Launch of WHO operational guide on priorities in planning person-centred hepatitis B and C testing services

Global HIV, Hepatitis and STIs Programmes

World Health Organization, Headquarters

Global webinar | 05 December 2024

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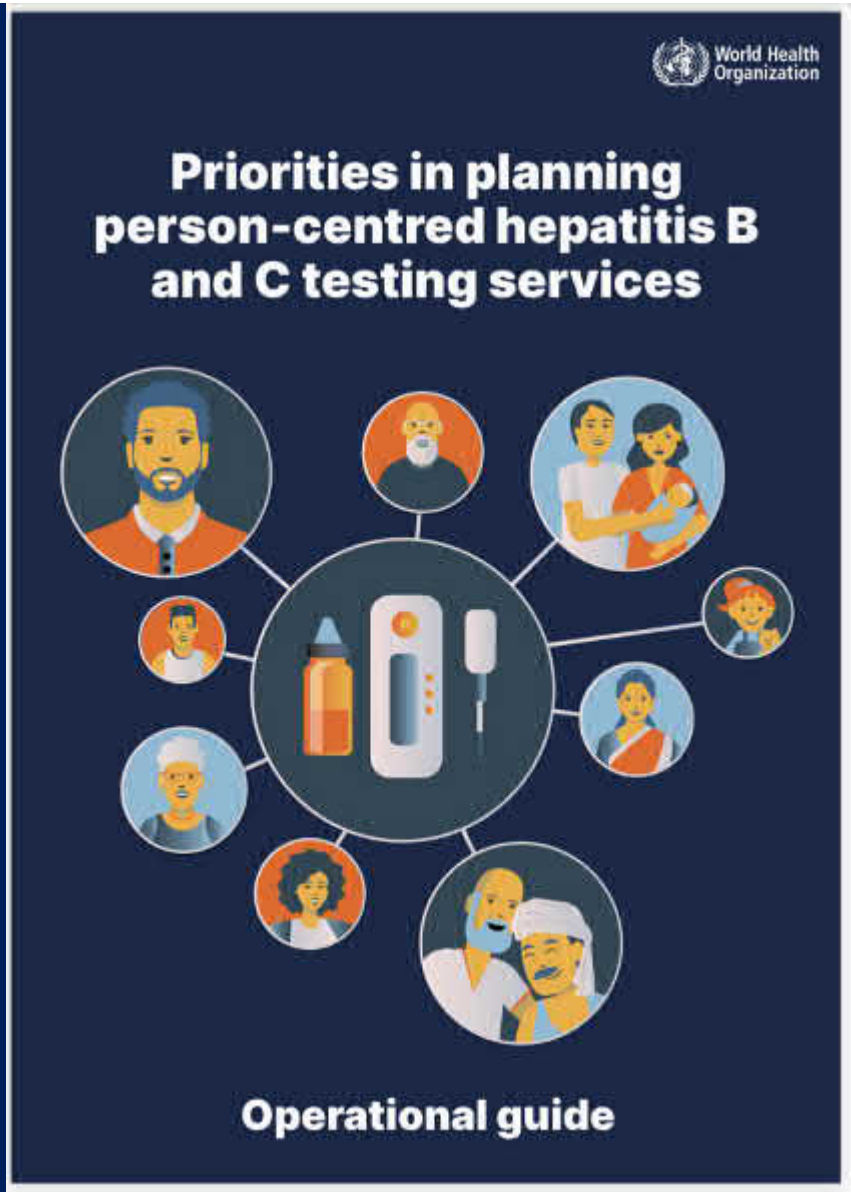

Overview

- Rationale
- About the guide
- The framework
- Key enablers in implementing effective testing services
- Takeaway messages

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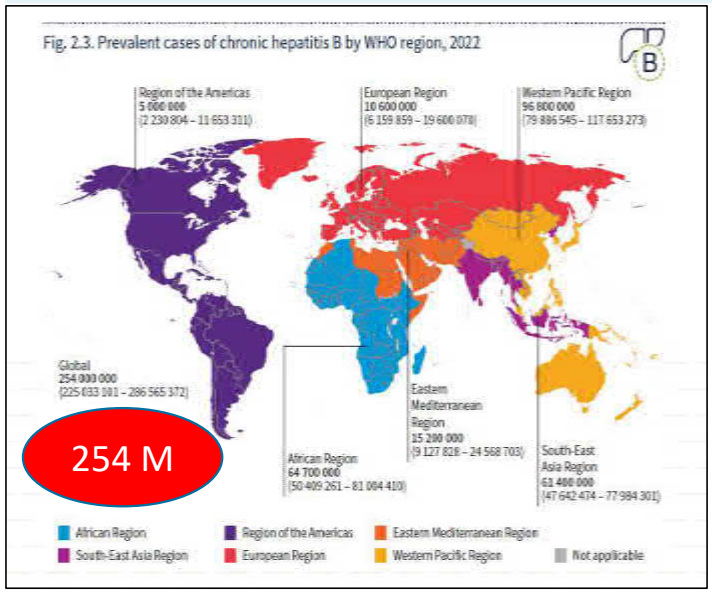
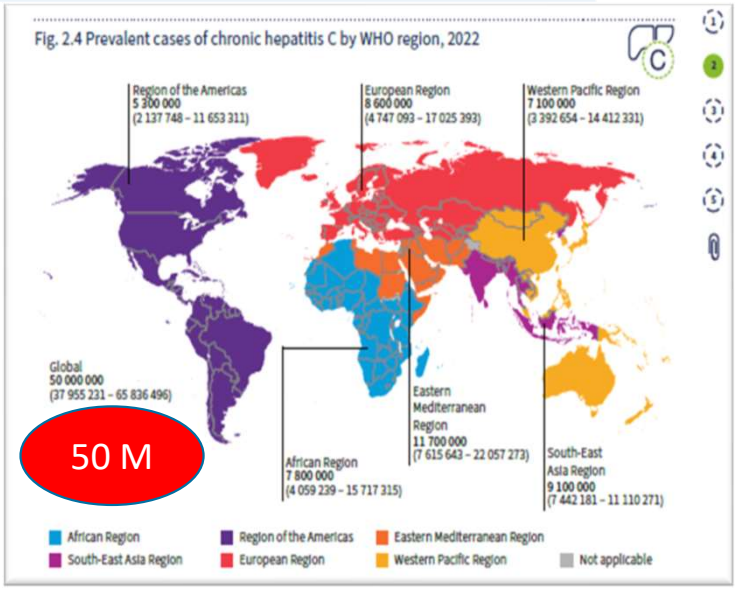
In 2022 viral hepatitis is the second leading cause of death among communicable diseases

- **Viral hepatitis is the only communicable disease for which mortality is increasing:** 1.3 million people died from viral hepatitis in 2022, up from 1.1 million deaths in 2019.





10 countries represent 2/3 of the global burden of HBV & HCV

Country
China
India
Indonesia
Nigeria
Pakistan
Ethiopia
Bangladesh
Viet Nam
Philippines
Russian Federation

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Source: https://www.who.int/publications/i/item/9789240091672

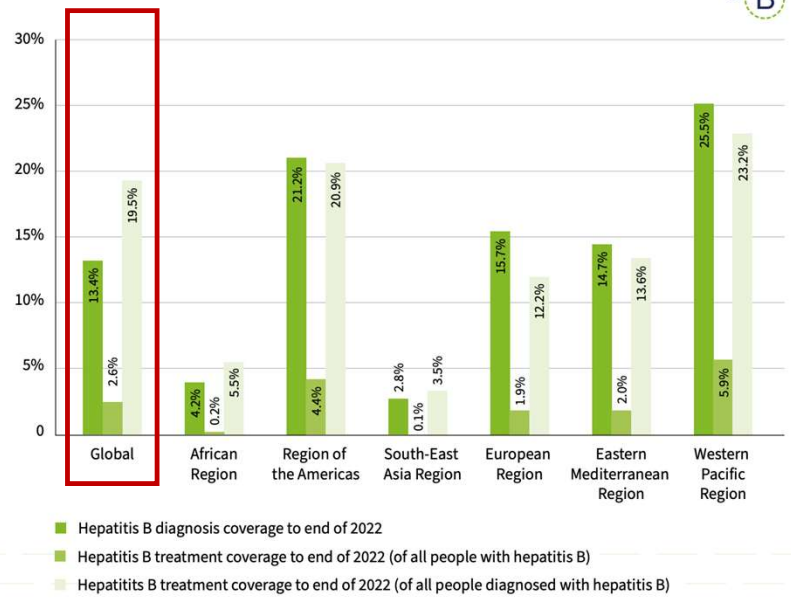
Most people with chronic hepatitis B and C remain undiagnosed and untreated – far below targets

Global targets

Path to elimination	Diagnosed	Treated
Elimination	90%	80%
Gold	80%	70%
Silver	70%	60%
Bronze	60%	50%

