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Deceased Organ Donor HTLV Screening Practices Postelimination of Universal Screening in the United States

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Background. In the United States, universal screening for human T-lymphotropic virus (HTLV) in deceased organ donors was discontinued in 2009. Since then, the transplant guideline suggests considering targeted screening. However, the outcomes of this change in HTLV screening have not been evaluated. **Methods.** Using the Organ Procurement and Transplantation Network database between 2010 and 2022, we analyzed the HTLV antibody screening frequency and seroprevalence in potential deceased organ donors and their correlations with HTLV infection risks, including race and high-risk behaviors for blood-borne pathogen infection. Although targeted screening has not been established for HTLV, we hypothesized that screening rates should correlate with the proportions of donors with infection risk if screening is targeted. We also evaluated the organ utilization of HTLV-seropositive donors. **Results.** Of 130 284 potential organ donors, 22 032 (16.9%) were tested for HTLV antibody. The proportion of donors tested for HTLV varied between Organ Procurement Organizations (median [interquartile range], 3.8% [1.0%–23.2%]; range, 0.2%–99.4%) and was not correlated to HTLV infection risks. There were 48 seropositive donors (0.22%), and at least 1 organ from 42 of these donors (87.5%) was transplanted. The number of organs recovered and transplanted per donor was significantly lower in HTLV-seropositive than in HTLV-negative donors (recovered, 2 [2–3] versus 3 [3–5], $P < 0.001$; transplanted, 2 [1–3] versus 3 [2–4], $P < 0.001$). However, HTLV-1 infection was not attributed as the cause of nonrecovery except for only 1 HTLV-seropositive donor. **Conclusions.** HTLV screening practices varied across the United States. Our findings suggest that targeted screening was not performed after the elimination of universal screening.

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Infection screening of organ donors is essential to prevent donor-derived transmission; however, appropriate screening methods have not been completely established, especially for rare pathogens, such as human T-lymphotropic virus (HTLV).[1] HTLV-1 is a pathogenic human retrovirus endemic in the Caribbean, parts of South America, sub-Saharan Africa, Oceania, and southwestern Japan.[2] Although most infected individuals remain life-long asymptomatic carriers,

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The data that support the findings of this study are available from the Organ Procurement and Transplantation Network.

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approximately 5% develop devastating diseases, such as adult T-cell leukemia/lymphoma (ATLL) and HTLV-1-associated myelopathy (HAM). Currently, no established treatment eliminates HTLV-1 or cures the associated diseases.[3,4] HTLV-2 is endemic in some indigenous populations in the Americas and people who use intravenous drugs in the United States and Europe.[5,6] There is no convincing evidence linking HTLV-2 to human disease. HTLV-1 and HTLV-2 infections were reported in 0.005% and 0.015% of first-time blood donors in the United States between 2000 and 2009, respectively.[7] HTLV seropositivity is associated with older age, female sex, non-White race, and behaviors that increase the risk of bloodborne pathogen transmission, such as nonmedical intravenous drug use.[7,8] HTLV infection is diagnosed via a 2-step process composed of screening and confirmatory assays because screening assays have false positives and do not distinguish between HTLV-1 and HTLV-2.[9,10] HTLV screening assays available in the United States have excellent sensitivity and specificity (>99%).[11] Nonetheless, only a minute proportion of individuals with positive screening are true positives because of the low prevalence of HTLV in the United States.[7]

HTLV-1 is transmitted via solid organ transplantation from infected donors as well as via breastfeeding, sexual intercourse, intravenous drug use, and blood transfusion.[12] An anecdotal case report from Spain documented the development of HAM in 3 HTLV-1-naive organ recipients from a single HTLV-1-infected donor, with HTLV-1 DNA sequence analysis confirming donor-derived viral transmission.[13,14] In Germany, 2 HTLV-1-naive recipients developed ATLL and 1 developed HAM after receiving organs from an HTLV-1-infected donor.[15,16] The ATLL cells in these cases were of recipient origin, ruling out the transmission of donor-derived ATLL. Recent genetic analyses have demonstrated that HTLV-1 rapidly disseminates to recipient blood cells and donor-derived HTLV-1-infected cell clones, which remain nonmalignant, persistently survive in organ recipients after donor-derived infection.[17,18] A nationwide survey in Japan reported a donor-derived transmission rate of 87% and 40% incidence of HAM in HTLV-1-naive kidney recipients of infected donors.[19] In Japan, organ transplantation from HTLV-1-positive donors is contraindicated.[20] The British Transplantation Society guidelines also prohibit organ donation from individuals infected with HTLV-1 despite Great Britain's low HTLV prevalence.[21]

Using the US Organ Procurement and Transplantation Network (OPTN) data between 1987 and 2011, Tedla et al[22] reported that the proportion of HTLV-seropositive deceased organ donors was 0.16% and that these seropositive donors clustered in certain states. The 10 states with the highest numbers of positive donors (New York, Texas, North Carolina, Illinois, Pennsylvania, Michigan, Missouri, South Carolina, Delaware, and Florida) accounted for 56% of all positive donors. Although HTLV-1 infection is rare in the United States, experts in the field of HTLV research report concern that the HTLV prevalence may be significantly changing because of ongoing immigration.[23] The first case report of donor-derived HAM in the United States, which developed in a kidney recipient of an HTLV-1-infected donor who immigrated from the Dominican Republic, was published in 2014.[24] The second case of HAM after a kidney transplant in the United States was reported in 2015.[25] In this case, both the donor and recipient were of Jamaican origin, and their pretransplant HTLV-1 status was unknown.

Currently, in the United States, deceased organ donor HTLV screening is determined by individual Organ Procurement Organization (OPO) protocols/practices because the OPTN eliminated the screening requirement in 2009. This OPTN policy change was enacted because of unacceptable organ wastage from false-positive test results because of the overall low prevalence of HTLV infection in the United States.[9,26,27] Nevertheless, in 2019, the Infectious Diseases Community of Practice of the American Society of Transplantation suggested that OPOs consider targeted screening based on infection risk (eg, immigrants from high-prevalence countries).[1] However, trends in HTLV screening and seroprevalence in organ donors have not been evaluated since the OPTN policy change. We therefore designed this national database study to determine the current status of HTLV screening in the United States. Our primary study question was whether the current HTLV screening performed in the United States is targeted at a higher-risk population, and we hypothesized that OPOs have performed targeted screening.

MATERIALS AND METHODS

Data Source

This study used deidentified registry data from the OPTN. The OPTN data system includes information on all donors, waitlisted candidates, and transplant recipients in the United States submitted by the members of the OPTN. The Health Resources and Services Administration, US Department of Health and Human Services provides oversight to the activities of the OPTN contractor. This study was approved by the University of Utah Institutional Review Board (approval No. IRB_00149997). Informed consent was waived, given the use of the publicly available deidentified data set.

Study population and outcomes

The cohort included potential deceased organ donors from January 1, 2005, to September 30, 2022, based on OPTN data as of September 30, 2022 (Figure 1). We chose the study start date of 2005 because the OPTN began collecting data for the variable "HTLV antibody in deceased organ donors (HTLV_DON)" in June 2004. The database does not differentiate between HTLV-1 and HTLV-2 nor report whether confirmatory testing was performed. Therefore, HTLV seropositivity in this study could reflect false positivity, true HTLV-1 infection, or true HTLV-2 infection. We analyzed donor characteristics separately for the universal HTLV screening period (2005–2009) and the post–universal screening period (2010–2022).

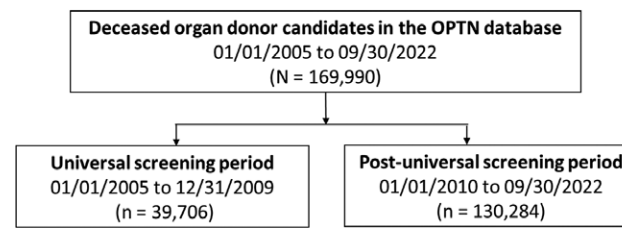

FIGURE 1. Study flowchart. HTLV, human T-lymphotropic virus; OPTN, Organ Procurement and Transplantation Network.

Outcomes of interest included (1) the frequency of HTLV screening and seropositive donors in 2010–2022; (2) characteristics of HTLV-seropositive donors; and (3) associations of HTLV screening practices with HTLV infection risk, including donor race, high-risk behaviors for blood-borne pathogen infection, and the frequency of HTLV-seropositive donors in 2005–2009. We defined donors with high-risk behaviors using "increased risk for blood-borne disease transmission according to the US Public Health Service (PHS) guidelines (PHS-risk)" in the OPTN data set, although the PHS-risk was not developed for HTLV infection. The PHS guideline, which was first issued in 1994 and focused only on HIV infection risk, was revised in 2013 and 2020.[28] The guideline was modified in 2013 to identify the increased risk for transmitting hepatitis B virus (HBV) and hepatitis C virus (HCV) in addition to HIV, and the 2020 version also targets these 3 viruses.[29,30] The 2013 version, which covered the most period of the present study, designated donors as increased risk if donors met any of 14 risk criteria during the 12 mo before organ procurement, such as drug injection for nonmedical reasons, man who has had sex with another man, and sex in exchange for money or drugs (**Supplemental Methods, SDC,** http://links.lww.com/TXD/A699). We also investigated organ utilization of HTLV-seropositive donors.

