OPTN Pediatric Transplantation Committee
Meeting Summary
November 17, 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 11/17/2021 to discuss the following agenda items:

1. Information Technology (IT) Update
2. Voting Item: Review Proposed Policy Language Changes to Policy 15.2
3. Project Updates

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

1. Information Technology IT Update

IT staff presented an update on the Multi-Factor Authentication project, including the roll out plan and preparations UNet users can take.

Data Summary:

Multi-Factor Authentication will be rolled out in 2022. After implementation, utilizing Authy will be required for everyone logging into UNet.

Users can download and setup an Authy account now to ensure there will be no issues after implementation. For questions, visit *https://unos.org/technology/unet/mfa/* or contact the Multi-Factor Authentication support team.

Summary of discussion:

The Chair inquired about anticipated problems and issues others have brought up in regards to the multi-factor authentication. Staff stated that one of the more difficult problems was that histocompatibility labs often don't allow foreign devices in their workspace, so they helped the labs get the desktop app set up as an alternative. Another issue was the usage of the app when individuals are in a location that may not have cellular service and whether the app would still work. Staff explained that normally push notifications would come through with cellular service; however, without service, there is a 6-digit code that a phone will continually generate that can be entered to access the app.

There was no further discussion.

2. Voting Item: Review Proposed Policy Language Changes to Policy 15.2

The Committee reviewed the proposed changes to OPTN Policy 15.2 from the Ad hoc Disease Transmission Advisory Committee (DTAC)-Pediatric Workgroup and voted to send the language out for public comment in January 2022.

Summary of discussion:

The Chair thanked members of the Committee who participated in the discussions of the DTAC-Pediatric Workgroup and explained that they worked alongside the Centers for Disease Control (CDC) to discuss CDC regulations and what they felt would be appropriate. The Chair emphasized that there was agreement across agencies that had been a part of developing the initial policy.

A member stated that it's unclear how long prior to transplant the pre-transplant infectious disease testing must be done. The member noted that it would not seem reasonable if the testing had been done 2 years prior to transplant. A member stated that there isn't a time limit and explained that, as the DTAC-Pediatric Workgroup was looking at data, the incidence of HIV, HBV, and HCV cases in the 10 years old or less population were so rare that the consensus was it wasn't necessary to repeat that testing in a child. The Chair noted that decision was also supported by the CDC.

A member also noted that there could be certain clinical situations where a physician feels it's necessary to retest those candidates who are 10 years old or less and they can do that, but it won't be required.

A member mentioned that the burden isn't just around pre-transplant testing, but also the burden of blood needed in post-transplant testing. The member inquired if there had been discussions regarding requirements for post-transplant testing. The member explained that they understand the pre-transplant testing concerns might be different in terms of potential for donor transmission; however, it can be a problem to draw blood due to the volume needed for post-transplant testing, particularly in the smallest patients and infants, when other clinical testing is needed.

The Chair inquired what the post-transplant infectious disease testing requirements were. A member stated that it is one test 4-8 weeks after transplant. The Chair stated that the DTAC-Pediatric Workgroup had wanted to concentrate on patients on the wait list who would be sicker and they didn't want to make those sick patients get repeat testing upon admission for transplant. The Chair noted that this bring up a good point on whether or not these candidates need infectious disease testing afterwards and it might be helpful to look at data once this change has been implemented.

A member suggested, instead of creating an exemption for post-transplant infectious disease testing, that the window could be broadened. For example, in an infant, it's not easy to draw blood and there may be other tests that require blood draw as well so broadening the window for post-transplant infectious disease testing would be helpful. The member mentioned that it could be broadened to 2-12 or 16 weeks and that would allow for more flexibility to get the necessary amount of blood while and avoid conflicts with other clinical lab draw needs or anemia, which is commonly present after a heart transplantation. The Chair suggested keeping this as a possible discussion point in case it is brought up during the public comment period.

A HRSA representative explained that the reason for the 4-8 week period in post-transplant infectious disease testing is to try to identify Hepatitis B virus (HBV), since it can be detected later on. The recipient, except for liver recipients, may also have another blood draw at 6 months and certainly at one year to ensure they are negative for HBV.

Staff also noted that the post-transplant testing was out of the scope of for this project, since it was only addressing pre-transplant infectious disease testing when it was approved by the Policy Oversight Committee (POC).

A member inquired if a candidate would need to be tested again if they turn 11 while waiting for a transplant. The Chair stated that that would be correct. The member explained that they think this change to pre-transplant infectious disease testing will be helpful because they have non-compliant pediatric candidates due to not being able to draw a sufficient amount of blood for these tests – with post-transplant testing there's at least a little bit of time to get the amount of blood needed.