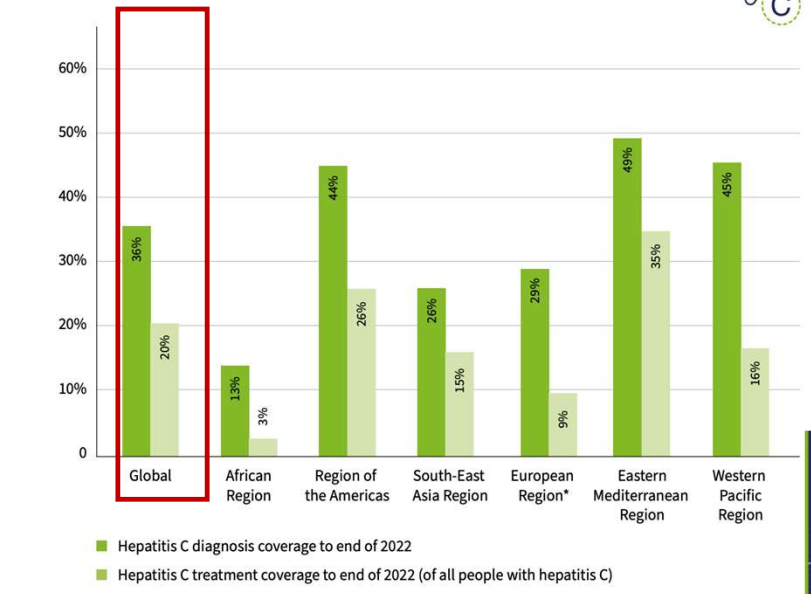
In 2022, **13% of the 254 million** people with hepatitis B have been diagnosed

Fig. 2.5. Coverage of hepatitis B testing and treatment by WHO region, 2022



In 2022**, 36% of the 50 million** people with hepatitis C have been diagnosed

Fig. 2.6. Coverage of hepatitis C testing and treatment by WHO region, 2022



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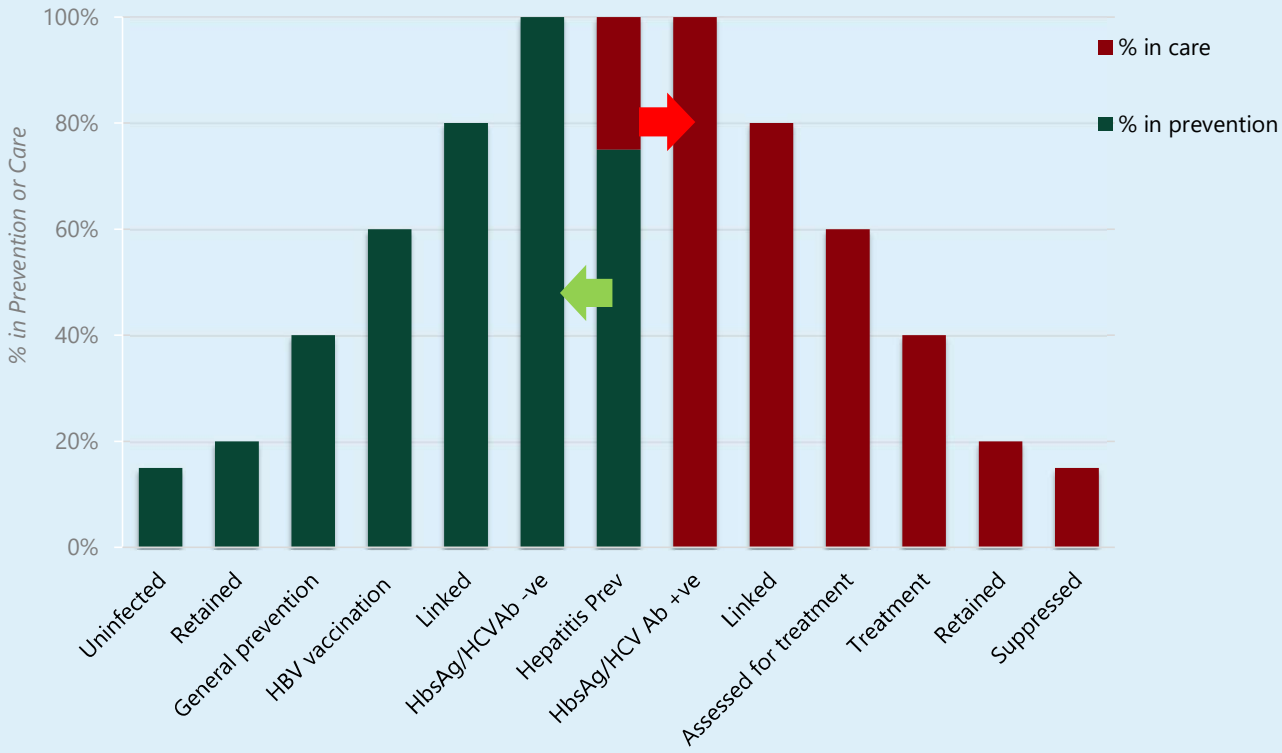
Source: https://www.who.int/publications/i/item/9789240091672

Testing is the first step in accessing hepatitis B and C prevention, care and treatment services, making it a critical component of national responses.



Source: Modified from Frits van Griensven, 2014 Thailand

About the operational guide: 5 reasons to use this guide

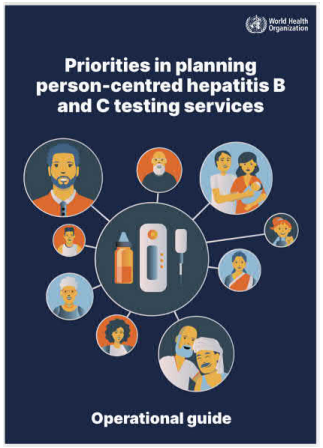
Supports countries operationalizing WHO recommendations for hepatitis B and C testing

Provides a 5-step framework for planning person-centred hepatitis B and C testing approaches that consider national priorities, contextual factors and differentiated service delivery

Emphasizes integration, community involvement and differentiated service delivery models

Country case examples from England, Georgia, Morocco and Uganda demonstrating key enablers and good practices

Annexes of consolidated recommendations and diagnostic products



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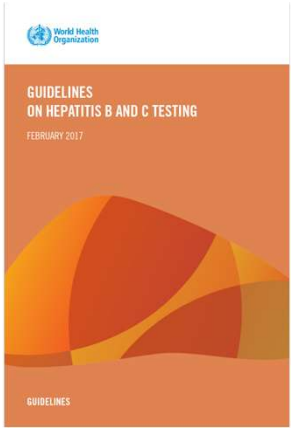
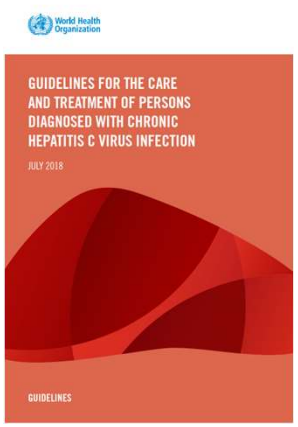
https://www.who.int/publications/i/item/9789240104082

WHO hepatitis B and C testing recommendations including:

Who, where, how and simplified service delivery strategies to enhance testing and linkage to care and treatment



2017



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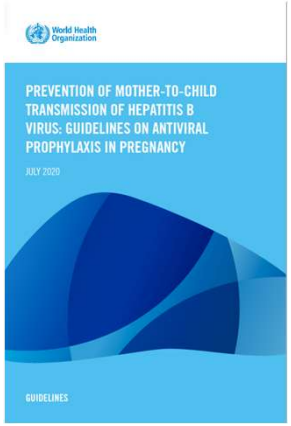
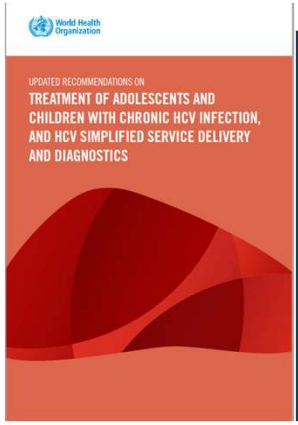
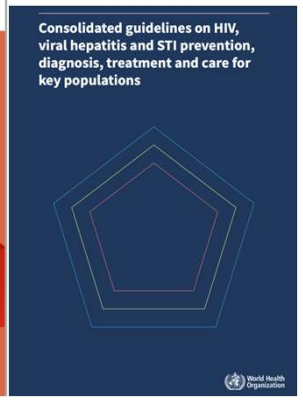
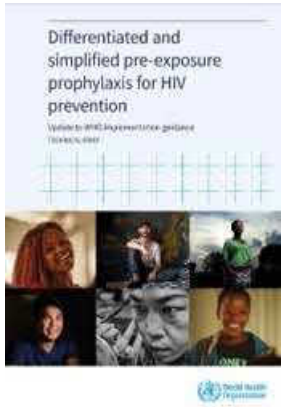
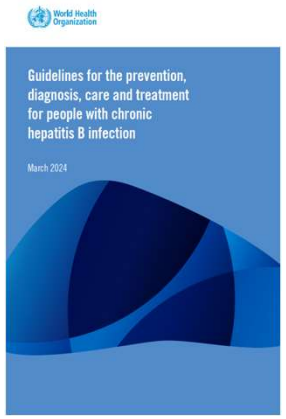


