

## Original Article

# Trends in Sero-Epidemiology of Human Immunodeficiency Virus in Voluntary Blood Donations in Iran, 2008–2013

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## Abstract

**Background:** Various strategies are implemented to increase blood safety. However, there is always a small amount of residual risk. The amount of risk is associated with the incidence and prevalence of infection in the community. Since increases in the prevalence and changing the pattern of HIV transmission have been observed in the community, monitoring of HIV prevalence among general population and blood donors is necessary. This study aimed to determine the prevalence of HIV in Iranian blood donations. Demographic status and donation type were also investigated in HIV positive blood donors.

**Methods:** In the time frame of this study (2008 – 2013), the records of 11,504,231 donations were analyzed and all relevant data were extracted from the central database of the Iranian Blood Transfusion Organization. Demographic characteristics and type of donations were investigated. Descriptive and analytical statistics were used to summarize the obtained data.

**Results:** A total of 421 blood donations were HIV sero-positive. Trends in HIV prevalence from 2008 to 2013 per 100000 donations were found as follows: 3.8, 4.3, 3.8, 3.8, 3, and 2.9, respectively. The average prevalence was 3.6 per 100000. The prevalence rate showed a fluctuation from 3.8 to 2.9 per 100000. Gradual reduction has occurred in HIV sero-prevalence but the difference is not statistically significant. The risk of HIV sero-positivity was higher in single and female blood donors. The prevalence of HIV was much higher among donations from first-time than from regular and lapsed donors.

**Conclusions:** The low prevalence rate of HIV in Iranian blood donations suggests the effectiveness of current safety strategies. However, implementing new strategies or improving the existing ones are advisable.

**Keywords:** Blood donation, blood donors, HIV

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## Introduction

HIV/AIDS remains one of the most serious challenging socioeconomic and legal issues for global health in the world. The number of HIV infected individuals has been estimated around 75 million worldwide.<sup>1</sup> The first case of AIDS in Iran was reported in 1986. Since then, the number of HIV/AIDS cases has increased steadily. The first wave of epidemic came from plasma derivatives and the second wave of concentrated epidemic pertained to injecting drug users; now, Iran stands on the verge of a third wave which is spread sexually. According to the reports of Iran's ministry of health, the number of registered people living with HIV was 27,041 until 2013. Estimates show that by the end of 2014, the number of people living with HIV/AIDS is about 78,290. Predictions for 2015 will be about 126,300, which represents a 35% increase over the period of 2011 to 2015 (Figure 1).<sup>2</sup>

One of the medical practices affected by HIV/AIDS epidemic is blood transfusion therapy. It is also of considerable issue in the issue of blood safety and many claims on blood providing

centers are related to HIV transmission via transfusion of blood products or plasma derivatives. From the early years of HIV/AIDS identification, the possibility was raised that the disease is transmissible through blood transfusion and remarkable progress was achieved in terms of understanding and also reducing the risk of HIV transmission through blood transfusions. Interviews with blood donors in order to exclude donors with high-risk behaviors and laboratory screening tests were the main interventions by blood transfusion centers to reduce the risk of HIV transmission. The prevalence of HIV sero-positivity and monitoring of its trend on blood donors directly provide a measure of how successful donor selection and screening system are. This prevalence is directly related to two major factors. First, HIV sero-prevalence among the general population as potential volunteers for blood donation; second, the successful and comprehensive blood donor selection and screening system. Moreover, other blood safety measures (such as call back, confidential unit exclusion (CUE), etc.) could add extra safety layers to blood supply of blood transfusion organizations.<sup>3</sup> The CUE is an option in blood donation process in which a blood donor, at the end of donation, confidentially states that the blood unit should not be used.

