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Original Article

# Prevalence and Trends of Transfusion-Transmissible Infections and Study of Confidential Unit Exclusion among Blood Donors in Kurdistan Province of Iran

**Mahtab Maghsoodlu[1]M.D., Pejman Salehifar[2]M.Sc., Parisa Rahimzadeh[2]M.Sc. Woria Babahajian[2]M.Sc., Saylan Mohammadi[2]M.Sc., Serveh Babahajian[2]M.Sc. Masoumeh Souri[2]M.D., Mohammad Saied Karimian[2]M.D. Shirin Ferdowsi[1,2*]Ph.D.**

[1]Blood Transfusion Research Center, High Institute for Research and Education in Transfusion Medicine, Tehran, Iran.
[2]Kurdistan Blood Transfusion Organization, Sanandaj, Iran.

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## A B S T R A C T

**Background and Aims:** Evaluation of the prevalence of transfusion-transmissible infections (TTIs) in blood donors is a valuable index of donor selection and blood safety. This study was conducted to explore the prevalence and trends of TTIs markers and study of confidential unit exclusion (CUE) option among blood donors in Kurdistan province in the west of Iran.

**Materials and Methods:** We conducted a cross-sectional analysis on all volunteer donors from 2007 to 2014. Serologic tests were performed to detect TTIs markers. The seropositive results were confirmed using the confirmatory assays.

**Results:** Of 197568 cases of the blood donated during 2007 and 2014, 0.29% was positive for Hepatitis B surface antigen, 0.006% for anti-human immunodeficiency virus and 0.06% for anti-hepatitis C virus. The prevalence of human immunodeficiency virus remained stably below 0.02% during the study period whereas the prevalence of Hepatitis B surface antigen showed a downward trend over the period of 8 years. The trend of hepatitis C virus infection frequency had increasing patterns from 2007 to 2009 and decreasing patterns thereafter to 0.05%. CUE was chosen in 1442 (0.7%) donations. Out of this number, 864 (59.9%) were first time blood donors and 578 (40.08%) repeat donors. CUE-positive donations had significantly higher risk of TTIs markers ($p< 0.000$).

**Conclusions:** The prevalence rate of viral infections has been reduced to low levels in blood donations over the 8 years. Moreover, CUE is considered an effective option for identifying donors with increased risk of TTIs markers.

*Corresponding Author: Blood Transfusion Research Center, High Institute for Research and Education in Transfusion Medicine, Tehran, Iran. **P.O. Box:** 14665-1157, **Tel/Fax:** +982144720740, **Email:** ferdowsishirin@gmail.com

## Introduction

One of the problems in providing safe blood units is the risk of transfusion-transmissible infections (TTIs). Viral infections such as hepatitis C virus (HCV), hepatitis B virus (HBV) and human immunodeficiency virus (HIV) are the greatest concerns [1]. Screening for TTIs is a routine practice to guarantee the safety of blood products. Moreover, monitoring the trends in the prevalence of TTIs in blood donors will provide a mechanism to evaluate the safety of the blood supply and the effectiveness of donor deferral criteria [2]. To improve the safety of the blood, other measures, such as the use of confidential unit exclusion (CUE), have also been adopted by many blood banks. The main goal of the CUE process is detecting donors who are infected but are in the window period. This process was designed for detecting donors who denied their involvement in high-risk activities during the pre-donation interview [2] and an opportunity to confidentially exclude their blood [3]. In 2015, World Health Organization (WHO) reported that the prevalence of HBV, HCV and HIV infections among donors varies from 0.008% to 6.08%, 0.004% to 1.96%, and 0.0004% to 2.0%, respectively in different parts of the world [4]. The prevalence of HBV, HIV and HCV infections in Iran is 0.7% [5], 0.004% [2] and 0.5% [6] in blood donors, respectively. Therefore, this study was conducted to report the prevalence and trends of TTIs infections and the prevalence of CUE among blood donors in Kurdistan province, west of Iran, during an eight-year period. To our knowledge, this is the first report that extensively examines TTIs markers among the donor population in this part of Iran.

