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Focused risk-based testing for chronic hepatitis B virus infection

Introduction

Hepatitis B virus (HBV) infection is one of the major causes of chronic liver diseases, accounting for high mortality from cirrhosis and hepatocellular carcinoma (HCC). In 2019, an estimated 296 million people were living with chronic HBV infection and 820 000 people died from HBV-related causes worldwide. The burden of HBV infection is disproportionately high in Western Pacific and African Regions, particularly in low- and middle-income countries. Despite the high global disease burden due to chronic HBV infection and the availability of effective antiviral treatment with tenofovir or entecavir, the majority (90%) of people infected with HBV remain unaware of their infection in 2019, and therefore frequently present with advanced disease and pose a transmission risk to the others [1].

Testing and diagnosis of HBV infection is the gateway for access to both prevention and treatment services, which is a crucial component of an effective response to hepatitis B epidemic. Testing not only enables early identification of people with chronic HBV infection for necessary care and treatment, but also serves as an opportunity to link people to preventive interventions to reduce transmission, for example through hepatitis B vaccination, counselling on risk behaviours and provision of prevention commodities.

WHO recommendations on hepatitis B testing

In 2017, World Health Organization (WHO) published the first guidelines on testing for chronic HBV and hepatitis C virus (HCV) infection [2], complementing the published guidance on prevention, care and treatment of chronic HBV [3] and HCV infection [4]. The public health approach to strengthening and expanding current testing practices is outlined in the WHO guidelines for use across populations.

Apart from routine antenatal testing and screening of blood donors, WHO strongly recommends offering focused risk-based testing in all settings to individuals most affected by HBV infection because of their higher-risk behaviours or exposures. In settings with intermediate (≥2%) or high (≥5%) hepatitis B surface antigen (HBsAg) seroprevalence, WHO recommends general population-based screening with linkage to prevention, care and treatment services. These different testing

approaches should make use of existing health facility-based or community-based testing opportunities or programmes. Details of WHO recommendations for different testing approaches and populations for HBV infection are summarised in Table 1.

Table 1. Summary of WHO recommendations on testing for chronic HBV infection

Testing approach and population	Recommendations
General population testing	*Conditional recommendation:* **In settings with an intermediate (≥2%) or high (≥5%) HBsAg seroprevalence in the general population**, it is recommended that all adults have routine access to and be offered HBsAg serological testing with linkage to prevention, care and treatment services.
Routine testing in pregnant women	***Strong recommendation:*** **In settings with an intermediate (≥2%) or high (≥5%) HBsAg seroprevalence in the general population**, it is recommended that HBsAg serological testing be routinely offered to all pregnant women in antenatal clinics, with linkage to prevention, care and treatment services. Couples and partners in antenatal care settings should be offered HBV testing services.
Focused risk-based testing in most affected population	***Strong recommendation:*** **In all settings**, it is recommended that HBsAg serological testing and linkage to care and treatment services be offered to the following individuals ● **Adults and adolescents from populations most affected by HBV infection, i.e.** – who are part of a population with higher HBV seroprevalence (e.g. mobile/migrant populations from high/intermediate endemic countries) – who have a history of exposure and/or high-risk behaviours for HBV infection (e.g. people who inject drugs (PWID), people in prisons and other closed settings, men who have sex with men (MSM),sex workers, people with HIV, family members and children of persons with HBV infection); ● **Sexual partners, children and other family members, and close household contacts** of those with HBV infection; ● **Health-care workers:** in all settings, it is recommended that HBsAg serological testing be offered and hepatitis B vaccination given to all health-care workers who have not been vaccinated previously; ● **Adults, adolescents and children with a clinical suspicion of chronic viral hepatitis** (i.e. symptoms, signs, laboratory markers)
Blood donors	**In all settings,** screening of blood donors should be mandatory with linkage to care, counselling and treatment for those who test positive. *(adapted from 2010 WHO guidance on screening donated blood or transfusion transmissible infection)*

The WHO recommendations were formulated based on consideration of evidence mainly from cost–effectiveness analyses [5-13] together with data on HBsAg seroprevalence in different settings and populations, and in the general population with considerations of feasibility and cost. WHO identified that the key drivers of cost-effectiveness include antiviral drug and testing costs, as well as linkage to care and adherence to treatment.

