

Notice of OPTN Policy Change

Pediatric Candidate Pre-Transplant HIV, HBV, and HCV Testing

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| Sponsoring Committee: | Ad Hoc Disease Transmission Advisory (DTAC) and Pediatric Transplantation Committees |
| Policy Affected: | <i>15.2: Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements</i> |
| Public Comment: | January 27 – March 23, 2022 |
| Board Approved: | June 26, 2022 |
| Effective Date: | July 1, 2022 |

Purpose of Policy Change

Incidence of human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) in pediatric candidates less than 12 years of age is very low, while the risk of adverse medical outcomes from overdrawing blood directly prior to transplant is a greater concern. This policy change removes a requirement for pediatric candidates less than 12 to receive HIV, HBV, and HCV testing during the hospital admission for transplantation. Testing for candidates who are less than 12 years of age can now be done any time prior to transplant.

Proposal History

In December 2020, the OPTN Board of Directors approved modifications that aligned OPTN policy with the 2020 U.S. Public Health Service (PHS) Guideline issued by the Centers for Disease Control and Prevention (CDC). One change included requiring all HIV, HBV, and HCV testing to occur during hospital admission for transplant but prior to anastomosis of the first organ. In April 2021, after the proposed changes were enacted, the OPTN received a letter expressing concerns about unnecessary and potentially harmful pre-transplant blood draws for pediatric candidates. The DTAC and Pediatric Transplantation Committee collaborated with members from the CDC to review the concerns and consider potential modifications to policy on a joint workgroup. The Committees, following the workgroup recommendation, agreed that the timing requirement was not necessary from a patient safety perspective, so should be removed. Additionally, [the CDC has amended the 2020 U.S. PHS Guideline.](#)

There was general support for this proposal throughout public comment; however, after reviewing public comment feedback, the Committees decided to change the age threshold from 11 to 12 years old since the incidence of HIV, HBV, and HCV was still very low. The OPTN Board of Directors approved the proposal at their June 27, 2022 meeting.

Summary of Changes

This proposal changes policy so that all candidates less than 12 years of age are not required to receive HIV, HBV, and HCV testing during hospital admission for transplant. Those candidates must still be tested any time prior to transplant and the testing must be documented. This proposal does not change which tests must be performed; it only removes the requirement that testing must occur during hospital admission for transplant.

Implementation

Transplant programs will not have to perform HIV, HBV, and HCV testing during hospital admission for transplant for candidates less than 12 years of age. Instead, those candidates may receive the required testing at any time prior to transplant. Transplant programs will also have to educate staff on this policy change.

The OPTN will provide notice to members for a July 1, 2022 implementation. This date is concurrent with the same change to the 2020 U.S. PHS Guideline published by the CDC in the *Morbidity and Mortality Weekly Report*.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

1 **15.2 Candidate Pre-Transplant Infectious Disease Reporting and** 2 **Testing Requirements**

3 ~~To be eligible for an organ transplant,~~ transplant candidates must be tested for:

- 4 1. HIV using a CDC recommended laboratory HIV testing algorithm
- 5 2. Hepatitis B surface antigen (HBsAg)
- 6 3. Hepatitis B core antibody (total anti-HBc)
- 7 4. Hepatitis B surface antibody (HBsAb)
- 8 5. Hepatitis C antibody (anti-HCV)
- 9 6. Hepatitis C ribonucleic acid (RNA) by nucleic acid test (NAT)

10 unless the testing would violate state or federal laws.

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12 Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting
13 equivalent requirements as determined by CMS using FDA-licensed, approved, or cleared tests.

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15 For all candidates 12 years or older, ~~C~~andidate samples must be drawn during the hospital admission
16 for transplant but prior to anastomosis of the first organ.

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18 If the candidate is known to be infected with HIV, HBV, or HCV, then testing for the known viral infection
19 or infections is not required, however the other tests required according to this policy must still be
20 performed.

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22 Candidates who test positive for HIV, hepatitis B, or hepatitis C must be offered appropriate counseling.

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24 The OPTN permits HIV test positive individuals as organ candidates if permitted by the transplant
25 hospital. Care of HIV test positive organ candidate and recipients must not deviate from general medical
26 practice.