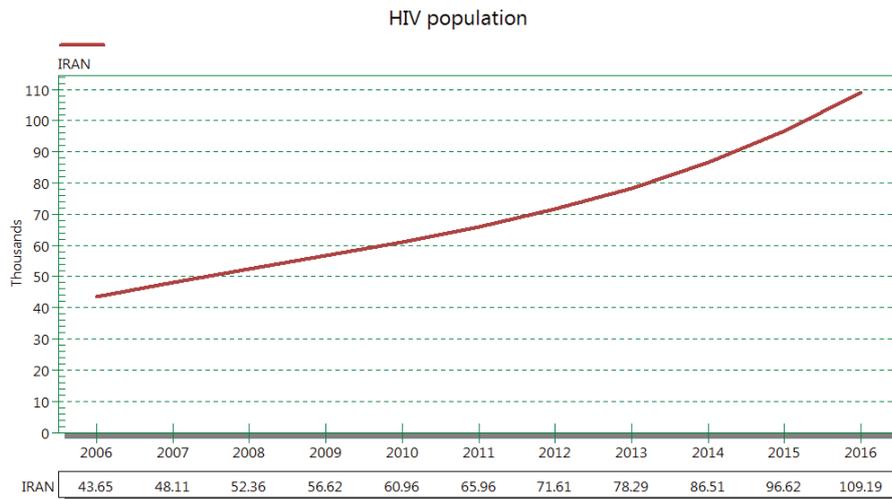
In Iran, laboratory screening of blood units for HIV started in 1989 and the overall frequency of HIV sero-positivity has been reported around 0.004% by Abolghasemi, et al.<sup>4</sup> Based on a study on HIV trend among blood donations during a 4-year period, the prevalence decreased from 0.005% to 0.004%.<sup>5</sup>

Typically, it is expected that the increased incidence of

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**Figure 1.** Estimated number of People living with HIV during 2006–2016. (Source: Islamic Republic of Iran AIDS Progress Report. 2014).

communicable diseases in the general population should increase the risk of infection through blood donors. However, interventions are carried out by blood transfusion centers, such as education, voluntary blood donation, emphasis on repeated blood donors and laboratory testing influence the final outcome. Despite these improvements, the risk of transmission is not zero.

The aim of this study was to provide information on the trend of HIV sero-positivity among Iranian blood donors over a period of 6 years and compare it with the trend of sero-positivity in the general population. Concomitantly, we investigated a variety of interventions which are undertaken by the Iranian Blood Transfusion Organization (IBTO) to increase blood safety. Analysis of these data would be helpful to evaluate the blood donor selection process.

## Materials and Methods

In this cross-sectional retrospective study, all data from blood collection centers throughout the country were extracted from the central database of IBTO, to assess the trend of HIV sero-positivity. The timeframe was 2008 – 2013. HIV positive blood donors' characteristics such as age, gender, educational level and type of donation were also investigated. Based on types of blood donation, blood donors were divided into three groups: first-time, lapsed and regular donors. According to IBTO definitions, a donor who donates for the first time is a first-time blood donor, a blood donor who has a history of donation but the interval between two donations is more than one year is categorized as lapsed donor, and a regular donor is one who has donated blood more than once during one year.

To evaluate the trend of HIV sero-reactivity over the study period, data were gathered on 11,504,231 allogenic blood donations. Based on the standard operation procedures of IBTO, all volunteers were initially interviewed by a physician and if they managed to meet the requirements of qualification, they would be accepted for blood donation. Then, the next step was laboratory screening for viral markers and rapid plasma reagin test (RPR). Initially reactive samples were retested in duplicate within 24h; repeatedly reactive samples thereafter were retested with a confirmatory screening assay [Anti HIV-I/II (Biotest) HIV BLOT 2.2 (Genelabs)]. Data of confirmed HIV sero-positive blood

donors and total number of donation were extracted from the database and annual sero-prevalence was calculated per 100,000 blood donors. Passive HIV surveillance data were extracted from the Iranian center for diseases control database and estimation of HIV sero-prevalence was calculated in the general population based on UNAIDS spectrum model. Spectrum software was used to estimate HIV epidemic and determine the consequences of the HIV epidemic.

The SPSS software version 18 (Chicago, IL, USA) was used to analyze the collected data. Descriptive and analytical statistics were used to summarize the data obtained. The prevalence (percentage and 95% confidence interval) of HIV was calculated in each year per 100,000 blood donations. The relative risk (RR) was calculated to compare the risks between categorical variables and 95% confidence interval for relative risk were also determined.

The chi-square test was used to test the association between groups and  $P$ -value  $< 0.05$  was considered significant. The study was approved by the IBTO Ethics Committee.

## Results

During the period of March 2008 through March 2013, 11,504,231 blood donations have been recorded at the IBTO central database. Since 2008, the number of blood donations increased from 1,784,246 to 2,001,791 in March 2013 with a total increment of almost 14%. Most blood donors were male (annual mean  $94.3\% \pm 0.007\%$ ). Their mean age increased from  $33.9 \pm 11.09$  to  $35.68 \pm 10.6$  years ( $P < 0.001$ ). Overall, donations from first-time, lapsed and regular donors accounted for 29.1%, 24% and 46.9% of all donations, respectively. Donors' demographic and donation characteristics are shown in Table 1.

