

TRANSFUSION COMPLICATIONS: Estimate of the residual risk of transfusion-transmitted human immunodeficiency virus infection in sub-Saharan Africa: a multinational collaborative study

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ABBREVIATIONS

Ab(s) = antibody(-ies);

Ag = antigen;

IDI(s) = interdonation interval(s);

RR = residual risk

CONFLICT OF INTEREST

The authors declare no conflict of interest associated with this study.

ABSTRACT

BACKGROUND

Sub-Saharan Africa remains the epicenter of the human immunodeficiency virus (HIV) pandemic. However, there is a lack of multicenter data on the risk of transfusion-transmitted HIV from blood centers in sub-Saharan Africa.

STUDY DESIGN AND METHODS

The incidence of HIV infections in the blood donations collected in the main blood banks of five countries (Burkina Faso, Congo, Ivory Coast, Mali, and Senegal) was determined to estimate the current transfusion risk of HIV infection using the incidence rate/window period model.

RESULTS

The risk of transfusion-transmitted HIV infections associated with the window period varied from 1 in 90,200 donations (Senegal) to 1 in 25,600 (Congo). Considering the five participating blood centers as a whole, the incidence rate of HIV-positive donors per 100,000 person-years was 56.6 (95% confidence interval [CI], 47.1-67.9); the residual risk (RR) was 34.1 (95% CI, 7.8-70.7) per 1 million donations, which represents 1 in 29,000 donations (95% CI, 1/128,000-1/14,000).

CONCLUSION

RR estimates varied according to the country. This is potentially due to a lower incidence of HIV infection in the general population or to a more efficient selection of blood donors in the countries with the lowest risk. The estimates of the transfusion risk of HIV infection in each country are important, both to assess the impact of current preventative strategies and to contribute data to policy decisions to reinforce transfusion safety.

INTRODUCTION

Sub-Saharan Africa remains most severely affected by the human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) pandemic. This public health concern extends to transfusion-transmitted HIV.^{1,2} Ironically, resources devoted to blood screening are extensive in industrialized countries where HIV prevalence and incidence are low and the residual transfusion risk has become immeasurably small (approximately one infection per 1 to 2 million units^{3,4}). In contrast, HIV incidence and residual risk (RR) remain high in sub-Saharan Africa, yet resources are lacking.⁵ According to the World Health Organization (WHO), blood transfusion is responsible for up to 5% of HIV transmission in sub-Saharan Africa.⁶

Despite screening of blood donations with serologic assays (detection of HIV antibody [Ab]), the risk of transfusion-transmitted HIV persists, mainly due to blood donations collected during the pre-seroconversion window period, which occurs shortly after the donor is infected and before the serologic markers for the infection can be detected. African blood banks that have implemented screening algorithms assay combining anti-HIV Abs and p24 antigen (Ag) have managed to shorten the window period, but it remains longer than that which would be obtained with nucleic acid testing (NAT).

It is important to estimate the transfusion risk of HIV infection as precisely as possible, both to monitor the impact of currently implemented preventive safety measures and to motivate for further measures to decrease established risk. Current knowledge of transfusion risk in sub-Saharan Africa is drawn from old studies, examining small numbers of blood donors, often limited to only single blood centers.⁷⁻⁹ Another recent approach aiming to assess the risk in sub-Saharan Africa consisted of the use of a mathematical model parameterized with data available in the literature.¹⁰ However, there is a lack of good, multicenter data on the risk of transfusion-transmitted HIV from blood centers in sub-Saharan Africa.

For this reason, we determined the incidence of HIV infections in the blood donations collected in the main blood banks of five countries. We used a modified window period model to estimate the current transfusion risk of HIV infection. This information may be useful to adapt the national policy for blood transfusion to the local situation as well as to audit interventions targeting transfusion safety in sub-Saharan Africa.

