Prevalence and trends of human immunodeficiency virus, hepatitis B virus, and hepatitis C virus among blood donors in Iran, 2004 through 2007

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BACKGROUND: Evaluation and monitoring the prevalence of transfusion-transmissible viral infections in blood donors is a valuable index of donor selection and blood safety. This study analyzed the trends of blood-borne infections among Iranian blood donations during 4 years.

STUDY DESIGN AND METHODS: Viral screening results of 6,499,851 allogeneic donations from 2004 through 2007 were analyzed. All donations were screened for hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), and syphilis. The prevalence of HBV, HCV, and HIV infections per 100,000 donations and 95% confidence interval was calculated. The p value was estimated by chi-square test.

RESULTS: The prevalences of HBV, HCV, and HIV decreased during the 4-year study from 2004 through 2007. The overall prevalence was 0.56% for HBV, 0.004% for HIV, and 0.13% for HCV. There was a significant and impressive decrease in hepatitis B surface antigen prevalence from 0.73% in 2004 to 0.41% in 2007. The prevalence of HIV appeared to have decreased from 0.005% in 2004 to 0.004% in 2007 although the decrease was not significant. HCV prevalence showed a slight decline in blood donations from 0.14% in 2005 to 0.12% in 2007.

CONCLUSION: The trends of transfusion-transmitted infection prevalence in Iranian blood donations suggest that most of the safety measures employed in recent years in Iran have been effective.

Infections of blood-borne viruses, mainly human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) are a worldwide public health problem and particularly in developing countries represent significant causes of morbidity and mortality.[1-4] Major routes of transmission of these viruses are direct contact with blood, intravenous injection, transfusion of blood, and also sexual contact, although the latter is not considered as a major route in the case of HCV and HBV.[5-8] Transfusion-associated infections have been drastically decreased in those countries where routine serologic screening of donors is implemented.[9-11] Since foundation of the Iranian Blood Transfusion Organization (IBTO) in 1974, screening of blood donations for hepatitis B surface antigen (HBsAg) became obligatory. However, in Iran screening of blood donations became mandatory for HIV from 1989 and for HCV from 1996.

Evaluation and monitoring the prevalence of these viruses in blood donations is a valuable index for assessing quality of processes such as donor selection and public education, screening methods, and potential risk of

ABBREVIATIONS: IBTO = Iranian Blood Transfusion Organization; TTI(s) = transfusion-transmitted infection(s).

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TABLE 1. The screening test kits (2004-2007)

Years	Screening tests		
	HBsAg*	HIV antigen/antibody	Anti-HCV*
2004	ETI-MAK-4 (DiaSorin)	Anti-HIV-1/2 (Biotest)*	Anti-HCV (Avicenna)
2005	Enzygnost HBsAg5.0 (Dade Behring)	Anti-HIV-1/2 (Biotest)*, HIV antigen/antibody (Bio-Rad)†	Anti-HCV (Avicenna)
2006	Enzygnost HBsAg5.0 (Dade Behring)	HIV antigen/antibody (Bio-Rad)†, HIV antigen/antibody (bioMérieux)†	Anti-HCV (Avicenna), Anti-HCV 3.0 Enhanced Save (Ortho), HCV Ultra (bioMérieux)
2007	Enzygnost HBsAg5.0 (Dade Behring)	HIV antigen/antibody (bioMérieux)†, HIV antigen/antibody (Bio-Rad)†	HCV Ultra (bioMérieux), Anti-HCV 3.0 Enhanced Save (Ortho)

* Third-generation assay.
† Fourth-generation assay.

TABLE 2. The confirmatory test kits (2004-2007)

Years	Confirmatory tests		
	HBsAg confirmatory tests	HIV WB*	HCV RIBA*
2004	HBsAg confirmatory test (DiaSorin)	HIV BLOT 2.2 (Genelabs)	HCV BLOT 3.0 (Genelabs)
2005	HBsAg confirmatory test (Dade-Behring)	HIV BLOT 2.2 (Genelabs)	Inno-LIA HCV Score (Innogenetics)
2006	HBsAg confirmatory test (Dade-Behring)	HIV BLOT 2.2 (Genelabs)	HCV BLOT 3.0 (Genelabs)
2007	HBsAg confirmatory test (Dade-Behring)	HIV BLOT 2.2 (MP Diagnostics)	HCV BLOT 3.0 (MP Diagnostics)

* Third-generation assay.

transfusion-transmitted infections (TTIs). The safety of the blood supply can be estimated by monitoring the prevalence of viral markers amongst the donor population.[12-14]

In this study, the changes in rates of viral markers including HBsAg, anti-HIV, HIV antigen/antibody, and anti-HCV in a 4-year period of 2004 and 2007 are evaluated by analyzing the data of screening tests on all allogeneic blood donations across the country. This is the first report on the trend of blood-borne infections, HBV, HIV, and HCV markers, in Iranian blood donations.

