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ORIGINAL RESEARCH

Prevalence and Trends of Transfusion-Transmissible HBV Infection Among Blood Donors in Southwestern China: A Six-Year Retrospective Study

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Objective: Hepatitis B virus (HBV) infection is a significant global public health concern, with variable prevalence rates across regions. The prevalence of transfusion-transmitted HBV infection (TT-HBV) via donated blood necessitates an evaluation of blood safety and potential risks to the population. This study assessed the prevalence of HBV infection among blood donors in Southwestern China over 6 years.

Methods: We analyzed 903,023 blood donations from a central blood center in Southwestern China between January 2017 and December 2022. The prevalence of HBV in donations was determined for one-time and repeat donors, considering birth cohorts and covariates. Demographic characteristics, donation frequency, and anti-HBV antibody status were analyzed to estimate the incidence of TT-HBV.

Results: One-time donors provided 47.78% of the samples, and 52.22% were from repeat donors. The HBV prevalence decreased from 1.0% in 2017 to 0.87% in 2022 in one-time donors and from 0.30% to 0.09%, respectively, in repeat donors. A significantly lower HBV prevalence was identified in the post-1992 birth cohort (0.33%) than in the pre-1992 birth cohort (1.67%). The estimated incidences of TT-HBV occurring from one-time donors, repeat donors, post-1992 birth cohort donors, and pre-1992 birth cohort donors were 20.76, 13.84, 0.82, and 20.98 per 10^4 person-years, respectively.

Conclusion: Our findings indicate a decreasing trend in HBV prevalence among blood donors in Southwestern China over the 6-year study period. This decline may be attributed to the widespread administration of HBV vaccinations and stringent screening measures implemented by blood donation centers. Continuous monitoring for HBV among blood donors is necessary to evaluate the effectiveness of preventive measures and inform future strategies to reduce transmission.

Keywords: hepatitis B virus, transfusion-transmitted infections, epidemiology, vaccination

Introduction

Chronic hepatitis B virus (HBV) infection is a common cause of cirrhosis and hepatocellular carcinoma globally.[1] Although a vaccine against HBV infection has been widely administered, there are 296 million individuals with chronic hepatitis B worldwide, making HBV infection a significant global health concern, particularly in regions with high prevalence, such as China.[2]

A recent meta-analysis which used a random-effects model found a 6.1% HBsAg positivity rate among the Chinese population. Notably, the prevalence of HBV infection in China varies significantly across regions, with higher prevalences in the Southwestern and southern regions.[3] Southwestern China, including provinces such as Chongqing,

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Sichuan, and Yunnan, has been identified as a relatively high HBV prevalence area.[4] Therefore, understanding the prevalence of HBV infection among volunteer blood donors in this region is crucial for developing effective prevention and control strategies.

Vaccination against HBV is the most effective public health intervention for reducing its burden worldwide. In China, a universal vaccination program was introduced in 1992 that targeted infants and incorporated subsequent catch-up campaigns.[5] Previous studies have demonstrated the positive impact of HBV vaccination in certain provinces of China.[6,7] However, its impact on the HBV prevalence among voluntary blood donors in the Southwestern region remains unclear. Consequently, assessing the influences of these campaigns in Southwestern China is crucial to determining their effectiveness in reducing new infections.

Although HBsAg screening is standard for all blood donations, blood centers in China voluntarily implemented nucleic acid testing (NAT) from 2010 to 2014 to prevent transfusion-transmitted HBV infection (TT-HBV). In 2015, NAT became a mandatory component of blood screening programs.[8] Nevertheless, HBV transmission may occur through donated blood when HBV DNA is below the threshold of NAT detection in the "window period" (WP) or due to occult HBV infection (OBI).[9,10] Carriers of anti-hepatitis B core antibodies (HBcAb) with or without anti-hepatitis B surface antibodies (HBsAb) have extremely low levels of HBV DNA and exhibit OBI.[11,12] Many countries with low HBV prevalences have incorporated HBcAb testing into blood screening, as its presence indicates past or present HBV exposure.[13,14]

This study aimed to investigate the prevalence of HBV infection among blood donors and to evaluate the incidence of TT-HBV. In addition, we analyzed the data from blood donation screening tests at a central blood center in Southwestern China, examining the effect of sociodemographic and vaccination factors on HBV prevalence. Moreover, we investigated the positivity rates of HBcAb testing among the different groups to provide testing recommendations.