Focused risk-based HBV testing in most affected populations

In all settings, WHO strongly recommends HBsAg serological testing of specific populations most affected by HBV infection, who are either part of a population with higher HBV seroprevalence (such as some mobile or migrant populations from high or intermediate endemic countries, and some indigenous populations), or having a high risk of acquisition attributed to risk behaviours and/or exposure. Examples include –

(a) people who inject drugs (PWID);
(b) people in prisons and other closed settings;
(c) men who have sex with men (MSM);
(d) sex workers;
(e) people living with HIV; and
(f) sexual partners, family members and children of HBV-infected people.

Focused testing also involves clinically guided testing approach with a clinical suspicion of chronic viral hepatitis. Features that may indicate underlying chronic HBV infection include clinical evidence of existing liver disease, such as cirrhosis or HCC, or where there is unexplained liver disease, including abnormal liver function tests or liver ultrasound. For disease management, testing for chronic HBV infection is clinically indicated in some patients, such as (i) persons with end-stage renal disease, including pre-dialysis, haemodialysis, peritoneal dialysis, and home dialysis patients and (ii) persons needing immunosuppressive therapy, including chemotherapy, immunosuppression related to organ transplantation, and immunosuppression for rheumatological or gastroenterologic disorders [14, 15].

In addition to the above, it is recommended in all settings that HBsAg serological testing should be offered to healthcare workers. Hepatitis B vaccination is recommended for all healthcare workers who have not been vaccinated previously, as well as persons at high risk of HBV infection [16].

Key benefits of focused risk-based testing

Focused risk-based testing approaches can make use of the existing opportunities and infrastructure for health facility-based testing (e.g. primary care clinics, inpatient wards and outpatient clinics, including specialist dedicated clinics such as HIV, sexually transmitted infections (STI) and tuberculosis clinics), as well as community-based testing (e.g. home-based testing or door-to-door outreach; workplace; places of worship, parks, bars and other venues; schools; through campaigns (screening alongside that for non-communicable diseases, such as diabetes and hypertension)) [17]. Knowingly, focused testing in health facilities can increase the uptake of viral hepatitis testing and facilitate referral to care and other services. Moreover, focused testing in most affected populations is likely to be associated with higher rates of case-finding. Finally yet importantly, focused risk-based testing may be a more readily feasible approach if resources to undertake general population screening are lacking.

Use of serological assays

WHO recommends using a serological assay that meets minimum quality, safety and performance standards (with regard to both analytical and clinical sensitivity and specificity) to detect HBsAg for the diagnosis of chronic HBV infection. The serological assay could be in either rapid diagnostics test (RDT) or laboratory-based immunoassay format. Assays should meet minimum acceptance criteria of either WHO prequalification of in vitro diagnostics (IVDs) or a stringent regulatory review for IVDs. The WHO list of prequalified IVD products is available online (https://extranet.who.int/pqweb/vitro-diagnostics/vitro-diagnostics-lists).

In settings where existing laboratory testing is already available and accessible, laboratory-based immunoassays are recommended as the preferred assay format. However, in settings with limited access to laboratory testing and/or in populations where access to rapid testing would facilitate linkage to care and treatment, use of RDTs is recommended to improve access.

As outlined in the American Association for the Study of Liver Diseases (AASLD) 2018 Hepatitis B Guidance, hepatitis B screening should be performed using both HBsAg and hepatitis B surface antibody (anti-HBs). Screening for hepatitis B core antibody (anti-HBc) to determine prior exposure is not routinely recommended but is an important test in selected patients, such as people living with HIV and those who are about to undergo HCV, anti-cancer or other immunosuppressive therapies or renal dialysis [15]. The Asian-Pacific clinical practice guidelines recommend that

screening for chronic HBV infection should include serological tests for HBsAg (*strong recommendation, high quality of evidence*), anti-HBs and total anti-HBc (*weaker recommendation, moderate quality of evidence*) [14].

