

## OPTN Ad Hoc Disease Transmission Advisory Committee

### Meeting Summary

April 25, 2022

Conference Call

**Ricardo La Hoz, MD, FACP, FAST, FIDSA, Chair**

**Lara Danziger-Isakov, MD, MPH, Vice Chair**

### Introduction

The Ad Hoc Disease Transmission Advisory Committee met via Citrix GoToMeeting teleconference on 04/25/2022 to discuss the following agenda items:

1. Pediatric Candidate Pre-Transplant HIV, HBV, HCV Testing

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

#### 1. Pediatric Candidate Pre-Transplant HIV, HBV, HCV Testing

The Committee reviewed public comment feedback for the joint proposal with the Pediatric Committee on Pediatric Candidate Pre-Transplant HIV, HBV, HCV Testing.

#### Background:

The amount of blood needed for pre-transplant HIV, HBV, and HCV testing of small, low weight pediatric candidates can lead to adverse medical outcomes from blood overdraw. The DTAC and Pediatric Committees proposed modifying policy so that all candidates younger than 11 years of age are not required to receive HIV, HBV, and HCV testing during hospital admission for transplant.

To date, there have been no reported transmissions of HIV, HBV, or HCV from pediatric donors, and no cases of donor-derived HIV or HCV transmission to pediatric recipients.

Pediatric candidates have a higher incidence of co-morbidities, anemia, and low weight, which makes them more vulnerable to negative impacts of blood overdraws. Only about 1-5% of a healthy child's total blood volume can be safely drawn at one time. In addition, blood is needed for purposes other than infectious disease testing at the time of transplant.

The goal for the proposal is to avoid unnecessary repeat testing, and the workgroup identified 11 as an age indicative of the onset of adolescence.

#### Public Comment Feedback:

Public comment was overall supportive across member type and region. In general, commenters noted that the proposal swiftly addressed an important issue and improved safety while increasing program flexibility. Themes include weight threshold, age, timeframe of testing.

- **Public Comment Feedback:** Include weight threshold of between 20 to 30 kg in addition to age threshold, as causes of renal failure may be associated with syndromes that impact growth and may extend to children older than 10.
  - **Workgroup Feedback:** Workgroup considered age inclusive enough, since original concern for underweight infants (letter mentioned 10 kg)

- Overdrawing blood for 20 kg child would mean 32 to 40 ml blood draw at one time. Most blood draws 2.5-3 ml, might be multiple, but not same risk for 20 kg child. In addition, a 20 kg child would be included in the proposed policy if under 11.
  - Adding weight alongside age would provide additional complexity for transplant programs
  - Concern about higher potential for risky behaviors over the age of 11
- **Public Comment Feedback:** Consider making the age threshold 12 instead of 11, to align with lung and liver allocation
  - **Workgroup Feedback:** Changing behaviors with adolescence and pre-adolescence, means a conservative threshold regarding risk of HIV HBV and HCV exposure would be appropriate
    - 11 still very inclusive towards the concern for blood overdrafts with underweight infants and small children
    - 11 aligns with CDC change
- **Public Comment Feedback:** Should there be a maximum timeframe set for the testing to occur before transplant?
  - **Workgroup Feedback:** Workgroup did consider including alternate timeframe but concurred baseline testing would be sufficient given the extremely low risk of HIV HBV and HCV in this population
    - Baseline testing could be at time of evaluation and documented in the patient's file
    - Aligns with CDC change

The public comment analysis, including all comments received, was available within the meeting materials.

### Discussion

A CDC representative asked what feedback the members opposed to the change gave. UNOS staff explained that the written feedback given did not seem in opposition to the proposal itself, but instead was points for the committee to consider.

One member stated that DTAC should consider the potential for vertical transmissions in newborns, and whether maternal screening should be required. Another member stated that this does not seem necessary to require at this point, since there have been no reported cases of undetected infections in this population. Another member pointed out that NAT testing is also more likely to detect infections in these cases than antibody testing, and NAT testing is already required. Another member pointed out that policy is only intended to be the minimum requirements and not encompass all clinical decisions, and that the current policy addresses the primary issue of pediatric patient safety. Members agreed that this policy is appropriate as is.

Multiple pediatric specialist members commented that it would be highly unlikely for a patient over 11 years old to be under 15 kilograms, and that the primary concern for blood draw volume is patients under 15 kilograms. Another member mentioned that the workgroup did evaluate the data on weight distribution of recent candidates, and the requirement developed did encompass them.

One member commented that the age requirement developed should be based on science, not other policies, and that 11 was chosen due to the potential increase in risk factors in adolescence. Another member mentioned that the CDC data had also shown an increase in hepatitis rates at the age of 12, and that this change is in alignment with the proposed CDC change. The CDC member clarified that the increase was above the age of 12, and that 13 was the cutoff. Another member pointed out that the patients in the 11-12 age group below the weight threshold are nonexistent, so it likely wouldn't make a difference in patient safety for blood volumes, but another commented that consistency may be easier for programs to understand. A CDC member stated that they would not be concerned about the change, as the data still supports that this is a low risk age group for incident infection, but that they will follow up with the CDC.

The committee then reviewed the policy language.

### **Upcoming Meetings**

- May 3, 2022
- May 23, 2022

## Attendance

- **Committee Members**
  - Charles Marboe
  - Dong Lee
  - Gary Marklin
  - Gerald Berry
  - Jason Goldman
  - Kelly Dunn
  - Raymund Razonable
  - Ricardo La Hoz
  - Sam Ho
  - Sarah Taimur
  - Stephanie Pouch
- **HRSA Representatives**
  - Marilyn Levi
  - Raelene Skerda
- **CDC Representatives**
  - Ian Kracalik
  - Pallavi Annambhotla
  - Rebecca Free
  - Sridhar Basavaraju
- **FDA Representatives**
  - Brychan Clark
- **UNOS Staff**
  - Amelia Devereaux
  - Cole Fox
  - Courtney Jett
  - Kelley Poff
  - Rebecca Brookman
  - Sandy Bartal
  - Susan Tlusty
- **Pediatric Workgroup Attendees**
  - Emily Perito
  - Evelyn Hsu
  - Marian Michaels
  - Rachel Engen