OPTN

Public Comment Proposal

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

OPTN Ad Hoc Disease Transmission Advisory and Pediatric Transplantation Committees

Prepared by: Cole Fox and Rebecca Brookman
UNOS Policy and Community Relations Department

Contents

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

Affected Policies:	*Policy 15.2: Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements*
Sponsoring Committees:	*Ad Hoc Disease Transmission Advisory and Pediatric Transplantation*
Public Comment Period:	*January 27, 2022 – March 23, 2022*
Board of Directors Date:	*June 27, 2022*

Executive Summary

OPTN *Policy 15.2: Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements* specifies that all candidate human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) testing must occur during hospital admission for transplant but prior to anastomosis.[1] Requiring the testing directly prior to transplant when the candidate has other testing and blood drawn simultaneously may lead the cumulative volume of blood drawn to be greater than what is recommended, especially for low-weight pediatric candidates. The overdrawing of blood could result in serious adverse medical outcomes, such as anemia or cardiac arrest, and require blood transfusion to replace the blood volume.[2] While the risk of adverse medical outcomes from overdrawing blood is greater for pediatric candidates, the risk of HIV, HBV, and HCV disease transmission among the pediatric population is much lower than it is with other candidates.[3] The proposed changes remove the testing time requirement for all candidates younger than 11, an age identified with initiation of adolescence, which in turn is associated with changing risk behaviors that could impact incidence of HIV, HBV, or HCV.[4] Candidates aged 10 and younger would still be required to comply with all testing requirements but would no longer be required to have this testing repeated right before transplant.

The proposal aligns with the OPTN strategic goal to improve transplant recipient safety by removing an unnecessary timing requirement that could incur the need for a blood transfusion for certain pediatric candidates, while still ensuring all necessary testing is performed to avoid infectious disease transmission.

[1] OPTN *Policy 15.2: Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements* (Accessed November 7, 2021)

[2] Stephen. (2011). *Blood sample volumes in child health research: Review of safe limits*. ResearchGate; World Health Organization. DOI:10.2471/BLT.10.080010

[3] Jones JM, Kracalik I, Levi ME, et al. Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection — U.S. Public Health Service Guideline, 2020. MMWR Recomm Rep 2020;69(No. RR-4):1–16. DOI: http://dx.doi.org/10.15585/mmwr.rr6904a1

[4] Elizabeth M. Alderman, Cora C. Breuner, COMMITTEE ON ADOLESCENCE, Laura K. Grubb, Makia E. Powers, Krishna Upadhya, Stephenie B. Wallace; Unique Needs of the Adolescent. *Pediatrics* December 2019; 144 (6): e20193150. 10.1542/peds.2019-3150. Available at https://publications.aap.org/pediatrics/article/144/6/e20193150/37985/Unique-Needs-of-the-Adolescent?autologincheck=redirected

Purpose

The timing requirement for pediatric candidates less than 11 to repeat HIV, HBV, and HCV testing directly prior to transplant is not necessary from a patient safety perspective. Incidence of HIV, HBV, and HCV with this population is very low and unlikely to change from baseline testing,[5] while the risk of adverse medical outcomes from overdrawing blood directly prior to transplant is greater.[6]

Background

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 but prior to anastomosis. The OPTN Pediatric Transplantation Committee, American Society of Transplantation, Transplant Families, and Society for Pediatric Liver Transplantation expressed concern about this requirement for pediatric candidates, given concerns about the amount of blood drawn directly prior to transplant.[7] However, the proposed changes were passed by the Board without modification to ensure alignment with the 2020 PHS Guideline and to mitigate risk of HIV, HBV, and HCV transmission through transplantation, which was a primary objective of the Guideline[8] and aligning OPTN policy.[9]

In April 2021, after the proposed changes were enacted, the OPTN received a letter expressing renewed concerns about unnecessary pre-transplant blood draws for pediatric candidates.[10] The OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) collaborated with the Pediatric Transplantation Committee and members from the Centers for Disease Control (CDC) on a DTAC-Pediatric Workgroup (the Workgroup) to address the concerns. The Workgroup agreed that the timing requirement for pediatric candidates was not necessary to protect pediatric candidates from disease transmission and that the repeat blood draw could be risky for low weight pediatric candidates, indicating that the policy should be modified.[11] The Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) of the HHS Office of Infectious Disease and HIV/AIDS Policy (OIDP) reviewed and unanimously supported the proposed changes described in this proposal.[12]

