
Fateme Mohammadali PhD1,2, Ali Akbar Pourfathollah PhD*1,3

Abstract

Background: Evaluating trends in blood donors’ infectious diseases is essential for monitoring the safe supply of blood, donor screening effectiveness, and the occurrence of infections in the blood donor population which consequently gives an idea of the epidemiology of these diseases in the community. The aim of the present study was to assess the prevalence of hepatitis B, hepatitis C, HIV and syphilis by carrying out confirmatory tests in Tehran’s blood transfusion center between 2005 and 2011.

Methods: This was a retrospective study conducted at Tehran’s Blood Transfusion Center (TBTC) from 2005 to 2011. All donor serum samples were screened for HBV, HCV, HIV and syphilis using third generation ELISA kits and RPR test. Initial reactive samples were tested in duplicate. Confirmatory tests were performed on all repeatedly reactive donations. For statistical analysis, T-test, ANOVA and Chi-square test were carried out on SPSS software and 95% confidential intervals (95% CI) were used.

Results: Over a period of six years (March 2005 to March 2011), a total of 2,026,628 donations were collected. Out of the total blood donors, 10,476 were positive for HBV, HCV, HIV and syphilis. The overall frequency of HBS Ag, anti-HCV, HIV Ag/Ab and syphilis antibodies were 388,112, 5.4 and 10.5 per 100,000 donations, respectively. The prevalence of HBV among blood donors showed a downward trend over the period of six years. The trend of HCV fluctuated during the period under study, peaking in 2007. The trend of HIV infection frequency had increasing patterns in 2011. The trend of syphilis infection frequency was increasing in 2008 and decreasing after that.

Conclusion: Generally, it seems that the declining trend in prevalence of blood-borne infections indicates the effectiveness of screening methods and selection of appropriate donors. Higher prevalence of blood-borne infections in males, low educated, married, first-time donors and donors who referred to the mobile centers requires a different planning in these groups.

Keywords: blood donors, HIV, HCV, HBV, frequency, syphilis

Introduction

In a lifetime, one in three people will need blood transfusions and blood products. Blood transfusions save millions of lives but unsafe transfusion practices put millions of people at risk of transfusion transmissible infections (TTIs). 1,2 Unhealthy blood transfusions not only affect the recipients but also affect their family and the community in terms of economic cost. Therefore, supplying safe blood and blood components is a global concern. 3

In order to maintain a safe blood supply, donor deferral, new donor screening assays and pathogen inactivation of blood components are being used. 4,5 In Iran, for example, all donated blood is screened for HIV, hepatitis B, hepatitis C and syphilis.

Evaluating trends in blood donors’ infectious disease rates is not only essential for monitoring the safe supply of blood and donor screening effectiveness but it also allows the data on the prevalence of transfusion transmissible infections among blood donors to be used as part of an assessment of the occurrence of infections in the blood donor population and consequently gives an idea of the epidemiology of these diseases in the community. 6 For example, the increase in incidence and prevalence rate of an infectious agent may reflect changes in population risks, may result from the introduction of new screening technique or confirmatory method which results in improved detection of infected individuals, or an increased number of false positive results.

Surveillance of infectious disease markers in the blood donor population is important in recognizing trends in prevalence and incidence of transfusion related infections. It also provides an opportunity to estimate the risk of an infectious donation inadvertently entering the blood supply. 8

The aim of the present study was to assess the prevalence of the HIV, hepatitis B, hepatitis C and syphilis by carrying out confirmatory tests in Tehran Blood Transfusion Center in 2005 – 2011.

Materials and Methods

This was a retrospective study conducted at Tehran Blood Transfusion Center (TBTC). All blood eligible donors who donated blood from 2005 to 2011 were investigated. The medical and socio-demographic histories of 2,659,447 people who referred to TBTC were recorded in the MAK database. Donors who were selected by medical screening based on standard criteria for blood donation participated in the study. 2,144,337 donors were
eligible to donate blood. All 2,144,337 donor serum samples were screened for HBV, HCV, HIV and syphilis.

A first-time blood donor is identified as a donor who donates for the first time and only once. A regular donor is defined as a donor who has donated more than once during 1 year and a repeated donor is any donor who has a history of previous donation but the interval between the two donations is more than 1 year.

