



Raising the Bar: Updates In Organ Transplantation
for People with HIV/AIDS

Sapna A. Mehta, MD, FIDSA

Director, Transplant Infectious Diseases
Clinical Director, NYU Langone Transplant Institute
Associate Professor of Medicine
NYU Grossman School of Medicine, New York, NY



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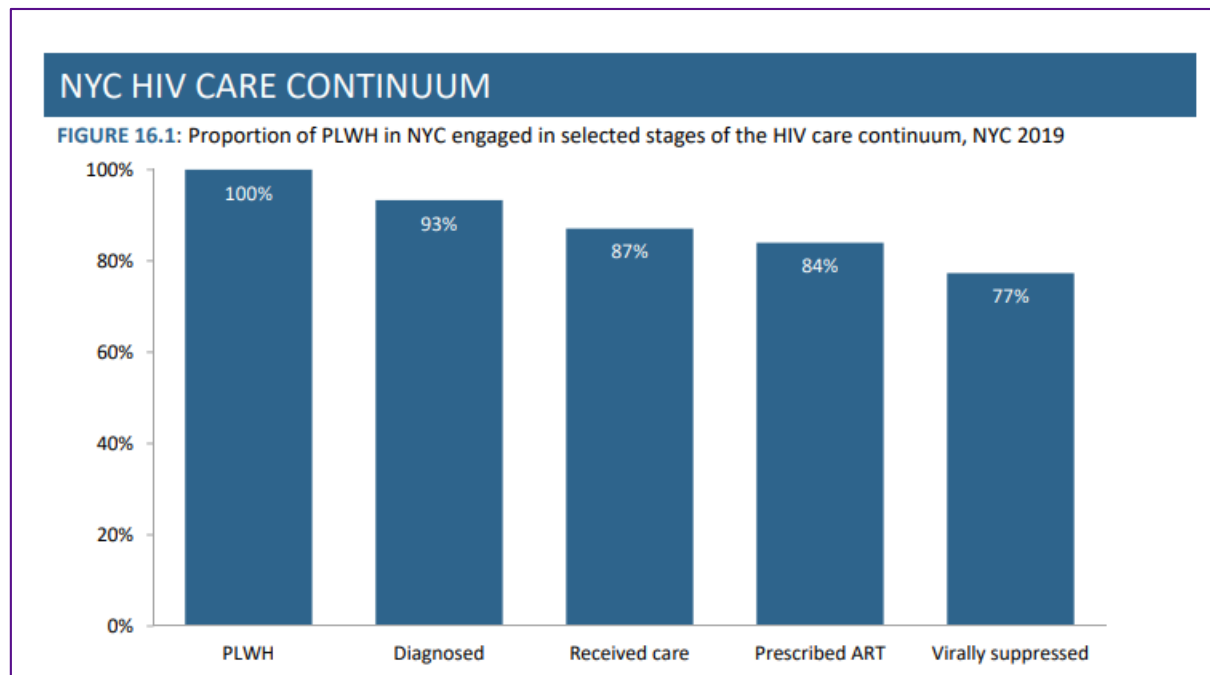
Overview

- Evolution of organ transplantation options for people living with HIV (PLWH)
 - Success of HIV treatment and longer life expectancy
 - Abdominal transplantation for PLWH
 - Thoracic transplantation for PLWH
 - HIV Organ Policy Equity (HOPE) Act
- Recent lessons in transplantation for PLWH
 - Access to kidney and liver transplant under the HOPE Act
 - HOPE kidney and liver transplant clinical outcomes
 - Living kidney donors with HIV
- Future directions
 - HOPE heart and lung transplants
 - Managing newer antiretroviral therapy (ART) agents in transplant recipients
 - Increasing organ donation awareness among PLWH

EVOLUTION OF ORGAN TRANSPLANTATION OPTIONS FOR WITH HIV (PLWH)



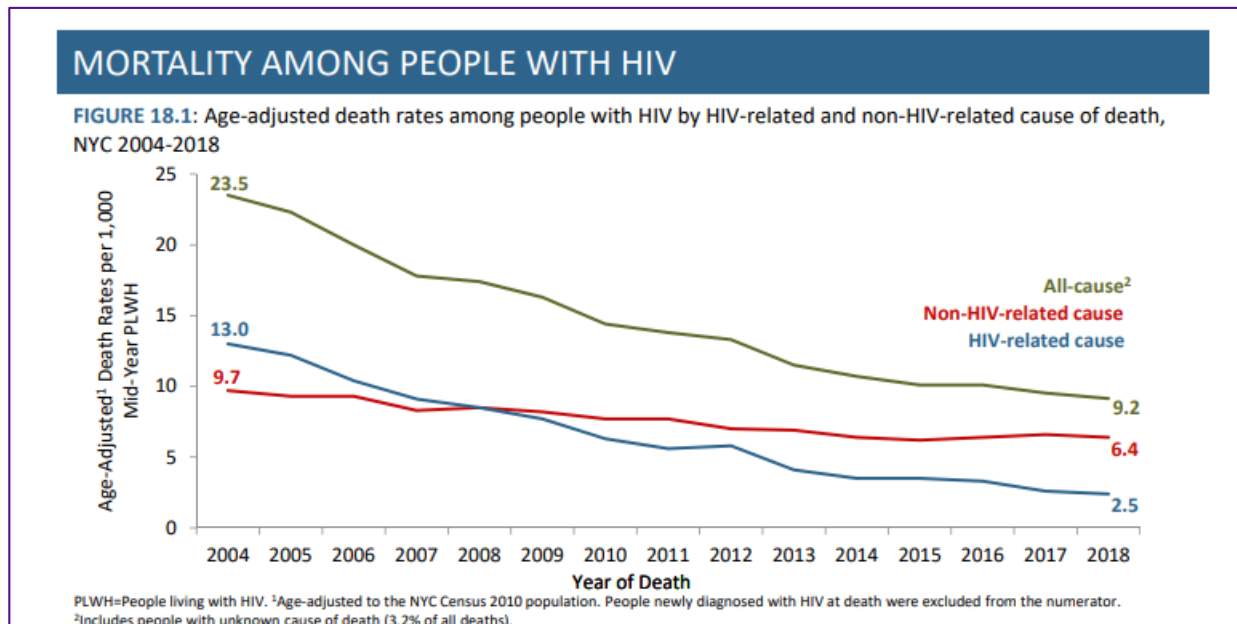
Success of Antiretroviral therapy (ART) for HIV infection



PLWH: People Living with HIV

<https://www1.nyc.gov/assets/doh/downloads/pdf/dires/hiv-surveillance-annualreport-2019.pdf>

Success of Antiretroviral therapy (ART) for HIV infection



<https://www1.nyc.gov/assets/doh/downloads/pdf/dires/hiv-surveillance-annualreport-2019.pdf>

The Need for Transplantation Among People Living with HIV Infection

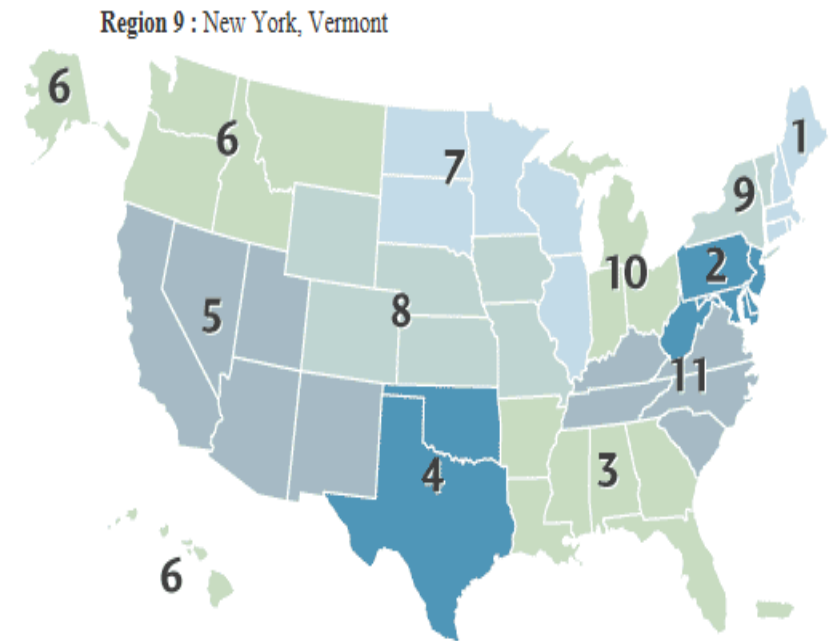
- Chronic diseases are leading causes of death in the U.S.
 - End-stage liver disease is the 2nd most common cause of non-AIDS related death
 - Co-infection with hepatitis B and hepatitis C viruses is common
 - Chronic liver disease presents at a younger age
 - Survival after first episode of HCV-related liver cirrhosis decompensation is reduced when compared to HIV uninfected patients (16 months vs. 48 months)
 - End-stage renal disease
 - 7.4% of HIV-infected patients have chronic kidney disease (CKD) in North America
 - Incidence of HIV-associated nephropathy
 - Increasing prevalence of CKD requiring dialysis among patients with HIV infection

Waiting List Candidates – Kidney Transplant (2001-2012)

Characteristic	HIV+, n=1636	HIV-, n=72,297	P Value
Region			<0.001
1	70 (4.3%)	2629 (3.6%)	
2	433 (26.5%)	11,479 (15.9%)	
3	217 (13.3%)	8865 (12.3%)	
4	57 (3.5%)	4520 (6.3%)	
5	240 (14.7%)	14,043 (19.4%)	
6	16 (1.0%)	2100 (2.9%)	
7	118 (7.2%)	6851 (9.5%)	
8	27 (1.7%)	3399 (4.7%)	
9	228 (13.9%)	6092 (8.4%)	
10	94 (5.8%)	6789 (9.4%)	
11	136 (8.3%)	5530 (7.7%)	

PRA, panel reactive antibody; HCV+, hepatitis C virus seropositive; ECD, expanded criteria donor; BMI, body mass index.
^aPoor functional status defined as hospitalization, use of wheelchair, or limited mobility.

United Network of Organ Sharing (UNOS) Regions



Locke et al. Access to Kidney Transplantation Among HIV-Infected Waitlist Candidates. Clin J Am Soc Nephrol 12: 467-475, 2017.

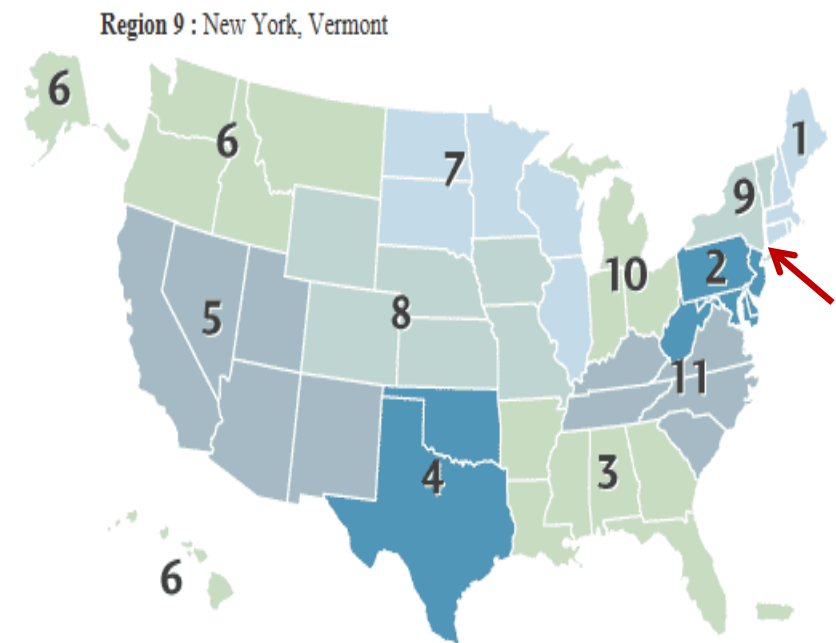
Waiting List Candidates – Kidney Transplant (2001-2012)

Table 1. (Continued)

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United Network of Organ Sharing (UNOS) Regions



New York in top 3 regions with highest % of waitlisted patients with HIV-infection

The Wait for HIV-infected Kidney Transplant Candidates

- HIV-infected candidates 28% less likely to undergo kidney transplant after adjustment for race, age, comorbidities, dialysis time, panel reactive antibodies (PRA), UNOS region and willingness to accept hepatitis C- infected kidneys
- Lower 5-year survival compared to HIV-negative counterparts (64% vs. 94%)
- 47% lower likelihood of having a live donor kidney transplant
- More likely to be removed from the waiting list

HOW DO PATIENTS WITH HIV INFECTION DO AFTER TRANSPLANT?

Outcomes after Kidney Transplantation for HIV-infected Recipients

- Early cohort study data:
 - Induction immunosuppression with lymphocyte-depleting agents was often avoided
 - Many patients on protease inhibitors for HIV treatment → lower doses of immunosuppression due to CYP 450 pathway drug-drug interactions
 - Patient survival: 85% at 1 year and 80% at 3 years
 - High rate of rejection: 55% → lower graft survival compared to HIV-negative recipients
 - High rate of delayed graft function (DGF) of 61% compared to HIV-negative recipients
- Recent cohort study data (2010-2017):
 - Patient survival improved to 100% at 1 and 3 years
 - Lower rates of rejection and DGF rate improved to 36%
- **National registry data shows no higher risk of infection with induction immunosuppression**

Survival Benefit in HIV-infected Kidney Transplant Recipients

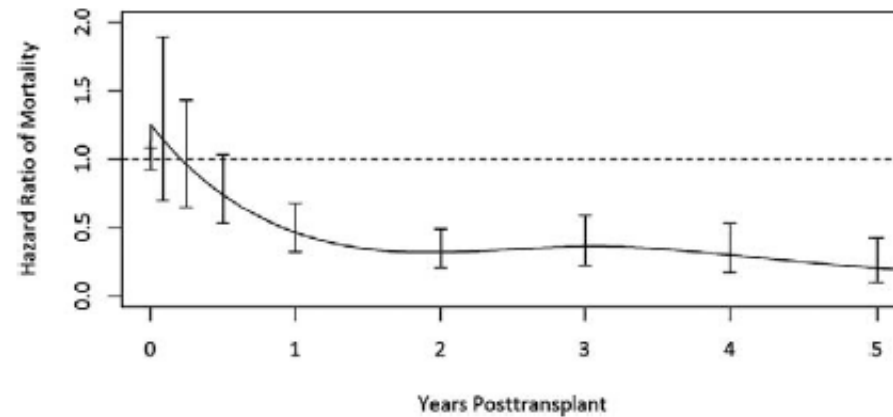


FIGURE 1. Adjusted relative mortality risk among HIV+ kidney transplant recipients compared with remaining on dialysis.

**79% lower
mortality risk**

Locke et al. Survival Benefit of Kidney Transplantation in HIV-infected Patients. *Annals of Surgery* 2017; 265:605-608.