## Materials and Methods

This study was conducted at the Kurdistan Blood Transfusion Center over a period of 8 years (between 2007 and 2014). All donors were classified as first time if they had a history of only one donation. Repeat donor status was defined as having donated more than once during the study period. Serologic tests were performed on all donations using commercial products to detect surface antigens of the HBV (HBsAg), antibodies against the HCV (anti-HCV) and antibodies against the HIV types 1 and 2 (anti-HIV 1/2). All initially positive samples were retested. These seropositive results were confirmed using the HBs Ag confirmatory assay, HIV I/II western blot, and HCV recombinant immunoblot assay. Regarding HIV, the HIV western blot-negative samples were further evaluated for the presence of HIV P24 antigen and the reactive samples were confirmed using the monoclonal neutralization assay (Table 1). In addition, the use of the CUE option was studied among the donors. The frequencies of the replies to the CUE were calculated in respect to gender, age and category of donation.

**Statistical analysis**

Statistical analysis was carried out using SPSS 16 software and comparisons were evaluated with Chi-square test.

**Table 1.** Kits used for donor screening, 2007-2014

| Screening test kits | | | |
|---|---|---|---|
| **Year** | **HBsAg screening test kit (Manufacturer)** | **Anti-HCV screening test kit (Manufacturer)** | **HIV Ag/Ab screening test kit (Manufacturer)** |
| **2007-2009** | Enzygnost HBsAg 5.0 (Dade Behring, Germany) | HCV 3.0 with enhanced SAVe (Ortho- Clinical Diagnostics, USA), Hepanostica Anti-HCV Ultra (BioMerieux, France) | Genscreen Plus HIV Ag-Ab (Bio-Rad, USA), Vironostika HIV Uni-Form II Ag/Ab (BioMerieux, France) |
| **2010** | Enzygnost HBsAg 5.0 (Dade Behring, Germany), Enzygnost HBsAg 6.0 (Siemens, Germany) | HCV 3.0 with enhanced SAVe (Ortho- Clinical Diagnostics, USA), Hepanostica Anti-HCV Ultra (BioMerieux, France) | Genscreen Plus HIV Ag-Ab (Bio-Rad, USA), Vironostika HIV Uni-Form II Ag/Ab (BioMerieux, France) |
| **2011** | Enzygnost HBsAg 6.0 (Siemens, Germany) | HCV 3.0 with enhanced SAVe (Ortho- Clinical Diagnostics, USA), Hepanostica Anti-HCV Ultra (BioMerieux, France) | EIAgen Detect HIV 4 Total Screening Kit (Adaltis, Canada) |
| **2012-2014** | Enzygnost HBsAg 6.0 (Siemens, Germany) | EIAgen HCV Ab test (Adaltis Canada) | EIAgen Detect HIV 4 Total Screening Kit (Adaltis ,Canada) |
| **Confirmatory test kits** | | | |
| **Year** | **HBsAg confirmatory test (Manufacturer)** | **HCV RIBA (Manufacturer)** | **HIV Western Blot (Manufacturer)** |
| **2007-2008** | HBsAg confirmatory test (Dade Behring, Germany) | MP Diagnostics HCV BLOT 3.0 (MP Biomedicals, USA) | HIV Blot 2.2 (Genelabs diagnostics, Singapore), MP Diagnostics HIV Blot 2.2 (MP Biomedicals, USA) |
| **2009** | HBsAg confirmatory test (Dade Behring, Germany), HBsAg confirmatory test (Siemens, Germany) | HCV Blot 3.0 (Genelabs diagnostics, Singapore) | HIV Blot 2.2 (Genelabs diagnostics, Singapore), MP Diagnostics HIV Blot 2.2 (MP Biomedicals, USA) |
| **2010** | HBsAg confirmatory test (Siemens, Germany) | MP Diagnostics HCV BLOT 3.0 (MP Biomedicals, USA) | MP Diagnostics HIV Blot 2.2 (MP Biomedicals, USA) |
| **2011** | HBsAg confirmatory test (Siemens, Germany) | HCV Blot 3.0 (Genelabs diagnostics, Singapore) | MP Diagnostics HIV Blot 2.2 (MP Biomedicals, USA) |
| **2012-2014** | HBsAg confirmatory test (Siemens, Germany) | MP Diagnostics HCV BLOT 3.0 (MP Biomedicals, USA) | MP Diagnostics HIV Blot 2.2 (MP Biomedicals, USA) |

