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The Future of HOPE is Now: The State of HIV+ to HIV+ Kidney Transplantation in the United States

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Abstract

Purpose of the review—We report the current state of HIV-to-HIV kidney transplantation in the United States and remaining challenges in implementing this practice nationally.

Recent findings—The HIV Organ Policy Equity (HOPE) Act, which was the first step in unlocking the potential of HIV+ organ donors, mandates clinical research on HIV+ to HIV+ transplantation. As of March 2019, there have been 57 HOPE donors, including both true and false positive HOPE donors resulting in more than 120 transplants.

Summary—The HOPE Act, signed in 2013, reversed the federal ban on the transplantation of organs from HIV+ donors into HIV+ recipients. Ongoing national studies are exploring the safety, feasibility and efficacy of both kidney and liver transplantation in this population. If successfully and fully implemented, HIV+ to HIV+ transplantation could attenuate the organ shortage for everyone waiting, resulting in a far-reaching public health impact.

Keywords

HIV infection; solid organ transplantation; end stage renal disease; kidney transplant; HOPE Act

INTRODUCTION

The HOPE (HIV Organ Policy Equity) Act was passed in 2013 to initiate research on the use of organs from HIV-infected (HIV+) donors (D+) for transplantation into HIV+ recipients (HIV D+/R+). This review serves to outline key issues in kidney transplantation in the HIV R+, major milestones in the implementation of the HOPE Act, the aims of ongoing HOPE in Action studies, and discuss ongoing clinical and logistical challenges.

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CONFLICTS OF INTEREST

None

KIDNEY TRANSPLANTATION IN THE HIV+ PATIENT

Effective antiretroviral therapy (ART) is responsible for the dramatic increase in life expectancy for HIV+ individuals. Though many HIV+ individuals with access to high quality health care can have normal life expectancies, chronic kidney and liver diseases are growing causes of morbidity and now surpass opportunistic complications of HIV as leading causes of death in some cohorts [1]. Approximately 10–30% of HIV+ people develop chronic kidney disease (CKD) [2] secondary to HIV associated nephropathy (HIVAN), nephrotoxic ART, renal disease associated with common co-infections such as hepatitis B (HBV) and hepatitis C (HCV), as well as concomitant atherosclerotic cardiovascular disease, hypertension, and diabetes [3]. Approximately 0.5–1.4% of the nearly 500,000 patients on dialysis in the United States are HIV+; which translates to approximately 900 incident cases per year [4].

Once on dialysis, survival of HIV+ patients is poor: a study in the modern ART era reported a 63% 5-year survival compared to 94% in matched HIV- counterparts [5]. Consequently, over the past 20 years, kidney transplantation (with organs from HIV- donors) has emerged as the ideal treatment for carefully selected HIV+ transplant candidates [6, 7], offering an 80% lower mortality than dialysis [8]. We conducted a study of the Scientific Registry of Transplant Recipients (SRTR) and found 1,698 HIV+ patients on the kidney wait list nationally [9]. These patients were disproportionately young, black and male. Since 2003, there has been a more than a ten-fold increase in the number of HIV+ kidney transplants performed (Figure 1).

We conducted a national study examining long-term outcomes among 510 HIV+ kidney transplant recipients in which we found similar 5-year (75.0% versus 75.8%, P=0.58) and 10-year graft survival (55.9% versus 56.0%, P=0.49) compared with HIV- controls (HR, 1.06; 95% CI, 0.85 to 1.33; P=0.61). HIV+ recipients had similar overall survival compared with HIV- controls at 5 years (88.7% versus 89.1%, P=0.50) and 10 years post-transplant (63.5% versus 77.6%, P=0.10) (HR, 1.26; 95% CI, 0.98 to 1.69; P=0.13) [10]. In the NIH Multi-Site Study (HIV-TR), patient and graft survival were excellent at 5 years: 88% and 70% respectively [11]. The successful implementation of transplantation for appropriate HIV+ transplant candidates, however, is limited by the ever-present organ shortage [12].

In South Africa, where access to dialysis is limited and HIV prevalence is staggeringly high, there have been encouraging outcomes of 30 HIV D+/R+ transplants [13, 14]. The first four were reported in NEJM 2010, with 100% patient survival, excellent graft function, no episodes of rejection, and maintenance of HIV control; subsequent transplants have proven similarly successful. This practice was not possible initially in the US since recovering organs from HIV D+ was federally banned until the HOPE Act.