Survival Benefit in HIV-infected Kidney Transplant Recipients

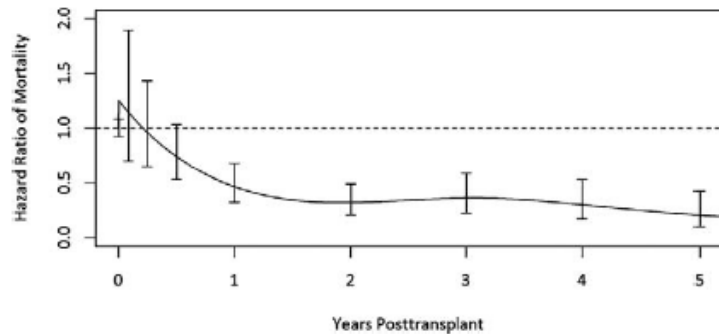


FIGURE 1. Adjusted relative mortality risk among HIV+ kidney transplant recipients compared with remaining on dialysis.

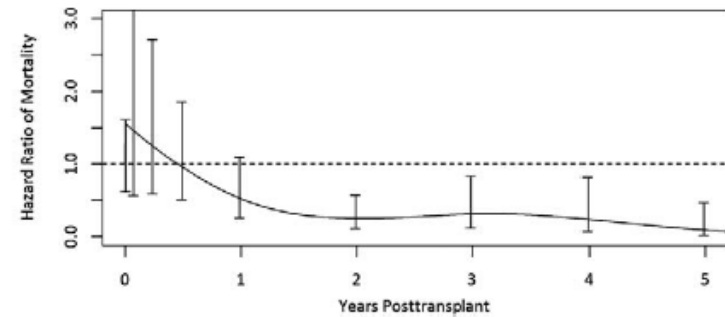


FIGURE 3. Adjusted relative mortality risk among HIV/HCV coinfecting kidney transplant recipients compared with remaining on dialysis.

79% lower mortality risk

Locke et al. Survival Benefit of Kidney Transplantation in HIV-infected Patients. *Annals of Surgery* 2017; 265:605-608.

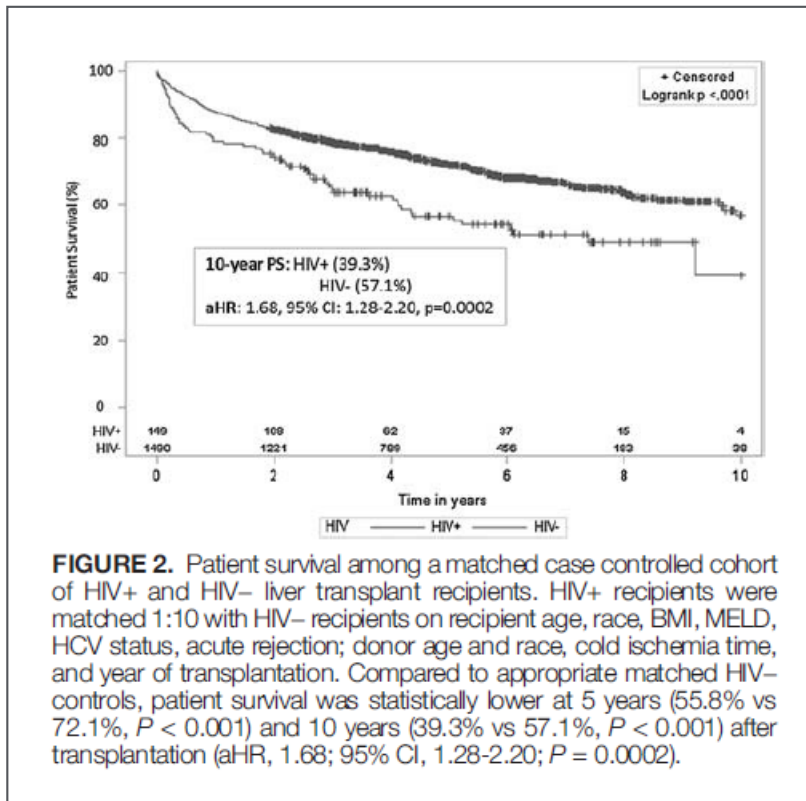
Outcomes after Liver Transplantation for HIV-infected Recipients

Locke JE, Durand C, Reed RD, MacLennan PA, Mehta S, Massie A, Nellore A, DuBay D, Segev DL. Long-term Outcomes After Liver Transplantation Among Human Immunodeficiency Virus-Infected Recipients. Transplantation. 2016 Jan;100(1):141-6.

- HIV monoinfected cohort study
- First-time liver transplant recipients
- Matched with HIV- recipients on age, race, BMI, HCV infection, MELD* score and acute rejection + donor age and race, cold ischemia time and year of transplant
- Outcomes compared in 2 eras: before and after introduction of integrase-strand transfer inhibitors

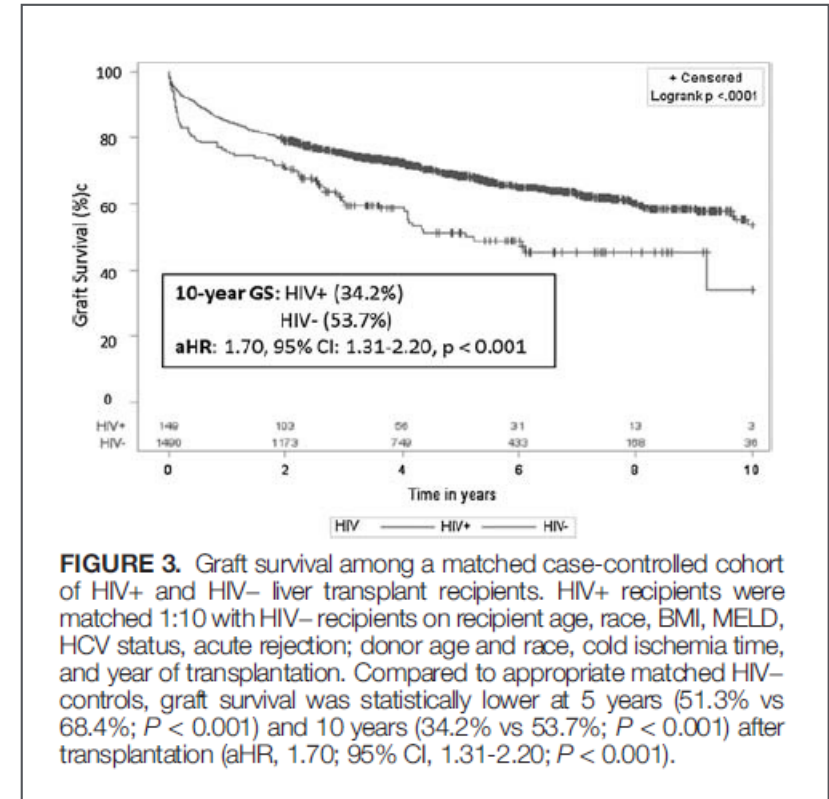
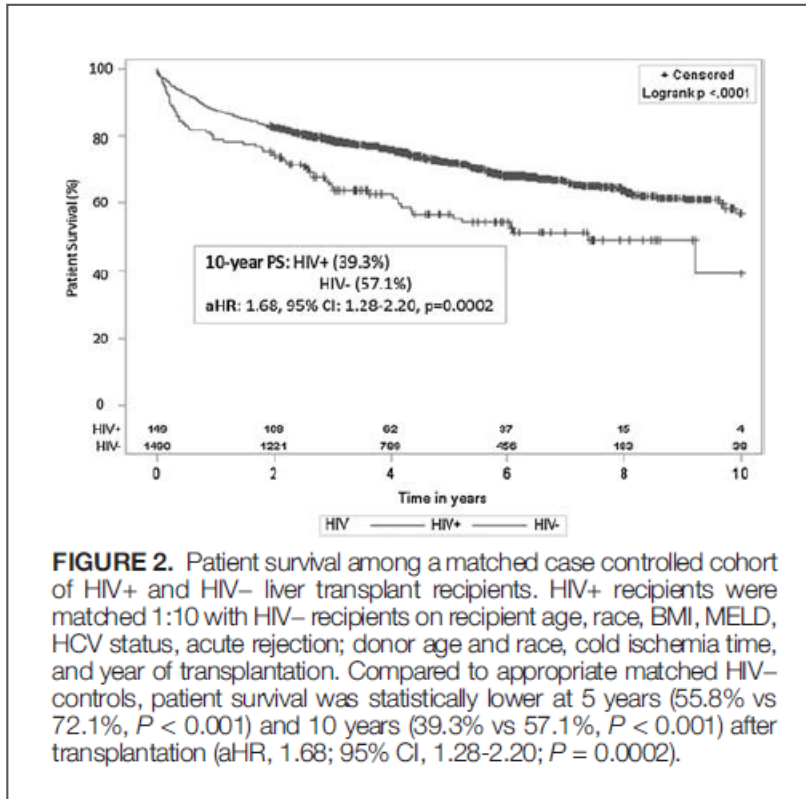
*Modified for End-Stage Liver Disease

Survival in HIV-infected Liver Transplant Recipients



Locke JE, Durand C, Reed RD, MacLennan PA, Mehta S, Massie A, Nellore A, DuBay D, Segev DL. Long-term Outcomes After Liver Transplantation Among Human Immunodeficiency Virus-Infected Recipients. *Transplantation*. 2016 Jan;100(1):141-6. doi: 10.1097/TP.0000000000000829. PMID: 26177090; PMCID: PMC4684452.

Survival in HIV-infected Liver Transplant Recipients



Locke JE, Durand C, Reed RD, MacLennan PA, Mehta S, Massie A, Nellore A, DuBay D, Segev DL. Long-term Outcomes After Liver Transplantation Among Human Immunodeficiency Virus-Infected Recipients. *Transplantation*. 2016 Jan;100(1):141-6. doi: 10.1097/TP.0000000000000829. PMID: 26177090; PMCID: PMC4684452.

Early concern around selection of immunosuppression

TABLE 2. Induction and maintenance immunosuppression regimen by HIV-status

	HIV-negative (n=93,027)	HIV-positive (n=516)	<i>P</i>
Induction therapy			<0.001
None	21.4	35.1	
ATG	43.5	25.8	
IL-2 inhibitor	23.1	33.5	
Alemtuzumab	12.0	5.6	
Maintenance therapy			<0.001
Neither	5.0	9.3	
CNI-based	89.0	83.7	
Sirolimus-based	6.1	7.0	



Locke et al. Immunosuppression Regimen and the Risk of Acute Rejection in HIV-Infected Kidney Transplant Recipients. *Transplantation* 2014; 97: 446-450.

Early concern around selection of immunosuppression

TABLE 3. Risk of AR within the first posttransplantation year among HIV-infected KT recipients

	Rejection (1 year, RR)	95% CI	P
Induction therapy			
None	Reference		
ATG	0.39	0.18–0.87	0.02
IL-2 inhibitor	1.11	0.66–1.86	0.7
Alemtuzumab	1.6	0.8–3.2	0.2
Maintenance therapy			
CNI-based	Reference		
Sirolimus-based	2.15	1.2–3.87	0.01
Neither CNI or sirolimus-based	1.21	0.58–2.54	0.6

The multivariate modified Poisson regression model adjusted for recipient age, race, PRA, degree of HLA match, and history of prior transplantation; donor age, race, and CIT; and center experience.

2.6 lower risk of rejection with ATG
2.2 higher risk of rejection with sirolimus

Locke et al. Immunosuppression Regimen and the Risk of Acute Rejection in HIV-Infected Kidney Transplant Recipients. *Transplantation* 2014; 97: 446-450.

Similar Incidence of Infection


Table 3. Incidence of infections in kidney transplant patients.

	HIV–			HIV+			Relative risk			p
	n	Rate	%	N	Rate	%	95% CI			
Bacterial infections	21	17.07	72.4%	23	18.25	67.7%	0.89	0.52	1.52	0.67
Pulmonary	6	4.88	20.7%	7	5.56	20.6%	0.84	0.29	2.44	0.75
<i>Haemophilus</i> spp.	0	0.00	0.0%	3	2.38	8.8%	0.14	0.01	2.72	0.19
<i>Pseudomonas</i> spp.	1	0.81	3.4%	0	0.00	0.0%	2.93	0.12	71.22	0.51
<i>Streptococcus pneumoniae</i>	0	0.00	0.0%	1	0.79	2.9%	0.33	0.01	7.91	0.49
<i>Nocardia</i> spp.	0	0.00	0.0%	1	0.79	2.9%	0.33	0.01	7.91	0.49
Other/unknown	5	4.07	17.2%	2	1.59	5.9%	2.48	0.49	12.55	0.27
Kidney and urinary tract	7	5.69	24.1%	14	11.11	41.2%	2.05	0.86	4.90	0.11
<i>Escherichia coli</i>	5	4.07	17.2%	5	3.97	14.7%	1.02	0.34	3.45	0.97
<i>Enterobacter</i> spp.	0	0.00	0.0%	6	4.76	17.6%	3.31	0.76	233.85	0.08
<i>Klebsiella</i> spp.	1	0.81	3.4%	1	0.79	2.9%	1.02	0.06	16.20	0.99
<i>Proteus</i> spp.	0	0.00	0.0%	1	0.79	2.9%	0.33	0.01	7.91	0.49
Other/unknown	1	0.81	3.4%	1	0.79	2.9%	1.02	0.06	16.20	0.99
Skin	5	4.07	17.2%	1	0.79	2.9%	0.02	0.02	1.73	0.15
Other ^a	3	2.44	10.3%	1	0.79	2.9%	0.34	0.04	2.24	0.35
Unidentified/missing culture	7	5.69	24.1%	4	3.17	11.8%	2.36	0.51	12.63	0.31
Viral infections	6	4.88	20.7%	5	3.97	14.7%	1.38	0.34	5.83	0.76
CMV	4	3.25	13.8%	0	0.00	0.0%	0.11	0.01	2.10	0.14
HHV8	1	0.81	3.4%	3	2.38	8.8%	3.07	0.32	29.14	0.33
Other viruses	1	0.81	3.4%	2	1.59	5.9%	2.05	0.19	22.31	0.56
BKV	7	5.69	19.4%	5	3.97	12.8%	0.71	0.23	2.19	0.56
Fungal	1	0.81	3.4%	3	2.38	8.8%	0.38	0.01	4.84	0.63
Parasitic	1	0.81	3.4%	3	2.38	8.8%	0.38	0.01	4.84	0.63
Opportunistic ^b	9	7.14	26.5%	13	10.32	38.2%	1.63	0.53	5.24	0.44
Bacteria	2	1.59	5.9%	1	0.79	2.9%	1.74	0.09	108.48	1.00
Viruses	5	3.97	14.7%	5	3.97	14.7%	1.13	0.23	5.65	1.00
Parasites	1	0.79	2.9%	3	2.38	8.8%	0.23	0.00	2.51	0.35
Fungi	1	0.79	2.9%	4	3.17	11.8%	3.33	0.25	185.99	0.35
Total	29	23.58	100.0%	34	26.98	100.0%	0.90	0.58	1.39	0.63

CMV: cytomegalovirus; BKV: BK virus.

^aOther – hepatic abscess; biliary tract infection.