Materials and Methods

Study Setting

Chongqing is one of the four direct-administered municipalities in China, with a permanent resident population of 32 million and a central urban area population of 10.48 million.[15] The Chongqing Blood Center is one of the largest multifunctional and modern blood collection and supply service institutions in Southwestern China. It integrates blood collection and supply, teaching, and scientific research across 11 districts, two medical universities, and nearly 300 hospitals in Chongqing.

Study Design and Populations

The HBV data collected from the Chongqing Blood Center between January 2017 and December 2022 were analyzed. We evaluated the prevalence of HBV (HBV DNA and/or HBsAg positive donations) in blood donors with different demographic characteristics over 6 years and the incidence of HBV (NAT yield with or without HBcAb/HBsAb positivity) between January 2021 and December 2022. The study was approved by the Research Ethics Committee of the Chongqing Blood Center (protocol number: 2021-018-01; May 18, 2021) and was conducted in accordance with the Declaration of Helsinki. All donors at the blood center were volunteers verified for eligibility prior to blood donation in accordance with the current Chinese national blood donation criteria. This ensured authenticity of the results. People aged between 18 and 60 years, with a body weight >50 kg (male) or >45 kg (female), and good physical and mental health were considered eligible. As this study utilized database data, the requirement for informed consent was waived, as total donor anonymity was maintained. However, in the Blood Center, written informed consent was obtained from all participants to allow the use of anonymized test results and scientific research of their blood samples before blood donation.

Serological and Nucleic Acid Testing

The Chongqing Blood Center screens all blood donors using enzyme-linked immunosorbent assay (ELISA) to test for HBsAg positivity. Notably, two reagents from different manufacturers were used (DiaSorin, UK; Wantai Biotechnology,

China), and positivity for HBsAg was confirmed when both assays were positive. For samples that exhibited reactivity with only one assay, retesting was performed using the same method. Transcription-mediated amplification (PROCLEIX Ultrio Plus on Tigris platform, Grifols, Spain) was used for HBV DNA detection (limit of detection [LOD] 95%: 3.4 IU/mL for HBV). Multiplex positive donations (using NAT) were discriminated using virus-specific discriminatory assays (LOD 95%: 4.1 IU/mL for discriminatory HBV test). Donations for which two different HBsAg assays were reactive, the HBV-NAT test results were reactive, or one HBsAg assay and NAT test were reactive were considered positive. Donations that were HBsAg single-ELISA-reactive and non-NAT-positive were excluded from the study because of the unknown infection status. Notably, a small number of blood samples with HBsAg single-ELISA-reactive results have previously been confirmed as HBV infection.[16,17] This was <0.01‰ of total blood donations in the present study.

Complementary Serological Testing

HBcAb (anti-HBc) testing is usually a supplementary test at Chinese blood centers and is not a part of routine screening because of its high prevalence. For NAT-positive and HBsAg-negative (NAT yield) infections without follow-up samples, residual plasma was used to confirm infection status. In the present study, NAT yield donations were further categorized based on anti-HBc and anti-HBs positivity from January 2021 to December 2022.

Data Sources and Analysis

All calculations were based on data from the SPRING donor electronic database, which contains donation, deferral, and demographic data such as sex, age, and nationality of all blood donors in Chongqing's main urban areas (used by the Chongqing Blood Center). Donors were categorized into one-time (OT) or repeat donors based on their status at the last donation during the observation period. Repeat donors had records of prior donations within or outside the observation period, whereas OT donors had no recorded prior donations, contributing only once during the observation period. The HBV prevalence was calculated by dividing the number of blood donors who tested positive during the study period by the total number of donations per year; this was expressed as percent (%).[18] Calculations were performed annually. The incidence was calculated as the number of incident cases divided by the total time at risk, measured in person-years (PY). Demographic data were extracted from the donation records of each donor for donations between January 2017 to December 2022, and variables such as sex, age, donation type, and ethnicity were evaluated. These data were recoded using SPSS (version 22.0; IBM Corp, USA) for statistical analyses. Comparisons of proportions were conducted using the chi-square test, with a significance level of 5% ($P < 0.05$). The 95% confidence intervals (95% CIs) of the estimated incidence rate were calculated using the Clopper-Pearson method. Binary logistic regression was employed to explore the factors influencing the detected results. Notably, the dependent variable was the screening result (0 for negative and 1 for positive), whereas the independent variables included sex, age, ethnicity, birth cohort, year(s) of donation, and donation frequency. The calculated odds ratios (ORs) and 95% CIs are reported in the tables.

