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Journal
Transfusion, 56(2)

ISSN
0041-1132

Authors
Vo, Michelle T
Bruhn, Roberta
Kaidarova, Zhanna
et al.

Publication Date
2016-02-01

DOI
10.1111/trf.13381

Peer reviewed

HHS Public Access

Author manuscript

Transfusion. Author manuscript; available in PMC 2017 February 01.

Published in final edited form as:

Transfusion. 2016 February ; 56(2): 457–465. doi:10.1111/trf.13381.

A retrospective analysis of false-positive infectious screening results in blood donors

Michelle T. Vo[1], **Roberta Bruhn**[2], **Zhanna Kaidarova**[2], **Brian S. Custer**[2,3], **Edward L. Murphy**[2,3], and **Evan M. Bloch**[2,3]

[1]School of Public Health, University of California at Berkeley, Berkeley, California

[2]Blood Systems Research Institute, San Francisco, California

[3]University of California at San Francisco, San Francisco, California

Abstract

BACKGROUND—False-positive infectious transfusion screening results remain a challenge with continued loss of both donors and blood products. We sought to identify associations between donor demographic characteristics (age, race, sex, education, first-time donor status) and testing false positive for viruses during routine blood donation screening. In addition the study assessed the prevalence of high-risk behaviors in false-positive donors.

STUDY DESIGN AND METHODS—Blood Systems, Inc. donors with allogeneic donations between January 1, 2011, and December 31, 2012, were compared in a case-control study. Those with a false-positive donation for one of four viruses (human immunodeficiency virus [HIV], human T-lymphotropic virus [HTLV], hepatitis B virus [HBV], and hepatitis C virus [HCV]) were included as cases. Those with negative test results were controls. For a subset of cases, infectious risk factors were evaluated.

RESULTS—Black race and Hispanic ethnicity were associated with HCV and HTLV false-positive results. Male sex and lower education were associated with HCV false positivity, and age 25 to 44 was associated with HTLV false positivity. First-time donors were more likely to be HCV false positive although less likely to be HBV and HTLV false positive. No significant associations between donor demographics and HIV false positivity were observed. A questionnaire for false-positive donors showed low levels of high-risk behaviors.

CONCLUSION—Demographic associations with HCV and HTLV false-positive results overlap with those of true infection. While true infection is unlikely given current testing algorithms and risk factor evaluation, the findings suggest nonrandom association. Further investigation into biologic mechanisms is warranted.

Consequent to advances in donor selection and infectious disease testing, blood transfusion in the United States is remarkably safe. The use of US Food and Drug Administration

Address reprint requests to: Evan M. Bloch, MD, MS, Blood Systems Research Institute, 270 Masonic Avenue, San Francisco, CA 94118; ebloch@bloodsystems.org.

CONFLICT OF INTEREST

The authors have disclosed no conflicts of interest.

(FDA)-licensed screening assays with reported sensitivities approaching 100%,[1] robust confirmatory testing, and established testing algorithms to optimize probability of detection has rendered transfusion-transmitted infectious disease a relatively rare occurrence. Indeed, the estimated residual risk of transfusion-transmitted hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), and human T-lymphotropic virus (HTLV-I/II) is conservatively less than 1 in every 1 million units transfused.[2]

However, false-positive test results remain a challenge. Unlike false-negative test results, false-positive results do not pose an immediate risk to recipient health; however, they are still problematic. From 1995 to mid-2008, approximately 64,000 allogeneic donors at the American Red Cross (ARC) were deferred based on HTLV false-positive enzyme immunoassay results, representing 130,000 US donors.[3] Similarly, among first-time ARC donors who donated whole blood between 1995 and 2002, approximately 13,000, 57,000, and 20,000 donors were deferred for unconfirmed reactive results on HBV, HCV, or HIV, respectively.[4] Total donor deferral attributed to false-positive test results, irrespective of first-time donor status or allogeneic blood donation type, is conceivably higher.

False-positive test results have significant implications for donors and blood centers. Foremost, despite recognition that the results likely represent laboratory or random error, donors may be permanently deferred from future donation. In the case of HIV, HCV, and hepatitis B surface antigen (HBsAg) deferral is implemented with immediate effect. Those with a false-positive HTLV or hepatitis B core result are allowed a second opportunity to donate; their blood products from the first donation are discarded nonetheless. Even when reinstatement—a cumbersome and highly regulated process that requires interval repeat testing—is possible, this often leaves donors anxious and confused, dissuading future donation attempts.[5,6] From a blood center perspective, false-positive donations also represent a financial burden, whereby costs generated both prior to obtaining the test result (i.e., blood collection and processing) as well those following (i.e., blood disposal, donor notification, and management) cannot be recovered.[7] Beyond the financial burden, deferral of false-positive donors impacts the blood supply, particularly where rare donors are concerned.

Although a previous study did identify certain demographic groups that had an increased prevalence of unconfirmed, repeat-reactive (false-positive) results,[8] recent data on the factors associated with false-positive results for HIV, HTLV, HBV, and HCV in blood donors are lacking. We therefore sought to determine associations between donor characteristics and false-positive results from infectious marker screening. A secondary objective of our study was to estimate the prevalence of high-risk behaviors in false-positive donors. Identifying patterns in behavior may allude to a previously established cause for false-positive test results given a hypothesis that high-risk behavior is independently linked to false-positive results.