Over the 6-year period, a total of 421 blood donations were detected with positive HIV tests. We used exact binomial distribution (Clopper-Pearson) to calculate the prevalence of HIV (exact 95% CI) in each year per 100,000 blood donations. For each year, the following findings were revealed: 3.8 (95%CI: 2.9% – 4.8%), 4.3 (95%CI: 3.4% – 5.3%), 3.8 (95%CI: 3.0% – 4.8%), 3.8 (95%CI: 3% – 4.7%), 3 (95%CI: 2.6% – 4.3%) and 2.9 (95%CI: 2.3% – 3.8%), respectively. The average prevalence was 3.6 per 100,000. The prevalence rate of HIV per 100,000 donations showed a fluctuation from 3.8 in 2008 to 2.9 in 2013

**Table 1.** Donors demographic and donation characteristics

Year	Donations/ Unit	Gender		Type of donation			Marital status		Age (Mean $\pm$ SD)
		Male	Female	First-time	Elapsed	Repeated	Married	Single	
2008	1784246	1667216 (93.4%)	117030 (6.6%)	652978 (36.6%)	403796 (22.6%)	727472 (40.8%)	1294404 (72.5%)	489842 (27.5%)	33.9 $\pm$ 11.09
2009	1791477	1683857 (94%)	107620 (6%)	610627 (34%)	413122 (23%)	767728 (43%)	1325823 (74%)	465653 (26%)	34.5 $\pm$ 10.9
2010	1889850	1770468 (93.7%)	119382 (6.3%)	592069 (31%)	437554 (23%)	860227 (46%)	1418539 (75.1%)	471311 (24.9%)	34.87 $\pm$ 10.8
2011	1986992	1874443 (94.3%)	112549 (5.7%)	536205 (27%)	470922 (23.7%)	979865 (49.3%)	1516835 (76.3%)	470157 (23.7%)	35.04 $\pm$ 10.7
2012	2049875	1944034 (94.8%)	105841 (5.2%)	506160 (24.7%)	502394 (24.5%)	1041321 (50.8%)	1593485 (78.8%)	438956 (21.2%)	35.17 $\pm$ 10.7
2013	2001791	1912370 (95.5%)	89421 (4.5%)	450403 (22.5%)	534478 (26.7%)	1016909 (50.8%)	1574534 (79%)	416917 (21%)	35.68 $\pm$ 10.6
<b>Total</b>	<b>11504231</b>	<b>10852388 (94.3%)</b>	<b>651843 (5.7%)</b>	<b>3348442 (29.1%)</b>	<b>2762266 (24%)</b>	<b>5393572 (46.9%)</b>	<b>8723620 (76%)</b>	<b>2752836 (24%)</b>	---

**Table 2.** HIV seropositivity rate among blood donors and general population

Year	Prevalence in population (per 100,000)	Donations/ unit	HIV seropositive donations	Prevalence in blood donations (per 100,000)	95% CI
2008	81	1784246	68	3.8	2.9–4.8
2009	85	1791477	77	4.3	3.4–5.3
2010	88	1889850	72	3.8	3–4.8
2011	90	1986992	75	3.8	3–4.7
2012	93	2049875	69	3.0	2.6–4.3
2013	96	2001791	60	2.9	2.3–3.8
<b>Total</b>	<b>533</b>	<b>11504231</b>	<b>421</b>	<b>3.6</b>	<b>3.3–4</b>

(Table 2). It was observed that a gradual reduction occurred in HIV sero-prevalence but the observed variation was not statistically significant ( $P = 0.71$ ). In HIV-positive blood donors, variables such as age, gender, marital status, occupation, education level, and donation type were evaluated. They were middle aged with a mean age of  $34.2 \pm 8.6$  years. There was no significant difference in mean age between seropositive and seronegative groups ( $P = 0.1$ ). Most of the HIV-positive donated blood belong to blood donors who were male (3.4 per 100,000). A remarkable percentage of HIV positive blood donors were married (3.3 per 100,000), although the risk of HIV sero-positivity was 38% higher in single compared to married blood donors ( $P = 0.004$ ). Marital status of 11 (2.6%) of HIV sero-positive donors remained obscure. Regarding occupational status, they were categorized as self-employed, official, workers and farmers, housewives and unemployed with proportions of 56%, 19%, 14%, 9%, and 2%, respectively. As for education level, the majority of HIV positive donors came from an illiterate population, followed by up to college graduation and the academic degree of bachelor or higher by rates of 59%, 33% and 8%, respectively. First-time donors accounted for 76.5% of HIV-positive donations. The overall prevalence of HIV was 9.6, 2.3 and 6.5 per 100,000 donations in first-time blood donors, lapsed and regular blood donors, respectively, which was significantly higher in first-time blood donors compared to lapsed and regular blood donors ( $P < 0.001$ ). The relative risk of HIV sero-positivity in male versus female blood donors was 0.5; this means that the