To provide evidence for HIV D+/R+ transplantation in the US, we analyzed data from two national registries and conservatively estimated a potential of 300–500 HIV D+ per year [15, 16]. After engaging national HIV/AIDS advocacy groups and transplantation organizations, we lobbied Congress to draft a bill which was unanimously passed; and in November 2013, the HOPE Act was signed into law [17]. The worsening and catastrophic opioid epidemic is

likely to contribute more HIV+ deceased donors to the pool: the number of donors nationally with drug intoxication reported as the mechanism of death increased from 342 (4.3%) in 2010 to 1,382 (13.4%) in 2017 ($p<0.001$) [18, 19].

MILESTONES IN HOPE ACT IMPLEMENTATION

The HOPE Act had a three-part mandate. First, the Department of Health and Human Service (DHHS) revised the federal ban on recovery of organs from HIV D+ to allow transplantation within research protocols; this was accomplished on June 8, 2015 [20]. Second, the Organ Procurement Transplant Network (OPTN) wrote policies for the use of HIV D+, including documentation of local Institutional Review Board (IRB) approval and a requirement to submit regular safety reports. These changes were implemented on November 21, 2015 [21]. Third, the National Institutes of Health (NIH) developed the Final Human HOPE Act Safeguards and Research Criteria on November 25, 2015 [22]. Our institution opened the first clinical trial under these criteria and received approval from OPTN on January 8, 2016. The objective of this pilot study was to evaluate the safety of HIV D+/R+ kidney and liver transplantation [23]. In March 2016, as part of this protocol, the first HIV D+/R+ kidney and liver transplants were performed at Johns Hopkins Hospital.

HOPE IN ACTION TRIALS

Encouraging results from the pilot study provided the foundation for two NIH-funded U01 multicenter trials of kidney and liver transplantation which launched in April 2018 and January 2019, respectively [24]. These studies are ongoing and designed to generate evidence and guidance necessary to inform HIV D+/R+ policies by studying the feasibility, safety and effectiveness of HIV-to-HIV transplantation.

HIV+ DECEASED ORGAN DONORS

Federal deceased donor criteria state that eligible HIV D+ must be free of active invasive opportunistic complications of HIV. There is no viral load or CD4 requirement. A donor organ biopsy and description of effective post-transplant ART is required. Other criteria are left to investigator teams including allowing consideration of donors with untreated HIV, co-infection with HCV or HBV, prior AIDS diagnosis, and donation after cardiac death (DCD). The optimal evaluation for a potential HIV D+ would include comprehensive data on the donor's HIV history, ART treatment history and resistance, however the time constraints of the deceased donor process is such that it is not always feasible to obtain comprehensive information prior to organ procurement as some of these tests take weeks to complete.

There are several reasons why the experience and characteristics of HIV+ kidney donors in South Africa is not generalizable to the US. There are key differences between the HIV+ population with respect to race, gender, age, and socio-economic status. In addition, there are differences in HIV subtypes, modes of HIV acquisition, prevalence of HCV coinfection, average viral load and CD4 count, access to ART, type and number of available ART regimens, and access to HIV-specific health care. Other epidemiologic differences include

HIV prevalence (17.8% in South Africa vs. 0.6% in US), annual HIV deaths (310,000 in South Africa vs. 17,000 in US), and transmitted drug resistance (< 5% in South Africa vs. 10–18% in US) [25].

HIV+ LIVING KIDNEY DONORS

HIV+ kidney transplant candidates on the wait list have a 28% lower likelihood of receiving a transplant and a 47% lower rate of living donor transplantation compared to their HIV- counterparts [9]. Wait list candidates are most likely to identify a potential living donor from within their own social network, and for HIV+ individuals, this may translate into identification of donors who are also HIV+. There have been concerns about whether donating a kidney would be safe for an HIV+ individual given the increased risk of CKD in this population. In order to quantify this risk, our group compared the cumulative incidence of ERSD among 41,698 HIV+ individuals in the North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD) with 16,025 HIV- matched peers in the National Health and Nutrition Examination (NHANES) III for various low-risk clinical scenarios based on age, race, renal function, HIV viral load, and CD4+ count [26]. We found that in subgroups with no co-morbidities and well-controlled HIV, the risk increase associated with HIV for a 40-year old was 1 per 10,000 among white females, 2 per 10,000 among white males, 10 per 10,000 among black females, and 11 per 10,000 among black males, risks comparable to that of cigarette smoking, which is not a contraindication to kidney donation. National criteria state that living donors should have well controlled HIV (CD4+ T-cell count > 500 for 6 months before donation; undetectable viral load, no evidence of opportunistic infections).

