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[Submitted Electronically]

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Attn: (Docket No. CDC-2011-0011) Public Health Service Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) through Solid Organ Transplantation

Dear Dr. Kuehnert:

Thank you for the opportunity to comment on this important proposed Public Health Service Guideline. We write on behalf of the Infectious Diseases Society of America (IDSA) and the HIV Medicine Association (HIVMA), representing nearly 10,000 physicians, scientists and other health care professionals devoted to patient care, prevention, public health, education, and research related to infectious diseases (ID) including HIV/AIDS. Our members care for patients of all ages with serious infections and also are deeply engaged in research and programmatic activities to respond to infectious diseases globally.

We agree that the 1994 guideline needs to be updated to more accurately reflect the most current science and clinical practice, and to include Viral Hepatitis in addition to HIV. We congratulate the Expert Panel and the Review Committee for their commendable work on the document, but hope that you will take into consideration the following points as you work to finalize the guidelines:
1) Need for an Amendment to Federal Transplantation Law: We are pleased that the document’s recommendations for further research includes (on page 19) the need for study of the risk-benefit of transplanting organs from HIV-infected donors into HIV-infected recipients. Such research is critical given the need for transplants in HIV-infected recipients and improved outcomes with the availability of highly active antiretroviral therapy (HAART). The document states that “legal analysis” of the National Organ Transplant Act (NOTA) of 1984 “may be required” because the Organ Procurement and Transplantation Network (OPTN) is prohibited by law from recovering organs from HIV-positive donors. We would urge you to actively work with IDSA, HIVMA and other interested organizations to help educate policy makers about the need for a change in federal law to allow for clinical research on the safety and effectiveness of HIV-infected-to-HIV-infected organ transplantation. A diverse group of medical societies and other organizations are on record in support of such a policy change, including:

**Medical Societies:**
- HIV Medicine Association
- Infectious Diseases Society of America
- The American Academy of HIV Medicine
- American Medical Association
- American Society for the Study of Liver Disease
- American Society of Transplant Surgeons
- American Society of Transplantation
- Association of Organ Procurement Organizations
- Gay and Lesbian Medical Association
- Renal Physicians Association

**Other Organizations:**
- AIDS United
- The AIDS Institute
- amfAR, The Foundation for AIDS Research
- Lambda Legal
- National Coalition for LGBT Health
- National Minority AIDS Council
- Treatment Access Group (TAG)
- United Network for Organ Sharing (UNOS)

2) Editorial Issues: The authors are to be commended on the detailed nature of these guidelines. However, we are concerned that the daunting length of the document (more than 100 pages) will limit its effectiveness and utilization. From an editorial standpoint:

A. We believe the Executive Summary is too long and not clearly distinguished from the guidelines themselves. Conversely, the guidelines contain a lot of information that should more aptly be part of the introduction (for example, Table 2). We would recommend re-organizing the Executive Summary to make it a true summary of the recommended changes to the 1994 guideline and to differentiate it from the full-length guidelines.
B. To help address length considerations, we question whether it is necessary to include Table 5, with a list of all the companies that offer HIV testing (this could be moved to an Appendix). Also, Figures 4 through 10 are confusing and do not add to the manuscript; their content would be better reported in the textual section. Similarly, Figures 12-15 are not adding much to the guideline. They would be more fitting for a research paper, and should be dropped or moved to an Appendix.

C. We also note that some statements seem to be unclearly written or lacking in specificity, while others appear altogether unnecessary. For example, Recommendation 1 does not specify who is responsible for notifying “all prospective donors” about the process, and the second recommendation does not specify who is responsible for discussing prospective risks with family members. Recommendation 2, concerning ascertainment of risk, does not specify if a clinician should query all listed individuals about known risk behaviors or just one of them. We also note that the document does not address the ethical question of whether next of kin should be notified of a positive test if they were previously unaware and the ‘donor’ never consented to that testing, nor to disclosure to family members.

D. We also believe it would be helpful to clarify what is meant by “the general nature of the donor evaluation process” (p. 11). In addition, in Recommendation 7, it is unclear whether the document really means to refer to ‘blood vessels’ or all tissues.

3) Concerns with Risk Assessment Process: More substantively, we share concerns expressed in other public comments that the lack of evidence to justify the entire risk assessment process, as described in the document, could do more harm than good. We are concerned that, as written, the process of risk assessment will have the effect of reducing transplantations without substantially impacting safety. The document contains an abundance of data regarding risk factors for the various viruses. However, we are not convinced that a nebulously defined process for ascertaining risk would improve safety beyond what can be accomplished with rapid and complete screening with serology and Nucleic Acid Testing (NAT).