MATERIALS AND METHODS

Study design

An analysis was conducted of all allogeneic donations that were collected at Blood Systems, Inc. (BSI) centers between January 1, 2011, and December 31, 2012. The donations were identified using BSI's data warehouse. Donations that fulfilled study eligibility were included in a case-control study to evaluate the association between demographic characteristics and false positivity for HTLV, HIV, HBV, and/or HCV. The following donation types were included in the study: plateletpheresis, concurrent platelet and plasma, plasma by apheresis, double red blood cells (RBCs), concurrent RBCs and plasma, and whole blood donations. Cases and controls were selected based on final nucleic acid testing (NAT) and serologic test results for each of the four viruses. All testing was performed at Creative Testing Solutions. For cases in our study, a false-positive donation was defined as a donation that tested repeat reactive during initial serologic screening but the result was not confirmed during confirmatory testing (Fig. 1, simplified algorithm); all cases were NAT negative for HIV, HBV, and HCV. Although rare, donors who tested false positive for more than one virus were excluded. Individuals whose donations were seronegative for antibody screening for all infectious markers (HTLV, HIV, HBV, and HCV) and nonreactive for NAT, when applicable (i.e., HIV, HBV, and HCV), were selected as controls. Only donors who tested negative over the course of all their donations in this time period were included. All autologous, directed, and therapeutic donations were also excluded from the analysis, as were donations from donors under the age of 18. The data were analyzed in aggregate and were devoid of personal identifiers; therefore, the study was considered exempt from human subjects research approval under section 46.101(b) of 45 CFR 46.

We leveraged the separate donor risk factor study to further evaluate risk factors for false-positive test results beyond basic demographics. Detailed methods are described elsewhere.[9] In brief, all donors who were repeat reactive (either confirmed positive or unconfirmed) at BSI, ARC, and New York Blood Center were asked to complete a questionnaire pertaining to sociobehavioral risk factors (e.g., sexual history, drug and needle use, and medical history) that might have contributed to their testing positive. Our study evaluated BSI donors exclusively, of whom 42% of unconfirmed (false-positive) donors responded during the 2-year study period and were included in the analysis. Therefore, the study population of our behavioral analysis represents a subset of the same donor population used for our study of demographic risk factors.

Statistical analysis

Donors were included only once in our donor-based analysis. Data cleaning and analysis was performed using computer software (SAS 9.3, SAS Institute, Inc., Cary, NC; and STATA 12, StataCorp, College Station, TX). Age was calculated at time of index donation for cases and at the midpoint of the study period for controls since controls did not have index donations. Education was classified by the highest degree earned. In cases where the database contained contradictory information on race, race information from the most recent donation was used. Logistic regression modeling was used to analyze the relationship between demographic characteristics and the likelihood of testing false positive for the four

specific infections. Explanatory variables included age, sex, race, education, country of birth, and first-time donation status. Both bivariable and multivariable analyses were performed, with significance defined as a p value of less than or equal to 0.05. Due to small numbers of persons in some combinations of age, sex, and race categories only a descriptive analysis of the risk factor questionnaire data was performed.

RESULTS

Study population

A total of 1,881,738 eligible donations were collected between January 1, 2011, and December 31, 2012 at BSI centers. A total of 1441 false-positive donors were included in our study as cases (Table 1), for which 627 risk factor questionnaires were available. The majority of donors were white; Hispanic donors represented the largest minority group. Mean age was approximately 40 years in both donor groups, and males and females were similarly represented. First-time donors represented approximately 30% of donors in the true-negative and false-positive groups. Of the 813,550 donors who donated, 801,034 donors contributed donations that were negative for the four infectious markers. Complete demographic information was available for 748,134 donors, and after excluding donors who were under 18, a total 657,803 true-negative donors were included as controls in our study.

Demographic associations with false positivity

All false-positive donors—In both bivariable and multivariable analyses, sex, first-time donor status, and education were not significantly associated with false-positive results; in contrast, age and race/ethnicity were strongly associated with this outcome (Table 2). Specifically, in multivariable analysis, ages 25–34 (odds ratio [OR], 1.22; 95% confidence interval [CI], 1.03–1.44; $p = 0.020$), black race (OR, 1.73; 95% CI, 1.38–2.17; $p < 0.0001$), and Hispanic ethnicity (OR, 1.42; 95% CI, 1.25–1.62; $p < 0.0001$) were significantly associated with a false-positive result.

HBV—In both bivariable and multivariable regression, HBV false positivity was negatively associated with first-time donor status and education less than high school completion (Tables 3 and 4). In the multivariable analysis, first-time donor status (OR, 0.67; 95% CI, 0.50–0.89; $p = 0.005$), an education level of less than high school completion (OR, 0.51; 95% CI, 0.30–0.86; $p = 0.017$), and education equivalent to high school graduate (OR, 0.77; 95% CI, 0.60–1.00; $p = 0.050$) appeared to be “protective” against testing false positive for HBV. By comparison, age and race/ethnicity were not significant predictors of our outcome in either bivariable or multivariable analyses.

