CDC Updates 2013 Guideline for Assessing Organ Donors for HIV, HBV, and HCV to Address ASTS Concerns

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On June 26, 2020, the Centers for Disease Control (CDC) released a report entitled, "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" ("2020 Guideline"). The 2020 Guideline supersedes the 2013 PHS "Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation" (2013 Guideline). The 2020 Guideline is responsive to many of the concerns initially raised by ASTS when the 2013 Guideline was adopted and culminates a multi-year effort by ASTS and others. As acknowledged by CDC:

> In response to feedback from the transplant community; universal adoption of donor HIV, HBV, and HCV NAT screening; and availability of highly effective therapies for these three viral diseases, PHS has revised recommendations previously included in the 2013 PHS guideline to reflect recent, organ transplant-specific evidence and to increase the use of organs while continuing to maintain transplant recipient safety. (Citations omitted.)

Recommendations that have changed since the 2013 PHS guideline include:

- Updated criteria for identifying donors at risk for undetected donor HIV, HBV, or HCV infection;
- The removal of any specific term to characterize donors with HIV, HBV, or HCV infection risk factors;
- Universal organ donor HIV, HBV, and HCV nucleic acid testing; and
- Universal post-transplant monitoring of transplant recipients for HIV, HBV, and HCV infections.

The 2020 Guideline recommendations are categorized into six topic areas. The principal changes made by 2020 Guideline with respect to each topic are noted below:

- Risk assessment of living and deceased donors: The 2020 Guideline removes any specific label (e.g., "increased risk donor") to describe donors with risk factors for acute HIV, HBV, and HCV infection, modifies the risk criteria, and provides that the risk criteria are to be applied during the 30 days (rather that during the 12 months) before organ procurement. The 2020 Guideline removes from the risk factors hemodialysis; newly diagnosed or treated syphilis, gonorrhea, chlamydia, or genital ulcers; hemodilution of the blood sample used for infectious disease testing, and female sex with a man who has had sex with another man.

- Living and deceased solid organ donor testing: The 2020 Guideline specifies that, for deceased donors, the donor specimen should be collected within 96 hours before organ procurement and, for living donors, testing should be performed as close as possible to the surgery but at least within the 28 days before organ procurement**.** The 2020 Guideline requires the following types of testing:
    - HIV: NAT and anti-HIV
    - HBV: NAT, anti-HBc, and HBsAg
    - HCV: NAT and anti-HCV

- Transplant candidate informed consent: The 2020 Guideline eliminates the recommendation for a separate, specific informed consent when a donor is identified as high risk, but does require that transplant centers include this information in informed consent discussions with transplant candidates or their medical decision-makers.

- Recipient testing and vaccination: The 2020 Guideline recommends pre-transplant and post-transplant testing for HIV, HBV, and HCV infections for all recipients, regardless of donor risk criteria during hospital admission for transplant but before transplant. The 2020 Guideline also retains the recommendation that all organ transplant candidates be vaccinated against HBV infection.

- Tracking and reporting of donor-derived disease transmission events: The 2020 Guideline retains the recommendations in the 2013 Guideline unchanged.

Summarizing, then, the 2020 Guideline includes the following recommendations with respect to the timing of testing:

TABLE 3. Testing recommendations for deceased and living donors and for transplant recipients, by type of assay and timing of testing

Donor or recipient	Type of assay	Timing of testing
Deceased donor	Anti-HIV and HIV NAT; total anti-HBc, HBsAg, and HBV NAT; anti-HCV and HCV NAT	96 hours before organ procurement
Living donor	Anti-HIV and HIV NAT; total anti-HBc, HBsAg, and HBV NAT; anti-HCV and HCV NAT	As close as possible to the surgery but at least within 28 days before organ procurement
Transplant candidate (pretransplant)	CDC HIV testing algorithm*; total anti-HBc, HBsAg, and anti-HBs; anti-HCV and HCV NAT	Before transplantation during hospital admission for transplant
Transplant recipient (posttransplant)	HIV, HBV, and HCV NAT	4–6 weeks after transplant†

Abbreviations: anti-HBc = antibodies to hepatitis B virus core antigen; anti-HCV = antibodies to hepatitis C virus; anti-HIV-1/2 = antibodies to HIV-1/2; HbsAg = hepatitis B surface antigen; HBV = hepatitis B virus; HCV = hepatitis C virus; HIV = human immunodeficiency virus; NAT = nucleic acid testing.
* **Source:** CDC; Association of Public Health Laboratories. Laboratory testing for the diagnosis of HIV infection: updated recommendations. Atlanta, GA: US Department of Health and Human Services, CDC. https://stacks.cdc.gov/view/cdc/23447.
† Clinicians caring for liver recipients should maintain heightened awareness of the potential for delayed appearance of HBV infection and consider additional testing for HBV NAT at 1 year. Solid organ recipients who develop signs or symptoms of liver injury (e.g., jaundice or elevated liver function tests) after transplantation should be retested for viral hepatitis even if previous hepatitis B and hepatitis C testing was negative.

The 2020 Guideline applies only when donors do not have laboratory evidence of HIV, HBV, or HCV infection. When organs from HIV-infected donors are used, OPOs and transplant centers should refer to the regulatory framework resulting from enactment of the HIV Organ Policy Equity (HOPE) Act. The 2020 Guideline specifically acknowledges that while some reports suggest complications associated with the transplantation of HCV-infected donor organs into uninfected recipients and while such transplants may raise insurance concerns, “Early evidence suggests that DAA prophylaxis or treatment of HCV-negative recipients of organs from HCV-viremic donors is safe and effective with high rates of sustained virologic response.” When organs from HCV-infected donors are used, the 2020 Guideline recommends that:

- Transplant centers that offer transplantation of organs from HCV-viremic donors to HCV-negative recipients should develop and maintain a plan for education and informed consent of HCV-negative transplant candidates who are considering an organ from an HCV-viremic donor.
- Transplant centers should ensure development of a testing and treatment protocol for their transplant program for HCV-negative transplant candidates who receive an organ from an HCV-viremic donor.
- Transplant centers should ensure payment- and reimbursement-related barriers will not result in a delay of HCV diagnosis or treatment of recipients who receive organs from HCV-viremic donors.

- Clinicians caring for recipients of organs from donors with HCV infection or recent drug injection for nonmedical reasons should maintain awareness of multiple rapidly changing infectious disease risks associated with drug injection for nonmedical reasons, including but not limited to hepatitis A virus, HBV, HCV, HIV, and bacterial and fungal infections , and monitor organ recipients accordingly.
- In accordance with state requirements for reporting notifiable infectious diseases, if an organ recipient becomes newly infected with HCV, the transplant center should notify public health authorities in the recipient's residence jurisdiction. (Citations Omitted.)

The 2020 Guideline specifically states that these considerations are distinct from the recommendations for transplanting organs from donors without laboratory evidence of HIV, HBV, or HCV infection and are not required to be incorporated into OPTN policy.