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Prevalence, Incidence, and Residual Risks for Transfusion Transmitted HIV-1/2 Infection among Chinese Blood Donors

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Abstract

Background—There is little data on HIV prevalence, incidence or residual risks for transfusion transmitted HIV infection among Chinese blood donors.

Methods—Donations from five Chinese blood centers in 2008–2010 were screened using two rounds of ELISA testing for anti-HIV-1/2. A reactive result in either or both rounds led to Western Blot confirmatory testing. HIV prevalence and demographic correlates among first time donors, incidence rate and demographic correlates among repeat donors were examined. Weighted multivariable logistic regression analysis examined correlates of HIV confirmatory status among first time donors. Residual risks for transfusion transmitted HIV infection were evaluated based on incidence among repeat donors.

Results—Among 821,320 donations, 40% came from repeat donors.1,837 (0.34%) first time and 577 (0.17%) repeat donations screened reactive for anti-HIV-1/2, among which 1,310 and 419 were tested by Western Blot. 233 (17.7%) first time and 44 (10.5%) repeat donations were confirmed positive. Estimated prevalence was 66 infections per 100,000 (95% CI: 59–74) first time donors. Estimated incidence was 9/100,000 (95% CI: 7–12) person-years among repeat donors. Weighted multivariable logistic regression analysis indicate that first time donors 26–45 years old were 1.6–1.8 times likely to be HIV positive than those 25 years and younger. Donors with some college or above education were less likely to be HIV positive than those with middle school education, ORs ranging from 0.35 to 0.60. Minority were 1.6 times likely to be HIV positive than Han majority donors (OR: 1.6; CI: 1.2–2.1). No difference in prevalence was found between gender. Current HIV TTI residual risk was 5.4 (1.2–12.5) infections per million whole blood donations.

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Conclusion—Despite the declining HIV epidemic China, estimated residual risks for transfusion transmitted HIV infection are still high, highlighting the potential blood safety yield of NAT implementation in donation screening.

Keywords

HIV infection; blood donors; China; Prevalence; Incidence; Residual Risks

INTRODUCTION

HIV infection through blood donation and transfusion is one of the major reasons for the rapid increase of HIV/AIDS cases in China around late 1980s and early 1990s, accounting for about 30% of all infections identified from 1985–2005[1]. Since then, Chinese authorities have made continuous efforts to improve the safety of China's blood supply including closing illegal blood collection agencies in the mid-1990s, implementing a new blood donation law in 1998, and updating standard protocols for donor screening as well as blood and blood product management over the past decade. These proactive strategies have greatly reduced the HIV infections associated with blood donation and transfusion, which dropped to 10.7% among all reported HIV/AIDS cases in 2005[2]. Furthermore, the increase in financial support for national HIV/AIDS prevention and treatment programs as well as government organized AIDS awareness programs since 2004[3] also contributed to the reduced risks of transmission through blood donation and transfusion. A further decline of HIV/AIDS transmission related to blood and blood products (5.5% of all new infections) in 2009 was reported, or about 2,640 out of an estimate of 48,000[1].

Chronologically, the decline in blood donation and transfusion related HIV infections corresponded to a critical transition from paid blood donors especially commercial plasma donors to unpaid voluntary donors most of whom made whole blood donations in China and the implementation of pre-donation donor selection and post-donation screening processes. In 2008, almost all the blood collected for clinical transfusion in China came from unpaid voluntary donors[4]. In 2009, the government claimed that all collected blood products were screened for HIV[3]. Interestingly, despite these historical changes in blood donation regulations, blood product management policies, donor and donation screening processes, there are few reports on the current prevalence and incidence of HIV infections in the donor population or reliable estimates of the current residual risks of transfusion transmitted HIV infection in China.

Meanwhile, high prevalence of HIV has been frequently reported in certain regions and specific subpopulations in China. By 2009, six provinces were defined as high prevalence areas where more than 10,000 HIV/AIDS cases had been cumulatively reported in each over the past decade[1]. With a rapid increase in HIV prevalence among men who have sex with men (MSM) that went as high as 10–19% in certain regions such as Chongqing[5,6] and hetero-sexual transmission becoming the major route of transmission throughout the country, the spreading trend into the general population has made HIV/AIDS an imminent threat to the public health as well as the safety of blood supply. In 2009, AIDS had surpassed tuberculosis, rabies, and viral hepatitis to become China’s leading cause of death among all infectious diseases[7].