Interventions to improve the uptake of testing and linkage to care and prevention

All facility- and community-based hepatitis testing services should adopt and implement strategies to enhance uptake of testing and linkage to care. For example, peer and lay health worker support in community-based settings for promoting HBV test could increase the testing rates, compared to groups received no or unrelated educational interventions [18]. Other interventions may include clinician reminders to prompt provider-initiated, facility-based HBV testing in settings that have electronic records or analogous reminder systems, and provision of hepatitis testing as part of integrated services within mental health or substance use services.

It is important to identify the most strategic mix of facility- and community-based testing opportunities, as well as the use of integration, decentralization and task-sharing, to best reach those with undiagnosed infection and populations at high risk.

Current situation in Hong Kong

Local epidemiology of HBV infection

In Hong Kong, an epidemiological study conducted by the University of Hong Kong gauged a prevalence of hepatitis B surface antigen (HBsAg) at 7.2% among local population in 2015 – 16 [19], amounting to about 540 000 HBV cases. The same study also found that close to 50% of the HBsAg-positive participants were not aware of their infection status.

It was estimated that around 194 000 alive patients had been ever diagnosed with HBV infection in Hospital Authority (HA) as of the end of 2015 [20]. The estimated diagnosis rate was around 36% only.

Screening of blood donors

Screening of blood donors for HBsAg has been in place to prevent transfusion-transmitted HBV infection in Hong Kong since 1978. Currently, all donated blood is screened for HBV surface antigen and nucleic acid, HCV antibody and nucleic acid, HIV types I and II antibodies and antigen and HIV-1 nucleic acid, Human T-Lymphotropic Virus (HTLV) types I & II antibodies and syphilis antibody. The

HBsAg prevalence among new blood donors has been declining from 8.0% in 1990 to 1.0% in 2020 [21].

Routine antenatal screening and prevention of mother-to-child transmission of HBV

Universal screening of pregnant women for HBsAg during each pregnancy and linkage with care and treatment services have been in place since 1980s to reduce the risk of mother-to-child transmission (MTCT) of HBV. There is a declining trend of HBsAg prevalence among antenatal women (from 11.3% in 1990 to 3.4% in 2020).

In addition, from August 2020 onwards, HBV DNA testing is provided to all HBV-infected women giving birth in HA hospitals, so as to identify those with high viral load (i.e. ≥ 200 000 IU/mL) who will be referred to hepatologist for use of maternal antiviral prophylaxis and follow-up as appropriate. Between September 2020 and August 2021, 960 HBV-infected pregnant women were identified in the antenatal clinics of Department of Health (DH) or HA. Of these, 16% had high viral load and were referred to hepatology clinics for consideration of antiviral use. After review by physicians, 88% started on antiviral prophylaxis.

Since 1988, universal childhood hepatitis B vaccination has been in place. Newborn babies of HBV-infected mothers are given hepatitis B immunoglobulin together with hepatitis B vaccination at birth. As one of the most affected populations, babies born to HBV-infected mothers have also been offered with post-vaccination serologic testing on HBsAg and anti-HBs since January 2022.

Focused testing in populations at risk of HBV infection in Hong Kong

HBV screening is routinely provided in some clinical settings for disease management. For people with HIV attending the three designated HIV clinics run by DH or HA, baseline HBV screening has been in place for years. In HA, testing for viral hepatitis, including hepatitis B, are performed for patients when clinically indicated. For instance, persons donating organs and patients receiving renal dialysis, cytotoxic or immunosuppressive therapy (e.g. chemotherapy for malignant diseases, immunosuppression related to organ transplantation and for rheumatologic disorders) are screened for HBV.

In addition, there are local recommendations on HBV screening for MSM attending STI/HIV services at baseline, and at intervals informed by risk assessment [22]. With effect from April 2022, HBV and HCV screening is integrated with STI

screening for all new cases of MSM and commercial sex workers attending Social Hygiene Clinics of DH. For existing cases, those MSM engaging in high-risk sexual behaviours (e.g. chemfun) and potential exposure will also be offered screening depending on the exposure history.