HCV—All demographic characteristics, with the exception of age, were significantly associated with HCV false-positive results in both bivariable and multivariable analyses (Tables 3 and 4). After all covariates were adjusted for, females had decreased odds of testing false positive (OR, 0.64; 95% CI, 0.52–0.78; $p < 0.0001$) while first-time donor status (OR, 1.70; 95% CI, 1.38–2.08; $p < 0.0001$), black (OR, 3.06; 95% CI, 2.21–4.22; $p < 0.0001$), and Hispanic (OR, 1.51; 95% CI, 1.19–1.92; $p = 0.001$) race/ethnicity had highly significant associations with false positivity. Donors with an education of less than high

school education (OR, 1.33; 95% CI, 1.03–1.71; p = 0.026) also had higher odds of false-positive results.

HTLV—In both bivariable and multivariable regressions, HTLV false positivity was positively associated with age and race/ethnicity and negatively associated with first time-donor status (Tables 3 and 4). After all other variables were adjusted for, black (OR, 1.83; 95% CI, 1.25–2.67; p = 0.002) and Hispanic (OR, 1.63; 95% CI, 1.32–2.01; p < 0.0001) race/ethnicity and being ages 25 to 34 (OR, 1.66; 95% CI, 1.25–2.22; p = 0.001) and 35 to 44 (OR, 1.58; 95% CI, 1.17–2.13; p = 0.003) were associated with an increased odds of testing false positive for HTLV; in contrast, first-time donor status was protective against testing false-positive for HTLV (OR, 0.71; 95% CI, 0.57–0.88; p = 0.002).

HIV—HIV false positivity was not significantly associated with any of the variables in either bivariable or multivariable analyses (Tables 3 and 4).

Risk factor questionnaire

The results of the risk factor questionnaire are summarized in Table 5. Among all false-positive donors, approximately 76% reported being monogamous in the past year. Sex with high-risk partners was rare, with less than 1% reporting ever having had a sex partner with HIV or a partner who engaged in men who have sex with men and approximately 2% reported ever having had a sexual partner with hepatitis. A reported history of medical procedures, such as transfusion and transplantation, was low (8 and 2%, respectively), and that of needle-stick injury was similarly uncommon (4%). Although a history of STDs ever and in the past year was slightly higher among HTLV false-positive donors (17.80 and 14.82%, respectively) compared to other groups (which ranged from 8% to 9% and 0% to 9%), significant variation was not observed across the four false-positive donor groups. In general, false-positive donors were not engaging in high-risk behaviors.

DISCUSSION

In our study, we sought to evaluate the demographic characteristics of blood donors in relation to false-positive test results for HIV, HTLV, HBV, and HCV that arose during donor screening. Surprisingly, donors of black or Hispanic race/ethnicity were significantly associated with false positivity for HCV and HTLV. Male sex and lower education were associated with HCV false positivity and age 25 to 44 was associated with HTLV false positivity. While first-time donor status was more likely to be associated with HCV false-positive results, it was less likely to be associated with HBV and HTLV false-positive results. In the subset of false-positive subjects who completed the risk factor interview, reported behavioral risk factors frequencies were low.

There are multiple hypotheses as to why false-positive test results occur. Foremost, false-positive results are attributed to nonspecific antibody reactivity, which appears to be associated with heightened immune responses.[10] There are a diverse array of medical events or conditions that have been associated with false-positive results.[11,12] These include but are not limited to recent vaccination (e.g., influenza or hepatitis), viral infection, autoimmune disease, liver disease (e.g., cirrhosis), hyper-gammaglobulinemia, and multiple pregnancies.

Nonspecific polyreactive antibodies (predominantly IgM) are normally present in plasma and are thought to contribute to false-positive results as a result of binding (albeit weakly) with a variety of different, and structurally unrelated, foreign antigens.[13,14] In addition, some heterophile antibodies, which are produced in response to external antigens, have been shown to cross-react with self-antigens and bind indiscriminately to a number of different epitopes.[15,16]

False-positive test results are also assay dependent. For example, when repeat-reactive samples are tested with a different, secondary immunoassay (sequential immunoassay testing) before undergoing confirmatory testing, concordant false-positive results are less likely to occur, thus reducing reliance on confirmatory testing.[17] In one study, Sharma and coworkers[18] observed increased nonspecific test results for HBsAg kits after changes in assays, kit manufacturers, and even within-assay lot numbers as well, thus contributing to donor deferral.