FALSE POSITIVE DONORS

An unexpected benefit of the HOPE Act is that it has facilitated the allocation of kidneys from donors with suspected false-positive HIV tests, that is, potential donors who had no known history of HIV but had unanticipated, discordant HIV screening tests. Prior to the HOPE Act, kidneys from these donors were generally discarded because of the potential risk of unintentionally transmitting HIV. All deceased donors are screened with an HIV antibody (Ab) test and increased risk donors must also have an HIV nucleic acid test (NAT) [27, 28]. Most (68%) OPOs test *all* donors with HIV NAT, regardless of infectious risk donor (IRD) status [29]. After acquisition, HIV Ab can take 3 to 12 weeks to develop. During this window period, molecular assays that detect viral particles, i.e., a NAT, or that detect HIV antigen (Ag) can diagnose infection within days [30]. The combination of tests is designed to capture acute HIV infection in window period, in other words, Ab-/ NAT+; however, these assays have false positive rates of 0.1–0.5%. In current practice in deceased donor evaluation, there may be insufficient time for confirmation of suspected false-positive HIV screening tests and current OPTN policy does not provide guidance on what to do in these cases [31]. Since the HOPE Act, 16 kidney transplants from the first 10 donors with suspected false-positive HIV tests have been reported with excellent outcomes. These young donors had minimal medical co-morbidities. Given the number of deceased donors tested each with HIV Ab and NAT and the known false positive rates of these assays, we estimated that there will be 50–100 false-positive HOPE donors annually [30].

CLINICAL CHALLENGES

There are biologic issues specific to HIV that are important in the implementation of HIV D+/R+ transplantation [32–34]. One of the main theoretical risks is donor-to-recipient HIV superinfection, defined as recipient acquisition of a distinct HIV strain from the donor. HIV superinfection has been reported with ongoing intravenous drug use (IVDU) and sexual transmission [35]. Potential HIV+ transplant recipients must be on effective ART, and superinfection is thought to occur rarely on ART, however the viral inoculum that occurs with an organ is much higher than that associated with IVDU or sexual transmission. If the donor's virus has significant antiretroviral resistance, superinfection could lead to HIV breakthrough and progression of HIV. Ideally, one would have complete information on any donor HIV resistance at the time of transplant however HIV resistance tests take several weeks to result. While this testing is possible with living kidney donors, in deceased donor transplantation, physicians must rely on medical record review and clinical judgement. Future studies of rates of antiretroviral resistance among HIV+ deceased donors in the US are anticipated.

Increased rates of acute rejection in HIV+ kidney recipients have been reported [36]. Debate continues on the ideal immunosuppression regimen in this population due to concerns about increased rates of infection with lymphocyte depleting regimens. We studied 830 HIV+ recipients between 2000 and 2014 captured by the SRTR and found that those who received induction with anti-thymocyte globulin (ATG) had lower rates of AR (wRR 0.59, 95% CI 0.35–0.99). Induction was not associated with increased infections.

Another theoretical risk of HIV+ donor kidney transplantation is the risk of HIV-associated kidney disease in the allograft. One study of 19 HIV+ kidney transplant recipients (of HIV- organs) demonstrated that although plasma HIV RNA was undetectable, in some recipients, HIV infection of podocytes was observed, resulting in nephrotic-range proteinuria, progressive focal segmental glomerulosclerosis (FSGS) and subsequent renal dysfunction. This complication was not reported in the NIH HIV-TR study [37] or in the South African studies of HIV D+/R+ transplantation [14]. In this study, HIV was also seen to asymptomatically infect tubular cells with little clinical manifestation [38].

