

OPTN Liver & Intestinal Organ Transplantation Committee
PELD/Status 1B Criteria Workgroup
Meeting Summary
September 17, 2020
Conference Call

Evelyn Hsu, M.D., Chair

Introduction

The PELD/Status 1B Criteria Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 09/17/2020 to discuss the following agenda items:

1. Status 1B Criteria: MELD/PELD Threshold
2. Status 1B Criteria: Gastrointestinal Bleeding
3. Sorting within Status 1B

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

1. Status 1B Criteria: MELD/PELD Threshold

The Workgroup reviewed the MELD/PELD threshold in Status 1B criteria.

Summary of Data

The Workgroup reviewed the following information from 2018-2019:

- Data on Status 1B exceptions to evaluate program behavior.
- Data on pediatric Waitlist registrations removed for death or too sick to transplant by lab MELD/PELD and diagnosis
- Data on the percent of Waitlist registrations that submitted Status 1B forms by case outcomes with diagnosis at listing and lab MELD/PELD score at time of form submission
- Data on Status 1B requests that do not meet standard criteria by case outcome

The Workgroup also reviewed current policies and exception guidance for chronic liver disease in pediatric Status 1B requirements.

Summary of Discussion

The Chair noted any changes the Workgroup recommends should be consistent across policies and guidance. The Workgroup discussed proposed language changes to *Pediatric Status 1B Requirements* under *Policy 9.1.C.2.c* and *9.1.C.2.d* and corresponding language in the exception guidance which would remove the current MELD/PELD threshold.

Some members commented the proposed changes may be overbroadening the criteria, which might be a risk to sicker patients. A member suggested the Workgroup could pair this effort with making sure some degree of priority was preserved for sicker patients. Several members commented the current threshold of MELD/PELD 25 is arbitrary and data could be used to specify a different threshold. Another member commented updating PELD may eliminate the need for Status 1B.

The Workgroup generally agreed the patients that meet the proposed criteria should not be prevented from receiving a transplant. However members are concerned about overcrowding within the criteria and how to properly prioritize Status 1B patients.

Next Steps

The Workgroup will continue to discuss proposed policy and guidance language changes.

2. Status 1B Criteria: Gastrointestinal Bleeding

Next, the Workgroup reviewed language in the current Status 1B criteria policy and guidance language related to the transfusion threshold of gastrointestinal bleeding.

Summary of Data

Current *Policy 9.1.C.2.c* and *9.1.C.2.d* includes the following criteria language:

“Has gastrointestinal bleeding requiring at least 30 mL/kg of red blood cell replacement within the previous 24 hours”

Additionally, the Workgroup reviewed data on the classification of hemorrhagic shock and circulating blood volumes in children provided by medical journal articles.

Summary of Discussion

The Workgroup discussed proposed language changes to the gastrointestinal bleeding language under *Policy 9.1.C.2.c*:

“Has gastrointestinal bleeding requiring at least 30 mL/kg of red blood cell replacement within the previous 96 hours or 20 mL/kg in the previous 24 hours”

A member commented the proposed change attempts to reach some threshold that is also a meaningful metric on bleeding. The member further commented gastrointestinal bleeding is physiologically significant as gastrointestinal bleed of any amount has been associated with significant mortality. A member commented the history of bleeding is important to include.

Another member requested detail on the number of patients under each of the Status 1B criteria and their mortality rates. The Workgroup generally agreed with the updated numbers in the proposed language, but some members suggested adding more context to the language.

Next Steps

The Workgroup will continue to discuss proposed policy language changes.

3. Sorting within Status 1B

The Workgroup reviewed language in current policy regarding sorting within Status 1B.

Summary of Data

The Workgroup reviewed current language in *Policy 9.7.A: Points for Waiting Time*, *9.7.B: Points Assigned by Blood Type*, and *9.8.D: Sorting Within Each Classification*. Within each status 1B allocation classification, candidates are sorted in the following order:

- Total waiting time and blood type compatibility points (highest to lowest), according to *Policy 9.7: Liver Allocation Points*
- Total waiting time at status 1B (highest to lowest)

Summary of Discussion

The Workgroup considered whether there are certain subpopulations within Status 1B that should be prioritized relative to others. The Workgroup considered the following subpopulations:

- Liver-intestine
- Re-transplant
- Age less than two
- Metabolic disease
- Tumor
- Chronic liver disease

The Chair requested data on subpopulations to see mortality over time. A member recommended adding nutrition depletion to the list of subpopulations.

Next Steps

The Workgroup will continue discussions on the next call. Additionally, Workgroup members will review available research on identified PELD characteristics to determine if they should be included in a future modelling request.

Upcoming Meetings

- October 15, 2020

Attendance

- **Workgroup Members**
 - Walter Andrews
 - Clark Bonham
 - Regino Gonzalez-Peralta
 - Julie Heimbach
 - Evelyn Hsu
 - 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
 - Andrew Wey
- **UNOS Staff**
 - Matt Cafarella
 - Betsy Gans
 - Julia Foutz
 - Lindsay Larkin
 - Karen Williams
 - Joann White