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# Living kidney donors with HIV: experience and outcomes from a case series by the HOPE in Action Consortium

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## Summary

**Background** Living kidney donation is possible for people living with HIV (PLWH) in the United States within research studies under the HIV Organ Policy Equity (HOPE) Act. There are concerns that donor nephrectomy may have an increased risk of end-stage renal disease (ESRD) in PLWH due to HIV-associated kidney disease and antiretroviral therapy (ART) nephrotoxicity. Here we report the first 3 cases of living kidney donors with HIV under the HOPE Act in the United States.

**Methods** Within the HOPE in Action Multicenter Consortium, we conducted a prospective study of living kidney donors with HIV. Pre-donation, we estimated the 9-year cumulative incidence of ESRD, performed genetic testing of apolipoprotein L1 (APOL1), excluding individuals with high-risk variants, and performed pre-donation kidney biopsies (HOPE Act requirement). The primary endpoint was ≥grade 3 nephrectomy-related adverse events (AEs) in year one. Post-donation, we monitored glomerular filtration rate (measured by iohexol/Tc-99m DTPA [mGFR] or estimated with serum creatinine [eGFR]), HIV RNA, CD4 count, and ART.

**Findings** There were three donors with two-four years of follow-up: a 35 year-old female, a 52 year-old male, and a 47 year-old male. Pre-donation 9-year estimated cumulative incidence of ESRD was 3.01, 8.01, and 7.76 per 10,000 persons, respectively. In two donors with APOL1 testing, no high-risk variants were detected. Biopsies from all three donors showed no kidney disease. Post-donation, two donors developed nephrectomy-related ≥grade 3 AEs: a medically-managed ileus and a laparoscopically-repaired incisional hernia. GFR declined from 103 to 84 mL/min/1.73 $m^2$ at four years (mGFR) in donor 1, from 77 to 52 mL/min/1.73 $m^2$ at three years (eGFR) in donor 2, and from 65 to 39 mL/min/1.73 $m^2$ at two years (eGFR) in donor 3. HIV RNA remained <20 copies/mL and CD4 count remained stable in all donors.

**Interpretation** The first three living kidney donors with HIV under the HOPE Act in the United States have had promising outcomes at two-four years, providing proof-of-concept to support living donation from PLWH to recipients with HIV.

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Keywords: HIV Organ Policy Equity Act; HOPE Act; Living kidney donation; Transplantation from donors with HIV to recipients with HIV; HIV to HIV transplantation; HIV donation

## Research in context

### Evidence before this study

We searched PubMed for studies of living kidney donation by people living with HIV (PLWH) for recipients with HIV. We combined the search terms "living kidney donation" and "living kidney donors" with "HIV." We excluded 4 cases of unintentional HIV transmission from donors unknown to have HIV to recipients without HIV. We identified 3 retrospective case reports of living kidney donation by PLWH to recipients with HIV, published between 2019 and 2020. In all 3 cases, the PLWH donated to their partners as part of clinical care. Post-donation estimated glomerular filtration rate (eGFR) was 84.4 mL/min/1.73 $m^2$ out to 7 years follow-up in the first case; the other two cases provide one-year eGFR values of 68 and 53 mL/min/1.73 $m^2$.

### Added value of this study

Our study reports the first three living kidney donations by PLWH under the HIV Organ Policy Equity Act in the United States. Unlike the prior clinical case reports, we prospectively studied donation in PLWH under research protocols. Our study included rigorous pre-donation assessments including: estimation of 9-year end-stage renal disease risk, kidney biopsy, screening for genetic markers of increased risk for kidney disease, specifically variants of the apolipoprotein L1 (APOL1) gene, which is associated with a higher risk of ESRD and HIV-associated nephropathy in PLWH, and baseline measurement of glomerular filtration rate (mGFR) by iohexol or Tc-99m DTPA. Post-donation, we monitored for adverse events (AE) using standard AE reporting criteria and provide details on safety, kidney function, and HIV-related outcomes. Our study also included two cases of non-directed donation, highlighting unique motivations to donate among PLWH.

### Implications of all the available evidence

The available evidence provides proof-of-concept that PLWH can safely and successfully donate kidneys to transplant candidates with HIV. There is no evidence to suggest an increased risk of complications or occult underlying kidney disease that warrant additional special procedures, such as pre-donation kidney biopsy.

