OPTN Ad Hoc Disease Transmission Advisory Committee
Meeting Summary
December 6, 2022
Conference Call

Lara Danziger-Isakov, MD, MPH, Chair
Stephanie Pouch, MD, MS, Vice Chair

Introduction

The Ad Hoc Disease Transmission Advisory Committee) met via Citrix GoToMeeting teleconference on 12/06/2022 to discuss the following agenda items:

1. 1-Year Monitoring Report Align OPTN Policy with U.S. Public Health Service Guidelines, 2020
2. Site Survey Findings

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

1. 1-Year Monitoring Report Align OPTN Policy with U.S. Public Health Service Guideline, 2020

Staff presented on the 1-Year outcomes of the OPTN Update Data Collection to Align with U.S Public Health Service (PHS) Guideline, 2020 policy implementation.

This updated guideline helps assess organ donors and monitor transplant recipients for Human Immunodeficiency Virus (HIV), Hepatitis B (HBV), and Hepatitis C (HCV). Major changes included removing medical and social donor risk criteria not associated with transmission risk, removing the label of "increased risk," promoting patient education and informing candidates if a donor had any risk criteria, and adding testing for all transplant recipients 4-8 weeks post-transplant and HBV Nucleic Acid Testing (NAT) testing 11-13 months post-transplant for liver recipients.

The goals of this policy change are to increase the number of transplants while minimizing transmission risk, promote early identification and treatment, and provide a framework to assess risk/benefits when accepting/declining donors with risk criteria. These changes were implemented on March 1, 2021.

Data Summary:

This monitoring report focused on March 1, 2021-February 28, 2022.

Deceased donors by PHS risk factors for bloodborne disease transmission decreased post-policy by 10.3%. This decreased for adult and pediatric donors, along with heart, kidney, liver, and lung donors specifically. When risk factors are reported, there is a higher proportion of positive test results, most drastically for HCV.

Generally, the proportion of living donors that tested negative slightly increased post-implementation compared to pre-implementation. Across organ types, the proportion of deceased donors that did not report risk factors increased post-implementation compared to pre-implementation. For all test types, the proportion of negative test results remained similar across eras.

HBV, HCV, and HIV test results reported as 'Not Done' decreased, but there is still a large proportion of test results either reported as 'Not Done' or 'Not Reported' for candidates and recipients. There is an increase in proportion of negative test results across tests and organ types. The magnitude of increase in proportion of negative test results differs whether donors reported risk factors or not. There is a bigger

difference across eras among recipients who received organs from donors that did not report risk factors.

There was a decrease in utilization rates for kidneys. For kidney and liver, post-transplant survival probability was similar across eras whether risk factors are reported or not. For heart and lung post-transplant survival, probability is slightly lower post-implementation among recipients who received organ from donors that reported risk factors, but it is not statistically significant.

Summary of discussion:

The Chair stated she is surprised at the number of tests reported as 'Not Done' in the 4–8-week period post-transplant. Staff responded that this will be addressed in the next presentation. The Chair asked if one-year testing will be included in the 2-year monitoring report. Staff responded yes. CDC staff asked if there is a way to show the confidence around utilization rates. She notes that utilization went down for several organs regardless of risk factor. She asked what it means if it is observed across all donors. Staff responded that it is important to look at this in a setting of donors not reporting risk factors to properly determine what can be attributed to this policy implementation. Staff explained that utilization rates are impacted by several policies, SARS-CoV-2, and the increase in marginalized donors. She stated this is still being examined by staff.

2. Site Survey Findings

Site survey staff gave a presentation on how they are addressing the non-compliance with HIV, HBV, and HCV testing.

Staff explained that OPTN Contract task 3.6 requires the ongoing monitoring of OPTN Policies. Site Survey conducts routine reviews every 3 years. Instances of non-compliance typically require a corrective action plan (CAP) and a follow-up focused review. Repeat non-compliances or egregious violations go to the OPTN Membership and Professional Standards Committee. OPTN Policy 15.2 has a 75.5% compliance rate to date and OPTN Policy 15.3.C has a 67.5% compliance rate to date.

Reasons for lack of compliance with OPTN Policy 15.2 included HIV testing requirements being unclear. The document provided for guidance on HIV testing is a 68-page document from the CDC, which causes confusion. Positive HBV surface antibody tests have also caused confusion. OPTN Members voiced frustrations over the expedited implementation with a pre-implementation notice on 1/20/21 and a policy implementation on 3/1/21. They explained that IT systems take months to years to update, and this has caused manual addition of new orders upon each candidate admission, which often occurs the same day as transplant.

Lack of compliance with OPTN Policy 15.3.C reasoning included concerns over cost of NAT testing and patients/providers absorbing that expense, local labs not performing tests, and confusion over whether testing is required for all transplants versus just transplants from donors with risk criteria. Also, post-transplant coordinators do not assume care of recipients until discharge, and recipients are still in the hospital during the testing window.

When examining the 6-month transplant recipient follow-up (TRF) form, 22% of the forms' NAT results were either reported incorrectly as 'Not Done' when test results were available in the medical record or reported as 'Done' but obtained outside of the policy required 28–56-day post-transplant window. OPTN members noted that these tests take patient willingness to show up for follow-up appointments.

Summary of discussion:

The Chair stated she hopes the Committee can provide expertise and guidance to improve compliance. A member explained she has received feedback from transplant coordinators on testing not being

completed due to cancellations on serologies. These are often not noticed until after going to the operating room. She noted there is hesitation and pushback in living donor cases specifically since living donors come in for pre-op before the surgery date. She explained that living donors do not typically have bloodwork done right before preparing for surgery. A member said the 68-page CDC document for HIV testing algorithm needs reductionist guidance for programs. A member suggested having repeat testing include testing in addition to NAT testing within the 96-hour period. Staff responded this could be data collection additions examined by the Committee.

Upcoming Meeting

- January 3, 2022, 3PM EST, teleconference

Attendance

- **Committee Members**
  - Ann E. Woodley
  - Anil Trindade
  - Charles Marboe
  - Cindy Fisher
  - Dong Lee
  - Gerald Berry
  - Helen Te
  - Jason D. Goldman
  - Judith Anesi
  - Kelly Dunn
  - Lara Danziger-Isakov
  - Lorenzo Zaffiri
  - Michelle Kittleson
  - R. Patrick Wood
  - Sam Ho
- **HRSA Representatives**
  - Marilyn Levi
  - Jim Bowman
- **FDA Staff**
  - Scott Brubaker
  - Brychan Clark
- **CDC Staff**
  - Rebecca Free
- **UNOS Staff**
  - Lee Ann Kantos
  - Amelia Devereaux
  - Keighly Bradbrook
  - Krissy Laurie
  - Liz Friddell
  - Sandy Bartal
  - Susan Tlusty
  - Taylor Livelli