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Moving from the HOPE Act to HOPE in Action: Changing Practice and Challenging Stigma

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Abstract

Purpose of review: The HIV Organ Policy Equity (HOPE) Act, signed in 2013, reversed the federal ban on HIV-to-HIV transplantation. In this review, we examine the progress in HOPE implementation, the current status of HIV-to-HIV transplantation, and remaining challenges.

Recent findings: Pursuant to the HOPE Act, the Department of Health and Human Services revised federal regulations to allow HIV-to-HIV transplants under research protocols adherent to criteria published by the NIH. The first HIV-to-HIV kidney and liver transplants were performed at Johns Hopkins in March of 2016. Legal and practical challenges remain. Further efforts are needed to educate potential HIV+ donors and to support Organ Procurement Organizations. As of November 2017, there are 22 transplant centers approved to perform HIV-to-HIV transplants in 10 UNOS regions. To date, 16 Organ Procurement Organizations in 22 states have evaluated HIV+ donors. The NIH-funded HOPE in Action: A Multicenter Clinical Trial of HIV-to-HIV Deceased Donor Kidney Transplantation Kidney Trial will launch at 19 transplant centers in December of 2017. A HOPE in Action Multicenter HIV-to-HIV Deceased Donor Liver Trial is in development.

Summary: Significant progress toward full HOPE implementation has been made though barriers remain. Some challenges are unique to HIV-HIV transplantation, while others are amplifications of issues across the current transplant system. In addition to a public health benefit for all transplant candidates in the United States, partnership on the HOPE Act has the potential to address systemic challenges to national donation and transplantation.

Keywords

HIV; HOPE Act; HIV-infected donors; solid organ transplantation

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Conflicts of interest

Dr. Durand has received research grants from Bristol Meyers Squibb, Gilead Sciences, Merck Pharmaceuticals, and Viiv Healthcare. Dr. Durand has also served as a scientific advisor for Bristol Meyers Squibb, Gilead Sciences, and Merck Pharmaceuticals. The remaining authors have no conflicts of interest.

INTRODUCTION

From inception, the purpose of the HIV Organ Policy Equity (HOPE) Act has been to bring HIV+ individuals with end-stage organ disease more opportunities to receive transplants through expansion of the donor pool to include HIV+ deceased donors. Potential benefits of the HOPE Act are two-fold: to increase donor supply generally, which helps HIV+ and HIV- individuals on the waitlist, and to help HIV+ individuals specifically, as a vulnerable population with higher waitlist mortality. Our review will describe the HOPE Act and progress toward implementation.

ROAD TO HOPE

HIV+ individuals with end-stage organ disease experience excellent outcomes with transplantation [1–5]. Accordingly, there has been a marked increase in kidney and liver transplants performed in this population. At the same time, HIV+ individuals face increased mortality on the waitlist [6, 7] and lower access to transplant compared to HIV-uninfected candidates [8, 9]. In one study of HIV+ individuals with end-stage renal disease (ESRD), survival on hemodialysis at 5 years was 62.7% compared to 94.4% in matched HIV-uninfected peers [6]. Similar disparities are seen in end-stage liver disease. In one study of HIV+ individuals awaiting transplant at a high-volume US center, one-year mortality was 36% for HIV+ candidates compared to 15% for HIV- candidates matched for liver disease severity [7].

Organs from HIV+ donors represent novel solutions for this disparity. In kidney, HIV-to-HIV transplantation was successfully pioneered by Dr. Elmi Muller in South Africa with excellent results to date [10, 11]. The first 4 cases were reported in 2010 with no deaths, graft failures, or HIV virologic failure at one year. More recent outcomes for the South African cohort (n=27) confirm these findings with 5-year patient and graft survival of 74% and 84%, respectively. These encouraging results motivated the initiation of this strategy in the United States [11].

However, in the United States, the use of HIV+ donor organs was banned in an amendment of the National Organ Transplant Act of 1984. As such, our group sought to revise this federal regulation. A study of two national registries suggested potential for 300–500 HIV+ donors annually, a substantial increase in the donor pool [12]. This evidence, coupled with the support of national transplant and AIDS advocacy groups, provided the impetus for a two-year collaboration with Congress and HRSA [13]. In November 2013, the HOPE Act was passed by Congress and was signed into law by President Obama that year.

HOPE IN ACTION: LEGAL MILESTONES

The HOPE Act had 3 mandates to be completed within 2 years of signing (Figure 1). First, in June of 2015, the Secretary of the Department of Health and Human Services (HHS) enacted changes to the Final Rule to remove the restrictions on HIV+ donor organs. In its place, HHS instituted a new regulation that HIV+ donor organs could be transplanted into HIV+ individuals under research protocols aligned with federal safeguards and criteria. In

the future, HHS can determine that HIV-to-HIV transplantation is allowed outside of research [14].