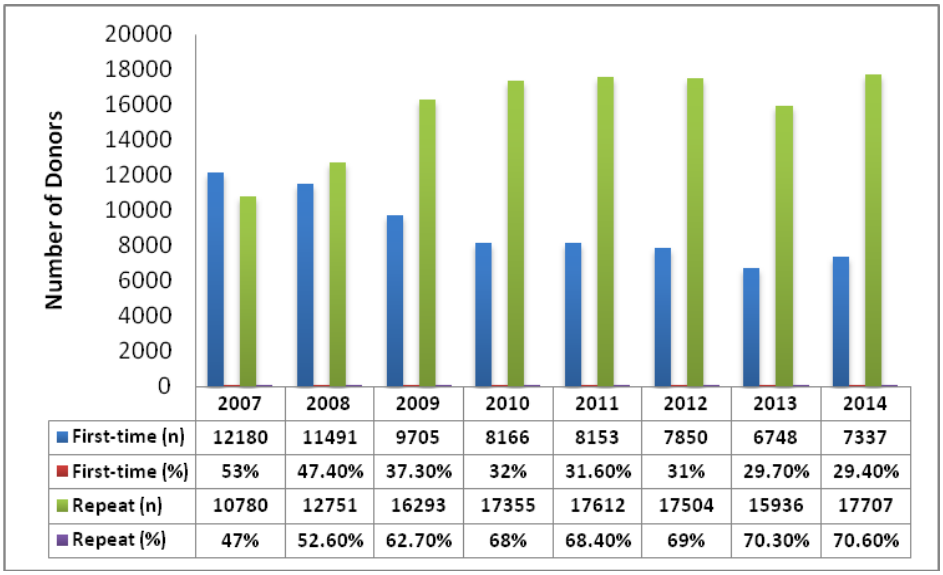
## Results

### Blood donor population

Of the qualified donors during 2007 to 2014, 197568 individuals donated their blood; 71630 (36.2%) donations were from first-time donors and 125938 (63.74%) from individuals who had donated blood two or more times. A total of 176104 (89.13%) donors were male and 21464 (10.86%) were female. Totally, 33.84% of the donations (66892) were from individuals aged 25 to 35. An increase in repeat donors was identified from 47% in 2007 to 70.6% in 2014 (Fig. 1).

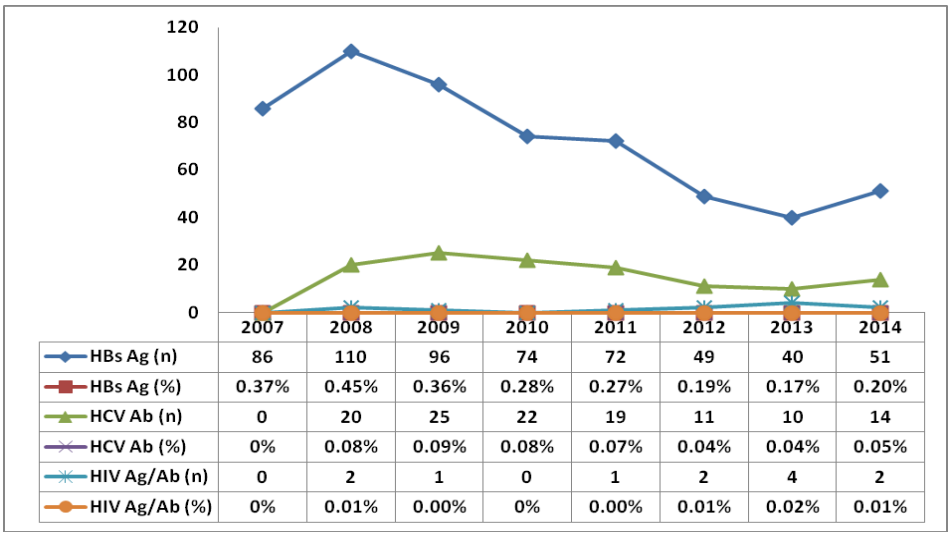
### Prevalence and trends of TTIs in blood donors