^bAll infections due to *Pseudomonas* spp., *Nocardia*, *Candida*, *Cryptococcus*, *Aspergillus*, *Pneumocystis*, *Cryptosporidium*, CMV, HHV8, and BK virus grouped together.

5 year follow-up period

 No difference between groups

Experiences with Cardiac Transplant in Era of cART

ORIGINAL ARTICLE BRIEF REPORT

Successful Cardiac Transplantation in an HIV-1– Infected Patient with Advanced Disease

Leonard H. Calabrese, D.O., Mary Albrecht, M.D., James Young, M.D., Patrick McCarthy, M.D., Marcus Haug, Pharm.D., John Jarcho, M.D., and Robert Zackin, Sc.D.

Transplant in 2001 Cleveland Clinic

Outcomes after Cardiac Transplant

Table 2: Baseline characteristics and clinical outcomes of patients with HIV infection undergoing HT in the cART era (1997–2014)

Patient (reference)	Country	YOT	Sex	Age at HT	HIV status at HT	cART before HT	CD4 cells/mm ³ at HT	Etiology of heart disease	Initial IS	Follow-up after HT (months)	Rejection/grade	Graft function at end of follow-up	Status	Cause of death
1 (23)	USA	1997	Female	>40	Negative	NA	NA	Nonischemic CM	CyA/MMF/P	120	Yes/3A	Normal	Alive	–
2 (3,15)	USA	2001	Male	42	Positive	Yes	637	Dilated CM	CyA/MMF/P/daclizumab	88	Yes/NR	Normal	Alive	–
3 (14,29)	USA	2001	Male	39	Positive	Yes	>250	Anthracycline-associated CM	CyA/MMF/P	43	Yes/3A	Normal	Dead	NR
4 (3)	USA	2005	Male	47	Positive	Yes	443	Dilated CM	CyA/MMF/P/daclizumab	40	Yes/NR	Normal	Alive	–
5 (3)	USA	2005	Male	19	Negative	NA	NA	Dilated CM	CyA/MMF/P/daclizumab	36	Yes/NR	Normal	Alive	–
6 (3)	USA	2007	Male	29	Positive	No	536	Dilated CM	CyA/MMF/P/daclizumab	14	Yes/NR	Normal	Alive	–
7 (5,13)	Spain	2007	Male	39	Positive	Yes	>500	Ischemic CM	FK/MMF/P	84	Yes/3A	Normal	Alive	–
8 (24)	USA	2007	Male	>60	Negative	NA	NA	Ischemic CM	FK/MMF/P/basiliximab/ATG	34	Yes/moderate	Impaired	Dead	MOF
9 (3)	USA	2008	Male	48	Positive	Yes	360	Dilated CM	CyA/MMF/P/daclizumab	6	No	Normal	Alive	–
10 (3)	USA	2008	Female	43	Positive	Yes	793	Dilated CM	CyA/MMF/P/daclizumab	3	No	Normal	Alive	–
11 (18)*	France	2008	Male	32	Positive	Yes	700	Dilated CM	NR	30	Yes/2R	Normal	Alive	–
12 (11)**	USA	2008	Male	47	Positive	Yes	360	Nonischemic dilated CM	NR	31	No	Normal	Alive	–
13 (21)	Italy	2009	Male	36	Positive	Yes	NR	Nonischemic dilated CM	CyA/EVR/P/ATG	36	Yes/2R	Normal	Alive	–
14 (12)**	USA	2009	Female	42	Positive	Yes	>450	Nonischemic dilated CM	FK/MMF/P	24	Yes/NR	Normal	Alive	–
15 (30)	Italy	2011	Male	42	Positive	Yes	NR	Dilated CM	FK/P	19	No	Normal	Alive	–

➤ Rejection was common

➤ Majority had good outcome

ATG, antithymocyte globulin; cART, combined antiretroviral therapy; CM, cardiomyopathy; CyA, cyclosporine; EVR, everolimus; FK, tacrolimus; HIV, human immunodeficiency virus; HT, heart transplantation; IS, immunosuppression; MMF, mycophenolate mofetil; MOF, multiorgan failure; NA, not applicable; NR, not reported; P, prednisone; USA, United States; YOT, year of transplantation.

*Percutaneous extracorporeal life support.

**Patient with left ventricular assist device implanted before HT.

Outcomes after Cardiac Transplant

Madan et al. American Journal of Transplantation, May 2019

- Review of nationwide Organ Procurement and Transplantation Network (OPTN) data from January 2004 and March 2017
- 43 adult heart transplant HIV+ recipients compared to propensity matched HIV- recipients
- No significant survival difference with up to 5 years of follow-up
 - Similar rate (32%) of cardiac allograft vasculopathy with up to 5 years follow-up
 - Post-transplant infection and rejection data for 28 of 43 patients
 - 5 (17.9%) hospitalized for infection within the first year post-heart transplant
 - 11 (39.3%) required treatment for acute rejection within the first year (vs. \leq 20% in overall HT population)

Experiences with Lung Transplant

The Atlantic

Popular

Latest

Sections ▾

Why This Man Was Refused a New Lung

People with HIV are still excluded from some life-saving organ transplants, based on guidelines that omit the most current science.



February 2014

CONSENSUS REPORT

International Guidelines for the Selection of Lung Transplant Candidates: 2006 Update—A Consensus Report From the Pulmonary Scientific Council of the International Society for Heart and Lung Transplantation

Jonathan B. Orens, MD,^a Marc Estenne, MD,^b Selim Arcasoy, MD,^c John V. Conte, MD,^a Paul Corris, MD,^d Jim J. Egan, MD,^c Thomas Egan, MD,^f Shaf Keshavjee, MD,^g Christiane Knoop, MD,^b Robert Kotloff, MD,^h Fernando J. Martinez, MD,ⁱ Steven Nathan, MD,^j Scott Palmer, MD,^k Alec Patterson, MD,^l Lianne Singer, MD,^g Gregory Snell, MD,^m Sean Studer, MD,ⁿ J. L. Vachiery, MD,^b and Allan R. Glanville, MD^o

CONSENSUS REPORT

International Guidelines for the Selection of Lung Transplant Candidates: 2006 Update—A Consensus Report of the Pulmonary Scientific Council of the International Society for Heart and Lung Transplantation

Jonathan B. Orens, MD,^a Marc Estenne, MD,^b Selim Arcasoy, MD,^c John V. Cozzari, MD,^d Jim J. Egan, MD,^e Thomas Egan, MD,^f Shaf Keshavjee, MD,^g Christiane Knoop, MD,^h Fernando J. Martinez, MD,ⁱ Steven Nathan, MD,^j Scott Palmer, MD,^k Alec Patterson, MD,^l Gregory Snell, MD,^m Sean Studer, MD,ⁿ J. L. Vachiery, MD,^b and Allan R. Glanville, MD,^o

2014 guideline
change to
relative
contraindication

- For patients infected with human immunodeficiency virus (HIV), a lung transplant can be considered in patients with controlled disease with undetectable HIV-RNA, and compliant on combined anti-retroviral therapy. The most suitable candidates should have no current acquired immunodeficiency syndrome–defining illness. Lung transplantation in HIV-positive candidates should be performed in centers with expertise in the care of HIV-positive patients.

2. General Contraindications

Lung transplantation remains a complex therapy with a significant risk of perioperative morbidity and mortality; therefore, it is important to consider the overall sum of contraindications and comorbidities. The following lists are not intended to include all possible clinical scenarios, but rather to highlight common areas of concern.

Absolute contraindications.

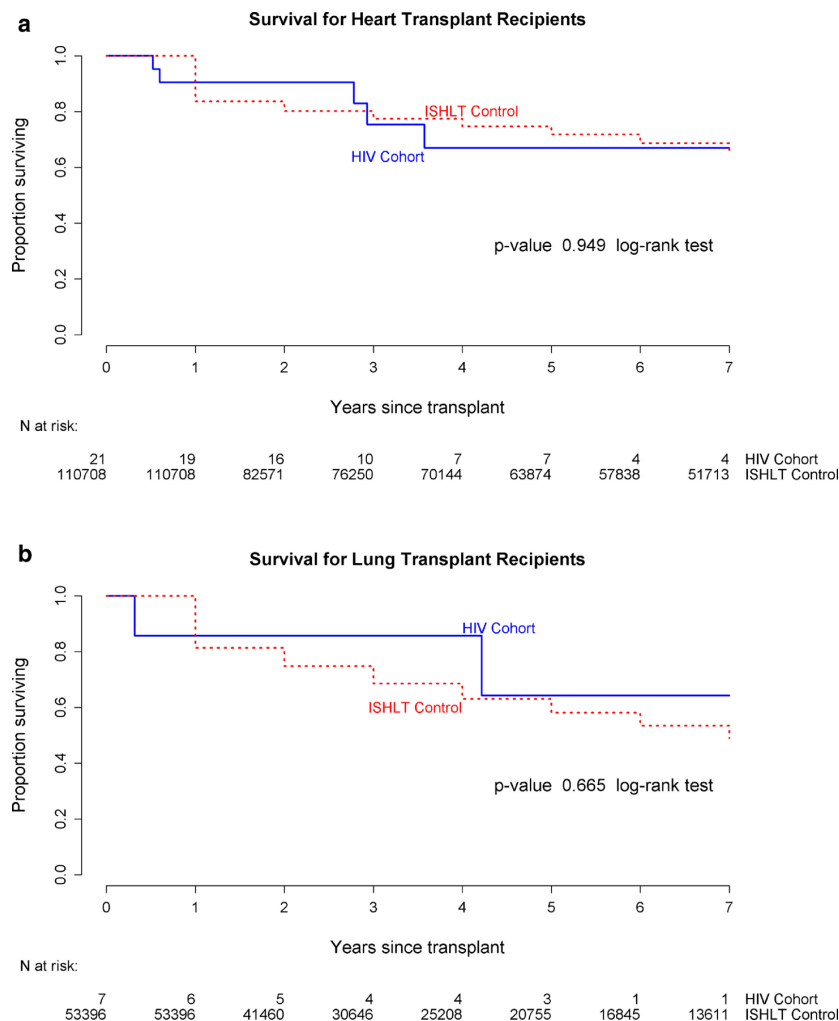
- Malignancy in the last 2 years, with the exception of cutaneous squamous and basal cell tumors. In general, a 5-year disease-free interval is prudent. The role of lung transplantation for localized bronchioalveolar cell carcinoma remains controversial.
- Untreatable advanced dysfunction of another major organ system (e.g., heart, liver, or kidney). Coronary artery disease not amenable to percutaneous intervention or bypass grafting, or associated with significant impairment of left ventricular function, is an absolute contraindication to lung transplantation, but heart-lung transplantation could be considered in highly selected cases.
- Non-curable chronic extrapulmonary infection including chronic active viral hepatitis B, hepatitis C, and human immunodeficiency virus.
- Significant skeletal deformity.
- Inability to follow medical advice or inability to follow therapy or office follow-up, or inability to attend to medical care.
- Significant psychiatric condition as defined by a psychiatrist, or inability to cooperate or comply with medical advice.
- Absence of reliable social support.
- Current or recent use of alcohol, tobacco, or narcotics within the last 6 months.

Heart and Lung Transplantation (LT) Outcomes in HIV-Positive Recipients

- 2000-2016, 14 participating sites in U.S. and Europe
- 21 heart transplant, 7 lung transplant and 1 heart & lung transplant recipient
 - ≥ 1 year follow-up with median follow-up 989 days
 - 7 patients on protease inhibitor therapy & 10 patients on NNRTI therapy for HIV treatment
 - Median baseline CD4 count 398 cells/ μ L
 - Only 2 patients received anti-thymocyte globulin (ATG)

Koval CE, Farr M, Krisl J, Haidar G, Pereira MR, Shrestha N, Malinis MF, Mueller NJ, Hannan MM, Grossi P, Huprikar S. Heart or lung transplant outcomes in HIV-infected recipients. *J Heart Lung Transplant*. 2019 Dec;38(12):1296-1305. doi: 10.1016/j.healun.2019.09.011. Epub 2019 Sep 25. PMID: 31636044.

Heart and Lung Transplantation (LT) Outcomes in HIV-Positive Recipients



Rejection was more common than expected in HT and may have contributed to decreased survival.

As with other HIV+ organ transplants, early, aggressive immunosuppression may be needed to avoid rejection.

Koval CE, Farr M, Krisl J, Haidar G, Pereira MR, Shrestha N, Malinis MF, Mueller NJ, Hannan MM, Grossi P, Huprikar S. Heart or lung transplant outcomes in HIV-infected recipients. *J Heart Lung Transplant*. 2019 Dec;38(12):1296-1305. doi: 10.1016/j.healun.2019.09.011. Epub 2019 Sep 25. PMID: 31636044.

Lung Transplantation Outcomes in HIV-Positive Recipients

Original Clinical Science—General



Lung Transplantation for People Living With HIV: Promising Mid-term Outcomes

Asher S. Ralphs,¹ Scott T. Anderson, BS,^{1,2} Blake T. Langlais, MS,³ Jonathan D’Cunha, MD, PhD,¹ and Pedro A. Reck dos Santos, MD, PhD¹

- 59 patients (80% since 2018)
- Propensity score matched control group
- PLWH with higher severity of lung disease before transplant
- Similar 1 year survival (91.9 % vs. 88,6%)
- Small subset with 3 year survival data similar

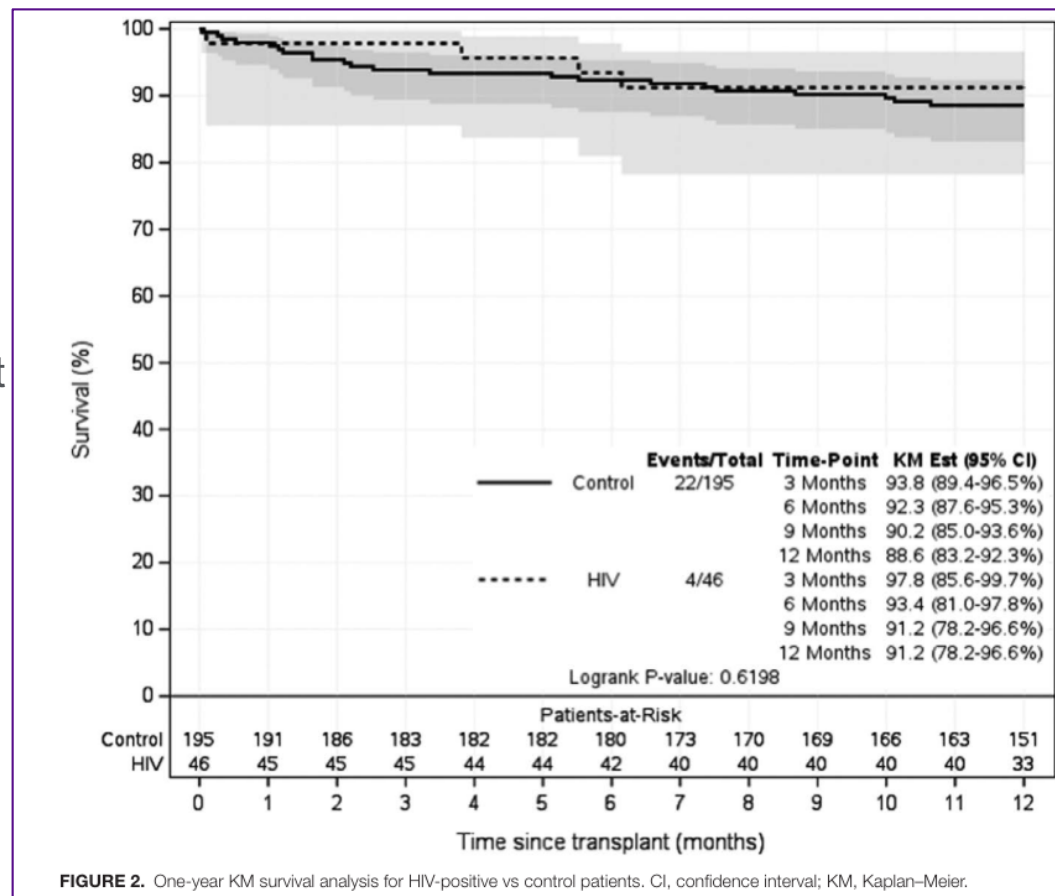


FIGURE 2. One-year KM survival analysis for HIV-positive vs control patients. CI, confidence interval; KM, Kaplan-Meier.