MATERIALS AND METHODS

The method used to estimate the HIV RR was based on the incidence/window period model.¹¹ With this method, RR is estimated by multiplying the incidence rate of HIV infection in repeat blood donors (expressed per 100,000 person-years) by the length of the pre-seroconversion window period (expressed as a fraction of a year). This length for anti-HIV was derived from published data: 22 days (range, 6-38 days).¹²

Five blood transfusion services belonging to five countries of sub-Saharan Francophone Africa participated in the study: Burkina Faso, Congo, Ivory Coast, Mali, and Senegal. For each participating center, the study period corresponded to the time for which established blood donation databases were available. Each center was invited to complete a questionnaire pertaining to the following: the duration of the study period; the total number of donors who donated blood at least twice during the study period; the total number of blood donations tested for HIV among the donors who donated blood at least twice during this period; the number of donors having made an

HIV-negative blood donation followed by an HIV-positive donation (whatever the interval between the two donations included in the study period); for included HIV-positive donors, the dates of the two donations, the assays used for the HIV Ab screening, and the obtained results in positive samples (sample/cutoff value or qualitative result for rapid tests); the method used to confirm positive results (additional testing on the same sample, confirmatory assay, or positive result in a subsequent sample); the type of donor (familial or volunteer); and the sex and age of all HIV-positive donors.

Incidence rates were calculated for the donors who donated at least twice during the study period. The number of incident cases (numerator) was the number of donors who gave a negative donation followed by a confirmed HIV-positive blood donation.

In the original model, the denominator, expressed as person-years, was calculated as the sum of the intervals in days (divided by 365) between the first and the last donation for all donors during the study period, irrespective of the HIV status. As this variable was not available for negative donors, the number of person-years was calculated as the number of donations made by individuals who have donated at least twice during the study period, by the mean interval (in years) between donations from these donors. For each center, the mean interdonation interval (IDI) in years was obtained by dividing the number of donations by the number of donors and by multiplying this ratio by the duration of the study period. The IDI for the seroconverting donors was calculated directly from the date of the last HIV-negative and the last HIV-positive donation. The 95% confidence intervals (95% CIs) of the incidence rates were obtained by the Fleiss quadratic method, which is adapted when proportions are low.

RESULTS

The total number of individuals who donated at least twice during the study period was 66,341 for the five participating countries, corresponding to a total of 192,109 blood donations. The mean number of blood donations per donor ranged from 1.2 to 3.3. Table 1 details these characteristics for each country. As detailed in Table 2, three countries (Burkina Faso, Ivory Coast, Mali) used a p24 Ag/Ab combination assay (Genscreen HIV Plus, Bio-Rad, Marnes-la-Coquette, France; Genscreen HIV Ag/Ab Ultra, Bio-Rad; or Murex HIV combination assay, Abbott, Rungis, France) for screening blood donations during the entire study period; one country (Senegal) used alternatively a p24 Ag/Ab combination assay or a rapid test (Determine HIV, Abbott) for screening; one country (Congo) changed its screening strategy over the study period (see Table 2). In all participating countries, positive results were not confirmed by a specific confirmatory assay, but with various other strategies (donation repeatedly positive with the screening assay, donation positive with a different assay, and/or result positive on a subsequent sample).

The number of incident HIV-positive donations, which ranged from 4 to 83 according to the different countries, is given in Table 1. These incident cases occurred predominantly in males in four countries. The mean (range) age of HIV-positive donors was 33.7 (28.8-40.3). The mean IDI ranged from 331 to 1111 days for all donors and from 123 to 408 days for HIV-positive donors.

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TABLE 1: Number of donors, blood donations, and incident cases of HIV-positive blood donations and mean IDIs in the five participating countries

Country	Months (study period)	Number of donors* having made at least two donations during the period	Number of donations made by these donors during the period	Mean number of donations per donor	Mean IDIs (days)		Number of HIV cases†	Sex ratio of HIV incident cases (male/female)	Mean age of HIV incident cases (years)
					All donors	HIV-positive donors			
Burkina Faso	36 (Jan 1, 2006 - Dec 31, 2008)	6,629	16,334	2.5	444	236	6	42125	31.3
Congo	72 (Dec 1, 2002 - Dec 5, 2008)	5,653	11,140	2	1111	217	22	42141	40.3
Ivory Cost	36 (Jan 1, 2003 - Dec 31, 2005)	42,799	134,918	3.1	347	273	83	58/25	32.4
Mali	24 (Jan 1, 2006 - Dec 31, 2007)	4,008	5,721	1.2	511	123	5	42095	28.8
Senegal	36 (Jan 1, 2006 - Dec 31, 2008)	7,252	23,996	3.3	331	408	4	0/4	33

* All were volunteer donors.