False-positive results have also been associated with distinct demographic groups. Ownby and colleagues[8] identified certain demographic groups with an increased prevalence of false-positive and indeterminate results for HIV, HTLV, HBV, and HCV. Specifically, HIV and HTLV false-positive results were significantly more prevalent among female donors, and HIV, HCV, and HBsAg false-positive results were more prevalent among nonwhite (black, Hispanic) donors. Furthermore, false-positive test results were comparatively more frequent in first-time than in repeat donors for all four viruses. The investigators postulated that there may be sex-, race-, or age-linked proteins that cross-react with testing materials. An older study of Swiss donors found that high proportions of sera, regardless of HIV status, had antibodies that react weakly with HTLV-I, indicating that these antibodies may be induced by immunologically similar compounds, in this case prevalent in the Swiss population.[19] Thus, it is conceivable that our results may be attributable both to the combination of assays used for blood screening and to the distinct characteristics of the donor population. However, it is unclear whether the observed cross-reactivity is attributable to inherent, biologic differences among blood donors or to external, social factors associated with race or first-time donor status.

Given that the observed risk for HTLV and HCV false positivity is similar to that of demographic predictors of true infection,[20,21] this may prompt concern that some false-positive test results represent low-grade or occult infections. However, in light of current testing algorithms that include parallel serologic and NAT for HIV, HBV, and HCV coupled with robust confirmatory testing, this is unlikely. Moreover, the results of the risk factor questionnaire, although representing only a subset of the total number of false-positive donors, showed low rates of high-risk behavior. Specifically, injection drug use—the leading risk factor for HCV infection—was rare in HCV false-positive donors and risk factors for true HTLV infection such as history of needle-stick exposures, transfusion, or unsafe sexual practices (e.g., multiple sexual partners) were similarly rare in HTLV false-positive donors.

Other findings also detract from a biologic mechanism of false positivity in our study population. For example, we observed a varied association between first-time donor status, a well-established risk factor for true infection (HBV, HCV, HIV, and HTLV)[9] and false

positivity. It follows that repeat donor status should have a lower risk whereby those who are truly infected should be “culled” from the donor pool given deferral at first presentation. However and in contrast, mixed associations were noted in our study depending on the infectious marker. Specifically, first-time donor status was positively associated with HCV false positivity and negatively associated with both HBV and HTLV false positivity and had no association with HIV. The absence of a pattern with respect to the direction of association across the markers is more in keeping with random rather than true association.

Similarly, no associations were observed between false positivity and date of collection, geography, and blood type (data not shown). One might postulate that seasonality could affect the incidence of false-positive test results given, for example, the timing of viral infections (e.g., colds and influenza with collection in the winter months) or hypersensitivity (e.g., seasonal allergies and collection in spring or summer); however, this was not shown in our study. Although only 1 year of data (2012) was used in a subanalysis, donations were fairly consistent throughout the year (7%–9% of the annual donations were collected in any given month). Although the collective incidence of false-positive test results was slightly higher in September and October (10%–12%), there was marked variation for the individual markers and seasonality was not shown to be significant. Likewise, false positivity was not associated with place of donation (a total of 12 states were represented in the study) or blood type.

Nonetheless, although there is insufficient evidence to support the hypothesis that the observed false-positive results represent true positives, there is still some evidence that suggests nonrandom association, particularly for HTLV and HCV. This warrants further study: longitudinal follow-up and interval repeat sampling of false-positive donors would be useful to show whether donors are persistently false positive or alternatively whether they do indeed demonstrate evidence of true infection. One possibility is that the observed results represent resolved or aborted infection. Furthermore, investigation into associations between demographic characteristics and false positivity by assay would be useful to ascertain whether race, age, sex, and first-time donor status associations remain. An improved understanding of this phenomenon could conceivably inform future development of assays.

We acknowledge that there are limitations to our study. Only blood donations from BSI were included in the study. Given nuanced differences in testing laboratories, reagents, and testing algorithms, our findings may limit generalizability to other settings. However, blood collected at BSI is tested using the same assays as the majority of blood centers in the United States, detracting from this being a significant limitation. Second, for the purpose of our analysis, only donations with false-positive test results for one infectious marker and negative for the remaining three were included. Donations with multiple false-positive results, although rare, were excluded, as were donations with a combination of negative, false-positive, and true-positive test results for the four infectious markers. Future studies on donors with false-positive results on multiple infections or combinations of true positive and false positive may be insightful. Finally, lack of data on behavioral risk factors of true-negative donors (the control group) limits the analysis beyond a basic description of false-positive donors. Poor response rates on select questions may also introduce bias, especially for questions with significant missing data. Despite these limitations, our study provides a

large, comprehensive analysis of all HTLV, HIV, HBV, and HCV false-positive donations within BSI between 2011 and 2012. Had there been no significant findings, it would suggest that false positivity is a random event in which case false-positive donors are fundamentally the same as true-negative donors. Instead, our findings suggest a nonrandom mechanism that affects donors differently based on their demographic characteristics.

Voluntary blood donors remain a low-risk population in which true infection of HTLV, HIV, HCV, and HBV is rare. Although the absolute rates of false-positive results remain low, approximately one million units of blood are donated at BSI centers alone each year; therefore an appreciable number of donations are still discarded due to false-positive test results. When real infection is rare, this can exceed the number of donations lost due to true-positive test results. Limited evidence suggests that some false-positive viral infection test results are not completely random. This merits further evaluation given the adverse effect on donors and the blood supply. Furthermore, special attention should also be considered in the counseling of first-time and minority donors who receive false-positive test results, ultimately with the goal of mitigating the long-term impact of these results on donors and donation centers alike.

