Preplanned Studies

A Multi-Regional Epidemiological Evaluation on Post-vaccination Serological Testing in Prevention of Vertical Transmission of Hepatitis B Virus — 10 Counties, 5 Provinces, China, 2019–2024

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Summary

What is already known about this topic?

Post-vaccination serologic testing (PVST) of infants born to hepatitis B virus (HBV) infected mothers is important for evaluating effectiveness of strategies for preventing mother-to-child transmission (MTCT) of HBV.

What is added by this report?

PVST was conducted in 43.7% of 7,425 infants born to HBV-infected mothers and showed that 0.8% of infants had breakthrough infections, indicating a very low level of prevention failure; anti-HBs positivity was 97.0% showing vaccine-induced protection; and 2.2% of HBV-exposed infants needed revaccination. Prevention failure was 12.7-fold higher among infants born to HBeAg-positive mothers.

What are the implications for public health practice?

MTCT prevention strategy is highly effective. PVST evaluates MTCT prevention strategy and identifies infants needing revaccination; its use should be increased. Findings support WHO's HBV elimination strategy.

ABSTRACT

Introduction: Infants born to HBsAg-positive mothers are exposed to hepatitis B virus (HBV) during childbirth and require timely hepatitis B vaccination (HepB) and hepatitis B immunoglobulin (HBIG) to prevent vertical transmission. Post-vaccination serological testing (PVST) determines whether HBV-exposed infants are protected, infected, or need revaccination. This study evaluated PVST implementation among HBV-exposed infants and the effectiveness of the recommended strategy to prevent mother-to-child transmission (MTCT) of HBV.

Methods: This observational study of infants born to HBsAg-positive mothers evaluated implementation of the MTCT prevention strategy and PVST follow-up across five provinces in China. Chi-square tests assessed timely HepB1 and HBIG administration and HepB series completion. PVST was used to evaluate MTCT prevention effectiveness. Bivariate analyses explored factors influencing infection and protection rates among HBV-exposed infants.

Results: Among 7,425 infants born to HBsAg-positive mothers, 94.8% received timely HepB1 and HBIG, and 99.5% completed the full HepB vaccination series. PVST was conducted in 3,243 (43.7%) infants; the median interval between HepB3 and PVST was 66 days (interquartile range: 47–114). 26 (0.8%) infants tested HBsAg-positive; 3,147 (97.0%) developed protective antibody levels; and 72 (2.2%) were neither infected nor protected, requiring revaccination. Maternal HBeAg positivity was a significant risk factor for MTCT prevention failure [adjusted odds ratio (a*OR*)=12.7, 95% confidence interval (*CI*): 4.7, 34.1].

Conclusions: The MTCT prevention strategy was highly effective. PVST for infants born to HBsAg-positive mothers enables evaluation of MTCT prevention strategies and improvement of strategy their effectiveness. PVST utilization should be expanded to test all HBV-exposed infants to ensure their protection and to further enhance the MTCT prevention.

Timely administration of a birth dose of hepatitis B vaccine (HepB) is critically important for preventing hepatitis B virus (HBV) infection by preventing vertical transmission of HBV during childbirth (*1*). According to the World Health Organization (WHO), the prevalence of chronic HBV infection among

children under five years of age declined from approximately 5% in the pre-vaccine era (1980s to early 2000s) to below 1% in 2019 (*2*). In China, the HepB immunization schedule provides the first dose (HepB1) within 24 hours of birth, followed by second (HepB2) and third (HepB3) doses at 1 and 6 months of age. The National Viral Hepatitis Prevention and Control Plan (2017–2020) set targets to maintain timely HepB1 coverage >90% and full-series coverage (HepB3) >95%. A 2020 nationally-representative survey found that among 1–4-year-old children, 91.54% received HepB1 ≤24 hours after birth and 99.21% completed HepB3. Among 1–14-year-old children, corresponding rates were 89.05% and 98.46%, indicating high ultimate coverage but persistent gaps in timely HepB1 administration (*3*). Universal HepB vaccination significantly reduced hepatitis B infection among children and adolescents. The 2020 national HBV seroepidemiological survey shoewd dramatic declines in hepatitis B surface antigen (HBsAg) prevalence, from 9.67% (in 1992) to 0.30% in children aged 1–4 years, and from 10.74% to 0.94% in 5–14-year-old (*4*).

