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Serologic testing after hepatitis B vaccination for babies born to mothers infected with hepatitis B virus

Introduction

Hepatitis B vaccination is one of the primary preventive measures for hepatitis B virus (HBV), in particular to mother-to-child transmission (MTCT), which accounts for most of the disease burden of chronic HBV infection in Hong Kong. World Health Organization (WHO) recommends that all infants should receive their first dose of hepatitis B vaccine as soon as possible after birth, preferably within 24 hours, followed by two or three doses at least four weeks apart to complete the vaccination series [1, 2]. As outlined in *Global health sector strategy on viral hepatitis, 2016 – 2021*, WHO has set clear targets at 90% coverage of (i) third-dose hepatitis B vaccination in children and (ii) hepatitis B birth-dose vaccination or other approach to prevent MTCT respectively by 2030 [3].

Efficacy and effectiveness of hepatitis B vaccination

The protective efficacy of hepatitis B vaccine is indicated by the presence of hepatitis B surface antibodies (anti-HBs) concentration at 10 mIU/mL or above measured 1 – 2 months after administration of the last dose of the primary vaccination series [4].

A primary three-dose series can induce protective antibody concentration in more than 95% of healthy infants, as shown by reviews of studies on the seroprotection after a primary course of recombinant hepatitis B vaccine administered to newborns. The final median seroprotection proportions did not vary appreciably by maternal hepatitis B surface antigen (HBsAg) status or hepatitis B immunoglobulin (HBIG) administration. The reviews also found that the final median seroprotection proportion was lower among infants with birth weights less than 2000 grams [2, 5, 6].

In a review and meta-analysis of 22 studies involving 11 090 subjects, the overall cumulative incidence of subclinical HBV breakthrough infection (at least two consecutive serum specimens positive for hepatitis B core antibodies (anti-HBc)) 5 – 20 years after primary vaccination was 0.7% (95% confidence interval [CI]: 0.5% – 1.0%), but none developed chronic HBV infection, suggesting a long-term

protection provided by hepatitis B vaccine in adequately vaccinated and immunocompetent individuals [7].

Similar findings were observed in a local 30-year cohort study involving 1112 neonates born to hepatitis B mothers recruited in 1983. Anti-HBs positivity (≥ 10 mIU/mL) was developed in 92.6% of the study subjects upon completion of the three-dose hepatitis B vaccination, while 3.5% were tested positive for HBsAg before the age of two. As no new infection was found after the second year of follow-up, this local study demonstrated direct long-term efficacy of neonatal hepatitis B vaccination in a high-risk cohort even though anti-HBs antibody levels of about two thirds of vaccinees dropped below 10 mIU/mL after 30 years [8].

Hepatitis B vaccination programmes are effective in reducing the incidence and prevalence of hepatitis B in many endemic countries [9, 10]. The WHO *Global progress report on HIV, viral hepatitis and sexually transmitted infections, 2021* estimated that scaled-up hepatitis B vaccination had steeply reduced the global prevalence of HBV infection among children younger than five years to 0.94% in 2019 [11], from 4.7% in the pre-vaccination era (which, according to the year of introduction can range from 1980s to the early 2000s in different countries) [12].

Despite the high effectiveness of the current strategy of hepatitis B vaccination, coupled with HBIG administration for HBV-exposed newborn babies, in preventing the development of chronic HBV infection in babies born to HBsAg-positive mothers, a small proportion of vaccinees do not mount an antibody response. In this connection, post-vaccination serologic testing (PVST) could be used to determine individual responses to vaccination. PVST is particularly important for persons in infancy or early childhood, in view of the high risk of chronicity following acute HBV infection in neonates (80 – 90%) and in young children under the age of 6 years (30 – 50%) [13]

International recommendations on PVST

Routine post-vaccination testing is **not** recommended by WHO. However, testing for immunity is recommended for individuals whose subsequent clinical management depends on knowledge of their immune status [2], such as:

(i) persons at risk of occupational exposure to HBV infection, e.g. health-care workers;
(ii) infants born to HBsAg-positive mothers;

(iii) chronic haemodialysis patients;
(iv) HIV-positive and other immunocompromised persons; and
(v) sex partners or needle-sharing partners of persons who are HBsAg-positive.

WHO Regional Office for the Western Pacific also emphasises the important role of PVST for babies born to HBsAg-positive mothers in assessing the effectiveness of MTCT prevention programme, when antenatal hepatitis B screening and vaccination programme are in place [14].