Nationwide annual reports of new HIV infections are often based on retrospective AIDS cases from distant infections years ago. HIV infections among blood donors, especially donations made within the window period, if undetected, would potentially result in future infections in transfusion recipients. In China, about 60% of donations come from first time donors[8] and NAT is not yet available at most blood centers. First time donors, in the US as

well as in China, were estimated to be more likely to have undetected infections than repeat donors[9–11], underscoring the importance of evaluating HIV prevalence, incidence, and transfusion transmitted residual risks in Chinese donor population, particularly in HIV high-prevalence regions. The aim of the present study was to evaluate the HIV prevalence and incidence among Chinese blood donors at five regional blood centers based on Western Blot confirmatory test results during 2008–2010 and to estimate the HIV TTI residual risks in these regions.

MATERIALS AND METHODS

Participants and Study Procedure

The Retrovirus Epidemiology Donor Study-II China Program (REDS-II China), funded by U.S. National Heart, Lung, and Blood Institute (NHLBI), was a collaboration between the Institute of Blood Transfusion (IBT) of Chinese Academy of Medical Sciences, China and Johns Hopkins University. The goal of REDS-II China was to investigate measures to improve blood safety in China, especially with regard to HIV-1/2, HBV, HCV, and syphilis infections among blood donors. Five Chinese regional blood centers were participants of this program: Yunnan Kunming Blood Center (Kunming, Yunnan), Urumqi Blood Center (Urumqi, Xinjiang), Luoyang Blood Center (Luoyang, Henan), Mianyang Blood Center (Mianyang, Sichuan), and Guangxi Blood Center (Liuzhou, Guangxi), annual collections from which composed approximately 3% of China's total donations. All five centers are located in HIV high-prevalence areas. The study protocol was approved by the institutional review boards at all participating institutions.

In routine practice, all Chinese candidate donors undergo a pre-donation screening that includes a health history questionnaire, a brief physical examination, and rapid tests for alanine aminotransferase (ALT) (at one center) and HBsAg (all five centers). The health history questionnaires have minor variations across the participating blood centers, but all contain the required screening items mandated by the Chinese Ministry Of Health (MOH). Donors who report having a history of diagnosis of syphilis, HIV, or any other sexually transmitted diseases or hepatitis, or having used illegal drugs or had multiple sexual partners, or being a man who had sex with other men are deferred. Donors must also pass a physical exam that measures body weight, temperature, blood pressure, and hemoglobin level. Finally, rapid testing procedures temporarily defer donors with elevated ALT level or a reactive HBsAg result.

According to the "Technical and Operational Guidelines and Procedures for Blood Centers" issued by Chinese Ministry of Health on December 31, 2011[12], since 1997, all successful donations had been subject to two rounds of post-donation routine testing for ALT, HBsAg, anti-HCV, anti-HIV-1/2, and syphilis, for which two different ELISA kits (imported or domestic) approved by the Chinese State Food and Drug Administration (FDA) were used at all five REDS II participating centers. An elevated ALT results in temporary deferral and disposal of the corresponding blood product. A reactive test for HBsAg, anti-HCV, anti-HIV-1/2 or syphilis leads to disposal of the corresponding blood product as well as permanent donor deferral. The use of two different ELISA assays in donation screening was to minimize the possibility of missing a false negative donation. The screening testing assays for HIV-1/2 used at five blood centers and their clinical diagnostic sensitivity and specificity are presented in Table 1.

HIV Confirmatory Testing

Confirmatory testing is not a routine practice at the blood centers. Samples of donations screened reactive for HIV-1/2 are sent to local Center for Diseases Control and Prevention

(CDC) laboratories for further testing and donor follow up counseling. For the REDS-II study, confirmatory testing for HBsAg, anti-HCV, anti-HIV-1/2 was performed on those screen reactive samples. This study only reports the data on HIV-1/2 confirmatory positive donations among all blood donations.