## Introduction

There is a growing need for kidney transplantation in people living with HIV (PLWH) due to an increased prevalence of end-stage renal disease (ESRD).[1,2] Organ shortages impact PLWH disproportionately, with longer waiting times and higher waitlist mortality,[3,4] and the number of living kidney donors has declined in the United States over most of the last 15 years.[5,6] The Congressional HIV Organ Policy Equity (HOPE) Act of 2013 can lessen these disparities by allowing for living donation from PLWH to recipients with HIV within research protocols.[7,8]

There may be additional benefits to living kidney donation among PLWH. In a survey of PLWH (n = 114) we found that 62% were willing to be living donors.[9] Furthermore, in a follow-up study that performed in-depth interviews among PLWH willing to be living donors, we identified unique motivations and benefits to donation, including solidarity with other PLWH and an opportunity to reduce HIV-related stigma.[10]

However, PLWH who undergo living donor nephrectomy may have increased biological risks, compared to donors without HIV, which are critically important to study. First, the risk of ESRD after donation may be increased for donors with HIV since HIV is independently associated with several types of kidney disease, and certain antiretroviral medications have renal toxicity.[11,12] In addition, PLWH have increased risk for chronic kidney disease (CKD), hypertension, and diabetes, compared with the general population; these comorbidities may contribute to progressive kidney diseases after kidney donation.[13] To better understand the interaction between HIV and living donor nephrectomy, we studied the outcomes of the first 3 living kidney donors with HIV under the HOPE Act in the United States.

## Methods

### Study design and participants

We performed a prospective study of living kidney donation among PLWH at three centers within the HOPE in Action Multicenter Consortium: Duke University, Johns Hopkins University, and Northwestern University. Each center had an independent protocol. In addition to standard clinical criteria for donation,[14] each study protocol included donor requirements as federally mandated by the HOPE Act Safeguards.[8] Specifically, donors must have: no active opportunistic infections, HIV RNA (viral load) <50 copies/mL, a CD4 T-cell count ≥500 cells/μL for the 6 months prior to donation, and a pre-donation biopsy with no evidence of a disease process that would either put the donor at increased risk of progressing to end-stage renal disease after donation or that would present a risk of poor graft function to the recipient.[8] Additionally, the Johns Hopkins and Northwestern study protocols excluded donors with high-risk haplotypes of the APOL1 gene that have been associated with a higher risk of ESRD and HIV-associated

nephropathy, a collapsing variant of focal segmental glomerulosclerosis in PLWH,[15,16] hypertension in donors less than 50 years old,[17,18] or active hepatitis C virus (HCV) infection.

Protocols were approved by each site's institutional review board (IRB); each site had approval from the Organ Procurement and Transplantation Network to perform these transplants. All participants provided written informed consent; donors provided explicit consent to be identified by name as donors and authors in this case series, and this was also approved by each IRB.

### Procedures

Donor characteristics, HIV history, social history, family history, physical examination, and laboratory measures were collected. We used a model previously published by Muzaale et al. to estimate the 9-year cumulative incidence of ESRD based on age, race/ethnicity, sex, diabetes, hypertension, estimated GFR (eGFR) by the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) 2009 creatinine equation, smoking history, HCV status, HIV viral load, CD4 count, history of acquired immune deficiency syndrome, and use of tenofovir disproxil fumarate.[19] Neither the HOPE Act Safeguards nor any study protocol included a specific threshold of estimated 9-year cumulative incidence as eligibility criteria.

Post-donation study visits occurred at months 3, 6, and annually to collect: physical exam, laboratory measures, hospitalizations, medications, serious adverse events, and nephrectomy-related ≥grade 3 adverse events (AEs) defined by National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAE)[20] through year 1. Recipient characteristics and outcomes were collected pre- and post-transplantation. Post-donation, investigators also asked each donor to identify their motivations for donation in an informal interview.

### Outcomes

The primary safety endpoint was the incidence of nephrectomy-related ≥grade 3 AEs in the first year post-donation. Glomerular filtration rate (GFR) was estimated using CKD-EPI 2009 (reported in text and tables) and CKD-EPI 2021 (reported in tables),[21] or measured (mGFR) by iohexol or technetium-99m-diethylenetriaminepeta-acetic acid (Tc-99m DTPA) scan, at pre-donation, month 6, and annually. HIV viral load and CD4 count were measured pre-donation, month 6, and annually.

### Role of the funding source

Study funders had no role in study design, data collection, data analysis, interpretation, writing of the report or decision to submit.

## Results

### Case 1

Donor 1 (Nina Martinez) was a 35 year-old female who acquired HIV at age 6 weeks (Table 1). Her reasons for donation included a desire for autonomy over her decision to donate since deceased donation can be limited by mechanisms of death and systemic barriers for PLWH.[22–25] Her intent was to direct her donation to a friend with ESRD; however, he died unexpectedly during the lengthy donor evaluation. Two additional directed donation attempts were deemed not possible due to ABO-incompatibility, so she ultimately decided upon non-directed donation.

Medical history included *C. difficile* infection, cervical dysplasia, herpes zoster, endometriosis, osteopenia, and depression. There was a history of ART resistance with a T215C mutation in reverse transcriptase. Medications included a single-tablet-regimen containing rilpivirine, tenofovir alafenamide, and emtricitabine, plus bupropion hydrochloride 300 mg daily.

Pre-donation, HIV viral load was <20 copies/mL; CD4 count was 631 cells/μL. Serum creatinine was 0.6 mg/dL; urine albumin creatinine ratio was 2.3 mg/g. No APOL1 risk variants were detected (Table 1). Abdominal CT showed a 0.2 cm non-obstructing calculus on the lower pole of the left kidney. She underwent a Tc-99m DTPA scan due to the stone, which demonstrated a split GFR of 57.9 mL/min/1.73 $m^2$ on the left kidney and 49.8 mL/min/1.73 $m^2$ on the right kidney, for a total GFR of 107.7 mL/min/1.73 $m^2$. Left kidney biopsy showed histologically unremarkable glomeruli, mild arteriosclerosis and arteriolar hyalinosis. The 9-year cumulative incidence of ESRD was estimated at 3.01 per 10,000 persons.

