



Implementation of Strategies to Prevent Mother-to-child Transmission of Hepatitis B Virus Infection, Thailand, 2016–2017

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Abstract

Mother-to-child transmission (MTCT) of hepatitis B virus can cause chronic liver disease. Thailand aimed to eliminate MTCT of hepatitis B virus by 2025. Strategies include hepatitis B surface antigen (HBsAg) screening for pregnant women, antiviral therapy for infected mother, hepatitis B birth dose vaccination (HepB-BD), HBV immunoglobulin (HBIG) administration and post-vaccination serologic testing (PVST) for infants born to HBsAg-positive mother. The objectives of this study were to assess the management of HBsAg-positive mothers and their infants. We reviewed medical records of HBsAg-positive pregnant women and their infants born during 1 Jan 2016–31 Dec 2017 at 14 hospitals in seven provinces to assess the percentage of women who were tested and treated for HBV and the percentage of infants born to them who received HepB-BD, HBIG and underwent PVST. All 69,303 pregnant women were screened for HBsAg and 1,179 (1.7%) were HBsAg positive. Of 1,179 HBsAg-positive women, 219 (18.6%) were tested for hepatitis B e-antigen (HBeAg) and 85 (38.8%) were HBeAg positive; 29 (2.5%) were tested for HBV DNA and 14 (48.3%) had viral load $\geq 200,000$ IU/mL. Of 90 women eligible for antiviral therapy, 16 (17.8%) received treatment. Among 1,144 infants with available records, HepB-BD and HBIG coverage was 99.3% and 45.8%. Of 966 children with follow-up records, 12.2% underwent PVST and all were HBsAg negative. In conclusion, while the coverage of maternal HBsAg screening and infant HepB-BD was high, few women received follow-up testing and treatment. HBIG administration for infants was low and PVST rate still needed improvement.

Keywords: hepatitis B virus, hepatitis B infection, mother-to-child transmission, Thailand

Introduction

Approximately 296 million people worldwide are living with chronic hepatitis B virus (HBV) infection, which can lead to cirrhosis, liver cancer, and death.^{1–3} HBV is transmitted through mother-to-child transmission (MTCT) and the likelihood of developing chronic HBV infection is up to 90%.^{4,5} The highest risk of perinatal infection occurs when a pregnant woman with HBV infection has positive hepatitis B e-antigen (HBeAg) or has a high HBV DNA viral load.^{6,7}

The foundation of prevention of HBV MTCT is universal HBV vaccination for the newborn within 24 hours of birth followed by two to three additional doses during infancy. Administration of HBV immunoglobulin (HBIG) to newborns of hepatitis B surface antigen (HBsAg)-positive mothers may provide an additional benefit to vaccination, especially when the mother is HBeAg positive.^{5,8} Maternal screening to identify women at high risk of HBV transmission with additional antiviral treatment starting at 28–32 weeks

gestational age until 4 weeks after delivery for certain HBV infected women, can decrease the risk of HBV transmission and has been recommended by the World Health Organization since July 2020.⁸⁻¹⁰

Thailand has the highest rate of hepatitis B causing hepatocellular carcinoma.¹¹ Since 1992, Thailand implemented universal HBV vaccination for all newborns and infants. The current vaccination schedule includes a hepatitis B vaccine birth dose (HepB-BD) within 24 hours of birth, and additional doses at two, four, and six months of age.¹² National coverage of HepB-BD and third dose hepatitis B vaccine have been >95% for the past decade.¹³ Universal HBV vaccination has led to a significant reduction in the HBV prevalence in Thailand, with the seroprevalence of HBsAg among people born after vaccine introduction of 0.6% compared to 4.5% among those born prior to the introduction of the HBV vaccine.¹²

