have had Hepatitis B and Hepatitis C after transplant, the blood hadn't been drawn on the candidate for a year or two years before transplant, so that left the physician struggling to decide whether the diseases were from the donor or not.

The Chair stated that it seems there's a possibility to suggest different wording for children of a certain age and size, just to reflect that this is a large blood volume to draw from them. It was suggested that there should be an investigation of what both committees' options are and a follow-up discussion with DTAC leadership. Staff stated that that's possible, and emphasized that members need to keep in mind that there is an OPTN policy development process and, because it involves consistency with the Final Rule, it may require some analysis that is beyond our scope.

## **2. Ad Hoc Multi-Organ Committee/Continuous Distribution Update**

The Committee received a presentation on the purpose and goals of the newly created OPTN Ad Hoc Multi-Organ Committee and reviewed how their work will parallel work being done with continuous distribution.

The Chair, being the pediatric representative on the OPTN Ad Hoc Multi-Organ Committee, requested feedback from members on important pediatric considerations that should be advocated for in a multi-organ lens. The following concerns were presented to the Committee: unintentional impact on pediatric waitlist, emphasis on combinations other than kidney-pancreas (KP), pediatric donors.

### Summary of discussion:

A member inquired if liver-intestine or intestine candidates are included in the work of this workgroup, and if not, why they aren't included in the multi-organ discussion. Staff explained that that will be addressed when the Committee starts looking at liver specific combinations as the shift to liver-intestine continuous distribution is happening, since they'll be worked on at the same time. The member inquired if that will be the Liver Committee's charge or if it will be the Multi-Organ Committee's charge. Staff explained that some of this discussion will be fluid and the Multi-Organ Committee will work with organ specific committees to figure out what work is handled by which committee.

The Chair stated that, when these discussions have come up before, the Committee has tried to be involved because their main concern is that pediatric recipients, particularly pediatric kidney recipients, are disadvantaged by adult multi-organ candidates. The Chair emphasized that the Committee would push to not have those candidates prioritized ahead of pediatric single organ recipients. The Chair mentioned that there has been pushback stating that that wasn't within the scope of the discussions.

A member stated that, as a pediatric transplant nephrologist, this is an incredibly crucial issue especially in areas that have large kidney-pancreas (KP) programs and, like the impact of any allocation policy on pediatric patients, it needs to be part of the conversation.

A member agreed with the above statement and mentioned that they have lost organs for pediatric kidney candidates to KP candidates and liver-kidney candidates, which was quite frustrating. It was noted that simultaneous liver-kidney (SLK) has been looked at in terms of indications for kidney outcomes in the adult group, so the member would agree that prioritizing adult liver-kidney or KP candidates over pediatric candidates certainly has been an issue.

A member mentioned that the SLK data was presented at Pediatric Academic Societies last month and that they view the creation of the Multi-Organ Committee and its collaboration with the Committee as a positive accomplishment.

A member emphasized that organ procurement organizations (OPOs) are wanting to transplant as many organs as possible, so, when a kidney gets taken away from a KP candidate, the chances of placing that pancreas are cut in half since the pancreas alone list will be half the size of the KP list. That's where the resistance is since OPOs are measured on organs transplanted per donor and every pancreas helps them towards that goal.

The Chair inquired if there's also financial rewards for transplanting as many organs as possible, in addition to the OPOs metrics awards. A member stated that that's possible, but with the new CMS final rule in place, where one-third of OPOs will be up for decertification in four years, it's a matter of survival.

### 3. OPTN Pediatric Liver Collaborative Update

The Committee reviewed the purpose of the Pediatric Liver Collaborative, which is to support efforts to improve processes and increase pediatric liver transplants by identifying and sharing effective practices in three key areas: (1) pre-transplant management, (2) split liver transplants, and (3) living donor transplants. The Collaborative engaged 13 pediatric liver programs and they participated in a 6 month active improvement phase from August 2020 to January 2021.

Preliminary Outcome Data <i>as of March 19, 2021</i> <i>data subject to change</i>		Data Comparison - One Year Prior Pre: 8/1/2019 - 1/31/2020 Project: 8/1/2020 - 1/31/2021	
Type of Pediatric Liver Transplant	Cohort	Nation	
Deceased and Living Donor	Slight decrease	Slight decrease	
Deceased Donor	Slight increase	Remained constant	
Living Donor	Decrease	Decrease	
Split Liver	Increase	Decrease	

#### Summary of discussion:

The Chair stated that these types of opportunities, while difficult during COVID-19, are really rewarding and the Committee would love to see an expansion of this project to all pediatric programs so programs can see efforts done by others and share their ideas.