She underwent laparoscopic nephrectomy of the left kidney without complications and was discharged home after three days. Approximately 15 months post-donation, she developed sinus tachycardia with an extensive negative work-up; tachycardia improved with nadolol, treatment with ferrous gluconate for iron deficiency without anemia,[26] and reduction of bupropion hydrochloride to 150 mg every other day. Hypercalcemia was noted at the end of year two and was attributed to calcium supplementation of 600 mg daily, which she began at month 14. All of these medications and supplements were later discontinued between 24 and 36 months post-donation without recurrence of symptoms.

mGFR by iohexol was 103, 83, 78, 86, and 84 mL/min/1.73 $m^2$ at pre-donation, 6 months, two, three, and four years post-donation, respectively (year 1 visit missed due to COVID-19 protections). eGFR was 118, 74, 74, 82, and 73 mL/min/1.73 $m^2$ at pre-donation, 6 months, one, two, three, and four years post-donation, respectively. ART remained unchanged and HIV viral load remained <20 copies/mL with a stable CD4 count (Tables 1 and 2).

The recipient (Table 3) had immediate graft function, received induction immunosuppression with antithymocyte globulin (ATG) and maintenance immunosuppression with mycophenolate mofetil (MMF), tacrolimus, and prednisone. eGFR has ranged from 39 to 47 mL/min/1.73 $m^2$ through four years post-transplant (Table 4). He

| Demographics | Donor 1 | Donor 2 | Donor 3 |
|---|---|---|---|
| Age at donation | 35 years | 52 years | 47 years |
| Sex | Female | Male | Male |
| Race | White | White | White |
| Hispanic/Latino ethnicity | Yes | No | No |
| Highest education | Bachelor's degree | Master's degree | Master's degree |
| Medical insurance type | Private | Private | Private |
| Employment status | Full time | Full time | Full time |
| **Recommended pre-donation evaluation criteria, regardless of HIV status** | | | |
| Smoking history | No | Yes | No |
| Family history of kidney disease | No | No | No |
| Blood pressure | 111/63 mmHg | 126/85 mmHg | 132/86 mmHg |
| Body mass index | 20.3 kg/m$^2$ | 30 kg/m$^2$ | 28.3 kg/m$^2$ |
| Glycated hemoglobin | 5.1% | 5.2% | 5.5% |
| Fasting total cholesterol | 189 mg/dL | 160 mg/dL | 217 mg/dL |
| Calcium | 9.6 mg/dL | 9.8 mg/dL | 10.1 mg/dL |
| Phosphorus | 3.2 mg/dL | 3.5 mg/dL | 3.3 mg/dL |
| Parathyroid hormone | 51 pg/mL | ND | ND |
| Serum creatinine | 0.6 mg/dL | 1.1 mg/dL | 1.3 mg/dL |
| eGFR* | 118 (120) mL/min/1.73 m$^2$ | 77 (81) mL/min/1.73 m$^2$ | 65 (68) mL/min/1.73 m$^2$ |
| mGFR, Tc-99m DTPA | 107.7 mL/min/1.73m$^2$ | 108.8 mL/min/1.73 m$^2$ | 108.3 mL/min/1.73 m$^2$ |
| mGFR, iohexol | 103 mL/min/1.73 m$^2$ | ND | 72 mL/min/1.73 m$^2$ |
| Urine ACR | 2.3 mg/g | 6.9 mg/g | 3 mg/g |
| Presence of hematuria | No | No | No |
| CMV IgG | Negative | Positive | Positive |
| **Additional pre-donation evaluation criteria, specific to research protocol for donors with HIV** | | | |
| Absolute CD4 | 631 cells/μL | 757 cells/μL | 521 cells/μL |
| HIV viral load | <20 c/mL | <20 c/mL | <20 c/mL |
| ART | RPV TAF FTC | ABC 3TC DTG | RPV DTG |
| Drug resistant mutations | T215C | None | Y181C, H221Y |
| Cystatin C | 0.59 mg/L | ND | ND |
| eGFR cystatin C | 125 mL/min/1.73 m$^2$ | ND | ND |
| Pre-implant kidney biopsy | Acceptable | Acceptable | Acceptable |
| APOL1 risk alleles | None | ND | None |

eGFR*, estimated glomerular filtration rate with Chronic Kidney Disease Epidemiology (CKD-EPI) 2009 equation and CKD-EPI 2021 equation estimate following in parentheses; mGFR, measured glomerular filtration rate; ND, no data; ACR, albumin/creatinine ratio; CMV, cytomegalovirus; IgG, immunoglobulin G; ART, antiretroviral therapy; RPV, rilpivirine; TAF, tenofovir alafenamide; FTC, emtricitabine; ABC, abacavir; 3TC, lamivudine; DTG, dolutegravir; APOL1, apolipoprotein L1.