Data Extraction

We extracted the following donor variables from the OPTN database: age, sex, race (reported by donor family/decision makers), brain death/circulatory death, diabetes, hypertension, Kidney Donor Profile Index (KDPI) referenced to the 2021 OPTN donor population,[31] HTLV antibody, HBV core (HBc) antibody, HCV antibody, HIV antibody, PHS-risk, OPO code, and donor home state. We also extracted the number of organs recovered, transplanted, and recovered but not transplanted (discarded), and the reason for nonrecovery to analyze how many organs were unrecovered because of HTLV-1 infection. We did not analyze the associations between HTLV-1 infection and organ discard because the database has no option indicating HTLV-1 infection.

Statistical Analysis

Baseline characteristics were summarized as means and SDs or medians and interquartile ranges (IQRs) for continuous variables and numbers and percentages for categorical variables. Categorical variables were compared using chi-square tests, and continuous variables were compared via *t* tests or Mann-Whitney *U* tests, as appropriate. Associations between the proportion of HTLV testing and HTLV infection risk by OPO and door home state were assessed using Spearman's correlation tests. We also depicted the US maps with the number and proportion of HTLV-seropositive donors as well as proportions of donors tested for HTLV antibodies and those with HTLV infection risk by OPO donor service area and donor home state. *P* values of <0.05 were 2-sided and considered statistically significant. Analyses were conducted using STATA version 17 (STATA Corporation, College Station, TX). Donor home state and donor HIV antibody results were missing in 1.1% and 3.8% of patients, respectively. Other variables were missing in <1% of patients. Missing data were not imputed.

RESULTS

HTLV Screening in 2005–2009

In 2005–2009, 39 619 of 39 706 potential organ donors (99.8%) were screened and 126 (0.32%) were positive for HTLV antibody (Figure 2; Table 1). HTLV-seropositive donors were older (mean ± SD age, 46 ± 15 versus 41 ± 19 y) and more frequently women (58.7% versus 40.7%) compared with negative donors. The proportions of donors with PHS-risk (13.5% versus 7.9%), HBc antibody (11.9% versus 5.7%), and HCV antibody (10.3% versus 4.1%) were higher in HTLV-seropositive than in negative donors; however, HIV antibody was not different (0% in both groups). HTLV antibody was more frequently positive in Black donors than in Hispanic and White donors (0.95%, 0.29%, and 0.17%, respectively; Table 2).

Figure 3 shows the distribution of HTLV-seropositive donors across the United States. HTLV-seropositive donors came from 36 states, mainly in the south and northeast (median [IQR] number of HTLV-seropositive donors by state, 1 [0–3]; range, 0–17; median [IQR] proportion by state, 0.2% [0%–0.4%]; range, 0%–2.1%; Figure 3A and B). The 12 states with the highest numbers (4–17 donors per state) accounted for 86 of 126 seropositive donors (68.3%; New York, Texas, North Carolina, Illinois, South Carolina, Missouri, Florida, Pennsylvania, Alabama, Delaware, Maryland, and New Jersey). Of 56 OPOs, 35 reported HTLV-seropositive donors (median [IQR] number of HTLV-seropositive donors by OPO, 1 [0–3]; range, 0–18; median [IQR] proportion by OPO, 0.2% [0%–0.5%]; range, 0%–1.3%; Figure 3C and D).

All donors had at least 1 organ recovered; however, the number of organs recovered per donor was significantly lower in HTLV-seropositive than in negative donors (median [IQR], 1 [1–3] versus 3 [3–4], $P < 0.001$; Table 3). Except for the liver (only 3% unrecovered), 31%–48% of HTLV-seropositive donor organs were unrecovered because of HTLV-1 infection. The proportion of donors who had at least 1 organ discarded

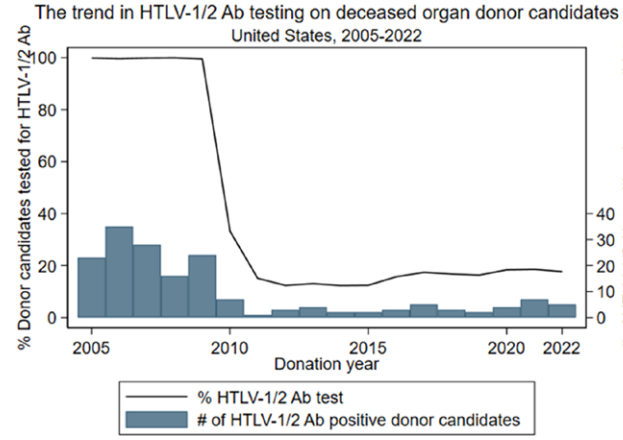

FIGURE 2. Trends in HTLV screening and seropositive deceased donor candidates between 2005 and 2022. HTLV antibody testing was performed on 99.8% and 16.9% of potential deceased organ donors in 2005–2009 and 2010–2022, respectively. In 2005–2009, 126 seropositive donor candidates (0.32%) HTLV- were reported (median [interquartile range] number per year, 24 [23–28]; range, 16–35). There were 48 seropositive donor candidates (0.22%) in 2010–2022 (median [interquartile range] number per year, 3 [2–5]; range, 1–7). Ab, antibody; HTLV, human T-lymphotropic virus.

TABLE 1.

Characteristics of deceased donor candidates based on HTLV serostatus

Characteristic	Total	HTLV Ab negative	HTLV Ab positive	HTLV Ab indeterminate	*P*
Year 2005–2009	N = 39 619	N = 39 491	N = 126	N = 2	
Age, y, mean (SD)	41 (19)	41 (19)	46 (15)	38 (52)	0.003
Sex					<0.001
Female	16 134 (40.7%)	16 059 (40.7%)	74 (58.7%)	1 (50.0%)	
Male	23 485 (59.3%)	23 432 (59.3%)	52 (41.3%)	1 (50.0%)	
Brain death/circulatory death					0.55
Brain death	35 863 (90.5%)	35 745 (90.5%)	116 (92.1%)	2 (100.0%)	
Circulatory death	3756 (9.5%)	3746 (9.5%)	10 (7.9%)	0 (0.0%)	
Diabetes	4329 (11.0%)	4312 (11.0%)	17 (13.5%)	0 (0.0%)	0.37
Hypertension	13 498 (34.3%)	13 436 (34.2%)	61 (48.4%)	1 (50.0%)	<0.001
Kidney Donor Profile Index	49 (31)	49 (31)	61 (30)	78 (28)	<0.001
Race					<0.001
White	26 668 (67.3%)	26 620 (67.4%)	46 (36.5%)	2 (100.0%)	
Black	6193 (15.6%)	6134 (15.5%)	59 (46.8%)	0 (0.0%)	
Hispanic	5535 (14.0%)	5519 (14.0%)	16 (12.7%)	0 (0.0%)	
Asian	885 (2.2%)	883 (2.2%)	2 (1.6%)	0 (0.0%)	
American Indian/Alaska Native	160 (0.4%)	159 (0.4%)	1 (0.8%)	0 (0.0%)	
Native Hawaiian/other Pacific Islander	66 (0.2%)	66 (0.2%)	0 (0.0%)	0 (0.0%)	
Multiracial	112 (0.3%)	110 (0.3%)	2 (1.6%)	0 (0.0%)	
High risk for blood-borne disease transmission (PHS-risk)	3111 (7.9%)	3094 (7.9%)	17 (13.5%)	0 (0.0%)	0.019
HBV core Ab positive	2264 (5.7%)	2249 (5.7%)	15 (11.9%)	0 (0.0%)	0.003
HCV Ab positive	1638 (4.1%)	1625 (4.1%)	13 (10.3%)	0 (0.0%)	<0.001
HIV Ab positive	4 (0.0%)	4 (0.0%)	0 (0.0%)	0 (0.0%)	0.91
Year 2010–2022	N = 22 032	N = 21 974	N = 48	N = 10	
Age, y, mean (SD)	41 (17)	41 (17)	48 (13)	38 (14)	0.007
Sex					0.65
Female	8928 (40.5%)	8901 (40.5%)	21 (43.8%)	6 (60.0%)	
Male	13 104 (59.5%)	13 073 (59.5%)	27 (56.3%)	4 (40.0%)	
Brain death/circulatory death					0.045
Brain death	17 302 (78.5%)	17 262 (78.6%)	32 (66.7%)	8 (80.0%)	
Circulatory death	4730 (21.5%)	4712 (21.4%)	16 (33.3%)	2 (20.0%)	
Diabetes	2759 (12.6%)	2748 (12.6%)	11 (23.9%)	0 (0.0%)	0.021
Hypertension	8076 (37.0%)	8050 (36.9%)	24 (53.3%)	2 (20.0%)	0.023
Kidney Donor Profile Index	48 (30)	48 (30)	67 (24)	44 (24)	<0.001
Race					0.12
White	15 796 (71.7%)	15 763 (71.7%)	27 (56.3%)	6 (60.0%)	
Black	3080 (14.0%)	3065 (13.9%)	14 (29.2%)	1 (10.0%)	
Hispanic	2726 (12.4%)	2717 (12.4%)	6 (12.5%)	3 (30.0%)	
Asian	298 (1.4%)	297 (1.4%)	1 (2.1%)	0 (0.0%)	
American Indian/Alaska Native	76 (0.3%)	76 (0.3%)	0 (0.0%)	0 (0.0%)	
Native Hawaiian/other Pacific Islander	28 (0.1%)	28 (0.1%)	0 (0.0%)	0 (0.0%)	
Multiracial	28 (0.1%)	28 (0.1%)	0 (0.0%)	0 (0.0%)	
High risk for blood-borne disease transmission (PHS-risk)	3003 (13.6%)	2990 (13.6%)	8 (16.7%)	5 (50.0%)	0.54
HBV core Ab positive	701 (3.2%)	694 (3.2%)	6 (12.5%)	1 (10.0%)	<0.001
HCV Ab positive	1009 (4.6%)	1004 (4.6%)	4 (8.3%)	1 (10.0%)	0.21
HIV Ab positive	27 (0.1%)	27 (0.1%)	0 (0.0%)	0 (0.0%)	0.81

