OPTN Pediatric Transplantation Committee
Meeting Summary
September 16, 2020
Conference Call

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

Introduction

The Pediatric Transplantation Committee (the Committee) met via Citrix GoToTraining teleconference on 09/16/2020 to discuss the following agenda items:

1. Pediatric Bylaw Implementation Update
2. Public Comment: Guidance Addressing the Use of Pediatric Heart Exceptions
3. Public Comment: Further Enhancements to the National Liver Review Board

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

1. Pediatric Bylaw Implementation Update

The Committee were updated on the Pediatric Bylaw implementation and application process.

Summary of discussion:

A member asked if there were any requirements that the listed patient families are notified that their programs are not pediatric certified and therefore are unable to transplant. Many families may not be aware of whether their respective programs are certified and that the programs may be skipping these offers until their application is completed and approved.

UNOS staff will check on this information.

Another member stated that there was a prior understanding from a programming point of view that a patient under 18 could not be listed if the program did not have approval for pediatrics. UNOS staff confirmed that programs would not be "shut off" but that there would be very close monitoring and reports on programs without an approved pediatric component that listed a pediatric patient. UNOS staff added that the ability for programs without an approved pediatric component to continue listing pediatric patients in the system was intended for the emergency pathway for heart and liver.

The Committee Chair asked who will determine if this information is conveyed to patient families that a program is not certified for pediatrics. UNOS staff indicated that it is potentially covered in OPTN bylaws appendix K but will follow up on this information.

A member asked for clarification on whether any program could list a pediatric patient despite not having a pediatric approved component or if the capability was only open to cases which fall under the emergency accepted pathway for heart and liver. UNOS staff stated that currently, there are no system limitations to listing of pediatric patients outside of an approved component, however transplantation outside of an approved component would spark review by the MPSC to investigate. The exact details of the monitoring and review plan post implementation are still being determined.

The Vice Chair asked if there would be updates to the Committee regarding the amount of patients listed at programs without an approved pediatric component. UNOS staff are currently working on next steps internally and will report back to the Committee on how they would convey this information.

Two members of the committee felt that the system ability for any program to continue listing pediatric patients could be used as a loophole to compliance with the pediatric bylaws. The members expressed concern that there did not seem to be enough enforcement to ensure that programs without a pediatric approved component would not list pediatric patients.

The Committee Chair clarified that previously, there was no focus or criteria that was in place beforehand and these bylaws were the first steps to instituting program standards. However, due to the controversial nature of these new bylaws, there will need to be close monitoring of this process once it has been implemented and considering what further refinements may need to be made.

Another member shared their surprise that programs without an approved pediatric component will maintain the ability in the system to list pediatric patients. The member expressed concern for patients and families who go all the way through the registration process with a program that may not have an approved pediatric component. A member stated that there needs to be caution in this process as there is a concern in having a patient listed at a program and the center is not certified for pediatrics. If this becomes a problem, there may be a need to revisit the bylaws to make restrictions for programs without certified pediatric components to list pediatric patients.

Another member stated that there is an understanding that heart and liver programs may need to retain their ability to list even without approved pediatric components for the emergency pathway for heart and liver but it is hard to understand why the system does not remove the ability for programs without an approved component of other organs ensure that those patients are listed at pediatric certified programs.

A member stated that it was very challenging to get support for this proposal from the community and approved by the board in part because there was an assumption that programs would lose their ability to list pediatric patients if they did not have an approved pediatric component. This assumption also led to the heart and liver exception pathway addition. A member stated that this issue may need to be addressed sooner rather than later because it would reflect very poorly to have programs without an approved pediatric component listing or transplanting pediatric patients.

Another member advocated that that the currently listed patients and families at programs without an approved pediatric component be notified. Another member stated that there are other challenges for families whose insurance may only cover them for particular centers and the strain for those that go through the process of getting their child listed and then having to find another program that is certified. This should also be taken into consideration.

A member stated that families would also feel equally deceived if they have their child listed at a particular program and then miss out on offers because the programs are not in compliance with the pediatric bylaws and therefore will not transplant their pediatric patients.

The Committee Chair asked for the Committee to be updated and included in the discussion of the process, specifically regarding notifying programs without an approved pediatric component that they must begin transitioning pediatric patients off their waitlist.

<u>Next Steps:</u>

- The Committee would like to have additional updates of the status of implementation and compliance in the bylaws process.