The WHO's 2030 goal to eliminate viral hepatitis as a major public health threat has an objective to achieve an HBsAg seroprevalence of ≤0.1% among children under five years old. Preventing mother-to-child transmission (MTCT) of HBV during childbirth is essential to achieve this objective. Co-administration of hepatitis B immunoglobulin (HBIG) with HepB1 enhances MTCT prevention efficacy (*5*). China's Guidelines for the Prevention and Treatment of Chronic Hepatitis B and the National Immunization Program Schedule for Children (2021 Edition) emphasize administering HepB1 and HBIG within 12 hours of birth to newborns of HBsAg-positive mothers (*6*). Post-vaccination serological testing (PVST) is used to determine the effectiveness of MTCT prevention in infants. PVST assesses HBsAg and anti-HBs antibody levels at 9–12 months of age or 1–2 months after vaccine series completion.

We evaluated timeliness of HepB vaccination and effectiveness of MTCT prevention strategies in children born during 2019–2024 in pilot counties/districts with established PVST surveillance. We determined factors associated with MTCT prevention failure and assessed impact of the current strategy, with an aim to provide evidence-based recommendations for optimizing MTCT prevention.

The study was conducted in selected counties across five provinces in China: Zhejiang (Jinyun and Suichang counties), Fujian (Shishi City and Huian County), Henan (Yuanyang and Sui counties, and Huaiyang District), Sichuan (Dujiangyan City and Lu County), and Gansu (Ganzhou District and Tongwei County). Study subjects included infants born to HBsAg-positive mothers during 2019–2024 and their mothers. Data collection encompassed demographics, prenatal HBV screening results, use of antiviral therapy during pregnancy, maternal HBIG use, delivery details, administration of HepB1, HBIG, and HepB3, PVST results, and HepB revaccination if indicated by PVST. Data were obtained from maternal and child health (MCH) institutions (information on mothers, pregnancies, deliveries, and HepB1 and HBIG administration), vaccination clinics (HepB2 and HepB3 data), and MCH laboratories (PVST results).

Infant-level outcomes were defined as: 1) PVST utilization: testing blood for HBsAg and HBsAb; 2) MTCT prevention success: HBsAg-negative and HBsAb-positive; 3) HBV infection: HBsAg-positive; 4) HBV susceptibility: HBsAg-negative and HBsAb-negative; 5) timely co-administration of HepB1+HBIG: HepB1 administered ≤24 hours and HBIG1 ≤12 hours after birth; and 6) timely completion of HepB3.

Statistical analysis was performed using Microsoft Excel 2019 (Microsoft Corp., Redmond, WA, USA) and SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). Descriptive statistics were used to summarize baseline characteristics. Outcomes are reported as proportions with 95% confidence intervals (*CI*). Chi-square tests (α =0.05, two-tailed) were used for univariate analysis, while multivariate analysis was conducted using unconditional logistic regression (α =0.05, two-tailed).

Table 1 shows characteristics of the subjects: 7,425 HBsAg-positive mothers and their liveborn, HBV-exposed infants. The mean maternal age was 31.19±4.39 years. Among these infants, 7,041 (94.8%) received timely HepB1 and HBIG co-administration, and 7,386 (99.5%) completed the HepB3 series. Among the infant subjects, 3,243 (43.7%) underwent post-vaccination serologic testing. The median interval between HepB3 administration and PVST was 66 days (interquartile range: 47–114). Of the infants with PVST, 26 (0.8%) were HBsAg-positive,indicating breakthrough infection. HBsAg positivity decreased by year from 1.7% in 2019 to 0.3% in 2023. Additionally, 3,147 (97.0%) infants were anti-HBs-positive, indicating vaccine-induced protection, while 72 (2.2%) infants tested negative for both HBsAg and

TABLE 1. Timely co-administration (HepB1 + HBIG1) and full-course vaccination in infants born to HBsAg+ mothers, 2019–2024.