Results

Sociodemographic Characteristics of Donors and Prevalence

Between January 2017 and December 2022, Chongqing Blood Center collected 806,652 (89.33%) whole blood donations and 963,71 (10.67%) apheresis donations. Notably, 471,602 (52.22%) and 431,421 (47.78%) donations were obtained from repeat and OT donors, respectively. The 18–25 years age group was the most common blood donor population (38.95%), and 410,787 (45.49%) donations were from individuals born after 1992. The donations included 496,358 males (54.97%) and 406,665 females (45.03%). The ethnic groups in China are divided into Han and ethnic minorities. In this study, blood donations from ethnic minorities and the Han group accounted for 4.6% and 95.4%, respectively. Based on the chi-square analysis, the overall HBV prevalence was associated with donation time, age, sex, birth cohort, donor type, and donation type, but not to ethnicity (Table 1).

Between January 2017 and December 2022, the prevalence of HBV positivity (HBsAg or HBV DNA positivity) gradually decreased in both males and females, with a consistently higher prevalence in males than females (Figure 1a). The HBV prevalence at all ages decreased significantly in 2017 compared with 2018 and slightly decreased from 2018 to 2021. The HBV

Table 1 Sociodemographic Characteristics of Blood Donors, 2017–2022

Donor characteristics	Overall donations		Negative		Positive		Prevalence (%)	χ2	P value
	N	(%)	N	(%)	N	(%)			
Donation type									
Apheresis	96371	10.67	96,267	10.67	104	2.42	0.11	81.02	<0.001
Whole blood	806652	89.33	802,461	89.33	4191	97.58	0.52		
Age									
18–25	351,766	38.95	350,861	38.95	905	21.07	0.26	1184	<0.001
26–35	203,040	22.48	202,339	22.48	701	6.32	0.35		
36–45	160,176	17.74	159,151	17.74	1025	23.86	0.64		
>45	188,041	20.82	186,377	20.82	1664	38.74	0.88		
Birth cohort									
Before 1992	492,236	54.51	488,972	54.51	3264	76	0.66	803.4	<0.001
After 1992	410,787	45.49	409,756	45.49	1031	24	0.25		
Sex									
Male	496358	54.97	493,705	54.97	2653	61.78	0.53	81.02	<0.001
Female	406665	45.03	405,024	45.03	1641	38.22	0.40		
Ethnicity									
Han	861482	95.40	857,361	95.40	4121	95.31	0.48	0.09	>0.05
National minority	41541	4.60	41,338	4.60	203	4.69	0.49		
Donor type									
One-time	431421	47.78	427,828	47.78	3593	83.66	0.83	2226.7	<0.001
Repeat time	471602	52.22	470,900	52.22	702	16.34	0.15		
Year									
2017	144,155	15.96	143,215	15.96	940	21.89	0.65	57.78	<0.001
2018	142,396	15.77	141,766	15.77	630	14.67	0.44		
2019	154,298	17.09	153,578	17.09	720	16.76	0.47		
2020	148,681	16.46	147,919	16.46	762	17.74	0.51		
2021	163,297	18.08	162,671	18.08	626	14.58	0.38		
2022	150,196	16.63	149,579	16.63	617	14.37	0.41		

prevalence was lower in the group aged ≤25 years than in older age groups, as well as in donors born after 1992 than in those born before 1992 (Figure 1b). The overall HBV prevalence for donors born before 1992 was 2.6 times higher than that for donors born after 1992, with rates of 0.65% and 0.25%, respectively (Figure 1c). The overall HBV prevalence decreased between 2017 and 2022, annual prevalence was 0.65, 0.44, 0.47, 0.51, 0.38, and 0.41, respectively (Figure 1d). Table 2 shows the prevalence of HBV in donors based on sociodemographic characteristics and birth cohorts. A higher HBV infection risk was found among whole blood donors than platelet donors. The HBV prevalence increased with age. A higher HBV infection risk was found among individuals aged >45 years than among those aged 18–25 years. Men had a higher HBV infection risk