Notably, after the Final Rule change, it was determined that some state regulations restricted HIV-to-HIV transplantation. A preliminary analysis using The Center for HIV Law and Policy's "State and Federal Laws and Prosecutions" database revealed that 14 states had laws pertaining to HIV-to-HIV transplantation [15]. A more comprehensive legal analysis is underway to further explore these preliminary findings. To date, two states, California and Delaware, have passed legislative action to ease restrictions, in 2016 and 2017, respectively [16–17].

The second step was the development of specific HIV-to-HIV transplant research criteria. This task was delegated to the National Institutes of Health (NIH) who received input from the Centers for Disease Control, the Health Resources and Services Administration, the Centers for Medicare & Medicaid Services, the Food and Drug Administration, and community stakeholders. Draft criteria were published in the Federal Register in June 2015 for a 60-day public comment period and the final HOPE Safeguards and Research criteria were published in November 2015 [18].

Finally, the Organ Procurement and Transplantation Network (OPTN) revised their standards for the acquisition and transportation of HIV+ donor organs. OPTN determined that centers must provide documentation of institutional review board approval and submit safety reports to OPTN to be granted a variance for HIV-to-HIV transplantation. These changes were implemented concurrent with the research criteria in November 2015 [19].

PROGRESS IN THE MEDICAL COMMUNITY: HOPE RESEARCH PROTOCOLS

There are unique biologic risks of HIV-to-HIV transplantation that should be considered. First, HIV+ recipients of HIV+ donor organs may become superinfected, that is infected with a second, distinct strain of HIV [20]. Superinfection has been observed with all modes of HIV transmission, including sexual and intravenous drug use [21, 22]. The viral inoculum that occurs with organ transplant may be higher than other modes. Clinically, HIV donor-to-recipient superinfection could lead to HIV virologic breakthrough if donor virus is not suppressed by the recipient antiretroviral therapy. Thus, careful donor selection and recipient monitoring is critical. Other unique risks include the potential for HIV-related organ disease, such as HIV-associated nephropathy, which will need to be investigated within research protocols.

The first IRB approved protocol of HIV-to-HIV deceased donor kidney and liver transplantation opened at Johns Hopkins University in January of 2016. This study evaluates the feasibility and safety of HIV+ deceased donor kidney and liver transplantation and informs a larger multicenter trial. Under this protocol, the first HIV-to-HIV kidney and liver transplants were performed at Johns Hopkins in March 2016 [23]. There are now 22 transplant centers with UNOS approval to perform HIV-to-HIV transplants (Table 1). Most

participating centers are partnering with Johns Hopkins University to share data within a multicenter pilot trial ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02602262), NCT02602262).

In collaboration with the NIH, our group designed a larger trial, the HOPE in Action Multicenter Kidney Study: a prospective multicenter, clinical trial of HIV+ deceased donor kidney transplants for HIV+ recipients. The primary objective of the trial is to determine whether an HIV+ deceased donor kidney transplant is safe and effective compared to an HIV-uninfected deceased donor kidney transplant. The trial will take place at 19 centers over 5 years and enroll 160 HIV+ kidney transplant recipients; 80 will receive HIV+ donor kidneys and 80 will receive HIV- donor kidneys (Figure 2). The trial is focused both on major transplant-related complications (death, graft failure, allograft rejection) as well as HIV-related complications including HIV virologic failure, AIDS-defining infections and HIV-related renal disease. In July of 2017, a cooperative agreement (U01AI134591) was awarded: HOPE in Action: A Multicenter Clinical Trial of HIV-to-HIV Deceased Donor Kidney Transplantation (Figure 1). A related trial of HIV+ deceased donor liver transplant is being planned and designed with the NIH.

PROGRESS TOWARD IMPLEMENTATION: ORGAN PROCUREMENT ORGANIZATIONS

The HOPE Act could not be implemented without changes to the legal and regulatory environment, carefully designed clinical research protocols, and an infrastructure for safety reporting. Significant progress has been made in the first two years: HIV-to-HIV transplantation has few remaining legal barriers and there is dedicated federal funding for a multicenter clinical trial. What remains to be accomplished to reach the predicted volume is implementing HIV+ donor registration and public education, ensuring timely hospital referrals for HIV+ potential donors, and evaluating HIV+ donor referrals. These tasks are generally held by OPOs, with support from HOPE participating transplant centers.