Hepatitis B surface Antigen (HBS Ag), HIV (Ag/Ab) and HCV

Table 1. The screening test kits (2005 – 2011)

<table>
<thead>
<tr>
<th>Years</th>
<th>HBs Ag</th>
<th>Anti-HCV</th>
<th>HIV Ag/Ab</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Screening kit (Manufacturer)</td>
<td>Specificity</td>
<td>Screening kit (Manufacturer)</td>
</tr>
<tr>
<td>2006–2005</td>
<td>ETI-MAK4 HBsAg (DiaSorin)</td>
<td>99%</td>
<td>Anti-HCV ( Avicenna)</td>
</tr>
<tr>
<td></td>
<td>Enzymost HBs Ag 5.0 ( Dade Behring)</td>
<td>99.88%</td>
<td></td>
</tr>
<tr>
<td>2007–2006</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>HCV 3.0 with enhanced SAvE (ORTHO)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Hepanostika HCV Ultra (bioMérieux)</td>
</tr>
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<td></td>
<td></td>
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</tbody>
</table>

Table 2. The confirmatory test kits (2005 – 2011)

<table>
<thead>
<tr>
<th>Years</th>
<th>HBsAg confirmatory test (Manufacturer)</th>
<th>HIV Western Blot</th>
<th>HCV RIBA</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006–2005</td>
<td>HBsAg confirmatory test (DiaSorin)</td>
<td>HIV BLOT 2.2 (Genelabs)</td>
<td>Inno-LIA HCV Score (Innogenetics)</td>
</tr>
<tr>
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<td>HBsAg confirmatory test (Dade-Behring)</td>
<td></td>
<td>HCV BLOT 3.0 (Genelabs)</td>
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<td>HCV BLOT 3.0 (MP Diagnostics)</td>
</tr>
<tr>
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<td>Inno-LIA HIV I/II Score (Innogenetics)</td>
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<td></td>
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</tbody>
</table>
Table 3. Prevalence rates (PR) per 100000 for HBV, HCV, HIV, and Syphilis by confirmatory tests between 2005 to 2011, Tehran blood donations.

<table>
<thead>
<tr>
<th>Years</th>
<th>NO of donations</th>
<th>HBs Ag</th>
<th>HCV Ab</th>
<th>HIV Ab</th>
<th>RPR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>NO PR/10^5 (95% CI)</td>
<td>NO PR/10^5 (95% CI)</td>
<td>NO PR/10^5 (95% CI)</td>
<td>NO PR/10^5 (95% CI)</td>
</tr>
<tr>
<td>2006–2005</td>
<td>304224</td>
<td>1745</td>
<td>573 (546–599)</td>
<td>342</td>
<td>112 (100–124)</td>
</tr>
<tr>
<td>2006–2007</td>
<td>314203</td>
<td>1426</td>
<td>454 (431–477)</td>
<td>327</td>
<td>104 (93–115)</td>
</tr>
<tr>
<td>2007–2008</td>
<td>351335</td>
<td>1475</td>
<td>420 (399–441)</td>
<td>498</td>
<td>142 (130–154)</td>
</tr>
<tr>
<td>2008–2009</td>
<td>351283</td>
<td>1236</td>
<td>352 (332–372)</td>
<td>404</td>
<td>115 (104–126)</td>
</tr>
<tr>
<td>2010–2011</td>
<td>366281</td>
<td>937</td>
<td>256 (240–272)</td>
<td>351</td>
<td>96 (86–106)</td>
</tr>
<tr>
<td>Total</td>
<td>2026628</td>
<td>7869</td>
<td>388 (380–396)</td>
<td>2280</td>
<td>112 (107–117)</td>
</tr>
</tbody>
</table>

Figure 1. Trends of HBV, HCV, HIV, and Syphilis infection between 2005 to 2011, blood donors, Tehran (the numbers of positive result tests were standardized for population).

Figure 2. Trends of HBV, HCV, HIV, and Syphilis infection based on blood donor age categories.

Figure 3. Trends of HBV, HCV, HIV, and Syphilis infection based on blood donor gender status.

Figure 4. Trends of HBV, HCV, HIV, and Syphilis infection based on blood donor marital status.
Ab were screened using third generation ELISA kits. Serum from all donors was tested for the presence of Treponemal antibodies using Rapid Plasma Reagin test (RPR) (Enison). During the period of study, the specificity of screening kits for HBsAg, anti-HCV and HIV antigen/antibody were similar (Table 1) with 100% sensitivity.

The initially reactive samples were tested in duplicate. The repeatedly reactive results were considered seropositive for their infections. Confirmatory tests were performed on all repeatedly reactive donations using the following tests: HBC Ab and HBS Ag confirmatory assay for HBS Ag positive samples, HCV RIBA for HCV Ab positive samples, HIV Western Blot for HIV Ag/Ab positive samples and FTA-ABS (Trinity biotech) for RPR positive samples (Table 2).