Standard practice for prevention of HBV MTCT in Thailand has also included universal maternal HBsAg screening and additional preventive measures for infants born to women with HBV infection. Infants born to HBV infected women should receive HepB-BD within 12 hours of birth followed by hepatitis B vaccine (HepB) at one, two, four, and six months of age as well as HBIG immediately after birth.¹⁴

In 2016, the World Health Organization announced that one of their goals was to eliminate HBV MTCT and reduce hepatitis B prevalence in children under 5 years to 0.1%. A HBV prevalence study in Thailand in 2016 indicated that the prevalence of HBV infection in children under 5 years in Thailand was 0.1%.¹² To achieve HBV MTCT elimination goal by 2025, Thailand launched a new strategy to eliminate MTCT of HBV in Thailand in 2018 which consists of four main indicators with the following minimum targets: 100% of pregnant women should be screened for HBsAg; 95% of pregnant women with a high risk HBV infection, as indicated by HBeAg positive or HBV DNA viral load $\geq 200,000$ IU/mL, should be prescribed Tenofovir treatment; 90% of all infants should receive HepB-BD within 12 hours of birth; and 90% of all infants born to HBV infected mothers should receive HBIG within 7 days.^{14,15} The strategy also recommends post-vaccination serologic testing (PVST) for children at 1 year of age, which consists of HBsAg and hepatitis B surface antibody testing.

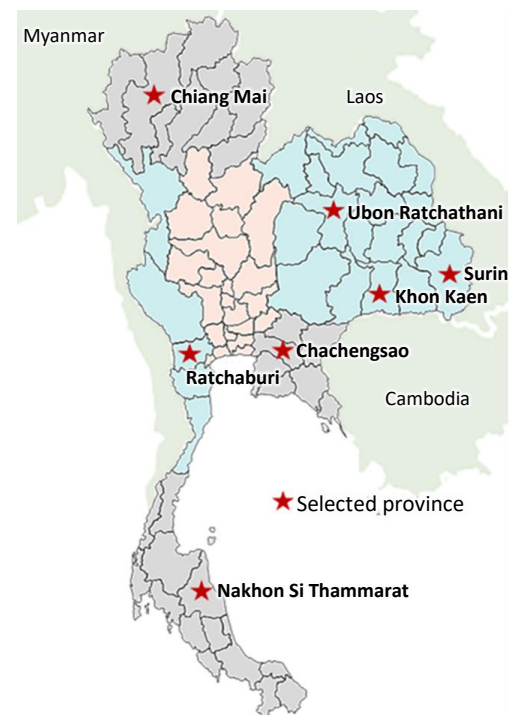
To support evidence-informed policy decision to strengthen the elimination of HBV MTCT, we conducted a survey to assess the management of HBsAg-positive mothers and their infants during 2016–2017, in an aim to identify gaps, challenges and opportunity for HBV MTCT in Thailand.

Methods

We conducted a retrospective survey to describe HBV MTCT practices in Thailand during 1 Jan 2016 to 31 Dec 2017.

Population and Sampling

We retrospectively reviewed medical records of pregnant women who gave birth during 2016–2017 and their infants in seven of the 77 provinces. These provinces are located in the Northern, North-eastern, Eastern, Western/Central and Southern regions of Thailand. Four of the seven provinces border Myanmar, Laos or Cambodia. From each province, one tertiary hospital and one district hospital was purposively selected (Figure 1).



The sites were distributed in seven out of the 77 provinces in Thailand, which are denoted by the stars. These seven provinces were Chiang Mai (Northern region), Ubon Ratchathani (North-eastern region), Surin (North-eastern region), Khon Kaen (North-eastern region), Chachoengsao (Eastern region), Ratchaburi (Central/Western region) and Nakhon Si Thammarat (Southern region).

Figure 1. Map of Thailand highlighting survey sites

Data Collection

At each hospital, we determined the total number of pregnant women and the number of HBsAg-positive pregnant women who delivered at the hospital during 1 Jan 2016 to 31 Dec 2017 by reviewing the labor room line list and hospital database. For women with a positive HBsAg result, we reviewed their medical records to abstract demographic, gravidity, lab results, and clinical management. For their infants, we abstracted demographic data, HepB-BD vaccination status, receipt of HBIG, and post-vaccination testing results.