MATERIALS AND METHODS

IBTO consists of 30 regional and 35 local blood transfusion centers and all of them reported aggregated data on donation numbers, type, demographic characteristics (age, sex, and educational level), and screening and confirmatory test results of HBV, HCV, and HIV monthly to IBTO headquarters in Tehran, capital city of Iran. Beside these reports for data collection, most blood transfusion centers sent their database, so the central database includes the results of 2,435,393 (71.6%) donations between 2006 (69.3%) and 2007 (72.5%) of 3,402,420 donations.

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

To assess changes in rates of TTI from 2004 to 2007, data on 6,499,851 allogeneic donations were analyzed. The donations were all screened for HBsAg, anti-HIV, HIV antigen/antibody (from 2005), anti-HCV, and treponemal antibodies as a marker for syphilis infection according to standard operating procedures at each center by approved and similar commercial kits across the country (Table 1). In addition the donations from Khorasan provinces in northeast Iran were also screened for anti–human T-lymphotropic virus-I/II.

During the period of study the sensitivity of screening tests for HBsAg and anti-HCV were similar.[14,15] According to the results of Boston Biomedica, Inc. (West Bridgewater, MA) panels, the sensitivity of anti-HIV from Biotest (Dreieich, Germany) and HIV antigen/antibody from Bio-Rad (Marnes-la-Coquette, France) and bioMérieux (Boxtel, The Netherlands) were similar. Confirmatory tests included the monoclonal neutralization assay for HBsAg, the third-generation recombinant immunoblot assay (RIBA 3.0) for HCV, HIV-I/II Western blot (WB) assay (Table 2).

The HIV WB-negative samples were tested for HIV p24 antigen and if they were repeatedly reactive, the monoclonal neutralization assay was carried out according to the approved algorithm shown in Fig. 1.

According to the IBTO regulation initial reactive donations were excluded and discarded, and the positive donors were permanently rejected for further donation. Donors who were confirmed to be positive in screening tests were notified and invited for postdonation counseling and follow-up, and in the case of HBsAg-positive donors the immediate family was recommended to be vaccinated.

In this study the trend of TTI prevalence was analyzed for all donations across the country and analyses on status

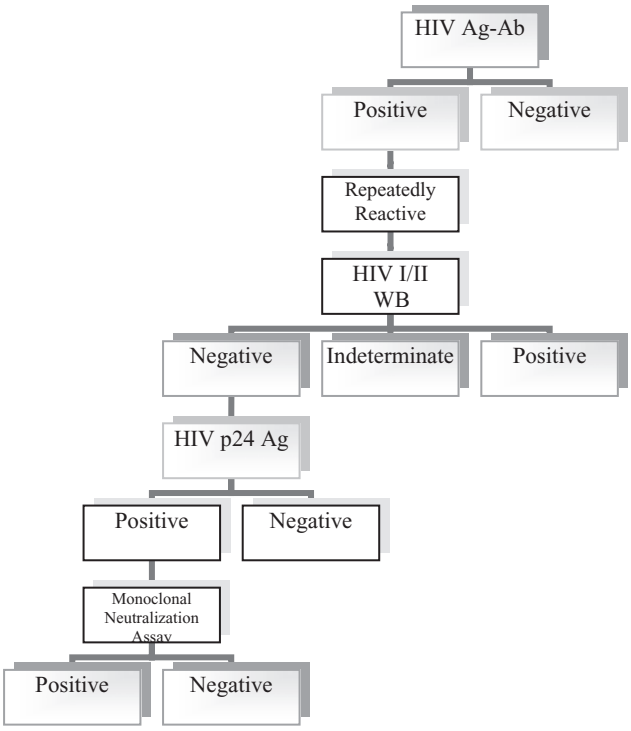

Fig. 1. Algorithm for confirmation of HIV antigen/antibody (Ag-Ab)–positive samples.

of donations, sex, and age with results of the screening tests were performed on 71.6% of all blood donations between 2006 and 2007. To define the prevalence of TTI, the number of positive donations for every year was divided by defined number of blood donations for each year and for assessing frequency of infection and prevalence of HBsAg, anti-HIV, or HIV antigen/antibody, and anti-HCV per 100,000 donations, and 95% confidence interval (CI) using a binomial distribution was calculated. The prevalence of first and last year of study was compared using chi-square test and considered significant if p value was less than 0.05.