† Defined as donors having made, during the study period, a HIV-negative donation followed by a HIV-positive donation.

The mean IDI ranged from 331 to 1111 days for all donors and from 123 to 408 days for HIV-positive donors. Table 3 indicates the incidence rates of HIV-positive donors per 100,000 person-years, and the RRas expressed per 1 million donations and as the prevalence of a unit HIV-infected but negative for HIVAb for each participating country. The incidence rates varied between the countries by a factor of 3.5, from 18.4 per 100,000 person-years in Senegal to 64.9 per 100,000 person-years in Congo. Only Senegal had an incidence rate.

In our study, new donors varied from 19% in Congo to 72% in Burkina Faso, giving a percentage of new blood donations going from 10% to 51%, when taking into account the frequency of donations in regular donors. We were guided by the hypothesis that in each country in our study, HIV incidence would be three times higher in new donors than in regular donors, and the estimated RR for all of the blood donations would vary from 1 per 55,000 in Senegal to 1 per 14,000 in Mali.

TABLE 2: Assays used for the screening of blood donations in the five participating countries

Country	Number of HIV incident cases	Assays used for the screening when the negative donation preceding the positive donation was tested	Assays used for the screening when the positive donation was tested	Confirmation methods
Burkina Faso	6	p24 Ag/Ab assay* (n = 6)	p24 Ag/Ab assay* (n = 6)	Donation repeatedly positive with the screening assay AND positive with a different assay AND positive on a subsequent sample.
Congo	22	p24 Ag/Ab assay* (n = 17) Ab assay† (n = 1) Ab assay† (n = 4)	p24 Ag/Ab assay* (n = 17) Ab assay† (n = 1) p24 Ag/Ab assay* (n = 4)	Donation repeatedly positive with the screening assay AND positive with a different assay.
Ivory Cost	83	p24 Ag/Ab assay* (n = 83)	p24 Ag/Ab assay* (n = 83)	Donation repeatedly positive with the screening assay OR positive with a different assay.
Mali	5	p24 Ag/Ab assay* (n = 5)	p24 Ag/Ab assay* (n = 5)	Donation positive with a different assay.
Senegal	4	Rapid test‡ (n = 2) p24 Ag/Ab assay* (n = 2)	p24 Ag/Ab assay* (n = 2) Rapid test‡ (n = 2)	Donation repeatedly positive with the screening assay AND positive with a different assay AND positive on a subsequent sample.

* Genscreen HIV Plus (Bio-Rad), Genscreen HIV Ultra (Bio-Rad), or Murex HIV combination assay (Abbott).

† Murex HIV1.2.0 (Abbott).

‡ Determine HIV (Abbott).

TABLE 3: Incidence rates and RR of transfusion-transmitted HIV infection associated with the window period in the five participating countries

Country	Months (study period)	Person-years	Number of incident cases	Incidence rates per 100,000 per year (95% CI)	RR per 1 million donations (95% CI)	RR per number of donations (95% CI)
Burkina Faso	36 (Jan 1, 2006 - Dec 31, 2008)	19,887	6	30.2 (12.3-69.3)	18.2 (2.0-72.1)	1/55,000 (1/500,000-1/13,900)
Congo	72 (Dec 1, 2002 - Dec 5, 2008)	33,918	22	64.9 (41.7-100.0)	39.1 (6.9-104.1)	1/25,600 (1/145,000-1/9,600)
Ivory Coast	36 (Jan 1, 2003 - Dec 31, 2005)	128,397	83	64.6 (51.8-80.6)	39.0 (8.5-83.9)	1/25,700 (1/118,000-1/11,900)
Mali	24 (Jan 1, 2006 - Dec 31, 2007)	8,016	5	62.4 (23.0-154.6)	37.6 (3.8-161.0)	1/26,600 (1/263,000-1/6,200)
Senegal	36 (Jan 1, 2006 - Dec 31, 2008)	21,756	4	18.4 (5.9-50.6)	11.1 (1.0-52.6)	1/90,200 (1/1,000,000-1/19,000)