***Table 1:*** **Pre-donation characteristics of living kidney donors with HIV.**

has had three hospitalizations: cytomegalovirus colitis 6 months post-transplant, *C. difficile* colitis 8 months post-transplant, and syphilis at year three, all of which resolved with treatment. HIV viral load remained <20 copies/mL. CD4 count increased after ATG from 16 cells/μL one month post-transplant to 288 cells/μL at year four (Table 4). The recipient said this transplant gives him an opportunity to fully maximize this second stage of life and allows him to achieve new goals.

## Case 2

Donor 2 (Karl Neumann) was a 52 year-old man who acquired HIV at age 42 (Table 1). He was a non-directed donor whose primary motivation for donation was to help someone discontinue dialysis and improve their quality of life; he also appreciated the opportunity to reduce HIV-associated stigma. He works in the transplant field, specifically in organ procurement.

Medical history included hypertension and obesity, which were medically-controlled with weight loss. He had a prior 15 pack-year smoking history but quit smoking and was able to lose approximately 50 pounds prior to nephrectomy. He had no prior opportunistic infections or ART resistance. Medication included a single-tablet combination of efavirenz, emtricitabine, and tenofovir disoproxil fumarate.

Pre-donation, HIV viral load was <20 copies/mL and CD4 count 757 cells/μL. Serum creatinine was 1.1 mg/dL; urine albumin creatinine ratio was 6.9 mg/g. Pre-donation ART was modified to a single-tablet regimen containing abacavir, lamivudine, and dolutegravir. mGFR was 108.8 mL/min/1.73 m$^2$ by Tc-99m DTPA

| | Donor 1 | Donor 2 | Donor 3 |
|---|---|---|---|
| **Post-donation follow-up outcomes, regardless of HIV status** | | | |
| Last follow-up time point | Year 4 | Year 3 | Year 2 |
| Blood pressure | 112/77 mmHg | 145/84 mmHg | 134/80 mmHg |
| SCr, year 1 | 0.99 mg/dL | 1.7 mg/dL | 1.93 mg/dL |
| Year 2 | 0.98 mg/dL | 1.6 mg/dL | 1.95 mg/dL |
| Year 3 | 0.90 mg/dL | 1.5 mg/dL | NA |
| Year 4 | 0.98 mg/dL | NA | NA |
| eGFR*, year 1 | 74 (76) mL/min/1.73 $m^2$ | 48 (51) mL/min/1.73 $m^2$ | 40 (41) mL/min/1.73 $m^2$ |
| Year 2 | 74 (76) mL/min/1.73 $m^2$ | 48 (51) mL/min/1.73 $m^2$ | 39 (41) mL/min/1.73 $m^2$ |
| Year 3 | 82 (84) mL/min/1.73 $m^2$ | 52 (55) mL/min/1.73 $m^2$ | NA |
| Year 4 | 73 (76) mL/min/1.73 $m^2$ | NA | NA |
| Urine ACR, year 1 | <4 mg/g | ND | 41 mg/g |
| Year 2 | 3 mg/g | 26 mg/g | 64 mg/g |
| Year 3 | <2 mg/g | 39 mg/g | NA |
| Year 4 | <2 mg/g | NA | NA |
| Calcium, year 1 | 9.7 mg/dL | 9.6 mg/dL | 9.6 mg/dL |
| Year 2 | 11.3 mg/dL | 9.6 mg/dL | 10.2 mg/dL |
| Year 3 | 9.5 mg/dL | 8.7 mg/dL | NA |
| Year 4 | 9.6 mg/dL | NA | NA |
| Phosphorus, year 1 | 3.9 mg/dL | 3.4 mg/dL | ND |
| Year 2 | 3.0 mg/dL | 4.4 mg/dL | 2.5 mg/dL |
| Year 3 | 2.3 mg/dL | 3.1 mg/dL | NA |
| Year 4 | 2.2 mg/dL | NA | NA |
| PTH, year 1 | 17 pg/mL | ND | ND |
| Year 2 | 58 pg/mL | ND | ND |
| Year 3 | 74 pg/mL | 44 pg/mL | NA |
| Year 4 | 67 pg/mL | NA | NA |
| **Post-donation follow up outcomes, specific to research protocol for donors with HIV** | | | |
| Cystatin C⁺, month 6 | 0.94 mg/L (87 mL/min/1.73 $m^2$) | ND | ND |
| Year 1 | ND | ND | ND |
| Year 2 | 0.91 mg/L (90 mL/min/1.73 $m^2$) | ND | ND |
| Year 3 | 0.90 mg/L (90 mL/min/1.73 $m^2$) | ND | NA |
| Year 4 | 1.0 mg/L (79 mL/min 1.73 $m^2$) | ND | NA |
| mGFR, iohexol, month 6 | 83 mL/min/1.73 $m^2$ | ND | ND |
| Year 1 | ND | ND | ND |
| Year 2 | 78 mL/min/1.73 $m^2$ | ND | ND |
| Year 3 | 86 mL/min/1.73 $m^2$ | ND | NA |
| Year 4 | 84 mL/min/1.73 $m^2$ | NA | NA |
| HIV viral load, year 1 | <20 c/mL | <20 c/mL | <20 c/mL |
| Year 2 | <20 c/mL | <20 c/mL | <20 c/mL |
| Year 3 | <20 c/mL | <20 c/mL | NA |
| Year 4 | <20 c/mL | NA | NA |
| Absolute CD4, year 1 | 473 cells/μL | 511 cells/μL | 984 cells/μL |
| Year 2 | 643 cells/μL | 574 cells/μL | ND |
| Year 3 | 599 cells/μL | 398 cells/μL | NA |
| Year 4 | 675 cells/μL | NA | NA |
| ART post-donation | RPV TAF FTC | ABC 3TC DTG | DOR 3TC DTG |
| Changes to ART due to renal function | No | No | No |

