

# Updated U.S. Public Health Service Guideline for Testing of Transplant Candidates Aged <12 Years for Infection with HIV, Hepatitis B Virus, and Hepatitis C Virus — United States, 2022

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The U.S. Public Health Service (PHS) has periodically published recommendations about reducing the risk for transmission of HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV) through solid organ transplantation (1–4). Updated guidance published in 2020 included the recommendation that all transplant candidates receive HIV, HBV, and HCV testing during hospital admission for transplant surgery to more accurately assess their pretransplant infection status and to better identify donor transmitted infection (4). In 2021, CDC was notified that this recommendation might be unnecessary for pediatric organ transplant candidates because of the low likelihood of infection after the perinatal period and out of concern that the volume of blood drawn for testing could negatively affect critically ill children.\* CDC and other partners reviewed surveillance data from CDC on estimates of HIV, HBV, and HCV infection rates in the United States and data from the Organ Procurement & Transplantation Network (OPTN)<sup>†</sup> on age and weight distributions among U.S. transplant recipients. Feedback from the transplant community was also solicited to understand the impact of changes to the existing policy on organ transplantation. The 2020 PHS guideline was accordingly updated to specify that solid organ transplant candidates aged <12 years at the time of transplantation who have received postnatal infectious disease testing are exempt from the recommendation for HIV, HBV, and HCV testing during hospital admission for transplantation.

## Background

Since 1985, the U.S. PHS has made recommendations to reduce the risk for HIV transmission through solid organ transplantation (1–4). In 2013, these recommendations were expanded to include guidance on mitigating the risk for HBV and HCV transmission from solid organ donors to transplant recipients and included: 1) identifying risk factors associated with HIV, HBV, and HCV infection among organ donors, and 2) laboratory testing of donors using both serologic and nucleic acid testing for HIV, HBV, and HCV (3,4).

\* [https://optn.transplant.hrsa.gov/media/4705/2021\\_05\\_24\\_dtac-full-cmte-mtg-summary.pdf](https://optn.transplant.hrsa.gov/media/4705/2021_05_24_dtac-full-cmte-mtg-summary.pdf)

<sup>†</sup> <https://optn.transplant.hrsa.gov/data/view-data-reports/> (Accessed June 23, 2022).

In 2020, the guideline was updated to reflect changes in the epidemiology of HIV, HBV, and HCV infections, advances in testing, and the availability of highly effective treatment for HIV and HBV infections and curative treatment for HCV (4). In addition to other updated recommendations, the 2020 PHS guideline specified that all transplant candidates should be tested for HIV, HBV, and HCV infections before transplantation, with testing to occur during hospital admission for transplant but before transplantation occurred (4). After implementation of the updated recommendations, CDC and the Health Resources and Services Administration (HRSA) continued to monitor the impact of guideline recommendations on organ safety and use, and received feedback from the transplant community about the requirement for repeat testing (i.e., after postnatal infectious disease testing) at the time of hospital admission for transplantation. Concerns were raised about the potential for harm that infectious disease testing might pose to some pediatric recipients because of blood volume loss from testing, including risks related to preoperative low body weight and blood volume, anemia, and exacerbation of underlying comorbid conditions (5). The probability of HIV, HBV, or HCV infection among some pediatric populations might be low after the perinatal period but before adolescence, thus obviating the need for additional testing (6,7). Therefore, the U.S. Department of Health and Human Services (HHS) considered changing recommendations for pediatric pretransplant testing based on age and weight.

## Methods

CDC and HRSA reviewed two relevant data sources. First, CDC HIV, HBV, and HCV surveillance data were reviewed for cases reported in the United States stratified by age group. This review was conducted to understand the risk for incident HIV, HBV, and HCV infections by age and thereby determine an age-based cutoff at which incident infections were of the lowest risk. Cases included incident HIV infections among persons aged <20 years in the United States and six territories and freely associated states during 2015–2019, and incident HBV and HCV infections among persons aged <20 years in the United States during 2019, the most recent years for which surveillance data were available (6). Second, data collected

by OPTN were reviewed to ascertain the number of transplants performed in the United States during 2016–2020, by age group and by transplant recipient candidate weight. The purpose of this review was to understand the number of patients affected by the 2020 PHS policy and to ensure that an age-based cutoff for an exemption is appropriate in light of the distribution of patients' weights, because patients with low pretransplant weight are those most likely to be harmed by additional blood volume loss.

HHS then met with relevant stakeholders from the transplant community during May–December 2021, to understand the implications of policy changes on organ transplantation and organ use (5). In December 2021, HHS convened the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) to present evidence and receive expert input on whether the 2020 PHS guideline recommendation pertaining to pretransplant testing of pediatric candidates should be revised (8). Subsequently, a draft recommendation was posted in the Federal Register to solicit public input on the proposed policy change and its anticipated impact on organ safety and use (9).