Values are expressed as number (%) otherwise indicated. *P* values were calculated to compare HTLV-seropositive vs negative donors.
Ab, antibody; HBV, hepatitis B virus; HCV, hepatitis C virus; HTLV, human T-lymphotropic virus; PHS-risk, increased risk for blood-borne disease transmission according to the US Public Health Service guidelines.

after recovery (34.1% versus 31.9%, $P = 0.60$) and the number of discarded organs was similar (0 [0–1] in both, $P = 0.33$) between groups. Eventually, the proportion of donors who had at least 1 organ transplanted (81.0% versus 93.6%, $P < 0.001$) and the number of transplanted organs (1 [1–2] versus 3 [2–4], $P < 0.001$) were significantly lower in HTLV-seropositive donors.

We also investigated the utilization of kidney grafts. The proportion of donors with at least 1 kidney recovered was significantly lower in HTLV-seropositive versus negative donors (46.0% versus 89.7%, $P < 0.001$; Table 3). Moreover, recovered kidneys were often discarded in HTLV-seropositive donors (55.2% versus 21.3%, $P < 0.001$). As a result, kidneys from HTLV-seropositive donors were significantly less often transplanted (23.8% versus 76.9%, $P < 0.001$). The most frequent reason for nonrecovery of HTLV-seropositive donor kidneys was positive HTLV-1 (39/79 [53.4%]; **Table S1, SDC,** http://links.lww.com/TXD/A699).

TABLE 2.

Donor HTLV antibody screening according to race

HTLV Ab	Total	White	Black	Hispanic	Asian	American Indian/Alaska Native	Native Hawaiian/other Pacific Islander	Multiracial
Year 2005–2009	N = 39706	N = 26729	N = 6207	N = 5546	N = 886	N = 160	N = 66	N = 112
HTLV Ab screening								
No	87 (0.2%)	61 (0.2%)	14 (0.2%)	11 (0.2%)	1 (0.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Yes	39619 (99.8%)	26668 (99.8%)	6193 (99.8%)	5535 (99.8%)	885 (99.9%)	160 (100.0%)	66 (100.0%)	112 (100.0%)
HTLV Ab results								
Negative	39491 (99.68%)	26620 (99.82%)	6134 (99.05%)	5519 (99.71%)	883 (99.77%)	159 (99.38%)	66 (100.00%)	110 (98.21%)
Positive	126 (0.32%)	46 (0.17%)	59 (0.95%)	16 (0.29%)	2 (0.23%)	1 (0.63%)	0 (0.00%)	2 (1.79%)
Indeterminate	2 (0.01%)	2 (0.01%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Year 2010–2022	N = 130284	N = 85880	N = 20681	N = 18991	N = 3229	N = 745	N = 364	N = 394
HTLV Ab screening								
No	108252 (83.1%)	70084 (81.6%)	17601 (85.1%)	16265 (85.6%)	2931 (90.8%)	669 (89.8%)	336 (92.3%)	366 (92.9%)
Yes	22032 (16.9%)	15796 (18.4%)	3080 (14.9%)	2726 (14.4%)	298 (9.2%)	76 (10.2%)	28 (7.7%)	28 (7.1%)
HTLV Ab results								
Negative	21974 (99.74%)	15763 (99.79%)	3065 (99.51%)	2717 (99.67%)	297 (99.66%)	76 (100.00%)	28 (100.00%)	28 (100.00%)
Positive	48 (0.22%)	27 (0.17%)	14 (0.45%)	6 (0.22%)	1 (0.34%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Indeterminate	10 (0.05%)	6 (0.04%)	1 (0.03%)	3 (0.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Values are expressed as number (%).
HTLV Ab, human T-lymphotropic virus antibody.

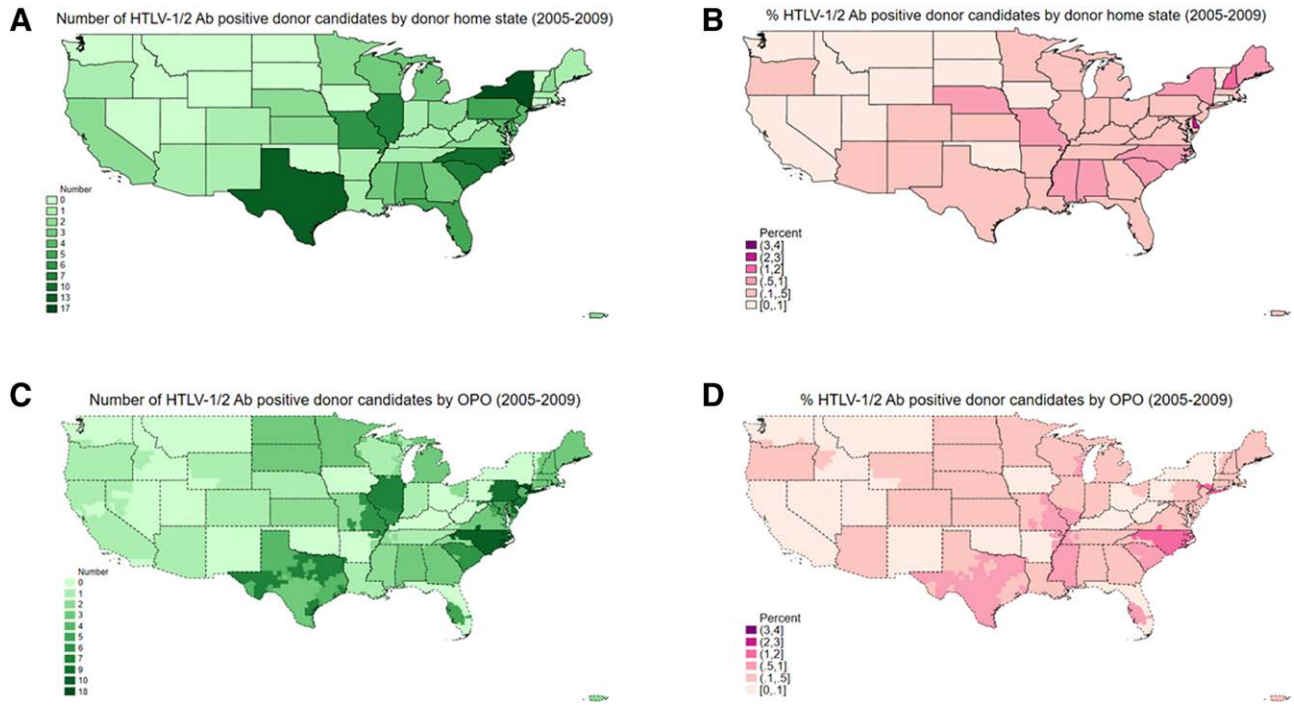

FIGURE 3. Distributions of HTLV-seropositive deceased donor candidates in 2005–2009. The numbers and proportions of HTLV-seropositive donor candidates in 2005–2009 according to the donor home state (A: median [interquartile range] number, 1 [0–3]; range, 0–17; B: median [interquartile range] proportion, 0.2% [0%–0.4%]; range, 0%–2.1%) and the OPO donor service area (C: median [interquartile range] number, 1 [0–3]; range, 0–18; D: median [interquartile range] proportion, 0.2% [0%–0.5%]; range, 0–1.3%). HTLV-seropositive donors were found in 36 of 50 states and 35 of 56 OPOs. Lines indicate state boundaries. Ab, antibody; HTLV, human T-lymphotropic virus; OPO, Organ Procurement Organization.