Acknowledgments

Funding for this study was provided by Blood Systems, Inc. and Dr Murphy's NHLBI career development award K24-HL-75036.

ABBREVIATIONS

ARC	American Red Cross
BSI	Blood Systems, Inc

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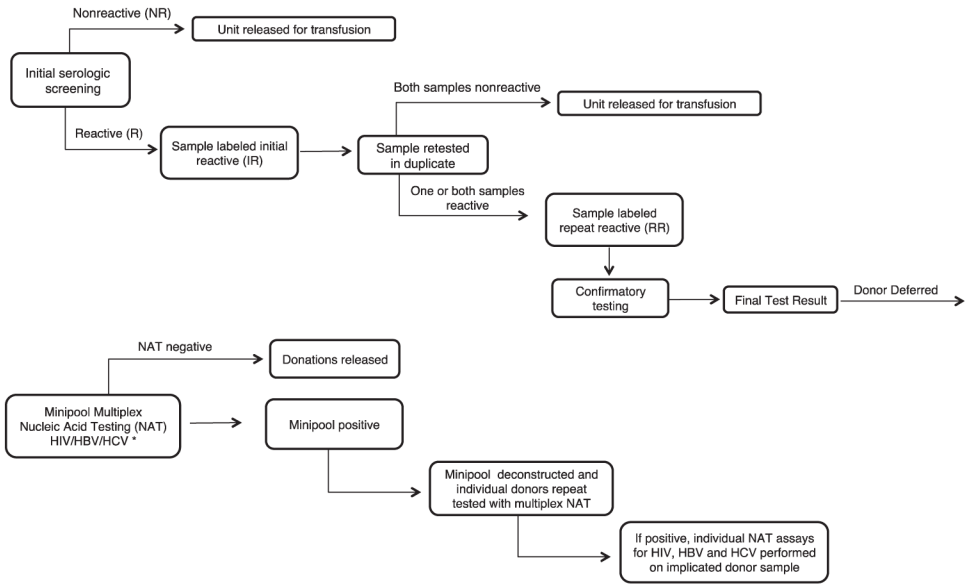

Fig. 1.

Infectious disease screening algorithm. *Multiplex NAT in the United States is performed in pools of 16 donor samples. NAT is conducted in parallel with serologic screening, thus assuring high sensitivity and specificity; it also enables capture of viremic donations in the preseroconversion “window” period. Note: NAT not available for HTLV-I/II transfusion testing.

TABLE 1

Demographics of the study population (n = 659,244)

		False positive				
Variable	**True negatives (n = 657,803)**	**FP (n = 1441)**	**HIV (n = 195)**	**HTLV (n = 512)**	**HBV (n = 309)**	**HCV (n = 425)**
Sex						
Female	325,624 (49.50)	680 (47.19)	88 (45.13)	270 (52.73)	160 (51.78)	162 (38.12)
Male	332,175 (50.50)	761 (52.81)	107 (54.87)	242 (47.27)	149 (48.22)	263 (61.88)
Total	657,799	1441	195	512	309	425
Age (years)						
18–24	157,376 (23.92)	335 (25.25)	40 (20.51)	94 (18.36)	72 (23.30)	129 (30.35)
25–34	121,760 (18.51)	316 (21.93)	40 (20.51)	129 (25.20)	54 (17.48)	93 (21.88)
35–44	107,888 (16.40)	254 (17.63)	39 (20.00)	107 (20.90)	47 (15.21)	61 (14.35)
45–54	122,239 (18.58)	253 (17.56)	37 (18.97)	94 (18.36)	57 (18.45)	65 (15.29)
55–64	97,771 (14.86)	196 (13.60)	25 (12.82)	62 (12.11)	55 (17.80)	54 (12.71)
65+	50,769 (7.72)	87 (6.04)	14 (7.18)	26 (5.08)	24 (7.77)	23 (5.41)
Total	657,803	1441	195	512	309	425
Race/ethnicity						
White	429,824 (70.42)	900 (63.83)	126 (67.02)	315 (62.75)	219 (72.52)	240 (57.42)
African American	23,941 (3.92)	88 (6.24)	2 (1.06)	32 (6.37)	8 (2.65)	46 (11.00)
American Indian	7626 (1.25)	15 (1.06)	5 (2.66)	1 (0.20)	4 (1.32)	5 (1.20)
Asian	16,426 (2.70)	29 (2.06)	6 (3.19)	7 (1.39)	7 (2.32)	9 (2.15)
Hispanic	121,929 (19.81)	359 (25.46)	47 (25.00)	141 (28.09)	60 (19.87)	111 (26.56)
Other	11,651 (1.91)	19 (1.35)	2 (1.06)	6 (1.20)	4 (1.32)	7 (1.67)
Total	610,397	1410	188	502	302	418
Education						
Less than HS graduate	61,855 (10.33)	131 (9.43)	23 (12.30)	35 (7.14)	21 (6.93)	52 (12.71)
HS graduate	354,782 (59.23)	859 (61.84)	103 (55.08)	319 (65.10)	171 (56.44)	266 (65.04)
Bachelor’s degree or higher	182,379 (30.44)	399 (28.73)	61 (32.62)	136 (27.76)	111 (36.63)	91 (22.25)
Total	599,016	1389	187	490	303	409
First-time donor						
Yes	197,098 (30.20)	437 (30.31)	54 (27.69)	125 (24.41)	68 (22.01)	189 (44.47)

Transfusion. Author manuscript; available in PMC 2017 February 01.

