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ESTIMATED RISK OF TRANSMISSION OF THE HUMAN IMMUNODEFICIENCY VIRUS BY SCREENED BLOOD IN THE UNITED STATES

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Abstract Background. In the United States, transmission of the human immunodeficiency virus (HIV) by blood transfusion occurs almost exclusively when a recently infected blood donor is infectious but before antibodies to HIV become detectable (during the "window period"). We estimated the risk of HIV transmission caused by transfusion on the basis of the window period associated with the use of current, sensitive enzyme immunosorbent assays and recent data on HIV incidence among blood donors.

Methods. We analyzed demographic and laboratory data on more than 4.1 million blood donations obtained in 1992 and 1993 in 19 regions served by the American National Red Cross, as well as the results of HIV-antibody tests of 4.9 million donations obtained in an additional 23 regions.

Results. We estimated that, in the 19 study regions, 1 donation in every 360,000 (95 percent confidence interval, 210,000 to 1,140,000) was made during the win-

dow period. In addition, it is estimated that 1 in 2,600,000 donations was HIV-seropositive but was not identified as such because of an error in the laboratory. We estimated that 15 to 42 percent of window-period donations were discarded because they were seropositive on laboratory tests other than the HIV-antibody test. When these results were extrapolated to include the additional 23 Red Cross service regions, there was a risk of 1 case of HIV transmission for every 450,000 to 660,000 donations of screened blood. If the Red Cross centers are assumed to be representative of all U.S. blood centers, among the 12 million donations collected nationally each year an estimated 18 to 27 infectious donations are available for transfusion.

Conclusions. The estimated risk of transmitting HIV by the transfusion of screened blood is very small and nearly half that estimated previously, primarily because the sensitivity of enzyme immunosorbent assays has been improved. (N Engl J Med 1995;333:1721-5.)

AFTER the practice of screening all blood donations for antibodies to the human immunodeficiency virus (HIV) was introduced in the United States in 1985, the transmission of HIV by transfusion decreased dramatically.¹ However, there has been continued concern about this route of HIV transmission,^{2,3} a marked decrease in the use of blood products,⁴ and increased demands to reduce the risk even further.

Currently, the risk of transmitting HIV by the transfusion of screened blood is almost completely due to the use of donations made during the "window period" when a recently infected donor is infectious but detect-

able HIV antibodies have not yet developed.⁵ The probability of a donation during this time is related to the duration of the window period and the incidence of HIV infection among blood donors.

Petersen et al.⁵ estimated that with the enzyme immunosorbent assays used to screen blood donations from 1985 through 1990, the average length of the window period was 45 days (95 percent confidence interval, 34 to 55). Using these values, Busch et al.⁶ later estimated that with contemporary enzyme immunosorbent assays involving recombinant, protein-based antibodies to HIV types 1 and 2, the window period was 20 days less — an average of 25 days (95 percent confidence interval, 9 to 41). Because the incidence of HIV among blood donors is very low and varies geographically, accurate estimates of the risk of HIV transmission by the transfusion of screened blood in the United States must be based on the study of many donations from many areas. We designed this study to calculate the risk of transmitting HIV through the transfusion of blood screened as seronegative by the contemporary HIV-antibody tests. We used information from regions

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across the United States for which blood services were provided by the American National Red Cross.

METHODS

Study Population

We collected information on all voluntary and directed blood donations from January 1992 through December 1993 in 19 regions served by the American National Red Cross. The 19 study regions were selected from all regions served by the Red Cross nationally because their computerized data-management systems were compatible with each other. The Red Cross collects approximately half the 12 million blood donations made annually in the United States, and the 19 study regions accounted for approximately 43 percent of all donations received by the Red Cross during the study period.

For all donors of voluntary or directed donations in the study regions, we collected demographic information, dates of both current and previous donations, and the results of all laboratory tests used to screen the donated blood. No personal identifiers, such as names or donor-identification numbers, were included with the data. Because many regions do not collect information on race or ethnic group, we limited our analysis of this variable to the six regions for which there was complete information. Among the 25 Red Cross regions in the continental United States that were not included in the study, we collected the results of HIV tests for 23 regions in which the reporting of those data was complete. For all persons who made voluntary or directed donations in these 23 nonstudy regions, we collected information on the number of donations and the number of HIV-positive units given by both repeat and first-time donors.