Candidacy evaluation for PLWH

- Infection history
- Antiretroviral resistance history
- Adherence to care and medications
- Cancer history
- Disclosure and peri-transplant social support

Candidate preparation

- Ideally an ART regimen that does not include protease inhibitor or cobicistat due to drug-drug interactions with calcineurin inhibitor therapy for transplant (CYP 450-3A pathway)
 - Prior genotypes
 - ART regimen change by primary care provider
 - Demonstrated virologic suppression following regimen change
- Updated cancer screening
- CD4 count every 4 months and HIV viral load monitoring every 6 months while awaiting transplantation
- Optimize nutritional status

Martin CJ, Muller E, Labadarios D, Veldman FJ, Kassier SM. Health-related quality of life and associated factors in HIV-positive transplant candidates and recipients from a HIV-positive donor. *Qual Life Res.* 2021 Jun 22. doi: 10.1007/s11136-021-02898-y. Epub ahead of print. PMID: 34156597.

Case: Kidney transplant candidate with HIV infection

- 31 yo man with history of hypertension, HIV infection since 2012, HIVAN with CKD
 - ART regimen: dolutegravir + darunavir/cobicistat
 - CD4 nadir 23, recent CD4 437/25%
 - Recent viral load <20 copies
 - Prior ART changes due to side effects (Biktarvy, Genvoya, Raltegravir)
 - Genosure data: M184V (viral load 51 copies)
 - Recently initiated dialysis
- ART change recommended to avoid drug-drug interactions with calcineurin inhibitor therapy (e.g. Tacrolimus) that will be needed after transplant to prevent rejection
- In partnership with HIV primary care provider, regimen changed to dolutegravir, lamivudine and rilpivirine

HIV-TO- HIV TRANSPLANTATION AND HOPE ACT

HIV-HIV Transplantation

Renal Transplantation between HIV-Positive Donors and Recipients

TO THE EDITOR: Nephropathy associated with infection with the human immunodeficiency virus (HIV) is the leading cause of end-stage renal disease (ESRD) in HIV-infected patients in South Africa.^{1,2} We practice in a resource-constrained environment where the use of dialysis is limited;

Table 1. Clinical Characteristics of HIV-Positive Recipients of a Transplant from an HIV-Positive Donor.*

Characteristic	Patient 1	Patient 2	Patient 3	Patient 4
Age (yr)	47	56	37	29
Sex	Male	Male	Male	Female
Before transplantation				
Diagnosis on renal biopsy	HIV-associated nephropathy	HIV-associated nephropathy and hypertensive nephropathy	Malignant hypertension	HIV-associated nephropathy
Creatinine ($\mu\text{mol/liter}$)	678	582	1712	725
CD4 count (cells/mm^3)	288	258	132	147
HIV viral load (copies/ml)	<50	<50	<50	<50
Antiretroviral regimen	Tenofovir, lamivudine, and lopinavir–ritonavir	Stavudine, lamivudine, and efavirenz	Stavudine, lamivudine, and nevirapine	Zidovudine, lamivudine, and nevirapine
After transplantation				
Antiretroviral regimen	Tenofovir, lamivudine, and lopinavir–ritonavir	Tenofovir, lamivudine, and lopinavir–ritonavir	Tenofovir, lamivudine, and lopinavir–ritonavir	Tenofovir, lamivudine, and lopinavir–ritonavir
CD4 count (cells/mm^3)				
At 6 mo	129	113	140	140
At 12 mo	253	119	112	220
HIV viral load (copies/ml)				
At 6 mo	<50	<50	<50	<50
At 12 mo	<50	<50	<50	<50

*South Africa experience-
Elmi Muller et al.*

Timeline of HOPE (HIV Organ Policy Equity) Act and Trials in the United States

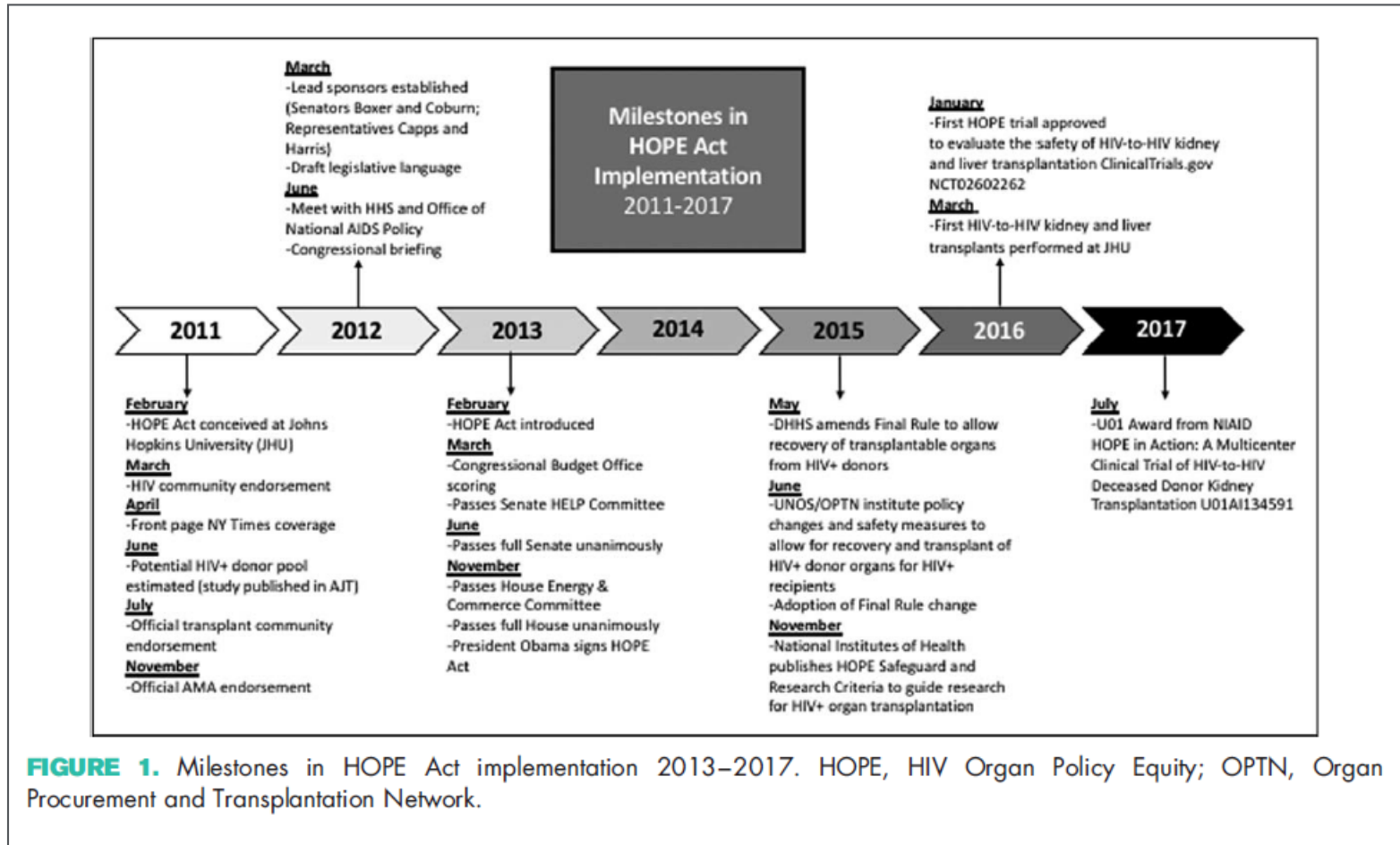
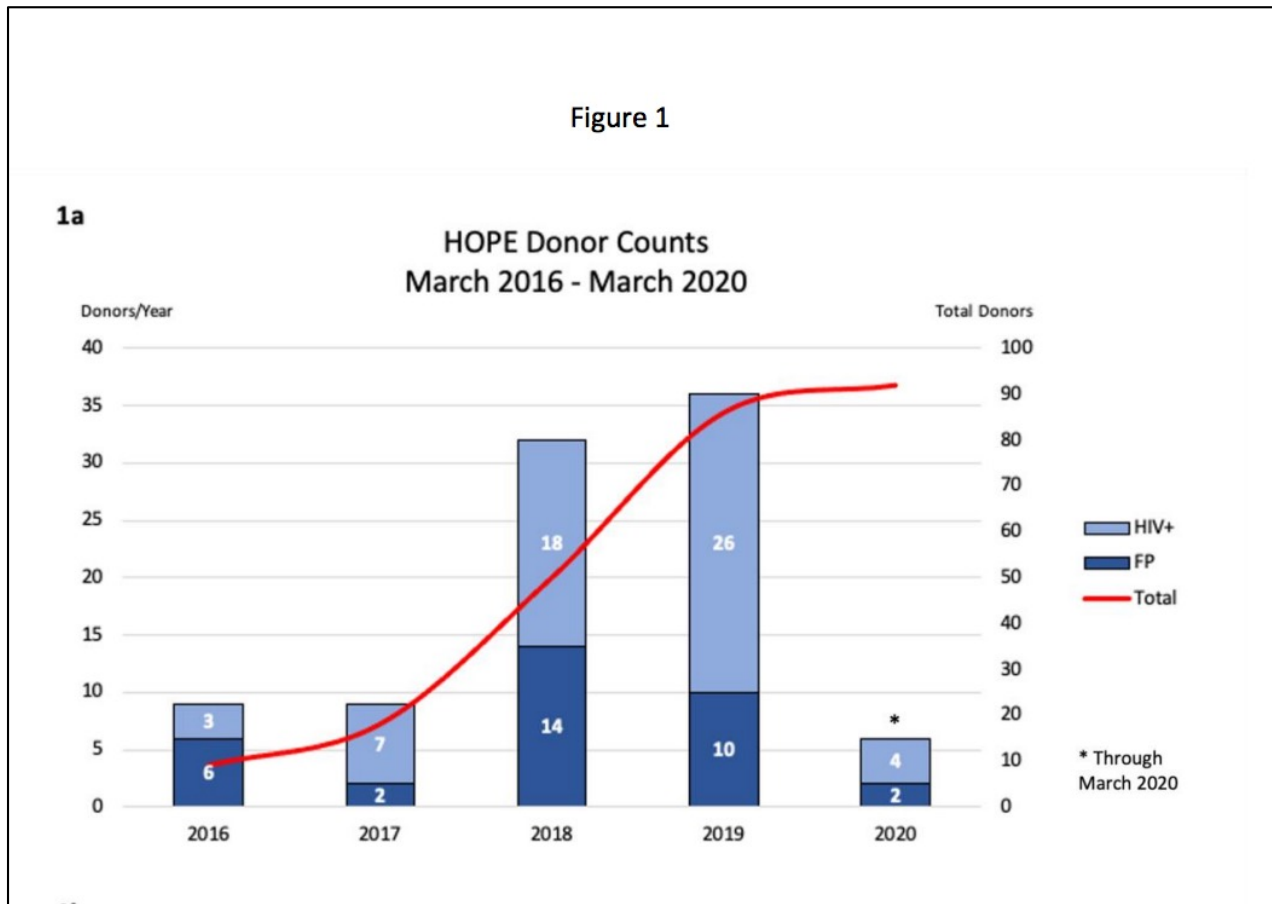


FIGURE 1. Milestones in HOPE Act implementation 2013–2017. HOPE, HIV Organ Policy Equity; OPTN, Organ Procurement and Transplantation Network.

from Moving from the HIV Organ Policy Equity Act to HIV Organ Policy Equity in action: changing practice and challenging stigma. Doby, Brianna L.; Tobian, Aaron A.R.; Segev, Dorry L.; Durand, Christine M. Current Opinion in Organ Transplantation. 23(2):271-278, April 2018.

HIV-infected Donor Pool



Werbel WA, Brown DM, Kusemiju OT, Doby BL, Seaman SM, Redd AD, Eby Y, Fernandez RE, Desai NM, Miller J, Bismut GA, Kirby CS, Schmidt HA, Clarke WA, Seisa M, Petropoulos CJ, Quinn TC, Florman SS, Huprikar S, Rana MM, Friedman-Moraco RJ, Mehta AK, Stock PG, Price JC, Stosor V, Mehta SG, Gilbert AJ, Elias N, Morris MI, Mehta SA, Small CB, Haidar G, Malinis M, Husson JS, Pereira MR, Gupta G, Hand J, Kirchner VA, Agarwal A, Aslam S, Blumberg EA, Wolfe CR, Myer K, Wood RP, Neidlinger N, Strell S, Shuck M, Wilkins H, Wadsworth M, Motter JD, Odum J, Segev DL, Durand CM, Tobian AAR; HOPE in Action Investigators. **National Landscape of HIV+ Deceased Organ Donors in the United States.** *Clin Infect Dis.* 2021 Aug 28:ciab743. doi: 10.1093/cid/ciab743. Epub ahead of print. PMID: 34453519.