Variable	True negatives (n = 657,803)	False positive				
		FP (n = 1441)	HIV (n = 195)	HTLV (n = 512)	HBV (n = 309)	HCV (n = 425)
No	455,453 (69.80)	1005 (69.69)	141 (72.31)	387 (75.59)	241 (77.99)	236 (55.53)
Total	652,551	1442	195	512	309	425

FP = false positive.

TABLE 2

Demographic associations with a false-positive result for any of the four viruses

	All FP bivariable analysis			ALL FP multivariable analysis		
Variable	**OR**	**95% CI**	**p value**	**OR**	**95% CI**	**p value**
Age (years)						
18–24	1.00			1.00		
25–34†	1.22	1.05–1.42	0.012	1.22	1.03–1.44	0.020
35–44	1.11	0.94–1.30	0.226	1.13	0.95–1.35	0.191
45–54	0.97	0.83–1.14	0.736	1.01	0.83–1.21	0.951
55–64	0.94	0.79–1.12	0.505	1.02	0.84–1.25	0.823
65+	0.81	0.64–1.02	0.072	0.91	0.71–1.17	0.469
Female	0.92	0.82–1.01	0.080	0.91	0.82–1.01	0.074
First-time donor	1.00	0.90–1.12	0.965	0.97	0.86–1.09	0.562
Race						
White	1.00			1.00		
African American†	1.76	1.41–2.19	0.000	1.73	1.38–2.17	0.000
American Indian	0.94	0.56–1.57	0.810	0.96	0.58–1.61	0.888
Asian	0.84	0.58–1.22	0.366	0.83	0.57–1.21	0.329
Hispanic†	1.42	1.25–1.60	0.000	1.42	1.25–1.62	0.000
Other	0.78	0.49–1.23	0.281	0.79	0.50–1.25	0.316
Highest degree						
Less than HS graduate	0.97	0.79–1.18	0.747	0.90	0.72–1.12	0.340
HS diploma or equivalent	1.11	0.98–1.25	0.095	1.05	0.93–1.19	0.430
Bachelor’s degree or higher	1.00			1.00		

*Columns on the left represent unadjusted ORs and columns on the right represent ORs derived from multivariable analysis.

†Significant at $p < 0.05$.

FP = false positive; HS = high school.

TABLE 3

Unadjusted demographic associations with false-positive results, by virus*

	HBV			HCV			HTLV			HIV		
Variable	**OR**	**95% CI**	**p value**	**OR**	**95% CI**	**p value**	**OR**	**95% CI**	**p value**	**OR**	**95% CI**	**p value**
Age (years [baseline: 18–24 years])												
18–24	1.00			1.00			1.00			1.00		
25–34	0.97	0.68–1.38	0.863	0.93	0.71–1.22	0.604	1.77†	1.36–2.31†	0.00	1.29	0.83–2.00	0.251
35–44	0.95	0.66–1.38	0.794	0.69†	0.51–0.94†	0.017	1.66†	1.26–2.19†	0	1.42	0.91–2.21	0.118
45–54	1.02	0.72–1.44	0.914	0.65†	0.48–0.87†	0.004†	1.29	0.97–1.71	0.083	1.19	0.76–1.86	0.444
55–64	1.23	0.87–1.75	0.249	0.67†	0.49–0.93†	0.015†	1.06	0.77–1.46	0.72	1.01	0.61–1.66	0.981
65+	1.03	0.65–1.64	0.89	0.55†	0.35–0.86†	0.009†	0.86	0.56–1.32	0.488	1.08	0.59–1.99	0.793
Female	1.10	0.88–1.37	0.423	0.63†	0.52–0.76†	0.000†	1.14	0.96–1.35	0.144	0.84	0.63–1.11	0.223
First-time donor	0.65†	0.50–0.85†	0.002†	1.85†	1.53–2.24†	0.000†	0.75†	0.61–0.91†	0.00	0.88	0.65–1.21	0.445
Race												
White	1.00			1.00			1.00			1.00		
African American	0.66	0.32–1.32	0.241	3.44†	2.51–4.72†	0.000†	1.82†	1.27–2.62†	0.001	0.28	0.07–1.15	0.078
American Indian	1.03	0.38–2.77	0.954	1.17	0.48–2.84	0.722	0.18	0.03–1.27	0.09	2.23	0.91–5.47	0.078
Asian	0.84	0.39–1.78	0.642	0.98	0.50–1.90	0.956	0.58	0.27–1.23	0.156	1.25	0.55–2.82	0.599
Hispanic	0.97	0.73–1.29	0.855	1.64†	1.31–2.06†	0.000†	1.59†	1.30–1.94†	0	1.32	0.95–1.85	0.099
Other	0.67	0.25–1.81	0.434	1.08	0.51–2.28	0.849	0.7	0.31–1.57	0.392	0.59	0.14–2.37	0.453
Highest degree												
Less than HS	0.56†	0.35–0.89†	0.014†	1.68†	1.20–2.37†	0.003†	0.76	0.52–1.10	0.15	1.11	0.69–1.80	0.665
HS diploma or equivalent	0.79	0.62–1.01	0.056	1.5†	1.18–1.91†	0.001†	1.21	0.99–1.47	0.068	0.87	0.63–1.19	0.381
Bachelor's degree or higher	1.00			1.00			1.00			1.00		