Definition of Repeat and First-Time Donors

We defined repeat donors as those who had made a recorded donation of blood during the three years before the donation they made in 1992 or 1993. Donors in the 19 study regions who had not given blood during the preceding three years but who had done so previously were reclassified as first-time donors, as were those for whom there was no recorded date of an earlier donation in the region's data system (this group included both repeat donors from other regions and first-time donors who described themselves as repeat donors). Donors who described themselves as first-time donors but for whom the date of an earlier donation was recorded in the region's data system were reclassified as repeat donors. For the 23 nonstudy regions, we assumed that the proportion of HIV-positive and HIV-negative repeat donors who would be reclassified as first-time donors according to the above method was the same as in the 19 study regions.

Laboratory Tests

During the two-year study period, all blood donations were tested for HIV antibody, hepatitis B surface antigen, hepatitis B core antibody, hepatitis C antibody, antibody to *Treponema pallidum*, elevated levels of alanine aminotransferase, and antibody to human T-cell leukemia virus type I (HTLV-I). Results of the tests for HTLV-I, hepatitis C antibody, or both were not available in three study regions. In addition, blood was screened for HIV type 1 and HIV type 2 with a recombinant, protein-based combination enzyme immunosorbent assay (Abbott, North Chicago, Ill.), and reactive specimens were retested again in duplicate. Repeatedly reactive specimens were tested by the Western blot assay licensed by the Food and Drug Administration (FDA) (Cambridge Biotech, Worcester, Mass.). Specimens confirmed as seropositive by Western blot assay according to the manufacturer's instructions at the reference laboratory of the American National Red Cross were considered positive for HIV antibodies. Because less than 1 percent of donors whose blood specimens repeatedly test as reactive by enzyme immunosorbent assay and as indeterminate by the Western blot assay subsequently seroconvert to positivity by the Western blot assay,⁷⁻⁹ donations that tested as indeterminate by the Western blot assay were excluded from the analysis.

General Approach

To determine the risk of transmitting HIV by the transfusion of screened blood, we first estimated the probability that a donation

would be made during the window period of HIV infection on the basis of the duration of the window period^{5,6} and the incidence of HIV among blood donors. We then estimated the proportion of HIV-seropositive donations that were incorrectly determined to be seronegative as a result of laboratory error. We calculated the overall risk of transmitting HIV through the transfusion of screened blood by adding the risks associated with window-period donations to those associated with donations misclassified because of laboratory errors. Finally, we subtracted the estimated proportion of infectious donations that were not made available for transfusion because they had tested positive on screening tests other than the HIV-antibody test. These calculations yielded the estimated proportion of all donations that were infectious for HIV but that tested negative by HIV-antibody tests and all other screening tests used.

Incidence of HIV among Blood Donors

We calculated the overall incidence rate of HIV infection (the number of new infections per person-year of observation) from a weighted average of the incidence rates among repeat and first-time donors. The incidence rate among repeat donors in the 19 study regions was calculated as the number of such donors who seroconverted (those who tested HIV-positive at a donation made in 1992 or 1993 and HIV-negative at their previous donation) divided by the number of person-years of observation. The total number of person-years of observation was obtained by adding the number of person-years of observation for both the seronegative and the seroconverting repeat donors. The number of person-years of observation for seronegative donors in the 19 study regions was calculated as the number of donations made by seronegative repeat donors multiplied by the average interval between donations. To compute the number of person-years of observation for donors who seroconverted, we assumed that seroconversion occurred halfway between the dates of the seronegative and the seropositive donations. Because no data were available on the intervals between donations in the 23 nonstudy regions, we assumed that the average intervals in those regions were the same as those in the 19 study regions. We calculated the incidence of HIV among repeat donors in the nonstudy regions by dividing the number of seropositive repeat donors by the estimated number of person-years of observation.

The incidence of HIV among first-time donors cannot be measured directly, because a recent HIV infection cannot be distinguished from an older infection. When HIV testing first became available in 1985, no donors had been excluded because of a positive HIV-antibody test. The seroprevalence of HIV at that time was thus equivalent to the cumulative incidence of HIV among both first-time and repeat donors. At that time, the prevalence of HIV (and therefore its cumulative incidence) among first-time donors was 1.8 times that among repeat donors.¹⁰ We therefore assumed that the incidence rate of HIV among first-time donors in our study population was 1.8 times that among repeat donors.