The HIV Western Blot -negative samples were tested for HIV p24 antigen and if repeatedly reactive, monoclonal neutralization assay was carried out.

Statistical analysis was carried out using SPSS software. T-test and ANOVA were performed for quantitative comparison and chi-square test was performed for qualitative comparison. For assessing the frequency of infection, the prevalence of HBsAg, HIV Ag/Ab, HCV Ab and syphilis per 100,000 donations and 95% confidential intervals (95% CI) was used.

**Results**

Over a period of six years (March 2005 to March 2011), a total of 2,026,628 donations were collected with an average of 337,771 donations per year. Volunteer donors constituted 100% of total blood donors. All blood donor volunteers were accepted for blood donation after medical interview based on the Iranian blood donation guidelines. The electronic database helped to identify the donors previously deferred on the basis of Hepatitis B, C, HIV and RPR. For every blood donor, HBs Ag, HCV Ab, HIV Ab/Ag and syphilis per 100,000 donations and RPR tests were performed for HBV, HCV, HIV and syphilis detection, respectively.

Out of the total blood donors, the results were positive for one or more infectious disease tests (HBV, HCV, HIV and syphilis).
in 10476 donors, 9918 (95%) were males and 558 (5%) were females, with a male to female ratio of 17.7:1. Table 3 shows the prevalence rates (PR) per 100,000 for HBV, HCV, HIV, and Syphilis for the years 2005 to 2011. The mean age of blood donors with positive test results was 38 ± 10.5 years.

From 2005 to 2011, a decreasing trend was observed in the frequency of HBs Ag. The trend of HCV prevalence rate was increasing in 2007 but became decreasing again after that. The trend of HIV infection frequency had an increasing pattern in 2011. The trend of syphilis infection frequency was increasing in 2008 and decreasing after that. [Z and \( P \) values for HBV, HCV, HIV and RPR were 16.93, \( P < 0.001 \), 2.41, \( P < 0.016 \), 2.09, \( P < 0.035 \) and 0.11, \( P = 0.9 \), respectively, (Cochran-Armitage Trend Test)], (Figure 1). The trends of HBV, HCV, HIV and syphilis infections based on age, gender, marital status, blood donation status, educational and occupational categories and center of blood donation are given in Figures 2 – 8.

The trends of HBV, HCV, HIV and syphilis infections based on blood donation status are given in Table 4. First time blood donors show a higher prevalence of infectious markers as compared to repeated and regular donors.

In this study, we observed that infectious markers were more prevalent in the 31 – 40 year old, male, married, low educated with non-governmental occupation donors. A decreasing trend was observed in donors who referred to fixed blood centers.

**Discussion**

Transfusion of blood and blood products is a life saving measure and helps in numerous patients worldwide; however, blood transfusion is an important mode of transmission of infection to the recipients. The main purpose of Iranian blood transfusion organization is providing the safe blood and blood products with the best quality for patient according to the national standards.

In this study, the overall frequency of HIV Ag/Ab, anti-HCV, HBS Ag and syphilis antibodies were 5.4, 112, 388 and 10.5 per 100,000 donation, respectively.

The overall frequency of HBS Ag in this study was 388 per 100,000. In our study, the HBV prevalence among blood donors showed a downward trend over the period of six years.

The first estimates of the prevalence of HBV infection in Iran that were carried out on blood donors during the early years of the foundation of the Blood Transfusion Organization about 35 years ago, indicated that approximately 3% of Iranians were chronic carriers.10

Our result is in agreement with Amini’s study in 1998 – 2007,11 and 2004 – 2007,12 among blood donors of different provinces of Iran. The prevalence of confirmed HBs Ag in Khedmat’s study in 2003 – 2005 in Tehran Blood Transfusion Center was reported about 600 per 100,000.8 Similar declines in HBV infection have been reported among blood donors in studies by Khedmat and Amini12 in Iran. This declining pattern is also observed in numerous countries; in African countries such as Nigeria, a decline of 9.20 to 6.32 is reported from 2006 – 2009 by Salawu.13 In Saudi Arabia, a decline of 2.58 to 1.67% is reported from 1998 to 2001.15 Turkey reports a decrease from 4.92% to 2.10% in the period 1989 – 2004.16 In contrast, in Eastern India...
a significant increase of 1.28 to 1.66% has been reported.17

