

Frequently Asked Questions

Transplantation of organs from HIV-infected donors to HIV-infected recipients

What is the objective?

The objective is to repeal the outdated federal ban on the transplantation of organs from HIV-infected donors. Allowing the use of these organs for HIV-infected patients who require transplants has the potential to save 1,000 lives per year and to save taxpayers around \$500,000 in Medicare savings per patient transplanted.^{1,2}

Transplantation has emerged as not only the standard of care treatment for HIV-infected patients with organ failure, but a cost-saving procedure as well.³ More than 100,000 patients are currently on the active waiting list for organ transplants in the United States, and about 50,000 are added to the list each year. However, fewer than 30,000 transplantations are performed annually.⁴ Tragically, many patients die while waiting for a transplant.

Is it currently possible to even conduct research in the transplantation of organs from HIV-infected donors to HIV-infected recipients without changing the law?

No. Only by repealing the current federal ban would it be possible to carefully study the safety and outcomes of these transplants in the same way that transplantation of HIV-infected recipients with uninfected donor organs has been carefully studied. Continued clinical and comparative-effectiveness research is required in this area once these procedures become a possibility for HIV-infected patients. Currently physicians in South Africa are doing this research, but the outdated ban makes such research currently impossible in the United States.

What is the relevant law that needs to be amended?

The relevant law is the National Organ Transplant Act (NOTA), which prohibits the recovery of organs from donors "infected with the etiologic agent for acquired immune deficiency syndrome" (Public Law 100-607).⁵ The wording of NOTA (not referring specifically to HIV) reflects the profound lack of knowledge about this disease during the time it was written.

When was the ban enacted?

The National Organ Transplant Act 1984 was amended in 1988 to prevent the recovery of organs from donors infected with HIV. At that time, the amendment may have made sense, but it is now medically outdated. The language of the law reflects the intense atmosphere of fear that accompanied the discovery of AIDS, as little was known at the time about the etiology of this rapidly spreading disease. ***In fact, as reflected in the language of the current statute, the human immunodeficiency virus (HIV) had not even yet been identified as the cause of AIDS.*** Notably, the same health omnibus bill banning the transplantation of organs that might transmit AIDS also provided funding for AIDS research, directed the Centers for Disease Control and Prevention (CDC) to study the epidemiology of AIDS, and began national education efforts on AIDS prevention.

What has changed since the discovery of HIV/AIDS in the 1980s?

The understanding of HIV/AIDS and the medical community's ability to manage the condition have profoundly grown since HIV/AIDS was first discovered, representing perhaps one of the most impressive success stories in modern medicine.⁶ What used to be a rapid death sentence has become a manageable chronic disease. Highly active antiretroviral therapy (HAART) has dramatically improved life expectancy and quality of life in HIV-infected patients. HIV-infected patients are living much longer, many with life expectancies mirroring those in the general population.

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What are the applicable medical concerns among patients living with HIV?

Now that HIV-infected patients are living longer, other chronic conditions such as kidney and liver failure have emerged.⁷⁻⁹ These are conditions for which *organ transplant is the standard of care treatment*. Many people with HIV experience high rates of serious co-morbidities including HIV-associated nephropathy (HIVAN), hepatitis C virus co-infection, and HAART toxicity which can cause kidney and liver failure. These diseases progress more rapidly in patients infected with HIV.^{10,11} Hepatitis C virus co-infection among people with HIV is as high as 30% and liver failure associated with hepatitis C virus is now a major cause of death among people living with HIV/AIDS. Kidney failure is also a major cause of morbidity and mortality among these patients.¹² In fact, in the United States, HIV-associated nephropathy is the third leading cause of kidney failure among African American men -- behind diabetes and high blood pressure.^{13,14}

What safeguards will ensure HIV-infected organs are separate, and not mistakenly transplanted into uninfected patients?

To minimize the risk of inadvertently placing an HIV-infected organ into an uninfected recipient, the transplant community will draw on systems that have been put in place after years of transplanting organs from hepatitis C infected donors to hepatitis C infected recipients, as well as the robust, meticulous system for matching donors and recipients that is already in place.¹⁵ UNOS/OPTN (HRSA/HHS) has specific organ placement systems that only allow those patients that are medically able to accept an organ from a hepatitis C infected donor to appear on the list of possible recipients. There is very specific policy in place to ensure that in order to receive this opportunity of receiving the donated hepatitis C infected donor organ, the intended recipients name must appear on the list. This is verified several times throughout the process. In addition to these strict administrative processes, there are parallel robust safeguards in place at the level of the hospital and the surgeons. ***There has never been a case of an organ from a donor infected with hepatitis C accidentally allocated to an uninfected patient.*** A similar system utilized for HIV-infected patients would ensure that only HIV-infected patients would appear on this list, mirroring the experience with hepatitis C.

Are organs from HIV-infected donors viable to be transplanted into HIV-infected patients?

A surgical team in South Africa has reported results for at least 10 patients transplanted with kidneys from HIV-infected donors.¹⁶ Outcomes, while preliminary, are excellent, with patients remaining virally suppressed with stable kidney function up to three years after transplantation.

Which groups support using organs from HIV-infected donors for HIV-infected recipients?