Probability of a Donation during the Window Period

We calculated that the probability that a seronegative donation would be made during the window period was equal to the incidence rate of HIV among first-time and repeat donors, multiplied by the most recent estimate of the duration of the window period.^{5,6} In making these calculations, we assumed that the incidence of HIV, the distribution of intervals between donations, and the number of donations remained constant over time. In calculating confidence intervals for the 19 study regions, we assumed that the number of repeat donors who seroconverted followed a Poisson distribution and that uncertainty about the length of time between infection and the formation of detectable antibodies was independent of uncertainty about the number of seroconverting donors.

Laboratory Error

In this analysis, we defined a laboratory error as any technical or human error in the testing, recording, or discarding of donations that were unsuitable for transfusion. The probability that a laboratory error involving an HIV-infected unit of blood would occur was equal to the estimated probability of a laboratory error (0.5 per-

cent)¹¹⁻¹⁴ multiplied by the probability that the unit was HIV-infected (i.e., the seroprevalence of HIV).

Donations Discarded because of the Results of Other Tests

Blood donations were tested for hepatitis B, hepatitis C, syphilis, HTLV-I, and elevated levels of alanine aminotransferase in addition to HIV. A number of donations made during the HIV window period were discarded because they tested positive on one or more of these screening tests. Because the proportion of window-period donations that were positive on these screening tests could not be determined, we defined lower and upper bounds of our estimate by using two techniques. To calculate the lower bound, we measured the proportion of donations made by HIV-positive repeat donors before seroconversion (i.e., donations that may have been made during the window period) that tested positive on screening tests other than HIV-antibody tests. This proportion would represent an underestimation of the number of units discarded because of the results of other tests, because it would not take into account window-period donors who were excluded because of positive laboratory tests and who did not return and make seropositive donations.

For the upper bound of our estimate, we calculated the proportion of HIV-positive donations that also tested positive on at least one laboratory test other than HIV-antibody tests. With this proportion, the number of infectious units discarded would be overestimated because the results of the other laboratory tests might have become positive after the donor became HIV-seropositive.

RESULTS

Study Population

During the study period, 4,119,095 donations were made in the 19 study regions, among which 3,050,357 donations (74.0 percent) were made by repeat donors. A total of 318 donations (7.7 per 100,000) were HIV-seropositive, 250 (23.4 per 100,000) from first-time donors and 68 (2.2 per 100,000) from repeat donors. As in the population at large,¹⁵ HIV-positive blood donors were more likely than HIV-negative donors to be young (mean age, 31.9 vs. 37.5 years; $P < 0.001$ by a two-tailed t-test), male (68 percent vs. 54 percent; relative risk, 1.8; 95 percent confidence interval, 1.4 to 2.3), and black (57 percent vs. 7 percent; relative risk, 16.6; 95 percent confidence interval, 12.3 to 22.4). In addition, HIV-positive blood donors were more likely to test positive on all other screening tests, with the exception of the test for HTLV-I (Table 1).

In the 23 nonstudy regions, 4,928,224 donations were made, 4,098,223 of which (83 percent) were reported to be from repeat donors (regardless of the date of the previous donation). Of 173 donations that were HIV-seropositive (3.5 per 100,000), 99 (11.9 per 100,000) were from first-time donors, and 74 (1.8 per 100,000) were from repeat donors.

Incidence of HIV

The overall incidence rate of HIV among repeat donors in the 19 study regions was 3.4 per 100,000 person-years. This rate differed according to region (range, 0 to

Table 1. Results of Screening Tests Other Than the HIV-Antibody Test among Blood Donations from First-Time and Repeat Donors in 19 Service Regions of the American National Red Cross, 1992–1993, According to Donor's HIV Status.

TYPE OF TEST	FIRST-TIME DONORS (N = 1,068,738)		REPEAT DONORS (N = 3,050,357)	
	HIV-POSITIVE (N = 250)	HIV-NEGATIVE (N = 1,068,488)	HIV-POSITIVE (N = 68)	HIV-NEGATIVE (N = 3,050,289)
	% of donations testing positive*			
Hepatitis B core antibody	35.6	2.4	19.1	0.7
Hepatitis B surface antigen	3.2	0.1	4.4	<0.1
Hepatitis C antibody	11.4	0.8	6.4	0.2
Serologic test for syphilis	7.2	0.3	5.9	0.3
Elevated alanine aminotransferase levels	10.0	2.5	2.9	1.5
HTLV-I antibody	0	0.1	0	<0.1
Any of these	46.0	5.6	26.5	2.6

*Some donations tested positive on more than one screening test.