Data Management and Analysis

We entered the data into Epidata version 3.1 (Odense, Denmark) or Microsoft Excel (Redmond, Washington, USA) using double data entry. We used Epi Info version 7.2.1.0 (Atlanta, Georgia, USA) and Microsoft Excel for data analysis. We conducted descriptive analyses to describe the prevalence of HBsAg among pregnant women and estimate the percentage of HBsAg-infected women who were tested for HBeAg and/or HBV DNA, were seen by an internist, and received anti-viral medication. Among infants born to HBsAg-positive women, we calculated the percentage of receiving timely HepB-BD vaccine (within 12 and 24 hours), total HepB-BD (received any time), HBIG, and post-vaccination testing with HBsAg and/or hepatitis B surface antibody.

Ethics

The survey was undertaken under the authority of the Thai Ministry of Public Health to conduct a review of medical records in government hospitals for program evaluation purposes. The participants' data remained confidential within the Ministry of Public Health.

Results

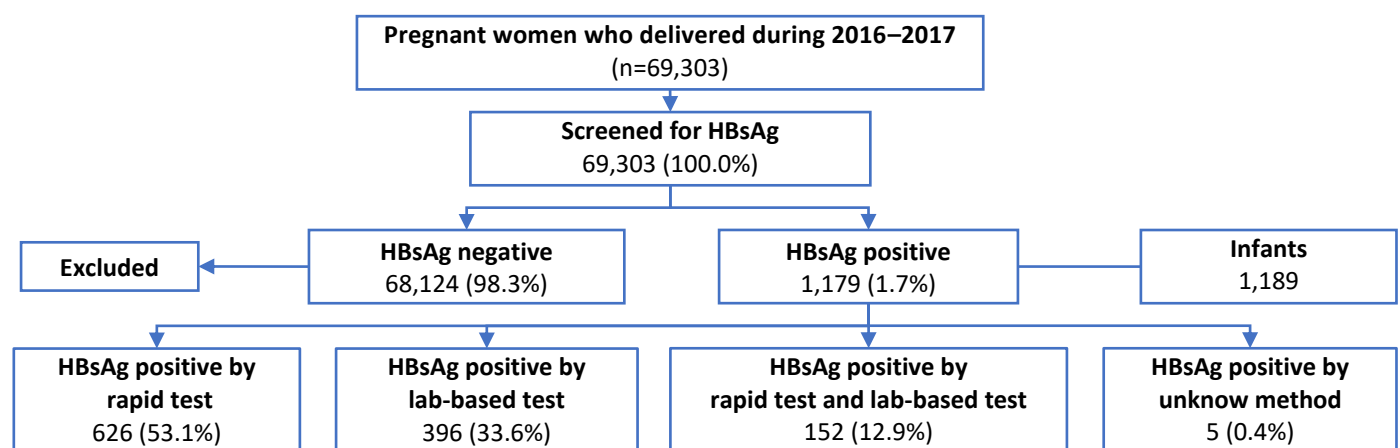
General Characteristics of HBsAg-positive Women and Their Infants

We reviewed the records of 69,303 pregnant women who delivered in the selected hospitals during the survey period (Figure 2). All women were screened for HBsAg, and the HBsAg prevalence was 1.7% (n=1,179). The mean age of HBsAg-positive pregnant women was 30 years and most (81.0%) were Thai nationals (Table 1). Most women lived in the North-eastern region (44.4%) followed by the Northern region (26.2%). There were 1,189 infants (including 10 sets of twins) born to the 1,179 women who tested positive for HBsAg. Of the 1,189 infants, 585 (50.7%) were male. Among 1,180

infants with a recorded birth weight, 1,048 (88.8%) were normal (weight $\geq 2,500$ grams). The mean birth weight was 3,032 grams. Among 1,173 infants with a record of gestational age, 1,036 (88.3%) were full term (gestational age ≥ 37 weeks).

