

OPTN Ad Hoc Disease Transmission Advisory Committee**Meeting Summary****December 5, 2023****Conference Call****Lara Danziger-Isakov, MD, MPH****Stephanie Pouch, MD, MS****Introduction**

The Ad Hoc Disease Transmission Advisory Committee (the Committee) met via Webex teleconference on 12/05/2023 to discuss the following agenda items:

1. Presentation: Compliance with OPTN Policy 15.2

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

1. Presentation: Compliance with OPTN Policy 15.2

Following concerns identified in their November 7, 2023 [meeting](#), the Committee received a presentation about pediatric transplant program compliance with [OPTN Policy 15.2: Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements](#). Policy 15.2 requires that all candidates receive specific testing for human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) prior to transplant. For candidates 12 years or older, samples for the required testing must be collected during hospital admission for transplant, but before transplantation begins.

The Committee was asked what type of targeted education should be distributed to transplant programs to help comply with OPTN Policy 15. 2.

Data Summary:

The data were based on site survey reviews at children's hospitals since the implementation of *Align OPTN Policy with U.S. Public Health Service Guideline, 2020*¹ in March 2021. Site surveys are conducted on a 3-year cycle, therefore, not all programs have been surveyed since policy implementation.

- *Policy 15.2* has a 71.89% compliance rate
- Findings among 122 noncompliant records:
 - 62 records (50%) – HCV nucleic acid testing (NAT) was not done due to misunderstanding that it is not required when HCV antibody test is negative
 - 27 records (22%) – testing was done before hospital admission for transplant; all were done prior to the implementation of *Pediatric Candidate Pre-Transplant HIV, HBV, and HCV Testing*² in July 2022, meaning that some of these 27 records would now be considered compliant
 - 15 records (12%) – HIV testing not done due to misunderstanding of CDC recommended algorithm

¹ https://optn.transplant.hrsa.gov/media/4250/align_202phsguideline_202012_policynotice.pdf

² https://optn.transplant.hrsa.gov/media/yh4bm0k5/06272022_policy-notice_pediatric-candidate-pre-transplant-hiv-hbv-and-hcv-testing2.pdf

- July 2022 policy change was received favorably
- Cancellation of tests close to time of transplant prove difficult for compliance with policy
- Not every member has been surveyed since the March 2021 policy change – anticipation of no significant change to the compliance rate until the completion of the survey cycle

Summary of discussion:

Decision #1: There was interest among the Committee to pursue efforts to educate the community about Policy 15.2.

The Committee discussed potential explanations for misunderstanding about which HCV tests are required. A CDC representative commented that OPTN Policy 15.2: *Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements* clearly states both HCV antibody test and HCV NAT are required and questioned the source of confusion over these requirements. Regarding noncompliance due to missing HCV NAT, the Chair commented that some programs default to a laboratory order called HCV antibody with reflex testing for convenience; this order ensures that candidates who have a positive HCV antibody test result subsequently receive HCV NAT using their initial sample, thus, avoiding a return visit for additional samples. The Chair explained, given that most candidates receive a negative result on the HCV antibody test, their samples would not undergo HCV NAT if HCV antibody with reflex testing were ordered. The Committee considered communicating this potential mistake to transplant programs, so that candidates' default order sets may be reviewed.

The Committee discussed providing additional education to pediatric and adult transplant programs to reinforce which infectious disease (ID) tests are required and the differences between them, potentially via OPTN webinar. It was discussed that compliance data related to ID testing from adult transplant programs may reflect similar findings. The importance of preventing further corrective action and promoting success with compliance was emphasized. The Chair expressed interest in potentially collaborating with OPTN Member Quality on a webinar to reinforce policy requirements for pre- and post-transplant ID testing.

Next steps:

The Committee will assist in the development of educational resources for the community in the Spring of 2024.

Upcoming Meeting

- January 22, 2023

Attendance

- **Committee Members**
 - Lara Danziger-Isakov
 - Dong Heun Lee
 - R. Patrick Wood
 - Maheen Abidi
 - Anil J. Trindade
 - Tanvi Sharma
 - Cindy Fisher
 - Gerald Berry
 - Kelsey McDavid
 - Helen Te
 - Michelle Kittleson
 - Sarah Taimur
 - Sridhar Basavaraju
 - Sam Ho
- **HRSA Representatives**
 - Marilyn Levi
- **FDA Representatives**
 - Brychan Clark
 - Scott Brubaker
 - Isabel Griffin
- **SRTR Staff**
 - n/a
- **UNOS Staff**
 - Tamika Watkins
 - Liz Friddell
 - Cole Fox
 - Logan Saxer
 - Leah Nunez
 - Sandy Bartal
 - Sara Langham
 - Susan Tlusty
- **Other Attendees**
 - n/a