---

[5] Jones JM, Kracalik I, Levi ME, et al. Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection — U.S. Public Health Service Guideline, 2020. MMWR Recomm Rep 2020;69(No. RR-4):1–16. DOI: http://dx.doi.org/10.15585/mmwr.rr6904a1

[6] Stephen. (2011). *Blood sample volumes in child health research: Review of safe limits*. ResearchGate; World Health Organization. DOI:10.2471/BLT.10.080010

[7] *Align OPTN Policy with U.S. Public Health Service Guideline, 2020* Public Comment Feedback. August – September 2020. Available at https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/align-optn-policy-with-us-public-health-service-guideline-2020/

[8] Jones JM, Kracalik I, Levi ME, et al. Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection — U.S. Public Health Service Guideline, 2020. MMWR Recomm Rep 2020;69(No. RR-4):1–16. DOI: http://dx.doi.org/10.15585/mmwr.rr6904a1

[9] Align OPTN Policy with U.S. Public Health Service Guideline, 2020. Available at https://optn.transplant.hrsa.gov/media/3933/align_policy_with_phs_guideline_2020_pc.pdf

[10] Letter on behalf of Pediatric Transplant Program at Indiana University (INIM) and the Indiana Transplant Quality Committee. May 14, 2021.

[11] OPTN DTAC-Pediatric Workgroup Meeting Summary. June 22, 2021. Available at https://optn.transplant.hrsa.gov/media/4764/dtac-pediatric_wg_summary_62221.pdf

[12] HHS OIPD Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) Meeting, December 1, 2021.

Overview of Proposal

The DTAC and Pediatric Committee propose modifying policy so that all candidates younger than 11 years of age are not required to receive HIV, HBV, and HCV testing during hospital admission for transplant. Instead, these candidates may receive testing at any time between when they are waitlisted and transplantation. This proposal does not change which tests must be performed; it only removes a requirement for when the testing must occur.

Low Risk of HIV, HBV and HCV for Younger Populations

There have been no reported transmissions involving HIV, HBV, or HCV from pediatric organ donors, nor cases of donor-derived HIV or HCV transmissions identified in pediatric recipients.[13] The CDC presented data to the Workgroup indicating rates of HIV, HBV, or HCV infection are extremely low in children.[14] It is important to note limitations of the data in the ability to stratify by younger pediatric versus adolescent populations, but these data still provide a valuable overview of the low incidence across infection type for younger persons. For children under 13 years of age, rates of HIV were 3.2 per 100,000 from 2015-2019.[15] This rate reflects that almost 40% of children with HIV infection had it detected within the first year of life. The incidence of HIV in children has been declining in conjunction with perinatal elimination efforts. Rates of acute HCV were even lower, at 0.1 per 100,000 in those persons under 20. HBV incidence was at 0.0 per 100,000 for persons under 20 in 2019.[16] Figures 1 and 2 show that, while the rate of these infections for other age groups fluctuated, both HCV and HBV reflect very low rates of infection for younger persons consistently through the years surveilled. The Committees consider this evidence supports that removing the requirement for testing to occur directly prior to transplant for certain pediatric candidates would not incur a patient safety risk or undermine efforts to mitigate disease transmission.

[13] Green, M, Taranto, S, Covington, S, Michaels, M, Wolfe, C, Kaul, D, "Pediatrics & Donor Derived Disease Transmission: The US OPTN Experience [abstract]. American Journal of Transplantation 15, suppl 3 (2015). https://europepmc.org/article/M

[14] Jones JM, Kracalik I, Levi ME, et al. Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection — U.S. Public Health Service Guideline, 2020. MMWR Recomm Rep 2020;69(No. RR-4):1–16. DOI: http://dx.doi.org/10.15585/mmwr.rr6904a1

[15] Ibid.

[16] Ibid.

Figure 1: Rates of acute HBV infection in persons <20 years in the U.S. 2019[17]