RESULTS

The data collected from all the blood transfusion centers across the country showed that a total of 6,499,851 donations were tested in IBTO laboratories during the 4-year period from 2004 through 2007, where 39% were regular, 22% were lapsed, and 39% first-time blood donors. A gradual increase in regular donations from 35% in 2005 to 40% in 2007 was observed. It was noteworthy that a large percentage of donors were educated: 64% had a high school certificate or some kind of university degree. The nonremunerated voluntary donations increased in these years from 96% in 2004 to 100% in 2007. The majority of donors were men (91%) and 58% were under 35 years of age.

The overall prevalence of HBV was 0.56%, which showed a decline from 0.73% in 2004 to 0.41% in 2007 ($p < 0.0000001$; Table 3). The overall prevalence of HIV infection was 0.004%. Its prevalence was constant during 2004 to 2005 followed by a gradual but not significant decline from 0.005% in 2005 to 0.004% in 2007 ($p = 0.11$). The overall prevalence of anti-HCV during the study period was 0.13% and increased from 0.13% in 2004 to 0.14% in 2005 but gradually declined to 0.12% in 2007 ($p = 0.04$; Table 3).

In the central database, data of 2,435,393 donations between 2006 and 2007 of 3,402,420 donations were analyzed. For HBsAg in all of repeat, lapsed, and first-time donations, the prevalence rate decreased. The HBsAg frequency was slightly higher in males than females. It increased by age in males and females but the prevalence decreased from 2006 to 2007 in all of age groups (Table 4).

Anti-HCV showed decreases in repeat and lapsed but slightly increased in first-time blood donations. Anti-HCV prevalence in female donations was significantly lower than male donations ($p < 0.0001$), but the frequency of anti-HCV in all age groups in male donors was similar (Table 5). In comparison, between 2006 and 2007, the frequency of HIV in repeat donations was significantly less than first-time donations ($p < 0.0001$; Table 6).

DISCUSSION

The results obtained from this study clearly demonstrate a declining trend in prevalence of TTIs in donations between 2004 and 2007 (Table 3). The estimated frequency of HBsAg donations entering the blood supply shows a significant and impressive decrease over the 4-year study period (Table 3). During 2006 to 2007 the prevalence of HBsAg declined in different age groups and similar to what was seen in general population the frequency increased with age (Table 4).[16] Similar declines have been reported among blood donors from western countries such as the United Kingdom (1993-2001) and the United States (1995-2002),[17,18] as well as various countries in this region like Turkey, which reports a decrease from 4.92% to 2.10% in the period 1989 through 2004.[19] In Saudi Arabia among blood donors a reduction from 2.58% to 1.67% was reported from 1998 to 2001.[20] In contrast, in some countries such as the United States (1991-1996), Canada (1990-2000), and North of India (1997-2002) a fairly steady prevalence of HBV infection among the blood donors has been reported.[9,12,21]

Regarding HIV infection, the second National Survey in Iran, which was carried out on the general population in 1999 reported a prevalence of 0.0086%. The more recent official reports from the Iranian Center for Disease Control in 2007 mention increased numbers, 16,090 (0.023%)

TABLE 3. Prevalence of HBV, HIV, and HCV infections per 100,000 blood donations units in Iran, 2004 to 2007

Year	Donations/ unit	HBV infections/ unit	HBV infections/10^5 donations	95% CI	HIV infections/ unit	HIV infections/10^5 donations	95% CI	HCV infections/ unit	HCV infections/10^5 donations	95% CI
2004	1,494,282	10,866	727	713-741	76	5.0	3.9-6.1	1902	127	121-133
2005	1,603,149	9,731	607	595-619	79	4.9	3.8-6.0	2323	145	139-151
2006	1,667,412	8,607	516	505-527	60	3.6	2.7-4.5	2119	127	122-132
2007	1,735,008	7,052	406	397-416	68	3.9	3.0-4.8	2071	119	114-124
Total	6,499,851	36,256	558	546-569	283	4.4	3.4-5.4	8415	129	123-134

TABLE 4. Prevalence of HBV rate/10^5 donations in different donation status, age groups, and sex, 2006 to 2007

