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The prevalence and trends of transfusion-transmissible infectious pathogens among first-time, voluntary blood donors in Xi'an, China between 1999 and 2009

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SUMMARY

Objectives: The prevalence of infectious diseases is increasing in developing countries, and this may threaten the biological safety of donated blood. This study analyzed trends in the prevalence of transfusion-transmissible infectious pathogens among Chinese, first-time, voluntary blood donors from 1999 to 2009 to evaluate the potential for disease transmission.
Methods: From 1999 to 2009, all first-time donors at the Xi'an Blood Service (XBS) were screened for hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), and syphilis infections using enzyme-linked immunosorbent assays (ELISA); results were confirmed using alternative commercial kits. The prevalence and temporal trends were analyzed using the Cochran–Armitage trend test and other appropriate methods.
Results: From 1999 to 2009, 263 299 first-time blood donors were analyzed. The overall prevalence rates were 1.16% for HBV, 0.51% for HCV, 0.02% for HIV, and 0.31% for syphilis. There was a significant decrease in the trend for HBV and HCV infections, while a significant increase was found for syphilis. The prevalence of HIV infection remained low and stable during the study period.
Conclusions: These findings suggest that HBV infection is the primary threat to blood safety, while the increasing prevalence of syphilis might also be a potential threat.

1. Introduction

Blood products, such as blood components for both transfusions and plasma derivatives, are essential therapeutics in modern medicine. Red blood cell transfusions are vital in saving lives during emergencies and in other cases where interventions are necessary.[1] For example, blood coagulation factor concentrates dramatically improve the life expectancy and quality of life of hemophilia patients. Until recently, blood products were considered to be purely physiological materials that were not expected to be harmful. However, during the early 1990s in Henan Province of China, a large number of human immunodeficiency virus (HIV) cases were found in people who had previously been paid to donate blood.[2] In addition to HIV, hepatitis B virus (HBV) and hepatitis C virus (HCV) were found to be associated with blood transfusions in Chinese adults.[3–5]

The safety of the blood supply can be estimated by monitoring the prevalence of viral markers in the donor population. A higher prevalence of donations containing infectious contaminants is found in first-time blood donors compared to repeat donors. Therefore, the evaluation and monitoring of these viruses in first-time blood donors is essential for controlling the potential risk of transfusion-transmissible infections (TTIs).[6] Long-term trends in the rates of infectious diseases among blood donors may also reflect trends in the population risk. Each year the Xi'an Blood Service (XBS) collects more than 20 000 blood units from first-time blood donors, and since 1999, has maintained a research database of all blood donations, including all test results. The database provides a unique opportunity for monitoring the trends in blood-borne infections among blood donors over time. In this study,

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changes in viral markers, including HBV surface antigen (HBsAg), antibodies to HCV (anti-HCV), and antibodies to HIV (anti-HIV), over an 11-year period (1999 through 2009) were evaluated by analyzing the screening test data from allogeneic blood donations at XBS.

2. Methods

The XBS covers 17 regions located across Shaanxi Province, China. All of the XBS regions use standard blood donor recruitment and donation testing procedures. The XBS headquarters in Xi'an, the capital of Shaanxi Province, collects and records blood donations from all of the regions and manages these records in a centralized database. The data analyzed in this report were extracted from the XBS database. The data obtained from the XBS database were examined for any duplications, which were subsequently removed, and checked for any missing values, and then supplemented with confirmatory test results.

For the purpose of this study, data from 263 299 first-time whole-blood donors obtained from 1999 to 2009 were analyzed. A first-time donor was defined as a donor who had not previously donated blood according to the blood center's current records or according to the person's own report. The donations were all screened for HBsAg, anti-HCV, anti-HIV-1/2 or HIV antigen/antibody, and anti-*Treponema pallidum* (anti-TP) using enzyme-linked immunosorbent assays (ELISA) in accordance with the standard operating procedures at each center, using the same commercial kits approved by the Ministry of Health of the People's Republic of China; results were confirmed with alternative commercial kits (Table 1). The tests used included a monoclonal neutralization assay for HBV, an enzyme immunoassay method with an alternative assay for HCV, *Treponema pallidum* particle agglutination assays for syphilis, and an ELISA repeated in duplicate followed by a Western blot for HIV (Table 1). A double-positive donor who was confirmed as being truly positive was permanently disqualified from further donation and was invited for free counseling and follow-up. Vaccinations were recommended for the immediate family members of HBsAg-positive donors.

To define the prevalence of TTIs, the number of TTI-positive donations during each year was divided by the total number of blood donations that year, and the 95% confidence interval (CI) was calculated using a binomial distribution. The prevalence across different years was compared using the Chi-square test. The Cochran–Armitage trend test (Z) was used to determine any significant trends in the rates of infected donations over time.[7–9] Statistical significance was set at $p < 0.05$. All statistical tests were performed using SAS 9.1 (SAS Institute, Cary, NC, USA).