Table 1. Characteristics of pregnant women who tested positive for HBsAg and infants at selected hospitals in Thailand, 2016–2017

Characteristic	n	%
Demographic data, n=1,179		
Mean age (years) =30	-	-
Nationality		
Thai	955	81.0
Myanmar	151	12.8
Lao	26	2.2
Other	24	2.0
Unknown	23	2.0
Region of residence		
North-eastern	523	44.4
Northern	309	26.2
Southern	115	9.8
Eastern	105	8.9
Western	87	7.4
Central	29	2.5
Other	7	0.6
Unknown	4	0.3
Gravidity		
1	358	30.4
2	447	37.9
≥ 3	355	30.1
Unknown	19	1.6
Demographic data of infants (n=1,189)		
Male (n=1,153)	585	50.7
Birth weight (grams) (n=1,180)		
Normal ($\geq 2,500$ g)	1,048	88.8
Low ($< 2,500$ g)	132	11.2
Gestational age at birth (n=1,173)		
Term (≥ 37 weeks)	1,036	88.3
Preterm (< 37 weeks)	137	11.7



HBsAg: Hepatitis B surface antigen. Of the 69,303 pregnant women delivered during 2016–2017 and all were screened for HBsAg. Among these, 1,179 (1.7%) were HBsAg positive. All of the HBsAg-positive women and their 1,189 infants (including 10 pairs of twins) were included in the review.

Figure 2. Participant flow diagram

Maternal HBV Diagnostic Testing

Of the 1,179 HBsAg-positive mothers, 626 (53.1%) were tested for HBsAg by RDT, 396 (33.6%) were diagnosed by a lab-based test (indirect ELISA or CMIA), 152 (12.9%) had both RDT and lab-based test, and 5 (0.4%) had an unknown testing method. Among the 132 women who received HBsAg testing at a district hospital, 117 (88.6%) were tested by RDT, 14 (0.6%) had a lab-based test, and 1 (0.8%) had both RDT and lab-based test. Among the 1,047 women who received HBsAg testing at a tertiary hospital, 509 (48.6%) were tested by RDT, 382 (36.5%) had a lab-based test, 151 (14.4%) had both RDT and lab-based test, and 5 (0.5%) had an unknown testing method.

Women who were initially tested by an RDT should have had a confirmatory lab-based test; however, only

19.5% (152/778) of women diagnosed with HBsAg by an RDT had a confirmatory lab-based test.

Evaluation of Maternal HBV Risk Status and Treatment for Mothers at High Risk of Mother to Child Transmission

Of the 1,176 HBsAg-positive mothers whose medical records included a field for HBeAg results, 219 (18.6%) received HBeAg testing (Table 2). All but 4 of these women were tested for HBeAg in tertiary hospitals. By region, the proportion of women tested for HBeAg varied from 32.8% (North-eastern Region) to 1.0% (Eastern Region). Among the 219 women who had a test result for HBeAg, 85 (38.8%) were positive. The percentage of women who tested positive for HBeAg ranged from 64.3% (Northern Region) to 18.2% (Southern Region). Few women from the Central, Eastern and Western regions who were tested for HBeAg had either negative or missing results.