HIV+ Donor Registration and HOPE Public Education

Studies of potential HIV+ deceased donors in the US assessed clinical suitability through retrospective analysis of medical record data [12, 24]. An additional consideration of potential HIV+ donors in practice is organ donor registration and authorization rates. HIV+ individuals may believe it is illegal to register as a donor. Stigma related to HIV disclosure may pose a barrier to discussions with next-of-kin about donation decisions. Research has shown that when potential donors have discussed their donor status with next-of-kin, donation is more likely [25, 26].

In a cross-sectional survey of 115 HIV+ individuals at a Johns Hopkins clinic, only 22% were registered as donors, while 80% were willing to be donors [27]. A high willingness to donate among this cohort was encouraging, since the surveyed population was primarily African American, a community in which lower donor authorization rates have been observed [28, 29]. However, if HIV+ individuals are under-registered as a population, OPOs approaching families of potential HIVDD could experience lower authorization rates. Only 18% of respondents in our study had discussed donation with their families [27]. An effort to

track and improve donor registration rates within the HIV+ community will be an important step for OPOs.

Educating the public about HIV+ donation requires effort from institutions and advocacy groups. The intersection of transplantation and stigma around HIV was encountered in the early 2000s when HIV+ individuals were first considered for transplants [30]. Now, OPOs must navigate new questions from the public about the ethics and safety of HIV-to-HIV transplantation [31, 32]. For example, for states with low registration rates [33], does talking with the media or public about HIVDD have potential negative consequences, based on potential registrants' political or cultural identifications? Is there potential for loss of support for donation from local political or religious figures? In areas of the country where HIV-related stigma is strong [34], intelligently navigating regional differences is an important consideration for OPOs.

Some HOPE participating OPOs have received questions about the safety of the transplant system to protect against donor-derived HIV infection as well as questions about efficacy or "deservingness" of HIV+ transplant candidates. While this barrier may be amplified in the context of HIV-to-HIV transplantation, concerns about deservingness have also been seen as a challenge to donation generally [35]. Updating public education materials, training OPO teams, and constructing a more inclusive narrative through connecting with the community of people living with HIV requires time and resources.

Hospital Referrals of HIV+ Potential Donors

Process breakdowns between OPOs and referring hospitals are particularly relevant for implementation of a research protocol that expands the donor pool. Specifically, three categories of failure may prove to be significant in the identification of potential HIV+ deceased donors: missed hospital referrals, late hospital referrals, and de-escalation of care [36]. Do hospitals know that HIV+ individuals meeting clinical triggers for organ donor referral have the potential to be donors [9]? Are calls made by hospitals at the same rates, with the same timeliness, as HIV- deceased donors? Are providers aware of the HOPE Act or their local OPO's participation in research? Do hospitals preserve the option for donation approach with the next of kin if the potential donor is HIV+?

HIV+ Donor Evaluation

At a time when progress toward HOPE implementation requires investment from OPOs, in 2017, UNOS reported the fifth consecutive year of record-high organ transplants. While several factors contributed to the gains in deceased organ donation, the opioid epidemic is perhaps the most significant [37]. As OPOs are called more frequently for donor referrals due to the devastation of opioid-dependence related deaths, they have increased procurement staff to meet the needs of increased donor activity. In times of high donor activity, OPOs may not dedicate additional resources for staff training about HIV+ donor evaluation, management, and recovery. On the other hand, overdose death donors are categorized as increased infectious risk donors (IRD) and many are found to be seropositive for hepatitis C virus (HCV+) infection. As OPOs gain experience with IRD and HCV+ donors, many of the same policies and procedures are relevant for potential HIV+ donors. Thus, training staff to

evaluate HIV+ donors may not require major new initiatives: instead, HOPE protocols can be incorporated into existing policies.

Another potential challenge to HIV+ donor evaluation by OPOs is lack of experience in working with HIV+ individuals as potential organ donors. Before the HOPE Act, OPOs trained teams to avoid potential transmission of HIV to transplant recipients. Although extremely rare, donor-derived HIV infection from solid organ transplantation in a widely-covered case in November 2007 made an impact on transplant providers [38]. Mitigating risk of donor-derived infection through performing accurate donor evaluation is important to the safety of the transplant system [39]. To that end, OPOs had prioritized timely rule-outs for deceased donor referrals where positive HIV serostatus is known or discovered during donor evaluation. In fact, it was predicted that efforts to minimize HIV transmission would result in lost organs due to false positive screenings [40]. Pursuant to the HOPE Act, organs from donors without a history of HIV who have an unexpected positive result on an HIV antibody or nucleic acid test screen can be recovered and transplanted to HIV+ recipients within HOPE protocols. Due to the transplant system's hard work to minimize donor-derived HIV infection, and the historical illegality of HIV+ organ donation under NOTA, many experienced OPO frontline staff have limited clinical experience with HIV+ individuals in a donation setting.