Globally, the recommendations on PVST for infants born to HBsAg-positive mother have been included in immunisation practice guidelines in many developed countries, such as the United Kingdom [15], the United States [16], Canada [17], Australia [18] and New Zealand [19]. In 2016, China also officially provided policy recommendations on PVST for newborns of HBsAg-positive mothers in the National Immunisation Programme for the first time [20], and pilot PVST programme was implemented in some administrative areas, such as Chongqing Municipality, Zhejiang, Jiangxi and Fujian provinces [21].

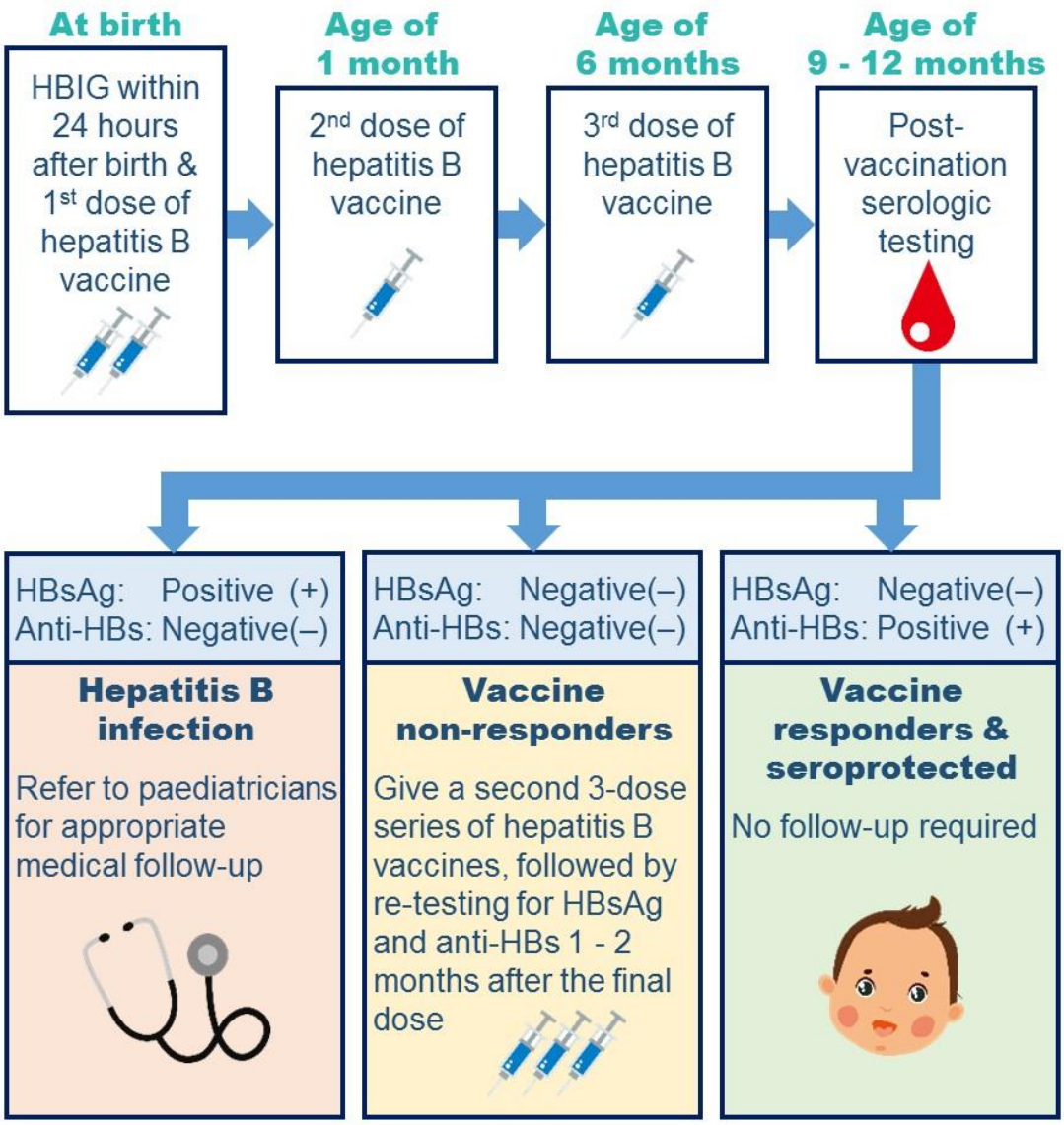
MTCT prevention strategies and initiative on PVST in Hong Kong

In Hong Kong, routine screening of pregnant women for HBsAg, universal childhood hepatitis B vaccination, administration of HBIG to babies born to HBsAg-positive mothers and provision of maternal antiviral prophylaxis to infected mothers with high viral load have been in place to prevent MTCT of HBV. For newborn babies in Hong Kong, the standard vaccination regimen consists of three doses of hepatitis B vaccine administered at birth and at the age of 1 month and 6 months respectively. The coverage rate for the third-dose hepatitis B vaccine among babies born locally has been consistently high (>98%) [22].