2020









2024

2022

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Table 2. Summary of WHO recommendations and guidance on "who to test" for hepatitis B and C infection

Testing among general population	Hepatitis B	Hepatitis C
General population testing in intermediate or high seroprevalence settings (≥2%)[1]	In settings with a ≥2% HBsAg seroprevalence in the general population, it is recommended that all adults and adolescents have routine access to and be offered HBsAg serological testing.	In settings with a ≥2% HCV antibody (anti-HCV) seroprevalence in the general population, it is recommended that all adults and adolescents have routine access to and be offered anti-HCV serological testing.
Birth-cohort testing for specific age groups known to have higher HCV prevalence than the general population		All adults in a specific identified birth-cohort of older persons (or above a certain age) with higher HCV infection risk[2] than the overall general population may be offered anti-HCV serological testing.
Routine testing among specific populations	**Hepatitis B**	**Hepatitis C**
Pregnant women	All pregnant women should be tested for HIV, syphilis and HBsAg at least once and as early as possible during pregnancy.	While there is no specific recommendation for HCV testing in pregnant women, it may be considered in settings of ≥2%[1] HCV antibody seroprevalence as part of general population testing.[3]
Blood donors	In all settings screening of all blood donors for HBsAg and HCV antibodies should be mandatory *(10)*.	
Adults, adolescents and children with a clinical suspicion of chronic viral hepatitis	In all settings adults, adolescents and children with a clinical suspicion of chronic viral hepatitis (symptoms, signs, laboratory markers)[4] should be offered HBsAg and anti-HCV serological testing.	
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 not previously vaccinated.	
Focused testing among most affected populations	**Hepatitis B**	**Hepatitis C**
Key populations	In all settings adults and adolescents from key populations (men who have sex with men, sex workers, people who inject drugs, trans and gender-diverse people, people in prison and other closed settings) should be offered HBsAg and anti-HCV serological testing.	
	Testing PrEP users for HBsAg once, at or within one to three months of PrEP initiation (or later if not available around initiation), is strongly encouraged, particularly in highly endemic countries *(11)*.	HCV antibody testing is strongly encouraged at or within one to three months of PrEP initiation (or later if not available around initiation), and every 12 months thereafter, where PrEP services are provided to populations at high risk of HCV infection *(11)*.
		People at ongoing risk and a history of treatment-induced or spontaneous clearance of HCV infection may be offered 3–6 monthly testing for presence of HCV viraemia.
Sexual partners, children and other family members and close household contacts of those with HBV infection	In all settings it is recommended that HBsAg serological testing be offered to sexual partners, children and other family members and to close household contacts of those with HBV infection.[5]	Children of mothers with chronic hepatitis C (especially if HIV-coinfected) may be offered anti-HCV serological testing.[7]
	Infants born to mothers with presence of HBsAg should be tested for HBsAg between 6 and 12 months of age to screen for evidence of hepatitis B infection.[6]	
Certain mobile or migrant adult and adolescent populations from ≥2% HBV or HCV seroprevalence countries [1]	In all settings adults and adolescents from key populations (men who have sex with men, sex workers, people who inject drugs, trans and gender-diverse people, people in prison and other closed settings) should be offered HBsAg and anti-HCV serological testing.	
Adults and adolescents from certain indigenous populations	In all settings routine serological testing for HBsAg and/or anti-HCV should be offered to indigenous populations identified as having higher HBV or HCV seroprevalence than general population.	
Adults and adolescent living with HIV, other STIs and TB	In all settings adults and adolescents living with HIV, TB or STIs should be offered HBsAg and HCV serological testing.	
Persons exposed in health care settings (for example, patients with thalassaemia, haemophilia, haemodialysis, history of multiple blood transfusions or recurrent intensive care, surgical procedures or other health care exposure risks).	In all settings adults and adolescents with increased HBV or HCV risks and history of health care exposure should be offered HBsAg and anti-HCV serological testing.	
Persons exposed outside the health care system via invasive procedures with transmission risk via contaminated equipment (for example, unsafe tattooing, body piercing, circumcision or other unsafe cultural practices such as scarification).	In all settings adults and adolescents with increased HBV or HCV risks and history of exposure via invasive procedures outside of the health care system should be offered HBsAg and anti-HCV serological testing.	

Annex 1

Consolidated WHO hepatitis B and D testing recommendations

Who to test (testing approach)	• General population testing (where HBV seroprevalence ≥2%) [1] • Focused testing in most-affected populations [2] • Routine testing of pregnant women; blood donors; people with clinical signs of chronic viral hepatitis; [3] health care workers [4] • Among people testing HBsAg positive for hepatitis B.[5]	
Where to test (service delivery approaches)	**Facility-based and community-based testing** • **Integration** of hepatitis testing, care and treatment with other services (such as HIV services and primary care) to increase the efficiency and reach of hepatitis services; • **Task-sharing** with trained non-specialist doctors and nurses to expand access to diagnosis, care and treatment; • **Decentralizing** testing and treatment services at primary health facilities or HIV and ART clinics to promote access to care.	
How to test	*General note: All assays should meet minimum quality, safety and performance standards (regarding both analytical and clinical sensitivity and specificity)* [6]	
Serological testing	**Choice of assay:** **For the diagnosis of chronic HBV in adults, adolescents and children (>12 months of age) [7], a serological assay (in either RDT or laboratory-based immunoassay format) [8] is recommended to detect HBsAg.** • In settings where laboratory testing is already available and accessible, laboratory-based immunoassays are recommended as the preferred assay format. • In settings where there is 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. **Serological testing strategies:** • In settings or populations with an HBsAg seroprevalence of ≥0.4%,[9] a single serological assay for detection of HBsAg is recommended. • In settings or populations with a HBsAg seroprevalence of <0.4%,[9] confirmation of HBsAg positivity on the same immunoassay with a neutralization step or a second, different RDT assay for detection of HBsAg may be considered.	**Strategies promoting testing uptake and linkage to care** 1. **Use of DBS specimens** for HBsAg serology testing may be considered in settings where: • there are no facilities or expertise to take venous whole blood specimens; or • RDTs are not available or their use is not feasible; or • there are persons with poor venous access (for example, in drug treatment programmes, prisons). 2. **Clinician reminders** to prompt provider-initiated, facility-based HBV serological testing in settings that have electronic records or analogous reminder systems. 3. **Peer and lay health worker support in community-based settings**.
Hepatitis D testing among those HBsAg-positive	People with chronic hepatitis B (HBsAg positive) may be diagnosed with hepatitis D by using a serological assay to detect total anti-HDV, followed by an NAT to detect HDV RNA and active (viraemic) infection among those who are anti-HDV-positive.[10]	**Reflex testing** for anti-HDV antibody testing following a positive HBsAg test result, and also for HDV RNA testing (where available) following a positive anti-HDV antibody test result, may be used as an additional strategy to promote diagnosis.
Measuring HBV DNA to guide treatment eligibility and monitor response	• **Laboratory-based HBV DNA assays:** Directly following a positive HBsAg serological test result, the use of HBV DNA nucleic acid testing (NAT) (quantitative or qualitative) is recommended as the preferred strategy to assess viral load level for treatment eligibility and to monitor treatment response. • **Point-of-care HBV DNA assays:** Point-of-care HBV DNA nucleic acid test (NAT) assays may be used as an alternative approach to laboratory-based HBV DNA testing to assess HBV DNA level for treatment eligibility and to monitor treatment response.	1. **HBV DNA reflex testing:** Where available, HBV DNA testing for those testing positive for HBsAg may be used as an additional strategy to promote linkage to care and treatment. This can be achieved either through laboratory-based reflex HBV DNA testing using a sample already held in the laboratory or through clinic-based reflex testing in a health care facility with immediate sample collection following a positive HBsAg RDT. 2. **The use of DBS specimens** to test for HBV DNA for diagnosis of HBV viraemia may be considered in settings where: • there is a lack of access to sites or nearby laboratory facilities for NAT or of timely delivery of specimens to a laboratory; or • there are persons with poor venous access (for example, in drug treatment programmes, prisons).