2. Public Comment: Guidance Addressing the Use of Pediatric Heart Exceptions

A representative from the OPTN Heart Transplantation Committee (Heart Committee) presented their Guidance Addressing the Use of Pediatric Heart Exceptions to the Committee.

Summary of discussion:

A member stated that overall they supported the proposal and that there may be some cases in which single ventricles may not be amenable to Ventricular Assist Devices (VAD) and that should be taken under consideration. The member continued by stating opposition to including sensitization to help determine whether a Coronary Allograft Vasculopathy candidate should be considered for Status 1A listing by exception. The member suggested that the review board routinely get feedback regarding the review process and potentially re-evaluate. This is an important initiative.

Another member stated that there is believed to be a plan to monitor further data for 6 months and a year to determine progress of the changes being made.

A member stated that the guidance document should be seen as a resource and is a work in progress over the course of time. With this in mind, it should be easy to move forward with this document as it exists.

One member commented their support of the Heart Committee's efforts and in particular their soliciting and receptivity to feedback from the community. The member urged the Heart Committee to be aware and intentional about striking a balance of equity between single ventricle and cardiomyopathy exception patients.

Another member agreed that sensitization should not be included. Another member noted that there had been feedback regarding the 5-10 kilogram consideration for VAD placement particularly in regards to programs that feel less confident about placing them. A member commented that the national review structure will be beneficial to the transplant community and that the guidance document does not provide new requirements to cover all scenarios but are guidance to help assist programs.

The Vice Chair asked if there was language built into the document to point out that the document will be updated as needed to accommodate any changes in the process.

A member stated that there has been some feedback in regards to this and that this would be built into the document to specify this.

A member noted that there will need to be onboarding for members who join the review team to help emphasize that this is just guidance and it is not set requirements for every case. The member also noted that if the congenital heart disease patients have been disadvantaged by the use of exceptions than adult patients who are status 4 should not be prioritized over pediatric patients who are status 2 and the issue should be addressed through policy rather than an exception resolution.

Vote: 4 Strongly Support, 4 Support, 1 Neutral/Abstain, 0 Oppose, 0 Strongly Oppose

Next Steps:

The comments received by the Committee will be synthesized into a formal statement that will be submitted for public comment.

3. Public Comment: Further Enhancements to the National Liver Review Board

A representative from the OPTN Liver Transplantation Committee (Liver Committee) presented their Further Enhancements to the National Liver Review Board (NLRB) proposal to the Committee.

Summary of discussion:

Several members spoke in support of the proposal. One member asked if the Liver Committee had seen greater consistency in MELD scores across regions. The presenter shared that the primary goal of the NLRB is to get more consistent review of cases and that it has done so. The member shared that they were still seeing a wide variety of case approvals. The presenter agreed that there still is variability in case approval by the NLRB, which is an opportunity for improvement. However, the presenter noted that it has improved and is better than it was before.

The Vice Chair noted that there will be additional pediatric liver guidance in the near future since there is currently a PELD liver workgroup. The presenter also noted that pediatric cases are more susceptible to variability.

Vote: 9 Strongly Support, 0 Support, 0 Neutral/Abstain, 0 Oppose, 0 Strongly Oppose

Next Steps:

The comments received by the Committee will be synthesized into a formal statement that will be submitted for public comment.

Upcoming Meetings

- September 16, 2020 (teleconference)

Attendance

- **Committee Members**
  - Brian Feingold
  - Caitlin Shearer
  - Douglas Mogul
  - Emily Perito
  - Evelyn Hsu
  - George Mazariegos
  - Jennifer Lau
  - Johanna Mishra
  - Joseph Hillenburg
  - Kara Ventura
  - Abigail Martin
  - Rachel White
  - Regino Gonzalez-Peralta
  - Samantha Endicott
  - Warren Zuckerman
  - William Dreyer
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Chris Folken
  - Jodi Smith
  - Marilyn Levi
  - Raelene Skerda
- **UNOS Staff**
  - Betsy Gans
  - Eric Messick
  - Joann White
  - Julia Foutz
  - Kiana Stewart
  - Krissy Laurie
  - Lloyd Board
  - Roger Vacovsky
  - Sarah Konigsburg
- **Other Attendees**
  - Sharon Bartosh – public
  - Shelley Hall – Heart Transplantation Committee
  - James Trotter – Liver and Intestine Transplantation Committee