Donations screened reactive for HIV-1/2 on one or both ELISA tests were sampled, barcode labeled, and stored in −20°C freezers at blood centers until they were shipped in batches to local CDC laboratories and IBT laboratory on a monthly basis. For confirmatory anti-HIV-1/2 testing, local CDC used AUSIA anti-HIV-1/2 Immunoblot Kit (Hangzhou Ausia Biological Technology Company, Ltd, Hangzhou, China) whereas IBT used HIV Blot 2.2 (MP Diagnostics, Singapore). Confirmatory testing results from both local CDC and IBT were reported back to blood centers. A confirmed positive result from either local CDC lab or IBT lab was considered HIV positive. Blood Centers subsequently entered these confirmatory results with barcodes into a computer file and replaced barcodes with encrypted donor and donation IDs before sending the file to the Data Coordinating Center where confirmatory testing results were merged with the donation database for analysis.

Statistical Analysis

Number and percentage of anti-HIV-1/2 screen reactive donations collected in the study period were tabulated by center and first time vs. repeat donor status. First time and repeat donor status was defined based on donors' self report of number of previous donations. Those who reported no previous donation were defined as first time donors whereas those who reported one or more previous donations were defined as repeat donors. HIV prevalence, defined by number of donations that were confirmed positive over the total number of donations from first time donors, was calculated by center and demographic characteristics.

Among the donations collected in the months when confirmatory tests for anti-HIV-1/2 were conducted, percentages of screen reactive donations that were confirmed positive at the five blood centers were calculated. These confirmatory positive rates were then applied to all of the screen reactives among first time donations to generate the number of confirmed positive donations in three years and the estimated prevalence by center and categories of donor characteristics.

Similarly, the number of incident infections among repeat donors was estimated as the total number of screened reactive donations from repeat donors times the confirmatory positive rate among screen reactive repeat donations. The incidence rate among repeat donors was the estimated number of incidents among repeat donors divided by the total person time contributed by repeat donors. The total person time was calculated as the sum of all inter-donation intervals among repeat donors. However, the inter-donation interval is unknown for the repeat donor's first donation in the study period. These inter-donation intervals were estimated to be equal to the average inter-donation interval among repeat donors. The average inter-donation interval was estimated in a survival regression analysis using data from all repeat donations[13].

To evaluate the demographic correlates of HIV positive donations among first time donors, weighted logistic regression analysis was performed, adjusting for center difference and assigning different weights to donations with and without confirmatory testing results. All statistical analyses were performed using SAS™ Windows 9.2 software (SAS Institute, 2008). An α level of 0.05 was defined as statistically significant.

Transfusion transmitted residual risks were calculated based on incidence among repeat donors using the following algorithm:

Residual Risk = (Incidence rate among repeat donors X Infectious Window Period in days)/ 365.25 days

All five blood centers used 3rd generation ELISA screening assays for HIV testing during the study priod (Table 1), specificity and sensitivity of which met WHO standard as required by Chinese FDA. The decision to use two different ELISA assays was an artitrary decision made by Chinese MOH at the beginning of HIV screening among blood donations, although there are few published data illustrating the advantage of using two over one ELISA assays in donation screening. Neither is there any mathematical model synthesizing the sensitivity and specificity or infectious window period when two different ELISA assays are used. Infectious window period for anti-HIV-1/2 testing was therefore based on the average of 22 (6–38) days for 3rd generation EIA screening[14].

RESULTS

From January 1, 2008 to December 31, 2010, a total of 821,320 whole blood and apheresis platelets donations with post donation screening results were collected at five Chinese blood centers. Across all centers, 491,717 or 60% of all donations came from first time donors. A majority of donations (65%) came from donors 35 years old or younger. Donors with high school, middle school or less education contributed 43% of all donations. Male donors (59%) and donors of Han ethnicity (87%) comprised the main donor pool at all five blood centers.