Annex 2

Consolidated WHO hepatitis C testing recommendations

Who to test (testing approach)	• General population testing (where HCV seroprevalence ≥2%) [1] • Focused testing in most-affected populations [2] • "Birth cohort" testing [3] • Routine testing of blood donors and people with clinical signs of viral hepatitis. [4]	
Where to test (service delivery approaches)	**Facility-based and community-based testing** • **Integration** of HCV testing and treatment with existing care services, ideally at the same site, and **decentralization** to peripheral health facilities, to increase access to diagnosis, care and treatment • **Task-sharing** with trained non-specialist doctors and nurses to expand access to diagnosis, care and treatment. **Self-testing** should be offered as a testing approach in addition to existing HCV testing services.	
How to test	*General note: All assays should meet minimum quality, safety and performance standards (with regard to both analytical and clinical sensitivity and specificity).*[5]	
Serological testing	**Choice of assay and serological testing strategy:** In adults, adolescents and children (>18 months of age)[6]: A single HCV serological assay (antibody or antibody/antigen) using either RDT or laboratory-based immunoassay format for initial detection of serological evidence of past or present infection, prior to NAT for evidence of viraemia. In settings where there is limited access to laboratory infrastructure and testing and/or in populations where access to rapid testing would facilitate linkage to care and treatment, RDTs are recommended.	1. **The use of DBS specimens** for HCV antibody serology testing may be considered in settings where: • there are no facilities or expertise to take venous whole blood specimens; or • RDTs are not available or their use is not feasible; or • there are persons with poor venous access (for example, in drug treatment programmes, prisons). 2. Clinician reminders to prompt provider-initiated, facility-based HCV serological testing in settings that have electronic records or analogous reminder systems. 3. *Peer and lay health worker support in community-based settings.* 4. **HCV self-testing** as a testing approach in addition to HCV testing services.
Confirmation of HCV viraemia	• Directly following a reactive HCV antibody serological test result, **laboratory-based quantitative or qualitative NAT** for detection of HCV RNA is recommended as the preferred strategy. • **An assay to detect HCV core antigen**, with comparable clinical sensitivity to laboratory-based HCV RNA NAT assays, can be an alternative approach. • **Point-of-care HCV RNA viral load assay** can be an alternative approach to laboratory-based HCV RNA NAT assays.	1. **Reflex HCV RNA viral load** testing in those with a positive HCV antibody test result as an additional key strategy to promote linkage to care and treatment. This can be achieved either through laboratory-based reflex HCV RNA testing using a specimen already held in the laboratory or through clinic-based reflex testing in a health facility with immediate specimen collection following a positive HCV antibody RDT. 2. **The use of DBS specimens** to test for HCV RNA for diagnosis of HCV viraemia may be considered in settings where: • there is a lack of access to sites or nearby laboratory facilities for NAT or provision for timely delivery of specimens to a laboratory; or • there are persons with poor venous access (for example, in drug treatment programmes, prisons).
Assessment of HCV treatment response **Retesting of persons with ongoing risk**	1. **Laboratory-based qualitative or quantitative NAT** for detection of HCV RNA should be used as test of cure at 12 or 24 weeks after completion of antiviral treatment (that is, SVR12 or SVR24). 2. **Point-of-care HCV RNA NAT** with a limit of detection comparable to those of laboratory-based assays can be used as an alternative approach as test of cure. People at ongoing risk and a history of treatment-induced or spontaneous clearance of HCV infection may be offered 3–6 monthly testing for presence of HCV viraemia.[7] To detect presence of viraemic infection, the use of quantitative or qualitative nucleic acid testing (NAT) for detection of HCV RNA, or alternatively an assay to detect HCV core antigen, can be performed.	

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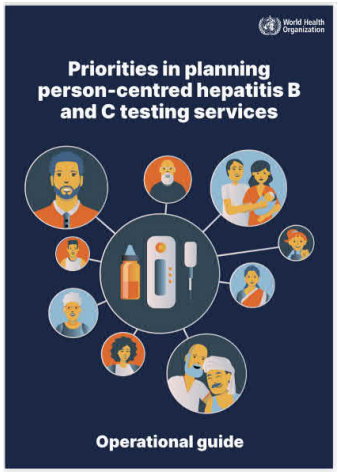

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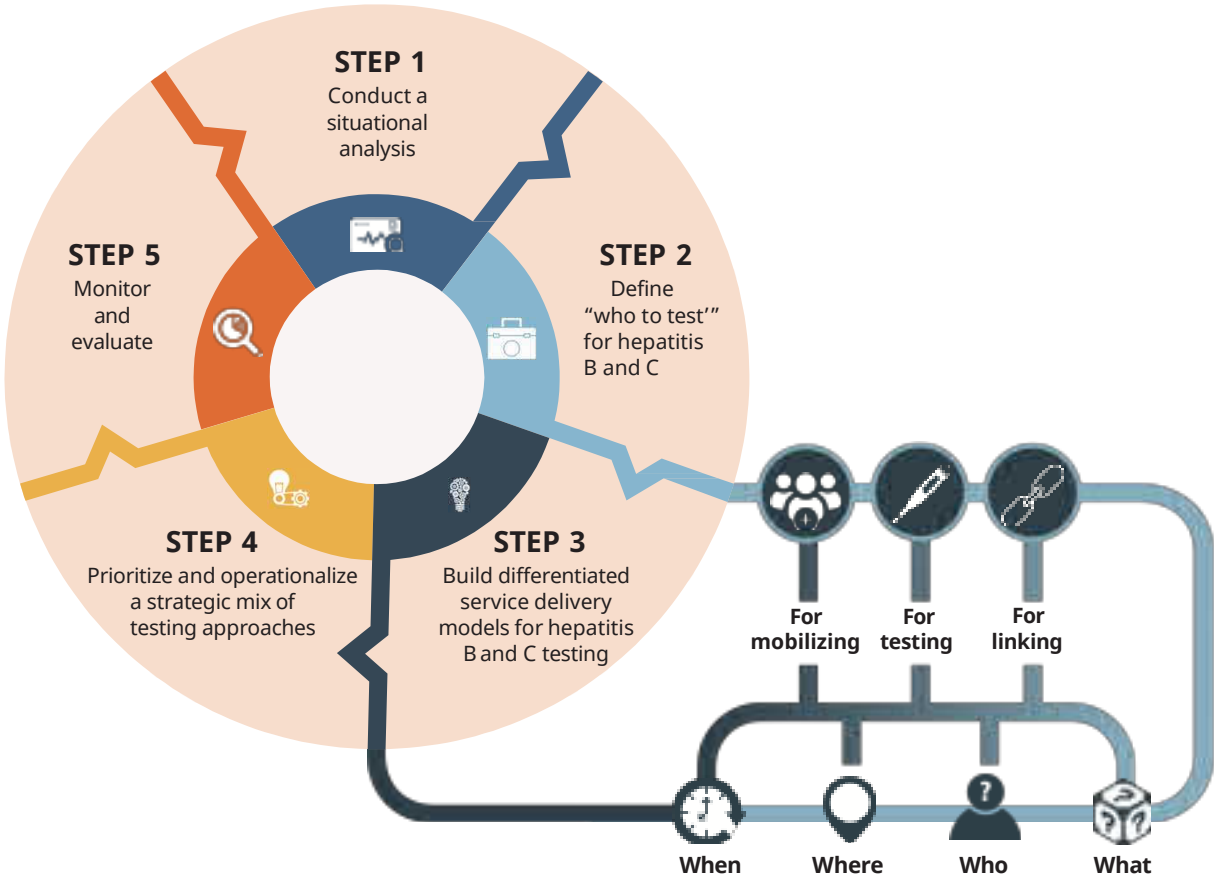
https://www.who.int/publications/i/item/9789240104082

Framework for planning hepatitis B and C testing services



Step 1: Conduct situational analysis

> The selection and mix of hepatitis B and C testing approaches with the greatest public health impact must be based on a situational analysis

- Analyze the HBV and HCV epidemiology in the general population and specific populations
- Assess programmatic response and gaps
- Assess the health care system structure and capacity and identify opportunities for integration
- Assess financial resource availability

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Step 2: Define ”who to test” for hepatitis B and C

1. ROUTINE TESTING AMONG GENERAL POPULATION
General population testing in HBV or HCV seroprevalence ≥2% settings
Birth-cohort testing for specific age groups known to have high HCV seroprevalence
2. ROUTINE TESTING AMONG SPECIFIC POPULATIONS
Pregnant women for HBV
Blood donors for HBV and HCV
Adults, adolescents, children with clinical suspicion of chronic viral hepatitis
Health care workers for HBV
3. FOCUSED TESTING AMONG MOST AFFECTED POPULATIONS
Key populations and people living with HIV, STI or TB
Sexual partners, children and household members of those with HBV infection
Certain indigenous, migrants and displaced peoples from high prevalence setting
Persons exposed in or outside healthcare settings

