

OPTN Pediatric Transplantation Committee**Meeting Summary****April 27, 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 4/27/2022 to discuss the following agenda items:

1. Public Comment Feedback and Vote: *Pediatric Candidate Pre-Transplant HIV, HBV, and HCV Testing* proposal
2. Pediatric Lung Data Request
3. Project Updates

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

1. Public Comment Feedback and Vote: *Pediatric Candidate Pre-Transplant HIV, HBV, and HCV Testing* proposal

The Committee reviewed public comment feedback on their co-sponsored *Pediatric Candidate Pre-Transplant HIV, HBV, and HCV Testing* proposal. The proposal was broadly supported across regions and member types during public comment. The following are the most common themes from public comment feedback:

- Inclusion of weight threshold
- Align age threshold with other OPTN policies
- Define a time frame for testing

Members reviewed the policy language and voted to send the proposal to the Board of Directors in June 2022.

Summary of discussion:

A member stated that the OPTN Ad hoc Disease Transmission Advisory Committee (DTAC)-Pediatric Workgroup came to a consensus that there was nothing particular about 11 years old being the onset of adolescence and using less than 12 years old as the threshold seemed to align with other policies, make the policy more user friendly, and decrease the likelihood of inadvertent errors. The member also highlighted that this policy change doesn't mean that these candidates under 12 years old won't get tested, because typically the testing will be done during evaluation, it's just that repeat testing won't be done during hospital admission for transplant.

The Chair stated that the DTAC-Pediatric Workgroup worked very quickly after receiving the letter of concern and expressed appreciation for the cooperation from the members who worked on this proposal.

A member requested clarity on the policy language and inquired if the policy should read "[f]or all candidates 12 years and older, candidate samples must also be drawn during the hospital admission for

transplant but prior to anastomosis of the first organ". The member stated that it seems the policy is stipulating that, in addition to all candidates being tested for the diseases, samples for candidates 12 years and older must also be drawn at that time frame.

A member mentioned that the question seems to be whether all candidates 12 years and older must be tested during evaluation and during hospital admission for transplant. The member explained that candidates are not required to be tested before hospital admission in policy; however, many programs perform these tests during evaluation. So this policy change would allow those candidates who are less than 12 years old to only be tested once.

A member emphasized that this is a bare minimum requirement, so if centers believe that their candidates should be tested annually for human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) then the programs can do that. This proposal is meant to establish a bare minimum baseline while giving flexibility to programs.

A member suggested that the policy be changed to state what needs to be tested for at transplant admission and between evaluation and anastomosis for those candidates who are 11 and younger, instead of prescribing exact serologies for all candidates at evaluation.

Staff explained that the clause ("[f]or all candidates 12 years and older") is written as a clarifier. The general purpose of the policy is to state when these tests must occur, but, in the instance where a candidate is 12 or older, the tests must occur at this specific time.

A member mentioned that the policy language is confusing. Staff inquired what exactly in policy is confusing. The member stated that it says transplant candidates must be tested for the following things, regardless of size and age. Then, for all candidates 12 years and older, samples must be drawn during the hospital admission for transplant. The member inquired if this would be a second draw for those candidates. Staff explained that these tests must occur and, for candidates 12 years and older, there's a time frame specified for when those test must occur.

The member inquired why the time frame for these tests is immediately before transplant and what the time frame is for candidates younger than 12 years old. Staff explained that the policy does not specify a time frame for candidates younger than 12 years old. The DTAC-Pediatric Workgroup discussed the inclusion of a time frame, but concluded that it wasn't necessary after reviewing information from the Centers for Disease Control (CDC) that demonstrated the risk of HIV, HBV, and HCV transmission for younger pediatric candidates is very low. Staff explained that candidates younger than 12 still have to get the tests done, but it isn't specified when the tests must be done. Staff also mentioned that, if audited, programs would be evaluated solely on the basis that the testing was performed, instead of when the testing was done, for candidates younger than 12 years old.

A member explained that the testing is done immediately before transplant for reasons in the adult population. For instance, an adult patient on the kidney list may be waiting 5 years before they get their kidney and would have many years to potentially contract these diseases. The member noted that this timing requirement is important because it allows the transplant community to track whether infections are being passed from the donor to the recipient or they are pre-existing infections. The member further explained that this exception is being proposed because young children aren't typically engaging in behaviors that would put them at risk for these diseases, so it probably wouldn't matter as much that the testing occurs right before transplant.

The Chair stated that this proposal aims to clarify that it's only those candidates who are 12 and older that need the testing done right before transplant.

A member stated that it seems programs would want to know these tests results prior to the hospital admission for transplant. A member explained that most transplant centers do more than the minimum required testing and will do what is appropriate for their patient. The member emphasized that this policy is designed to track potentially transmissible infectious diseases from donor to recipient, so the OPTN can have good data. The Chair emphasized that the intent of this policy is not a clinical guide or for the management of patients, but instead is meant to accurately track transmissions.

A member inquired if there's any verbiage that should be included in the policy to clarify that particular point. The Chair stated that including that verbiage would then have to pertain to all policy – there would have to be a clinical qualifier for how programs should be managing their patients and that is not the intention of most policy language.