NA, not applicable; SCr, serum creatinine; eGFR*, estimated glomerular filtration rate with Chronic Kidney Disease Epidemiology (CKD-EPI) 2009 equation and CKD-EPI 2021 equation estimate following in parentheses; ACR, albumin/creatinine ratio; PTH, parathyroid hormone; Cystatin C⁺, estimated glomerular filtration rate with CKD-EPI Cystatin C 2012 equation following in parentheses; ND, no data; ART, antiretroviral therapy; RPV, rilpivirine; TAF, tenofovir alafenamide; FTC, emtricitabine; ABC, abacavir; 3TC, lamivudine; DTG, dolutegravir; DOR, doravirine.

***Table 2:*** **Post-donation outcomes of living kidney donors with HIV.**

| Demographics | Recipient 1 | Recipient 2 | Recipient 3 |
|---|---|---|---|
| Age at transplant | 47 years | 52 years | 48 years |
| Sex | Male | Male | Male |
| Race | Black | Black | White |
| Hispanic/Latino ethnicity | No | No | Yes |
| **Pre-transplant evaluation criteria, regardless of HIV status** | | | |
| Comorbidities | Hypertension, diabetes | Hypertension, diabetes | Hypertension |
| Body mass index | 27.8 kg/m$^2$ | 20.1 kg/m$^2$ | 30.2 kg/m$^2$ |
| CMV IgG | Positive | Positive | Positive |
| **Pre-transplant evaluation criteria, specific to research protocol for recipients with HIV** | | | |
| Prior opportunistic infection | None | None | None |
| Absolute CD4 | 1017 cells/μL | 511 cells/μL | 1211 cells/μL |
| HIV viral load | <20 c/mL | <20 c/mL | <20 c/mL |
| ART | RAL TDF FTC | RAL DRV$^r$ ETR | DTG RPV |

CMV, cytomegalovirus; IgG, immunoglobulin G; ART, antiretroviral therapy; RAL, raltegravir; TDF, tenofovir disproxidil fumarate; FTC, emtricitabine; DRV$^r$, ritonavir-boosted darunavir; ETR, etravirine; DTG, dolutegravir; RPV, rilpivirine.

***Table 3:*** **Pre-transplant characteristics of recipients with HIV.**

| | Recipient 1 | Recipient 2 | Recipient 3 |
|---|---|---|---|
| **Post-transplant outcomes, regardless of recipient HIV status** | | | |
| Transplant length of stay | 4 days | 26 days | 12 days |
| Induction immunosuppression | ATG | Basiliximab | Basiliximab |
| Maintenance immunosuppression | Tacrolimus, Pred, MMF | Tacrolimus, Pred, MMF | Tacrolimus, Pred, MMF |
| Any rejection | No | Yes | Yes |
| eGFR*, month 6 | 43 (39) mL/min/1.73 m$^2$ | 57 (52) mL/min/1.73 m$^2$ | 59 (62) mL/min/1.73 m$^2$ |
| Year 1 | 43 (39) mL/min/1.73 m$^2$ | 38 (35) mL/min/1.73 m$^2$ | 59 (62) mL/min/1.73 m$^2$ |
| Year 2 | 47 (43) mL/min/1.73 m$^2$ | 52 (47) mL/min/1.73 m$^2$ | 54 (56) mL/min/1.73 m$^2$ |
| Year 3 | 39 (36) mL/min/1.73 m$^2$ | 55 (51) mL/min/1.73 m$^2$ | NA |
| Year 4 | 38 (35) mL/min/1.73 m$^2$ | ND | NA |
| **Post-transplant outcomes, specific to research protocol for recipients with HIV** | | | |
| HIV viral load, year 1 | <20 c/mL | <20 c/mL | <20 c/mL |
| Year 2 | <20 c/mL | <20 c/mL | <20 c/mL |
| Year 3 | <20 c/mL | <20 c/mL | NA |
| Year 4 | <20 c/mL | NA | NA |
| Absolute CD4, month 1 | 16 cells/μL | 28 cells/μL | 49 cells/μL |
| Year 1 | 380 cells/μL | 156 cells/μL | 288 cells/μL |
| Year 2 | 254 cells/μL | 258 cells/μL | 708 cells/μL |
| Year 3 | 242 cells/μL | 270 cells/μL | NA |
| Year 4 | 280 cells/μL | NA | NA |
| ART post-transplant | BIC TAF FTC | RAL DRV$^r$ ETR | DOR 3TC DTG |