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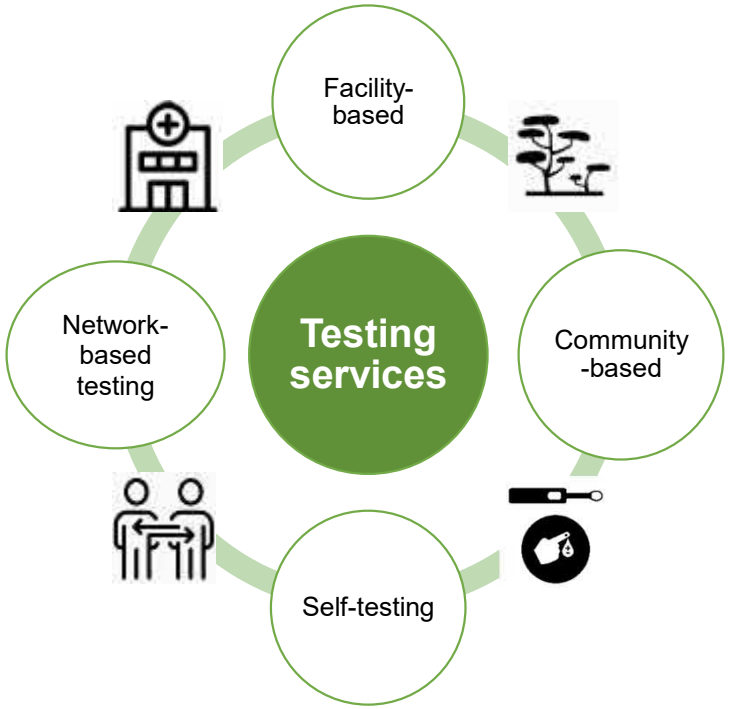
Hepatitis D

- **All individuals with positive HBsAg**
- **When universal anti-HDV testing not feasible, prioritize**:
  - people born in **HDV-endemic** countries, regions and areas;
  - people with **advanced liver disease**, those receiving HBV treatment; and those with features suggesting HDV infection (such as low HBV DNA with high ALT levels);
  - people considered to have **increased risk** of HDV infection (haemodialysis recipients, people with HCV and/or HIV, PWID, SW, MSM

Step 3: Build differentiated service delivery models for hepatitis B and C testing



MOBILIZING	TESTING	LINKING
Mass public broadcasting	Facility-based	Referral
Provider-initiated for facility attendees	Focused community-based	Accompanying
Targeted group information in communities	HIV self-testing*	Peer-support
Index contact notification	Index contact testing	Same-day provision of services (i.e., ART, PrEP)
Social network-based recruitment	Social network-based testing	Friendly services
Concurrent offer of other testing/screening/health service provision		In person, phone or virtual follow-up
For benefits of prevention		

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Step 3: Build differentiated service delivery models for hepatitis B and C testing

	Mobilizing and creating demand	Testing services	Linkage to care
When	**Frequency and timing** • continuous mobilization at testing sites • intermittent: targeted time for campaigns • focused: specific times to reach specific populations (eg outreach)	**Frequency and timing:** • frequency: routine testing, one-time test, mass campaign • timing: times when specific populations may be reached for testing or re-testing	**Timing of linkage activities and frequency of follow-up:** • Immediate link to molecular testing/liver disease assessment following positive serology • Schedules test of cure for HCV, periodic HBV monitoring
Where	**Location of mobilization:** • online, print, radio media • community and outreach • health facilities (including prisons).	**Location of testing:** • health-facilities (including prisons), pharmacies • community and outreach • self-test.	**Location of linkage and treatment:** • via phone • health facilities • community/home visits • reflex testing.
Who is providing services	**Who does the mobilizing?** • health care workers • lay providers • peer workers • family members.	**Who does the testing?** • health care workers • lay providers • peer workers • self-testing.	**Who supports linkage to prevention or treatment initiation?** • health care workers • lay providers • peer workers • family members.
What	**What package of services and demand creation interventions?** • Information about where and why to test and how to link to prevention and treatment; hepatitis testing alone or with other services.	**Hepatitis testing alone or integrated with other services? What interventions to promote testing?** • Integrated with HIV, TB, STI testing, NCD, cancer and other age-specific screening campaigns, where appropriate • POC testing, dried blood spot (DBS), reflex testing.	**What linkage interventions? What interventions to enhance linkage to care?** • Prevention: harm reduction services, HBV vaccination, condoms, HIV and STI testing • Treatment • Patient navigation, reflex testing.

Step 3: Build differentiated service delivery models for hepatitis B and C testing

WHO recommendations to promote testing uptake and linkage to care

Box 4: WHO recommendations on strategies to promote testing and diagnosis, and linkage to care and treatment for viral hepatitis

1. **Decentralization, integration and task sharing:** WHO recommends expanding HCV testing and treatment services, ideally at the same site, at lower-level facilities through decentralization, integrating them with primary care, harm reduction programmes, prison health services and HIV services *(6)*. Task sharing is encouraged, allowing trained non-specialist doctors, nurses, peer and lay providers to deliver HCV testing, care and treatment. These approaches can be adapted for HBV services *(6)*.
2. **POC testing:** Using POC HBV DNA and HCV RNA assays is recommended as an alternative to laboratory-based tests for diagnosing viraemic HBV and HCV infections, respectively, particularly in marginalized populations and hard-to-reach communities with limited access to health care *(4, 6)*.
3. **Reflex testing:** Reflex HBV DNA testing for HBsAg-positive individuals and HCV RNA testing for anti-HCV-positive individuals is recommended to promote linkage to care *(4, 6)*. Reflex testing for anti-HDV antibody following a positive HBsAg test result, and also reflex HDV RNA testing (where available) following a positive anti-HDV antibody test result, can streamline the diagnostic process by eliminating the need for extra clinic visits *(4)*. Reflex testing can be laboratory- or clinic-based.[1]
4. **Dried blood spot sampling (DBS):** DBS for serological and nucleic acid test (NAT) assays for HBV and HCV can enhance testing access in settings with limited facilities, in persons with poor venous access, or when timely delivery of specimens to laboratories is not feasible *(3, 6)*.
5. **Peer and lay health worker support:** Utilize peer and lay health workers to support community-based/led testing efforts *(3, 6)*.
6. **Clinician reminders:** Implement clinician reminders in electronic records or similar systems to prompt facility-based HCV testing for patients in high-risk birth cohorts or those who report risk behaviours *(3)*. This strategy can also apply to HBV testing.

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Step 4: Prioritize and operationalize a strategic mix of testing approaches

Building on:

- situational analysis
- applying the WHO recommendations on “who to test”
- differentiated service delivery models

Countries should develop an optimal mix of testing approaches that are best adapted to their unique context.

- **A modular approach serves as a guide to support countries in designing an optimal mix of testing approaches, based on priorities, stage of hepatitis response and established targets**
- **The modules are not mutually exclusive, and they can overlap at any time during the hepatitis response and during any phase of the response.**

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Step 4: Prioritize and operationalize a strategic mix of testing approaches

Module 1

IN ALL SETTINGS: Routine testing of pregnant women, blood donors, health care workers and people with clinical suspicion of chronic viral hepatitis

Table 4. Examples of testing locations, demand creation and linkage to care for routine testing in all settings

Who to test	Where to test	Mobilizing and demand creation	Linkage to care
HBV testing of all pregnant women[1]	Routine testing for HBV, HIV and syphilis at prenatal and antenatal clinics, family planning clinics and community-based outreach services.	Facility-based education and awareness-raising initiatives using culturally tailored messaging during consultations and in pamphlets. Community-based education and awareness-raising through outreach by community workers and through reproductive health community groups, community events (for example, faith-based events and baby showers). Partner involvement and couples testing and counselling, based on woman's consent and choice and if safe to do so.	Linkage to further HBV testing, diagnosis and treatment, ideally offered at the same site; can include POC viral load testing or use of DBS and reflex testing. Prevention services, including antiviral for prevention of mother-to-child transmission (PMTCT) of HBV and treatment for mother's own health; testing of sexual partners, children and household members (and HBV vaccination where required); infant HBV vaccination, including timely birth dose. Linkage may be facilitated by community and lay health workers. All relevant HIV and STI testing and prevention services should be offered.
HBV and HCV testing of all blood donors	Routine testing (preferably onsite) of all blood donors at all facilities and mobile units offering blood donation.	Targeted education and awareness-raising campaigns about the importance of hepatitis testing as part of the blood donation process, safety of the blood supply and the impact of donations on community health. Distribute pamphlets at blood donation facilities explaining hepatitis, bloodborne virus testing procedures and the importance of regular testing for all donors.	Support with coordinated pathways to access both viral load testing and diagnostic services and treatment and care.
HBV and HCV testing of all adults, adolescents and children with clinical suspicion of chronic viral hepatitis (that is, signs, symptoms or laboratory markers)	Routine testing, based on clinical signs for chronic viral hepatitis, at all health facilities including hospitals (inpatient and outpatient departments, emergency department (ED), etc.) and primary care and community-based services.	Tailored education and awareness-raising that address the link between hepatitis infections and liver disease and highlight symptoms of chronic hepatitis and liver cancer. Training of physicians about signs of clinical suspicion of chronic viral hepatitis and liver disease. Collaboration between specialists and general practitioners in primary care to ensure testing for hepatitis and to integrate with liver disease and cancer management.	HCV and HBV testing, diagnosis and treatment services are ideally offered at the same site, at hospitals and primary health care (PHC) clinics (through decentralization and integration) and can include POC viral load testing. Other options include use of DBS and reflex testing. Community and lay health workers can be helpful to support linkage to care. Hepatocellular carcinoma surveillance among people with confirmed chronic viral hepatitis. May consider relevant HIV and STI testing services as well as assessment of other co-morbidities.
HBV testing of all health care workers[2]	Routine HBV testing of health care workers, ideally at their workplaces.	Onsite testing and education of all health care workers before they start employment. Regular education and training, for example, seminars/grand rounds, as part of prevention, infection control and blood safety training.	Hepatitis B vaccination given to all health care workers who are not immune and have not been vaccinated previously. If indicated, linkage to HBV diagnosis and treatment.