Table 2. Follow-up testing for pregnant women with HBV infection at selected tertiary hospitals, by region, Thailand, 2016–2017

Region	HBeAg tested			Positive HBeAg			HBV DNA viral load tested			Viral load $\geq 200,000$ IU/mL		
	N	n	%	N	n	%	N	n	%	N	n	%
Northern	309	14	4.5	14	9	64.3	309	2	0.6	2	0	0.0
North-eastern	525	172	32.8	172	69	40.1	525	13	2.5	13	8	61.5
Central	28	1	3.6	1	0*	0.0	28	1	3.6	1	0*	0.0
Southern	115	11	9.6	11	2*	18.2	115	7	6.1	7	3*	42.9
Eastern	105	1	1.0	1	0*	0.0	105	1	1.0	1	0	0.0
Western	87	18	20.7	18	5*	27.8	87	5	5.7	5	3	60.0
Other country	7	2	28.6	2	0	0.0	7	0	0.0	-	-	-
Total	1,176	219	18.6	219	85	38.8	1,176	29	2.5	29	14	48.3

*Unknown results. HBV: hepatitis B virus. HBeAg: hepatitis B e-antigen. HBV DNA: hepatitis B deoxyribonucleic acid.

Of the 1,176 HBsAg-positive mothers whose records included information on HBV DNA viral load testing, 29 (2.5%) had a test result. Of these, 14 (48.2%) had a viral load $\geq 200,000$ IU/mL. None of the women who delivered in a district hospital were tested for HBV DNA viral load. Nine women were both HBeAg positive and had HBV DNA $\geq 200,000$ IU/mL.

Among 1,176 HBsAg-positive women who had HBeAg or HBV DNA viral load testing, 90 (7.7%) were high-risk for HBV MTCT due to a viral load $\geq 200,000$ IU/mL, presence of HBeAg, or both. Of these 90 women, 21 (23.3%) were seen by an internist for follow up of their

HBV infection (Table 3). The percentage of high-risk women seen by an internist varied by region of residence, from 14.1% in the North-eastern region to 60.0% in the Southern and Western regions. Of the 21 women seen by an internist, 16 (76.2%) were prescribed an antiviral medication (lamivudine or tenofovir). There were six women with pre-existing HBV or HIV who were already receiving an antiviral medication from an internist at the time of their pregnancy. The percentage of high-risk women who received an antiviral medication varied from 60.0% in the Northern region to 100.0% in the Southern and Western regions.

Table 3. Management of pregnant women at high risk of mother to child transmission of HBV infection at selected tertiary hospitals in Thailand, 2016–2017

Region	High risk maternal status (HBeAg positive or viral load $\geq 200,000$ IU/mL)			Referred to internist			Prescribed antiviral treatment		
	N	n	%	N	n	%	N	n	%
Northern	309	9	2.9	9	5	55.6	5	3	60.0
North-eastern	525	71	13.5	71	10	14.1	10	7	70.0
Central	28	0	0.0	-	-	-	-	-	-
Southern	115	5	4.3	5	3	60.0	3	3	100.0
Eastern	105	0	0.0	-	-	-	-	-	-
Western	87	5	5.7	5	3	60.0	3	3	100.0
Other country	7	0	0.0	-	-	-	-	-	-
Total	1,176	90	7.7	90	21	23.3	21	16	76.2

Management of Infants Born to HBsAg-positive Mothers

Records for 1,144 of the 1,189 infants (96.2%) were available for analysis. HepB-BD coverage was 99.3% overall, 99.2% for tertiary hospitals, and 100.0% for district hospitals (Table 4). HepB-BD coverage was 100.0% for all regions except for the Northern (97.8%) and North-eastern (99.8%) regions, where results were missing for 7/313 and 1/530 records, respectively. Among the 1,136 newborns who received HepB-BD, 1,104 (97.1%) received HepB-BD within 24 hours, as recommended by World Health Organization guidelines, and 32 (2.8%) were uncertain of HepB-BD administration time.² Among 1,104 newborns who received HepB-BD within 24 hours, 705 (63.8%) received it within 12 hours of birth.

