



October 1, 2019

Via E-mail

James Berger
Designated Federal Official
Office of Infectious Disease and HIV/AIDS Policy
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-1850

Re: 84 FR 44904; [Request for Information-Revisions to the PHS Guideline for Reducing Human Immunodeficiency Virus \(HIV\), Hepatitis B Virus \(HBV\), and Hepatitis C Virus \(HCV\) Through Organ Transplantation; Extension of Comment Period](#)

Dear Mr. Berger

On behalf of the American Society of Transplantation (AST), we are appreciative of this opportunity to submit comments to the Office of the Assistant Secretary for Health in response to the Request for Information on the Revisions to the PHS Guidelines for Reducing HIV, HBV, and HCV through Organ Transplantation. The AST is an organization of more than 4,000 transplant professionals dedicated to advancing the field of transplantation and improving patient care by promoting research, education, advocacy, organ donation, and service to the community.

The AST is supportive of the removal of the label “increased risk donors” and expects that this will promote broader acceptance of these otherwise well-functioning grafts. We agree that the label of increased risk has become both obstructionist to donor acceptance and less relevant with advanced testing and treatments.

We offer the following comments for the specific potential revisions to the 2013 Guidelines from the Society’s Infectious Disease Community of Practice:

1. Test all organ donors for HIV, HBV, and HCV using serological tests (including total antibody to hepatitis B core antigen [total anti-HBc], hepatitis B surface antigen [HBsAg], and hepatitis C antibody [anti-HCV]) and NAT.

1a. For living potential donors, testing should continue to be performed as close as possible to the surgery, but at least within the 7-day time period prior to organ recovery.

The AST was unable to come to consensus on the recommendation to decrease the time of testing living donors to 7 days. Those against it noted the rarity of events, ability to emphasize education

and the logistical difficulty for having living donors get repeat testing within 7 days of procurement. Perhaps loosening to “ideally within 7 days but must be within 28 days” would work.

1b. For deceased donors, the donor specimen should be collected within 72 hours prior to organ recovery with results of these screening tests available at the time of organ recovery. If the donor sample used for testing was collected more than 24 hours prior to organ recovery, an additional donor specimen should be collected in the immediate 24 hours prior to organ recovery and tested for HIV, HBV, and HCV by NAT. Results of these screening tests should be made available as soon as possible, even if these results might not be available at the time of organ recovery.

We feel the requirement to repeat NAT is not ideal given the lack of feasibility and increased burden for OPOs, rarity of this being an issue and the potential for loss of organs due to transplant centers waiting for results despite the CDC intention of just having the results come in later (which will not decrease transmission just allow for earlier recognition).

2. Regardless of donor risk profile for HIV, HBV, or HCV, transplant programs should test all organ recipients:

2a. Before transplantation for HIV, HBV, and HCV using NAT and serologic tests including total anti-HBc, HBsAg, anti-HCV, and hepatitis B surface antibody (anti-HBs);

Recipients can be tested with serologic tests alone before transplant, unless they have independent risk factors for de novo acquisition of these viruses, when NAT testing would be appropriate. Ideally, they should be tested at the time of evaluation, yearly while on the waitlist and during the transplant admission prior to implantation of the donor organ, but could also leave timing up to recommendations from professional societies such as the AST.

b. At 4-6 weeks following transplantation for HIV, HBV, and HCV (with NAT); and

c. At 12 months following transplantation for HBV (with NAT).

Most agree with testing of all recipients with HIV/HBV/HCV NAT early post-transplant and repeat testing for HBV at 1 year based on the data, but some concerns were raised about ensuring insurance coverage of testing.

(AST members do note that this practice is far easier to make part of the standard team protocol than to set separate protocol for those who received an IT donor organ. It was also suggested that this may reduce patient anxiety for those who received IR donors if everyone is getting tested.)

3. OPOs should ascertain whether any of the following medical or social risk criteria were present in potential organ donors within 30 days prior to organ recovery:

We support the change to 30 days.

- a. Sex with a person known/suspected to be HIV, HBV, or HCV infected**
- b. Being a man who has had sex with another man**
- c. Sex in exchange for money/drugs**
- d. Non-medical drug injection**
- e. Sex with a person with history of non-medical drug injection**
- f. Incarceration for >72 consecutive hours**
- g. Child breastfed by a mother with HIV**
- h. Child born to a mother with HIV, HBV, or HCV**

OPOs should identify donors for whom medical and social history is unknown at the time of organ recovery, which is also considered a risk criterion.

Some of our members feel that trying to label donors based on potentially unreliable secondhand history is fraught with problems and that it might be an improvement to only label those with + tox screen, track marks, drug paraphernalia or known IVDU.

The majority of NAT negative transmission events were from IVDU donors that died of a drug overdose. Although the last HIV transmission reported in 2011 was from a living donor with MSM history, this donor was only tested by serology and it was done > 2 months prior to donation. This would not be missed with the current donor testing criteria with NAT.

5. Remove any specific label (e.g., “increased risk donor”) to describe donors with risk factors for undetected HIV, HBV, or HCV infection, with inclusion of additional strategies to enhance recipient safety.

The AST agrees with the removal of “IRD” moniker but felt that it was unfortunate that there isn’t a way to address the distinction of increased infectious risk from “marginal donor organ” that has a risk for poorer outcome. Some of the group felt discomfort in not having a term to designate risk although admittedly “increased risk” is very vague and confusing.

6. No requirement for specific informed consent with recipients who are considering acceptance of these organs, though recipients would still be informed of certain donor risk factors.

There was confusion within our membership about this statement. We suggest that the PHS clarify what exactly would be required when using one of these donors. Institutions will need to be cognizant of the fact that they may need to ensure documentation of having explained the risks to the recipient.

Members of our Pediatric Community of Practice shared the following thoughts:

- The “risks” associated with this guideline are almost infinitesimally small. Having a separate process to handle these offers — as we do currently — is unnecessarily biasing. Our families are often very concerned about these risks in their young children, causing unnecessary concern, and occasional refusal of well-functioning organs.
- The removal of “hemodilution” from the guideline is enormously important in pediatrics. Our pediatric donors are somewhat less likely to screen positive for some of the other relevant exposures (e.g., IVDA, MSM), and therefore, a relatively large proportion of our increased risk organs are identified as such due to hemodilution.
- Despite years of experience with this policy, we do not have evidence that our onerous consent guidelines are “protecting” our recipients from HIV, for example.
- We support this proposal. These changes are long overdue, and we applaud the ambitious changes outlined in this document. We believe that these changes could help to connect good organs with needy pediatric recipients.

We appreciate the opportunity to submit these comments and would be pleased to work with the Office of the Assistant Secretary for Health or the PHS to expand upon these thoughts. If you have any questions or if we can be of any further assistance, please contact our Executive Director, Shandie Covington, at scovington@myast.org.

Sincerely,

A handwritten signature in cursive script, appearing to read "Emily Blumberg".

Emily A. Blumberg, MD, FAST
President