HTLV Screening in 2010–2022

The frequency of HTLV screening sharply decreased after the requirement was eliminated; however, 22032 of 130284 potential donors (16.9%) were still tested for HTLV (Figure 2). We compared characteristics between tested and nontested donors (Table 4). Although there was statistical significance between tested and nontested donors because of the large sample size, age (41 ± 19 y in both groups), and the percentage of women (40.5% versus 39.2%) were similar between groups. Proportions were lower in HTLV antibody

TABLE 3.

Organ utilization according to HTLV serostatus

Characteristic	Total	HTLV Ab negative	HTLV Ab positive	HTLV Ab indeterminate	*P*
Year 2005–2009	N = 39 619	N = 39 491	N = 126	N = 2	
All organs					
Donor with at least 1 organ recovered	39 619 (100.0%)	39 491 (100.0%)	126 (100.0%)	2 (100.0%)	–
Donor with at least 1 organ discarded after recovery	12 647 (31.9%)	12 604 (31.9%)	43 (34.1%)	0 (0.0%)	0.60
Donor with at least 1 organ transplanted	37 050 (93.5%)	36 946 (93.6%)	102 (81.0%)	2 (100.0%)	<0.001
No. of organs recovered per donor, median (interquartile range)	3 (3–4)	3 (3–4)	1 (1–3)	2 (2–3)	<0.001
No. of organs discarded after recovery per donor, median (interquartile range)	0 (0–1)	0 (0–1)	0 (0–1)	0 (0–0)	0.33
No. of organs transplanted per donor, median (interquartile range)	3 (2–4)	3 (2–4)	1 (1–2)	2 (2–3)	<0.001
No. of donors by total organs transplanted					<0.001
0 (no organs transplanted)	2569 (6.5%)	2545 (6.4%)	24 (19.0%)	0 (0.0%)	
1	6337 (16.0%)	6267 (15.9%)	70 (55.6%)	0 (0.0%)	
2	6025 (15.2%)	6019 (15.2%)	5 (4.0%)	1 (50.0%)	
3	10 852 (27.4%)	10 830 (27.4%)	21 (16.7%)	1 (50.0%)	
4	5966 (15.1%)	5962 (15.1%)	4 (3.2%)	0 (0.0%)	
≥5	7870 (19.9%)	7868 (19.9%)	2 (1.6%)	0 (0.0%)	
Organs unrecovered because of HTLV-1 infection					
Heart	–	–	49 (39%)	–	–
Lung[a]	–	–	110 (44%)	–	–
Liver	–	–	4 (3%)	–	–
Kidney[a]	–	–	77 (31%)	–	–
Pancreas	–	–	61 (48%)	–	–
Intestine	–	–	46 (37%)	–	–
Kidney					
Donor with at least 1 kidney recovered	35 481 (89.6%)	35 422 (89.7%)	58 (46.0%)	1 (50.0%)	<0.001
Donor with at least 1 kidney discarded after recovery	7578 (21.4%)	7546 (21.3%)	32 (55.2%)	0 (0.0%)	<0.001
Donor with at least 1 kidney transplanted	30 413 (76.8%)	30 382 (76.9%)	30 (23.8%)	1 (50.0%)	<0.001
Year 2010–2022	N = 22 032	N = 21 974	N = 48	N = 10	
All organs					
Donor with at least 1 organ recovered	22 025 (100.0%)	21 967 (100.0%)	48 (100.0%)	10 (100.0%)	0.90
Donor with at least 1 organ discarded after recovery	6925 (31.4%)	6901 (31.4%)	20 (41.7%)	4 (40.0%)	0.13
Donor with at least 1 organ transplanted	20 588 (93.4%)	20 538 (93.5%)	42 (87.5%)	8 (80.0%)	0.095
No. of organs recovered per donor, median (interquartile range)	3 (3–5)	3 (3–5)	2 (2–3)	3 (2–3)	<0.001
No. of organs discarded after recovery per donor, median (interquartile range)	0 (0–1)	0 (0–1)	0 (0–1)	0 (0–2)	0.12
No. of organs transplanted per donor, median (interquartile range)	3 (2–4)	3 (2–4)	2 (1–3)	2 (1–3)	<0.001
No. of donors by total organs transplanted					<0.001
0 (no organs transplanted)	1444 (6.6%)	1436 (6.5%)	6 (12.5%)	2 (20.0%)	
1	3021 (13.7%)	3002 (13.7%)	18 (37.5%)	1 (10.0%)	
2	4248 (19.3%)	4239 (19.3%)	7 (14.6%)	2 (20.0%)	
3	5292 (24.0%)	5278 (24.0%)	10 (20.8%)	4 (40.0%)	
4	3277 (14.9%)	3274 (14.9%)	3 (6.2%)	0 (0.0%)	
≥5	4750 (21.6%)	4745 (21.6%)	4 (8.3%)	1 (10.0%)	
Organs unrecovered because of HTLV-1 infection					
Heart	–	–	0 (0%)	–	–
Lung[a]	–	–	2 (2%)	–	–
Liver	–	–	0 (0%)	–	–
Kidney[a]	–	–	0 (0%)	–	–
Pancreas	–	–	0 (0%)	–	–
Intestine	–	–	0 (0%)	–	–
Kidney					
Donor with at least 1 kidney recovered	20 805 (94.4%)	20 759 (94.5%)	37 (77.1%)	9 (90.0%)	<0.001
Donor with at least 1 kidney discarded after recovery	5124 (24.6%)	5103 (24.6%)	18 (48.6%)	3 (33.3%)	<0.001
Donor with at least 1 kidney transplanted	17 486 (79.4%)	17 453 (79.4%)	27 (56.2%)	6 (60.0%)	<0.001

Values are expressed as number (%) otherwise indicated. *P* values were calculated to compare HTLV-seropositive vs negative donors.
[a]The right/left lungs and kidneys were counted separately (ie, 2 lungs and 2 kidneys from 1 donor).
HTLV Ab, human T-lymphotropic virus antibody.

TABLE 4.

Characteristics of potential deceased donors according to HTLV screening in 2010–2022

Characteristic	Total (N = 130 284)	HTLV Ab not tested (N = 130 284)	HTLV Ab tested (N = 22 032)	*P*
Age, y, mean (SD)	41 (17)	41 (17)	41 (17)	<0.001
Sex				<0.001
Female	51 384 (39.4%)	42 456 (39.2%)	8928 (40.5%)	
Male	78 900 (60.6%)	65 796 (60.8%)	13 104 (59.5%)	
Brain death/circulatory death				<0.001
Brain death	103 925 (79.8%)	86 623 (80.0%)	17 302 (78.5%)	
Circulatory death	26 358 (20.2%)	21 628 (20.0%)	4730 (21.5%)	
Kidney Donor Profile Index	49 (30)	50 (30)	48 (30)	<0.001
Diabetes	16 284 (12.6%)	13 525 (12.6%)	2759 (12.6%)	0.99
Hypertension	46 053 (35.7%)	37 977 (35.4%)	8076 (37.0%)	<0.001
Race				<0.001
White	85 880 (65.9%)	70 084 (64.7%)	15 796 (71.7%)	
Black	20 681 (15.9%)	17 601 (16.3%)	3080 (14.0%)	
Hispanic	18 991 (14.6%)	16 265 (15.0%)	2726 (12.4%)	
Asian	3229 (2.5%)	2931 (2.7%)	298 (1.4%)	
American Indian/Alaska Native	745 (0.6%)	669 (0.6%)	76 (0.3%)	
Native Hawaiian/other Pacific Islander	364 (0.3%)	336 (0.3%)	28 (0.1%)	
Multiracial	394 (0.3%)	366 (0.3%)	28 (0.1%)	
High risk for blood-borne disease transmission (PHS-risk)	26 777 (20.6%)	23 774 (22.0%)	3003 (13.6%)	<0.001
HBV core Ab positive	6671 (5.1%)	5970 (5.5%)	701 (3.2%)	<0.001
HCV Ab positive	9634 (7.4%)	8625 (8.0%)	1009 (4.6%)	<0.001
HIV Ab positive	222 (0.2%)	195 (0.2%)	27 (0.1%)	0.040
HTLV Ab				
Negative	–	–	21 974 (99.7%)	–
Positive	–	–	48 (0.2%)	–
Indeterminate	–	–	10 (0.0%)	–
Organ recovery/discard/transplant				
Donor with at least 1 organ recovered	130 221 (100.0%)	108 196 (99.9%)	22 025 (100.0%)	0.22
Donor with at least 1 organ discarded after recovery	41 810 (32.1%)	34 885 (32.2%)	6925 (31.4%)	0.020
Donor with at least 1 organ transplanted	121 004 (92.9%)	100 416 (92.8%)	20 588 (93.4%)	<0.001
No. of organs recovered per donor, median (interquartile range)	3 (2–4)	3 (2–4)	3 (3–5)	<0.001
No. of organs discarded after recovery per donor, median (interquartile range)	0 (0–1)	0 (0–1)	0 (0–1)	0.019
No. of organs transplanted per donor, median (interquartile range)	3 (2–4)	3 (2–4)	3 (2–4)	<0.001
No. of donors by total organs transplanted				<0.001
0 (no organs transplanted)	9280 (7.1%)	7836 (7.2%)	1444 (6.6%)	
1	19 706 (15.1%)	16 685 (15.4%)	3021 (13.7%)	
2	25 466 (19.5%)	21 218 (19.6%)	4248 (19.3%)	
3	31 078 (23.9%)	25 786 (23.8%)	5292 (24.0%)	
4	19 183 (14.7%)	15 906 (14.7%)	3277 (14.9%)	
≥5	25 571 (19.6%)	20 821 (19.2%)	4750 (21.6%)	
Kidney recovery/discard/transplant				
Donor with at least 1 kidney recovered	120 606 (92.6%)	99 801 (92.2%)	20 805 (94.4%)	<0.001
Donor with at least 1 kidney discarded after recovery	29 850 (24.8%)	24 726 (24.8%)	5124 (24.6%)	0.66
Donor with at least 1 kidney transplanted	101 185 (77.7%)	83 699 (77.3%)	17 486 (79.4%)	<0.001