IMPACT OF HOPE IN ACTION IN THE FIRST THREE YEARS

Successful implementation of HIV D+/R+ transplantation requires that the HIV+ community, organ procurement organizations (OPOs) and transplant centers are appropriately informed and prepared. As part of HOPE in Action, we have explored knowledge and attitudes towards the HOPE Act among these key stakeholders.

We conduced 114 one-on-one surveys with HIV+ individuals at a clinic in Baltimore, MD between August and October 2016. Among participants (median age 55; 48% female; 91% Black), 90% of respondents believed that HIV+ people should be permitted to donate organs, and 73% thought that using HIV+ donor organs would reduce discrimination [39]. Eighty percent of respondents were willing to be deceased donors. Although nearly all respondents (93.0%) had discussed their HIV status with their next-of-kin, few had

discussed their willingness to donate with them (17.8%) or were registered organ donors (21.1%).

We performed a survey of all 58 OPOs regarding knowledge and attitudes towards the HOPE Act. Fifty-five (95%) OPOS responded and reported support for the HOPE Act and research related to HIV D+/R+ transplantation. The number of referrals of HIV+ donors per OPO was highly variable, ranging from 0 to 276 with 3 OPOs reporting more than 100 referrals. We estimated a potential of 2,164 HIV D+ referrals nationally per year [40], but recognize that many of these referrals might not be eligible donors due to medical reasons or systemic barriers such as late referrals by donor hospitals, lack of brain death testing, low donor registration or authorization rates. With education and training, OPO engagement in HOPE is increasing. In 2016, 16/58 OPOs had evaluated a potential HIV D+; in 2018, the number had increased to 37, and as of March 2019, 46 OPOs (79.3%) were evaluating HOPE donor referrals.

In 2018, we conducted a national survey of transplant centers and found that 50/209 transplant centers reported plans to perform HIV D+/R+ transplants. While ≥1 center in every UNOS region reported planning HIV D+/R+ protocols, the vast majority were clustered in the eastern US [41]. These centers had 2.9-fold higher median annual transplant volume (159 vs 54, $P < 0.01$), higher proportion of transplants using infectious risk donor organs (15% vs 12%, $P < 0.01$), and were located in areas with a higher prevalence of HIV compared to centers not planning to implement HIV D+/R+ transplantation. As of March 2019 according to the OPTN, 31 transplant centers have an active HOPE variance [42].

Since the first HOPE deceased donor kidney transplant in March 2016, there have been 57 HOPE donors as of March 2019, including both true and false positive HOPE donors resulting in more than 120 transplants. Kidney transplant outcomes have not yet been published but reports are anticipated in the near future. The HIV+ first HIV living donor kidney transplant took place at Johns Hopkins in March 2019; and several centers have active protocols listed with OPTN with more HIV+ living kidney donations expected (Figure 2).

CONCLUSION

Organs from HIV D+ represent a unique resource for HIV+ individuals on the transplant waitlist. In addition, every HIV R+ that receives an organ from an HIV D+ decreases the wait time and mortality for HIV- individuals. Therefore, if successfully and fully implemented, HIV D+/R+ transplantation could attenuate the organ shortage for everyone waiting, resulting in a far-reaching public health impact. Future directions include exploring short-term and long-term graft and patient survival.

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This study used data from the Scientific Registry of Transplant Recipients (SRTR) September 2018 public release. The SRTR data system includes data on all donor, wait-listed candidates, and transplant recipients in the US, submitted by the members of the Organ Procurement and Transplantation Network (OPTN), and has been described elsewhere. The Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services provides oversight to the activities of the OPTN and SRTR contractors. The analyses described here

are the responsibility of the authors alone and do not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products or organizations imply endorsement by the U.S. Government. The data reported here have been supplied by the Hennepin Healthcare Research Institute (HHRI) as the contractor for the Scientific Registry of Transplant Recipients (SRTR). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy of or interpretation by the SRTR or the U.S. Government.

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KEY POINTS

1. The HIV Organ Policy Equity (HOPE) Act was the first step in unlocking the potential of HIV+ organ donors; ongoing national studies are exploring the safety, feasibility, and efficacy of kidney transplantation in this population.
2. As of March 2019, there have been 57 HOPE donors, including both true and false positive HOPE donors resulting in more than 120 transplants.
3. So as to maximize the benefit of utilizing HIV+ organ donors, successful implementation of the HOPE Act requires that the HIV+ community, organ procurement organizations, and transplant centers are appropriately informed and prepared.