NA, not applicable; ATG, antithymocyte globulin; Pred, prednisone; MMF, mycophenolate mofetil; eGFR*, estimated glomerular filtration rate with Chronic Kidney Disease Epidemiology (CKD-EPI) 2009 equation and CKD-EPI 2021 equation estimate following in parentheses; ND, no data; ART, antiretroviral therapy; BIC, bictegravir; TAF, tenofovir alafenamide; FTC, emtricitabine; RAL, raltegarvir; DRV$^r$, ritonavir-boosted darunavir; ETR, etravirine; DOR, doravirine; 3TC, lamivudine; DTG, dolutegravir.

***Table 4:*** **Post-transplant outcomes of recipients with HIV.**

scan (Table 1). Kidney biopsy revealed histologically unremarkable glomeruli. The 9-year cumulative incidence of ESRD was estimated at 8.01 per 10,000 persons.

He underwent laparoscopic donor nephrectomy and was discharged home after one day. Post-donation, he developed a ventral hernia that required laparoscopic repair on day 456 and again on day 910.

Pre-donation mGFR was 108.8 mL/min/1.73 m$^2$, and eGFR was 77, 48, 48, and 52 mL/min/1.73 m$^2$ at pre-donation, one, two, and three years post-donation, respectively. ART remained unchanged and HIV viral load stayed at <20 copies/mL with a stable CD4 count (Table 2).

The recipient (Table 3) received induction immunosuppression with basiliximab and maintenance

immunosuppression with MMF, tacrolimus, and prednisone (Table 4). The recipient experienced Banff 2A rejection on post-transplant day 10 and was treated with ATG (total dose 6 mg/kg) on post-transplant days 26 through 28. Renal function has been stable with an eGFR range of 38–57 mL/min/1.73 $m^2$ through 3 years. A kidney biopsy at one year post-transplant demonstrated borderline inflammation, mild arteriosclerosis, and calcineurin inhibitor toxicity. The recipient's immunosuppression was modified to prednisone and monthly belatacept beginning post-transplant at month 20.

The recipient's ART was raltegravir, ritonavir-boosted twice daily darunavir, and etravirine. HIV viral load remained <20 copies/mL; CD4 count increased from 28 cells/μL one month post-transplant to 270 cells/μL at three years. The recipient expressed that the transplant had given him hope for a sustainable future with family and friends.

### Case 3

Donor 3 (Reed Benedict) was a 47 year-old man who acquired HIV at age 39 (Table 1). His motivations for donation included helping his husband who was living with HIV and ESRD.

Past medical history included syphilis, hepatitis A, hepatitis B infection, methicillin-resistant *Staphylococcus aureus*-related furunculosis, recurrent *C. difficile* infection, and depression. ART resistance testing was completed pre-donation; however, results were not available at the time of transplant. Medications included a single-tablet regimen containing elvitegravir with cobicistat, emtricitabine, and tenofovir alafenamide, plus desvenlafaxine.

Pre-donation, HIV viral load was <20 copies/mL and CD4 count was 521 cells/μL. Serum creatinine was 1.3 mg/dL; urine albumin creatinine ratio was 3 mg/g. No APOL1 risk variants were detected. During evaluation, the donor was found to have elevated blood pressure. Retinal exam and transthoracic echocardiogram were normal. Blood pressure normalized after stopping desvenlafaxine; therefore, he was considered eligible despite age <50 years. Pre-donation, the clinical team decided to change ART to rilpivirine and dolutegravir in order to avoid tenofovir alafenamide. Tc-99m DTPA scan revealed mGFR of 108.3 mL/min/1.73 $m^2$. Kidney biopsy showed mild acute tubular necrosis, arteriosclerosis, and very mild tubulo-interstitial disease. The 9-year cumulative incidence of ESRD was estimated at 7.76 per 10,000 persons.

The donor underwent laparoscopic nephrectomy and was discharged home after a day but readmitted the following day with ileus, which was managed medically. The patient had hypertension diagnosed during this admission and nifedipine 30 mg was started.

Pre-donation mGFR with iohexol was 72 mL/min/1.73 $m^2$. eGFR was 65, 40, and 39 mL/min/1.73 $m^2$ at pre-donation, one- and two-years post-donation, respectively (Tables 1 and 2).

On day 41 post-nephrectomy, ART was changed to dolutegravir, lamivudine, and doravirine when proviral genotypic resistance testing showed Y181C and H221Y mutations. HIV viral load remained <20 copies/mL and CD4 count was stable (Table 2).