Values are expressed as number (%) otherwise indicated.

Ab, antibody; HBV, hepatitis B virus; HCV, hepatitis C virus; HTLV, human T-lymphotropic virus; PHS-risk, increased risk for blood-borne disease transmission according to the US Public Health Service guidelines.

tested versus nontested donors for PHS-risk (13.6% versus 22.0%), HBc antibody (3.2% versus 5.5%), HCV antibody (4.6% versus 8.0%), and HIV antibody (0.1% versus 0.2%). HTLV antibody was slightly more often tested in White than in Black and Hispanic donors (18.4%, 14.9%, and 14.4%, respectively; Table 2). Organ utilization was comparable between tested and nontested donors (Table 4).

Associations Between HTLV Screening Practice in 2010–2022 and HTLV Infection Risk

We analyzed the associations between the proportion of donors tested for HTLV antibody in 2010–2022 and the proportion of donors with HTLV infection risk by OPO and donor home state. The donor proportions tested for HTLV varied across OPOs (median [IQR], 3.8% [1.0%–23.2%]; range, 0.2%–99.4%; Figure 4A) and donor home states (median [IQR], 8.4% [4.1%–22.9%]; range, 0%–62.8%; Figure 5A). HTLV screening was mainly performed in southern and northeastern states, and the US map gave us the impression that HTLV screening was associated with non-White race and HTLV-seropositive donors in 2005–2009 in the areas (Figures 3–5). However, we found no significant correlation between HTLV screening and HTLV infection risk, including PHS-risk, race, and the number and proportion of HTLV-seropositive donors in 2005–2009 per OPO (Figure 6; **Table S2, SDC,** http://links.lww.com/TXD/A699).

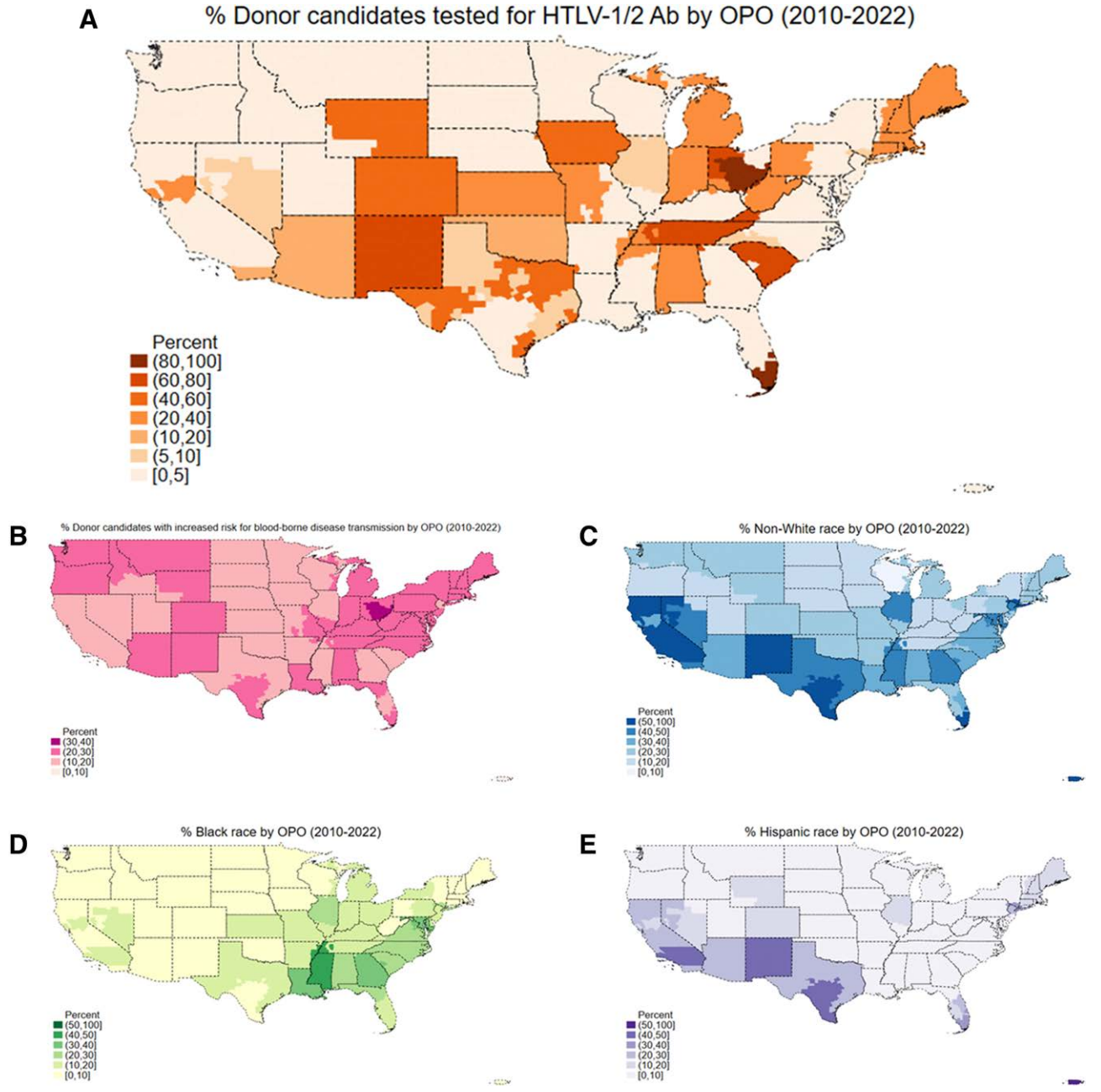

FIGURE 4. The proportion of HTLV antibody testing and infection risk in 2010–2022 by OPO. A, The proportion of donor candidates tested for HTLV antibody in 2010–2022 according to the OPO donor service area (median [interquartile range], 3.8% [1.0%–23.2%]; range, 0.2%–99.4%). B–E, Proportions of donor candidates with increased risk for blood-borne disease transmission (B), non-White race (C), Black race (D), and Hispanic race (E). Lines indicate state boundaries. Ab, antibody; HTLV, human T-lymphotropic virus; OPO, Organ Procurement Organization.