Western Blot confirmatory tests were available from 72% of all screen reactive samples. At two of the blood centers (Kunming and Liuzhou), 38% and 32% of screen reactive samples respectively were not saved due to operation issues during the early phase of the study, and thus did not have confirmatory test results. Donor characteristics and serological markers for HBsAg, anti-HCV, Syphilis of the anti-HIV-1/2 screen reactive samples without confirmatory test results were examined in preliminary analysis and were not different from those with confirmatory test results. We therefore inferred that the available anti-HIV-1/2 confirmatory test results from these two blood centers were representative of all of their screen reactive donations. In the other three blood centers, 97%–100% of all screen reactive samples had confirmatory test results.

Anti-HIV-1/2 screening reactivity

Overall, 2,414 or 0.29% of all donations were reactive for anti-HIV-1/2 (Table 2). Screening reactive rates varied greatly by center, from as low as 0.016% in Luoyang to as high as 0.52% in Liuzhou. About 0.34% or 1,837 first time donors and 0.17% or 577 repeat donors were permanently deferred due to their reactive serologic status. First time donors were twice likely to be reactive for anti-HIV-1/2 than repeat donors (0.34% vs. 0.17% reactive rates).

Western Blot confirmatory positivity

Table 2 also presents the confirmatory positive rates for screen reactive samples saved by all centers. Of all screen reactive donations, 1,310 from first time donors and 419 from repeat donors were further tested by Western Blot, among which 233 first time and 44 repeat donations were confirmed positive. Across five centers, confirmatory positive rates were 17.7% for first time and 10.5% for repeat donors. Assuming the same confirmatory positive rates among first time and repeat donors, we estimated that 327 first time and 60 repeat donors were HIV positive across five centers during the study period in 2008–2010. The estimated number of HIV positive donors by center and first time vs. repeat donor status are presented in Table 2.

Prevalence of HIV and correlates of HIV infection among first time donors

Based on the confirmatory test results, we calculated the HIV prevalence by blood center among first time donors (Table 3). Among almost half a million first time donors, 327 were HIV positive. Liuzhou and Kunming displayed the highest prevalence of 151 and 100 per 100,000 first time donors respectively. Luoyang presented the lowest prevalence of 2 per 100,000 first time donors. The average prevalence of HIV-1/2 across five blood centers was 66 per 100,000 donors.

Table 3 also displays the estimated HIV prevalence by donor characteristics as well as the demographic characteristics associated with HIV infectious status after adjusting for center differences in weighted logistic regression analysis. Results of logistic regression analysis suggested that first time donors 25 years old and younger seemed to be the safest, with the lowest HIV prevalence of 45 (95% CI: 38–53) per 100,000 donors. Donors in the age range of 26–45 were more likely to be HIV positive than donors who were 25 years or younger (OR: 1.83, 95% CI: 1.41–2.39 for 26–35 years old; OR: 1.64, 95% CI: 1.16–2.32 for 36–45 years old). Donors from minority ethnic groups displayed a higher likelihood of being HIV positive than Han donors (OR: 1.59, 95% CI: 1.21–2.10). In addition, donors with associate degree or having completed college and above education were less likely to be HIV positive than donors with middle school education (OR: 0.60, 95% CI: 0.43–0.84 for those with associate degrees; OR: 0.35, 95% CI: 0.24–0.53 for those who had completed college and above education). Donors with high school education and techinician certificates also had lower probabilities, albeit not statistically significant, than those with middle school education of being HIV positive (OR: 0.73, 95% CI: 0.53–1.01 for High School education; OR: 0.79, 95% CI: 0.56–1.12 for those with technician certificates). No difference in HIV prevalence was found between male and female donors.

HIV incidence and seroconversion among repeat donors

Survival regression analysis on the inter-donation interval among all repeat donors generated an average inter-donation interval of 1.978 (95% CI: 1.961–1.995) years. We then calculated the total person time contributed by all repeat donors and estimated the incidence rates per 100,000 person-years (Table 4). Liuzhou, Kunming, and Urumqi blood donors displayed higher incidence rates (15, 13, and 11 per 100,000 person-years respectively) that paralleled their higher prevalence rates than the other two blood centers. The incidence rates at Mianyang and Luoyang blood centers were 7 and 0.6 infections per 100,000 person-years respectively. Luoyang had the lowest incidence rate among the five blood centers, which is 15 times lower than the average of 9 per 100,000 person-years across all blood centers.