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Module 2

Table 5. Examples of testing locations, demand creation and linkage to care for testing of most affected, priority populations

Who to test	Where to test	Mobilizing and demand creation	Linkage to care
Key populations: (men who have sex with men, sex workers, people who inject drugs, trans and gender-diverse people, people in prison and other closed settings) and people living with HIV, people living with TB, people with STIs diagnoses	Routine testing at hospitals and primary care facilities and community-based services serving key populations (for example, antiretroviral HIV treatment (ART) clinics, pre-exposure prophylaxis (PrEP) programmes, TB clinics, STI clinics, drug treatment and harm reduction services, prisons, drop-in centres), as well as homeless centres, other peer-led services and by outreach. Additionally, HCV self-testing can be offered in all settings. Secondary distribution of HCV self-tests to partners and injecting network. Clinician reminders in electronic records or similar systems to prompt facility-based HBV and HCV testing.	Communication campaigns using digital media, social media, radio/ television/print, dating apps addressing specific key populations (with, for example, infographics, videos and testimonials). Mobile and outreach awareness-raising and testing in areas frequented by members of key populations, such as nightlife districts, community centres, drop-in centres. Health awareness days (for example, World Hepatitis Day (28 July). Peer-led education and testing, including integrated with PrEP and with other STI/HIV testing services.	Linkage to further HBV and HCV testing, diagnosis and treatment, ideally offered at the same site; can include POC viral load testing. Other options include use of DBS or reflex testing. Where this is not possible, strong linkage between different levels of the health care system are required. Peer workers support linkage to care. Members of key populations who self-test need specific and well-coordinated pathways to diagnosis services. HIV and STI testing services including family planning, prevention services (for example, condom and lubricant distribution, PrEP). Hepatitis B vaccination; link or continue harm reduction services for people who inject drugs.
Indigenous populations and migrants and mobile people from high prevalence countries	Testing at health facilities and community-based services, including indigenous-led/controlled clinics and culturally appropriate services trusted by communities. Testing may be integrated with health promotion and targeted screening initiatives for communicable diseases and NCDs (for example, hypertension, diabetes). Additionally, HCV self-testing can be offered. Clinician reminders in electronic records or similar systems to prompt facility-based HBV and HCV testing.	Culturally appropriate education and awareness-raising initiatives in local languages, imagery and stories to convey the importance of hepatitis testing. Dissemination can take place on digital and social media, television, radio, newspaper and at community gatherings. For both indigenous and migrant or mobile populations, involve community leaders in awareness-raising and testing initiatives (for example, workshops and community gatherings to tackle stigma and discrimination). Community-based and peer-led education and mobile testing services to reach remote and underserved communities.	Linkage to further HBV and HCV testing, diagnosis and treatment, ideally at the same indigenous-led or culturally appropriate site for migrant and mobile people. Can include POC viral load testing. Other options include use of DBS or reflex testing. Peer and community workers support and coordinate and link to care, treatment and prevention. HIV and STI testing services, including family planning, prevention services (for example, condom and lubricant distribution, PrEP); hepatitis B vaccination.
People exposed in health care settings or via invasive medical or traditional procedures (for example, thalassaemia, haemophilia and receiving multiple transfusions, haemodialysis, in intensive care, tattooing, cutting)	Routine testing in all health care facilities providing these services. Clinician reminders in electronic records or similar systems to prompt facility-based HBV and HCV testing.	Tailored education via mass media or at health facilities: Use of television, radio, print media, digital platforms, social media to disseminate information at clinics about the importance of hepatitis testing for people with history of potential exposure. Health awareness days: Using health awareness days (for example, World Thalassaemia Day (8 May), World Hepatitis Day (28 July) to highlight testing campaigns. Community events: Using health fairs, workshops and local events at community centres to provide information and offer on-site testing.	Linkage to further HBV and HCV testing, diagnosis and treatment. Linkage to all relevant prevention services, including HBV vaccination where indicated.
Sexual partners, children and other family members, and close household contacts of those with HBV	HBV testing and partner services at prenatal and antenatal clinics, family planning clinics, primary care clinics and community-based outreach services. Clinician reminders in electronic records or similar systems to prompt facility-based HBV testing of partners, children and household contacts of those with HBV.	Education and awareness through community support groups for families and networks of people living with HBV. Promote HBV testing during routine health care visits. Community discussions to reduce stigma associated with HBV testing (for example, normalize conversations about HBV in family settings).	Linkage to further HBV testing, diagnosis and treatment, ideally offered at the same site; can include POC viral load testing. Other options include use of DBS or reflex testing. Where this is not possible, strong linkages between different levels of health care system are required. Peer workers and community groups support linkage to care. All HBV prevention (including hepatitis B vaccination) services as appropriate. All HIV and STI testing services as relevant to context.

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Module 3

Priorities in general population testing

Table 6. Examples of testing locations, demand creation and linkage to care for testing of in general population

Who to test	Where to test	Mobilizing and demand creation	Linkage to care
General populations Prioritization can be based on specific birth cohort and/or geographical area with higher HBV or HCV prevalence.	Routine HBV and HCV testing by general practitioners in primary-care facilities during routine health visits and in hospitals as part of standard protocols, including in outpatient communicable and NCD clinics, liver or sexual health clinics, inpatient wards and emergency departments. Integrated HBV and HCV testing in age-specific screening and prevention programmes for NCDs, such as hypertension; diabetes; breast, cervical, prostate and colorectal cancers. This may include national or regional health campaigns offering mass testing in facilities and by mobile outreach. Outreach mobile testing in community centres, pharmacies. HCV self-testing may be offered additionally. Secondary distribution to partners and social networks may be considered. Clinician reminders in electronic records or similar systems to prompt HBV or HCV testing for patients in high-risk birth cohorts.	Mass and social media – for example, television, radio, print and social media – disseminate information about the importance of hepatitis testing, success stories/ benefits of early detection and instructions on how and where to get tested. Health awareness days such as World Hepatitis Day highlight age-based testing campaigns. Include HBV and HCV testing in national or regional health awareness campaigns for other diseases. Integrate with and partner in community events (for example, health fairs, workshops, faith-based events) to provide information and on-site mobile testing. Train doctors, nurses, pharmacists and other health care professionals to discuss the importance of testing during routine visits and to provide personalized recommendations.	HCV and HBV testing, diagnosis and treatment services are ideally offered at the same site, at hospital or PHC level (through decentralization and integration). Services can include POC viral load testing as well as reflex testing. Other options include use of DBS. Community and lay health worker can support linkage to care. People who are self-testing need specific and well-coordinated pathways to confirmatory testing and diagnosis services.

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Step 5: Monitor and evaluate

> **Ensuring that hepatitis testing programmes are reaching their intended populations and identifying previously undiagnosed persons requires continuous monitoring and evaluation**

- Data and a robust evidence-base should guide the response, but lack of this information is not a reason to stop or not initiate a response
- Available data should be used, and burden and cascade of care data should be strengthened.