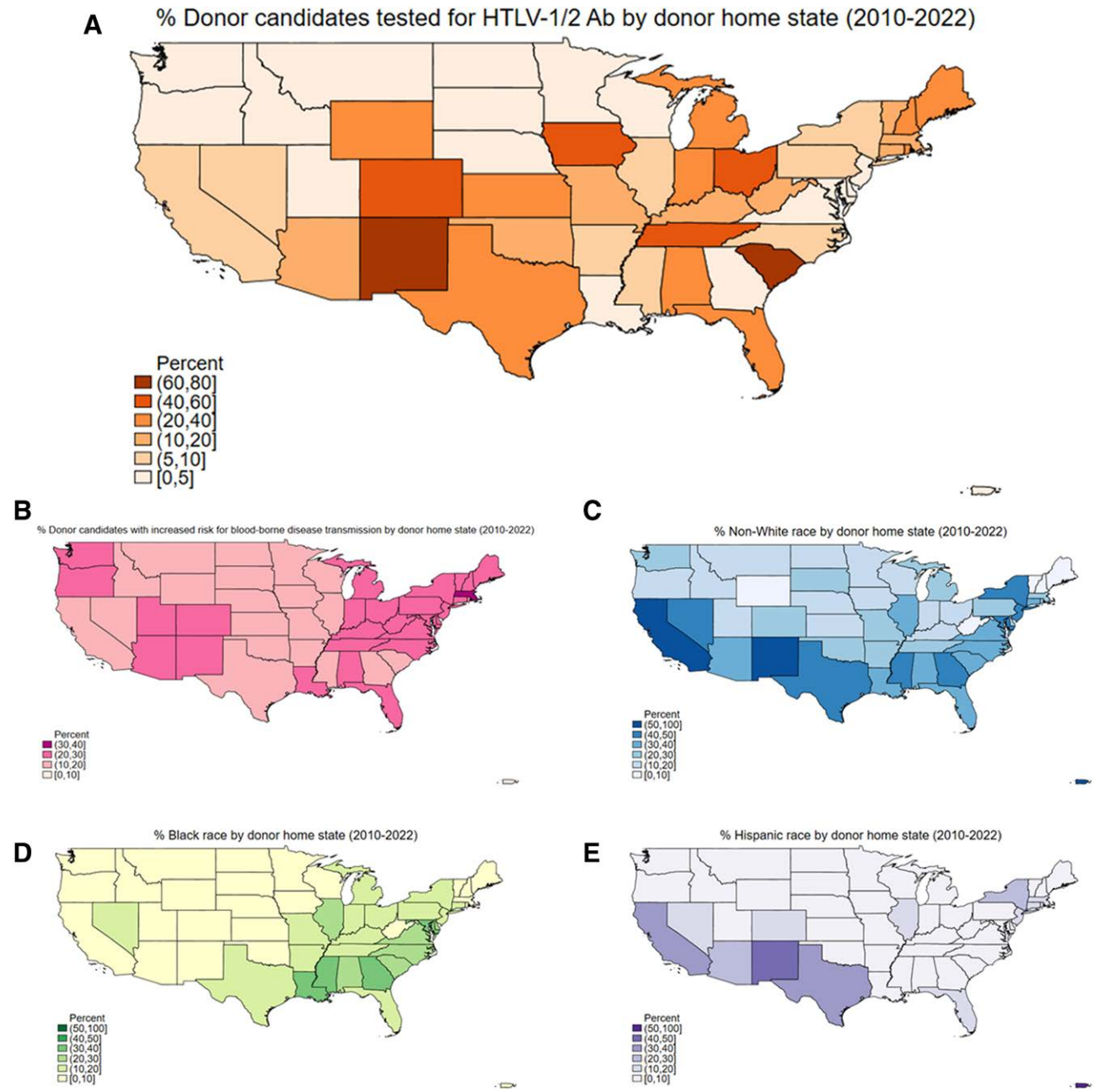

FIGURE 5. The proportion of HTLV antibody testing and infection risk in 2010–2022 by donor home state. A, The proportion of donor candidates tested for HTLV antibody in 2010–2022 (median [interquartile range], 8.4% [4.1%–22.9%]; range, 0%–62.8%). B–E, Proportions of donor candidates with increased risk for blood-borne disease transmission (B), non-White race (C), Black race (D), and Hispanic race (E). Ab, antibody; HTLV, human T-lymphotropic virus.

There were also no correlations per donor home state except for a weak correlation between HTLV screening and PHS-risk (Spearman's ρ = 0.31, *P* = 0.026; **Figure S1, SDC,** http://links.lww.com/TXD/A699).

Given the wide variety of the screening frequencies across OPOs, we anticipated that the associations between overall rates of HTLV testing and risk factors (ie, higher testing rates among the White population and those without PHS-risk in Tables 1 and 2) might be influenced by the limited number of OPOs with high rates of HTLV testing. To address these potential effects, we evaluated the associations between HTLV testing and infection risk only for OPOs whose testing rates were <20% (38/56 OPOs included). Results showed that donor proportions tested for HTLV were similar between races (3%–4%) but were still higher in donors without PHS-risk or antibodies to blood-borne viruses than those with these factors (**Table S3, SDC,** http://links.lww.com/TXD/A699). We additionally calculated the percentage of HTLV testing per race and per presence/absence of PHS-risk in each OPO. The proportions of HTLV testing were similar across races and close to the overall testing proportions within OPOs (Figure 7A), suggesting that race did not influence HTLV testing decisions. However, HTLV testing tended to be conducted more often among donors without PHS-risk (Figure 7B).

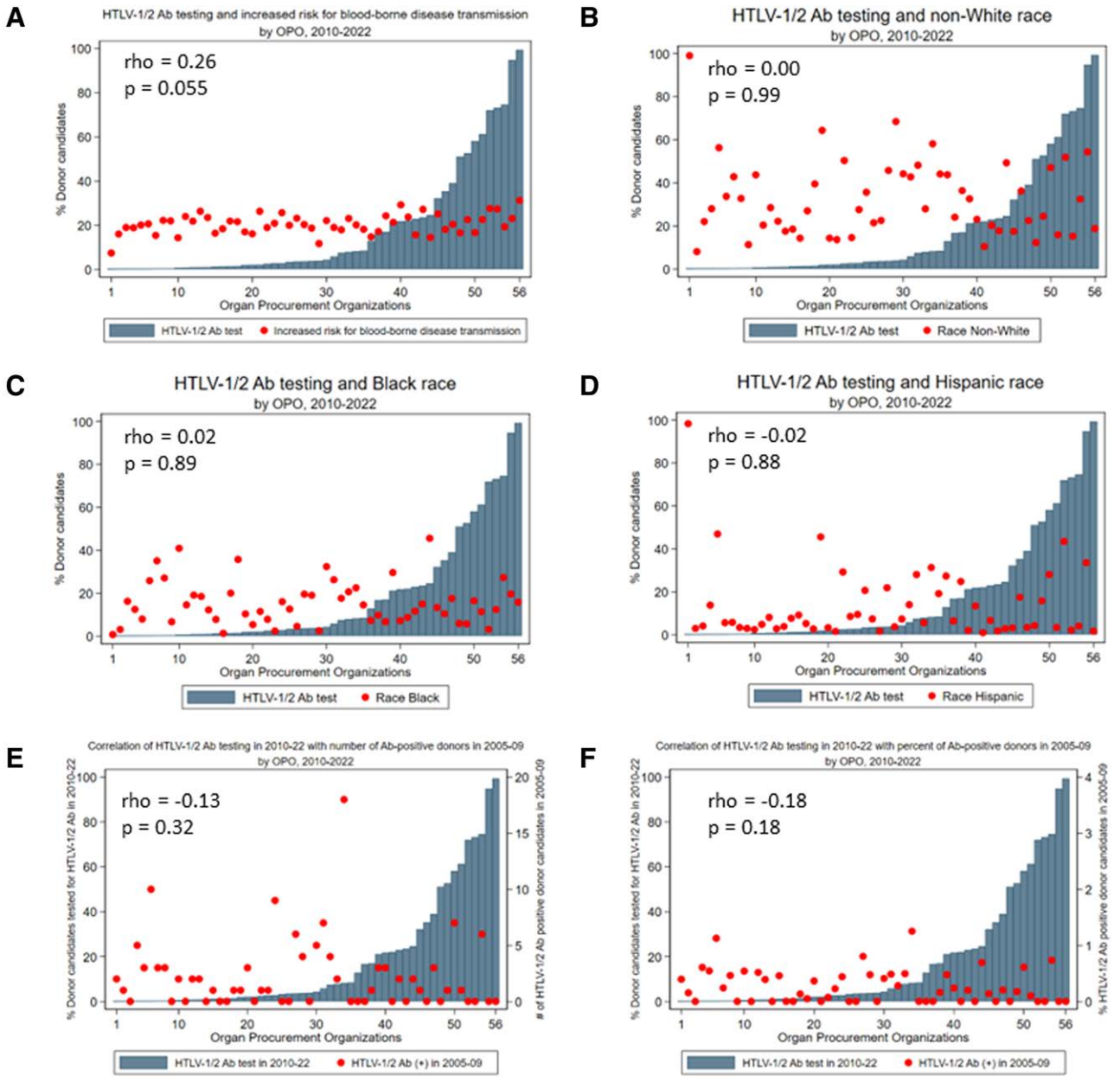

FIGURE 6. Associations of HTLV antibody testing in 2010–2022 with HTLV infection risk by OPO. Figures show the proportions of donor candidates tested for HTLV antibody in 2010–2022 and those of donors with increased risk for blood-borne disease transmission (A), non-White race (B), Black race (C), Hispanic race (D), and the number (E) and proportion (F) of HTLV-seropositive donors in 2005–2009 by OPO. The proportions of donors tested for HTLV in 2010–2022 varied between the OPOs (median [interquartile range], 3.8% [1.0%–23.2%]; range, 0.2%–99.4%). No significant correlations were found between the proportions of HTLV antibody testing and each characteristic (Spearman correlation test). OPO names are listed in **Table S2** (**SDC,** http://links.lww.com/TXD/A699). Ab, antibody; HTLV, human T-lymphotropic virus; OPO, Organ Procurement Organization.