To control for shorter IDIs among HIV-positive donors compared to IDIs among negative blood donors, another study proposed multiplying the incidence rate by an adjustment factor that represented the mean IDI for all donors divided by the mean IDI for seroconverting donors.¹⁴ If this adjustment factor is applied to the incidence data from our study the risk would be greatly increased for Congo (1/5000) and Mali (1/6400), while for the three other countries, the impact would be much less important (Burkina Faso, 1/29,000; Ivory Coast, 1/20,200; Senegal, 1/111,000) because their differences between IDIs among HIV-positive and HIV-negative blood donors is less important.

DISCUSSION

Surprisingly little research had been done to assess the risk of HIV transmission by blood transfusion in sub-Saharan Africa, and most published studies are constrained by small number of blood donations or blood donors, cross-sectional design, and data from hospital-based blood banks only. However, reliable information on the risk of transfusion-transmitted HIV infection is of great importance, to monitor the efficacy of current preventive measures and to convince authorities (governments or international organizations) of the need to improve transfusion safety. Our study is the first to quantify the risk of transfusion-transmitted HIV infection across sub-Saharan Africa through the combined participation of blood centers of five countries using a common method (incidence of HIV infections in repeat donors).

RR estimates differed according to country with Senegal displaying the lowest risk when compared to the other countries. This may be due to a lower incidence of HIV infection in the general population in Senegal or to improved selection of blood donors. Our estimates are lower than the previously published data for two countries (1/8562 donations in Guinea¹⁵ and 1/5780 donations in Ivory Coast⁹). Plausible reasons for this difference for Guinea include an earlier study period (1999-2000) with small size population (529 donors). The difference with Ivory Coast is more difficult to explain, since the study periods overlap. For Senegal, a previous study estimated the risk to 1 per 28,571,16 which is consistent with our findings.

A recent study using a mathematic model applied to literature data shows that the median overall risk of acquiring HIV infection from a single unit of whole blood in sub-Saharan Africa was 1 per 1000 units,¹⁰ which is higher than the overall risk observed in our study. For the four countries included in both studies, estimates were lower (Congo, 1/1313 vs. 1/25,600 in our study; Ivory Coast, 1/1231 vs. 1/25,700; Mali, 1/1250 vs. 1/26,600; Senegal, 1/615 vs. 1/90,200). These differences may be partly explained by the fact that the model used by Jayaraman and colleagues¹⁰ is based on estimates of HIV prevalence in donors going back more than 5 years that may have since decreased. The observed decrease in HIV prevalence of Senegalese donors from 2.23% in 2003 to 0.80% in 2005 supports this explanation as the prevalence in the model of Jayaraman and colleagues was 3%.¹⁶ Moreover, the estimates of transfusion risk are based on prevalence, while incidence would be more adequate. Finally, the model included the risk linked to blood donations, which would not be screened for HIV infection, while our estimates only relate to the risk from the preseroconversion "window period," since all blood donations were screened for HIV infection in our five participating centers.

It would be interesting to compare the HIV incidence in the general population with that estimated in blood donors. Unfortunately, estimates of incidence in the general population are difficult to obtain. A recent review of published studies on HIV incidence in 44 countries of sub-Saharan Africa¹⁷ showed that only 15 of them had available incidence estimates. Among them, only one is included in our study, Ivory Coast, where HIV incidence in pregnant women was between 1 and 3%.¹⁸ In consequence, the estimated incidence in repeat blood donors would be between 15 and 50 times lower than that estimated in pregnant women.