PVST for babies born to HBV-infected women will be introduced in early 2022 tentatively to further enhance the current MTCT prevention strategies. These babies would be tested for both anti-HBs and HBsAg at the age of 9 – 12 months, or 1 – 2 months after administration of the last dose of the vaccine for delayed vaccination series (Figure 1).

Serologic testing after hepatitis B vaccination for babies born to mothers infected with hepatitis B virus

Figure 1. Flowchart of PVST



Notes:

- PVST should not be performed before the age of 9 months to avoid detection of passive anti-HBs from HBIG administered at birth.
- For babies with delayed primary vaccination series, PVST should be conducted 1 – 2 months after the last dose of the primary series.
- In case of defaulted scheduled PVST appointment, PVST can be offered to babies up to the age of 24 months.

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The initiative of PVST is one of the key actions in *Hong Kong Viral Hepatitis Action Plan 2020 – 2024*, launched in October 2020 [23]. The purposes of PVST are threefold –

(i) to identify babies born to HBV-infected women who do not have an adequate immune response to an initial hepatitis B vaccine series and thus require re-vaccination;
(ii) to enable early identification of HBV-infected babies to ensure appropriate medical care for them; and
(iii) to provide useful systematic information to monitor the programme and overall prevention strategy.

Serological markers included in the testing

PVST consists of testing on both HBsAg and anti-HBs.

HBsAg test is used to exclude or confirm a current HBV infection.

Anti-HBs test checks the immunity against HBV infection. A positive test result refers to an anti-HBs level at 10 mIU/mL or above. A positive anti-HBs test result together with a negative HBsAg test result in PVST would imply that the babies are seroprotected and MTCT of HBV has been stopped.

Anti-HBc test can indicate prior natural infection with HBV at undefined time point. However, anti-HBc testing in infants is not recommended due to possible detection of passively acquired maternal anti-HBc in infants born to HBsAg-positive mothers up to the age of 24 months [24].

Timing of serologic testing

PVST should be conducted for babies at the age of 9 – 12 months (minimum age of 9 months).

For babies with delayed primary vaccination series, PVST should be conducted 1 – 2 months after the last dose of the primary series.

The timing of PVST is critical to guide appropriate follow-up actions.

As suggested from the data in the Enhanced Perinatal Hepatitis B Prevention Program in the United States, the optimal timing of PVST is 1 – 2 months after the final dose of hepatitis B vaccine due to the lower levels of measured anti-HBs with increasing time after vaccination [25]. PVST undertaken at increasing intervals after the final vaccine dose could result in misclassification of some seroprotected infants as vaccine non-responders and therefore lead to unnecessary re-vaccination.

Nevertheless, PVST should not be performed earlier than the age of 9 months to avoid detection of passive anti-HBs from HBIG administered at birth and maximise the likelihood of detecting late HBV infection. In this regard, it is recommended to conduct PVST at age 9 – 12 months for babies who complete the vaccination as scheduled.

Follow-up actions

Babies not responding to the primary vaccination series would be given a second 3-dose course of hepatitis B vaccines, followed by PVST.

Infected babies would be referred to paediatricians for medical follow-up.

Most individuals who do not respond to a primary 3-dose series with anti-HBs antibody concentrations less than 10 mIU/mL do respond to an additional 3-dose vaccination series [2]. A systematic review and meta-analysis of management options for adults who responded poorly to hepatitis B vaccination found that seroconversion rate after additional three doses could reach 80% or above [26]. Other studies or PVST programmes showed a seroconversion rate greater than 90% after reimmunisation of infants or children who did not respond to the primary perinatal vaccination [27, 28, 29, 30].