A member inquired if there had been discussion on aligning the age threshold with the Model for End-Stage Liver Disease (MELD). The Chair explained that the DTAC-Pediatric Workgroup didn't want to align with MELD because, once patients are adolescents, the risk of disease transmission increases goes up and they wanted those adolescent candidates to have testing performed during hospital admission for transplant.

A member wanted clarification on the fact that the chance for HCV rises after age 11. The Chair stated that the risk rises after adolescence, but the DTAC-Pediatric Workgroup wanted a nice catchment for when adolescent behaviors might be starting and they agreed on 11 years old. The member inquired whether this decision was made without data. The Chair explained that the DTAC-Pediatric Workgroup's objective was to save the smallest pediatric candidates from having that significant of an amount of blood drawn and, at age 11, it became hard to make the argument that the amount of blood needed for these tests was prohibitive. The Chair also emphasized that the DTAC-Pediatric Workgroup wanted to apply a broad criteria to all the candidates that need blood drawn for these tests in order to still align with the 2020 U.S. Public Health Service Guidelines instead of just screening every candidate.

The Chair inquired about the timeline for this proposal. Staff explained that the proposal will need to be reviewed by the POC, which will the recommend the proposal to the Executive Committee to be slated for public comment. The proposal is anticipated to go out for January 2022 public comment and then will go to the Board of Directors in June 2022.

The Committee unanimously approved sending this proposal out for public comment in January 2022.

3. Project Updates

The Committee reviewed updates on the following projects:

- Kidney & Pancreas (KP) Continuous Distribution (CD)
    - The KP CD Workgroup is finishing up phase 2 of the project (converting attributes into points and currently discussing placement efficiency attributes
    - The Workgroup is submitting a request for feedback during the January 2022 public comment cycle, which will include the analytical hierarchy process (AHP)/community exercise
- PELD/Status 1B
    - Liver Committee voted to send out for public comment in January 2022 a proposal that includes:
        - MELD 3.0 for adults and adolescents
            - Adolescent candidates stick with MELD 3.0 and both male and female adolescent candidates be provided the 1.33 "female" points
        - Pediatric End-Stage Liver Disease (PELD) Creatinine (Cr) for pediatric candidates (under age 12)
        - Changes to Status 1A and 1B
        - Updates to Pediatric National Liver Review Board (NLRB) to account for PELD Cr
- Pediatric Heart ABO-incompatible (ABOi)
    - Submitted a data request – waiting for results before continuing discussion
        - Data request should be done by the end of this year
- Multi-Organ Transplantation (MOT) Committee
    - MOT Committee reviewed draft policy during their 11/1 meeting
    - Pediatric Committee's question about 12 to 18 year old pediatric lung candidates was shared with MOT Committee leadership
        - Address question before approval of the draft policy

Summary of discussion:

KP CD

The Chair stated that it would be really helpful for members from the pediatric kidney community to generate a list of organizations that the KP CD Workgroup reach out to in order to ensure all of the stakeholders and being given the opportunity to provide feedback.

The Chair mentioned that lung continuous distribution ended up weighing pediatrics quite a bit and that they hope that the KP CD Workgroup does that as well. The Chair inquired about the themes that have come up in conversations when trying to advocate from a pediatric standpoint.

A member stated that a big theme has been to make sure that the appropriate weight is given to the pediatric points when calculating the composite score. The member explained that an appropriate weight will allow those patients to be advantaged for the organs that best suit them.

A member stated that another interesting point brought up in these discussions is how difficult this framework is to explain to professionals in the transplant community, meaning it will be even more difficult for patients and families to understand. The member emphasized that the transplant community needs to continuously work on way to make this understandable to the ley person.

The Chair inquired if the KP CD Workgroup has decided on the set number of points to distribute for pediatric priority. A member explained that the KP CD Workgroup is currently looking at each individual attribute and determining the rating scales (how points will be assigned). The pediatric rating scale was binary (yes/no), so candidates would either receive points for being less than 18 years old or not receive points at all if they were 18 or older. The member noted that some attributes' rating scales are a bit more complicated, such as placement efficiency, so the KP CD Workgroup is still working through some of those discussions.