3. Results

The data collected from XBS showed that there was a total of 263 299 first-time donations that were tested in the XBS laboratories during the 11-year period under study. The majority of the donors were men (64.48%), and 84.65% were under 40 years of age. In the XBS database there was a total of 3057 confirmed HBsAg-positive donations, 1352 confirmed anti-HCV-positive donations, and 41 confirmed anti-HIV-positive donations among the 263 299 first-time donors between 1999 and 2009. Tables 2 and 3 show the prevalence rates of the infectious disease markers HBsAg, anti-HIV, and anti-HCV that were confirmed among first-time whole-blood donors by sex and age. The overall prevalence was 1.16% for HBV (95% CI 1.12–1.20%), 0.51% for HCV (95% CI 0.49–0.54%), 0.02% for HIV (95% CI 0.01–0.03%), and 0.31% for syphilis (95% CI 0.29–0.33%) (Table 2). HBV infection was the most common reason for donor disqualification from donating blood (approximately 70%).

The prevalence rates of HBsAg decreased over time among both sexes, except in 2001. After controlling for age and gender, we found that HBV infection was more common in men (1.26%, 95% CI 1.20–1.31%) than in women (1.00%, 95% CI 0.93–1.06%) (Chi-square = 33.76, $p < 0.0001$), and both men and women in the 30–39 years age group had the highest prevalence of HBV infection. The prevalence in men was significantly higher than in women in the 30–39, 40–49, and >50 years age groups ($p < 0.05$). The prevalence of HBV decreased with age in women, with the highest prevalence observed in the <29 years age group (1.07%, 95% CI 0.98–1.16%) and the lowest prevalence observed in the >50 years age group (0.67%, 95% CI 0.40–1.04%). The prevalence of HBV decreased over time ($Z = -33.88$, $p < 0.0001$), peaking in 2001 (2.74%, 95% CI 2.53–2.96%) and decreasing rapidly until 2004. The prevalence of HBV was stable between 2005 and 2009 (Table 2). Overall the prevalence of HBsAg decreased dramatically over the 11 years, from 1.88% (95% CI 1.69–2.09%) in 1999 to 0.59% (95% CI 0.52–0.68%) in 2009.

Anti-HCV prevalence rates decreased over time in both sexes. HCV prevalence in blood donors showed a gradual decline, from 1.14% in 1999 to 0.42% in 2009 ($Z = -13.88$, $p < 0.0001$). HCV infection in women (0.63%, 95% CI 0.58–0.68%) was significantly higher than in men (0.45%, 95% CI 0.42–0.48%) (Chi-square = 38.12, $p < 0.0001$) (Table 3). After controlling for both age and gender, we found that men in the 40–49 years age group (0.80%, 95% CI 0.67–0.94%) and women in the 30–39 years age group (0.94%, 95% CI 0.81–1.08%) had the highest prevalence of HCV. The prevalence of HCV in men in the 30–39 years age group (0.63%, 95% CI 0.55–0.72%) was significantly lower than that in women (0.94%, 95% CI 0.81–1.08%) in the same age group (Chi-square = 16.14, $p < 0.0001$). In general, HCV prevalence decreased by 6.32% (0.072% of the original prevalence) per year between 1999 and 2009.

The prevalence of HIV infection was low and stable during the research period ($Z = 1.24$, $p = 0.21$), and there were no statistically significant differences observed among any of the age and gender groups. Males older than 50 years had a slightly higher HIV prevalence than those in the other age groups.

A significant increase in syphilis prevalence was observed ($Z = 3.26$, $p = 0.001$). Men in the 40–49 years age group (0.73%, 95% CI 0.61–0.86%) and women in the >50 years age group (0.60%, 95%

Table 1
Screening tests and confirmatory test kits (1999–2009)

Test items	Screening tests	Confirmatory tests
HBsAg (1999–2009)	HBsAg test (Lizhu Diagnostics, China)	HBsAg test (DiaSorin, Italy)
Anti-HCV(1999–2009)	Anti-HCV (Beijing Wantai, China)	Anti-HCV (DiaSorin, Italy)
Anti-HIV-1/2 (1999–2004)	Anti-HIV-1/2 (Beijing Wantai, China)	Anti-HIV-1/2 (Bio-Rad, France)
HIV antigen/antibody[a] (2005–2009)	HIV antigen/antibody (Beijing Wantai, China)	HIV antigen/antibody (Bio-Rad, France)
Anti-TP (1999–2009)	Anti-TP (Lizhu Diagnostics, China)	Anti-TP (Fujirebio Diagnostics, Japan)

HBsAg, hepatitis B surface antigen; anti-HCV, antibody to hepatitis C virus; anti-HIV, antibody to human immunodeficiency virus; anti-TP, antibody to *Treponema pallidum*; EIA, enzyme immunoassay.
[a] The HIV antigen/antibody combo assays replaced the antibody-only EIA in 2005.