OPTN

Notice of OPTN Policy Changes

Improve Deceased Donor Evaluation for Endemic Diseases

Sponsoring Committee: Ad Hoc Disease Transmission Advisory Committee (DTAC)
Policies Affected: *2.9: Required Deceased Donor Infectious Disease Testing*
Public Comment: January 19, 2023-March 18, 2023
Board Approved: June 26, 2023
Effective Date: Pending implementation and notice to OPTN members

Purpose of Policy Changes

These changes aim to decrease donor-derived transmission from organ transplantation. *Strongyloides* and *T. cruzi* (Chagas) are endemic diseases that have high potential for morbidity and potential mortality if transmitted to recipients. As organ offer patterns continue to change, increased awareness, testing, and communication for potential endemic diseases across regions is necessary.

Proposal History

- The OPTN Membership and Professional Standards Committee asked the DTAC for clarity on endemic disease testing.
- The Endemic Diseases Subcommittee of the DTAC was formed in November 2021.
- In 2022, the Endemic Diseases Subcommittee of the DTAC reviewed the potential gaps in education and policy regarding certain endemic diseases that presented significant patient safety risks, and for which identification and treatment strategies exist but are not in common use.
- The Endemic Diseases Subcommittee recommended universal screening for *Strongyloides* and targeted screening for *T. cruzi* (Chagas) in September 2021.
- The proposal was generally supported during public comment.
- DTAC made the post public comment changes to align with feedback from the community:
    - Removed proposed requirement that *T. cruzi* (Chagas) results be available pre-transplant.
    - Amended test types allowed to be used for *Strongyloides* screening.

Summary of Changes

The following policy changes were passed by the OPTN Board of Directors:

1. Universal antibody screening of all deceased donors for *Strongyloides* using a:
    - Food and Drug Administration (FDA) licensed, approved, cleared, or Class 1, 510(k)-exempt test, or
    - Laboratory Developed Test (LDT), as described by the FDA.
2. Infectious disease testing for all potential deceased donors whose donor history reflects the donor's birthplace was in a country classified as endemic for Chagas disease by the Centers for

Disease Control and Prevention (CDC) at the time of testing. The OPTN maintains a list of countries currently classified as endemic for Chagas disease by the CDC. This testing must be performed using an FDA licensed, approved, or cleared donor screening test for *T. cruzi* antibody.

- Within 72 hours of receipt of a positive *T. cruzi* antibody donor screening test, the host OPO must submit a sample for confirmatory testing. Confirmatory testing requires either submission through the CDC or performance of at least two different FDA licensed, approved, or cleared antibody diagnostic tests.

Implementation

These policy changes will require organ procurement organizations (OPOs) to set up agreements or modify testing protocols to obtain lab testing for *Strongyloides* and *T. cruzi* (Chagas). OPOs will need to modify deceased donor screening questions and documentation for identifying donors that were born in countries endemic for Chagas disease. Additional testing may require additional communication with transplant programs and staff education. Histocompatibility laboratories will also need to implement these changes if they perform deceased donor infectious disease testing.

These changes will require transplant hospitals to set up protocols to review new infectious disease results and provide recipient treatment and monitoring plans as appropriate. Modifications to deceased donor testing may require modifications to medical record systems, particularly for transplant specific modules. These changes will also require staff education.

This proposal would require implementation in the OPTN Computer System; specifically, the OPTN Donor Data and Matching System and the Data System for the OPTN.

This proposal requires the submission of official OPTN data that are not presently collected by the OPTN. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in §121.11 of the OPTN Final Rule will be collected through Office of Management and Budget (OMB) approved data collection forms. Therefore, after OPTN Board approval, the forms will be submitted for OMB approval under the Paperwork Reduction Act of 1995. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

Affected Policy Language

New language is underlined (<u>example</u>) and language that is deleted is struck through (~~example~~).

2.9 Required Deceased Donor Infectious Disease Testing

The host OPO is responsible for ensuring that *all* of the following infectious disease testing is completed in Clinical Laboratory Improvement Amendments (CLIA) certified laboratories, or in laboratories meeting equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS):

1. Blood and urine cultures
2. Infectious disease testing for all potential deceased organ donors using FDA licensed, approved or cleared tests, as listed below:
    a. HIV antibody (anti-HIV) donor screening test or HIV antigen/antibody (Ag/Ab) combination test
    b. HIV ribonucleic acid (RNA) by donor screening or diagnostic nucleic acid test (NAT)

c. Hepatitis B surface antigen (HBsAg) donor screening test
d. Hepatitis B core antibody (total anti-HBc) donor screening test
e. Hepatitis B deoxyribonucleic acid (DNA) by donor screening or diagnostic nucleic acid test (NAT)
f. Hepatitis C antibody donor screening test (anti-HCV)
g. Hepatitis C ribonucleic acid (RNA) by donor screening or diagnostic nucleic acid test (NAT)
h. Cytomegalovirus (CMV) antibody (anti-CMV) donor screening or diagnostic test
i. Epstein-Barr Virus (EBV) antibody (anti-EBV) donor screening or diagnostic test
j. Syphilis donor screening or diagnostic test
k. Toxoplasma Immunoglobulin G (IgG) antibody test

Donor samples for all required HIV, HBV, and HCV testing must be obtained within 96 hours prior to organ procurement.

3. Infectious disease testing for all potential deceased lung donors using an FDA licensed, approved, cleared, or emergency use authorized, lower respiratory specimen test for SARS-CoV-2 (COVID-19) by nucleic acid test (NAT)

   Lower respiratory specimen test results for SARS-CoV-2 by nucleic acid test (NAT) must be available pre-transplant of lungs.

4. Infectious disease testing for all potential deceased donors for *Strongyloides* antibody, using either
   - an FDA licensed, approved, cleared, or Class 1, 510(k)-exempt test or
   - a Laboratory Developed Test (LDT), as described by the FDA.

5. Infectious disease testing for all potential deceased donors whose donor history reflects the donor's birthplace was in a country classified as endemic for Chagas disease by the CDC at the time of testing. The OPTN maintains a list of countries currently classified as endemic for Chagas disease by the CDC. This testing must be performed using an FDA licensed, approved, or cleared donor screening test for *T. cruzi* antibody.

   Within 72 hours of receipt of a positive *T. cruzi* antibody donor screening test, the host OPO must submit a sample for confirmatory testing. Confirmatory testing requires either
   - submission through the CDC or
   - performance of at least two different FDA licensed, approved, or cleared antibody diagnostic tests.