Generally, the prevalence of HBV infection is lower in the United States and western Europe (0.1% – 0.5%) while it is reported to be higher (5% – 15%) in southeast Asia and China.18 In Canadian blood donors, the rate of HBS Ag positivity was 0.007 percent in repeated donors and 0.06 percent in first-time donors in 2006.19

Our study is different from reports in other parts of the world such as Australia with 0.01,20 India with 0.66%,21 Saudi Arabia with 1.5%,22 Punjab of Pakistan with 4.93,23 Nigeria with 7.50%,13 or Ethiopia with 25%.24

Recent reports from blood donors show a much greater decrease from almost 3% in early studies to 1.79% in 1998,25 and 0.41% in 2007,26 and in the case of Tehran, 0.51%.25 Our study indicated a rate of 0.38% in blood donors.

Generally, it seems that vaccination against HBV in all neonates since 1992 and selected groups such as health care workers, pregnant women, families of HBS Ag positive donors, multi-transfused patients and their families, progress in recruitment of a safer donor population, confidential unit exclusion (CUE) applying, computerized data registry of blood donors, increase public knowledge about blood-borne infections and routes of transmission, implementing voluntary blood donation to 100%, removing replacement donation, and the increasing number of regular donations may have also contributed to the observed decline.11

Considering the fact that the screening tests in use during the past decade were of similar sensitivity, that uniform confirmation procedures were used and the tests were performed in laboratories with similar proficiency and technical capabilities, it is reasonable to assume that the decline observed may have been due to the effectiveness of the donor selection procedure being practiced by the IBTO during the recent years. In this procedure, donors with certain risk factors are excluded from the blood donor pool.

Our result is different from population-based studies. In one study performed during 1990 – 1991 on 39,841 subjects randomly selected from all the country, a mean prevalence of 1.7% was observed for hepatitis B surface antigen (HBsAg) positivity. This study included subjects as young as two years old.27

In a study by Merat27 performed on 5,678 randomly selected subjects in general population in three provinces of Iran for the presence of HBsAg, the rate of HBsAg positivity in the total of 3 provinces was 2.6% and in Tehran province, it was 2.3%. It seems that other than being population-based, this study has commented on the prevalence of HBV infection in rural areas of Iran. Also, the authors demonstrated that exposure rates were higher in rural vs. urban areas of Iran. Furthermore, the study population was composed of more females than males, whereas many previous studies have almost exclusively addressed males. This is especially true for blood donor studies where the female population has always been much smaller.

The overall frequency of Anti HCV in this study was 112 per 100,000. The first study on HCV prevalence in Iran was on healthy blood donors in 1994 and showed a seroprevalence of 0.25%.28 In that year, blood donors were unselected and anyone was allowed to donate blood.

The prevalence of confirmed HCV positive cases in blood donors in 2003-2005 was reported about 100 per 100,000 in a study by Khodabandeloo’s.8

In Amini’s study, the prevalence of HCV among Iranian blood donors was 0.13%, in which the data were collected from all the blood transfusion centers across the country in a total of 6,499,851 donations during the four year period from 2004 through 2007.12

In Khodabandeloo’s study, results of 48 studies done in 26 provinces or cities with total samples of 10,739,221 blood donors were combined and meta-analyzed; the pooled prevalence rate of HCV infection among blood donors in Iran provinces and cities was estimated at 0.5%. However, the authors showed that the prevalence of HCV is variable in different cities and provinces. The highest rate of pooled prevalence of HCV infection was in Kashan, a city in Isfahan province, at 1.09%, and the lowest prevalence was in South Khorasan province with a rate of 0.03%. The result of Tehran Province was comparable with our study.

In comparison with countries in this geographic region, we have the lowest rate of HCV infection.30 Our finding is lower than other parts of the world, such as Ethiopia with 13.3%,22 Punjab of Pakistan with 4.06,23 Nigeria with 0.86%,13 and India with 0.84.17 The global seroprevalence of HCV among blood donors varies from 0.4% to 19.2%.31

Reports on the prevalence of HCV infection in special populations in Iran are as high as 11% – 25% for patients on hemodialysis, 11% – 52% for intravenous drug abusers, 15% – 76% for hemophilia and thalassemia patients and 0.5% in the general population.32

The frequency of HCV exposure in the general population in Iran had increased from 0.3% in 1997 to approximately 1% in 2006.12 In Merat’s study, performed on 6583 randomly selected subjects from the general population in Iran, the prevalence of anti-HCV was reported to be 0.5%, while in this study the prevalence of HCV in Tehran province was 0.3%.32 The Authors suggest that the prevalence of HCV infection in Iran is rising, and in the future, hepatitis C will replace hepatitis B as the most common cause of chronic viral liver disease in Iran because while a vaccine exists for HBV, there is no vaccine for HCV.