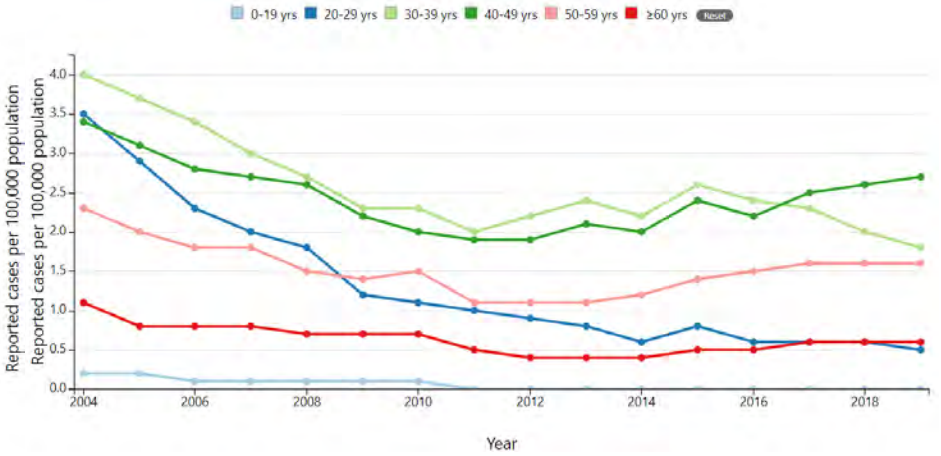
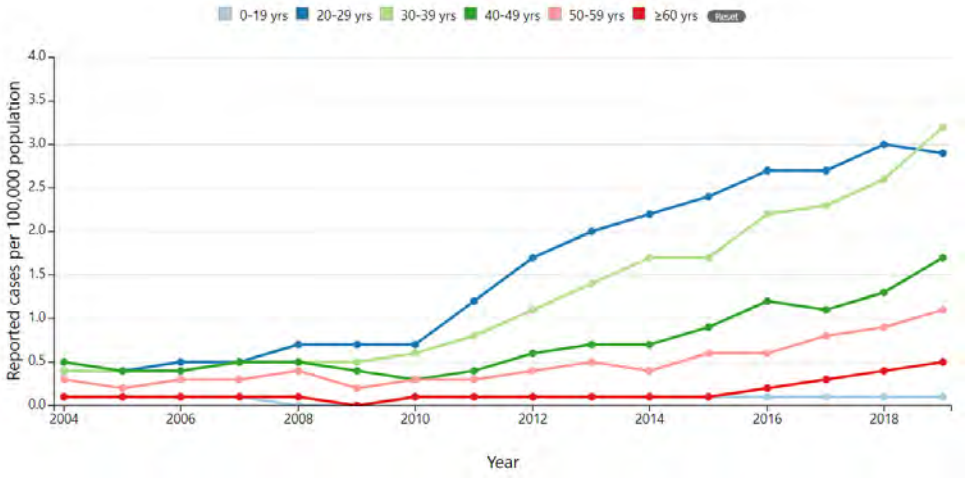


Figure 2: Rates of acute HCV infection in persons <20 years in the U.S. 2019[18]



Risk to Pediatric Candidates from Overdrawing Blood

Appropriate blood draw percentages for children are impacted by low weight concerns and risks associated with anemia and co-morbidities, with only about 1-5% of a healthy child's total blood volume that can be safely drawn at any one time.[19] At time of transplant, blood is drawn for other purposes than just infectious disease testing, so the blood draw requirement needs to be considered not just in

[17] Figure 2.4 of 2019 Viral Hepatitis Surveillance report, CDC: https://www.cdc.gov/hepatitis/statistics/2019surveillance/Figure2.4.htm
[18] Figure 3.4 of 2019 Viral Hepatitis Surveillance report, CDC: https://www.cdc.gov/hepatitis/statistics/2019surveillance/Figure3.4.htm
[19] Howie, S. R. (2010). Blood sample volumes in child health research: review of safe limits. *Bulletin of the World Health Organization*, *89* (1), 46–53. https://doi.org/10.2471/blt.10.080010

isolation but in conjunction with the total blood volume needed to be drawn at time of transplant. Pediatric candidates often have incidences of co-morbidities, anemia and low weight which makes them more vulnerable to negative impacts of blood overdraws than adults.[20] There is also a high prevalence of anemia among pediatric populations.[21]

Avoidance of Repeat Testing

The Workgroup discussed that typically, in transplant program practice, blood draws occur when a candidate is evaluated and added to the waiting list in order to create a baseline. Workgroup members questioned whether it was appropriate or necessary for programs to then be required to perform another blood draw on pediatric candidates during the hospital admission for transplant. Avoidance of repeat testing was mentioned in the public comment feedback for the Align OPTN Policy with 2020 PHS Guideline proposal[22] and the feedback expressed support for providing an alternative for pediatric candidates. By removing the timeframe for pediatric candidates, the proposed solution avoids unnecessary repeated testing of a vulnerable population while still maintaining a "baseline" draw prior to transplant. Removing the timing requirement would avoid the possibility of false positives which, given the low risk of infection in this population, may be proportionally higher.[23]

It is also important to note that, in alignment with the PHS Guideline, OPTN policy requires testing for all candidates for HIV, HBV, and HCV at 4-8 weeks post-transplant.[24] So while these candidates will still receive pre-transplant infectious disease testing for HIV, HBV, and HCV, they will also receive post-transplant testing to ensure patient safety is maintained. Pediatric candidates may be receiving organs from adults that have different risk associated HIV, HBV, and HCV, highlighting that post-transplant testing is an important safety measure that is unaffected by the changes in this proposal and will continue.