Variable	No. observed (*N*=7,425, %)	Timely co-administration (HepB1 + HBIG1)		Full-course vaccination with HepB	
		No. observed (*N*=7,041)	Rate (%)	No. observed (*N*=7,386)	Rate (%)
Province					
Zhejiang	496 (6.7)	472	95.2	489	98.6
Fujian	4,087 (55.0)	3,930	96.2	4,072	99.6
Henan	1,141 (15.4)	1,006	88.1	1,139	99.8
Sichuan	993 (13.4)	973	98.0	989	99.6
Gansu	708 (9.5)	660	93.2	697	98.5
Maternal age (years)					
15–24	436 (5.9)	411	94.3	433	99.3
25–29	2,238 (30.1)	2,107	94.1	2,221	99.2
30–34	3,119 (42.0)	2,970	95.2	3,104	99.5
35–50	1,632 (22.0)	1,553	95.2	1,628	99.8
Ethnicity					
Han	7,099 (95.6)	6,725	94.7	7,060	99.5
Other	326 (4.4)	316	96.9	326	100.0
Maternal education					
Junior high school and below	5,299 (71.4)	5012	94.6	5,271	99.5
High school and above	2,125 (28.6)	2,028	95.4	2,114	99.5
Maternal occupation					
Farmer	1,475 (19.9)	1,374	93.2	1,470	99.7
Other	5,950 (80.1)	5,667	95.2	5,916	99.4
HBV infected time (y)					
≤5	3,412 (46.0)	3,219	94.3	3,393	99.4
>5	4,013 (54.0)	3,822	95.2	3,993	99.5
Maternal receipt of HBV DNA tested					
Yes	842 (11.4)	820	97.4	835	99.2
No	6,568 (88.6)	6,209	94.5	6,537	99.5
Maternal receipt of antiviral therapy during pregnancy					
Yes	386 (5.2)	373	96.6	383	99.2
No	7,038 (94.8)	6,667	94.7	7,002	99.5
Maternal HBeAg status during pregnancy					
Negative	5,582 (75.2)	5,295	94.9	5,558	99.6
Positive	1,675 (22.6)	1,594	95.2	1,663	99.3
Unknown	166 (2.2)	150	90.4	163	98.2
Infant sex					
Male	3,958 (53.3)	3,758	94.9	3,936	99.4
Female	3,463 (46.7)	3,281	94.7	3,446	99.5
Birth weight (kg)					
≥2.50	7,198 (97.0)	6,839	95.0	7,164	99.5
<2.50	225 (3.0)	201	89.3	220	97.8

Continued

Variable	No. observed (*N*=7,425, %)	Timely co-administration (HepB1 + HBIG1)		Full-course vaccination with HepB	
		No. observed (*N*=7,041)	Rate (%)	No. observed (*N*=7,386)	Rate (%)
Pregnancy duration (weeks)					
≥37	7,022 (94.6)	6,687	95.2	6,987	99.5
<37	401 (5.4)	353	88.0	397	99.0
Maternal parity					
1	2,105 (28.4)	1,986	94.4	2,096	99.6
2	3,936 (53.0)	3,753	95.4	3,916	99.5
≥3	1,381 (18.6)	1,301	94.2	1,371	99.3
Mode of delivery					
Vaginal delivery	3,942 (53.1)	3,717	94.3	3,917	99.4
Caesarean section	3,482 (46.9)	3,323	95.4	3,468	99.6

Abbreviation: HBV=hepatis B virus; DNA=deoxyribonucleic acid; HBeAg=hepatis B e-antigen; HepB1 + HBIG1=first dose of hepatitis B vaccine plus hepatitis B immunoglobulin; HepB=hepatitis B vaccine.

anti-HBs and required revaccination. No significant difference in maternal HBeAg status was observed between infants with PVST (22.2% HBeAg+) and those without PVST(23.0% HBeAg+) (*P*=0.56) (Supplementary Table S1, available at https://weekly.chinacdc.cn/).

Table 2 shows univariate analyses of HBsAg-positivity (MTCT prevention failure) and HBsAb positivity in infants by demographic, maternal, and delivery characteristics. There were significant differences in HBsAg positivity by maternal age and HBeAg status. There were significant differences in HBsAb positivity by maternal occupation, maternal HBV DNA testing, and receipt of HBIG during pregnancy (*P*<0.05). In multivariate logistic regression, maternal HBeAg-positivity was significantly associated with infant HBsAg-positivity (a*OR*=12.7, 95% *CI*: 4.7, 34.1).