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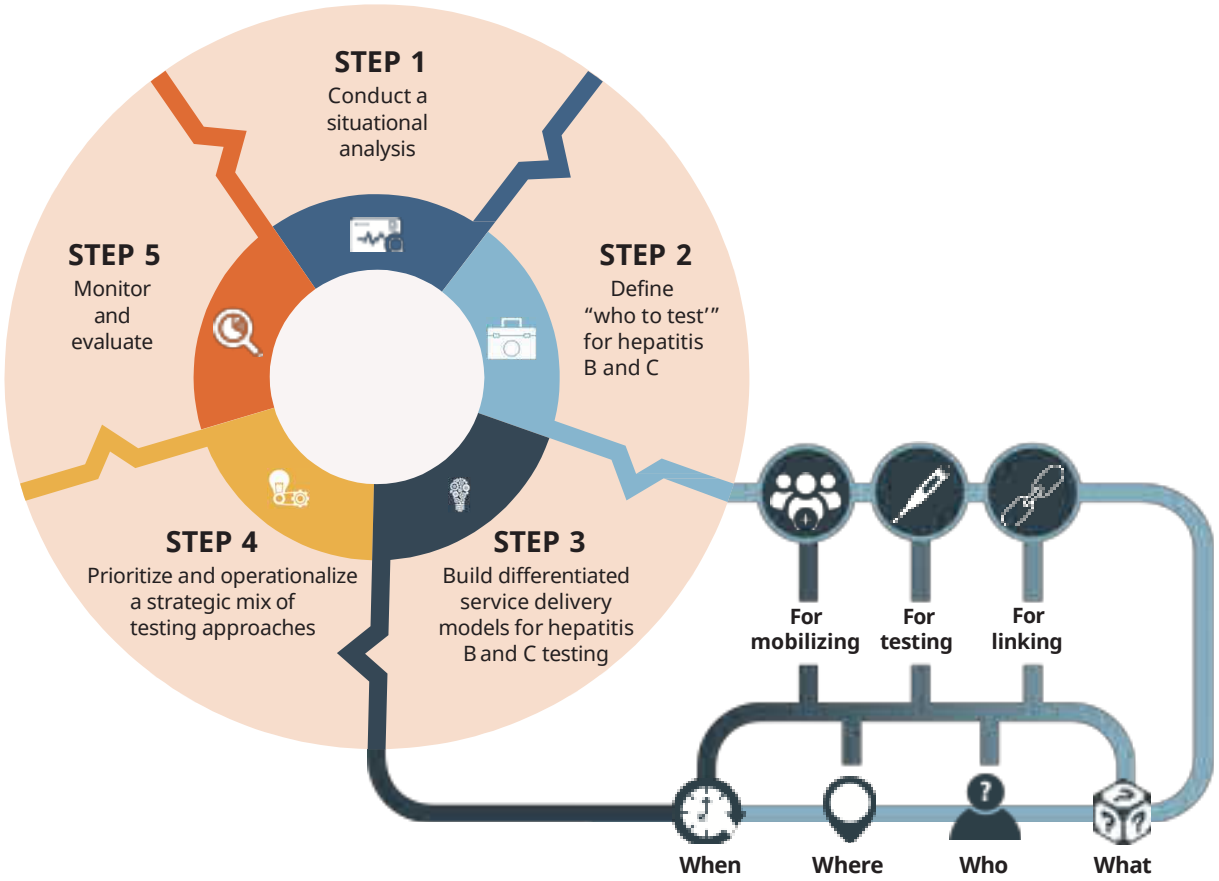
Framework for planning hepatitis B and C testing services



About the operational guide: 5 reasons to use this guide

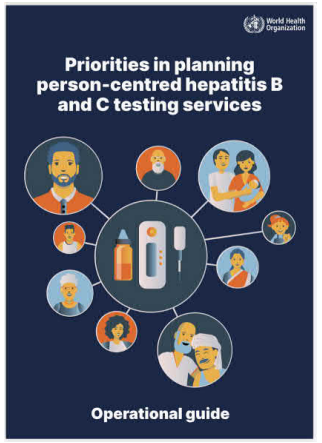
Supports countries operationalizing WHO recommendations for hepatitis B and C testing

Provides a 5-step framework for planning person-centred hepatitis B and C testing approaches that consider national priorities, contextual factors and differentiated service delivery

Emphasizes integration, community involvement and additional key enablers

Country case examples from England, Georgia, Morocco and Uganda demonstrating key enablers and good practices

Annexes of consolidated recommendations and diagnostic products



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https://www.who.int/publications/i/item/9789240104082

Key enablers in implementing viral hepatitis testing

- Political commitment
- Enabling policy, legal and regulatory environment
- Data-driven decision-making
- Community engagement and awareness-raising
- Integrated workforce education
- Access to quality-assured products
- Establishment of quality management systems at testing sites
- Hepatitis B and C testing services integrated with existing services and other disease programmes

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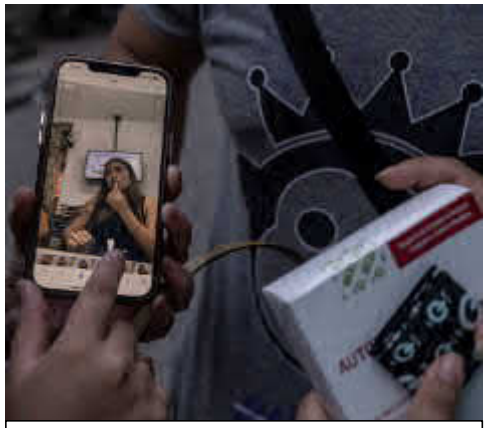
Opportunities for integrating hepatitis testing services



- Integrate health promotion and demonstration of self-test for HCV, HIV and syphilis
- Integrate self-test distribution & network-based testing for partner, family/household, social network

- Facility-based services for KPs, ANC: e.g. ART//harm reduction, outreach
- General populations: NCDs (hypertension, diabetes, cancer screening), in PHC, outpatient and emergency departments

- Community-based onsite POC HIV, HCV, HBV testing

Combined "Test and Treat" Campaigns for Human Immunodeficiency Virus, Hepatitis B, and Hepatitis C: A Systematic Review to Provide Evidence to Support World Health Organization Treatment Guidelines

For every HIV case detected, integrated triple HIV/HBV/HCV testing could identify 5 HBV and 3 HCV additional cases

- Integrate HIV, HCV, HBV rapid testing in mobile PrEP clinics

Community engagement, awareness-raising and stigma elimination

- Delivery of viral hepatitis services depends on empowered individuals, families and communities as advocates of policies that promote enhanced and equitable access to testing and treatment

- Participatory approaches ensure the incorporation of community experiences and promote ownership and accountability

- Community involvement should continue throughout planning, implementation and evaluation.

> **Every person we diagnose with hepatitis is not just someone we need to treat; they are also advocates and partners in advancing our hepatitis response**

Box 5: Reducing stigma and discrimination and creating an enabling environment

The implementation of testing must be accompanied by efforts to address the stigma and discrimination that discourage many people from accessing essential services *(2)*:

- Actively involve and empower people with hepatitis B, C, and D and civil society organizations to raise awareness and promote equitable access to hepatitis testing services.
- Reform restrictive laws and policies to remove barriers to health services, particularly for vulnerable populations, and foster supportive community and health care environments.
- Educate health care workers regularly to eliminate stigma and discrimination, ensuring that patients receive respectful and compassionate care. Protect workers with safety programmes and vaccinations to prevent hepatitis transmission.
- In health campaigns integrate messages promoting a society free from stigma and discrimination.
- Generate data on how stigma and discrimination impact the populations affected by viral hepatitis. Use these data to argue for law and policy reforms.

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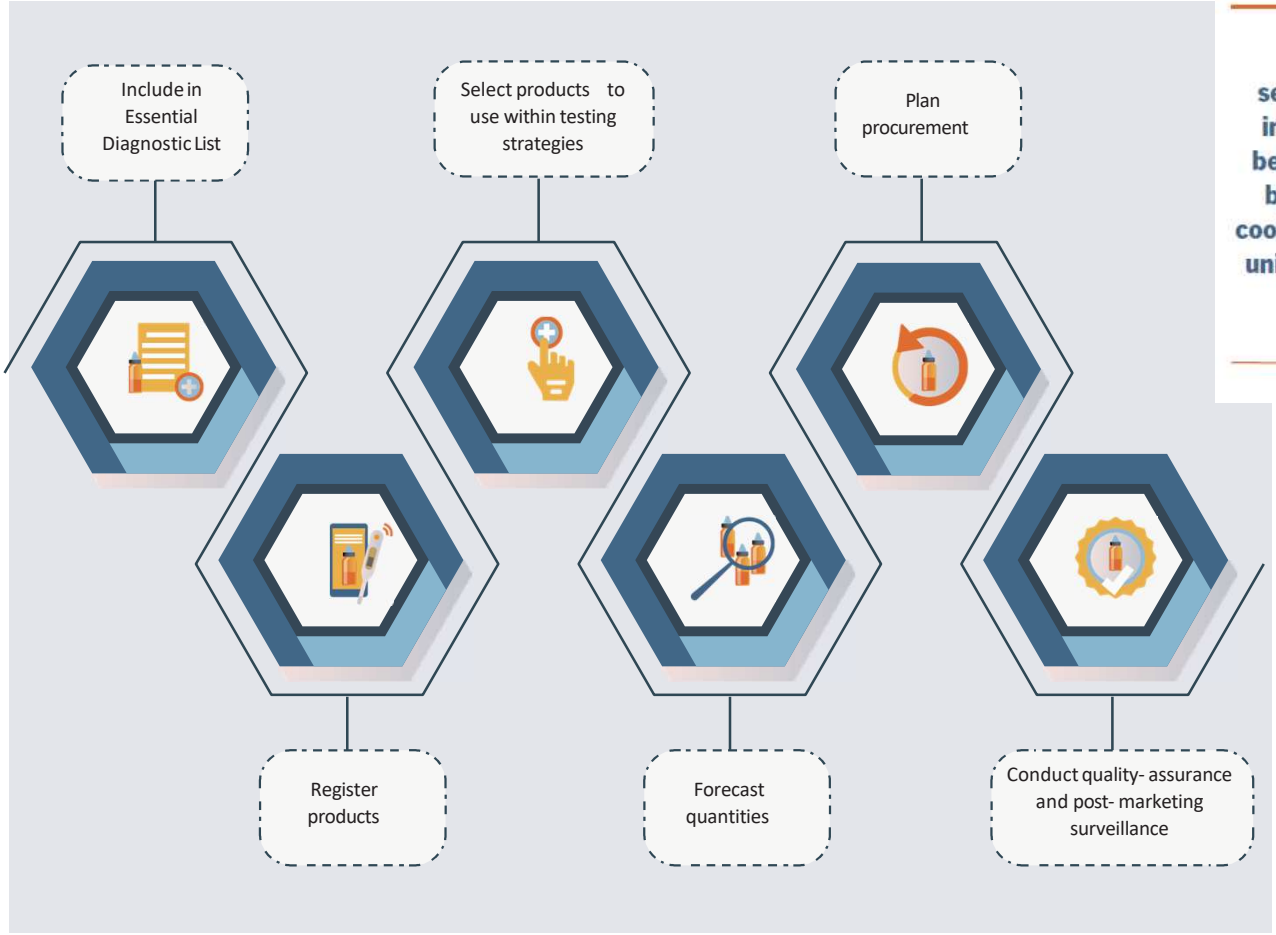
Figure 2. Planning selection and procurement of products