The comparison between prevalence in the general population and estimated RR in the five participating countries indicates that our results are plausible: the countries having the highest HIV transfusion risk (Ivory Coast and Congo) are also those with the highest prevalence in the general population (4.7 and 3.2%, respectively) while Senegal, which had the lowest risk, had also lowest prevalence (0.7%); Burkina Faso, which had an intermediate risk, also had prevalence between these two groups of countries (1.8%).¹⁹

Our approach has limitations, with potential for both underestimation as well as overestimation of risk. One of the causes of the underestimation may be the false-negative results due to the lack of sensitivity of rapid tests reported to be linked with a low Ab titer²⁰⁻²² or to the viral diversity.^{23,24} The latter may extend to viral variants not recognized by serologic tests in Africa due to divergent HIV-1 subtypes; for example, Subtypes A1, D, and C are predominant in Eastern and Southern Africa, whereas recombinant forms such as CRF02-AG and CDF06-cpx represent the majority in Western Africa.²⁵ The risk of HIV transmission by transfusion may also stem from poor quality or poor performance of assays,²⁶ linked to lack of technical expertise or to unfavorable conditions in which the test kits are stored and the assays are performed as well as unforeseen equipment failure and deficient or absent quality assurance.^{27,28}

Underestimation of risk may also arise through incomplete accounting donations and restricting study to donors who have donated twice during the observational period. In South Africa, the RR linked to the window period was three times higher in new donors (1/18,323) than in regular donors (1/55,393).²⁹

An underestimation may be due to lower mean IDI in HIV-positive donors than in HIV-negative donors. Since for Congo and Mali the mean IDI in HIV-positive donors was much lower than in HIV-negative donors, our data appeared to show that the probability of an infectious window period donation may be greater than the mean probability, as calculated by the basic equation of the incidence/window period model.

Overestimation of risk may be due to the occurrence of both false-negative results on the donation preceding the positive donation and false-positive results in the "HIV-positive" donation due to the absence of a reliable confirmatory strategy, leading to the misclassification of the donor as an incident case. Another cause of overestimation is the window period length used in our study, which was that established with Ab assays (22 days).

Indeed, although different methods for the Ab screening were used, our RR model was based on a single window period estimate across all countries. The window period would be reduced by 5 or 6 days with the HIV combined p24 Ag and Ab assay,³⁰ which was used in some of the participating centers.

The limited study period and number of participating centers impose a limitation on the findings, particularly with respect to comparisons between countries. Finally, our results may not be widely generalizable, for example, to smaller, rural African blood centers, since our data were derived from major blood centers in the capitals of each study country. Hemovigilance studies estimate HIV RR by testing all blood recipients before and several months after transfusion to identify newly HIV-infected recipients. While such studies have been conducted in France and other countries, they would be very difficult to perform in sub-Saharan Africa. Our results therefore constitute the most reliable data available at this time on the transfusion risk for HIV infection in sub-Saharan Africa, despite the acknowledged limitations.

There are a number of measures that can be adopted to address residual transfusion risk. Foremost is a strengthening of donor selection and restricting blood donations to regular, volunteer, nonremunerated blood donors, recruited from groups at low risk of blood-borne and sexually transmitted agents. Collections from paid donors, who are known to be at higher risk than other donors, should be discouraged.³¹ In our study, all donors were volunteer,

nonremunerated blood donors, suggesting that other measures should be adopted, for example, rigorous biologic screening of blood donations and improved quality control systems in African centers as recommended by the WHO.³²

These measures should serve as an adjunct to other public health interventions, such as improving transfusion practice to avoid unnecessary blood transfusions and prevention and proactive management of pathologies associated with anemia in sub-Saharan Africa, for example, obstetric hemorrhage, nutritional deficiencies, and malaria and other infectious diseases, all of which may lead to downstream blood transfusion.

These measures are all the more important since other measures are not applicable in the large majority of countries of sub-Saharan Africa: HIV NAT, as routinely practiced in blood banks of most industrialized countries, would bring a significant benefit to transfusion safety, as reported by some African studies.^{26,33} However, its cost and technical and logistic constraints make it inapplicable to most African blood banks, except in South Africa, where the residual transmission risk of HIV by transfusion has been estimated to 1 in 479,000 after the implementation of NAT.²⁹ HIV Ag/Ab assays³⁴ could be more broadly used on a cheaper manner than NAT.

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