

Meeting Summary

OPTN Liver and Intestinal Transplantation Committee OPTN Pediatric End- Stage Liver Disease (PELD)/Status 1B Work Group Meeting Summary July 15, 2021 Conference Call

Evelyn Hsu, MD, Chair

Introduction

The OPTN Pediatric End- Stage Liver Disease (PELD)/Status 1B Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 07/15/2021 to discuss the following agenda items:

- 1. Analysis Report: Model fit for adolescent candidates
- Status 1B- Model for End- Stage Liver Disease (MELD)/PELD threshold for candidates with chronic liver disease

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

1. Analysis Report: Model fit for adolescent candidates

The Work Group reviewed the results of the request to examine model fit in adolescent candidates.

Summary of discussion:

A member confirmed that the PELD- Creatinine (Cr) model predicted more adolescent candidates would have higher scores. The presenter explained that a smaller number of adolescent candidates will spend time in the 10-19 PELD score range and more time at higher and lower score ranges because the PELD-Cr model has a larger spread.

A member asked for clarification on a graphic that modeled mortality rate per person- year by comparing the prospective MELD and PELD models. The presenter explained that indirectly, the graphic showed the MELD NA model's prediction of higher mortality rates in adolescents when compared to 18 year olds. Another member suggested the Work Group also review overall mortality rate data that examines model fit in adolescent children.

Next steps:

The Work Group will use these results to inform future decisions in their re-evaluation of the pediatric liver allocation system.

2. Status 1B- Model for End- Stage Liver Disease (MELD)/PELD threshold for candidates

The Work Group discussed updating the MELD/PELD thresholds for candidates with chronic liver disease.

Summary of discussion:

A member confirmed that data showing *pediatric chronic liver disease waitlist removals with each characteristic by removal reason* included candidates who already have 1B status. This member continued that it would be valuable for the Work Group to know which candidates do not already have 1B status at waitlist removal. Another member confirmed that the majority of candidates that were

diagnosed with chronic liver disease, but did not meet the MELD/PELD threshold had their status 1B requests approved. UNOS staff commented that it would be possible to remove candidates who already had a status 1B registration in order to understand more about those candidates that did not meet standard criteria.

A member asked for the Work Group's input on the MELD/PELD threshold. The Work Group weighed lowering the threshold to 15 against removing the threshold altogether. A member noted that if the PELD score is further adjusted after selecting any new threshold, the selected number may not retain its relevancy in the coming years. Some members agreed that the removal of the MELD/PELD threshold could be the best option as it is simple and according to the data, this change should not overwhelm the 1B category. A couple of members responded that the removal of the MELD/PELD threshold may provide more opportunities for gaming, as transplant programs would no longer be required to provide a clearly-defined level of medical urgency due to liver failure. Other members responded to this idea, stating that there is reduced risk and occurrence of gaming in pediatric transplantation.

A member suggested assessing the score distribution of candidates that were diagnosed with chronic liver disease, but did not meet the MELD/PELD threshold to help inform any potential changes to the threshold. Another member agreed with this as a next step and added that the Work Group may need to present the OPTN Liver and Intestinal Organ Transplantation Committee with a few potential solutions supported by data and Work Group member expertise in order to determine the best option. The Work Group agreed that the threshold should not remain at 25.

Next steps:

The Work Group will continue to review Status 1B data and discuss options for updating the MELD/PELD thresholds for candidates with chronic liver disease. The OPTN Liver and Intestinal Organ Transplantation Committee will receive an OPTN PELD/Status 1B project update in early August.

Upcoming Meetings

• August 19, 2021

Attendance

• Work Group Members

- o Regino Gonzalez- Peralta
- o Evelyn Hsu
- o Allison Kwong
- o Julie Heimbach
- o Steven Lobritto
- o John Magee
- o Emily Perito
- o Sarah Schwarzenberg
- o Sara Rasmussen
- o Jorge Reyes

• HRSA Representatives

- o Jim Bowman
- o Marilyn Levi

SRTR Staff

- o Katie Audette
- o John Lake
- o David Schladt

UNOS Staff

- o Rebecca Brookman
- o Matt Cafarella
- o Julia Foutz
- o Savannah Holmes
- o Leah Slife
- o Niyati Upadhyay