Appropriate Pediatric Age Group

In discussing what the applicable age for exemption from the pre-transplant timing requirement for testing should be, the Workgroup considered that risk behavior can change with adolescence and the timing exemption for testing directly prior to transplant should not apply to adolescents given that adolescents engage in risk behaviors more frequently than younger pediatric candidates.[25] The PHS Guideline describes two risk criteria for HIV, HBV, and HCV that relate to pediatric candidates: child born to a mother with HIV, HBV, or HCV and child breastfed by a mother with HIV.[26] Verification of the risk

[20] Stephen. (2011). *Blood sample volumes in child health research: Review of safe limits*. ResearchGate; World Health Organization. DOI:10.2471/BLT.10.080010

[21] Khan, L. (2018). Anemia in Childhood. *Pediatric Annals*, *47*(2), e42–e47. https://doi.org/10.3928/19382359-20180129-01

[22] https://optn.transplant.hrsa.gov/governance/public-comment/align-optn-policy-with-u-s-public-health-service-guideline-2020/

[23] OPTN DTAC-Pediatric Workgroup Meeting Summary. July 30, 2021. Available at https://optn.transplant.hrsa.gov/media/3qeb2r5t/2021_07_30_dtac-peds-wg_mtg-summary.pdf

[24] OPTN Policy *15.3.C: Required Post-Transplant Infectious Disease Testing*. Accessed December 15, 2021.

[25] Elizabeth M. Alderman, Cora C. Breuner, COMMITTEE ON ADOLESCENCE, Laura K. Grubb, Makia E. Powers, Krishna Upadhya, Stephenie B. Wallace; Unique Needs of the Adolescent. *Pediatrics* December 2019; 144 (6): e20193150. 10.1542/peds.2019-3150. Available at https://publications.aap.org/pediatrics/article/144/6/e20193150/37985/Unique-Needs-of-the-Adolescent?autologincheck=redirected

[26] JM Jones, I Kracalik, ME Levi, et al, "Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection — U.S. Public Health Service Guideline, 2020," Morbidity and Mortality Weekly Report, 69, (No. RR-4), June 26, 2020, 1-16, http://dx.doi.org/10.15585/mmwr.rr6904a1.

related to these criteria can be ascertained through pre-transplant testing when the pediatric candidate is listed for transplant; given these criteria reflect infancy and would be present upon initial evaluation, the risk according to these criteria is unlikely to increase or change in the interval between initial testing and candidate transplant. The other risk criteria detailed in the PHS Guideline relate to sexual experiences and drug use.[27] These behavioral criteria have limited applicability for younger pediatric candidates, who are already at extremely low risk of HIV, HBV, or HCV incidence.

The Workgroup considered it important that the proposed change be as inclusive as possible of pediatric candidates who may be impacted by adverse medical outcomes associated with overdrawing blood. The Workgroup also considered it important to avoid inclusion of older pediatric candidates whose behavioral patterns may demonstrate more risk than younger children. Given potential risk behaviors, adolescents may benefit from the timing requirement of testing directly prior to transplant to compare with baseline testing.[28] The Workgroup identified 11 as an age indicative of the onset of adolescence in the literature;[29] this accorded with member experience of when behavior changes may start impacting candidate risk associated with HIV, HBV, and HCV incidence.[30] The Workgroup identified a cohort of candidates 10 and younger as both low risk for HIV, HBV, and HCV incidence, while also having more risk for the potential for negative medical outcomes post-transplant associated with severely low weight, co-morbidities and anemia. This achieved the Workgroup's balance between mitigating HIV, HBV, and HCV risk while minimizing risk of negative medical outcomes from blood overdraws for a vulnerable population.