The prevalence of HIV, HBV and HCV was observed to be 0.006% (12 donors), 0.29% (578 donors) and 0.06% (121 donors), respectively. In our study, the HBsAg and HCV Ab prevalence among blood donors indicated a downward trend over the period of eight years (Fig. 2). The prevalence of HIV remained stable below 0.02% during the study period, whereas the prevalence of HBs Ag decreased from 0.45% to 0.2% between 2008 and 2014. Prevalence of confirmed HCV positive results in donating blood has also decreased from 0.08% in 2010 to 0.05% in 2014. Five donors had multiple infections: 4 donors were infected with HCV and HIV while another suffered from HBV and HCV infections. All the subjects were male, first time blood donor, with the mean age of 38 years and schooling below 12 years. When grouping (HCV, HIV, and HBV) by years, the percentage was decreasing from 2008 (0.54 %) to 2014 (0.26 %). During our study, most of the infection was HBsAg 578/711 (81.2%) followed by HCV 121/711 (17 %); the least was HIV 12/711 (1.6 %).




| | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 |
|---|---|---|---|---|---|---|---|---|
| First-time (n) | 12180 | 11491 | 9705 | 8166 | 8153 | 7850 | 6748 | 7337 |
| First-time (%) | 53% | 47.40% | 37.30% | 32% | 31.60% | 31% | 29.70% | 29.40% |
| Repeat (n) | 10780 | 12751 | 16293 | 17355 | 17612 | 17504 | 15936 | 17707 |
| Repeat (%) | 47% | 52.60% | 62.70% | 68% | 68.40% | 69% | 70.30% | 70.60% |

**Fig. 1.** Number of donors in Kurdistan province, 2007–2014




| | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 |
|---|---|---|---|---|---|---|---|---|
| HBs Ag (n) | 86 | 110 | 96 | 74 | 72 | 49 | 40 | 51 |
| HBs Ag (%) | 0.37% | 0.45% | 0.36% | 0.28% | 0.27% | 0.19% | 0.17% | 0.20% |
| HCV Ab (n) | 0 | 20 | 25 | 22 | 19 | 11 | 10 | 14 |
| HCV Ab (%) | 0% | 0.08% | 0.09% | 0.08% | 0.07% | 0.04% | 0.04% | 0.05% |
| HIV Ag/Ab (n) | 0 | 2 | 1 | 0 | 1 | 2 | 4 | 2 |
| HIV Ag/Ab (%) | 0% | 0.01% | 0.00% | 0% | 0.00% | 0.01% | 0.02% | 0.01% |

**Fig. 2.** Trends of HBV, HCV and HIV infections among blood donors in Kurdistan province, 2007-2014

**Prevalence of TTIs in CUE-positive versus CUE negative donors**

Over the 8 years, the CUE 'do not use my blood' option was chosen by 1442 (0.7%) donors. Out of this number, 864 (59.9%) were first time blood donors and 578 (40.08%) repeat donors. Table 2 displays the CUE frequency according to donation status, gender, age and education. CUE-positive donations had significantly higher risk of TTIs markers (Table 3). The high frequencies of serological tests were obtained for the anti-HCV serologic marker (1.24%), followed by anti-HBV (0.69%). For the anti-HIV (0.2%) serological marker, frequencies were 0.2% in CUE-positive donors. Higher HCV seroprevalence among males compared to females was statistically significant (p<0.019).