Apart from the above, newly recruited healthcare workers are also screened for both HBsAg and hepatitis B surface antibody. Hepatitis B vaccination is offered to them, where appropriate [23].

Gaps in diagnosis of HBV infection in Hong Kong

Given the large number of undiagnosed people in Hong Kong, the current screening practices in place including routine screening in pregnant women and blood donors, together with opportunistic HBV screening approaches targeted at those groups at higher risk, are not sufficient to achieve the WHO target of diagnosis rate at 60% by 2025 and 90% by 2030 [24].

Having examined the local situation and international experience, the Steering Committee on Prevention and Control of Viral Hepatitis (SCVH) recommended that both diagnosis and treatment capacity for HBV infection should be built up in order to meet the substantial demand of population-based HBV screening and subsequent long-term care. The SCVH considered that focused risk-based testing of populations at higher risk of HBV infection would be a pragmatic way to start scaling up HBV screening in Hong Kong, in order to meet the WHO's target of 90% diagnosis rate and 80% treatment rate among eligible patients by 2030. It can be an expedient and short-term strategy while expansion of treatment and care capacity of HBV infection is being addressed in parallel.

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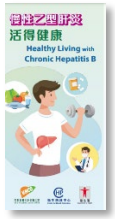
Useful resources

Description of materials	Hyperlink	QR code	Cover
Presentation slides – Focused risk-based testing for chronic hepatitis B virus infection	https://www.hepatitis.gov.hk/english/health_professionals/files/Focused_risk_based_HBV_screening_web.pdf		
Video – Hong Kong Viral Hepatitis Action Plan 2020-2024	https://youtu.be/VaHs-DZWXEM		
Video – Hepatitis B can cause cancer Get tested and treated early	https://youtu.be/E7k-SSmXXfY		
Pamphlet – What You Need To Know About Hepatitis B	https://www.hepatitis.gov.hk/tc_chi/resources/files/Pamphlet_need_to_know_hepatitis_B.pdf		
Pamphlet – 3-Dose Vaccines to Prevent Hepatitis B	https://www.hepatitis.gov.hk/tc_chi/resources/files/leaflet2020_2.pdf		
Pamphlet – Healthy Living with Chronic Hepatitis B	https://www.hepatitis.gov.hk/tc_chi/resources/files/Healthy_HepB-Pamphlet-w3c.pdf		
Pamphlet – Oral Antiviral Treatment for Hepatitis B	https://www.hepatitis.gov.hk/tc_chi/resources/files/pamphlet-Oral-w3c.pdf		

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Poster – Hepatitis B can cause cancer Get tested and treated early	https://www.hepatitis.gov.hk/tc_chi/resources/files/poster_hepatitis_B_cancer_treated_early.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: 0.5-1

CNE: 1

Validity Period: 15 July 2022 – 31 December 2023

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-SS
Family Physicians[1]	N/A	N/A
Obstetricians and Gynaecologists	1	PP-PN
Ophthalmologists	1	CME-PP
Orthopaedic Surgeons	1	PP-B
Otorhinolaryngologists	0.5	PP-2.2
Paediatricians	1	E-PP
Pathologists	1	CME-SS
Physicians	1	SS-SO
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.

[1] Participated HKCFP members are suggested to apply accreditation directly to HKCFP through additional accreditation (post-accreditation) with supporting documents

Focused risk-based testing for chronic HBV infection

1. Which of the following is **NOT** a correct description about the epidemiology of hepatitis B?
   A. HBV infection is one of the major causes of chronic liver diseases, including cirrhosis and liver cancer.
   B. In 2019, an estimated 296 million people were living with chronic HBV infection worldwide.
   C. The burden of HBV infection is disproportionately high in European Region, particularly in high-income countries.
   D. Globally, the majority (90%) of people infected with HBV remain unware of their infection in 2019.
   E. In Hong Kong, a local prevalence study conducted by the University of Hong Kong in 2015 - 16 gave an HBsAg prevalence of 7.2% among general population.