*ORs derived from bivariable analyses.

†Significant at $p < 0.05$.

HS = high school.

TABLE 4

Independent demographic associations with false-positive results, by virus*

	HBV			HCV			HTLV			HIV		
Variable	**OR**	**95% CI**	**p value**	**OR**	**95% CI**	**p value**	**OR**	**95% CI**	**p value**	**OR**	**95% CI**	**p value**
Age (years [baseline: 18–24 years])												
18–24	1.00			1.00			1.00			1.00		
25–34	0.82	0.56–1.19	0.290	1.08	0.81–1.45	0.593	1.66†	1.25–2.22†	0.001†	1.43	0.88–2.35	0.152
35–44	0.73	0.49–1.09	0.119	0.89	0.63–1.23	0.470	1.58†	1.17–2.13†	0.003†	1.59	0.96–2.62	0.069
45–54	0.76	0.52–1.12	0.165	0.92	0.66–1.28	0.632	1.19	0.87–1.63	0.282	1.35	0.81–2.25	0.249
55–64	0.88	0.59–1.31	0.534	1.1	0.78–1.56	0.593	1.02	0.72–1.46	0.892	1.17	0.66–2.06	0.586
65+	0.80	0.49–1.31	0.371	0.93	0.58–1.48	0.756	0.84	0.53–1.34	0.475	1.32	0.68–2.54	0.413
Female	1.06	0.84–1.33	0.614	0.64†	0.52–0.78†	0.000†	1.12	0.94–1.34	0.214	0.87	0.65–1.17	0.367
First-time donor	0.67†	0.50–0.89†	0.005†	1.7†	1.38–2.08†	0.000†	0.71†	0.57–0.88†	0.002†	0.90	0.64–1.26	0.543
Race												
White	1.00			1.00			1.00			1.00		
African American	0.65	0.30–1.38	0.261	3.06†	2.21–4.22†	0.000†	1.83†			0.30	0.07–1.21	0.091
American Indian	1.14	0.42, 3.08	0.795	1.09	0.45–2.66	0.842	0.19	0.03–1.34	0.095	2.34	0.95–5.77	0.063
Asian	0.83	0.39–1.77	0.625	0.95	0.48–1.85	0.874	0.6	0.28–1.26	0.177	1.2	0.52–2.74	0.669
Hispanic	1.05	0.78–1.42	0.731	1.51†	1.19–1.92†	0.001†	1.63†	1.32–2.01†	0.000†	1.34	0.94–1.90	0.111
Other	0.73	0.27–1.96	0.526	1	0.47–2.12	0.99	0.8	0.33–1.68	0.485	0.6	0.15–2.42	0.471
Highest degree												
Less than HS	0.51†	0.30–0.86†	0.017†	1.22	0.83–1.81	0.308	0.81	0.49–1.15	0.327	1.31	0.75–2.28	0.350
HS diploma or equivalent	0.77†	0.60–1.00†	0.050†	1.33†	1.03–1.71†	0.026†	1.15	0.94–1.42	0.182	0.89	0.64–1.24	0.481
Bachelor's degree or higher	1.00			1.00			1.00			1.00		

*ORs derived from multivariable analyses.

†Significant at $p < 0.05$.

HS = high school.

TABLE 5

Risk factors reported by donors with false-positive results, by virus and combined*