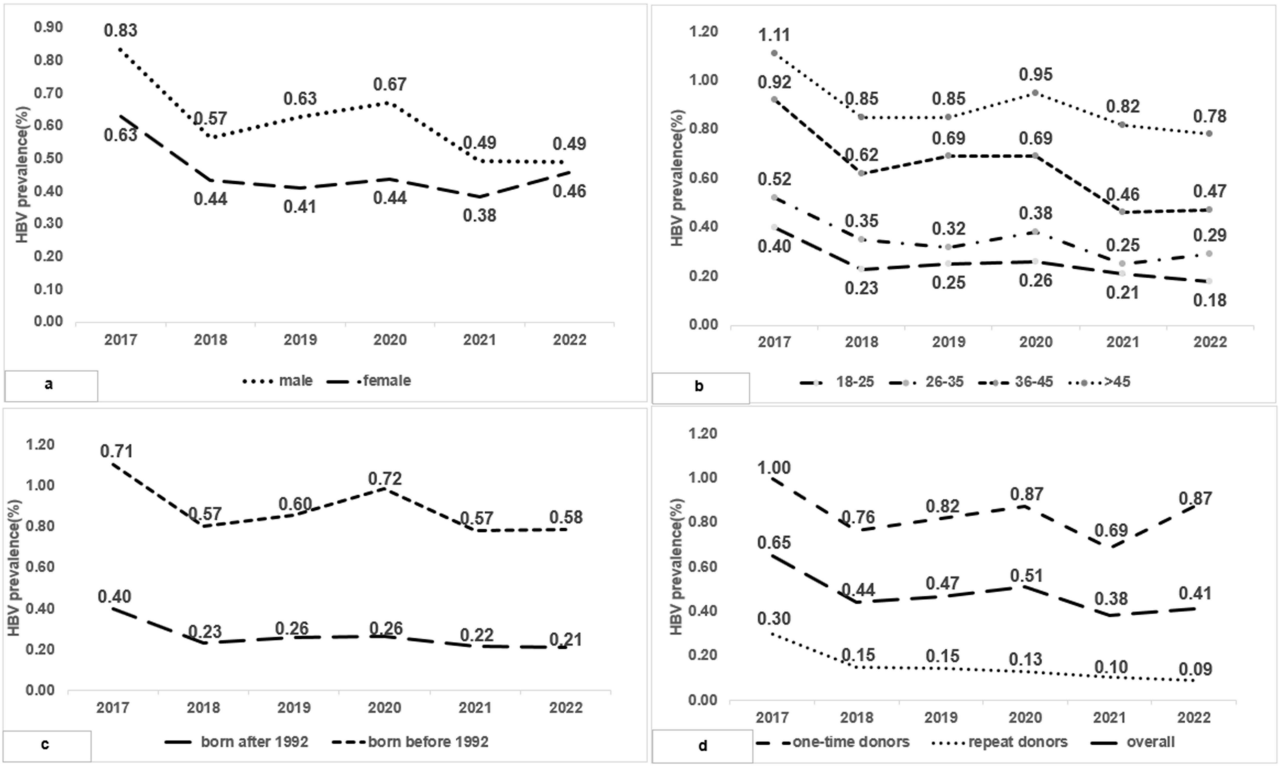

Figure 1 HBV prevalence by sex, age, birth cohort and donor type in blood donors between 2017 and 2022. (**a**–**d**) HBV prevalence by sex (**a**), age (**b**), birth cohort (**c**) and donor type (**d**) per 100 donations annually from 2017 to 2022.
Abbreviation: HBV, Hepatitis B virus.

than women. The risk was also higher among people born before 1992 than among those born after 1992. Compared with 2017, the HBV infection risk decreased in the following five years. The HBsAg positivity rate was 0.50%, 0.33%, 0.35%,0.37%, 0.29%, 0.30%, and the NAT yield rate was 0.15%, 0.11%, 0.11%, 0.14%, 0.10%, 0.11% respectively, from 2017 to 2022.

HBV Prevalence in OT and Repeat Donors

The prevalence of HBV was further analyzed based on OT and repeat donors. Among donors aged <25 years, donations from OT and repeat donors were 55.33% (238703) and 23.97% (113063) of the total donations, respectively. The HBsAg positivity rate

Table 2 Logistic Analysis of Demographic Characteristics Associated with HBV Infections, 2017–2022

Characteristics	Collections	HBsAg Positive			NAT Yield		
	N of Donations	N	(%)	OR (95% CI)	N	(%)	OR (95% CI)
Donation type							
Apheresis	96371	62	0.06	0.15 (0.0.12, 0.18)	42	0.04	0.31 (0.24,0.37)
Total whole blood	806652	3148	0.39	1	1043	0.13	1
Age							
18–25	351766	856	0.24	1	49	0.01	1
26–35	203040	572	0.28	1.16 (1.04, 1.29)	129	0.06	4.56 (3.28, 6.34)
36–45	160176	755	0.47	1.95 (1.77, 2.15)	270	0.17	12.12 (8.94, 16.43)

(*Continued*)

Table 2 (Continued).