Experience of PVST programme in other places

The acceptance and compliance to the testing cascade remain the major implementation challenges in PVST programme. The experience in Macau found that only three quarters of subjects (980/1315; 74.5%) had completed primary hepatitis B vaccination and PVST according to the protocol [29]. In China, parents' refusal of venous blood sample collection was one of the common reasons for

missing PVST, leading to a low participation rate at 65.6% in some provinces (Henan, Sichuan, Jilin and Gansu) in 2014 [31] and loss to follow up rate reaching 20% in the pilot PVST programme initiated in 2016 [21]. The uptake rate of PVST in overseas programmes was also suboptimal (from 25.1% in 1994 to 55.7% in 2008 in the United States [32]; 32.9% – 58.3% in the United Kingdom [33, 34]). It could be improved by enhancement in case management with more intensive follow-up and close collaboration between professional groups [35], or with support in programme evaluation [28].

It is important to acknowledge that PVST in babies born to HBV-infected mothers is an essential strategy to ensure full protection for vaccine non-responders and appropriate medical care for infected babies. It will further enhance the prevention of MTCT of HBV, with a view to realising an "HBV-free generation" in Hong Kong and progressing towards the elimination of the public health threat posed by hepatitis B.

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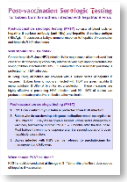
Useful resources

Description of materials	Hyperlink	QR code	Cover
Factsheet – Post-vaccination Serologic Testing for babies born to mothers infected with hepatitis B virus	https://www.hepatitis.gov.hk/doc/pdf/PVST_factsheet.pdf		
iCE Activities – Prevention of mother-to-child transmission of hepatitis B virus	https://www.hepatitis.gov.hk/english/health_professionals/files/iCE_PMTCT_of_HBV.pdf		
Presentation slides – Serologic testing after hepatitis B vaccination for babies born to mothers infected with hepatitis B virus	https://www.hepatitis.gov.hk/english/health_professionals/files/PVST_website.pdf		
Presentation slides – Prevention of mother-to-child transmission of hepatitis B	https://www.hepatitis.gov.hk/english/health_professionals/files/Prevention_of_MTCT_of_HBV_web.pdf		
Public health talk – Stop mother-to-child transmission of hepatitis B	https://www.hepatitis.gov.hk/tc_chi/news_activities/files/mother2child_Hepatitis_B.pdf		
Video – Hong Kong Viral Hepatitis Action Plan 2020-2024	https://youtu.be/VaHs-DZWXEM		
Video – Stop mother-to-child transmission to realise a hepatitis B-free generation	https://youtu.be/5_FFuOKVVb4		

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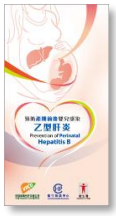
Pamphlet – Prevention of Perinatal Hepatitis B	https://www.hepatitis.gov.hk/tc_chi/resources/files/leaflet2020_3.pdf		
Pamphlet – Stop Maternal Transmission of Hepatitis B	https://www.hepatitis.gov.hk/tc_chi/resources/files/stop-transmiss-leaflet-w3c.pdf		
Pamphlet – 3-Dose Vaccines to Prevent Hepatitis B	https://www.hepatitis.gov.hk/tc_chi/resources/files/leaflet2020_2.pdf		
Poster – Prevention of Perinatal Hepatitis B	https://www.hepatitis.gov.hk/tc_chi/resources/files/poster2020_3.pdf		
Poster – Stop Maternal Transmission of Hepatitis B	https://www.hepatitis.gov.hk/tc_chi/resources/files/poster2020_4.pdf		
Poster – 3-Dose Vaccines to Prevent Hepatitis B	https://www.hepatitis.gov.hk/tc_chi/resources/files/poster2020_2.pdf		

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Test paper

Please submit the completed answer sheet within the validity period by email to hepatitis@dh.gov.hk.

CME/CPD point: 0.5-1

CNE/PEM point: 1

Validity Period: 28 September 2021 to 27 September 2022

College/ Programme	CME/ CPD Point	CME/CPD Category
Anaesthesiologists	1	PP-NA
Community Medicine	1	AP-SS
Dental Surgeons	1	OA-SS
Emergency Medicine	1	CME-PP
Family Physicians	1	OEA-5.02
Obstetricians and Gynaecologists	1	PP-PN
Ophthalmologists	1	CME-PP
Orthopaedic Surgeons	1	B
Otorhinolaryngologists	0.5	PP-2.2
Paediatricians	1	Cat E (active)
Pathologists	1	CME-SS
Physicians	1	PP-PP
Psychiatrists	1	SS-OL
Radiologists	1	B-PP
Surgeons	1	CME-PP
MCHK CME Programme for Practising Doctors who are not taking CME Programme for Specialists	1	Passive (Accredited by DH)

Please contact respective authorities directly for CME/CPD accreditation if it is not listed above.