Repeat donors with middle school education and those within the age range of 26–35 had the highest incidence rates. Meanwhile, the youngest repeat donors, that is, donors 25 years and younger, showed higher incidence rates than those above 35 years of age (10 vs. 7 and 3 among 36–45 and 46–55 years old respectively). Similarly, repeat donors with associate degrees who comprised a large part of the donor pool also displayed an incidence rate of 11 per 100,000 person-years, only next to the 12 per 100,000 person-years rate among those with middle school education. Repeat donors of the Han majority and female donors showed lower incidence rates than the minority and male repeat donors respectively.

Among the estimated 60 HIV positive repeat donors, 16 were hypothetically HIV positive donors who did not have sample confirmation due to administration errors. We located the previous negative donations of 44 donors, among whom 23 made previous negative donations within the study period of 2008–2010. These 23 donors were highly likely recent seroconverters with an average interval of 341 (range: 84–793) days between their previous negative donation and the HIV positive one. The other 21 negative donations were made in

the period of December 11, 2001 to November 26, 2007, with an average inter-donation interval of 752 days, ranging from 223–2664 days.

Residual risks for transfusion transmitted infection

Based on the average infectious window period of 22 (6–38) days using 3rd generation ELISA assays for screening, the estimated residual risk for transfusion transmission infection was 5.4 (95% CI: 1.2–12.5) infections per million whole blood donations. Table 5 presents the HIV TTI residual risks by blood center.

DISCUSSION

This study examines the prevalence and incidence of HIV infections among blood donors in five Chinese blood centers located in HIV high-prevalence areas and estimated the TTI residual risks of HIV based on all donations collected in 2008–2010. The overall HIV prevalence is estimated to be 66 per 100,000 donations among first time donors. The overall incidence is 9 per 100,000 person-years. Based on these data, the residual risk for transfusion transmitted HIV infection in HIV high-prevalence areas in China during 2008–2010 is estimated to be 5.4 (95% CI: 1.2–12.5) infections per million whole blood donations.

The overall prevalence among blood donors in these HIV high-prevalence regions is lower than the global average of 0.8% among adult population aged 15–49[15], with great variations by region, ranging from 2 to 151 per 100,000 donors. There are many social, cultural, historical, and political factors attributing to the large variations in prevalence and incidence by region, which are convoluted with the differences between Han majority and minorities since many minorities live in the high prevalence areas where injection drug use is a local culture. A discussion of the complexity of each factor and the interaction between multiple factors is beyond the scope of this paper. One important issue related to blood donation and transfusion, however, is that an early outbreak of HIV infections in China was attributed to former commercial plasma donors who were infected at illegal blood collection stations in Henan Province, and was disproportionately located in some underdeveloped villages in the east and south of the province. Since then, the central and local government have taken serious measures to restrain the spread of the infection especially in the outbreak area[1,3]. As a likely consequence, Luoyang Blood Center, although geographically very close to where the early outbreak occurred, has the lowest current HIV prevalence and incidence rates among all five blood centers.

Among Chinese donors at participating blood centers, higher prevalence and incidence are found among 26–35 year-olds with less education than other donors. Meanwhile, higher HIV incidence rate is also found among the youngest repeat donors (< 25 years) than older repeat donors. These findings are consistent with data from the United States that reported the highest incidence rates among 20–29 year olds in 2009[16] and the global report that young adults (15 years old and above) accounted for 40% of new adult infections in 2008[15]. These young Chinese HIV positive donors with less education are highly likely sexually active therefore might have already put their sexual partners at high risks for infection while posing a threat to the public health and blood supply.

No significant gender difference in prevalence was found, despite that male donors displayed twice the incidence rate than female donors. The higher incidence in male than female donors was consistent with many recent reports on the rapid rise of HIV infections among MSM in China[2,5,6,17]. For fear of the double social stigma against MSM and HIV positive people in China[18,19], many MSMs are bi-sexual and some are even married, contributing to the increasing importance of heterosexual transmission as the most important

HIV transmission route in China[1]. HIV cases among women had doubled in the past decade[17,20]. The increase in female HIV infection could potentially result in an increase of vertical transmission and thus an increase in the HIV prevalence among infants[20,21].