HTLV-seropositive Donor Candidates in 2010–2022

Of the 22 032 tested donors in 2010–2022, 48 (0.22%) were HTLV-seropositive (Table 1). We investigated the comment sections in DonorNet to obtain information regarding confirmatory testing. Among the 48 seropositive donors, 5 donors had descriptions indicating that confirmatory assays were conducted. However, only one donor's records indicated a negative result; results for the remaining donors were not documented. HTLV-seropositive donors were older than negative donors (48 ± 13 versus 41 ± 17 y); however, the female proportion was not significantly different (43.8% versus 40.5%). HTLV-seropositive donors had higher KDPI (67 ± 24 versus 48 ± 30) and more often had circulatory death (33.3% versus 21.4%), diabetes (23.9% versus 12.6%), and hypertension (53.3% versus 36.9%). Although HBc antibody was more frequently positive in HTLV-seropositive than in HTLV-negative donors (12.5% versus 3.2%), PHS-risk, HCV antibody, or HIV antibody were not significantly different. There was a higher proportion of HTLV-seropositive donors in Black than in Hispanic and White donors (0.45%, 0.22%, and 0.17%, respectively; Table 2).

HTLV-seropositive donors were found in 20 states, mainly in the south and northeast (median [IQR] number of HTLV-seropositive donors by state, 0 [0–1]; range,

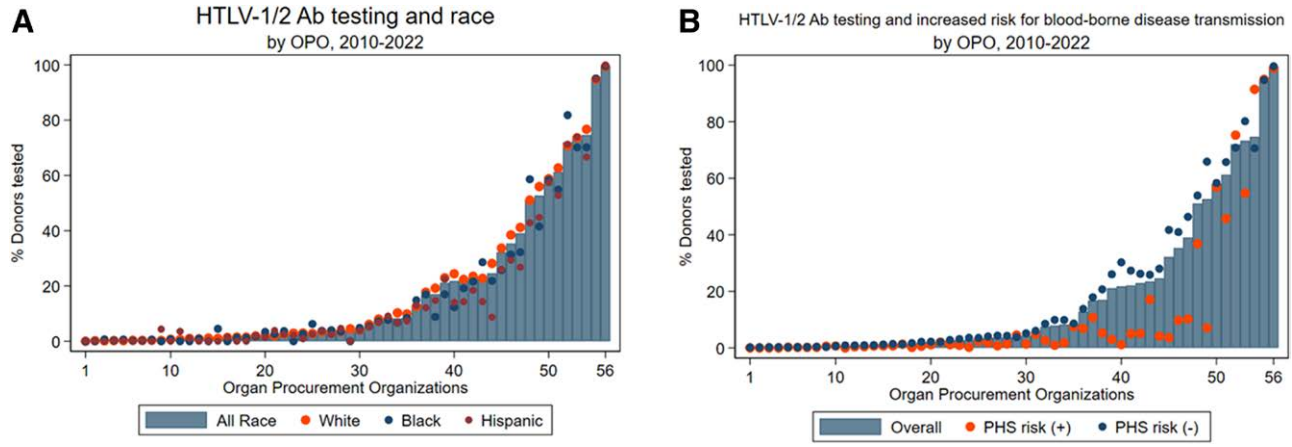

FIGURE 7. Associations of HTLV antibody testing in 2010–2022 with race and increased risk for blood-borne disease transmission by OPO. A, The proportions of HTLV antibody testing among all donor candidates, and White, Black, and Hispanic donors per OPO. B, The proportions of HTLV antibody testing among all donor candidates and those with and without increased risk for blood-borne disease transmission (PHS-risk) per OPO. OPO names are listed in **Table S2** (**SDC,** http://links.lww.com/TXD/A699). Ab, antibody; HTLV, human T-lymphotropic virus; OPO, Organ Procurement Organization; PHS-risk, increased risk for blood-borne disease transmission according to the US Public Health Service guidelines.

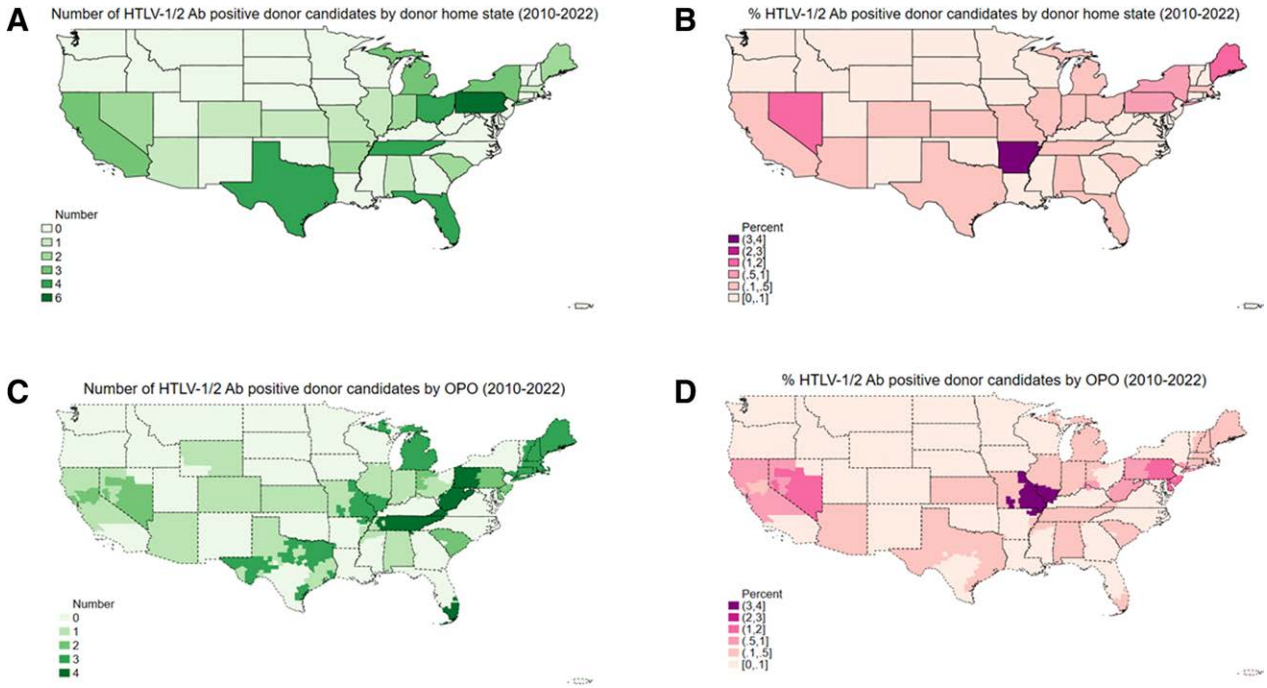

FIGURE 8. Distributions of HTLV-seropositive deceased donor candidates in 2010–2022. The numbers and proportions of HTLV-seropositive donor candidates in 2010–2022 according to the donor home state (A: median [interquartile range] number, 0 [0–1]; range, 0–6; B: median [interquartile range] proportion, 0% [0%–0.2%]; range, 0%–3.3%) and the OPO donor service area (C: median [interquartile range] number, 0 [0–1]; range, 0–4; D: median [interquartile range] proportion, 0% [0%–0.2%]; range, 0%–3.2%). HTLV-seropositive donors were found in 20 of 50 states and 24 of 56 OPOs. Lines indicate state boundaries. Ab, antibody; HTLV, human T-lymphotropic virus; OPO, Organ Procurement Organization.

0–6; median [IQR] proportion by state, 0% [0%–0.2%]; range, 0%–3.3%; Figure 8A and B). Of 56 OPOs, 24 reported HTLV-seropositive donors (median [IQR] number of HTLV-seropositive donors by OPO, 0 [0–1]; range, 0–4; median [IQR] proportion by OPO, 0% [0%–0.2%]; range, 0%–3.2%; Figure 8C and D).