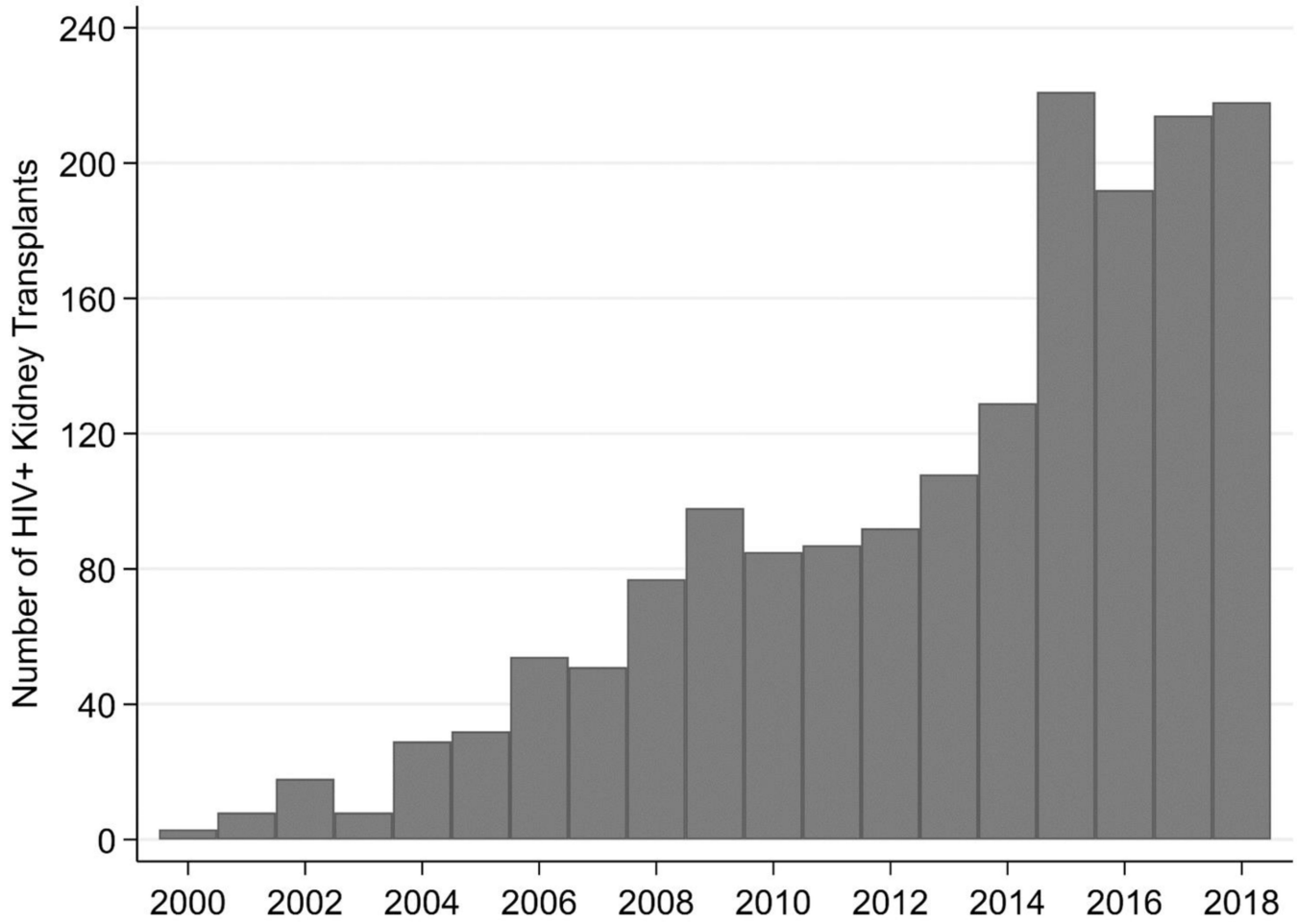

FIGURE 1. Transplants of HIV+ Recipients in the United States 2000–2018.

This figure represents the number of HIV+ transplant recipients (of both HIV+ and HIV- organs) between 2000 and 2018 based on SRTR data.