DISCUSSION

This real-world study evaluated the effectiveness of the current HepB vaccine- and HBIG-based strategy for preventing mother-to-child transmission of HBV during childbirth. Based on post-vaccination serologic testing of HBV-exposed infants, we found an exceptionally low prevention strategy failure rate of 0.8%. Vaccination induced protective antibody levels in 97.0% of HBV-exposed infants, while the remaining 2.2% were neither infected nor protected, requiring revaccination to ensure protection. The PVST utilization rate was 43.7% among these HBV-exposed infants, and the 66-day median interval between the last dose of HepB vaccine and PVST was appropriate for accurate test results. Our findings strongly support the HepB vaccine- and HBIG-based strategy for prevention of vertical transmission and demonstrate the importance of increasing PVST utilization among HBV-exposed infants in China.

The 43.7% PVST rate we observed is lower than previously reported PVST follow-up rates in China. A retrospective study in Jilin, Henan, Sichuan, and Gansu provinces found a PVST rate of 66% (*7*). Zhejiang Province (2016–2020) and Bao'an District in Shenzhen City, Guangdong Province (2017–2019) reported PVST rates of 67% (*8*) and 54% (*9*), respectively. The suboptimal PVST compliance rate and wide provincial variation we identified highlight a critical gap in monitoring MTCT prevention strategies and underscore the need for improved adherence to PVST protocols.

The MTCT prevention failure rate of 0.8% that we found is slightly lower than the 1.1% rate in the USA (*10*) and the 3.7% rate reported in a four-province study (*11*), but slightly higher than the 0.77% rate observed in Zhejiang Province (*8*), suggesting regional variation in implementation of HBV MTCT prevention measures. HBeAg positivity was a significant risk factor for breakthrough infection, consistent with other studies (*7*,*11*), reinforcing the importance of prenatal HBV serological screening to identify high-risk pregnancies (*12*).

Encouragingly, 97.0% of HBV-exposed infants developed protective hepatitis B surface antibody (anti-HBs), providing likely lifelong protection from HBV infection. This finding was similar to the 97% anti-

TABLE 2. Maternal characteristics, HBsAg and HBsAb positivity in infants, and associated risk factors based on PVST results..

Variable	No. with PVST (*N*=3,243)	HBsAg status		HBsAb status	
		No. positive (*N*=26)	Rate (%)	No. positive (*N*=3,147)	Rate (%)
Maternal age (years)*					
15–24	215	2	0.9	210	97.7
25–29	963	14	1.4	928	96.4
30–34	1,340	6	0.5	1,299	96.9
35–50	725	4	0.6	710	97.9
Maternal ethnicity					
Han	3,115	25	0.8	3,024	97.1
Other	128	1	0.8	123	96.1
Maternal education					
Junior high school and below	2,187	13	0.6	2,117	96.8
High school and above	1,056	13	1.2	1,030	97.5
Maternal occupation†					
Farmers	881	9	1.0	840	95.3
Other	2,362	17	0.7	2,307	97.7
HBV infected time (years)					
≤5	1,410	9	0.6	1,373	97.4
>5	1,833	17	0.9	1,774	96.8
Maternal HBV DNA tested†					
Yes	469	4	0.9	462	98.5
No	2,761	22	0.8	2,672	96.8
Maternal receipt of antiviral therapy during pregnancy					
Yes	202	2	1.0	197	97.5
No	3,040	24	0.8	2,949	97.0
Maternal HBeAg status during pregnancy*					
Negative	2,420	5	0.2	2,370	97.9
Positive	745	19	2.6	704	94.5
Unknown	77	2	2.6	72	93.5
Received HBIG during pregnancy†					
Yes	41	1	2.4	40	97.6
No	2,950	24	0.8	2,860	97.0
Unknown	248	1	0.4	243	98.0
Infant sex					
Male	1,687	15	0.9	1,639	97.2
Female	1,554	11	0.7	1,506	96.9
Birth weight (kg)					
≥2.50	3,121	26	0.8	3,025	96.9
<2.50	120	0	0.0	120	100
Pregnancy duration (weeks)					
≥37	3,058	26	0.9	2,965	97.0
<37	183	0	0.0	180	98.4