This effort has been widely supported by the medical community at large (American Medical Association, HIV Medicine Association, Infectious Diseases Society of America, American Academy of HIV Medicine, American Society for Study of Liver Disease, Gay and Lesbian Medical Association), the transplant community (American Society of Transplant Surgeons, American Society of Transplantation, United Network for Organ Sharing, Association of Organ Procurement Organizations, North American Transplant Coordinators Association), and the HIV community (Human Rights Campaign, AIDS Institute, American Foundation for AIDS Research, Lambda Legal, National Coalition for LGBT Health, National Association of People With AIDS, National Minority AIDS Council, Treatment Access Group). In addition, in its recent Public Health Service Guidelines, the CDC wrote that research on these types of transplants needs to be conducted, but noted that current law would need to be changed to allow for such transplants.¹⁷

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Do any groups oppose this legislative change?

To the best of our knowledge, no groups oppose this change.

Can HIV-infected patients receive transplants if they are in kidney or liver failure?

HIV-infected patients are currently eligible to receive transplants from uninfected donors. Though in the early era of HIV/AIDS, HIV-infected patients were considered medically ineligible to receive transplants, medical advances have made transplantation for HIV-infected patients safe and feasible. In a recent national, multicenter, National Institutes of Health (NIH)-funded study, Dr. Peter Stock (UCSF Medical Center) and colleagues demonstrated that well-selected HIV-infected kidney transplant recipients can have organ and patient survival rates comparable to those in uninfected recipients.¹² This encouraging experience shows that transplant immunosuppression (the powerful drugs that transplant recipients take to prevent their bodies from rejecting organs) does not necessarily counteract the ability to suppress HIV with HAART.

What are the benefits of using organs from HIV-infected donors?

Using organs from donors infected with HIV for recipients infected with HIV will have a widespread, positive public health impact:

1. Uninfected patients will be transplanted faster because HIV-infected patients can draw from a unique organ supply which is inappropriate for the majority of patients on the waitlist.
2. HIV-infected patients will be transplanted faster. Some patients can wait as long as 7-10 years for their transplants, and many die waiting.¹⁸ Drawing on parallel experiences with transplanting organs from hepatitis C infected donors to hepatitis C infected recipients, research has demonstrated that using organs from donors infected with hepatitis C for recipients with hepatitis C is a safe long-term strategy that is highly beneficial for many hepatitis C infected patients, significantly reducing waiting times (by 1-2 years or more) and risk of death on the waiting list.^{19,20} A similar advantage for HIV-infected patients who will accept HIV-infected organs can be expected, but this would only be possible if NOTA is revised.
3. More HIV-infected patients will be referred for transplant. A recent study demonstrated that HIV-infected patients are listed for transplants at lower rates than their uninfected counterparts.²¹ Since there would be more HIV-infected organs available than there are HIV-infected patients listed for transplantation, better referral for HIV-infected patients should not cause further burden to the waiting list.

Would agreeing to accept an organ from an HIV-infected donor cause HIV-infected patients to "lose their place in line" for an organ from an uninfected donor on the regular waiting list?

No, HIV-infected patients who agree to accept organs from HIV-infected donors would not be bypassed and thus "lose their place in line" if they agree to accept an organ from a donor with the same infection. If an organ became available from an uninfected donor sooner than one from an HIV-infected donor, that patient would be offered the uninfected organ in the same manner as an uninfected patient (based on established criteria, i.e. waiting time, blood/tissue compatibility). By opting-in through informed consent to receive an organ from a donor with the same infection, HIV-infected patients would be increasing the likelihood that they would be transplanted faster because organs from HIV-infected donors are inappropriate for uninfected patients. A quicker road to transplantation benefits patients who are waiting because of the substantial risk of death on the waiting list.

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What are the risks of using organs from HIV-infected donors?

The true risks are unknown -- that is why research is needed in this area. The risk of superinfection (a new infection occurring in a patient having a preexisting infection) will need to be better understood. However, transplanting organs from stable, virally suppressed HIV-infected donors into stable, virally suppressed HIV-infected recipients is likely to be safe based on what is known about disease transmission risk in other settings.²² In addition, the potential risks of such a procedure must be weighed against the great risk of the patient dying (10-20% per year) while on the waiting list for an uninfected organ.²³

What are the costs of reversing the law?

Actually, reversing this law would save money. Since the care of patients with kidney failure in the United States is covered as part of the Medicare End Stage Renal Disease Program (which consumes 6.6% (>\$20 billion) of the entire Medicare budget), these transplants will save Medicare approximately \$500,000 per patient.² In the setting of health care and budget crises, transplantation—in addition to saving lives—makes economic sense by saving taxpayers money.

Which organs can HIV-infected patients accept?

The majority of patients (>80%) on the transplant waiting list are waiting for kidneys, followed by livers. As major causes of morbidity and mortality in HIV-infected patients are kidney and liver failure, these trends follow for HIV-infected patients waiting for transplants as well. Cardiovascular disease has also emerged as a leading cause of death in HIV-infected patients. Consequently, HIV-infected patients have also successfully undergone heart and lung transplants with survival rates comparable to those in uninfected recipients.^{24,25}

Who can you contact if you have any questions?

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