Our findings of both prevalence and incidence rates among blood donors in participating blood centers in HIV high-prevalence regions are consistent with the recent report that the HIV epidemic in China has slowed down[1]. However, without post donation NAT testing, the current residual risks of HIV infection through blood transfusion remain high. The estimated 5.4 infections per million whole blood donations is much higher than that in the United States 10 years ago and the current residual risks in other developed countries[9,22,23]. However, compared with the residual risk of 34.1 (95% CI 7.8–70.7) per 1 million donations in South Africa[24] and other developing countries such as Brazil where the residual risk is 11.3 (95% CI: 8.4–14.2) per 1 million donations[25], the residual risk for transfusion transmitted infection in China is substantially lower. Nevertheless, laboratory findings about the genetic diversity of some HIV-1 strains among these HIV positive donors indicated the likelihood of undetected HIV infections among blood donations that may result in transfusion transmitted infections[26,27]. Although our findings of HIV prevalence, incidence, and residual risks in these HIV high-prevalence areas may not be generalizable to the majority of Chinese regions, our data highlights the potential for significant yield of NAT implementation in the donation screening process. Assuming the same incidence rate, with a window period of 9 days, the implementation of mini-pool NAT testing will reduce transfusion transmission residual risks from 5.4 to 2.2 per million donations. If single NAT testing is implemented, assuming a window period of 5.6 (4–7) days, the residual risks for HIV TTI will be further reduced to 1.4 (95% CI: 0.8–2.3) infections per million donations[28]. Meanwhile, the availability of 4th generation ELISA assays and their possible implementation at Chinese blood centers in the near future is also expected to further mitigate the current TTI residual risks. On the other hand, China has the largest population in the world with an increasing demand of transfusion[29]. In the context of a highly mobile global population and increasing volume of international travels, if such residual risks were left unaddressed, the potentially accelerated infections caused by the current TTI residual risks in China would be magnified and become a re-surging threat to global health.

From the perspective donor recruitment, an alternative method to minimize the residual risks of transfusion transmitted HIV infection in China is to tap the repeat donor pool, as our data and other studies have consistently shown lower rates of HIV infections among repeat donors than first time donors[9,10]. Yet in China, repeat donors contribute only 40% of the donations, which is lower than in other developing countries[9,10,25]. Theoretically, recruiting more repeat donors will lower the overall HIV positive rate among blood donors and reduce the transfusion transmitted residual risks not only for HIV infection but also for other infections.

As one limitation of the study, due to the lack of corresponding regional prevalence and incidence data from the high prevalence regions where the blood centers are located, we were not able to compare the HIV prevalence and incidence rates in the healthy donors with those in the local general population. Second, due to the limitation of our 3-year donation database, we used the estimated inter-donation intervals to calculate incidence rates among repeat donors. If this inter-donation interval decreases or increases in length and the number of HIV positive donors remain stable, our estimated incidence rates will either increase or decrease as a consequence. More longitudinal studies are needed to provide accurate data on the return behaviors among Chinese repeat donors. Nevertheless, based on all available data and literature, our estimates should be very good proxies of the true population average. Third, approximately one third of screen reactive donations at two blood centers did not have confirmatory testing results available to us. These two centers were both among the top

high prevalence areas. Our estimates of prevalence and incidence for these two blood centers were based on the assumption that HIV positivity rate remained stable within the center and by social demographics over three years. Fourth, all five participating blood centers are located in high HIV prevalence regions and the total donations accounted for only 3% of annual donations in China. Despite the fact that these blood centers are typical medium- to large-sized Chinese blood centers, the HIV prevalence and incidence in these blood centers may not be representative of all Chinese blood centers. Fifth, our confirmatory testing could not distinguish "recently infected" donors from donors infected years ago therefore unable to identify newly infected first time donors. The incidence rates and HIV TTI residual risks are based solely on data from repeat donors therefore could be underestimates. Sixth, a number of dual ELISA inconclusive and/or Western Blot inconclusive results were identified but not analyzed in our study. These inconclusive results may underlie an early evolving HIV infection with low, undetectable antibody levels. However, we did not conduct repeat testing, counseling, or longitudinal follow-up of these donors to evaluate their risks of true HIV infectious status. Meanwhile, a rapid test of HBsAg is conducted at all five centers to screen out HBV infections. Whether the same rapid test also screens out HIV and HCV infections is unknown. If it does, the HIV prevalence and incidence estimates derived from our study will underestimate the real infection rates in the donor population. Finally, only serological HIV testing was performed in this study. Sero-negative window-period donors as well as non-window period infected donors with low anti-HIV-1/2 levels were not included, which could result in an underestimate of the incidence and residual risks.