Continued

Variable	No. with PVST (*N*=3,243)	HBsAg status		HBsAb status	
		No. positive (*N*=26)	Rate (%)	No. positive (*N*=3,147)	Rate (%)
Maternal parity					
1	1,042	10	1.0	1,011	97.0
2	1,646	13	0.8	1,599	97.1
≥3	552	3	0.5	534	96.7
Mode of delivery					
Vaginal delivery	1,639	14	0.9	1,598	97.5
Caesarean section	1,603	12	0.8	1,548	96.6
Timely receipt of HBIG					
No	60	1	1.7	59	98.3
Yes	3,183	25	0.8	3,088	97.0
Timely receipt of first HepB dose					
No	181	3	1.7	176	97.2
Yes	3,062	23	0.8	2,971	97.0

Univariate analysis results: * HbsAg group: $P<0.05$; † HBsAb group: $P<0.05$.
Abbreviation: PVST=post vaccination serological testing; HBV=hepatis B virus; DNA=deoxyribonucleic acid; HBsAg=hepatitis B surface antigen; HBsAb=hepatitis B surface antibody; HepB=hepatitis B vaccine; HBIG=hepatitis B immunoglobulin; HBeAg=hepatitis B e-antigen.

HBs seropositivity reported in Zhejiang (*8*). PVST effectively identifies infants who remain susceptible to HBV and need revaccination. Our finding that 2.2% of vaccinated HBV-exposed infants required revaccination is consistent with reported HepB vaccine non-response rates of 2.6%–10% (*12*).

Our study demonstrated high adherence to the WHO-recommended passive-active immunization protocol (HepB1 + HBIG1 within 24 hours of birth), with 95% timely HBIG1 administration and 95% timely co-administration of HepB1 and HBIG. Preterm infants had lower co-administration rates (89.33% *vs.* 95.01% in term infants) (*13*), consistent with findings from Anhui Province. China's rising preterm birth rate (*14*) poses a challenge to MTCT prevention (*15*–*16*).

Maternal antenatal interventions, including HBV DNA testing (14.46%) and antiviral therapy (6.23%), were underutilized. Among the 26 HBsAg-positive infants, 22 and 24 were born to mothers who did not receive DNA testing or antiviral treatment during pregnancy, respectively. Antiviral therapy in HBsAg-positive mothers with high viral loads reduces intrauterine and perinatal transmission risk (*17*–*18*). Limited access to HBV DNA testing in rural healthcare facilities may contribute to this gap (*8*), underscoring the need to strengthen prenatal screening and treatment infrastructure.

This study was subject to at least two limitations. Missing data on the exact timing of HepB1 administration (i.e., <12 or <24 hours after birth) precluded evaluating strategy effectiveness with a first dose timing at shorter intervals within the first day of life. The number of breakthrough infections was too small to determine factors associated with breakthrough infection other than maternal HBeAg status. For example, there were too few breakthrough infections to evaluate shorter time frames for administration of HepB1 and HBIG. Because HBV DNA testing was not standard of care, we were unable to analyze breakthrough infections by quantitative DNA analysis. Future research with larger study populations is needed to address these limitations.

In conclusion, the MTCT prevention strategy in China is highly effective, with only 0.8% of infants born to HBV-infected mothers experiencing breakthrough infections. PVST monitoring for children born to HBsAg-positive mothers enables collection of MTCT prevention data and evaluation of revaccination effectiveness in HBV-exposed infants, enhancing HBV MTCT prevention. However, PVST is underutilized, and PVST compliance rates vary by province. We recommend strengthening training and supervision of PVST to increase use of properly conducted PVST in China. Evaluation of PVST results is critically important to strengthen the HBV MTCT prevention strategy and to evaluate progress toward WHO's target of 0.1% HBsAg prevalence among all

children five years and under.

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SUPPLEMENTARY MATERIAL

SUPPLEMENTARY TABLE S1. Maternal and infant characteristics for infants completing and not completing post-vaccination serologic testing.