risk of HIV sero-positivity was half in men compared to women. The risk of HIV sero-positivity was 93% (RR = 0.07) lower in regular compared to first-time donors. In lapsed donors (RR = 0.24%), the the risk of HIV sero-positivity was 0.76% less than first time blood donors (Table 3).

Figure 2 presents an overview of changes in sero-prevalence of HIV in the Iranian general population compared to different donor categories during the period of study. Figure 3 provides a closer view of differences between donor types.

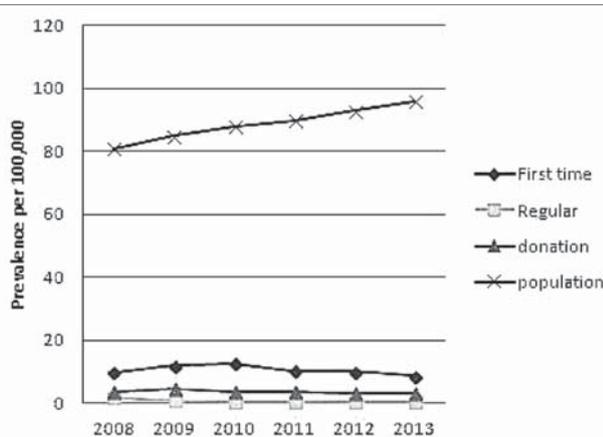
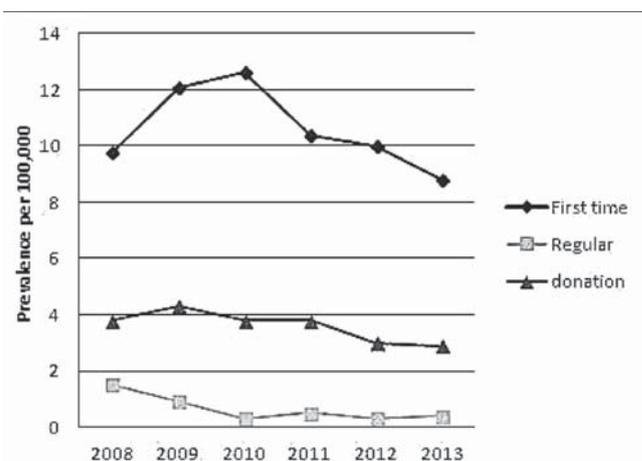
## Discussion

The goal and main findings of the study

In an effort to investigate HIV sero-prevalence and trends in voluntary blood donations in recent years, we performed a retrospective study on 11,504,231 blood donations. Over a period of six years, the overall frequency of HIV was 3.6 per 100,000 donations. During these years, despite the increasing number of blood donations (14%), HIV prevalence decreased among blood donations. The comparison between HIV sero-prevalence in blood donors and the general population indicated that despite a spreading pattern of infection in the general population, the prevalence in blood donors decreased from: 3.8/100,000 in 2008 to 2.9/100,000 in 2013 and did not follow the same pattern as the community. However, the rising of HIV infection rate in the general population shows a gentle slope in recent years, but

**Table 3.** Relative risk and 95% confidence intervals estimates in HIV sero-positive blood donors

Variables	Seropositive (10 <sup>5</sup> )	Relative Risk (RR)	95% CI
<b>Gender</b>			
Male	379 (3.4)	0.5	0.39–0.74
Female	42 (6.4)	---	---
<b>Marital status</b>			
Single	125 (4.5)	1.38	1.15–1.7
Married	285 (3.3)	---	---
<b>Donation Type</b>			
First-Time	322 (9.6)	---	---
Lapsed	64 (2.3)	0.07	0.048–0.096
Regular	35 (6.5)	0.24	0.18–0.31