The Chair also noted that there was a very important liver allocation change that happened in February 2020 with regards to the distribution of pediatric organs and inquired if that might have had some impact in the increases in split liver transplants, even though those participating programs were specifically chosen since they performed split liver transplants. Staff stated that that may be something that can be confirmed by reviewing the dates in the data.

#### **4. Current Progress of Abstracts/Presentations**

The Committee reviewed the progress of the following abstracts and presentations that members are collaborating on:

- Effect of Multi-Organ Allocation Priority on Pediatric Kidney Candidates (Pediatric Academic Societies)
  - Presentation was viewed on 5/2/2021
- Pediatric National Liver Review Board: What Happens to Waitlist Registrations With Denied Exception Forms (American Transplant Congress)
  - Presentation was recorded and will be a rapid fire oral presentation on 6/7/2021

#### Summary of discussion:

The Chair inquired if any members that collaborated on these efforts have anything additional to say. A member stated that the Effect of Multi-Organ Allocation Priority on Pediatric Kidney Candidates was a hot topic and everyone was excited to see the data. It was also noted that the longer term report out on the kidney allocation system will hopefully be submitted in the next week or so.

#### **5. Continuous Distribution Update**

The Committee received the following updates on the progress of the Kidney & Pancreas Continuous Distribution Workgroup and the Lung Continuous Distribution Workgroup:

- The Kidney & Pancreas (K&P) Workgroup is currently reviewing the HLA and cPRA data request results to help facilitate rating scale discussion
- The K&P Workgroup will review the pediatric data request after HLA and cPRA
  - The Committee's leadership will be invited to join
- The K&P Continuous Distribution concept paper is currently being written and will be going out for public comment in August 2021
- The Lung Workgroup is currently discussing review boards and multi-organ transplant
  - Will receive modeling results in a couple of weeks

#### Summary of discussion:

The Chair inquired if it would be appropriate to increase the amount of representatives from the Committee on the K&P Workgroup, for instance if a representative's term ends or if they can't make it to a meeting. Staff explained that rosters have to be formally approved, but mentioned they could discuss these transitions with the K&P Workgroup liaison.

## **6. Heart ABOi Project Update**

The Committee received an update that this project was approved by the Policy Oversight Committee on 5/12/2021 and that the first Workgroup meeting with both Heart Committee members and Pediatric Committee members will be scheduled within the next couple of weeks.

### Summary of discussion:

There was no discussion.

## **7. National Heart Review Board Suggestion**

The Committee reviewed a suggestion from a member regarding the National Heart Review Board going live within the next month. It was explained that this is an important topic for transplant families to hear about and it was suggested that it would be helpful to provide an explanatory video of this change.

### Summary of discussion:

The Chair inquired about next steps to move this idea forward. Staff explained that there will need to be some internal discussions about the technicalities of providing an explanation video, such as where it will be stored and who will be presenting this information, but they will keep the Committee updated.

### **Upcoming Meetings.**

- June 16, 2021 (Teleconference)

## Attendance

- **Committee Members**
  - Evelyn Hsu
  - Emily Perito
  - George Mazariegos
  - Abigail Martin
  - Brian Feingold
  - Caitlin Shearer
  - Douglas Mogul
  - Jennifer Lau
  - Johanna Mishra
  - Kara Ventura
  - Rachel Engen
  - Regino Gonzalez-Peralta
  - Samantha Endicott
  - Shellie Mason
  - Walter Andrews
  - Warren Zuckerman
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Chris Folken
  - Jodi Smith
- **UNOS Staff**
  - Rebecca Brookman
  - Matt Cafarella
  - Betsy Gans
  - Abby Fox
  - Beth Overacre
  - Courtney Jett
  - Glenda Bonner
  - Jean Teotonio
  - Julia Foutz
  - Kaitlin Swanner
  - Kate Breitbeil
  - Katrina Gauntt
  - Leah Slife
  - Matt Prentice
  - Susan Tlusty
- **Other Attendees**
  - Joseph Hillenburg
  - Lara Danziger-Isakov
  - Marian Michaels
  - Ricardo La Hoz