Records for 1,106 infants included data on HBIG, of which 507 (45.8%) received HBIG. Of these, 499 (98.2%) received HBIG within the first day of life. The percentage of infants receiving HBIG varied by region and type of hospital. None of the infants in the Southern (n=114) or Eastern (n=109) regions received HBIG, whereas 457 of 526 (86.8%) infants in the North-eastern region received HBIG. Of the 526 infants in the North-eastern region, a higher proportion of infants received HBIG at a tertiary hospital (93.0%) than at a district hospital (54.2%). However, in the Northern region, fewer infants at a tertiary hospital (2.2%) received HBIG than at a district hospital (56.3%).

Table 4. Proportion of infants who received hepatitis B birth dose vaccination (n=1,144) and hepatitis B immune globulin (n=1,106) at selected hospitals, by region and type of hospital, Thailand, 2016–2017

Region	Hepatitis B birth dose vaccination									Hepatitis B immune globulin								
	Tertiary hospital			District hospital			Total			Tertiary hospital			District hospital			Total		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
Northern	278	271	97.5	35	35	100.0	313	306	97.8	272	6	2.2	32	18	56.3	304	24	7.9
North-eastern	446	445	99.8	84	84	100.0	530	529	99.8	443	412	93.0	83	45	54.2	526	457	86.9
Southern	106	106	100.0	5	5	100.0	111	111	100.0	109	0	0.0	5	0	0.0	114	0	0.0
Eastern	110	110	100.0	5	5	100.0	115	115	100.0	105	0	0.0	4	0	0.0	109	0	0.0
Western	72	72	100.0	3	3	100.0	75	75	100.0	50	25	50.0	3	1	33.3	53	26	49.1
Total	1,012	1,004	99.2	132	132	100.0	1,144	1,136	99.3	979	443	45.3	127	64	50.4	1,106	507	45.8

Post-vaccination Serologic Testing (PVST) for Children Born to HBsAg-positive Women

Of 966 children with HBsAg data, 118 (12.2%) were tested for HBsAg, and all had a negative test result. Of 960 children, 117 (12.2%) were tested for hepatitis B surface antibody. Out of the 117 children tested for hepatitis B surface antibody, 112 (95.7%) had a positive test result indicating immunity to HBV, one

child was initially not immune but became immune after receiving an additional dose of HBV vaccine, and in four children, the result was missing.

Discussion

This study provided an overview of the practices to prevent MTCT of HBV in Thailand during 2016–2017, before nationwide introduction of Thailand's new

strategy to eliminate MTCT of HBV. The purpose of the study was to report the baseline situation before implementation of the strategy to prevent MTCT of HBV in Thailand.

In this study, 100% of pregnant women were screened for HBsAg, which highlights the success of Thailand's maternal screening policy.¹⁶ The maternal HBsAg prevalence of 1.7% indicates low HBV endemicity among pregnant women.² Despite the low HBsAg prevalence, only 18.6% of HBsAg-positive women received HBeAg and only 2.5% received HBV DNA viral load testing, with tests mostly provided by tertiary hospitals. These results are not unexpected because follow-up testing was not standard at the time and district hospitals in Thailand usually do not have the capacity to perform these tests. These results highlight key challenges for district hospitals; without these tests, pregnant women will need to be referred to tertiary hospitals for follow-up testing to ensure that those who are infected receive proper HBV treatment.

While only a small percentage of HBsAg-positive women received HBeAg or HBV DNA viral load testing, 38.8% of women who were tested for HBeAg were positive, and 48.3% of women who received HBV DNA viral load testing had levels $\geq 200,000$ IU/mL. These women were at high risk of transmitting HBV to their infants; however, only 23.3% were referred to internists for evaluation and initiation of antiviral medication. These results suggested that there were many women at high risk of transmitting HBV to their infants who were missed by the health system. Due to limit availability of internists, allowing general practitioners to prescribe antiviral medication to HBsAg-positive women could increase the proportion of women on antiviral treatment and better prevent MTCT of HBV.