For potential HIV+ donors with known HIV infection, there may be a lack of knowledge among OPO staff about HIV-specific donor criteria [18]. For example, studies estimating the size of the potential HIV+ donor pool excluded HIV+ donors with CD4 counts below 200 cells/uL [12], however the federal HOPE Safeguards and Research criteria do not specify a minimum CD4 threshold for an eligible HIV+ deceased donor (Figure 4). This guideline is supported by the fact that there were no CD4 exclusions applied to HIV+ donors in South Africa [10]. In addition, a recent study demonstrated that in the setting of brain death a donor's CD4 count may not be a reliable metric of infectious risk to the recipient [41]. The federal criteria are fairly minimal: 1) donors cannot have evidence of an active opportunistic infection, 2) any CD4 count or HIV plasma RNA level is allowed, as long as a study team can describe an effective post-transplant antiretroviral regimen in the recipient. These criteria allow transplant center teams to apply clinical judgement to accept organs from HIV+ donors on a case-by-case basis. OPOs may be unaware of this and, as a result, may be inadvertently ruling out potential donors.

In our collaborative work with OPOs on HOPE, we see momentum building for HOPE implementation. Since February 2016, OPOs have been partnering with Johns Hopkins on an NIH-funded project to characterize the epidemiology and biology of the potential HIV+ donor pool. To date, 16 of 58 OPOs (27.6%) have shared 1) clinical data and blood samples from HIV+ potential donors currently deemed medically-ineligible, or 2) clinical data and blood samples from HIV+ donors who proceed to have organs recovered for transplantation (Figure 3).

CONCLUSION

Since signing of the HOPE Act in 2013, significant milestones on the road to full implementation have been reached. Barriers to implementation remain and are multifactorial. Some of these issues are unique to HIV-to-HIV transplantation, however others are magnifications of known challenges to deceased organ donation within the national system. Close collaboration between the same stakeholders who worked toward passage of the HOPE Act could mitigate many of the challenges we have identified. With thoughtful partnerships, solutions developed to improve and increase HIV-to-HIV transplantation could address challenges to organ donation across the transplant system.

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Key Points

- Implementation of the HIV Organ Policy Equity (HOPE) Act through HIV-to-HIV organ donor recovery and transplantation has made progress since the bill became law in 2013.
- Some barriers to implementation are unique to HIV-to-HIV transplantation, however others are magnifications of known challenges to deceased organ donation within the national system.
- Thoughtful partnerships between the same stakeholders who worked toward passage of the HOPE Act could mitigate many of the challenges we have identified.

Figure 1.
Milestones in HOPE Act implementation 2013–2017. HOPE, HIV Organ Policy Equity; OPTN, Organ Procurement and Transplantation Network

Figure 2.
Study design of HOPE in Action. HOPE, HIV Organ Policy Equity; OPTN, Organ Procurement and Transplantation Network.

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Figure 4.

HIVDD research blood samples or donors for transplant by OPO. HOPE, HIV Organ Policy Equity; OPTN, Organ Procurement and Transplantation Network. HIVDD, HIV-to-HIV Deceased Donor.

Table 1.

Transplant Hospitals Participating in HOPE Act Protocols
 Legend: Shaded cells indicate participating center

Centers with Approved UNOS Variance	UNOS Region	Kidney - Deceased Donor	Liver - Deceased Donor	Kidney - Living Donor	Liver - Living Donor
Yale New Haven Hospital; New Haven, CT	1				
Massachusetts General Hospital; Boston, MA	1				
Johns Hopkins Hospital; Baltimore, MD	2				
Hahnemann University Hospital; Philadelphia, PA	2				
Georgetown University Medical Center; Washington DC	2				
University of Maryland Medical System; Baltimore, MD	2				
University of Pittsburgh Medical Center; Pittsburgh, PA	2				
University of Alabama Hospital; Birmingham, AL	3				
Emory University Hospital; Atlanta, GA	3				
Methodist Dallas Medical Center; Dallas, TX	4				
University of California San Francisco Medical Center; San Francisco, CA	5				
University of Minnesota; Minneapolis, MN	7				
Rush University Medical Center; Chicago, IL	7				
Northwestern Memorial Hospital; Chicago, IL	7				
University of Colorado Hospital/Health Science Center; Aurora, CO	8				
New York Presbyterian Hospital/Weill Cornell Medical Center; New York, NY	9				
Montefiore Medical Center; Bronx, NY	9				
NY Presbyterian Hospital/Columbia University Medical Center; New York, NY	9				
Mount Sinai Medical Center; New York, NY	9				
Indiana University Health; Indianapolis, IN	10				
Duke University Hospital; Durham, NC	11				
VCU Medical Center; Richmond, VA	11				