The recipient (Table 3) received induction immunosuppression with basiliximab and maintenance immunosuppression with MMF, tacrolimus, and prednisone (Table 4). They experienced Banff 1A rejection diagnosed on post-transplant day 7 and received ATG (total dose 6 mg/kg) on days 8–11. eGFR has been stable at 54 mL/min/1.73 $m^2$ through year 2. The post-transplant course was complicated by ureteral leak requiring nephrostomy tube and hospitalization three months post-transplant for hematuria after allograft biopsy. Kidney biopsy at one year post-transplant demonstrated focal glomerulosclerosis (11%), mild interstitial fibrosis, tubular atrophy, and mild arteriosclerosis without significant arteriolar hyalinosis. At day 42 post-transplant, recipient ART was changed from dolutegravir and rilpivirine to dolutegravir, lamivudine, and doravirine when the donor proviral genotype testing showed mutations associated with first-generation NNRTI resistance (Table 4). HIV viral load remained <20 copies/mL; CD4 count increased from 49 cells/μL at one month post-transplant to 709 cells/μL at 2 years. The recipient expressed gratitude, noting their experience has been rewarding, giving them a new lease on life and opening doors for others in the same position.

## Discussion

In this first series of living kidney donation in PLWH under the HOPE Act, we observed no serious complications related to nephrectomy. Pre-donation, all three donors had an estimated 9-year cumulative incidence of ESRD between 3.01 and 8.01 cases per 10,000 persons and had acceptable kidney biopsies. We observed expected post-donation kidney function declines with follow-up, and donors continued with excellent HIV control. Importantly, donors cited unique benefits and motivations, such as autonomy and reducing HIV-associated stigma.

For donor 1, in whom we had longitudinal mGFR values post-donation, we observed a 19 mL/min/1.73 $m^2$ decrease which was an 18% decline, similar to what is reported after nephrectomy for donors without HIV.[27] Prior to our case series, there have been three international single-patient case reports of living donor HIV-to-HIV kidney transplants that included donor outcomes.[28–30] The first occurred in Israel from a 41 year-old woman to her 50 year-old husband.[28] The second was an ABO-incompatible transplant in Germany from a 49 year-old man to his 51 year-old partner.[29] The third was in India, from a 48 year-old woman to her 52 year-old husband.[30] In the Israel case, the donor experienced

a 24% reduction in eGFR declining from 110 mL/min/1.73 $m^2$ to 84.4 mL/min/1.73 $m^2$ at one year and remaining stable through 7 years of follow-up.[28] The German case reported a one-year eGFR in the donor of 68 mL/min/1.73 $m^2$, but pre-donation eGFR was not reported.[29] The India case reported pre-donation mGFR 90 mL/min/1.73 $m^2$ based on DTPA and a one-year eGFR of 53 mL/min/1.73 $m^2$; percent reduction could not be calculated as neither pre-donation eGFR nor one-year DTPA mGFR was included in the report.[30] The literature also includes a case report in which a living kidney donor was later discovered to have HIV at the time of donation; after 11 years of follow-up, the donor is reported to have had no renal or HIV-related complications, with last GFR >80 mL/min/1.73 $m^2$.[31]

In our donors 2 and 3, post-donation eGFRs were <60 mL/min/1.73 $m^2$. It is not unusual for some donors to have GFR in this range after unilateral nephrectomy, and evidence suggests that reduced GFR alone does not lead to CKD-associated morbidity and mortality.[32] In addition, pre-donation mGFR in these donors were 40% and 66% higher than their eGFR. This suggests their post-donation eGFR may similarly underestimate their true renal function. Both donors were on integrase strand transferase inhibitors, which have been shown to inhibit creatinine secretion and lead to a lower eGFR calculated using creatinine, while not impacting mGFR.[33] Other ART have been shown to have a similar effect on creatinine excretion.[11] Post-donation, we cannot confirm that the mGFR remains substantially higher than eGFR because the physicians caring for these donors do not think additional GFR measurements are clinically indicated. Discordance between mGFR and eGFR should be kept in mind by HIV clinicians and transplant programs when referring and screening PLWH who want to donate, in order to avoid inappropriately excluding potential donors.

One of our donors had an elevated blood pressure prior to donation, which normalized after stopping desvenlafaxine. Post-donation, this donor did develop persistently elevated blood pressures requiring medication. In the prior case reports of living kidney donors with HIV, two donors were reported to have medically-controlled hypertension.[28,29] The first donor was reported to have progression of hypertension, requiring two agents to control their blood pressure,[28] and the other case report does not provide details on post-donation blood pressure control.[29] Development of onset hypertension or worsening of pre-existing hypertension is a known risk of donation generally.[34]

At two centers, our protocol included determination of APOL1 genotypes, due to the evidence that carriage of two high-risk APOL1 haplotypes can interact with HIV to greatly increase the risk of HIV-associated nephropathy.[15,16] The variant alleles are found on African-origin chromosomes; the combined haplotype frequency for African Americans is approximately 36%, with about 13% carrying two risk haplotypes.[35] We determined APOL1 genotypes in all donors, regardless of reported race, as race is not a proxy for genetic ancestry.[36] We did not detect any high-risk alleles in the two donors who had genotype testing results.

