

**OPTN Pediatric Committee
Meeting Summary
November 18, 2020
Conference Call**

**Evelyn Hsu, MD, Chair
Emily Perito, MD, Vice Chair**

Introduction

The Pediatric Committee (the Committee) met via teleconference on 11/18/2020 to discuss the following agenda items:

1. Bylaws Implementation Update
2. Kidney-Pediatric Project Discussion
3. Liver PELD/Status 1B Project Update
4. Median Model for End-Stage Liver Disease (MELD) at Transplant (MMAT) Project Discussion

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

1. Bylaws Implementation Update

The Committee received an update on the impending pediatric bylaws implementation from UNOS staff.

Data summary:

Programs with components:

- 268 applications are headed to December Board meeting for approval
- 112 programs opted-out of a component at this time
- 1 application presented for rejection

Recommended to the Board:

- 268 transplant programs at 124 transplant hospitals
- Impacting 1850 currently waitlisted pediatric patients (as of 10/31/20)
 - 1100 kidney patients
 - 397 heart patients
 - 314 liver patients
 - 21 pancreas patients
 - 18 lung patients

Programs without components:

- 7 transplant programs at 6 transplant hospitals
- Impacting 15 currently waitlisted pediatric patients (as of 10/31/20)
 - 5 liver patients
 - 3 heart patients
 - 7 kidney patients
- Each of these programs have been contacted to understand their plan for removing patients from their waitlist

Post-Bylaw Implementation Compliance

- Going forward OPTN/UNOS will monitor for pediatric patients added to a program's waitlist for any pediatric transplants that happen at a program without an approved pediatric component on a regular basis
- Any use of the emergency exception bylaw for status 1A heart and liver patients will also be evaluated
- The Membership and Professional Standards Committee (MPSC) may be reviewing any of these scenarios retrospectively on a case-by-case basis

Summary of discussion:

One member asked if there was a way to know where the 268 centers with an approved pediatric component are located and where the centers are that have opted out to know if there are geographical areas without pediatric transplant coverage?

A member of UNOS staff responded that they can't do that yet because the program applications and information are still being reviewed. Additionally, this information would need confidential measures before peer review. The staff member continued that after implementation, staff could provide a map where the programs with pediatric components are but can't disclose which programs have decided not to pursue a pediatric component.

One member asked if there is a communication to the programs without a pediatric approved component which would mandate for them to tell currently waitlisted patients about their change in status. A staff member explained that yes according to appendix K, UNOS has already started communication with the programs about this.

A member of the public asked if the UNet warning will appear for any current listings at programs without a pediatric component as well as new listings. A UNOS staff member explained that the system warning will be displayed for any inappropriate listing upon implementation, not just new listings after implementation. However, patients that fall into the emergency exception status of 1A will be able to retain their status after implementation until their standard deadline to renew the status at which point they would need to apply using the specific process under the new bylaw pathway.

One member asked who will review any information regarding inappropriate listings. A UNOS staff member replied that the UNOS member quality department will review through internal reporting measures. A member asked if the committee could also receive reporting on this as well. A member of UNOS staff responded that some data can be provided to the committee after implementation.

The Chair asked another member of the committee to comment on whether they felt that the heart emergency exception criteria were still relevant given that the criteria were set a few years back. The member responded that yes, they agreed that the criteria were still relevant.

A member asked if there is somewhere families can go to see the list of all approved programs. A UNOS staff member responded that yes, there is a master directory of all approved transplant programs on the OPTN website. A member asked if the target audience for that web page is families. A UNOS staff member explained that the web page just shows contact information for programs etc.

The Chair suggested that it may be beneficial to the community to write a manuscript detailing the whole bylaws process and a member of the public suggested that Eileen Brewer may be a good resource as she presented the proposal to the Board of Directors.

A member of HRSA asked who is evaluating emergency exception pathway cases at the OPTN. A UNOS staff member replied that the member quality department will be reviewing inappropriate registrations and that because there is not a subjective review process to this that the process will involve verifying documentation and will not be a subjective exception.

Next steps:

The Committee will continue to receive regular updates on the bylaws exception requests and standard monitoring reports.

2. Kidney-Pediatric Project Discussion

The Committee received an update and discussed the next steps for the Kidney-Pediatric project.

Data summary:

- On October 14th, the POC discussed the sequencing of the Kidney-Pediatric project.
- The POC decided that the work of further prioritizing pediatric candidates should be rolled into the efforts of continuous distribution.
- The POC considered several factors in their decision:
 - The kidney-pediatric project would be implemented in a circle system which will shortly be replaced by a continuous distribution framework.
 - The project falls under strategic priority goal #2 “Increasing equity in access to transplant” which is largely over-allocated.
 - The project requires a large amount of IT resources (4,000 hours) to implement but will only have short term benefit due to the impending work of continuous distribution which will replace the current circle framework.
- Further work in prioritizing pediatric candidates will be incorporated into the continuous distribution framework.
- Members of the Pediatric committee will join the Kidney continuous distribution workgroup and continue discussions from the Kidney-Pediatric project.
- The Pediatric committee will receive regular updates on the discussions and progress.

Summary of discussion:

The Chair noted a need to document the effort that was put forth and maintain the relationship with Kidney Continuous Distribution Workgroup (Kidney CD Workgroup). She also commented that the committee should focus on getting pediatric members onto the Kidney CD Workgroup.

There was discussion from the committee members about the importance of incorporating the pediatric prioritization into the kidney continuous distribution framework. One member noted that the new framework in and of itself would not solve the concerns of insufficient pediatric priority which is why incorporating the work will be a significant endeavor.