**Table 2.** Confidential unit exclusion use by donor demographics

| Demographic characteristics | | CUE positive (n, %) | CUE negative (n, %) | p-value |
|---|---|---|---|---|
| **Donation Status** | First-time | 864 (1.2%) | 70766 (98.79%) | 0.000 |
| | Repeat | 578 (0.45%) | 125360(99.54%) | |
| **Gender** | Female | 65 (0.3%) | 21399(99.69%) | 0.000 |
| | Male | 1377 (0.78%) | 174727 (99.21%) | |
| **Age** | ≥18 <25 | 202 (0.49%) | 40852 (99.50%) | 0.000 |
| | ≥25 <35 | 748 (1.11%) | 66144 (98.88%) | |
| | ≥35 <45 | 301 (0.58%) | 51671 (99.42%) | |
| | ≥45 <55 | 137 (0.45%) | 30028 (99.54%) | |
| | ≥55 <65 | 54 (0.72%) | 7431 (99.27%) | |
| **Education** | Less than 12 years schooling | 1038 (0.74%) | 137706 (99.25%) | 0.592 |
| | 12 or more years schooling | 404 (0.68%) | 58420 (99.31%) | |
| **Screening test** | HBV | 10 (0.69%) | 568 (0.28%) | 0.000 |
| | HCV | 18 (1.24%) | 103 (0.05%) | |
| | HIV | 3 (0.2%) | 9 (0.004%) | |

CUE= confidential unit exclusion; HBV= hepatitis B virus; HCV= hepatitis C virus; HIV= human immunodeficiency virus

**Table 3.** Frequency of TTI markers between CUE-positive and CUE-negative donations, according to the type of donor

| Years | CUE | Donor status | | p-value | HBs Ag | | p-value | HCV Ab | | p-value | HIV Ag/Ab | | p-value |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | First Time | Repeat | | Positive | Negative | | Positive | Negative | | Positive | Negative | |
| 2007 | N | 12124 | 10734 | 0.165 | 84 | 22783 | 0.005 | 0 | 22867 | 0 | 0 | 22867 | 0 |
| | P | 56 | 37 | | 2 | 91 | | 0 | 93 | | 0 | 93 | |
| 2008 | N | 11407 | 12714 | 0.000 | 109 | 24012 | 0.541 | 20 | 24101 | 0.751 | 0 | 24121 | 0.000 |
| | P | 84 | 37 | | 1 | 120 | | 0 | 121 | | 2 | 119 | |
| 2009 | N | 9599 | 16232 | 0.000 | 95 | 25740 | 0.040 | 18 | 25817 | 0.000 | 1 | 25834 | 0.936 |
| | P | 110 | 57 | | 1 | 166 | | 7 | 160 | | 0 | 167 | |
| 2010 | N | 8087 | 17291 | 0.000 | 73 | 25305 | 0.361 | 18 | 25360 | 0.000 | 0 | 25378 | 0 |
| | P | 79 | 64 | | 1 | 142 | | 4 | 139 | | 0 | 143 | |
| 2011 | N | 7977 | 17477 | 0.000 | 70 | 25384 | 0.222 | 19 | 25435 | 0.630 | 1 | 25453 | 0.912 |
| | P | 176 | 135 | | 2 | 309 | | 0 | 311 | | 0 | 311 | |
| 2012 | N | 7683 | 17396 | 0.000 | 47 | 25032 | 0.043 | 11 | 25068 | 0.728 | 1 | 25078 | 0.000 |
| | P | 167 | 108 | | 2 | 273 | | 0 | 275 | | 1 | 274 | |
| 2013 | N | 6664 | 15869 | 0.000 | 39 | 22494 | 0.153 | 9 | 22524 | 0.000 | 4 | 22559 | 0.870 |
| | P | 84 | 67 | | 1 | 150 | | 1 | 150 | | 0 | 151 | |
| 2014 | N | 7270 | 17295 | 0.000 | 51 | 24853 | 0.542 | 8 | 24896 | 0.000 | 2 | 24902 | 0.904 |
| | P | 108 | 73 | | 0 | 181 | | 6 | 175 | | 0 | 181 | |