A member mentioned that OPTN policy is not designed to dictate how individual centers treat individual patients and highlighted that this proposal does not limit in any way how a center can chose to treat their patients on a regular basis.

A member clarified that they were suggesting adding “for the purpose of...” to the policy to clarify why the blood is being drawn for HIV, HBV, and HCV tests right before transplant.

The Chair inquired if there is introductory language in OPTN Policy 15.2 that would state that. Staff explained that Policy 15 addresses identification of transmissible disease, but policy doesn't normally include qualifiers in language that explain the background or intent of the policy. Staff mentioned that qualifiers aren't appropriate for policy because policy is meant to be enforceable and monitorable, if necessary.

A member highlighted that everything in Policy 15.2 is already in policy, the proposal is just adding the language “[f]or candidates 12 years and older”.

Staff also explained that the proposal is removing “[t]o be eligible for an organ transplant” from policy because it is duplicative and policy should be as actionable as possible.

A member inquired if there are any members that have concerns about the underlying intent of the policy. There was no concern with the underlying intent of the proposal.

The Committee voted to send this proposal to the Board of Directors: 10 supported, 1 opposed, 0 abstentions.

A member inquired if the Committee and DTAC will have to vote on this proposal again by chance the CDC disagrees with changing the age threshold to 12 in their guidelines. Staff explained that there has been alignment with the CDC throughout the development of this proposal. The CDC endorsed this change and mentioned that they didn't anticipate any concerns. Staff mentioned that they will keep the Committee updated.

There was no further discussion.

2. Pediatric Lung Data Request

The Committee reviewed the following data request for final submission:

Data Request Purpose

- Establish a baseline understanding of waitlist mortality for patients ages 12-17
- Compare waitlist mortality to patients ages 0-11 and 18-24
- Use this analysis to provide recommendations for monitoring plan for lung continuous distribution

Data Request Components

Evaluating pediatric candidates between the ages of 0-11 and 12-17 years, and a comparison group of those 18-24 years old for 4 years pre and post the removal of DSA from lung allocation and compare to the anticipated impacts of continuous distribution through the TSAM modeling report for the following metrics, when sample size allows.

- Distribution of height and weight of these listed patients
- Primary diagnosis
- Waitlist mortality rates per 100 patient years
- Transplant rates per 100 patient years
- Median waiting time (if cohort allows)
- One and two year survival

Summary of discussion:

Staff explained that there had been some modifications to this data request and some back and forth communications, so they were presenting this to the Committee again for the final review before submitting the request.

The Chair stated that they believe this is a very appropriate use of the Committee's resources and expressed appreciation for the work and time that members and staff have put in to creating this data request.

The Chair inquired about the timeline of getting the results of this data request. Staff explained that they will follow up with their manager since the timeline isn't typically planned until after data requests have been submitted.

The Chair also inquired if the Committee should communicate with the OPTN Lung Transplantation Committee in order to share the results of this data request. Staff mentioned that they had made the support staff for the OPTN Lung Transplantation Committee aware of this request and can reach out to see if they would like a presentation of these results.

The Committee approved submitting the data request. There was no further discussion.

3. Project Updates

The Committee reviewed the status of their current projects and collaborations and specifically discussed the status of the Pediatric Heart ABO-incompatible (ABOi) project, which is sponsored by the OPTN Heart Transplantation Committee and will be going out for public comment in August 2022.

The Pediatric Heart ABOi Workgroup met on 3/31/22 to review the results of the data request they had submitted at the end of 2021.

The Workgroup proposed the following changes:

- Policy 6.6.B applying to candidates who are at least one year old, by expanding eligibility to candidates who are registered prior to turning 18 years old
- Expand ABOi eligibility to candidates registered prior to turning 18 years old who have low titer isohemagglutinin
- Allocate to ABOi with high titer per tertiary blood type match group for pediatric and adult donors for at least pediatric Status 1A candidates

The Workgroup still needs to:

- Determine the cutoff for establishing the low titer versus non-low/high titer

- Decide how to address the pediatric Status 1B and Status 2 recipients for ABOi

Summary of discussion:

The Chair stated it's important to add liver continuous distribution to the Committee's active collaborations and explained that the OPTN Liver Transplantation Committee is in the middle of determining their attributes; however, there hasn't been an invited pediatric representative to take part in those conversations as of yet. Staff explained that they will continue to provide the Committee with updates on the liver continuous distribution project and will work to include the pediatric perspective in those conversations.

Members of the Pediatric Heart ABOi Workgroup mentioned that they are close to finalizing this proposal and have another meeting scheduled on 5/4/22.

The Chair expressed appreciation for the work that members have contributed to this project and emphasized the importance for members to bring forward issues or questions that they are hearing or experiencing to the Committee so the Committee can start taking steps to address them.

There was no further discussion. The meeting was adjourned.

Upcoming Meetings.

- May 18, 2022 (Virtual)

Attendance

- **Committee Members**
 - Evelyn Hsu
 - Emily Perito
 - Abigail Martin
 - Brian Feingold
 - Caitlin Peterson
 - Caitlin Shearer
 - Dan Carratturo
 - Douglas Mogul
 - Jeff Dreyer
 - 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