HOPE Recipient Criteria

- Key inclusion criteria:
 - No active OI or neoplasm
 - HIV viral load < 50 copies on stable ART
 - CD4 count >200 within 16 weeks prior to transplant, for liver also if CD4 count >100 and no history of OI

HOPE Recipient Criteria

- Key inclusion criteria:
 - No active OI or neoplasm
 - HIV viral load < 50 copies on stable ART
 - CD4 count >200 within 16 weeks prior to transplant, for liver also if CD4 count >100 and no history of OI
- Exclude if :
 - History of progressive multifocal leukoencephalopathy (PML), chronic intestinal cryptosporidiosis > 1 month duration or primary CNS lymphoma
 - Any neoplasm except:
 - Resolved Kaposi's Sarcoma, in-situ anogenital carcinoma, adequately treated BCC or SCC of skin, solid tumors with disease-free for > 5 years, renal cell carcinoma disease-free for 2 years, leukemia (site discretion)
 - Pregnancy or breastfeeding
- Assessment by Independent Patient Advocate prior to study consent

Risks and Benefits

- Acute rejection: 2-4x higher rate
- Recurrent HIVAN (mixed data)
- Potential for increased rate of infection
- HIV superinfection
 - Viral inoculum with transplant likely higher than other modes of transmission
 - Protease inhibitors generally avoided in transplant recipients but are often required to treat resistant virus

Risks and Benefits

- Acute rejection: 2-4x higher rate
- Recurrent HIVAN (mixed data)
- Potential for increased rate of infection
- HIV superinfection
 - Viral inoculum with transplant likely higher than other modes of transmission
 - Protease inhibitors generally avoided in transplant recipients but are often required to treat resistant virus
- Shorter waiting time for candidates with HIV infection
- Expand donor pool decreasing waitlist time for all candidates

Transplant Infectious Diseases Care

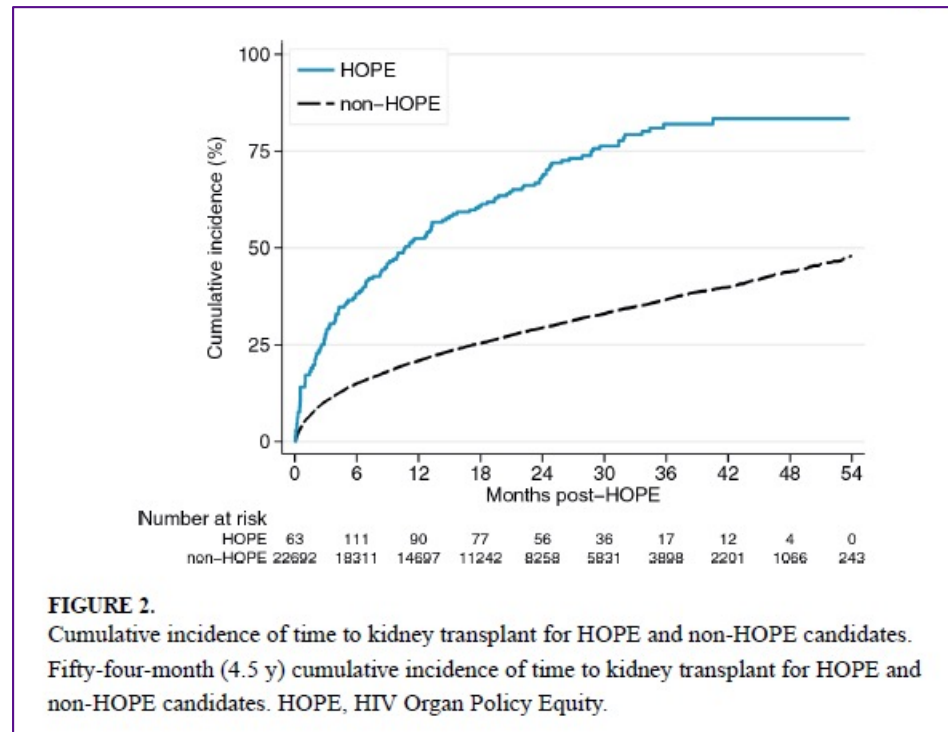
- Transplant Infectious Diseases Evaluation which includes review of HIV infection history with primary HIV care provider
- Pre-transplant determination of safe and effective antiretroviral regimen (background resistance acceptable if effective regimen)
- Donor evaluation at time of organ offer
- Peri-transplant and early post-transplant care with Transplant ID in coordination with HIV care provider
- Study visits- frequent in the first 3 months after transplant
- Subsequent transition of full HIV care to primary HIV provider in the absence of complications or acute infections

RECENT LESSONS IN TRANSPLANTATION FOR PLWH

Access to Kidney Transplantation since HOPE Act

Motter et al. *Wait Time Advantage for Transplant Candidates with HIV Who Accept Kidneys from Donors with HIV Under the HOPE Act*. Transplantation 2024 April 23.

- Included patients across 24 U.S. transplant centers
- HOPE candidate kidney transplant is more likely within 4.5 years overall (70% vs. 43% of non-HOPE candidates)
- Median wait time significantly shorter with median kidney transplant wait time of 10.3 months for HOPE candidates vs 60.8 months for non-HOPE candidates.



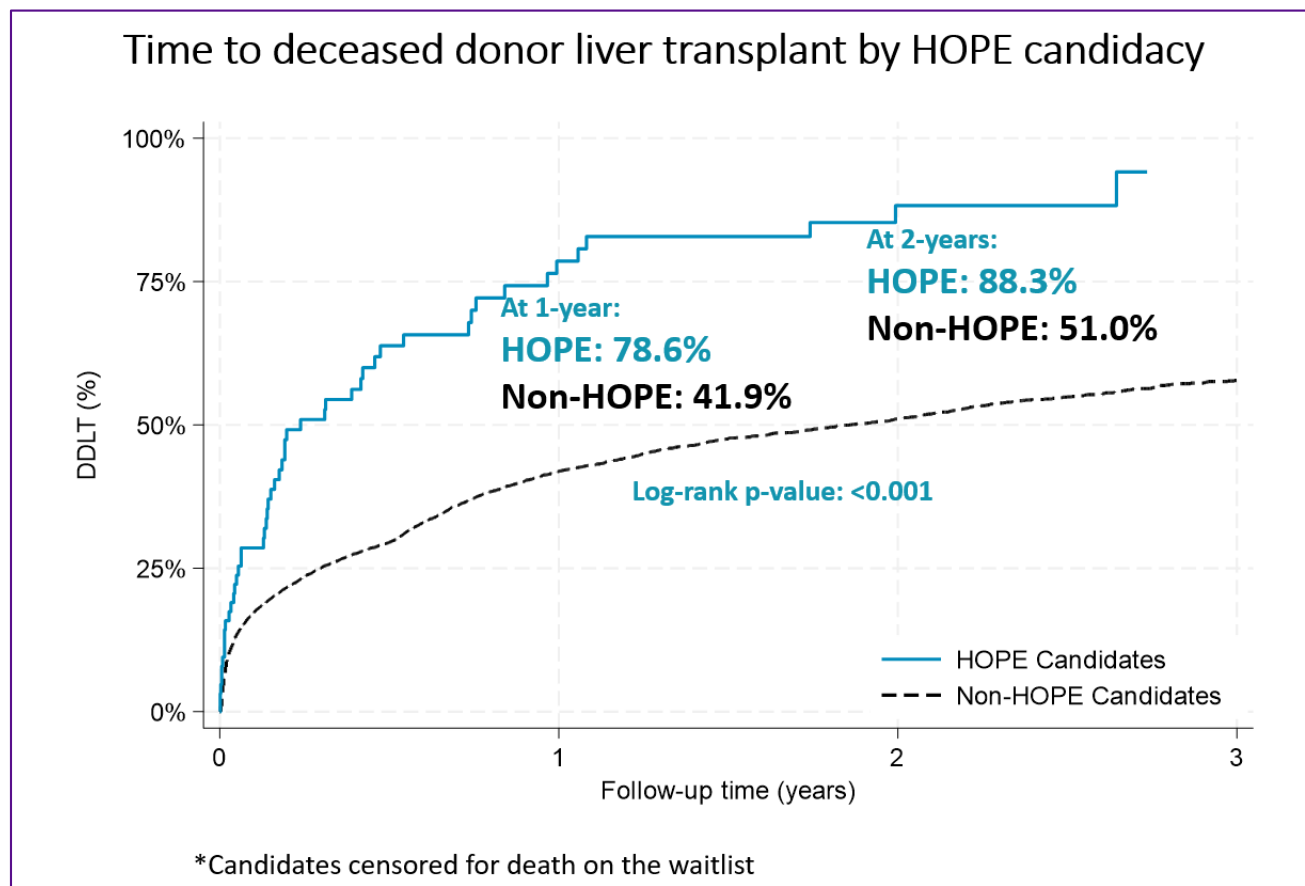
Access to Kidney Transplantation since HOPE Act

Motter et al. *Wait Time Advantage for Transplant Candidates with HIV Who Accept Kidneys from Donors with HIV Under the HOPE Act*. Transplantation 2024 April 23.

- HOPE candidates more likely to have >6 years on dialysis
- HOPE candidates less likely to undergo preemptive listing for kidney transplant (KT)
- Cumulative incidence of living donor KT 4% in HOPE group (vs. 26% in non-HOPE group)

Access to Liver Transplantation since HOPE Act

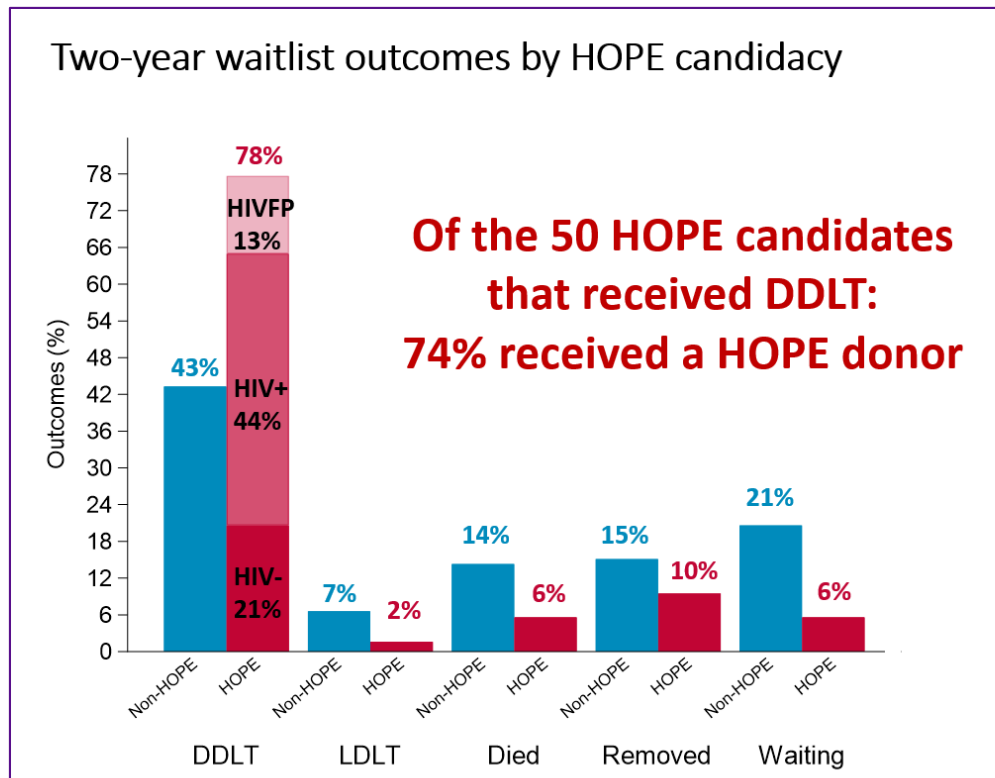
Nauroz/Massie et al. *Increased Rate of Deceased Donor Liver Transplant for Candidates Willing to Receive Organs from Donors With HIV*. American Transplant Congress 2024.



Access to Liver Transplantation since HOPE Act

Nauroz/Massie et al. *Increased Rate of Deceased Donor Liver Transplant for Candidates Willing to Receive Organs from Donors With HIV*. American Transplant Congress 2024.

- HOPE candidates were transplanted at a lower MELD score (20 vs. 29)
- HOPE candidates had a 4-fold higher deceased donor liver transplant rate than non-HOPE candidates (varied across MELD score)



Access to Liver Transplantation since HOPE Act

Nauroz/Massie et al. *Increased Rate of Deceased Donor Liver Transplant for Candidates Willing to Receive Organs from Donors With HIV*. American Transplant Congress 2024.

willingness to accept HOPE donors has increased access to liver transplantation

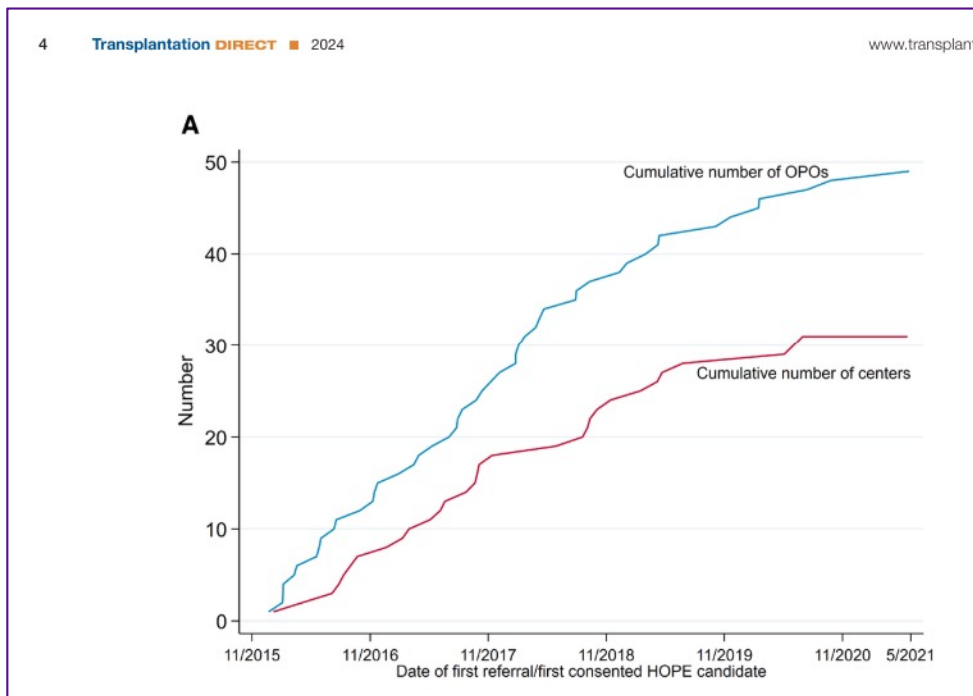
HOPE donors: trends to date and room for expansion



OPEN

Deceased Donors With HIV in the Era of the HOPE Act: Referrals and Procurement

Tao Liang, MSPH,¹ Jordan H. Salas, BS, MCR,^{1,2} Mary G. Bowring, MPH,¹ Oyinkan Kusemiju, MPH,¹ Brittany Barnaba, MS,¹ Matthew Winger, CPTC,³ Deborah McRann, MBA,⁴ Alghidak Salama, MD, MPA,⁵ R. Patrick Wood, MD,⁶ Allan Massie, PhD,⁷ William Werbel, MD, PhD,¹ Aaron A. R. Tobian, MD, PhD,⁸ Dorry L. Segev, MD, PhD,⁷ and Christine M. Durand, MD¹



- 24% procurement rate (high)
- 26% had non-medical reasons for nonprocurement:
 - Lack of donor registration or lack of authorization from donor's next of kin (42%)
 - Lack of waitlist candidates (21%)
 - No transplant center interest (20%)
 - OPO decision/concerns (15%)

