



American Society of Transplant Surgeons®

May 24, 2019

Robert R. Redfield, MD Director Centers for Disease Control and Prevention 1600 Clifton Road Atlanta, GA 30329-4027

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

Dear Director Redfield:

On behalf of the American Society of Transplant Surgeons (ASTS), I write to ask your assistance supporting specific changes related to the "Guidelines for Reducing HIV, HBV, and HCV Through Organ Transplantation." The ASTS is concerned that they have inadvertently contributed to an underutilization of transplantable organs and increased organ discards. Medical advances using nucleic acid testing (NAT) screening technologies (through recommendations by the CDC/PHS) and direct acting anti-viral therapeutics are having a significant positive impact on patient safety. An update of the "Guidelines" will now allow for enhancement of organ utilization without alteration in transmission risk or consequences of disease transmission.

ASTS attended and presented perspectives on this important topic to the HHS Advisory Committee on Blood & Tissue Safety & Availability (ACBTSA) meeting held April 15-16, 2019. Based on the content of the meeting, ASTS believes 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 deceased, such that a misleading history will be transmitted to the recipient and transplant center. In fact, many of the Committee members agreed and voted to eliminate social history as part of the recommended revisions to the Guidelines. Unfortunately, the vote was 5-4 in favor of continuing to include social history in the screening process, and so that component will be recommended to remain. We believe that is a mistake.

The ASTS:

1. Endorses the elimination of social history as part of the screening process.

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- 2. Endorses routine assessment of all deceased and living solid organ donors via NAT testing, medical history, and physical assessment as the criteria to determine risk of disease transmission of HCV, HBV, and HIV. The current recommendation is HCV NAT for all donors and only HIV and HBV for the "increased risk donors." We believe that deceased donor history is inherently inaccurate and recommend "universal precautions" by using NAT testing to assess donor risk for viral disease transmission of HCV, HBV, and HIV.
- 3. Endorses routine informed consent of all organ transplant recipients of viral disease transmission risks based on the above standardized screening methods.
- 4. Endorses routine ("universal") post-transplant NAT testing of all transplant recipients within 2 months of transplantation to detect possible transmission of HCV, HBV, and HIV.

Through these changes it will be possible to safely diminish organ discards and allow more individuals to receive the gift of life.

We are available to provide additional perspectives on our comments on the guidelines or provide any other information you would find useful. Please feel free to contact ASTS Executive Director Kim Gifford at kim.gifford@asts.org or 703-414-7870, or myself, ASTS President Dixon Kaufman, at Dixon.Kaufman@asts.org with any questions or requests.

Thank you for your time and willingness to consider assisting the transplant community in this matter.

Sincerely,

Dixon B. Kaufman, MD, PhD

President, ASTS