Markers	2006 Donations	2006 Positive	2006 Prevalence/10^5 donations	2006 95% CI	2007 Donations	2007 Positive	2007 Prevalence/10^5 donations	2007 95% CI
Status of donations								
Repeat	474,515	322	68	61-75	528,469	297	56	50-63
Lapsed	102,178	202	198	170-225	170,871	303	177	157-197
First time	579,136	5198	898	873-922	558,446	4445	796	773-820
Sex and age (years)								
Male								
<29	484,314	1860	384	367-401	524,698	1569	299	284-314
30-39	313,906	1538	490	466-514	338,116	1349	399	378-420
40-49	195,606	1308	669	633-705	219,488	1204	549	518-580
>50	775,25	594	766	705-828	85,756	522	609	557-661
Total	1,072,361	5300	494	481-508	1,168,058	4644	398	386-409
Female								
<29	32,752	106	324	262-385	35,030	80	228	178-278
30-39	21,770	95	436	349-524	22,796	84	368	290-447
40-49	18,576	109	587	477-697	20,355	98	481	386-577
>50	10,370	70	675	517-833	11,207	62	553	416-690
Total	83,468	380	455	410-501	89,388	324	362	323-402
Both male and female (years)								
<29	518,076	1966	379	363-396	559,728	1649	295	280-309
30-39	335,676	1633	486	463-510	360,912	1433	397	376-418
40-49	214,182	1417	662	627-696	239,843	1302	543	513-572
>50	87,895	664	755	698-813	96,963	584	602	554-651
Total	1,155,829	5680	491	479-504	1,257,446	4968	395	384-406

identified cases of infection.[16,22] However, the increase in frequency of HIV infection in the general population has been slower in recent years.[22]

It is, therefore, noteworthy that despite a rising pattern of infection in the general population the prevalence in blood donors decreased from 0.005% in 2004 to 0.004% in 2007 (Table 3) and did not show a similar increase. The HIV prevalence in blood donations in Iran (0.004%) was lower than Ukraine, 0.128% in 2001; Eastern European countries, 0.037% in 2004; and India, 0.35% to 0.44% in 2005.[23-26]

In this study the HCV prevalence shows a gradual decline in blood donations from 0.14% in 2005 to 0.12% in 2007, which for the donor population is an important achievement (Table 3). Whereas the frequency of HCV exposure in the general population in Iran had an increase from 0.3% in 1997 to approximately 1% in 2006,[1,27-31] the prevalence in the general population was approximately 2.5- to 8-fold higher than what was reported in blood donations in Iran.

Other countries such as the United Kingdom, Canada, the United States, and Germany reported similar declining trends among blood donors in their countries.[9,12,13,17,18] In various countries in this region a decline in the prevalence of HCV infection has also been reported; for example, in Saudi Arabia the prevalence among national blood donors has declined from 1.04% in 1998 to 0.59% in 2001, and in Lebanon blood donors, from 1.22% in 1997 to 0.33% in 2003.[20,32] The slight increase that was detected in anti-HCV prevalence in Iranian blood donors around 2005 may be due to two issues: the first explanation may be that in that particular year the total number of donations was higher (7%) than previous years mainly due to an increase in number of first-time donors. The second point that could have contributed to this phenomenon was that confirmation kits in use during that period were changed, leading to increase in number of confirmed positives. Various factors could have contributed to the declining prevalence of TTI; a number of more important contributing factors are discussed below.

TABLE 5. Prevalence of HCV rate/10^5 donations in different donation status, age groups, and sex, 2006 to 2007

	2006				2007			
Markers	Donations	Positive	Prevalence/10^5 donations	95% CI	Donations	Positive	Prevalence/10^5 donations	95% CI
Status of donations								
Repeat	474,515	134	28	24-33	528,469	112	21	17-25
Lapsed	102,178	83	81	64-99	170,871	99	58	47-69
First time	579,136	1339	231	219-244	558,446	1348	241	229-254
Sex and age (years)								
Male								
<29	484,314	607	125	115-135	524,698	605	115	106-125
30-39	313,906	504	161	147-174	338,116	553	164	150-177
40-49	195,606	295	151	134-168	219,488	275	125	111-140
>50	77,525	114	147	120-174	85,756	118	138	113-162
Total	1,072,361	1520	142	135-149	1,168,058	1551	133	126-139
Female								
<29	32,752	7	21	5-37	35,030	10	29	11-46
30-39	21,770	15	69	34-104	22,796	8	35	11-59
40-49	18,576	15	81	40-122	20,355	10	49	19-80
>50	10,370	6	58	12-104	11,207	4	36	1-71
Total	83,468	43	52	36-67	89,388	32	36	23-48
Both male and female (years)								
<29	518,076	614	119	109-128	559,728	615	110	101-119
30-39	335,676	519	155	141-168	360,912	561	155	143-168
40-49	214,182	310	145	129-161	239,843	285	119	105-133
>50	87,895	120	137	112-161	96,963	122	126	103-148
Total	1,155,829	1563	135	128-142	1,257,446	1583	126	120-132

