



**HIV Medicine Association Policy Statement:  
Federal Law Should Allow Clinical Research on the Safety and Effectiveness of  
HIV-Infected-to-HIV-Infected Organ Transplantation**

ADOPTED BY HIVMA: March 20, 2011

The HIV Medicine Association (HIVMA) of the Infectious Diseases Society of America represents physicians, scientists and other health care professionals who practice on the frontline of the HIV/AIDS pandemic. HIVMA strongly advocates effective public policies grounded in science.

Regulation of organ donation for all diseases with the exception of HIV resides appropriately with the Department of Health and Human Services, which has the medical expertise to regulate, monitor and maintain organ donation policies according to the latest available research findings. The legal ban on HIV-infected organ donation took effect in 1984 with the Federal National Organ Transplant Act of 1984 (42 U.S.C. § 274). Despite the significant progress made in understanding the etiology of HIV infection and its transmission over the past 30 years, HIV infection continues to be the only condition that automatically precludes the use of organs from HIV-infected deceased individuals by federal statute thereby prohibiting even the possibility of investigational studies involving such organs.

Major advances in treatment for HIV infection have since transformed HIV/AIDS from a terminal illness to a chronic disease for individuals with access to HIV therapies and expert medical HIV care. As a result, the life expectancy of people living with HIV/AIDS (PLWHA) now approaches that of uninfected individuals.<sup>1</sup> However, many people with HIV disease continue to experience high rates of serious co-morbidities, including infections caused by hepatitis C virus (HCV). Estimates of HCV co-infection among people with HIV are as high as 30 percent and end-stage liver disease associated with HCV is now a major cause of death among PLWHA.<sup>2,3</sup> End-stage renal disease is also a major cause of morbidity and mortality among PLWHA.<sup>4</sup>

Due to advances in medical management of HIV infection coupled with improvements in transplant outcomes, HIV infection is no longer a contraindication to solid organ transplantation, and transplantation can be the best clinical option for many patients with end-stage organ failure. However, a severe organ shortage in the United States leads to considerable mortality and morbidity for patients awaiting transplants. In the last 10 years, the total number of patients waiting for a kidney transplant increased 78 percent and deaths while waiting for a kidney increased 76 percent.<sup>5,6,7</sup>

For transplant candidates infected with HIV, deceased donors with the same infection could represent a source of organs.<sup>8</sup> Researchers estimate that there are approximately 500-600 potential deceased HIV-infected kidney and liver donors per year in the United States.<sup>9</sup> Organs from these deceased donors have the potential to save the lives of approximately 1,000 HIV-infected patients with liver and kidney

failure each year; however, research is needed to fully evaluate the safety and efficacy of organ transplantation between HIV-infected individuals. The legal ban on HIV-infected organ donation bars scientific exploration of HIV-infected organ donation as a potentially lifesaving measure for people living with HIV infection.

#### HIVMA's Position:

HIVMA supports changing federal law on HIV-infected organ donation under the Federal National Organ Transplant Act of 1984 (42 U.S.C. § 274), such that authority for regulating HIV-infected organ donation would reside with the Department of Health and Human Services. The change in policy is important to support medical progress and allow for the research necessary to fully evaluate HIV-infected organ donation to HIV-infected patients. We are not, however, advocating HIV-infected organ donation outside of clinical trials until the safety and efficacy of organ donation between individuals with HIV infection has been demonstrated.

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<sup>1</sup> van Sighem A, et al. Life expectancy of recently diagnosed asymptomatic HIV-infected patients approaches that of uninfected individuals. *AIDS*. 2010;24(10):1527-35.

<sup>2</sup> Sherman KE, Rouster SD, Chung RT, Rajcic N. Hepatitis C virus prevalence among patients infected with human immunodeficiency virus: a cross-sectional analysis of the US adult AIDS Clinical Trials Group. *Clin Infect Dis*. 2002;34:831-7.

<sup>3</sup> Thomas DL. Hepatitis C and human immunodeficiency virus infection. *Hepatology*. 2002;36(5 suppl 1):S201-9.

<sup>4</sup> Stock, P.G. et al, Outcomes of kidney transplantation in HIV-infected recipients. *N Engl J Med*. 2010 Nov 18;363(21):2058-9.

<sup>5</sup> Meier-Kriesche HU, Schold JD, Gaston RS, Wadstrom J, Kaplan B. Kidneys from deceased donors: maximizing the value of a scarce resource. *Am J Transplant*. Jul 2005;5(7):1725-1730.

<sup>6</sup> McCullough KP, Keith DS, Meyer KH, Stock PG, Brayman KL, Leichtman AB. Kidney and pancreas transplantation in the United States, 1998-2007: access for patients with diabetes and end-stage renal disease. *Am J Transplant*. Apr 2009;9(4 Pt 2):894-906.

<sup>7</sup> Schold J, Srinivas TR, Sehgal AR, Meier-Kriesche HU. Half of kidney transplant candidates who are older than 60 years now placed on the waiting list will die before receiving a deceased-donor transplant. *Clin J Am Soc Nephrol*. Jul 2009;4(7):1239-1245.

<sup>8</sup> Muller E, Kahn D, Mendelson M. Renal transplantation between HIV-positive donors and recipients. *N Engl J Med*. 2010;362(24):2336-7.

<sup>9</sup> Boyarsky BJ, Hall EC, Singer AL, Montgomery RA, Gebo KA, Segev DL. Estimating the potential pool of HIV-infected deceased organ donors in the United States. *American Journal of Transplantation*, 2011 (in press).