The Chair noted that geography is expressly called out in Final Rule or NOTA as something that shouldn't be taken into consideration when determining allocation. The Chair mentioned that they find the amount of time and space the placement efficiency attribute takes up in conversations interesting, especially since kidneys can weather a lot of ischemia time. A member stated that they think efficiency may be less important in the KP CD framework, but it doesn't change the fact that the KP CD Workgroup has to come up with a rating scale that makes sense. The member explained that the next phase of the project is prioritizing the attributes against each other, which will be when the importance of placement efficiency compared to other attributes is determined.

A member inquired if KP CD changes the kidney sequences or if kidney sequences will be worked on separately. A member stated that, from their understanding, continuous distribution will replace the sequences since a lot of the characteristics they were trying to address will now be taken into account by the attributes. A member stated that replacing the sequencing could affect pediatric access and inquired if the KP CD Workgroup has discussed whether pediatric candidates would get more priority for certain organs or if the priority would be the same for every organ. A member stated that the KP CD Workgroup hasn't discussed that point yet and explained that some attributes are based on either donor or recipient characteristics which both need to be taken into account when matching the best donor organ to the best recipient. The member stated the they believe the KP CD Workgroup will discuss adjusting the rating scales depending on specific donor characteristics, but as of now most attributes are based on recipient characteristics.

A member inquired about how disadvantaged patients are identified, since that was a theme from feedback gathered on the first concept paper. A member explained that there a different characteristics that could disadvantage patients. For example, in the kidney world, pediatric status would be a

characteristic that would identify disadvantage patients, but there's also (1) those with a high calculated panel reactive antibodies (cPRA) who are more likely to have positive cross matches with more donor organs, (2) those who have been waiting a particularly long period of time, and (3) disparities due to socioeconomic status and race, such as how the estimated glomerular filtration rate (eGFR) calculation disadvantages the African American population. The member further explained that the KP CD Workgroup is trying to incorporate these to the best of their abilities.

PELD/Status 1B

A member inquired if this proposal was consistent with what the Committee had suggested. The Chair stated that, in regards to the adolescent candidates, the Committee had suggested treating all patients under the age of 18 the same and assigning them a PELD Cr, so this proposal is not consistent with what was initially suggested. However, with all of the recommended changes, the PELD/Status 1B Workgroup felt that this decision is fine for adolescents. The Chair emphasized that the hope was to maintain pediatric oversight over the MELD score and continue insisting that the Liver & Intestine Committee look at this age group, even though it's a small number of patients, because it's problematic to consider a 12 year old the same as an 18 year old or 85 year old.

A member stated that they thought the problem was that there isn't enough post-acuity circles data to draw conclusions on whether adolescents are more similar to either children or adults, so instead the PELD/Status 1B Workgroup should ground their decision in a general and ethical understanding of where adolescents fit developmentally. The Chair stated that that that was the argument they had been trying to make from the pediatric perspective.

A member inquired whether this proposal will disadvantage teenagers. The Chair noted that the effect of this proposal on teenagers will need to be monitored; however, from looking at the data and provided that males and females have the same points, the Chair stated that they think this age group will continue to benefit. The Chair again emphasized that the result of this change may be unpredictable due to the use of data from a unique time period, so the teenage population should be monitored and there should be continued advocacy in order to optimize outcomes for them.

The Chair inquired about the minimum score for the PELD Cr and whether that was included in the proposal. Staff explained that the proposal recommends PELD Cr have a minimum score of 6. The Chair explained that the MELD score had a minimum of 6, but the PELD score could be negative; so, the proposal aims to align the PELD Cr and MELD scores.

Pediatric Heart ABOi

The Chair inquired about how the classification number works. A member explained that the classification number is the parsing of candidates within a heart status based on distance and blood group. The member explained that the classifications rankings are also different depending on whether the organ is from a pediatric or adult donor, since pediatric donors preferentially go to pediatric candidates.

MOT Committee

There was no discussion.

Upcoming Meetings.

- December 15, 2021 (Virtual)

Attendance

- **Committee Members**
  - Evelyn Hsu
  - Emily Perito
  - Abigail Martin
  - Brian Feingold
  - Caitlin Peterson
  - Caitlin Shearer
  - Douglas Mogul
  - Jennifer Lau
  - Johanna Mishra
  - Kara Ventura
  - Rachel Engen
  - Regino Gonzalez-Peralta
  - Shellie Mason
  - Warren Zuckerman
  - William Dreyer
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Raelene Skerda
- **SRTR Staff**
  - Christian Folken
  - Simon Horslen
- **UNOS Staff**
  - Rebecca Brookman
  - Matt Cafarella
  - Betsy Gans
  - Katrina Gauntt
  - Mike Ferguson
- **Other Attendees**
  - Melissa McQueen