**Figure 2.** Comparison of HIV sero-prevalence between population and Blood donors**Figure 3.** Sero-prevalence of HIV in Iranian blood donors

evidence indicates an increase in the involvement of female group and increasing contribution of transmission routes other than injecting drug use could be assessed as a hazard.<sup>6</sup>

#### Explanations of the results

In a trend study on Iranian blood donations (2004 – 2007) conducted by Amini, et al. an overall HIV sero-prevalence of 0.004% was reported.<sup>5</sup> In their study, despite the low HIV sero-prevalence in donated blood, a significant decline was not observed during the study period. The results of our study over a six-year period are almost similar to the previous study. Nevertheless, it should be emphasized that the decreasing pattern in blood donors regardless of increasing trend in general population is obvious. In another study in 2005 – 2011, which included only Tehran Blood Transfusion Center, the overall frequency of anti-HIV was reported 5.4 per 100,000 donations.<sup>7</sup> Also, Khedmat, et al. in the period 2003 – 2005 reported a prevalence of 0.004% in Tehran Blood Transfusion Center.<sup>8</sup> In other provinces such as Bushehr (2004 – 2008) and Yazd (2004 – 2010), the prevalence rate has been reported 0.011% and 3 per 100,000 donations respectively.<sup>9,10</sup>

The prevalence of HIV in blood donors varies widely among other countries. In a study conducted in a number of European

countries, the prevalence of HIV in blood donations in the years 1990 – 2004 have shown different trends, ranging from zero per 100,000 donations in 11 countries to 128.4 per 100,000 in Ukraine. In the Republic of Azerbaijan and Armenia which are located in East Europe and neighbor Iran, prevalence of HIV was 30.2 and 8.4 per 100,000 donations. These frequencies are much higher than the one in our study.<sup>11</sup> Different frequencies have been also reported in other countries. For example, in Turkey, a neighboring country of Iran, the overall HIV sero-prevalence was 0.001% over a 17-year period, while the changes in anti-HIV positivity were not significant.<sup>12</sup> In Pakistan, another neighboring country, 0.007% of blood donors were anti-HIV positive, about twice as high as ours.<sup>13</sup> In United Arab Emirates, the southern neighbor of Iran in the Persian Gulf, blood donors, a rate of 4 per 100,000 donations, which is similar to what we found.<sup>14</sup> In China, between the years 2000 – 2010, the overall prevalence of HIV among blood donors was 0.08%. However, the frequency varies in different regional centers.<sup>15</sup> Moreover, a systematic review in China showed an upward trend in the prevalence of HIV in volunteer donors.<sup>16</sup> In a study conducted in Indian volunteer blood donors (2008 – 2012), the frequency ranged from 0.03% to 0.17% (overall, 0.08%) which is very high compare to other countries in

the region.<sup>17</sup> This indicates that different factors might play a role in contributing to HIV seropositivity rate in different societies and each should be monitored individually, even in subgroups.

Gender specific prevalence of infected donations was 90.1% for males and 9.9% for females. The risk of HIV sero-positivity was half in men compared to women. Typically, more than 92% of Iranian donors are male<sup>4</sup>. Therefore, finding more cases of sero-positivity among male donors is not unexpected, but the risk of sero-positivity was twice higher in females compared to male donors which might be owing to the fact that women do not have ready access to Voluntary Counseling and Testing (VCT) services and are more comfortable to find their HIV sero-status by blood donation. Further studies can provide more detailed information and solutions. In a number of studies conducted in countries such as Brazil, Ghana, Nigeria and Namibia, no gender differences were reported in HIV-positive donors.<sup>18-21</sup>

The prevalence of HIV seropositivity was higher among first time donors and young single donors. The frequency among occupational groups was statistically significant. However, self-employment is a broad spectrum and vague category. In order to identify high-risk individuals, it is recommended to record details of donors' jobs.