Variable	PVST completion			χ^2	*P*
	No (*N*=4,182)	Yes (*N*=3,243)	Total (*N*=7,425)		
Province				2710.5	<0.001
Zhejiang	0 (0.0)	496 (15.3)	496 (6.7)		
Fujian	3,371 (80.6)	716 (22.1)	4,087 (55.0)		
Henan	252 (6.0)	889 (27.4)	1,141 (15.4)		
Sichuan	358 (8.6)	635 (19.6)	993 (13.4)		
Gansu	201 (4.8)	507 (15.6)	708 (9.5)		
Maternal age (years)				7.0	0.071
15–24	221 (5.3)	215 (6.6)	436 (5.9)		
25–29	1,275 (30.5)	963 (29.7)	2,238 (30.1)		
30–34	1,779 (42.5)	1,340 (41.3)	3,119 (42.0)		
35–50	907 (21.7)	725 (22.4)	1,632 (22.0)		
Maternal ethnicity				2.7	0.1
Han	3,984 (95.3)	3,115 (96.1)	7,099 (95.6)		
Other	198 (4.7)	128 (3.9)	326 (4.4)		
Maternal education				43.7	<0.001
Junior high school and below	3,112 (74.4)	2,187 (67.4)	5,299 (71.4)		
High school and above	1,069 (25.6)	1,056 (32.6)	2,125 (28.6)		
Maternal occupation				192.8	<0.001
Farmer	594 (14.2)	881 (27.2)	1,475 (19.9)		
Other	3,588 (85.8)	2,362 (72.8)	5,950 (80.1)		
HBV infected time (years)				14.2	<0.001
≤5	2,002 (47.9)	1,410 (43.5)	3,412 (46.0)		
>5	2,180 (52.1)	1,833 (56.5)	4,013 (54.0)		
Maternal receipt of HBV DNA test				56.7	<0.001
Yes	373 (8.9)	469 (14.5)	842 (11.4)		
No	3,807 (91.1)	2,761 (85.5)	6,568 (88.6)		
Maternal receipt of antiviral therapy during pregnancy				12.4	<0.001
Yes	184 (4.4)	202 (6.2)	386 (5.2)		
No	3,998 (95.6)	3,040 (93.8)	7,038 (94.8)		
Maternal HBeAg status during pregnancy				1.2	0.557
Negative	3,162 (75.6)	2,420 (74.6)	5,582 (75.2)		
Positive	930 (22.2)	745 (23.0)	1,675 (22.6)		
Unknown	89 (2.1)	77 (2.4)	166 (2.2)		
Infant sex				3.8	0.051
Male	2,271 (54.3)	1,687 (52.1)	3,958 (53.3)		
Female	1,909 (45.7)	1,554 (47.9)	3,463 (46.7)		
Birth weight (kg)				8.8	0.003
≥2.50	4,077 (97.5)	3,121 (96.3)	7,198 (97.0)		
<2.50	105 (2.5)	120 (3.7)	225 (3.0)		

Continued

Variable	PVST completion			χ^2	*P*
	No (*N*=4,182)	Yes (*N*=3,243)	Total (*N*=7,425)		
Pregnancy duration (weeks)				0.7	0.412
≥37	3,964 (94.8)	3,058 (94.4)	7,022 (94.6)		
<37	218 (5.2)	183 (5.6)	401 (5.4)		
Maternal parity				42.3	<0.001
1	1,063 (25.4)	1,042 (32.2)	2,105 (28.4)		
2	2,290 (54.8)	1,646 (50.8)	3,936 (53.0)		
≥3	829 (19.8)	552 (17.0)	1,381 (18.6)		
Mode of delivery				14.9	<0.001
Vaginal delivery	2,303 (55.1)	1,639 (50.6)	3,942 (53.1)		
Caesarean section	1,879 (44.9)	1,603 (49.4)	3,482 (46.9)		
HepB1+HBIG co-administration				13.9	<0.001
No	181 (4.3)	203 (6.3)	384 (5.2)		
Yes	4,001 (95.7)	3,040 (93.7)	7,041 (94.8)		
HepB full course				2.6	0.108
No	17 (0.4)	22 (0.7)	39 (0.5)		
Yes	4,165 (99.6)	3,221 (99.3)	7,386 (99.5)		

Abbreviaiton: PVST=post-vaccination serological test; HBV=hepatitis B virus; HBeAg=HBV e-antigen; HepB1+HBIG=first dose of hepatitis B vaccine plus hepatitis B immunoglobulin; DNA=deoxyribonucleic acid.