

**OPTN Liver & Intestinal Organ Transplantation
PELD/Status 1B Criteria Workgroup
Meeting Summary
October 15, 2020
Conference Call**

Evelyn Hsu, M.D., Chair

Introduction

The PELD/Status 1B Criteria Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 10/15/2020 to discuss the following agenda items:

1. PELD Characteristics Data Review
2. Status 1B Data Request

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

1. PELD Characteristics Data Review

The Workgroup reported back on their independent review of PELD characteristics data. While reviewing the evidence presentations, the Workgroup was asked to consider the following questions:

- Is there evidence that the characteristic predicts pediatric waitlist mortality?
- Is it currently collected by the OPTN?
- Should it be included in a future modeling request?

The Workgroup will use specified characteristics to submit a modeling request using an updated PELD score. The updated PELD calculation will be used to run a liver simulation allocation model (LSAM) to estimate the impact of the updated score on outcomes.

A member asked how Acuity Circles allocation will impact LSAM data. An SRTR representative informed the Workgroup the LSAM will need thousands of candidates to determine the effect of any characteristic change, therefore the modeling will need to use data from before Acuity Circles implementation. Additionally, given the small size of the pediatric group, the LSAM wouldn't simulate a long enough time span to show the difference a characteristic change may make. A member also commented the LSAM is unable to model changes in behavior or outcomes of split transplants.

Decompensated Chronic Liver Disease

A Workgroup member presented their literature review of decompensated chronic liver disease. The member reviewed relevant literature which compared outcomes of progressive liver disease with acute liver failure and Status 1B patients. The member reported there is evidence that the characteristic predicts pediatric waitlist mortality. The member further reported the OPTN currently collects minimal data related to decompensated chronic liver disease and they believe this characteristic should be included in a future modeling request.

Infections

A Workgroup member presented their literature review on infections. The member reviewed clinical studies on:

- Biliary atresia profiles, risk factors, and outcomes
- Spontaneous bacterial peritonitis in children with end-stage liver disease
- Infectious complications in pediatric liver transplant candidates
- Ascitic fluid infection in children with liver disease

The member reported there is evidence that the characteristic predicts pediatric waitlist mortality as the studies show infections increase waitlist and post-transplant mortality. The member further reported the OPTN does not currently collect this data and they believe this characteristic should be included in a future modeling request.

A member commented what constitutes as an infection may be too broad to be a PELD characteristic on its own. Another member commented it may be worth while to find a way to document specifically defined infections. Members also commented the goal should be to find predictors of infection.

Next Steps

The Workgroup will continue reviewing member's reports of literature and data reviews on the next call.

2. Status 1B Data Request

The Workgroup reviewed elements of a data request for Status 1B updates. The Workgroup requested the following data elements:

- Children who received dialysis twice in week prior to Waitlist removal
- Children on ventilator at time of Waitlist removal
- Children with grade 3-4 encephalopathy at time of Waitlist removal
- Variables of interest for each group:
 - Number
 - Age
 - Diagnosis category
 - Status 1A, Status 1B or Lab PELD/MELD score at listing and waitlist removal
 - Waitlist outcomes

Next Steps

The Workgroup members will review the elements of the data request independently and offer feedback and suggestions prior to the next call.

Upcoming Meetings

- November 19, 2020

Attendance

- **Workgroup Members**
 - Regino Gonzalez-Peralta
 - Steve Lobritto
 - George Mazariegos
 - Douglas Mogul
 - John Magee
 - Emily Perito
 - Sara Rasmussen
 - Sarah Schwarzenberg
 - James Trotter
- **HRSA Staff**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Michael Conboy
 - David Schladt
- **UNOS Staff**
 - Matt Cafarella
 - Julia Foutz
 - Lindsay Larkin
 - Victor Melendez
 - Matt Prentice
 - Leah Slife
 - Karen Williams
 - Joann White