To summarize, we present the first study using Western Blot confirmatory testing results to estimate HIV prevalence and incidence among Chinese blood donors from multiple HIV high-prevalence regions in China. Our data reveals potentially high residual risks for transfusion transmitted HIV infections in these regions. Without NAT testing in routine donation screening, the estimated TTI residual risks for HIV in these regions are much higher than in US, Canada, and other developed countries. Therefore, at present, continued effort in donor education and donation screening strategies, improved donor recruitment strategies to encourage the return of repeat donors, and the implementation of NAT testing at all blood centers in the near future are all critical to improve the blood safety and battle the spread of the disease into the general population in China.

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Table 1

Screening Test Kits Used at Each Blood Center[30]

Blood Center	First Round		Second Round	
	Test Kit	Sensitivity/Specificity, %	Test Kit	Sensitivity/Specificity, %
Kunming	Livzon (Zhuhai, China)	100/98.95	bioMérieux (France)	99.4/99.3
Urumqi	Wantai (Beijing)	100/99.65	bioMérieux (France)	99.4/99.3
Luoyang	Wantai (Beijing)	100/99.65	bioMérieux (France)	99.4/99.3
Liuzhou	Kinghawk (Beijing)	100/98.25	Kehua (Shanghai)/Bio-Rad (USA) *	100/97.55
Mianyang	InTec (Xiamen, China)	100/98.60	Wantai (Beijing)	100/99.65

* No clinical evaluation of the sensitivity and specificity of Bio-Rad (USA) test kit in China was reported. Sensitivity = True Positive/(True Positive + False Negative)*100%; Specificity = True Negative/(True Negative + False Positive)*100%.

Table 2

Number (%) of anti-HIV-1/2 screen reactive and Western Blot confirmed positive donations by first time and repeat donor status and blood center, 2008–2010

Blood Center	First Time				Repeat			
	Total Number of Donations	Number (%) of donations Screen Reactive	Number (%) of Screen reactive samples available for WB testing*	Number (%) of Screen reactive samples confirmed Positive by WB	Total Number of Donations	Number (%) of donations Screen Reactive	Number (%) of Screen reactive samples available for WB testing	Number (%) of Screen reactive samples confirmed Positive by WB
Kunming	187,545	1017 (0.54)	636 (62.5)	**117 (18.4)**	82,731	199 (0.24)	117 (58.8)	**13 (11.1)**
Urumqi	89,309	246 (0.28)	239 (97.2)	**33 (13.8)**	50,661	92 (0.18)	89 (96.7)	**11 (12.36)**
Luoyang	94,654	22 (0.02)	22 (100)	**2 (9.09)**	88,876	8 (0.009)	8 (100)	**1 (12.5)**
Liuzhou	64,283	439 (0.68)	300 (68.3)	**66 (22)**	62,832	221 (0.35)	148 (67.0)	**13 (8.8)**
Mianyang	55,926	113 (0.20)	113 (100)	**15 (13.1)**	44,503	57 (0.13)	57 (100)	**6 (10.5)**
Total	491,717	1837 (0.34)	1310 (71.3)	**233 (17.8)**	329,603	577 (0.17)	419 (72.6)	**44 (10.5)**

*For first time donors, (1837-1310) = 527 screen reactive samples were not available for WB confirmatory testing. For repeat donors, (577-419) = 158 screen reactive samples were not available for WB confirmatory testing due to center administration error.