16.27 per 100,000 person-years) (Table 2). The incidence rate among all donors (first-time and repeat) was estimated to be 4.1 per 100,000 person-years (range, 0 to 19.7). The incidence rate among repeat donors was estimated to be 2.0 per 100,000 person-years in the 23 nonstudy regions and 2.6 per 100,000 person-years in all 42 regions included in the analysis (Table 2).

Probability of a Window-Period Donation

In the 19 study regions, the probability that a donation was made during the window period was 1 in

Table 2. Estimated Incidence Rates of HIV Infection and Risks of Donation of Blood during the Window Period, 1992–1993, According to Service Region.

REGION No.	HIV INFECTION		DONATIONS IN 1992 AND 1993	
	INCIDENCE RATE/100,000 DONATIONS BY REPEAT DONORS	ESTIMATED RISK PER MILLION DONATIONS	TOTAL NO.	NO. EXPECTED PER YEAR DURING WINDOW PERIOD
1	0	0	168,690	0
2	0	0	279,167	0
3	0	0	152,849	0
4	0	0	130,595	0
5	0	0	121,997	0
6	0.90	0.72	254,095	0.09
7	1.07	0.88	196,536	0.09
8	1.16	1.24	151,186	0.09
9	1.55	1.26	131,786	0.08
10	1.70	1.38	328,820	0.23
11	2.43	2.10	103,971	0.11
12	2.49	2.12	297,211	0.31
13	2.75	2.27	397,382	0.45
14	2.80	2.27	77,457	0.09
15	4.22	3.79	101,682	0.19
16	5.12	4.40	397,003	0.87
17	5.52	4.43	184,615	0.41
18	8.44	6.96	454,159	1.58
19	16.27	14.32	189,894	1.36
23 nonstudy regions	2.02	1.63	4,928,224	4.01
All 42 regions	2.63	2.38	9,047,319	9.96

360,000 (95 percent confidence interval, 210,000 to 1,140,000). The probability that such a donation would be made by a repeat donor was 1 in 400,000; among first-time donors this probability was estimated to be 1.8 times that among repeat donors, or 1 in 220,000. The probability of a window-period donation varied according to region, ranging from none to 1 in 70,000. In the region with the highest probability of a window-period donation (14.32 per million donations), we estimated that there would be 1.36 such donations per year (Table 2). In all 42 regions, the probability of a window-period donation was 1 in 450,000.

Laboratory Error

The probability that an HIV-positive donation would be available for transfusion as a result of laboratory error was considered to be the probability of a laboratory error (0.5 percent) multiplied by the probability that a donation would be HIV-positive (7.7 in 100,000), or 1 in 2,600,000. If 1 of every 2,600,000 units was infectious for HIV but not detected as such because of laboratory error, the overall risk of an infectious donation in all 42 regions would be 1 in 380,000.

Donations Discarded because of the Results of Other Tests

Window-period donations would not be used if they tested positive on screening tests other than the HIV-antibody test. We analyzed the test results for 48 HIV-seronegative donations obtained in the 19 study regions from repeat donors before they seroconverted. Seven of these seronegative donations (15 percent) tested positive on other screening tests. Of the 318 HIV-positive units of blood given by first-time and repeat donors during the study period, 133 (42 percent) were also seropositive on other screening tests. If the proportion of seropositive donations positive on other tests was the same among the window-period donations, 42 percent of the window-period donations would have been discarded because of the positive results of the other tests. If 15 to 42 percent of all infectious donations were discarded because of the results of other tests, the estimated risk that an HIV-infectious donation would be available for transfusion in the 42 regions would range from 1 in 450,000 to 1 in 660,000.

DISCUSSION

We estimated that from 1 in 450,000 to 1 in 660,000 screened blood donations in the United States may transmit HIV. If the risk calculated in the American National Red Cross regions is equivalent to the risk outside the Red Cross system, we would expect that from 18 to 27 of the 12 million donations screened annually in the United States would be infectious for HIV. According to this estimate, if each donation is divided into an average of 1.8 components,⁴ 32 to 49 infectious components would be available for transfusion nationally each year. For the average transfusion recipient, who receives blood or blood components from 5.4 donors,¹⁰ the risk of receiving HIV-infectious blood would be essentially 5.4 times the risk associated with receiving

a transfusion from a single donor, or from 1 in 83,000 to 1 in 122,000. HIV-related disease would not develop in all recipients of these components, however, because an estimated 25 to 50 percent of recipients die within a year after their transfusions from underlying medical conditions,^{16,17} before HIV-related illness would be expected to occur.