Alignment with 2020 PHS Guideline

The OPTN is coordinating with the CDC so that the PHS Guideline and the OPTN policy continue to be consistent. A Federal Register Notice will solicit public comment regarding revising exempting solid organ transplant candidates ≤10 years of age at the time of transplant from the recommendation for HIV, HBV, and HCV testing during the hospital admission for transplant but prior to anastomosis of the first organ. Candidates would still need to have received the appropriate infectious disease testing outlined in both OPTN policy and 2020 PHS Guideline, but would no longer have to abide by the time requirement of testing directly prior to transplant.

NOTA and Final Rule Analysis

The Committees submit the following proposal under the authority of 42 U.S.C. 274(b)(2)(M), which requires the OPTN to "recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, polices, and procedures that address the unique health care needs of children..." A potential policy change would impact the timing requirement for pre-transplant testing of pediatric candidates in recognition of the differences in health and organ

[27] Ibid.
[28] OPTN DTAC-Pediatric Workgroup Meeting Summary. September 14, 2021. https://optn.transplant.hrsa.gov/media/hgyfhqy3/2021_09_14_dtac-peds-wg_meeting-summary.pdf
[29] Elizabeth M. Alderman, Cora C. Breuner, COMMITTEE ON ADOLESCENCE, Laura K. Grubb, Makia E. Powers, Krishna Upadhya, Stephenie B. Wallace; Unique Needs of the Adolescent. *Pediatrics* December 2019; 144 (6): e20193150. 10.1542/peds.2019-3150. Available at https://publications.aap.org/pediatrics/article/144/6/e20193150/37985/Unique-Needs-of-the-Adolescent?autologincheck=redirected
[30] OPTN DTAC-Pediatric Workgroup Meeting Summary. September 14, 2021. https://optn.transplant.hrsa.gov/media/hgyfhqy3/2021_09_14_dtac-peds-wg_meeting-summary.pdf

transplantation issues between children and adults, and the policy would be addressing the unique health care needs of children in terms of their lesser risk of HIV, HBV, and HCV, and their greater risk related to the higher blood-weight ratio.

The proposal is also submitted under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing….policies, consistent with recommendation of the Centers for Disease Control and Prevention, for the testing of organ donors and follow-up of transplant recipients to prevent the spread of infectious diseases."[31] Pre-transplant candidate testing helps prevent the spread of infectious diseases by providing a baseline for comparison with post-transplant testing results to identify whether transmission occurred through transplantation and limit the spread of infectious diseases.

Implementation Considerations

Member and OPTN Operations

Operations affecting Transplant Hospitals

Members will not have to perform HIV, HBV, and HCV testing directly prior to transplant for candidates under 11 years of age. Instead, those candidates may receive testing at any time they are on the waiting list for a transplant.

Operations affecting the OPTN

OPTN policy will be updated and a policy notice sent out to members.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

Operations affecting Organ Procurement Organizations

This proposal is not anticipated to affect the operations of organ procurement organizations.

Potential Impact on Select Patient Populations

This proposed policy change would positively impact pediatric candidates aged 10 and less by eliminating the risk of depleting their overall blood volume directly prior to transplant from repeat testing and avoidance of the subsequent medical issues caused by an unnecessary timeframe for infectious disease testing of a low risk population.

[31] 42 CFR §121.4(a)(ii)

Alternate Solutions Considered

Weight Threshold

The Workgroup discussed whether it would be appropriate to impose a weight or age cutoff to provide an exemption to the timing requirement, or include both weight and age when determining whether a candidate would be exempt from the timing requirement for HIV, HBV, and HCV testing.

Members discussed the use of age, weight, or both as the cut off for changing pre-transplant testing requirements. Members discussed age since the risk of transmission is significantly lower, but also discussed weight because solely age may not account for the older pediatric candidates with chronic diseases causing them to be of smaller stature and, therefore, also at risk when drawing extra blood. Members did agree that these patients do need testing at some point during evaluation, but that it is likely not necessary to repeat the testing. The CDC did bring up the concern of hemodialysis and the potential for hepatitis exposure; however, when analyzing the data for the PHS Guideline changes, they found an incredibly small risk of transmission through hemodialysis and postulated that the risk may also be lower in pediatric patients. One workgroup representative agreed that the risk of transmission through hemodialysis is likely further reduced in pediatric patients. Members agreed that 10 years old and less was an appropriate age cutoff for patients, based on age at time of transplant. Members agreed that 11 years and older is typically when a patient is considered an adolescent, and there may be different behavioral risk factors they encounter.[32]

Timeframe

The Workgroup considered different timeframe alternatives to simply requiring the testing during a patient's candidacy (between being listed and being transplanted, but not specifying a specific timeframe). Ultimately, the Workgroup agreed that the risk was low enough for these pediatric candidates that, as long as the testing occurred while they were listed for transplant, that timeframe would still sufficiently address the risk of disease transmission and requiring an alternative timeframe (e.g. 3 or 6 months from transplant) could be too prescriptive without addressing an additional risk.