TABLE 6. Prevalence of HIV rate/10^5 donations in different donation status, age groups, and sex, 2006 to 2007

	2006				2007			
Markers	Donations	Positive	Prevalence/10^5 donations	95% CI	Donations	Positive	Prevalence/10^5 donations	95% CI
Status of donations								
Repeat	474,515	0	0.0	0.0-0.0	528,469	2	0.4	0.0-0.9
Lapsed	102,178	2	2.0	0.0-4.7	170,871	2	1.2	0.0-3.1
First time	579,136	39	6.7	4.8-8.7	558,446	51	9.1	6.4-11.9
Sex and age (years)								
Male								
<29	484,314	13	2.7	1.1-4.3	524,698	13	2.5	1.1-3.8
30-39	313,906	16	5.1	2.5-7.6	338,116	20	5.9	3.4-8.5
40-49	195,606	4	2.0	0.1-4.0	219,488	14	6.4	3.0-9.7
>50	77,525	0	0.0	0.0-0.0	85,756	4	4.7	0.2-9.2
Total	1,072,361	33	3.1	1.9-4.3	1,168,058	51	4.4	3.2-5.5
Female								
<29	32,752	1	3.1	0.0-9.1	35,030	2	5.7	0.0-13.5
30-39	21,770	4	18.4	0.3-36.4	22,796	1	4.4	0.0-13.0
40-49	18,576	1	5.4	0.0-16.0	20,355	1	4.9	0.0-14.5
>50	10,370	0	0.0	0.0-0.0	11,207	0	0.0	0.0-0.0
Total	83,468	6	7.2	1.5-12.9	89,388	4	4.5	0.2-8.8
Both male and female (years)								
<29	518,076	14	2.7	1.3-4.1	559,728	15	2.7	1.3-4.1
30-39	335,676	20	6.0	3.4-8.5	360,912	21	5.8	3.5-8.2
40-49	214,182	5	2.3	0.4-4.3	239,843	15	6.3	3.1-9.4
>50	87,895	0	0.0	0.0-0.0	96,963	4	4.1	0.2-8.0
Total	1,155,829	39	3.4	2.2-4.6	1,257,446	55	4.4	3.4-5.4

A uniform and more efficient donor selection and deferral procedure is in place, which is carried out by trained medical doctors. In the same process allowing self-deferral before registration of donors and the setup of confidential unit exclusion may also be important. Undoubtedly, the decrease in number of replacement donations from 4% in 2004 to 0% in 2007 plays another significant role.[21,33,34]

Another crucial variable is an increase in the number of regular donations, since it has been well documented that first-time blood donors almost always pose a greater risk of infectious donation than repeat donors.[35-37] It is most unfortunate that due to incomplete application of computer software throughout the country in this period (2004-2007), it is not possible at this point to have the prevalence categorized in the three

groups of first-time, lapsed, and regular donors. In 2006 to 2007 the prevalence of HBsAg, HCV, and HIV in repeat donations was significantly less than first-time blood donations (Tables 4-6).

The educational efforts by IBTO and the Ministry of Health to increase public knowledge on blood-borne infections and routes of transmission are another important factor that should be considered. Increasing use of software and the existence of data registry of blood donors with a history of positive results in blood screening tests are other possible important factors having a role in the observed decline in prevalence. Finally, hepatitis B immunization programs of children, pregnant women, health care workers, families of HBsAg-positive donors, multitransfused patients, and their families also may play an important role in decreasing the occurrence of hepatitis B.

CONCLUSION AND RECOMMENDATIONS

The lower prevalence of TTI in blood donations compared to the general population and trends of their prevalence suggest that most of the safety measures employed at IBTO in the recent years have been effective. However, some extra strategies, examples of which follow, may contribute to improving blood safety in Iran to a higher level:

- Providing more information and education material about risk factors and the importance of safe blood donations in the general population.
- Encouraging more educated groups to donate. This may contribute to a decline in TTI prevalence in blood donors since these groups have better understanding of the screening educational material and may defer from donation if at risk.
- Increasing activities of voluntary counseling and testing centers which reduces the number of individuals donating blood just to be tested.
- Improving public health programs with a focus on counseling and screening of those engaged in high-risk activities.
- Improvement in donor recruitment and increasing regular donor proportion.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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