4) Donor Screening Recommendation Concerns: We also find the donor screening recommendations to be unnecessarily cumbersome. For example, the requirement to use an FDA approved test (in Recommendation 7) raises concerns that transplantation might be harmfully prevented or delayed. For instance, if a local laboratory has a Clinical Laboratory Improvement Amendments (CLIA)-certified approach to NAT that is not FDA approved and can be done rapidly, we question whether that would not be preferable to sending the testing out to a reference lab and waiting a week for results. We urge that the wording of this recommendation be revised to say “ordinarily” or “ideally” or “unless an equivalent more rapid option is available.”
The HBV recommendation also is confusing, and we recommend that you consider a NAT test for HBV. This is an important opportunity to prevent HBV transmission. The recipient of an organ from a NAT positive, total anti-HBV core-positive, hepatitis B surface antigen-negative donor might want hepatitis B immune globulin; while a NAT negative organ recipient would not.

5) **Tracking and Reporting:** We propose that CDC or another agency like UNOS create a central tracking system that would achieve the goal of surveillance and record-keeping.

6) **Need for Clarification and Consistency on MSM Donor Risk:** With respect to proposed changes from the 1994 guideline concerning MSM donor risk, the recommendations are not clear and require streamlining and further clarification. According to the 1994 guideline, *any potential donor with any of the listed behavioral risk factors, including “Men who have had sex with another man in the preceding 5 years,” should not donate organs regardless of HIV test results, “unless the risk to the recipient of not performing the transplant is deemed to be greater than the risk of HIV transmission and disease.”* The recommendation associated with this issue (Question #3, p. 73) states:

“To ascertain whether potential organ donors are average risk or at increased risk for having HIV, HBV, or HCV, prospective living donors and next-of-kin, as well as individuals familiar with deceased donors (i.e., life partners, cohabitants, friends, healthcare provider), should be interviewed in a confidential and sensitive manner about behaviors that may have increased the potential donor’s probability of HIV, HBV or HCV infection (Refer to Table 3 for risk factors).’

One then has to refer back to Table 3 (p. 13), where the seven sexual contact risk factors are listed (presumably based on the literature review), including: *Men who have had sex with another man (MSM) in the preceding 12 months.* We believe this narrowing of the window from 5 years to 12 months is a step in the right direction, but needs to be more explicitly stated, and linked to the evidence base supporting this change. Additionally – it is important to set a consistent standard for MSM donation. We also recommend shortening the look back period to six months, which is consistent with the HIVMA and IDSA Blood Donation Deferral Policy.

The sexual contact risk window for prospective MSM donors also should take into consideration the period between exposure and the ability of laboratory assays to detect infection. In addition, it should not be presumed that all sexual contact between MSM is inherently high risk – consideration should be given to the nature and risk level of sexual contact (e.g. protected vs. unprotected, anal sex vs. oral sex, etc.).
7) **Informed Consent Requirements Need Greater Balance:** We agree with concerns of other commenters regarding the risks attributed to the number of sexual partners, rather than assessing for high risk unprotected sex, and how this would limit the donor pool. We support guidelines that minimize the risk of disease transmission, but stress that in an era of donor shortages and increasing wait list mortality, counseling on potential risk factors must be balanced against the risks posed by wait list delays and associated mortality. Recommendations concerning requirements for informed consent regarding risk of transmissible disease (p. 15) should be balanced by clear communication of:

A. The likelihood of transmission of an infectious disease based on known risk factors for a given donor;
B. The risks of mortality and disease progression due to organ transplantation wait list delays;
C. The limits to available screening technologies (e.g. patients should be advised that no screening question or laboratory screening test can completely eliminate the risk for transmitting these infections);
D. The treatment repercussions and prognosis for possible types of infection in the statistically rare\(^1\) event that a disease transmission should occur.

Thank you for your consideration of our views. HIVMA and IDSA would welcome the opportunity to provide further feedback on revised guidelines or to assist you in any manner. We can be reached through HIVMA Policy Officer, Kim Crump at kcrump@hivma.org.

Sincerely,

Thomas G. Slama, MD, FIDSA
IDSA President

Judith A. Aberg, MD, FIDSA
Chair, HIVMA Board of Directors

CC: The Honorable Kathleen Sebelius
Secretary, Department of Health and Human Services

The Honorable Thomas Frieden, MD, MHP,
Director, Centers for Disease Control and Prevention

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\(^1\) The prevalence of confirmed positive tests among tissue donors was 0.093 percent for anti-HIV, 0.229 percent for HBsAg, 1.091 percent for anti-HCV, and 0.068 percent for anti-HTLV. The incidence rates were estimated to be 30.118, 18.325, 12.380, and 5.586 per 100,000 person-years, respectively. The estimated probability of viremia at the time of donation was 1 in 55,000, 1 in 34,000, 1 in 42,000, and 1 in 128,000, respectively. (Zou, Dodd, et al, “Probability of Viremia with HBV, HCV, HIV, and HTLV among Tissue Donors in the United States,” N Engl J Med 2004; 351:751-759, August 19, 2004).