Project Fiscal Impact

This proposal is projected to have a minimal fiscal impact on the OPTN, minimal fiscal impact on organ procurement organizations and transplant hospitals, and no impact on histocompatibility laboratories.

Projected Impact on Organ Procurement Organizations

There is minimal impact to organ procurement organizations.

Projected Impact on Transplant Hospitals

This proposal is not anticipated to have a large fiscal impact. Testing still needs to be performed, but allowing a larger time for testing to be completed for patient safety and clinical appropriateness may make it easier and eliminate the need for additional testing.

[32] OPTN DTAC-Pediatric Workgroup Meeting Summary. September 14, 2021. Available at https://optn.transplant.hrsa.gov/media/hgyfhqy3/2021_09_14_dtac-peds-wg_meeting-summary.pdf

There are no major resources required to implement. The approximate time to implement this proposal is less than one month and will consist of staff education and training, as well as any needed IT implementation.

There are no additional ongoing staffing requirements or staffing costs associated with this proposal for transplant hospitals.

There will be no changes to the ongoing cost, just a change in the timing of the required testing. However, it should be noted that if testing occurs prior to admission, as compared to during inpatient stay, reimbursement for costs may vary.

Candidate pre-transplant testing is reimbursable via the CMS cost report for organ acquisition costs, or by payer per pre-transplant testing rates. This proposal may also eliminate re-testing if the institution is unable to obtain testing during inpatient admission. As such, there may be a cost savings.

Projected Impact on the OPTN

This proposal is projected to have minimal fiscal impact to the OPTN; the impact reflects the time associated with communication to members, support of policy development, and post-implementation monitoring.

Post-implementation Monitoring

Member Compliance

At transplant hospitals, site surveyors will continue to review a sample of medical records, and any material incorporated into the medical record by reference, for documentation of either:

- Results of required HIV, HBV, and HCV tests
- Evidence that the candidate was already known to be infected with HIV, HBV, or HCV, if required tests for one or more of these infections were not performed in the required timeframe

Site surveyors will also continue to verify that required HIV, HBV, and HCV tests were performed using blood samples collected during hospital admission for transplant and prior to first anastomosis for recipients who were at least 11 years old at the time of anastomosis of the first organ. Site surveyors will begin verifying that required HIV, HBV, and HCV tests were performed using blood samples collected between waiting list registration and first anastomosis for recipients who were less than 11 years old at the time of anastomosis of the first organ.

Policy Evaluation

This policy will be formally evaluated at approximately one and two years post-implementation. The following metrics, and any others subsequently requested by the Committee, will be evaluated as data are available and sample size allows. Comparisons will be made pre/post policy when applicable, and metrics will be evaluated across all organs:

- Volume of proven/probable pediatric (0-17 years of age) specific potential donor derived disease transmission events (PDDTE) recipient cases reviewed by the Ad Hoc DTAC that were submitted through the UNet Improving Patient Safety Portal

- #/% of pediatric waiting list registrations by age (yr) group and weight (kg) group
- #/% of deceased donor pediatric recipients with a positive HIV, HCV, or HBV result on reported on the TRR, and the associated overall distribution of HBV, HCV, and HIV infectious disease test results for deceased donor pediatric recipients (positive, negative, not done, unknown)

Conclusion

This proposal removes an unnecessary timeframe from policy while still ensuring pediatric candidate safety prior to transplant. Even with the removal of the time requirement, pediatric candidates who are 10 years old or younger will still have a baseline test result, since it is already common practice to perform the HIV, HBV, and HCV tests during the candidate evaluation process. Within this cohort of pediatric candidates, the risk of HIV, HBV, and HCV transmission is significantly low while the risk of adverse medical outcomes from overdrawing blood is high; thus, this proposal aims to limit infectious disease transmission while addressing patient safety concerns.

OPTN

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

15.2 Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements

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

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

unless the testing would violate state or federal laws.

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

For all candidates greater than 10 years old, ~~C~~candidate samples must be drawn during the hospital admission for transplant but prior to anastomosis of the first organ.

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

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

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

#