Characteristics	Collections	HBsAg Positive			NAT Yield		
	N of Donations	N	(%)	OR (95% CI)	N	(%)	OR (95% CI)
>45	188041	1027	0.55	2.25 (2.05, 2.46)	637	0.34	24.40 (18.25, 32.63)
Birth cohort							
Before 1992	492236	2249	0.46	1.96 (1.57, 2.35)	1015	0.21	12.12 (9.70, 14.54)
After 1992	410787	961	0.23	1	70	0.02	1
Sex							
Male	496358	1912	0.39	1.21 (1.13, 1.30)	742	0.15	1.77 (1.55, 2.01)
Female	406665	1298	0.32	1	344	0.08	1
Ethnicity							
Han	861482	3055	0.35	0.95 (0.81, 1.12)	1066	0.12	1.00 (0.98, 1.02)
National minority	41541	155	0.37	1	49	0.12	1
Donor type							
One-time	431421	3010	0.70	16.56 (14.35, 19.11)	583	0.14	1.27 (1.13, 1.43)
Repeat time	471602	200	0.04	1	502	0.11	1
Year							
2017	144155	718	0.50	1	222	0.15	1
2018	142396	470	0.33	0.67 (0.60, 0.74)	160	0.11	0.73 (0.60, 0.89)
2019	154298	546	0.35	0.71 (0.64, 0.79)	174	0.11	0.73 (0.60, 0.89)
2020	148681	554	0.37	0.75 (0.67, 0.84)	208	0.14	0.91 (0.75, 1.10)
2021	163297	467	0.29	0.57 (0.51, 0.64)	159	0.10	0.63 (0.52, 0.78)
2022	150196	455	0.30	0.61 (0.54, 0.68)	162	0.11	0.70 (0.57, 0.86)

Abbreviations: N, number; NAT, nucleic acid testing; OR, odd ratio; CI, confidence interval; HBsAg, hepatitis B surface antigen.

increased with age, with the group aged >45 years exhibiting a 5.6-times higher rate than the group aged <25 years. The NAT yield was 15.87 times higher in OT donors than in repeat donors. Males constituted 51.92% and 57.75% of OT and repeat donors, respectively. The HBV prevalence among male blood donors, whether OT or repeat, was 1.43–2.23 times higher than that among female donors. In the logistic analysis of OT donors, the donors born before 1992 had a significantly higher prevalence than donors born after 1992 (odds ratio [OR]: 3.75, 95% CI: 3.47–4.06). Similar demographics were associated with the NAT yield categories (OR: 18.04, 95% CI: 13.39–34.31). In repeat donors, the HBV-NAT yield rate in donors born before 1992 was 9.42 times higher than in those born after 1992; however, no notable difference was observed in the HBsAg positivity rate between these groups. HBV prevalence among OT donors significantly decreased from 2017 to 2018 and slowly declined from 2018 to 2022. From 2017 to 2022, HBV prevalence among repeat donors decreased significantly compared with OT donors (Table 3).

Anti-HBs and Anti-HBc Positivity Rates

Between January 2021 and December 2022, 290,162 blood donors made 313,493 donations. Of these, 321 tested positive with the NAT assay (0.1%). Of the 321 positive blood donations, 291 (94.39%) were anti-HBc-positive, 189 (64.94%) were anti-HBs-positive, and 18 (5.6%) were HBV serum marker-negative. Among the 291 anti-HBc-positive blood

Table 3 Logistic Analysis of Demographic Characteristics Associated with HBV's Infections Among One-Time and Repeat Donors, 2017–2022