Risk factor	HIV (n = 91)	HTLV (n = 213)	HBV (n = 143)	HCV (n = 180)	All (n = 627)
Monogamous past year					
Yes	64 (72.73)	170 (80.19)	108 (75.52)	131 (72.78)	473 (75.92)
No	24 (27.27)	42 (19.81)	35 (24.48)	49 (27.22)	150 (24.08)
Sex with MSM partner ever					
Yes	1 (1.12)	2 (0.96)	1 (0.72)	2 (1.13)	6 (0.98)
No	88 (98.88)	206 (99.04)	138 (99.28)	175 (98.87)	607 (99.02)
Sex with hepatitis partner ever					
Yes	1 (1.12)	6 (2.93)	3 (2.19)	3 (1.72)	13 (2.15)
No	88 (98.88)	199 (07.07	134 (97.81)	171 (98.28)	592 (97.85)
Sex with HIV partner ever					
Yes	1 (1.10)	0	1 (0.71)	2 (1.12)	4 (0.65)
No	90 (98.90)	209 (100)	140 (99.29)	177 (98.88)	616 (99.35)
Sex with transfused partner ever					
Yes	3 (3.80)	11 (5.42)	11 (8.09)	10 (5.92)	35 (5.96)
No	76 (96.20)	192 (94.58)	125 (91.91)	159 (94.08)	552 (94.04)
Sex with IV drug user ever					
Yes	4 (4.65)	3 (1.45)	0	5 (2.87)	12 (1.99)
No	82 (95.35)	204 (98.55)	137 (100)	169 (97.13)	592 (98.01)
Exchange sex for money or goods ever					
Yes	0	2 (0.96)	1 (0.70)	1 (0.56)	4 (0.64)
No	91 (100)	207 (99.04)	141 (99.30)	179 (99.44)	618 (99.36)
Ever had STD					
Yes	8 (8.89)	27 (17.80)	12 (8.51)	16 (9.09)	63 (10.19)
No	82 (91.11)	184 (87.20)	129 (91.49)	160 (90.91)	555 (89.81)
STD in past year					
Yes	0	4 (14.82)	1 (9.09)	1 (6.25)	6 (9.68)
No	8 (100)	23(85.18)	10 (90.91)	15 (93.75)	56 (90.32)
Colonoscopy or endoscopy ever					

Transfusion. Author manuscript; available in PMC 2017 February 01.

Risk factor	HIV (n = 91)	HTLV (n = 213)	HBV (n = 143)	HCV (n = 180)	All (n = 627)
Yes	32 (35.16)	55 (26.32)	56 (39.44)	48 (26.67)	191 (30.71)
No	59 (63.84)	154 (73.68)	87 (60.65)	132 (73.33)	431 (69.29)
Transplant ever					
Yes	3 (3.33)	6 (2.90)	0	2 (1.11)	11 (1.78)
No	87 (96.67)	201 (97.10)	142 (100)	178 (98.89)	608 (98.22)
Transfusion ever					
Yes	6 (6.74)	17 (8.17)	10 (7.04)	15 (8.57)	48 (7.82)
No	83 (93.26)	191 (91.83)	132 (92.96)	160 (91.43)	566 (92.18)
Medical IV/IM injection ever					
Yes	63 (70.00)	160 (76.92)	116 (81.69)	132 (73.33)	471 (75.97)
No	27 (30.00)	48 (23.08)	26 (18.31)	48 (26.67)	149 (24.03)
Acupuncture ever					
Yes	5 (27.78)	4 (13.79)	2 (14.29)	2 (15.38)	13 (17.57)
No	13 (72.22)	25 (86.21)	12 (85.71)	11 (84.62)	61 (82.43)
Needle stick injury ever					
Yes	2 (2.20)	13 (6.22)	6 (4.23)	6 (3.33)	27 (4.34)
No	89 (97.80)	196 (93.78)	136 (95.77)	174 (96.67)	595 (95.66)
Exposed to other’s bodily fluids ever					
Yes	4 (4.44)	10 (4.83)	10 (7.14)	9 (5.06)	33 (5.37)
No	86 (85.56)	197 (95.17)	140 (92.86)	169 (94.94)	582 (94.63)
Family with HepB/HepC					
Yes	1 (1.14)	6 (2.88)	1 (0.71)	2 (2.23)	12 (1.95)
No	87 (98.86)	202 (97.12)	140 (99.29)	175 (97.77)	604 (98.05)
Used illegal drug (not IV) ever					
Yes	11 (12.09)	18 (8.53)	17 (11.97)	24 (13.41)	70 (11.24)
No	80 (87.91)	193 (91.47)	125 (88.03)	155 (86.59)	553 (88.76)
Tattoos ever					
0	62 (68.13)	141 (67.46)	99 (69.72)	123 (68.72)	425 (68.44)
1	10 (10.99)	30 (14.35)	18 (12.68)	21 (11.73)	79 (12.73)
1	19 (20.88)	38 (18.18)	25 (17.61)	35 (19.55)	117 (18.84)
Ear piercing ever					

Risk factor	HIV (n = 91)	HTLV (n = 213)	HBV (n = 143)	HCV (n = 180)	All (n = 627)
None	41 (45.05)	68 (32.54)	54 (38.03)	81 (45.25)	244 (39.29)
1 to 2	31 (34.07)	85 (40.67)	51 (35.91)	54 (30.17)	221 (35.59)
2	19 (20.88)	56 (26.79)	37 (26.06)	44 (24.58)	156 (25.12)
Body piercing ever					
None	80 (87.91)	185 (88.52)	122 (85.92)	156 (87.15)	543 (87.44)
1 to 2	9 (9.89)	19 (9.09)	15 (10.56)	15 (8.38)	58 (9.34)
2	2 (2.20)	5 (2.39)	5 (3.52)	8 (4.47)	20 (3.22)

* Data were obtained from a risk factor interview conducted for retrovirus and hepatitis virus and false-positive donors. Missing observations were not used in calculating column percentages.

MSM = men who have sex with men; IV = intravenous; IM = intramuscular.