TTI= transfusion-transmissible infections; CUE= confidential unit exclusion; HbsAg= hepatitis B surface antigen; HCV= hepatitis C virus; HIV= human immunodeficiency virus; N= negative; P= positive

## Discussion

In this cross-sectional study, 197568 individuals who had donated blood between 2007 and 2014 at Kurdistan province were examined. The prevalence rate of 0.29% for HBV was observed that was lower than those reported in the previous studies in Iran, i.e., 0.56% between 2004–2007 [2], and 0.38% between 2005–2011 [7] but was higher than that of the recent report from south of Iran i.e., 0.15% between 2004-2014 [8]. The prevalence of HCV infection in our study was 0.06% that is lower than other regions in Iran, i.e., 0.13% between 2004–2007 [2], 0.11% between 2005–2011 [7] and 0.1% between 2004-2014 [8]. In addition, the prevalence of HIV infection was 0.006% that is similar to previous studies from Iran, i.e., 0.0054% [7] and 0.004% [2, 8]. In Kurdistan Province, the prevalence of HIV remained stable below 0.02% during 2007-2014 whereas the prevalence of HBsAg and HCV decreased from 2009 to 2013. These findings are consistent with other reports in Iran. In Yazd province, the prevalence rate of hepatitis B, C and HIV infection decreased from 0.37%, 0.14% and 0% in 2004 to 0.14%, 0.05% and 0% in 2010, respectively [9]. In a study in Tehran [10], the prevalence rate of HBV, HCV and HIV in donors indicated a decline from 0.423%, 0.139% and 0.011% in 2008 to 0.153%, 0.069 % and 0.009% in 2013. In a recent study in south of Iran [8], the

seroprevalence rate of HBV and HCV from 2004 to 2014 showed decreasing trend from 0.46% to 0.06% and 0.329% to 0.045%, respectively, that was significant, whereas HIV infection had insignificant decline from 0.0173% in 2004 to 0.0028% in 2014. In our study, seroprevalence of TTIs was higher among male compared to female Kurdish donors. This finding may be due to the lower number of female donors. The majority of age-group donors were those ranging from 26 to 35 years (33.8%). This differs from the data published by WHO which reported that 45% of donors were aged 25 or lower [11].

On the other hand, in the present study, the CUE was chosen in 1442 (0.7%) donations, most frequently by first-time blood donors ($p<0.000$), by men ($p<0.000$) and by donors between 26-35 years old ($p<0.000$). This rate of CUE is higher than the previous reports on CUE (0.15-0.38% range) in the developed countries [12, 13]. In fact, higher rates have been reported to occur in Iran (0.6-0.92%) in Tehran Blood Transfusion Center [14, 15] and Brazil (1.1-3.2%) (16-19). Our results indicated that CUE-positive donations had significantly higher risk of TTIs markers ($p<0.000$). The association between CUE use and higher prevalence of serologic markers has been previously described [20-23]. In a study, Amini Kafi-Abad et al. [24] identified that CUE helps to enhance blood safety in Iran.

## Conclusions

Totally, the low prevalence rate of TTIs in blood donors and its decreasing trends demonstrates that the effective safety procedures have been performed at the Kurdistan blood transfusion organization during these years. In Kurdistan province, an increase in repeat donations was observed from 47% in 2007 to 70.6% in 2014. In addition, the function of CUE is critical in improving blood safety.

## Conflict of Interest

There is no conflict of interest in this article.

## Acknowledgements

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