Overall, the prevalence of HCV decreased in six years; however, it fluctuated during the period of study, peaking in 2007. This decrease can be attributed to the improved public knowledge on transfusion-transmitted infections and improvements in the safety measures employed in recent years32 such as The IBTO centers screening all blood donors for HCV prior to donation, using uniform standards, physical examination, application of strict questionnaires to potential donors, standard operating procedures and instruments, validation of procedures and training across the country, implementing voluntary blood donation to 100% since 2007, removing replacement donation, increasing number of regular donations, effective donor selection program such as confidential unit exclusion, improvement in automation, data registry of blood donors with history of positive screening tests, and using highly sensitive screening test kits.33

The increasing pattern of HCV in 2007 could be the result of a combination of several factors including a change in screening reagent used, actual changes in population risks, changes in basic population from which donors were recruited, increase in number of first-time donors, and effectiveness of prospective donor screening measures. Since the screening tests in use during the study were of similar sensitivity, it seems that increase in the number of first time donors could have contributed to this increase and it should be noted that people who may have been infected in the past year will be identified in this year.

The prevalence of infections among blood donors has been used as a surrogate marker for the prevalence of infections in the general population, although there are certain pitfalls like the exclusion
of people below 18 years and over 60 years and the low number of female donors. The prevalence of viral markers in the donor population is lower than the general population, because donors are a selected population at low risk of infectious diseases due to public education and donor health assessment.34

In this study, the overall frequency of anti-HIV was 5.4 per 100,000. In Iranian studies by Khedmat & Amini, the prevalence rates of anti-HIV western blot were about 4 and 4.4 per 100,000, respectively.8,12 In almost all European countries, the reported national HIV prevalence levels were lower than 10/100,000 donations.35 Compared to the European countries, this level of prevalence is relatively low.36 Our finding is lower than other parts of the world such as Ethiopia with 11.7%,24 Nigeria with 0.96%,23 and India with 0.39%.21 However, Punjab of Pakistan was negative for HIV.23

The overall frequency of syphilis antibodies in our study was 10.5 per 100,000. Our finding is lower than other parts of the world such as Ethiopia with 1.2%,24 India with 0.08%,21 and Nigeria with 2.61%.13 The prevalence of FTA-ABS results reported by Khedmat, et al. was 4 per 100,000.8

HIV and RPR trends showed a similar pattern but RPR confirmed rates over the time was shown more rapid than HIV confirmed results. It is essential to watch HIV after observing the rising pattern of syphilis. Increasing incidence of syphilis may be associated with rising rates of engaging in risky behaviors. These could be due to the fact that these pathogens are sexually transmitted, especially syphilis which has lesions that promote transmission of HIV infection.37

The recent official reports from the Iranian Center for Disease Control in 2007 mention increased (16,090 - 0.023%) identified cases of HIV infection.38,39 The prevalence of HIV in blood donors in 2011 shows a similar rising pattern of infection as in the general population.

In the present study, the sero-positivity rate of HIV, HCV, HBV and syphilis was significantly increased among first time blood donors compared to repeated and regular donors. This is in agreement with the previous studies.12,40-42 This significantly increased sero-prevalence among first time blood donors might be due to the fact that people who regularly donate blood usually have a profile of low risk of infection because they were selected many times.

The prevalence of all infections was found to be low among females; it may be that females made a smaller section of blood donors in Iran, because they were found to be anemic and did not fulfill the required criteria, or maybe, as mentioned in many studies, women were reported as a healthier source of blood in the community.43

In this study, the prevalence of infectious markers in married donors was higher. This increase might be due to family problems and sexual reasons reported in other studies.44

Higher prevalence of blood-borne infections in low educated donors emphasizes the necessity of educating about risk factors, routes of transmission and importance of safe blood donation in new donors and general population.

HBV, HCV, HIV and Syphilis also showed an increasing trend among donors referring to mobile blood centers and it might be due to incomplete application of computer software throughout in mobile centers in this period, therefore requiring a different planning in these groups.

It should be noted that, the overall prevalence of viral markers in the donor population is lower than the general population, because donors are a selected population at low risk of infectious diseases due to public education and donor health assessment.45

Acknowledgment

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