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1. Which of the following is **NOT** a correct description about the importance of post-vaccination serologic testing (PVST) for babies born to HBsAg-positive mothers?
   A. Chronicity is common following acute HBV infection in neonates and young children.
   B. The efficacy of hepatitis B vaccination in infants is low, and a large proportion of vaccinated babies do not mount adequate immune response.
   C. PVST is an essential strategy to ensure full protection from hepatitis B vaccination for high-risk babies.
   D. PVST is an essential strategy to identify high-risk babies who do not respond to the primary course of hepatitis B vaccination for offering second course of vaccination.
   E. PVST is an essential strategy to ensure appropriate medical care for infected babies.

2. Which of the following markers can indicate protective efficacy of hepatitis B vaccination?
   A. Hepatitis B surface antigen (HBsAg)
   B. IgM antibodies to hepatitis B core antigen (IgM anti-HBc)
   C. Total hepatitis B core antibodies (Total anti-HBc)
   D. Hepatitis B e antibodies (anti-HBe)
   E. Hepatitis B surface antibodies (anti-HBs)

3. According to World Health Organisation's recommendations, which of the following does **NOT** belong to the groups, for which serologic testing after hepatitis B vaccination is recommended?
   A. Health-care workers
   B. Infants born to HBsAg-positive mothers
   C. Chronic haemodialysis patients
   D. HIV-positive and other immunocompromised persons
   E. Young healthy adults

4. Which of the following is **NOT** part of the preventive measures for MTCT of HBV in Hong Kong?
   A. Routine screening of pregnant women for HBsAg
   B. Universal childhood hepatitis B vaccination
   C. Administration of HBIG to HBsAg-positive pregnant women
   D. Administration of HBIG to babies born to HBsAg-positive mothers
   E. Provision of maternal antiviral prophylaxis to HBsAg-positive mothers with high viral load

5. Which of the following is **NOT** the purpose of PVST programme for babies born to HBsAg-positive mothers in Hong Kong?
   A. To examine the liver function of all babies born to HBsAg-positive mothers
   B. To identify babies who do not have an adequate immune response to an initial hepatitis B vaccine series
   C. To arrange hepatitis B re-vaccination if needed
   D. To enable identification of HBV-infected babies for appropriate medical care
   E. To provide useful and systematic information to monitor the effectiveness of the overall MTCT prevention strategy

6. Which of the following serological marker(s) would be tested in the PVST prorgramme in Hong Kong?
   A. HBsAg only
   B. Anti-HBs only
   C. HBsAg and anti-HBc
   D. HBsAg and anti-HBs
   E. HBsAg, anti-HBs and anti-HBc

7. What level of anti-HBs concentration measured 1 – 2 months after the last dose of the primary vaccination series would be considered a reliable serological marker of long-term protection against HBV infection?
   A. ≥ 0.1 mIU/mL
   B. ≥ 0.5 mIU/mL
   C. ≥ 1.0 mIU/mL
   D. ≥ 5.0 mIU/mL
   E. ≥ 10.0 mIU/mL

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8. What is the best timing for conducting PVST on both HBsAg and anti-HBs for babies born to HBsAg-positive mothers and having completed hepatitis B vaccination at the age of 6 months?
   A. Within one week after the last dose of hepatitis B vaccine
   B. Before the age of 9 months
   C. At the age of 9 – 12 months
   D. At the age of at least 24 months old
   E. At the age of 6 years

9. Which of the following is the reason for conducting PVST at the minimum age of 9 months for babies born to HBsAg-positive mothers?
   A. To avoid detection of passively acquired anti-HBs from HBIG administered at birth
   B. To avoid detection of passively acquired maternal anti-HBc
   C. To optimise the acceptance and uptake of PVST
   D. Anti-HBs is not detectable before the age of 9 months
   E. The minimum age to offer a second course of HBV vaccination is 9 months

10. Which of the following is the recommended follow-up action for babies tested negative for both HBsAg and anti-HBs after primary series of hepatitis B vaccination?
   A. No follow-up action required
   B. Give a second 3-dose course of hepatitis B vaccination and re-test for HBsAg and anti-HBs after the final dose of the second course of hepatitis B vaccination
   C. Re-test for HBsAg again before giving a second 3-dose course of hepatitis B vaccination
   D. Re-test for anti-HBs again before giving a second 3-dose course of hepatitis B vaccination
   E. Refer to paediatrician immediately for medical follow-up