## Evidence

**HIV incidence among children.** Infants and children aged <13 years were at lowest risk for new HIV infections in the United States (6). During 2015–2019, diagnosis of 524 incident HIV infections among infants and children aged <13 years were reported in the United States and six territories and freely associated states (6). Overall, among children who received a diagnosis of an HIV infection, 181 (35%) were newborns aged 0–5 months, 23 (4%) were infants aged 6–11 months, 37 (7%) were children aged 12–23 months, and 283 (54%) were children aged 2–12 years (approximately 25 [5%] cases per year of age among children aged 2–12 years) (6). With effective efforts to eliminate perinatal transmission, prevalence and incidence of HIV infection among infants and children aged <13 years in the United States have been steadily decreasing (6). In contrast, persons aged 13–19 years are at substantially higher risk for acquiring a new HIV infection. Among 36,801 new HIV infections reported during 2019 in the United States and six territories and freely associated states, 1,667 (5%) were among persons aged 13–19 years (6).

**HBV and HCV incidence among children.** Incidence of acute HBV and HCV infection reported to CDC during 2019 among U.S. residents aged <20 years were 0 and 0.1 per 100,000 population, respectively (7). In addition, >90% of children aged 2 years and adolescents aged 13–17 years have been vaccinated against HBV infection<sup>§</sup> in the United States (10).

<sup>§</sup> <https://www.cdc.gov/nchs/fastats/immunize.htm>

**Pediatric transplants by age and weight.** During January 1, 2016–December 31, 2020, a total of 5,209 solid organ transplants were performed in the United States among infants and children aged <10 years (11). Among 5,202 (99.9%) of these recipients with weights reported, 1,528 (29%) weighed <20 pounds (9.1 kg), 2,383 (46%) weighed 20 to <40 pounds (9.1–18.1 kg), and 1,291 (25%) weighed ≥40 pounds (18.1 kg) (11). The 25th percentile of reported weights for this age group was 18 pounds (8.2 kg) (11). For transplant recipients aged 10–14 years, the 25th percentile of reported weights was 68 pounds (30.8 kg) (11).

ACBTSA voted in favor of changing the policy regarding the time frame for testing transplant candidates for HIV, HBV, and HCV infections pretransplant to exempt solid organ transplant recipient candidates who are aged ≤10 years at the time of transplantation. The initial policy proposal used an age-based cutoff of ≤10 years because of perspectives regarding the timing of adolescence. However, members of the transplant community subsequently communicated to HHS that an age-based cutoff of ≤12 years for pretransplant infectious disease testing would more closely align with other transplant policies related to testing, organ allocation, and co-morbid disease severity classification as well as preserve patient safety (5).

## Updated Recommendation

Based on a review of the available data, public comment, discussions with stakeholders from the transplant community, and input from the federal advisory committee, the 2020 PHS guideline (4) has been amended to recommend that candidates who are aged <12 years at the time of transplantation and who have received postnatal infectious disease testing are exempt from pretransplant HIV, HBV, and HCV testing during hospital admission for transplantation.

## Discussion

This revised guideline is intended to limit the potential risk for unnecessary blood volume loss associated with infectious disease testing for specific pediatric transplant candidates during hospital admission for transplantation and continue to minimize the risk for unexpected infectious disease transmission through transplantation. Posttransplant testing recommendations remain unchanged: testing for HIV, HBV, and HCV infections should be conducted for all transplant recipients at 4–6 weeks after transplantation, including those aged <12 years regardless of postnatal infectious disease testing. In updating this recommendation, HHS considered infection risk and the effect of blood volume loss by age and by weight; the data assessed included the number of affected transplant candidates as well as the distribution of transplant candidates by weight. Data related to weight were incomplete, and patient

## References

## Summary

## What is already known about this topic?

HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV) transmission can occur through solid organ transplantation.

## What is added by this report?

A 2020 U.S. Public Health Service recommendation to test transplant candidates for HIV, HBV, and HCV during the transplant hospital admission could result in potentially harmful blood loss in pediatric transplant candidates. Children aged <13 years are among those at lowest risk for new HIV infections, and incidence of acute HBV and HCV infection in U.S. residents aged <20 years is extremely low.

## What are the implications for public health practice?

Children aged <12 years who have received postnatal infectious disease testing are exempt from repeat pretransplant HIV, HBV, and HCV testing during hospital admission for transplant surgery.

weight can also fluctuate because of factors including underlying health conditions. As patients move from childhood into adolescence, individual-level behaviors that increase the risk for acquiring HIV, HBV, and HCV infections become more likely, irrespective of weight (6,7). This updated recommendation is based on transplant candidate age to more effectively protect those candidates at highest risk for potential harm from blood volume loss and maintain the ability to recognize pretransplant HIV, HBV, and HCV infections among populations at highest risk. CDC, HRSA, and other federal partners will continue to monitor the impact of the 2020 PHS guideline on organ safety and use.

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