2. Which of the following is **NOT** one of the four major testing approaches covered in the *WHO guidelines on hepatitis B and C testing* published in 2017?
   A. General population testing
   B. Focused testing in most affected populations
   C. Routine testing in pregnant women
   D. Screening among blood donors
   E. Universal serologic testing after hepatitis B vaccination

3. What are the WHO targets for diagnosis rate of hepatitis B by 2025 and by 2030 respectively?
   A. 30% by 2025 and 80% by 2030
   B. 30% by 2025 and 90% by 2030
   C. 50% by 2025 and 80% by 2030
   D. 60% by 2025 and 80% by 2030
   E. 60% by 2025 and 90% by 2030

4. According to the WHO guidelines, which of the following group is **NOT** part of the specific populations recommended for focused risk-based testing for HBV infection?
   A. Adults and adolescents from populations most affected by HBV infection
   B. Adults, adolescents and children with a clinical suspicion of chronic viral hepatitis
   C. Sexual partners, children and family members of those with HBV infection
   D. Travellers returned from HBV-endemic countries
   E. Health-care workers

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5. Which of the following is **NOT** part of the populations having a high risk of HBV acquisition attributed to risk behaviours and/or exposure?
   A. Individuals affected in a food poisoning outbreak
   B. Men who have sex with men
   C. People who inject drugs
   D. People with HIV
   E. Sex workers

6. Which of the following is **NOT** a clinical feature that may indicate clinically guided testing due to suspicion of chronic HBV infection?
   A. Clinical evidence of existing cirrhosis
   B. Clinical evidence of existing HCC
   C. Clinical evidence of upper respiratory tract infection
   D. Abnormal liver function tests
   E. Abnormal liver ultrasound

7. Which of the following is **NOT** the benefit for focused risk-based testing, as summarised in the WHO guidelines on testing for chronic HBV infection?
   A. It can make use of the existing opportunities and infrastructure for health facility-based testing, as well as community-based testing.
   B. It could be a mop-up testing approach while many HBV high-prevalence countries have already undertaken general population screening.
   C. Focused testing in health facilities can increase the uptake of viral hepatitis testing and facilitate the referral to care and other services.
   D. Focused testing in most affected populations is likely to be associated with higher rates of case-finding.
   E. Focused risk-based testing may be a more readily feasible approach if resources to undertake general population screening are lacking.

8. Which of the following is **NOT** a correct description about the use of serological assays?
   A. WHO recommends using a serological assay that meets minimum quality, safety and performance standards to detect HBsAg for the diagnosis of chronic HBV infection.
   B. The serological assay could be in laboratory-based immunoassay format, but not rapid diagnostics test (RDT).
   C. Assays should meet minimum acceptance criteria of either WHO prequalification of in vitro diagnostics (IVDs) or a stringent regulatory review for IVDs.
   D. In settings where existing laboratory testing is already available and accessible, laboratory-based immunoassays are recommended as the preferred assay format.
   E. In settings with limited access to laboratory testing and/or in populations where access to rapid testing would facilitate linkage to care and treatment, use of RDTs is recommended to improve access.

9. Which of the following group is **NOT** routinely screened for hepatitis B in Hong Kong?
   A. Blood donors
   B. Persons donating organs
   C. Infants born to HBsAg-negative mothers
   D. New cases of HIV patients
   E. Pregnant women

10. Which of the following is a correct description about hepatitis B testing in Hong Kong?
   A. Patients receiving renal dialysis, cytotoxic or immunosuppressive therapy in HA are not routinely screened for HBV.
   B. There are local recommendations on HBV screening for MSM attending STI/HIV services at baseline, and at intervals by risk assessment.
   C. Screening of blood donors for HBsAg has been in place to prevent transfusion-transmitted HBV infection in Hong Kong since 1950s.
   D. There is an increasing trend of HBsAg prevalence among pregnant women undergoing antenatal screening since 1990s.
   E. The current diagnosis rate of HBV infection in Hong Kong has already exceeded the WHO target by 2030.