Next steps:

The Committee will collaborate with the Kidney Committee to continue work on the work of prioritizing pediatric candidates in kidney allocation policy.

3. Liver PELD/Status 1B Project Update

The Committee received an update on the liver project and discussed next steps.

Summary of discussion:

The Committee skipped this agenda item in the interest of time.

4. Median Model for End-Stage Liver Disease (MELD) at Transplant (MMaT) Project Discussion

A member of the OPTN Liver Transplantation Committee provided an overview of an upcoming project proposal regarding median meld at transplant (MMaT).

Data summary:

Overview:

- In current liver allocation, candidates with a MELD exception, are assigned an exception score relative to the median MELD at transplant (MMaT) for the transplant program at which they are registered
- The MMaT/transplant program is calculated based on transplants performed within 250 nautical miles (NM) of the program in a previous 365 day period
- Most exception candidates are assigned MMaT-3
 - Ex: MMaT of transplant program is 30, exception candidates are listed at MELD 27
- PELD exceptions are assigned relative to the median PELD at transplant (MPaT) which is based on PELD transplants across the nation
 - All PELD exception requests are relative to national MPaT, which is 35
- MMaT/transplant program was designed to assign higher MELD score to exception candidates in areas where a higher MELD score is needed to access transplant

Problem: Transplant programs in close geographic proximity with different MMaT

- Exception candidates at the two programs have similar clinical condition but will have different exception scores
- Example:
 - MMaT in Philadelphia = 30
 - MMaT in NYC = 31
 - Exception candidate listed in NYC will have an exception score = 28, in Philadelphia 27
 - On many (but not all) match runs, candidate from NYC will be higher than candidate in Philadelphia

Proposed Solution:

- Instead of basing MMaT around transplant program, base MMaT around donor hospital
- Proposal would calculate MMaT scores for each **donor hospital** and all exception candidates would be assigned exception score relative to the MMaT for donor hospital where match is run
- Because MPaT is calculated for entire nation, disparity between programs does not exist and proposal does not change how MPaT is calculated

- MMaT/Donor Hospital:
 - Start with 150 NM circle around donor hospital
 - Increase circle size in increments of 50 NM if cohort not met
 - Exclude living donors, DCD donors, donors from more than 500 NM from transplant hospital, Status 1A/1B
- Minimum Exception Score:
 - Standardized and non-standardized exception scores have lower limit of 15
- Sorting within Liver Allocation:
 - Exception scores assigned relative to MMaT of donor hospital = exception scores change with each match run
 - Exception candidates can no longer be ranked by time at score or higher (scores will fluctuate)
 - Exception candidates ranked by time since submission of first approved exception
 - Lab candidates ranked by time at score or higher
 - Lab candidates ranked ahead of exception candidates of the same MELD/PELD
- Proposal does **not** change pediatric priority for pediatric donors

Additional Consideration:

- Currently, transplant programs request a specific score when submitting an exception request
- In proposed solution, transplant programs will not be able to submit request for a specific score as scores will fluctuate with each match run
- This change would also occur for PELD requests
- Programs will need to submit requests for MMaT or MPAT adjustments (i.e. MMaT-3, MMaT+2, MMaT+6)
- Programs would still be able to submit specific requests for MELD or PELD 40 and above and these scores would not be tied to MMaT (this is current policy)

Summary of discussion:

The Chair commented that the proposed policy seems to address disparities in the case of adults. The Chair asked if lab candidates would be prioritized over exception candidates and the presenter responded that the adult candidates would follow the adult sequencing but that it would likely have very little change or impact on pediatric exception candidates. A member of UNOS staff clarified that the proposed policy would prioritize lab MELD candidates over exception PELD candidates.

One member commented that this change could potentially disadvantage adolescent exception candidates and that the Committee should be active in evaluating this possible consequence. A committee member asked if this change to prioritization was data driven by waitlist mortality. The presenter responded that it was not based off of waitlist mortality but was a decision based on clinical judgment.

The Vice Chair noted that from the pediatric perspective, one focus has been on utilizing the exception criteria to ensure that these pediatric patients receive the proper prioritization and there may be some concerns about a policy proposal that would alter current prioritization. The Chair suggested that all pediatric scores be prioritized together regardless of if the candidate has an exception score. The Vice Chair spoke in support of this suggestion and also pointed out that there is currently a PELD workgroup and project focused on improving the PELD score and making the system less reliant on exception scores.

Next steps:

The Pediatric Committee will review the policy proposal during public comment and provide feedback to the OPTN Liver Transplantation Committee.

Upcoming Meetings

- December 16, 2020

Attendance

- **Committee Members**
 - Abigail Martin
 - Brian Feingold
 - Caitlin Shearer
 - Douglas Mogul
 - Emily Perito
 - Evelyn Hsu
 - George Mazariegos
 - Jennifer Lau
 - Johanna Mishra
 - John Barcia
 - Joseph Hillenburg
 - Kara Ventura
 - Regino Gonzalez-Peralta
 - Shellie Mason
 - Sam Endicott
 - Warren Zuckerman
- **HRSA Representatives**
 - Marilyn Levi
- **SRTR Staff**
 - Chris Folken
 - Jodi Smith
- **UNOS Staff**
 - Betsy Gans
 - Joann White
 - Julia Foutz
 - Kiana Stewart
 - Krissy Laurie
 - Leah Slife
 - Lloyd Board
 - Matt Prentice
- **Other Attendees**
 - Sharon Bartosh
 - James Trotter