HOPE Clinical Outcomes – Kidney Transplantation

American Journal of
TRANSPLANTATION

AST AMERICAN SOCIETY OF
TRANSPLANTATION ASTS

ORIGINAL ARTICLE

A prospective multicenter pilot study of HIV-positive deceased donor to HIV-positive recipient kidney transplantation: HOPE in action

Christine M. Durand✉, Wanying Zhang, Diane M. Brown, Sile Yu, Niraj Desai, Andrew D. Redd, Serena M. Bagnasco, Fizza F. Naqvi, Shanti Seaman, Brianna L. Doby, Darin Ostrander, Mary Grace Bowring, Yolanda Eby, Reinaldo E. Fernandez, Rachel Friedman-Moraco, Nicole Turgeon, Peter Stock, Peter Chin-Hong, Shikha Mehta, Valentina Stosor, Catherine B. Small, Gaurav Gupta, Sapna A. Mehta, Cameron R. Wolfe, Jennifer Husson, Alexander Gilbert, Matthew Cooper, Oluwafisayo Adebisi, Avinash Agarwal, Elmi Muller, Thomas C. Quinn, Jonah Odum, Shirish Huprikar, Sander Florman, Allan B. Massie, Aaron A. R. Tobian, Dorry L. Segev, on behalf of the HOPE in Action Investigators, ... [See fewer authors](#) ^

First published: 23 July 2020 | <https://doi.org/10.1111/ajt.16205> | Citations: 16

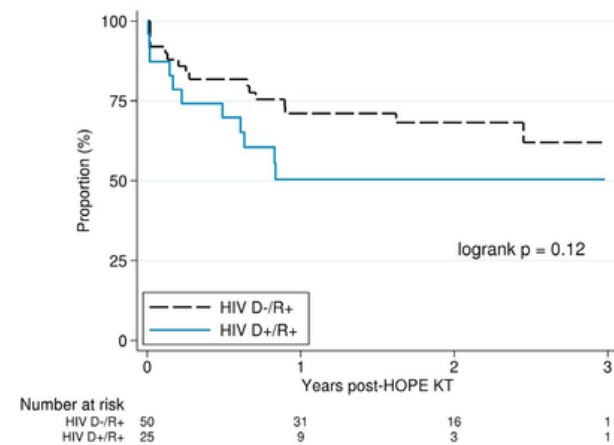
- 75 patients
 - 25 HIV D+/R+
 - 22 HIV D False-positive/R+
 - 28 HIV D-/R+
- 91% recipients were on INSTI-containing ART at time of transplant

HOPE Clinical Outcomes – Kidney Transplantation

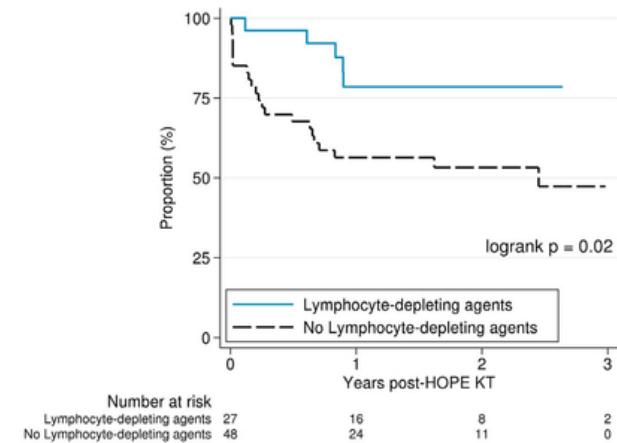
TABLE 3 Posttransplant outcomes

Outcomes	HIV D+/R+ N = 25	HIV D-/R+ N = 50	P value
Median follow-up time, y (IQR)	1.4 (1.1-2.3)	1.8 (1.4-2.6)	.14
Patient survival, no. (%) ^a	25 (100%)	75 (100%)	
Graft survival, no. (%)	23 (92%)	45 (90%)	>.99
Participants with delayed graft function, no. (%)	3 (12%)	21 (42%)	.01
Serious adverse events, per person-year ^b	1.1	1.1	.78
Participants with hospitalization due to infection, no. (%)	7 (28%)	13 (26%)	.85
Participants with opportunistic infection, no. (%)	4 (16%)	6 (12%)	.72
CMV viremia, no. (%)	3 (12%)	3 (6%)	.39
Esophageal candidiasis, no. (%)	0 (0%)	2 (4%)	.55
Candida glabrata fungemia, no. (%)	0 (0%)	1 (2%)	>.99
Bartonella infection of liver, no. (%)	1 (4%)	0 (0%)	.33
Participants with breakthrough HIV viremia, no. (%)	1 (4%)	3 (6%)	>.99
Participants with malignancy, no. (%)	0 (0%)	3 (6%)	.55
Kaposi sarcoma, no. (%)	0 (0%)	1 (2%)	>.99
Gastric adenocarcinoma, no. (%)	0 (0%)	1 (2%)	>.99
Oropharyngeal cancer, no. (%)	0 (0%)	1 (2%)	>.99
1-y eGFR filtration rate, mean, mL/min/1.73 m ²	63 (28)	57 (17)	0

B Rejection-free survival by donor HIV status



C Rejection-free survival by induction type



Durand CM, Zhang W, Brown DM, Yu S, Desai N, Redd AD, Bagnasco SM, Naqvi FF, Seaman S, Doby BL, Ostrander D, Bowring MG, Eby Y, Fernandez RE, Friedman-Moraco R, Turgeon N, Stock P, Chin-Hong P, Mehta S, Stosor V, Small CB, Gupta G, Mehta SA, Wolfe CR, Husson J, Gilbert A, Cooper M, Adebisi O, Agarwal A, Muller E, Quinn TC, Odum J, Huprikar S, Florman S, Massie AB, Tobian AAR, Segev DL; HOPE in Action Investigators. A prospective multicenter pilot study of HIV-positive deceased donor to HIV-positive recipient kidney transplantation: HOPE in action. *Am J Transplant*. 2021 May;21(5):1754-1764. doi: 10.1111/ajt.16205. Epub 2020 Aug 8. PMID: 32701209; PMCID: PMC8073960.

HOPE Clinical Outcomes – Kidney Transplantation

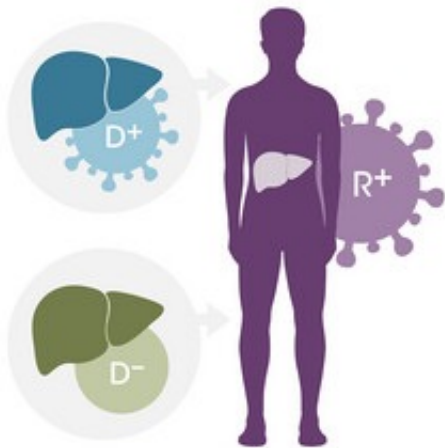
- Multicenter non-inferiority trial to assess safety and efficacy of HIV D+/R+ vs. HIV D-/R+ kidney transplants
 - 198 kidney transplants
 - No differences in 1-year patient survival, 1-year graft survival, or 1-year rejection rates (Durand, ATC 2023)
 - 3-year survival and 3- year rejection rate data forthcoming in 2024

HIV D+/R+ kidney transplant was **safe and noninferior** to HIV D-/R+ kidney transplant

Clinical outcomes: HOPE liver transplantation

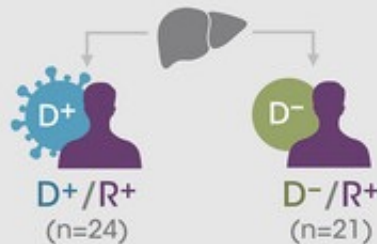
HOPE in action: A prospective multicenter pilot study of liver transplantation from donors with HIV to recipients with HIV

How do liver Tx outcomes compare between HIV-positive and HIV-negative donors to HIV-positive recipients?



Prospective, multicenter study

45 liver Tx to HIV+ recipients



Outcomes assessed using Cox and negative binomial regression

1-year patient survival:



83.3%



100%

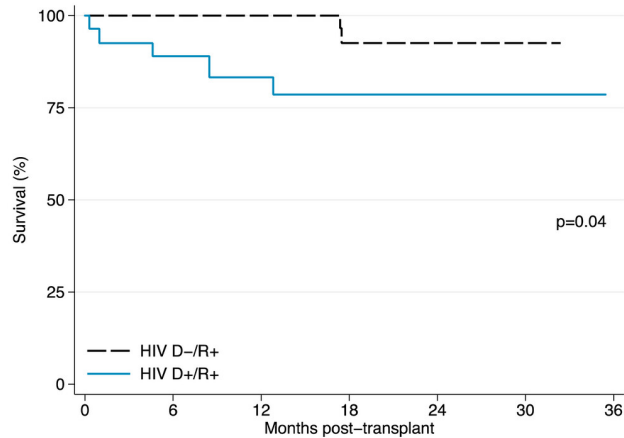
No difference in 1-year graft survival, rejection, HIV breakthrough, or severe adverse events

D+/R+ had more opportunistic infections, infectious hospitalizations, and cancer

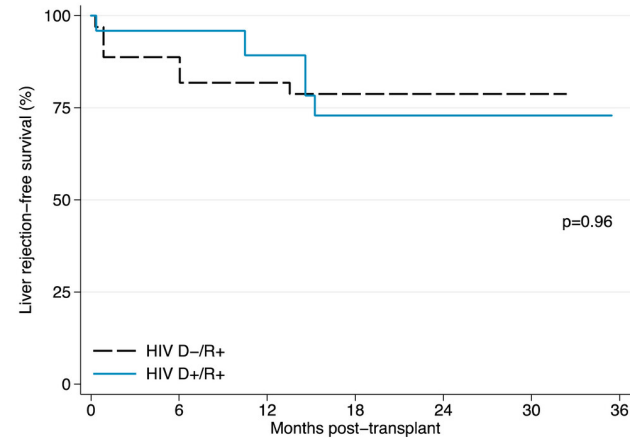
AJT

Clinical outcomes: HOPE liver transplantation

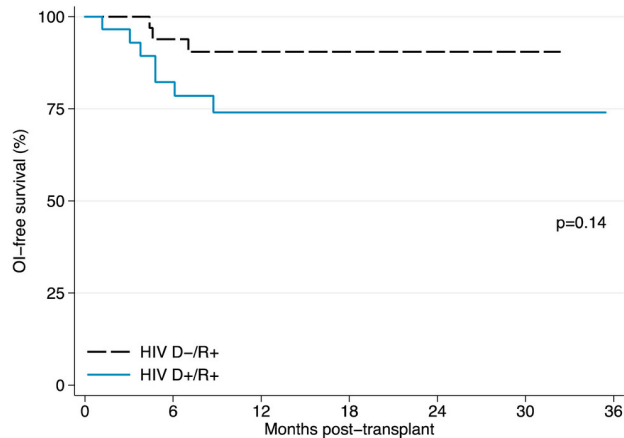
(A) Overall survival



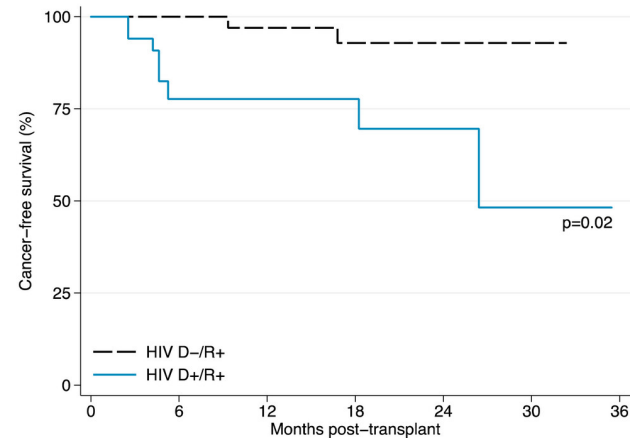
(B) Liver rejection-free survival



(C) Opportunistic infection-free survival



(D) Cancer-free survival



HIV and Living Donor Transplantation

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MEDICAL & BIOTECH

World's First HIV-to-HIV Kidney Transplant with Living Donor Performed Successfully

The ability to use organs from living HIV-positive individuals could increase the supply available for transplant

By Victoria Knight, Carmen Heredia Rodriguez, Kaiser Health News on March 29, 2019

Some view the legislation not only as an avenue to advance medicine, but also to challenge how people perceive HIV. The ability to donate an organ implies a certain level of health that was once thought impossible in people living with HIV, said Peter Stock, professor of surgery at the University of California-San Francisco and one of the pioneering surgeons in HIV organ transplants.

HIV-positive Living Donor Criteria

Donor criteria:

- Well-controlled HIV infection:
 - CD4 count ≥ 500 cells/mm³ for 6 months prior to donation
 - HIV-1 RNA <50 copies/mL
- No evidence of invasive opportunistic complications of HIV infection
- Pre-implant donor organ biopsy

Donor Outcomes :

- Progression to renal insufficiency
- Change in ART regimen as a result of organ dysfunction
- Progression to AIDS
- Failure to suppress viral replication (persistent HIV viremia)
- Death

Final Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected with HIV. Department of Health and Human Services.

<https://www.niaid.nih.gov/sites/default/files/hopeactcriteria.pdf>

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

Christine M. Durand,^{a,*} Nina Martinez,^b Karl Neumann,^c Reed C. Benedict,^d Arthur W. Baker,^e Cameron R. Wolfe,^f Valentina Stosor,^f Aneasha Shetty,^f Zachary C. Dietch,^f Leah Goudy,^f Michelle A. Callegari,^f Allan B. Massie,^g Diane Brown,^g Willa Cochran,^g Abimereki Muzaale,^h Derek Fine,^g Aaron A. R. Tobian,ⁱ Cheryl A. Winkler,^j Fawaz Al Ammary,^g and Dorry L. Segev,^g On Behalf of the HOPE in Action Investigators^k

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.

Living kidney donors with HIV: early experience from the U.S.