Characteristics	HBsAg Positive (OT)		NAT yield (OT)		HBsAg Positive (R)		NAT Yield (R)	
	N	OR (95% CI)	N	OR (95% CI)	N	OR (95% CI)	N	OR (95% CI)
Age (years)								
18–25	802	1	37	1	54	1	12	1
26–35	523	1.77 (1.58, 1.98)	80	5.85 (3.97, 8.64)	48	0.89 (0.59, 1.29)	49	4.02 (2.14, 7.56)
36–45	702	3.97 (3.59, 4.40)	147	17.89 (12.47, 25.66)	56	1.10 (0.75, 1.59)	123	10.84 (5.99, 19.61)
>45	983	5.79 (5.27, 6.36)	319	40.32 (28.67, 56.68)	42	0.64 (0.43, 0.96)	318	21.97 (12.34, 39.10)
Birth cohort								
Before 1992	2113	3.75 (3.47, 4.06)	536	18.04 (13.39, 34.31)	137	0.76 (0.36, 1.61)	479	9.42 (6.20, 14.32)
After 1992	897	1	47	1	63	1	23	1
Sex								
Female	1795	1	403	1	119	1	338	1
Male	1215	1.37 (1.27, 1.48)	180	2.08 (1.74, 2.47)	81	0.98 (0.73, 1.32)	164	1.58 (1.32, 1.91)
Ethnicity								
Han	2860	0.75 (0.63, 0.88)	542	0.93 (0.68, 1.28)	195	1.12 (0.46, 2.73)	495	2.04 (0.97, 4.30)
National minority	150	1	41	1	5	1	7	1
Year								
2017	626	1	102	1	92	1	120	1
2018	439	0.75 (0.66, 0.85)	80	0.84 (0.63, 1.13)	31	0.32 (0.21, 0.48)	80	0.64 (0.48, 0.85)
2019	511	0.81 (0.72, 0.91)	91	0.88 (0.67, 1.17)	35	0.34 (0.23, 0.50)	83	0.61 (0.46, 0.81)
2020	536	0.81 (0.72, 0.91)	133	1.24 (0.96, 1.61)	18	0.19 (0.12, 0.32)	75	0.62 (0.46, 0.83)
2021	454	0.67 (0.60, 0.76)	85	0.77 (0.58, 1.03)	13	0.12 (0.07, 0.21)	74	0.52 (0.39, 0.69)
2022	444	0.84 (0.74, 0.95)	92	1.07 (0.81, 1.42)	11	0.10 (0.05, 0.18)	70	0.47 (0.35, 0.63)

Abbreviations: N, number; OT, one-time donors; R, repeat donors; CI, confidence interval; OR, odd ratio; HBsAg, hepatitis B surface antigen.

donors, 177 (60.80%) had anti-HBs titers ≥10 mIU/mL, including 90 (30.93%) highly positive (≥100 mIU/mL) and 87 (29.9%) slightly positive (<100 mIU/mL) donations (Figure 2).

HBV Incidence

Between January 2021 and December 2022, 104,521 repeat blood donors have made 173,466 donations. Each repeat donor donated an average of 1.66 times per year in the Chongqing Blood Center. In total, 321 donations—177 and 144 from OT and repeat donors, respectively—tested positive using the NAT assay (0.10%). The incidence of NAT yield in OT donors was 1.46–3.22 times higher than that in repeat donors, with an overall incidence of 20.76 per 10^4 PY. In repeat donors, the HBV incidence was higher in those born before 1992 than in those born after 1992, with an overall incidence of 20.98 per 10^4 PY (Table 4).

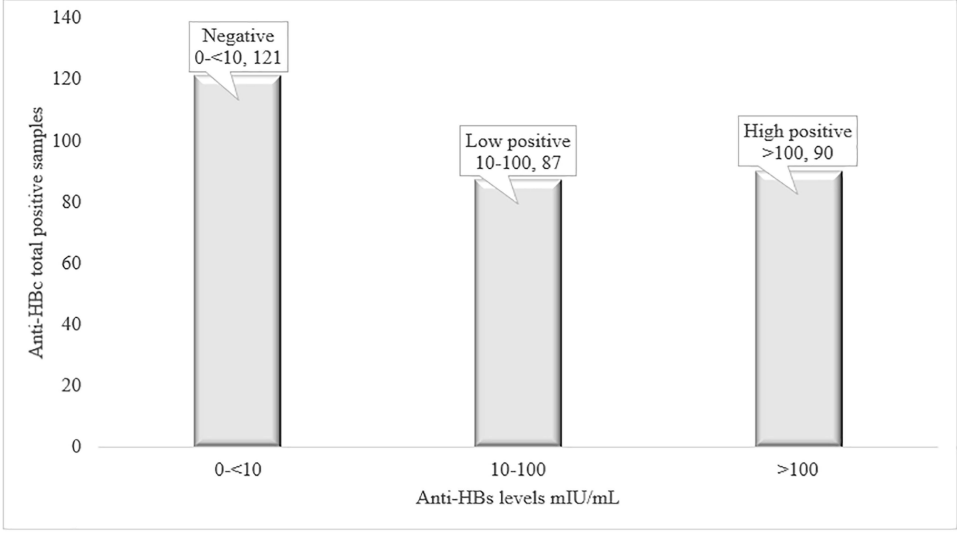

Figure 2 Anti-HBs levels of anti-HBc positive samples in NAT yield samples.
Abbreviations: Anti-HBs, Hepatitis B surface antibody; Anti-HBc, Hepatitis B core antibody.

