

**OPTN DTAC-Pediatric Workgroup  
Meeting Summary  
June 22, 2021  
Conference Call**

**Marian Michaels, MD, MPH, Chair**

## **Introduction**

The DTAC-Pediatric Workgroup met via Citrix GoToMeeting teleconference on 06/22/2021 to discuss the following agenda items:

1. Review Timing of HIV, HBV, HCV Blood Testing for Certain Pediatric Candidates

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

### **1. Review Timing of HIV, HBV, HCV Blood Testing for Certain Pediatric Candidates**

The DTAC and Pediatric Committees are collaborating in this Workgroup to discuss a potential change to policy and education to the community regarding the timing of blood testing for certain younger or low weight pediatric candidates.

#### Summary of discussion:

The Workgroup introduced themselves and their roles on the respective committees. The Workgroup agreed about the importance ensuring the safety of pediatric candidates in receiving blood draws prior to transplant while avoiding the risk of disease transmission.

The Workgroup reviewed background on the issue – that required testing for HIV, HBV HCV was already part of OPTN policy but the requirement to draw blood directly before transplant was part of the overall effort to align OPTN policy with the 2020 U.S. Public Health Service (PHS) timeline, implemented March 2021. Concerns about the timing of the testing arose from the policy change, with questions coming in about the volume of blood drawn from pediatric candidates being a higher ratio than for other candidates and posing more of a risk for low-weight pediatric candidates, while the risk of donor-derived transmission for young pediatric candidates being lower than for the general population.

The Workgroup reviewed the problem statement and affirmed it captured the problem – that pediatric candidates should still receive pre-transplant testing for HIV, HBV, and HCV, but that the testing need not be directly before transplant. The Workgroup reviewed data showing the distribution of pediatric recipients by transplant age group. Most recipients under 1 years old are liver or heart recipients.

The Workgroup discussed the implications of the available evidence. One issue is the varying percentage of acceptable blood draws for small pediatric patients, which can vary from 3.5 ml to 11 ml at one time. The Workgroup agreed that further evidence should be gathered regarding the potential for lower blood draw amounts for smaller pediatric candidates, and that a statement on blood draw amounts would be beneficial to give the community regarding the appropriate amount of blood to draw.

The Workgroup also discussed the timeframe of when the blood is drawn. Typically, by transplant program practice, blood draws may happen to create a baseline when the candidate is evaluated and added to the waiting list. Workgroup members questioned whether it was appropriate or necessary to then do another blood draw directly prior to transplant. The Workgroup discussed that potentially the

timeframe before the transplant should be – not upon hospital admission for transplant as it is in current policy – but potentially six months to a year prior to the transplant. A Workgroup member noted that vaccination status of pediatric candidates would be relevant for the blood draws, and that the time period should reflect a potential serological change because of vaccination. Twelve months may be too long to identify a potential opportunity to see if the candidate responded to the vaccine.

The Workgroup reviewed the current HIV, HBV and HCV testing required in OPTN Policy 15.2. These include antibody and PCR tests. Instead of trying to change the test required in OPTN policy, which align with the PHS Guideline, the Workgroup agreed focusing on extending the timeframe for the tests for certain pediatric candidates would be the best option. This reflects that the Workgroup still considers the HIV, HBV and HCV testing appropriate, but the timeframe should be revised for certain pediatric candidates.

The Workgroup considered whether age or weight should be the determinate for the relevant pediatric population that could be impacted by the blood draw requirement. The Workgroup agreed that age would be a better proxy to use because it can be inclusive of children with genetic conditions that may make them very underweight even as they age. The Workgroup tentatively agreed that age twelve may be an appropriate cutoff, since it is overly inclusive of outlier candidates that could be affected, but balances the fact that this younger population is at lower risk for HIV, HBV and HCV transmission. It also reflects the MELD (model for end-stage liver disease) score cutoff used in liver allocation, which is used to define pediatric priority. If weight were used, it could conceivably include very low weight adults with social behavior such as drug use that increases their risk for HIV, HBV or HCV transmission. The Workgroup agreed the focus for the extended timeframe should be pediatric candidates that have a lower risk of HIV, HBV, and HCV transmission; therefore, an age instead of a weight cutoff should be used to focus on the relevant population.

The Workgroup expressed interest in looking at false positive rates of HIV, HBV, and HCV either in OPTN data or in the literature. The Workgroup interest stems from the concern that a higher false positive rate exists for pediatric candidates who are at lower risk of testing positive.

The Workgroup agreed that a positive message or guidance to the community regarding minimizing the amount of blood drawn would be beneficial in addition to a policy change.

#### Next steps:

The Workgroup will continue discussing the acceptable low risk time period for when the testing should occur on the next Workgroup meeting. UNOS staff will set up a poll to determine when that meeting occurs. UNOS staff will look at available data regarding false positive rates in low risk populations for the tests listed in OPTN Policy 15.2. Workgroup members will talk to colleagues about the timing of testing prior to transplant. Generally the Workgroup supported an age cutoff of twelve, but will revisit and confirm on the next call. The Workgroup will also discuss and review potential messaging to the community regarding blood draws prior to an additional policy change.

#### **Upcoming Meetings**

- July 28, 2021 (teleconference)

## Attendance

- **Workgroup Members**
  - Emily Perito
  - Evelyn Hsu
  - Kelly Dunn
  - Lara Danziger-Isakov
  - Marian Michaels
  - Rachel Engen
- **HRSA Representatives**
  - Marilyn Levi
  - Jim Bowman
  - Raelene Skerda
- **UNOS Staff**
  - Abby Fox
  - Katrina Gauntt
  - Anne McPherson
  - Leah Slife
  - Rebecca Brookman
  - Sarah Booker
  - Susan Tlusty