- Donor experience
 - No serious complications related to nephrectomy
 - Expected post-donation kidney function decline during follow-up
 - Continued virologic suppression of HIV infection
 - Reasons for donation:
 - “Desire for autonomy over her decision to donate since deceased donation can be limited by mechanisms of death and systemic barriers for PLWH”
 - “Primary motivation for donation was to help someone discontinue dialysis and improve their quality of life;... opportunity to reduce HIV-associated stigma.”
 - “motivations for donation included helping his husband who was living with HIV and ESRD”
- Recipient experience
 - 2 of 3 did not receive induction ATG therapy and experienced early allograft rejection
 - Continued virologic suppression of HIV infection to years 2-4
 - eGFR >38 mL/min/1.73m³ at years 2-4

HIV-HIV Thoracic Organ Transplantation

ORIGINAL ARTICLE

WILEY  **Clinical TRANSPLANTATION**
The Journal of Clinical and Translational Research

Knowledge, attitudes, and planned practice of HIV-positive to HIV-positive transplantation in US transplant centers

Sarah E. Van Pilsum Rasmussen¹  | Mary Grace Bowring¹  | Ashton A. Shaffer^{1,2}  |
Macey L. Henderson¹  | Allan Massie^{1,2} | Aaron A. R. Tobian³ | Dorry L. Segev^{1,2} |
Christine M. Durand⁴ 

- 2016 survey with responses from 104 of 204 adult transplant centers
- 2 heart and 1 lung program planning HIV+ to HIV+ transplantation
- Organ-specific experience criteria per federal safeguards: 5 transplants in HIV+ recipients in prior 4 years

TABLE 5 Attitudes on HIV+ deceased and living donor eligibility

Transplant Center and Study Team Experience Criteria	Agree	Agree: but should not be organ-specific	Neutral	Disagree: should be no experience criteria
Transplant physician and HIV physician collectively have experience with at least 5 HIV D-/R+ transplants with the designated organs over the last 4 years	35.1	40.4	11.7	12.8

Table 2. Outcomes in the Transplant Recipients.*

Outcome	Lung Transplantation		Odds Ratio or Mean Difference (95% CI)†	Heart Transplantation		Odds Ratio or Mean Difference (95% CI)†
	Organ from HCV NAT- Positive Donor (N=28)	Organ from Donor without HCV Infection (N=44)		Organ from HCV NAT- Positive Donor (N=7)	Organ from Donor without HCV Infection (N=12)	
Mean donor ischemic time — min	327	281	46.65 (12.43 to 80.87)	269	236	33.64 (–20.50 to 87.78)
Mean cardiopulmonary-bypass time — min	185	199	–14.84 (–37.81 to 8.13)	167	170	–3.70 (–44.61 to 37.21)
Grade 3 pulmonary graft dysfunction at 72 hr — no. (%)	0	3 (7)	NE (0.26 to NE)	NA	NA	NA
Mean length of hospital stay after transplantation — days	14	21	–6.88 (–12.24 to –1.52)	49	72	–22.80 (–100.54 to 54.94)
Mean ICU stay after transplantation — days	6	10	–4.03 (–8.05 to –0.01)	38	36	2.12 (–77.28 to 81.52)
Patients with rehabilitation stay — no. (%)	13 (46)	17 (39)	0.73 (0.25 to 2.12)	0	7 (58)	NE (1.21 to NE)
Mean length of rehabilitation stay — days	31	32	–0.54 (–19.87 to 18.80)	NA	NA	
Patients with readmissions — no. (%)	22 (79)	36 (82)	1.22 (0.31 to 4.66)	3 (43)	9 (75)	3.69 (0.38 to 44.48)
Median readmissions — no.	2	2		1	2	
Patients with liver-function results >3 times upper limit of normal range — no. (%)‡						
<30 days after transplantation	2 (7)	5 (11)	1.66 (0.25 to 18.62)	3 (43)	8 (67)	2.53 (0.27 to 27.33)
≥30 days after transplantation	2 (7)	7 (16)	2.43 (0.42 to 25.83)	0	1 (8)	NE (0.10 to NE)
Stage 4 or 5 chronic kidney disease at 6 mo — no. (%)	8 (29)	9 (20)	0.65 (0.19 to 2.26)	2 (29)	4 (33)	1.24 (0.12 to 18.58)
Dialysis at 6 mo — no. (%)	1 (4)§	1 (2)	0.63 (0.01 to 51.10)	1 (14)	2 (17)	1.19 (0.05 to 82.40)
Respiratory failure at 6 mo — no. (%)	0	4 (9)	NE (0.43 to NE)	1 (14)	3 (25)	1.93 (0.12 to 122.13)
Acute cellular rejection for which treatment was indicated — no. of patients (%)	15 (54)	13 (30)	0.37 (0.12 to 1.09)	3 (43)	4 (33)	0.68 (0.07 to 7.06)
Graft survival — no. (%)						
1 mo	28 (100)	43 (98)	0 (0 to 61.23)	7 (100)	11 (92)	0 (0 to 66.79)
6 mo	28 (100)	43 (98)	0 (0 to 61.23)	7 (100)	10 (83)	0 (0 to 9.25)
Overall survival at 6 mo — no. (%)	28 (100)	43 (98)	0 (0 to 61.23)	7 (100)	10 (83)	0 (0 to 9.25)

* Data shown are from the analysis comparing the outcomes in the 35 patients who received organs from HCV-positive donors and had at least 6 months of follow-up with the outcomes in the 56 patients who received transplants from donors without HCV infection and had at least 6 months of follow-up. ICU denotes intensive care unit, NA not applicable, and NE could not be estimated.

† Estimates for categorical data are unadjusted odds ratios, and 95% confidence intervals are two-sided and were calculated with the use of Fisher's exact test. Estimates for continuous data are mean differences, and 95% confidence intervals were calculated with the use of t tests. The widths of the confidence intervals are not adjusted for multiple comparisons and should not be used to infer definitive differences between groups.

‡ The liver-function tests were measurements of alanine aminotransferase, aspartate aminotransferase, and alkaline phosphatase.

§ This patient began dialysis on day 9 after transplantation, and sofosbuvir–velpatasvir treatment was continued without any adverse events.

Considerations for hepatitis C-infected organs for HIV-infected recipients

- Some centers include recipient HIV infection as an exclusion criteria for use of hepatitis C-infected organs for hepatitis-C uninfected recipients
- HOPE in Action studies allow simultaneous consent for HCV D+/R- transplant
- Is prior data on worse post-transplant outcomes in HIV-HCV coinfecting patients applicable to donor-derived infection that is treated immediately?
 - Newer hepatitis C therapies

TABLE 3.

Multivariate Cox proportional hazards regression of associations^a with graft failure in liver transplant recipients in the pre-DAA (2008–2012) and DAA (2014–2019) eras

Pre-DAA era (ref. HIV ⁻ /HCV ⁻)	HR (95% CI)	<i>P</i>	DAA era (ref. HIV ⁻ /HCV ⁻)	HR (95% CI)	<i>P</i>
HIV ⁺ /HCV ⁺	1.85 (1.31-2.59)	<0.001	HIV ⁺ /HCV ⁺	1.24 (0.81-1.89)	0.308
HIV ⁺ /HCV ⁻	1.21 (0.77-1.91)	0.840	HIV ⁺ /HCV ⁻	1.23 (0.81-1.88)	0.324
HIV ⁻ /HCV ⁺	1.24 (1.19-1.29)	<0.001	HIV ⁻ /HCV ⁺	1.01 (0.96-1.07)	0.709

^aAdjusted for donor and recipient age and DCD graft use.

CI, confidence interval; DAA, direct-acting antiviral; DCD, donation after circulatory death; HCV, hepatitis C virus.

Cotter TG, Wang J, Lieber SR, Odenwald MA, Rich NE, Marrero JA, Singal AG, Mitchell MC, Aronsohn A, Charlton M, Fung J. "Raising HOPE": Improved Outcomes for HIV/HCV-coinfecting Liver Transplant Recipients in the Direct-acting Antiviral Era. *Transplant Direct*. 2021 Jun 8;7(7):e707. doi: 10.1097/TXD.0000000000001154. PMID: 34124343; PMCID: PMC8191686.

FUTURE DIRECTIONS

Access to Cardiac Transplant for HIV-infected Candidates

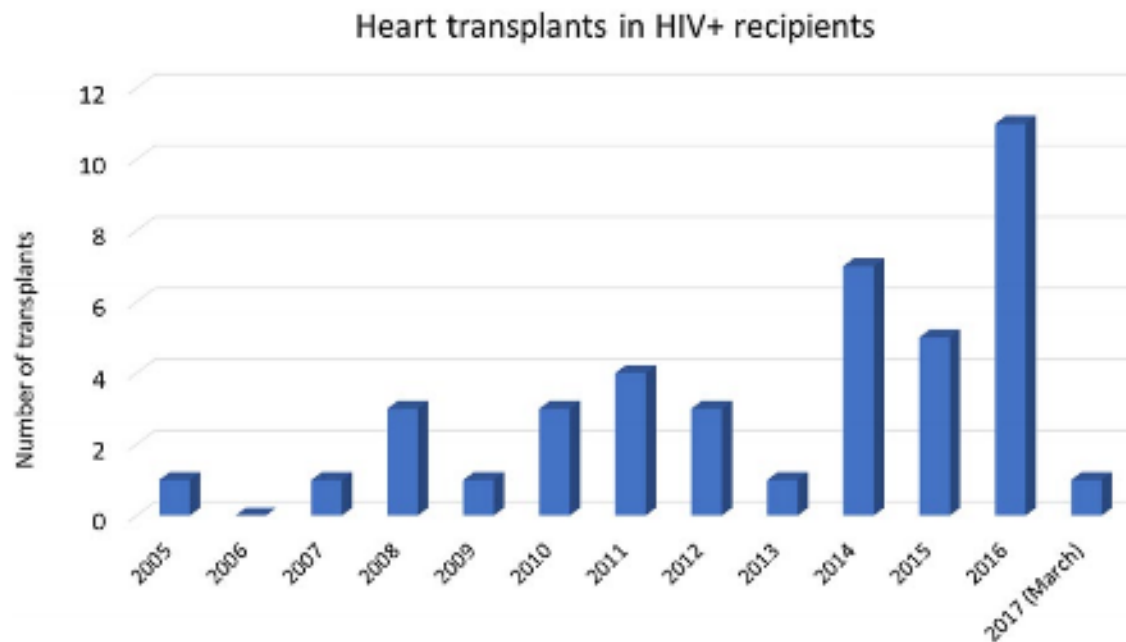


FIGURE 3 Trend of heart transplantations in HIV+ recipients in the United States. HIV+, human immunodeficiency virus positive [Color figure can be viewed at wileyonlinelibrary.com]

Access to Cardiac Transplant for HIV-infected Candidates

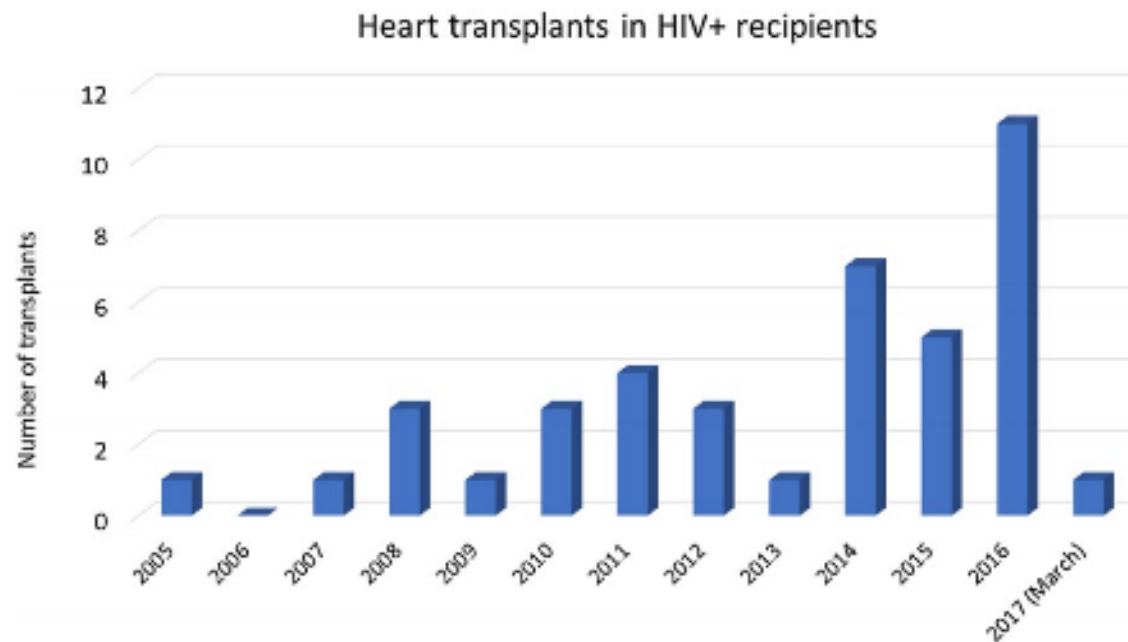


FIGURE 3 Trend of heart transplantations in HIV+ recipients in the United States. HIV+, human immunodeficiency virus positive [Color figure can be viewed at wileyonlinelibrary.com]

- 140 registered heart transplant centers in the United States
- 24 of 140 (<20%) had performed a HT in patients with HIV infection during study period
- 30% of HIV+ heart transplants performed in UNOS Region 9

First HOPE heart transplantation in the U.S.

HIV D+/R+ heart/kidney transplantation: First case report



Vagish Hemmige, MD, MS,^{a,b,#} Omar Saeed, MD, MS,^{a,b,#}
 Yoram A. Puius, MD, PhD,^{a,b} Yorg Azzi, MD,^{a,b}
 Adriana Colovai, PhD,^{a,b} Jamil Borgi, MD,^{a,b}
 Daniel J. Goldstein, MD,^{a,b} Marjan Rahmadian, MD,^{a,b}
 Anthony Carlese, DO,^{a,b} Ulrich P. Jorde, MD,^{a,b,¥} and
 Snehal Patel, MD^{a,b,¥}

From the ^aAlbert Einstein College of Medicine, Bronx, New York;
 and the ^bMontefiore Medical Center, Bronx, New York.

Patient with longstanding well-controlled HIV infection (on dolutegravir and rilpivirine) and ESRD initiated dialysis with subsequent decline in LVEF. Donor with undetectable HIV viral load and unknown ART history.

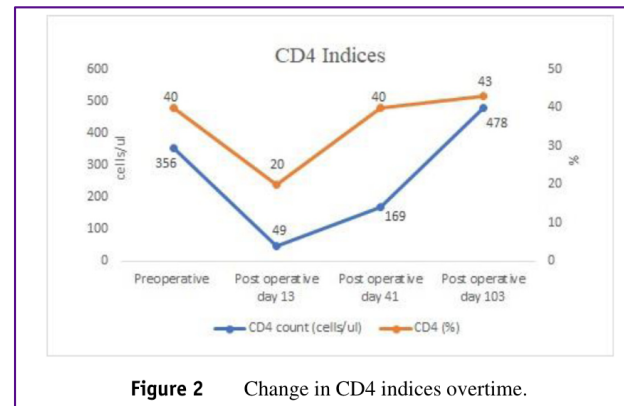
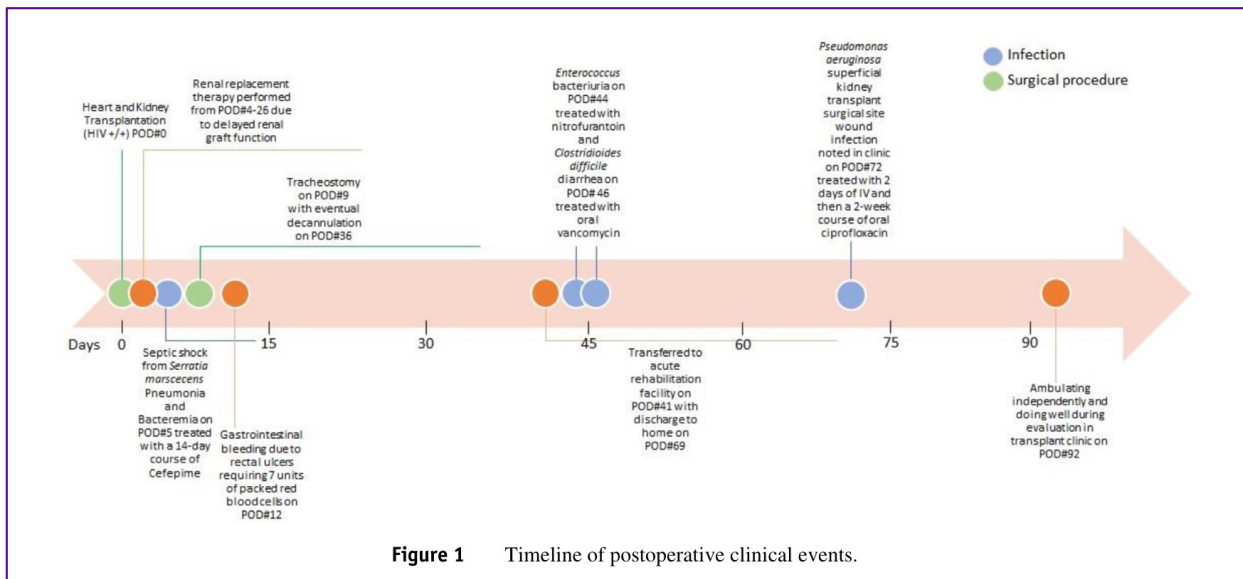


Figure 2 Change in CD4 indices overtime.