Regarding the type of donation, higher sero-prevalence was seen in blood from first time donors. Prevalence of HIV sero-positivity among first time donors is shown in Figure 3; it might be declared that the proportion almost remains in a constant range during the study period at almost 9/100,000 which is mostly less than the general population, but much higher compared to regular and lapsed donors. In the study by Amini, et al. in the period 2006 – 2007, the frequency of HIV in repeated donors was significantly lower than first-time donors.<sup>5</sup> Also, in other studies carried out in Iran, first time blood donors showed a higher HIV sero-prevalence compared to other donation types.<sup>7,9</sup> Chinese first-time blood donors also showed a higher HIV sero-prevalence.<sup>16</sup> In a study conducted in the countries of the WHO European Region, HIV sero-positivity in donations from first-time donors and repeat donors varied from 6.5 to 0.9 per 100,000, respectively.<sup>11</sup>

Regarding marital status, donations from single donors had the highest rate of infection. Similarly in other studies, such as Brazilian donors, HIV infections reported in singles have been higher than married donors.<sup>18</sup>

#### Implemented evidence-based strategies for blood safety

In blood transfusion centers, certain interventions are used to increase blood safety. These interventions have been adopted based on a comprehensive set of evidence-based strategies.<sup>22</sup> Recruiting non-remunerated low risk volunteers, donor counseling and donor selection performed by trained physicians, regular counseling workshops to train physicians, launching an integrated electronic database to monitor the data of registered and selected volunteers in the entire country, precise surveillance of transfusion-transmitted infections (TTIs) among different geographic areas besides the implementation of procedures like CUE, call back, professional post donation counseling for seropositive donors and their family could place tenacious barriers to protect the donation pool.<sup>5,23</sup> As pre-donation screening, a series of reading materials related to HIV and other transfusion transmitted infections are placed at the disposal of volunteers and they are asked to withdraw from donating blood if they have any of the risk factors. Moreover, in the pre-donation interview, the donors are directly asked about HIV-

related risk factors such as injecting drugs, homosexual behavior, or having a sexual relationship with a sex-worker. People who have these risk factors will not be accepted for blood donation. Another risk reduction strategy is using the confidential unit exclusion (CUE); IBTO has tried to prevent the entry of high-risk donors by using a CUE process since 2003. Implementation of continuous educational programs for target groups and providing donor educational materials are the other activities of IBTO to increase the level of blood safety. It seems that the collection of these strategies have been effective in reducing the risk of HIV transmission via blood transfusion.

As a threat to blood safety, there are some people who are among high risk behavior groups and would like to donate blood only to be tested for HIV; detecting and referring them to the VCT clinics to test and counsel without discrimination and stigma are other important measures of safety layers. In addition, applying programs to increase regular blood donation rates by persuading healthy first time and lapsed donors to donate blood regularly at least twice per year and training the donors to be more aware of TTI transmission routes and risk factors and motivating them to choose a safer life style, could altogether describe the noticeable progress of IBTO in supplying a very safe donation pool and forming a great difference between the prevalence of HIV positive donors compared to the Iranian general population.

One important reason for the impact of these interventions is the prevalence of TTI in multi-transfused recipients. Multi-transfused patients, such as  $\beta$ -thalassemia patients, are repeatedly exposed to blood products. Currently, it is estimated that there are about 25,000 cases of  $\beta$ -thalassemia in Iran who annually receive approximately 300,000 units of packed red cells. Previous studies have not reported any case of HIV transmission in this group of patients.<sup>24,25</sup>

It should be borne in mind that changing the picture of HIV epidemic in Iran and shifting toward infecting more women by sexual transmission than before might be evaluated as a threat to blood safety;<sup>6</sup> so, implementing new strategies or improving the existing ones are advisable. Safety measures such as implementation of nucleic acid testing (NAT) to decrease the window period of viral detection or developing counseling clinics to evaluate and assess the deferred volunteers, not just seropositive donors, could be helpful.

However, it is further emphasized that any work on a sensitive issue such as HIV should be established within the advocacy of all stakeholders like Ministry of Health, society, non-governmental organizations (NGOs) and any other related parts of community and government, or even sometimes consolidated local or international cooperation.

#### Potential limitations

The database we used was very huge in total donation history, so the data center provided us with the processed data; nevertheless, for sero-positive cases, we had access to details of every subject. In addition, regarding the occupation and educational level of seronegative donors, the details of data were not accessible.

In summary, regarding the current status of trend of HIV prevalence in Iranian blood donors, it is delightful that the safety measures employed in recent years have been efficacious, but new feature of HIV epidemiology in Iran should be noticed in strategic planning for blood safety. Promotional strategies to increase repeated blood donations and increasing the participation

of married donors can be effective to enhance blood safety.

## Authors' contributions

M. Z. designed the research, gathered the data and revised the article. A. A. P revised the manuscript. M. R. analyzed and interpreted the data. G. K. reviewed the literature, wrote the manuscript and revised the article.

## Competing interests

The authors have no conflicts of interest.

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