All our donors were required to undergo kidney biopsy prior to donation, in accordance with research guidelines mandated by the United States government.[8] No abnormalities were identified that indicated a higher risk for chronic kidney disease post-donation. In the international case reports of living donor HIV-to-HIV kidney transplants, no pre-donation biopsies were performed.[28–30] The biopsy requirement in the United States for PLWH goes beyond what is done in clinical practice for living kidney donors without HIV, for whom biopsies are only pursued if there is hematuria or other concerns during evaluation that warrant an invasive procedure to rule out occult disease.[14] In addition, the biopsy requirement lengthened the evaluation process for our first donor; this delay was particularly unfortunate because her intended first recipient died due to complications of ESRD. Of note, in 2020 the federal Advisory Committee on Organ Transplantation in the United States remarked that the HOPE Act requirement for pre-donation kidney biopsy for PLWH seems potentially unnecessary and merits reconsideration.[37]

Using a previously published multivariable Cox proportional hazards model specific for PLWH,[19] we estimated the 9-year cumulative incidence of ESRD to be between 3.01 and 8.01 cases per 10,000/persons for our three donors. The cumulative incidence estimate was derived from the linear function of explanatory variables for the individual, and the number of years of follow-up was set at 9 years. We found that this 9-year incidence in PLWH is 1.8-fold higher than observed among donor candidates with comparable demographic and clinical characteristics but no HIV diagnosis.[19] Nonetheless, donor candidates with HIV have a cumulative incidence of ESRD similar that observed among smokers, and this is not a contraindication to donation.[19,38]

One of our donors donated to a spouse, and two were non-directed donors. Our non-directed donors were motivated to donate, in part, by a commitment to reduce HIV-related stigma and to overcome barriers to donation for PLWH. A high willingness to donate has been found in PLWH, ranging from 62 to 72%, in surveys from the United States, the United Kingdom, and Taiwan.[9,39,40] In a qualitative study where we interviewed PLWH who expressed a desire to be living donors, interviewees cited altruistic motivations, such as wanting to help others, plus HIV-specific reasons and unique benefits such as: solidarity with PLWH, an opportunity to combat stigma and restore a sense of normalcy, a way to give back out of gratitude for medical advances in HIV, and a chance to contribute to science in general.[10] As providers consider risks of donation among PLWH,

emotional and psychological benefits should also be considered.

Two of our three recipients experienced early allograft rejection. Both had received basiliximab induction and subsequently required ATG treatment. In contrast, the recipient who received ATG induction had no rejection. This observation aligns with prior data suggesting that ATG induction is associated with a lower rejection risk in deceased donor kidney transplantation, specifically between donors with HIV and recipients with HIV.[41]

Limitations of our study include the fact that it is a small case series. The COVID-19 pandemic impacted living kidney donor transplantation in the United States, with many centers halting living donor transplants at the beginning of the pandemic. This was a barrier to recruitment and follow-up since in-person research visits were also limited. In addition, this report includes only early outcomes. The lifetime risk of ESRD in PLWH remains unknown post-donation, and larger studies with longer follow-up are needed. However, of note, the two to four years of follow-up in these three cases is longer than currently mandated follow-up in the United States for living donors without HIV.

Strengths of our study include that it is, to our knowledge, the first case series of living kidney donation in PLWH in the world; it includes donors at different transplant centers, with different demographics and motivations for donation. Donation and transplantation were done under research protocols with pre-defined inclusion criteria and assessment of APOL1 genotyping. Further, we used mGFR in addition to eGFR, the latter of which has been shown to have limitations in PLWH.[42]

In conclusion, we report the first three successful living kidney donations from donors with HIV to recipients with HIV under the HOPE Act, providing proof-of-concept that donation can be safe. The approach to evaluation and follow-up provides additional transplantation options to benefit both potential donors and recipients with HIV.

#### Contributors

CMD, CRW, VS, FAA, ABM, and DLS conceived and designed the study. CMD wrote the manuscript with revisions by NM, and all authors read and approved the final manuscript. CAW performed genetic testing and interpretation of those results. CMD, NM, VS, AS, ZD, LG, MC, WC, DF, DB, AART, FAA, helped with data acquisition and interpretation of the findings. All authors had full access to the data in the study and had final responsibility for the decision to submit the manuscript.

#### Data sharing statement

Study data are stored at Johns Hopkins University School of Medicine. Proposals to access de-identified data can be submitted to christinedurand@jhmi.edu after publication and, upon approval of data request, a data use agreement will be set up before data transfer.

#### Declaration of interests

DLS reports serving as a consultant and receiving honoraria for speaking from AstraZeneca, Novavax, Novartis, CareDx, Transmedics, Sanofi, CSL Behring, Jazz Pharmaceuticals, Veloxis, Mallinckrodt, and Thermo Fisher Scientific. CMD reports serving on a grant review committee for Gilead Sciences. AS reports serving on an advisory board for Veloxis Pharmaceuticals. All other authors of this manuscript have no conflicts of interest to disclose as described by *The Lancet*.

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