Discussion

Our findings reveal that HBV prevalence decreased over a 6-year period from 0.65% to 0.41% among all donors. The decline in prevalence was most notable in the post-1992 birth cohort, who were born after the rollout of infant HBV vaccinations in Southwestern China. Within this cohort, HBV prevalence was 0.66%, compared with 0.25% in cohorts born before 1992. During this period, the annual use of NAT prevented approximately 0.12% of transfusions with HBV-positive blood. The estimated incidence of HBV infection was 13.84 per 10^4 people, with the majority from HBcAb/HBsAb-positive NAT yield infections, which mainly originated from OT donors born before 1992.

The prevalence of HBV in 2022 identified in this study was 0.48% (serum HBV prevalence, 0.36%; NAT yield, 0.12%), a value close to that reported in South Africa (0.66%)[19] but higher than those reported in the United States ($49.47/10^5$)[20] and Italy ($175.6/10^5$).[19] The prevalence of HBV in Chongqing has further decreased compared with

Table 4 HBV Incidence in One-Time and Repeat Donors Between 2021 and 2022

Donors		NAT yield			NAT Yield Incidence /10^4 Person-Years				
		No. Positive	Donations	Person-Years	Anti-HBc/ Anti-HBs (+)	Incidence (95% CI)	Anti-Hbc and Anti-HBs (-)	Incidence (95% CI)	Total
One-time donors		177	140,027	/	164	19.49[a] (1638–23.02)	13	1.55[a] (0.52–3.61)	20.76 (17.51, 24.44)
Repeat donors		144	173,466	104,080	139	13.35 (11.22, 15.77)	5	0.48 (0.16, 1.12)	13.84 (11.67, 16.29)
Repeat donors	Born before 1992	141	112,791	67,675	137	20.24 (17.00–23.93)	4	0.59 (0.24, 1.72)	20.98 (17.68, 24.73)
	Born after 1992	3	60,675	36,405	2	0.55 (0.07, 1.98)	1	0.27 (0.01, 1.53)	0.82 (0.17, 0.24)

Notes: [a]Estimated one-time donor incidence was calculated from the observed repeat donor incidence multiplied by the NAT yield ratio.
Abbreviations: NAT, nucleic acid testing; CI, confidence interval; anti-HBc, hepatitis B core antibody; anti-HBs, hepatitis B surface antibody.

previous reports from Shenzhen, China (serum HBV prevalence, 0.75%)[21] and Anhui, China (0.83%).[22] This decline in prevalence is likely attributed to Chongqing's rapid economic development, as it has been established as the economic hub of Southwestern China over the past few decades.[23] Significant investments have been made in the Chongqing healthcare sector, resulting in improved medical standards and service. Notably, an increasing number of people born after 1992, when the infant HBV vaccination program was implemented in China, are now regular blood donors. Additionally, a higher number of donations were reported from OT than repeat voluntary blood donors in prior studies (1.08–2.04:1),[24] however, this situation is now reversed, and more repeat than OT donors are reported currently (presently 1.09:1 in Chongqing).

In this study, the post-1992 birth cohort had a lower HBV prevalence (0.33%) than the pre-1992 birth cohort (1.67%) in 2022, implying a 5-fold reduction. The reduction in HBV-positivity rates among blood donors in the Southwestern region following the implementation of the hepatitis B vaccination program was similar to that observed in other countries worldwide, with an 8-, 20-, and 1.2-fold decrease in HBV prevalence in South Africa;[19] Taiwan,[25] and Flanders, Belgium,[26] respectively. During the study period, HBV prevalence among OT donors born after 1992 gradually decreased from 0.75% to 0.40%; however, a certain proportion of individuals still tested positive for HBV. Moreover, the prevalence of HBV among repeat blood donors aged 18–25 years between 2017 and 2022 was relatively low but remained between 0.18–0.38%. Many studies have suggested a failure of basic immunity in newborns[27,28] or that the titer of anti-HBs decreases or even disappears with time,[29,30] which may explain these points, indicating the need for enhanced hepatitis B antibody monitoring and immunization among adolescents, especially in countries with high HBV prevalences.

The epidemiology of HBV infection in the Chongqing blood donor population, to some extent, reflects the situation in Southwestern China. The prevalence of HBsAg declined to 0.43% over the study period, most likely due to the nationwide HBV vaccination program. However, OBI prevalence remains a notable concern. In the present study, OBI prevalence (NAT yield with or without anti-HBc/anti-HBs positivity) was $13.84/10^4$, with a frequency of 1:1034, which is higher than those reported in Europe (median 1:9819), South Africa (median 1:8209), Shenzhen (1:7517), and Hong Kong (1:1245).[31–34] The elevated prevalence of OBI in Southwestern China could be attributed to the historically high HBV prevalence in the area before the introduction of the hepatitis B vaccination as well as to other factors such as vertical transmission from infected mothers to newborns, inadequate sterilization practices in healthcare settings, and a substantial carrier population.

