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American Society of Transplant Surgeons®

[Submitted electronically](#)

September 20, 2019

Mr. James Berger, MS, MT (ASCP), SBB
Designated Federal Official, Office of Infectious Disease and HIV/AIDS Policy
U.S. Department of Health and Human Services
Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA)
Mary E. Switzer Building
330 C Street SW, Room L001
Washington, DC 20024

RE: ACBTSA-RFI: PHS Revised Guidelines for Reducing Transmission of HIV, HBV, and HCV Through Organ Transplantation

Dear Mr. Berger:

The American Society of Transplant Surgeons (ASTS) is pleased to have the opportunity to submit these comments in response to proposed revisions to the 2013 PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation Request for Information (RFI). ASTS is a medical/surgical specialty society representing approximately 1,800 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

The ASTS recommends specific revisions to the 2013 PHS Guidelines, to increase transplantation and reduce organ discards, without alteration in transmission risk or consequences of disease transmission by:

- Using nucleic acid testing (NAT) screening technologies (through recommendations by the CDC/PHS) and direct acting anti-viral therapeutics, while retaining crucial patient safety protocols.
- Endorsing routine assessment of all deceased and living solid organ donors via nucleic acid testing (NAT), medical history, and physical assessment as the criteria to determine risk of disease transmission of HCV, HBV, and HIV. The risk of viral disease transmission with negative NAT screening is incredibly low. To our knowledge, there have been virtually no cases of HIV transmission in the past 10 years. If HIV, HCV, or HBV transmission should occur, these infections are treatable through ever-improving therapies and vaccines.

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- Supporting the removal of an unnecessary regulatory requirement to test living donors at 28 days and again at 7 days prior to donation.
- Endorsing routine informed consent of all organ transplant recipients of viral disease transmission risks based on the above standardized screening methods.
- Endorsing routine (“universal”) post-transplant NAT testing of all transplant recipients within 3 months after transplantation, to detect possible transmission of HCV, HBV, and HIV.
- Removing the term “increased risk.” We believe that deceased donor history is inherently inaccurate. Additionally, we recommend “universal precautions” by using NAT testing to assess donor risk for viral disease transmission of HCV, HBV, and HIV. The term “increased risk” misleads potential recipients to turn down a donor organ when an organ offer is made. This is especially a concern for pediatric candidates.
- Endorsing the elimination of social history as part of the screening process. We believe that continuing to include social history information of the deceased organ donors is counterproductive to the responsible use of organs for transplantation. We have always been concerned that third party historians have insufficient or inaccurate information about the decedent, such that a misleading history will be conveyed to the recipient and transplant center.

We believe that with these changes, it will be possible to safely give the gift of life to many more transplant candidates.

ASTS is pleased that the PHS Guidelines are being re-evaluated. We offer our help to move the field forward. If you have any questions regarding ASTS’ comments, please do not hesitate to contact Jennifer Nelson-Dowdy, ASTS Advocacy Manager, at jennifer.nelson-dowdy@asts.org.

Sincerely,

A handwritten signature in blue ink, appearing to read "L. Ratner", is positioned above the typed name.

Lloyd E. Ratner, MD, MPH
ASTS President