Long term outcomes of HIV D+/R+ heart transplantation are not yet evaluated

HOPE lung transplant on the near horizon



The image is a screenshot of a web article from DukeHealth. The top navigation bar is dark blue with white text: 'DukeHealth | Referring Physicians', 'Find a Specialist', 'Clinical Practice Today', 'Refer to Duke', and 'Connect'. The article title is 'Lung Transplant Team Moving Rapidly to Accept HIV-Positive Lungs'. Below the title is a sub-headline: 'Successful transplant for patient with HIV represents key first step'. There is a blue circular icon with a white dot next to the word 'Transplant'. The author is listed as 'By Tim Pittman' and the publication date is 'Published February 8, 2022'. At the bottom of the article preview is a 3D medical illustration of a human torso showing the lungs in a glowing orange-red color against a blue translucent body.

ARTICLE

Lung Transplant Team Moving Rapidly to Accept HIV-Positive Lungs

Successful transplant for patient with HIV represents key first step

● [Transplant](#)

By Tim Pittman
Published February 8, 2022

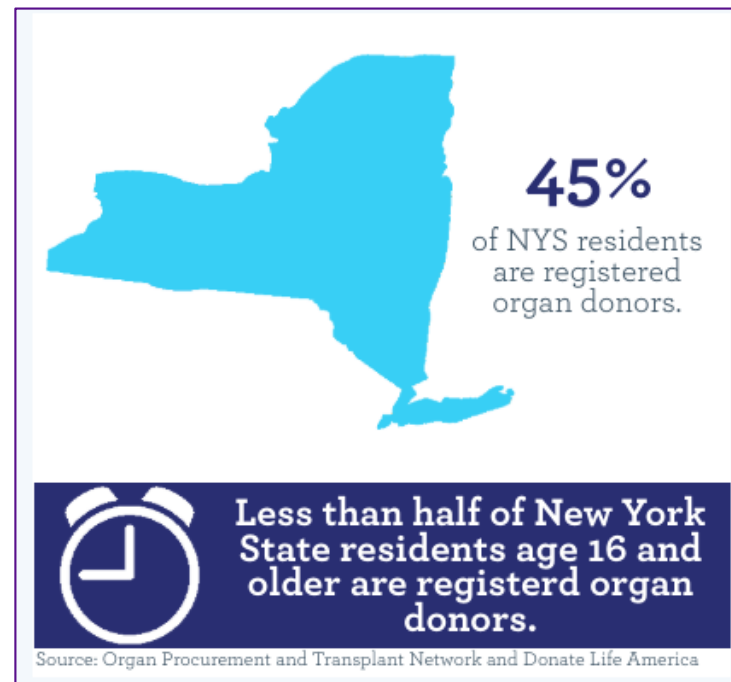


Newer ART agents and considerations for transplant patients

- New agents provide potential to ease medication burden such as with long-acting injectable ART
- Must balance patient preference and convenience with challenges of adjustment for drug interactions with transplanted related immunosuppressants
- Renal function can remain dynamic in the early post-transplant period
- Consider potential drug interactions with antimicrobials that are commonly needed in post-transplant setting (e.g. azole antifungals)

New York Region- wait times are long

- National waitlist time is 1-2 years, waitlist time in New York state is 3-5 years¹



¹LiveOnNY Fact Sheet 2021.

Willingness of PLWH to donate organs

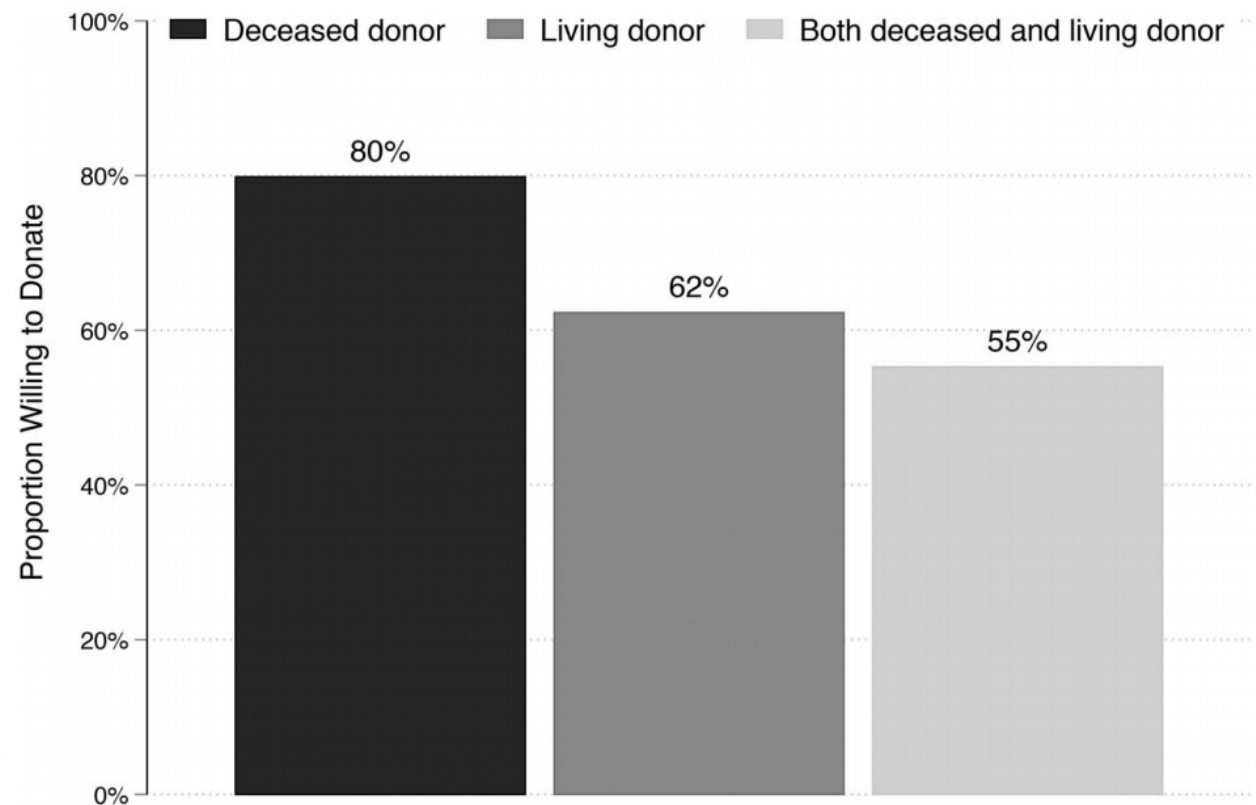


FIGURE 2. Proportion of respondents willing to donate organs (N = 114).

Nguyen et al. JAIDS Sept 2018.

Steps Towards Organ Donation among PLWH

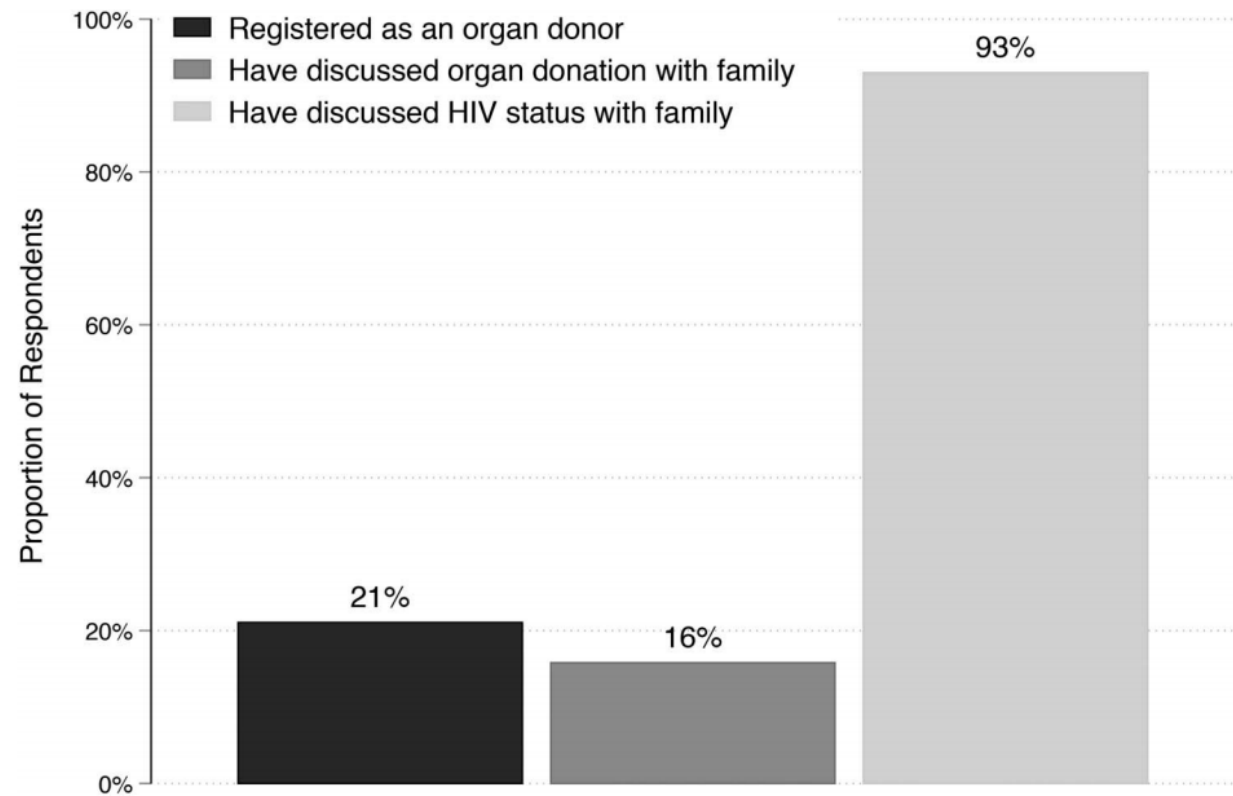


FIGURE 3. Organ registration rate and discussion with family (N = 114).

Nguyen et al. JAIDS Sept 2018.

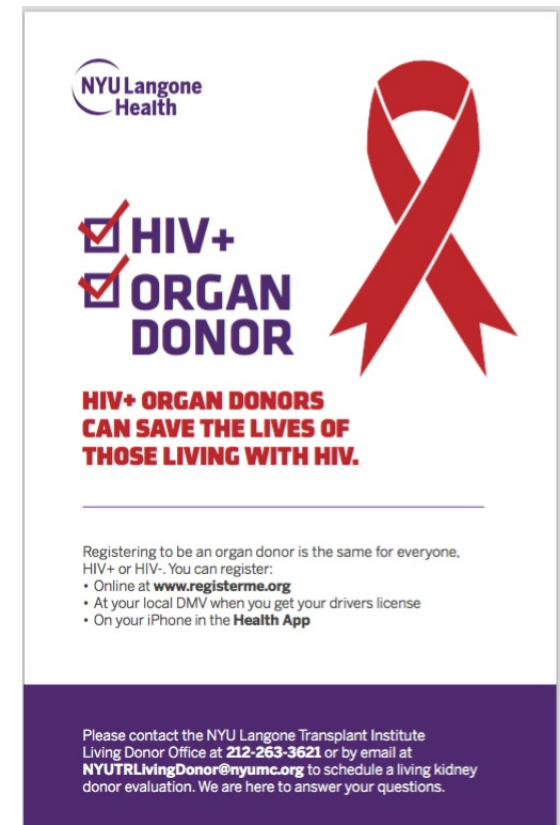
Living Donors with HIV Infection

- Motivations
 - Altruistic desire to help others
 - Solidarity with HIV-positive recipients
 - Desire to overcome HIV-related stigma
 - Gratification from improving a recipient's life
- Concerns
 - Possibility of prolonged recovery period
 - Organ failure
 - Transmission of another strain of HIV to recipients

Van Pilsum Rasmussen et al. Perceptions, motivations and concerns about living organ donation among people living with HIV. AIDS Care. 2018 May 3.

Opportunities to Discuss Organ Donation in Primary Care

- When the patient asks about organ donation
- When discussing end-of-life matters (e.g. power of attorney)
- When the patient expresses wanting to “give back”
- Incorporate into annual exam as part of health maintenance or social assessment



The poster features the NYU Langone Health logo in the top left. On the right is a large red awareness ribbon. In the center, there are two checkmarks, each with a red checkmark icon, followed by the text 'HIV+' and 'ORGAN DONOR' in bold blue letters. Below this, the text 'HIV+ ORGAN DONORS CAN SAVE THE LIVES OF THOSE LIVING WITH HIV.' is written in bold red letters. At the bottom, there is a list of registration methods: 'Online at www.registerme.org', 'At your local DMV when you get your drivers license', and 'On your iPhone in the Health App'. A purple footer bar at the bottom contains contact information for the NYU Langone Transplant Institute Living Donor Office.

NYU Langone Health

HIV+
 ORGAN DONOR

HIV+ ORGAN DONORS CAN SAVE THE LIVES OF THOSE LIVING WITH HIV.

Registering to be an organ donor is the same for everyone, HIV+ or HIV-. You can register:

- Online at www.registerme.org
- At your local DMV when you get your drivers license
- On your iPhone in the **Health App**

Please contact the NYU Langone Transplant Institute Living Donor Office at **212-263-3621** or by email at NYUTRLivingDonor@nyumc.org to schedule a living kidney donor evaluation. We are here to answer your questions.

Key Points

- There is a continued growing need for organ transplant for people living with HIV infection
- Clinical outcomes of abdominal organ transplant in HIV-infected recipients including under the HOPE Act are very good
- Limited data but good clinical outcomes for thoracic organ transplant in HIV-infected recipients
- The HOPE Act has improved access to kidney and liver transplantation for PLWH
- The early experience with living kidney organ donation for people living with HIV infection is promising
- Outreach and partnerships are needed to further raise community awareness of organ donation options for PLWH