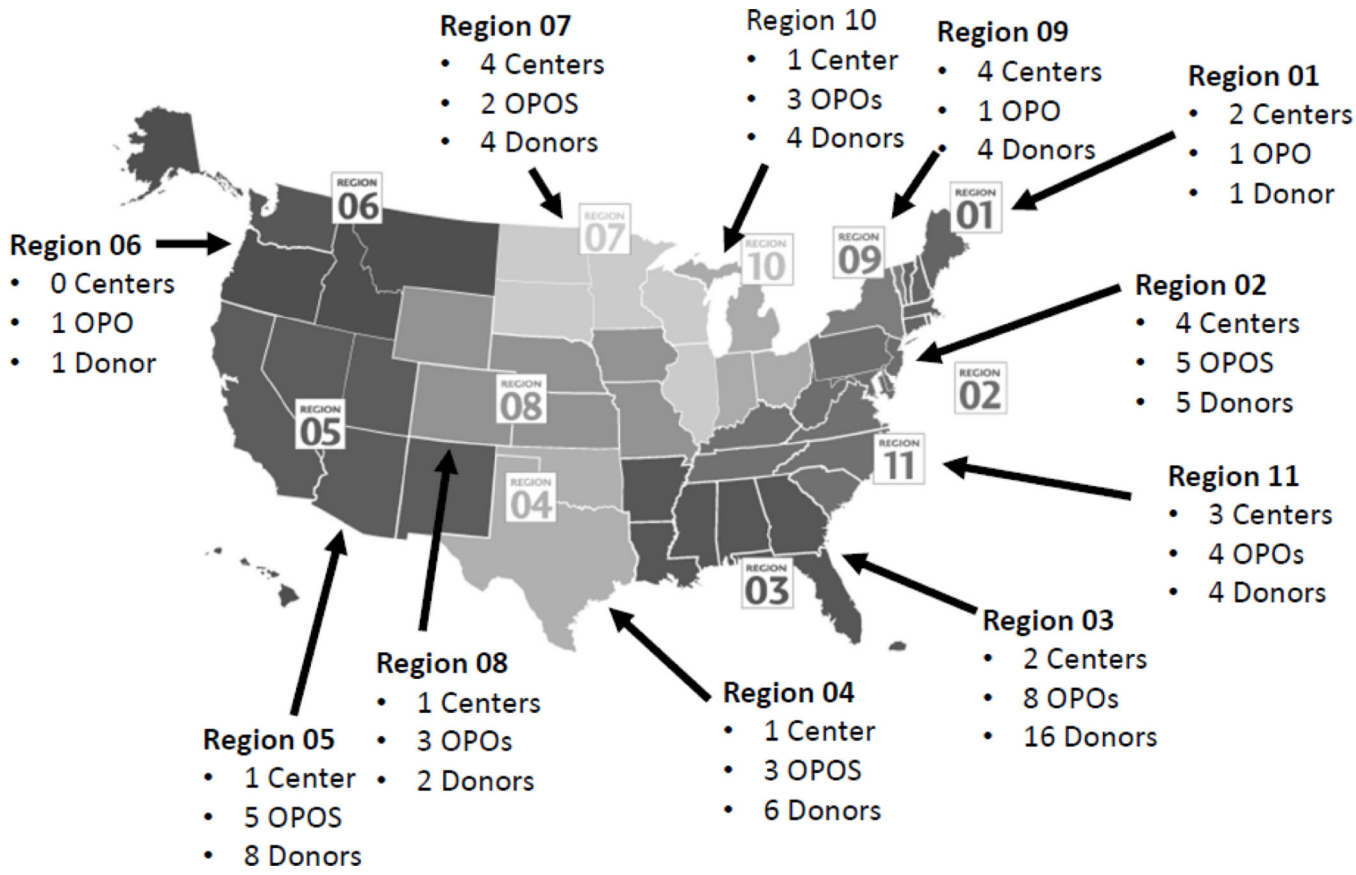

FIGURE 2. National Transplant Center, OPO, HOPE Donors January 2016 - March 2019

This is a map of the US divided by United Network for Organ Sharing (UNOS) regions. Each region has listed the number of transplant centers with an ongoing HOPE protocol, OPOs actively evaluating HOPE donors, and the number of HOPE donors who have had organs recovered for transplant as of March 2019.