Although all donors had at least 1 organ recovered, the number of organs recovered per donor was significantly lower in HTLV-seropositive than in negative donors (median [IQR], 2 [2–3] versus 3 [3–5], $P < 0.001$, Table 3). However, HTLV-1 infection was not the reason for nonrecovery except for the lung from 1 HTLV-seropositive donor (2%). The proportion of donors who had at least 1 organ discarded (41.7% versus 31.4%, $P = 0.13$) and the number of discarded organs were similar (0 [0–1] in both, $P = 0.12$) between groups. The proportion of donors who had at least 1 organ transplanted was not significantly different (87.5% versus 93.5%, $P = 0.095$); however, the number of transplanted organs (2 [1–3] versus 3 [2–4], $P < 0.001$) was significantly lower in HTLV-seropositive donors.

The proportion of donors with at least 1 kidney recovered was significantly lower in HTLV-seropositive versus HTLV-negative donors (77.1% versus 94.5%, $P < 0.001$; Table 3). Recovered kidneys were more often discarded in HTLV-seropositive donors (48.6% versus 24.6%, $P < 0.001$). Consequently, kidneys from HTLV-seropositive donors were significantly less often transplanted (56.2% versus 79.4%, $P < 0.001$). Major reasons for nonrecovery of HTLV-seropositive donor kidneys were "donor medical history" and "refusal by all national programs" (5/12 [41.7%] and 3/12 [25.0%], respectively; **Table S1, SDC,** http://links.lww.com/TXD/A699). Main reasons for discarding kidney included "no recipient located (list exhausted)" and "biopsy findings" (8/18 [44.4%] and 4/18 [22.2%], respectively; **Table S4, SDC,** http://links.lww.com/TXD/A699). Compared with 2005–2009, kidneys of HTLV-seropositive donors recovered more often in 2010–2022 (46.0% versus 77.1%). The proportions of kidney discard were similar between the 2 periods (55.2% versus 48.6%). Eventually, more kidneys from HTLV-seropositive donors were transplanted in 2010–2022 (23.8% versus 56.2%).

DISCUSSION

In this retrospective study of the OPTN database, we evaluated trends in HTLV screening and seroprevalence in potential deceased organ donors in the United States. Despite eliminating the screening requirement, 16.9% of potential donors were still tested for HTLV antibody in 2010–2022. The frequency of HTLV screening was substantially different across OPOs and donor home states, from almost 0% to 100%; however, HTLV screening did not correlate with HTLV infection risks. Of the screened potential donors, 0.22% of patients were HTLV-seropositive. Although organs were ultimately used from the vast majority (87.5%) of these seropositive donors, the number of transplanted organs per donor was significantly lower than that of seronegative donors.

In the universal screening period (2005–2009), 0.32% of deceased donors tested positive for HTLV antibodies. This proportion was much higher than that of blood donors (0.02%), which was determined using confirmatory testing.[7] Although studies using blood-donor data tend to underestimate infection prevalence because blood donors include only healthy people who deny high-risk behaviors, the high HTLV prevalence in deceased donor candidates likely suggests the existence of many false-positive and HTLV-2-positive donors. Nonetheless, characteristics of HTLV-seropositive donors in this period were similar to those of the previous HTLV studies: older age, female predominance, Black race, and high-risk behaviors.[5,7] In 2010–2022, despite concerns of some HTLV researchers that HTLV prevalence may be increasing, the proportion of seropositive donors was lower than in 2005–2009. Moreover, several characteristics of HTLV infection, such as female predominance and high-risk behavior, were not found in seropositive donors of 2010–2022. However, careful consideration is needed to interpret the results because they were not derived from universal screening, and HTLV screening in this period was in effect and not targeted. Available OPTN data from 2010 to 2022 may not reflect the true characteristics of HTLV infection in the United States.

Although we hypothesized that targeted screening was performed after 2010, the results did not support our hypothesis. HTLV screening per OPO and donor home state showed no correlation with the proportion of donors with HTLV infection risk factors. HTLV screening was not correlated with race and rather was conducted for donors who did not have PHS-risk or antibodies to other blood-borne viruses. Although OPO screening protocols are unavailable in this study, HTLV screening might not effectively target a high-risk population. Our findings suggest that current HTLV screening is not very effective or meaningful and that the transplant community should reconsider HTLV screening.

Although organs from most HTLV-seropositive donors were used for transplantation, the number of organs recovered and transplanted per donor was lower than that of seronegative donors. In 2005–2009, there were a significant number of unrecovered organs attributed to HTLV-1 infection (although many of those donors might have been false positive or HTLV-2 positive). However, in 2010–2022, HTLV-1 infection was not the reason for nonrecovery. Other conditions, such as donor organ quality and comorbidities, probably increased unrecovered organs, given that HTLV-seropositive donors were older and more frequently positive for HBV, with a greater proportion experiencing circulatory death. Although we anticipate that most seropositive donors whose organs were transplanted were likely to be considered HTLV-1 negative by OPOs based on confirmatory testing or other available information, there may be a possibility that HTLV seropositivity hardly affected the organ utilization decision in 2010–2022. Although it is unknown from the OPTN data set whether OPOs perform confirmatory assays, OPOs should perform and report confirmatory HTLV testing when screening assays are positive, even if timely confirmatory testing before transplantation is difficult. Confirmatory testing would eliminate unnecessary anxiety for organ recipients of false-positive donors, enable effective follow-up for those of true-positive donors, and help develop better HTLV screening protocols.

We also analyzed kidney graft utilization. In both 2005–2009 and 2010–2022 periods, the proportions of nonrecovery and discard were significantly higher in HTLV-seropositive donors. Consequently, their kidneys were less often transplanted. These results may be partly attributed to background characteristics, such as older age, higher proportions of diabetes and hypertension, and higher KDPI. Despite these lower utilization rates, the proportions of recovery and transplantation were notably higher in 2010–2022 than in 2005–2009. In 2005–2009, the primary reason for nonrecovery was HTLV-1 infection, suggesting that HTLV seropositivity strongly influenced the utilization decisions. Conversely, no donors of nonrecovery because of HTLV infection were reported in 2010–2022. However, our study may not definitively conclude that HTLV seropositivity did not affect the recovery decisions in 2010–2022, as the reasons for nonrecovery (eg, donor medical history and refusal by programs) lack specificity and may include donors with unrecovered kidneys because of HTLV infection within these categories.

The current OPTN policy of eliminating universal screening may be feasible given the substantial reduction in organ nonutilization because of HTLV infection and the absence of reported adverse effects.[32] However, our investigation suggests that the current HTLV screening does not target high-risk populations, potentially overlooking donor-derived HTLV infections. In addition, posttransplant

HTLV-1-associated diseases may be underreported because HAM is frequently misdiagnosed or overlooked, with reports from Japan indicating a median time from onset to diagnosis of 5 y.[33] Thus, the transplant community should continue pursuing better targeted-screening strategies rather than eliminate HTLV screening. As noted in the US guidelines, the donor's country of origin should be a fundamental consideration for targeted HTLV screening because post-transplant HAM cases in the United States have occurred among organ recipients of donors from HTLV-1 endemic regions.[1,24,25] Additionally, high-risk behaviors for blood-borne infections may need to be considered, given the mode of HTLV transmission.[7] A significant obstacle to developing and evaluating targeted HTLV screening is the lack of essential data, such as the actual HTLV prevalence among potential donors. Therefore, the collection of critical donor information should be enhanced, including country of origin and confirmatory test results for those with positive screenings. Furthermore, developing low-cost, rapid HTLV-1/2 confirmatory tests is essential to improve screening accuracy. We believe that our study contributes to understanding the current status and promotes national and global discussions on HTLV screening.

This study has limitations because of the limited data available in the OPTN database. First, we could not exclude false-positive results and (true or false positive) HTLV-2 infection or identify results of confirmatory testing. Although the US guidelines suggest that OPOs consider targeted screening based on infection risks (eg, immigrants from high-prevalence countries), we could not analyze whether OPOs considered the country of origin because of insufficient data.[1] Thus, we used donor race as a proxy for ancestry and socioeconomic status. In addition, PHS-risk was not specifically designed for HTLV infection. Therefore, these risk factors may not be the most optimal indicators for assessing HTLV infection risk. Finally, the results of this study may not be applicable to other countries, especially where HTLV-1 is more prevalent. We believe that organ transplantation from donors with confirmed HTLV-1 infection should be avoided, given the high risk of transmission and HAM.[1,19]

In conclusion, HTLV screening practices substantially varied across the United States, and our results do not suggest that targeted screening has been performed in the current era. Although the number of transplanted organs per donor was lower than that of seronegative donors, organ nonrecovery was not attributed to HTLV-1 infection. Effective screening strategies are needed to efficiently identify true HTLV-1-positive potential donors.

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