Our estimate of the risk of transmitting HIV by the transfusion of screened blood is smaller than earlier estimates,^{10,18-22} for several reasons. Most important, our estimate is based on the average 25-day window period that exists given contemporary recombinant, protein-based enzyme immunosorbent assays. Earlier studies of donations to the American Red Cross, based on estimated window periods of 56 days¹⁰ and 45 days¹⁸ with enzyme immunosorbent assays using whole-virus lysate, reported risks of HIV transmission of 1 in 153,000 and 1 in 225,000 donations, respectively. Second, our lower estimate of risk may be due in part to the use of a safer donor pool. Since the start of HIV-antibody testing of the blood supply, the seroprevalence of HIV among both first-time and repeat donors has declined annually, probably because of the recruitment of low-risk donors, the questioning of prospective donors,²³ and the exclusion of donors who test positive on laboratory screening tests. Third, our calculations were based on data for donations in service regions of the American National Red Cross across the United States. Other studies, using estimates based on smaller areas with a higher incidence of HIV, reported that from 1 in 68,000 to 1 in 82,000 blood donations may transmit HIV.^{20,21} Because our estimate was based on the window period associated with the use of contemporary enzyme immunosorbent assays, large numbers of donations, and areas with both high and low risks of HIV infection, it is more representative than previous estimates of the risk of HIV transmission by transfusion in the United States.

Although the probability of window-period donations varied regionally in our study, that probability was either very small or below our level of detection in nearly every region. Regional variation in the incidence of transfusion-associated acquired immunodeficiency syndrome (AIDS) has been reported previously and is strongly correlated with the regional incidence of AIDS in the general population.¹

Our estimate of the risk of transmission of HIV by the transfusion of screened blood has several limitations. First, the proportion of donations made during the window period that test positive on screening tests other than the HIV-antibody test cannot be determined. Second, our calculations of risk were based on data from the service regions of the American National Red Cross, and we do not know whether this risk is representative of that in other centers. Third, the interpretation of data from any one region is limited by the very small number of HIV-positive donations and the wide confidence limits of the risk estimate. Fourth, our estimate of the incidence of HIV in repeat donors assumes that all donors who seroconvert return to make a sero-

positive donation; donors who do not do so may have transmitted HIV in their donation before seroconversion but would not have been included in our analysis. Finally, the incidence of HIV among first-time donors cannot be measured; our calculations of risk relied on a 1985 estimate indicating that the incidence among first-time donors was 1.8 times that among repeat donors. The validity of this assumption is supported by a more recent study of HIV-positive blood donors in France who had "seroconverting" patterns on the Western blot assay (i.e., they were HIV-positive but did not have antibodies to p34 antigen or glycoprotein 41).²⁴ Although the absence of these bands may not always indicate recent seroconversion, first-time donors were 2.5 times more likely than repeat donors to have such patterns on the Western blot assay.

The probability that an infectious unit would not be identified as such because of a laboratory error was estimated to be 1 in 2.6 million.¹¹⁻¹⁴ Although other studies have reported lower error rates,^{25,26} our use of a higher rate still results in the conclusion that laboratory error made a small contribution to the overall risk.

The FDA and others have been considering new genetic techniques for further reducing the risk of transmitting HIV infection by the transfusion of blood donated during the window period,²⁷ and the FDA recently recommended testing all blood donations for HIV p24 antigen. Because the risk of transmitting HIV by transfusion is very small, new interventions will be of decreasing benefit, particularly in areas where the probability of a window-period donation is too small to be quantitated. On the basis of the estimated shortening of this period by testing for p24 antigen^{6,28} and our estimate of the risk of an HIV-infectious donation, we would expect p24 antigen testing to detect from 4 to 6 infectious units (that would not be removed by other screening tests) among the 12 million donated nationally each year. Implementing new techniques will require consideration of the cost of testing 12 million donations a year, will raise the issue of counseling and excluding donors who have false positive test results, and may attract high-risk donors who seek testing by a more sensitive test than is routinely offered. With a defined estimate of the risk associated with the transfusion of screened blood, we are better equipped to evaluate new techniques and make informed therapeutic and programmatic decisions to reduce HIV transmission by blood transfusion.

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