Table 3

Estimated HIV Prevalence by Center and Donor Characteristics among First Time (FT) Donors and Results of Weighted Multivariable Logistic Regression Analysis Predicting HIV Confirmatory Status

Donor Characteristics	# of Donations	Estimated # of HIV Positive Donors	Prevalence (1/100,000 FT donors & 95% CI	Results of Weighted Logistic Regression Analysis	
				Odds Ratio & 95% CI	p-Value
Total	491,717	327	66 (59–74)		
Blood Center					<.001
Kunming	187,545	187	100 (85–114)	1	
Urumqi	89,309	34	38 (25–51)	0.36 (0.24–0.53)	
Luo Yang	94,654	2	2 (0–5)	0.02 (0.01–0.08)	
Liuzhou	64,283	97	151 (121–181)	1.27 (0.95–1.69)	
Mianyang	55,926	15	27 (13–40)	0.29 (0.17–0.49)	
Age in Years					<.001
<= 25 years	298248	135	45 (38–53)	1	
26– 35	106977	123	115 (95–135)	1.83 (1.41–2.39)	
36– 45	68191	54	79 (58–100)	1.64 (1.16–2.32)	
46+	18296	12	66 (28–103)	1.24 (0.61–2.55)	
Gender					0.465
Female	209347	117	56 (46–66)	1	
Male	282370	211	75 (65–85)	1.09 (0.86–1.39)	
Ethnicity					<.001
Han	425723	235	55 (48–62)	1	
Others	65104	93	143 (114–172)	1.59 (1.21–2.1)	
Education					<.001
Middle School	114093	118	103 (85–122)	1	
High School Graduated	90438	58	64 (48–81)	0.73 (0.53–1.01)	
Technician Certificate	59323	50	84 (61–108)	0.79 (0.56–1.12)	
Associate Degree	107050	53	50 (36–63)	0.60 (0.43–0.84)	
Complete university & above	100042	23	23 (14–32)	0.35 (0.24–0.53)	

Table 4

Estimated incidence among repeat donors by blood center, 2008–2010

Donor Characteristics	Total # of donations	# of Confirmed positive	Total Person Time in Peron-years	Incidence per 100,000 person-years (95% CI)
Total	329,603	60	651954.7	9 (7–12)
Blood Center				
Kunming	82,731	22	163641.9	13 (8–20)
Urumqi	50,661	11	100207.5	11 (5–19)
Luo Yang	88,876	1	175796.7	1 (0–3)
Liuzhou	62,832	19	124281.7	15 (9–24)
Mianyang	44,503	6	88026.9	7 (3–15)
Age in Years				
<= 25 years	118859	24	235103.1	10 (7–15)
26– 35	90345	23	178702.4	13 (8–19)
36– 45	85445	11	169010.2	7 (3–12)
46+	34953	2	69137.0	3 (0–10)
Gender				
Female	128427	15	254028.6	6 (3–10)
Male	201174	46	397922.2	12 (8–15)
Ethnicity		0		
Han	288933	48	571509.5	8 (6–11)
Others	39803	12	78730.3	15 (8–27)
Education				
Middle School	80085	19	158408.1	12 (7–19)
High School Graduated	70538	12	139524.2	9 (4–15)
Technician Certificate	40024	6	79167.5	8 (3–16)
Associate Degree	73304	16	144995.3	11 (6–18)
Complete university & above	58091	7	114904.0	6 (2–13)

Table 5

Estimated Residual Risks of 3rd Generation ELISA Testing and 95% Confidence Intervals (# of infections per 1,000,000 whole blood donations) by Blood Centers, 2008–2010

Blood Center	Incidence per 100,000 person-years	Residual Risks with Infectious Window Period of 22 (range 6–38) days
Kunming	13 (8–20)	7.8 (1.3–20.8)
Urumqi	11 (5–19)	6.6 (0.8–9.4)
Luoyang	1 (0–3)	0.6 (0–3.1)
Liuzhou	15 (9–24)	9 (1.5–25)
Mianyang	7 (3–15)	4.2 (0.5–15.6)
Total	9 (7–12)	5.4 (1.2–12.5)