Thailand's immunization program has recommended universal, timely HepB-BD for all newborns to prevent MTCT of HBV for many decades.¹² In this survey, 99.3% of newborns received HepB-BD and 97.1% received HepB-BD within 24 hours of birth. The high HepB-BD coverage among the hospitals included in this survey are consistent with national HepB-BD coverage estimates.¹³ Coverage of HepB-BD received within 12 hours of birth was lower at 63.8%; although this result may be underestimated because the time of receiving HepB-BD was missing for almost half of the newborns. Because Thailand's new strategy includes administration of HepB-BD within 12 hours for all infants, it will be important for the time of administration to be documented in the medical records so this indicator can be measured. Anecdotally, data collectors noted that some medical records did not

include a field to record the time of vaccination, therefore we recommend that all medical record forms allow for complete HepB-BD documentation.

Although only 45.8% of eligible infants received HBIG, 97.1% of infants received the treatment within one day. There are a few possible reasons for the low HBIG coverage in this survey. First, only tertiary hospitals in Thailand stock HBIG, due to shortages, so infants born at district hospitals are less likely to receive the treatment. Second, some health facilities do not provide HBIG due to its high cost, while other health facilities charge parents for its use, and the parents may not be able to afford it. Third, none of the infants living in the Southern and Eastern regions received HBIG, possibly because health care workers do not offer this treatment to eligible newborn, as in some countries where lack of knowledge about indications for HBIG has led to missed opportunities to provide this treatment to eligible infants.¹⁷ Under Thailand's new strategy to eliminate MTCT of HBV, 90% of infants born to HBsAg-positive mothers should receive HBIG, so the challenges noted above should be addressed to reach this target.

The percentage of children who received post-vaccination serologic testing coverage, which was not part of standard of care at the time of the survey, was low, with only 12.2% of children receiving hepatitis B surface antibody testing and 12.2% receiving HBsAg testing. To ensure that all children receive PVST at 12 months of age, it is important to ensure that health care workers and parents are aware of this new recommendation.

There were a few limitations in this survey. First, both provinces and health facilities were selected by convenience sampling and Bangkok was not included, thus the results may not be representative of the entire country. Second, the proportion of tertiary and district hospitals might not be representative of the current proportion of hospitals in each region nor the entire country. Third, the study was a retrospective medical record review and some of the data were incomplete. Some women could have received antenatal care and delivery care at different hospitals, thus the information in their records might be incomplete at the hospital included in the study.

Conclusion

Thailand has made tremendous progress towards HBV control with high HepB-BD and third dose hepatitis B vaccine coverage. In September 2019, Thailand was one of the first countries to be verified as having achieved HBV control through immunization in the World Health Organization South-East Asia Region.¹⁸

The next step towards HBV elimination is to eliminate MTCT of HBV, as recommended in Thailand's new 2018 guidelines. The HBsAg prevalence among pregnant women in this study was low; however, the proportion of HBsAg-positive women who received follow-up testing and antiviral treatment was low. Most infants born to an HBV infected mother received the hepatitis B vaccine but only half of them received HBIG. This study identified several key challenges that should be addressed as Thailand implements its new policy. First, women who are HBsAg-positive should receive follow-up laboratory testing and women with high-risk infection should be referred to clinicians for antiviral therapy. Second, district hospitals should increase the availability of HBIG and ensure that children receive PVST testing. Third, capacity building on HBV MTCT elimination should be done at all levels.

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Conflicts of Interest

The authors have no conflicts of interest to declare.

Author Contributions

SJ designed the survey protocol and oversaw survey implementation. NP planned the survey implementation procedures, created the data abstraction form, participated in data collection, analyzed the data, and drafted the manuscript. JC and NW facilitated survey implementation with local authorities. TR reviewed and revised the data abstraction form. AAM reviewed the results and drafted the manuscript.

Disclaimer

The findings and conclusions in this paper are those of the authors and do not necessarily reflect the position of the Centers for Disease Control and Prevention.

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