In some countries, anti-HBc testing is mandated in the microbiological screening of donated blood. To deal with high positivity rates, people with anti-HBc positivity re-entry into the donor bank at anti-HBs titers of at least 100 mIU/mL and meet both HBsAg negative and HBV NAT negative are considered.[35] In our analysis of 321 HBV NAT yield samples, 291 and 189 samples exhibited anti-HBc positivity and anti-HBs positivity, respectively. Among the anti-HBc-positive cases, 30.93% of the samples had surface antibody levels >100 mIU/mL. Therefore, introducing universal anti-HBc testing for donor screening or relying on surface antibody levels to determine blood donation eligibility is unsuitable for countries such as China, owing to the potential waste of blood resources and the possibility of not detecting low viral loads.

In this study, the associations between demographic characteristics and HBV infection were also analyzed. The number of positive donors for each virus was higher in males, as most donors were male, which is consistent with the results from other studies.[36,37] Further, females tend to show a higher antibody response than males after receiving the HBV vaccine.[38] In addition, females seek healthcare services more frequently than males do, leading to early diagnosis, especially for infections transmitted through blood transfusions (such as prenatal screening), thereby reducing the likelihood of positive donations in this population.[39] Notably, varying results regarding the prevalence of hepatitis B among ethnicities within China have been reported previously.[24,40] Although people with certain ethnicities may have higher hepatitis B infection rates, the significance of these differences varies across studies.[41] According to observations, the population of people with minority ethnicities in the main urban area of Chongqing is relatively small, with no significant differences in the HBV-positivity rate among people of different ethnicities.

In the present study, the incidences of anti-HBc/anti-HBs positivity (mainly from OBI) and negativity (mainly from WP) in repeat donors were $20.24/10^4$PY and $0.59/10^4$ PY, respectively, and the incidence of OT donors was 1.46- to 3.22-

fold that of repeat donors. The incidence of HBV infection in this region was relatively high compared with lower-prevalence countries like the United States (1.25–1.59/10^5). However, in China, the regional incidence has reduced by 10-fold[42] compared to that in 2012. With the comprehensive use of NAT for blood screening in China since 2015, the risk associated with HBV WP has decreased significantly. The decreased HBV infection incidence in Southwestern China is consistent with the nationwide trends in incidence reduction before and after the introduction of the infant hepatitis B vaccination program in China.[43] In a retrospective study, low viral load (mainly from OBI and WP) was an important risk factor for TT-HBV infection.[44] In this study, a 12–27-times higher incidence of donors with OBI or in the HBV WP in OT than in the repeat donors was observed. The low viral load in OBI poses a challenge for NAT systems. In China, the sensitivities of different NAT systems are relatively high, ranging from 2.3–10 IU/mL. However, to save costs, many blood stations in China have adopted a pooling strategy, combining six or eight samples for testing. Consequently, the 95% LOD for HBV DNA has increased by more than 10-fold, posing a challenge for detecting samples from OBI or WP donors. In countries with a high HBV infection prevalence, the balance between detecting low HBV viral loads and cost-effectiveness should be considered.

One of the major limitations of this study is the lack of supplementary experimental data, as these are not routinely collected in Chinese blood banks. However, the present study included one supplementary experiment in the last 2 years of the study period. Owing to the lack of follow-up, only incidence rates (not residual risks) by group were considered. Owing to these limitations, the data obtained may not be accurate; however, they do illustrate the approximate magnitude of the situation. Future studies should include extended timeframes to capture trends in the context of blood donation and transfusion safety in Chinese blood banks. Additionally, a longitudinal study with follow-up on blood donor samples is needed for a more in-depth analysis of the residual risk associated with blood donation and transfusion, providing a better understanding of the long-term implications of the process.

Conclusions

In summary, the prevalence and incidence of TT-HBV in Chongqing among OT and repeat blood donors declined during the study period, reflecting the effectiveness of China's vaccine program. The increasing number of young people who participate in unpaid blood donation and become repeat donors further reduces the risk of TT-HBV. Considering the inclusion of anti-HBc in screening tests, a re-entry mechanism suitable for Chinese prevalence should be developed.

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Disclosure

The authors report no conflicts of interest in this work.

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