Viral hepatitis testing services should be included in national essential health benefit packages, supported by adequate financing and coordinated actions to advance universal health coverage and integration in primary health care

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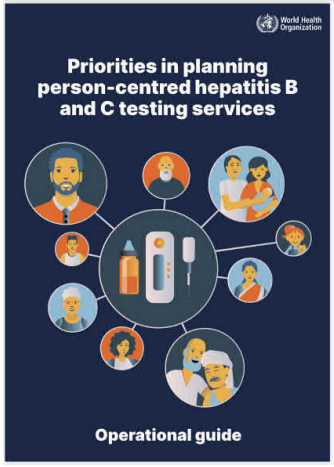

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4. Country case examples

Health promoters from the Union of Centers, Residents' Associations of Heliópolis and Region (UNAS) facilitate prevention activities of the "Heliópolis Investing in Life" project, aimed at promoting and disseminating information on HIV prevention and other STIs in the Heliópolis region in São Paulo, Brazil. © WHO / Dan Agostini

Morocco

Low HCV seroprevalence (0.5% in 2019) *(30)*; country population: 37.7 million in 2023 *(31)*

Mix of age-specific and focused HCV testing approaches delivered through decentralization and integration

Who to test

Adults ≥40 years of age plus most-affected priority populations (including key populations and people living with HIV)[†]

How to test and linkage to care

HCV antibody RDT, followed by POC HCV ribonucleic acid (RNA) confirmatory test

Where to test

Diverse facility-based and community-based settings: primary health care centres (targeting individuals over 40), public hospitals (regional and provincial), public and private laboratories, prisons, addiction centres, community/NGO-led services, HIV clinics, mobile clinics, antenatal clinics, haemodialysis centres, blood donor centres and military centres

Georgia

High chronic HCV prevalence (5.4% in 2015) *(33)*; country population: 3.8 million in 2023 *(31)*

Nationwide general population HCV testing through phased implementation: decentralization, integration and simplified testing strategies

Who to test

Entire adult population ≥18 years old. People with advanced liver disease are prioritized before expanding to the rest of population, including focused testing among priority population and age-specific testing. Initial phase began in the capital before expanding to other regions

How to test

HCV antibody test (RDT or laboratory-based), followed by HCV RNA (point-of-care and qualitative HCV RNA) or HCV core antigen confirmatory testing

Where to test

Hospitals (inpatient, outpatient), HIV clinics, PHC, harm reduction sites and community outreach, ANC, prisons and blood banks

United Kingdom of Great Britain and Northern Ireland

Low HCV and HBV prevalence (0.14% and 0.6% in 2022, respectively) *(37, 38)*; country population: 57.1 million in 2022 *(31)*

Opt-out testing for HBV, HCV and HIV among all adults presenting to emergency departments

Who to test

All adults 18 years or older having a blood test as part of their emergency department attendance.

How to test

BBV triple test: fourth generation HIV 1/2 antigen antibody immunoassay, HBsAg immunoassay and HCV antibody immunoassay with reflex HCV RNA on all positive HCV antibody tests.

Where to test

Select emergency departments across parts of England.

Situational analysis

In England around 62 600 adults age over 16 were estimated to be living with chronic hepatitis C in 2022, a 52% decrease from 129 400 in 2015, due to the substantial increase in testing and treatment *(38)*. In 2022 there were about 270 000 people living with chronic hepatitis B in England *(37)*. People who inject drugs are the main risk group for HCV infection, while being born in a country with high HBV prevalence is the main risk factor for HBV.

Key implementation enablers

1. **Policy and leadership support:** Strong governmental and institutional backing ensured that necessary resources, guidance and oversight were available. The programme has broad cross-party political support.
2. **Integration with existing systems:** By embedding the opt-out testing process into existing clinical workflows, the programme minimized disruption and ensured that staff could incorporate these tests with minimal additional burden (that is, when a blood test is already being ordered).
3. **Staff training and engagement:** Comprehensive training programmes helped ensure that health care workers were prepared to inform patients, manage testing procedures and handle results sensitively.
4. **Data systems:** Effective use of health information systems enabled efficient tracking of testing data, follow-up of results and coordination of care for patients who tested positive. The diagnosis rates are available by site and in real time, creating a sense of purpose and achievement for the staff involved in the pathway.
5. **Ability to localize:** While each site implemented broadly the same testing approach, the specific implementation method was localized using the same funding mechanism (that is, adding relevant staff according to site needs) helping to achieve further ownership.
6. **Patient communication:** Clear and consistent communication strategies were employed to increase patient understanding and acceptance of the testing process.
7. **Involvement of the community:** The Hepatitis C Trust and the British Liver Trust are instrumental partners in the programme, working alongside the National Health Service (NHS) England as well as the HIV NGOs. Also critical is practical peer support to those newly diagnosed or those re-diagnosed who were not in treatment.

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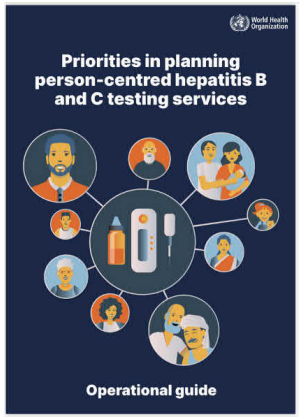

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Annex 4

Overview of available hepatitis B IVDs as of October 2024

	Serological testing to screen for HBV infection and diagnose acute and chronic HBV infection	Determining HBV DNA for treatment eligibility and monitoring treatment response and disease progression
WHO guidelines *(1)*	**HBsAg** – RDT or laboratory-based immunoassay.	**HBV viral load** Laboratory-based HBV DNA (qualitative or quantitative) NAT Point-of-care HBV DNA NAT Hepatitis B envelope antigen (HBeAg) – laboratory-based immunoassay.
Assay types listed in WHO Model List of Essential In Vitro Diagnostics	**Community settings and health facilities without laboratories**	
	HBsAg RDT	HBeAg RDT
	Clinical laboratories	
	for use in blood screening) HBsAg immunoassay.	Quantitative HBV NAT HBeAg immunoassay IgM anti-hepatitis B core antigen immunoassay.
Products with WHO prequalification[1]	**HBsAg RDT** • Bioline HBsAg WB (Abbott Diagnostics Korea Inc.) • Determine HBsAg 2 (Abbott Diagnostics Medical Company). **HBsAg immunoassay** • Murex HBsAg Version 3 with Murex HBsAg Confirmatory Version 3 (DiaSorin S.p.A, United Kingdom Branch) • DS-EIA-HBsAg-0,01 (RPC Diagnostics Systems).	**HBV DNA** None submitted to date. **HBeAg RDT, HBeAg immunoassay** Product category currently not prioritized for WHO prequalification.
Benchmark price	**HBsAg RDT prices paid by countries:** about US$ 1 per test Benchmark price: Global prices for HBsAg RDTs are generally comparable to those of RDTs across other disease areas.	**HBV viral load test prices paid by countries:** US$ 9.36–62.00 per test **Benchmark price:** Several HBV viral load test suppliers offer global access pricing at US$ 9–16 per test.
Products on the Global Fund list that are not WHO prequalified[1]	**HBsAg RDT** • OnSite HBsAg Combo Rapid Test (CTK Biotech Inc, USA) • First Response HBsAg Card Test (Premier Medical Corporation, India) • STANDARD Q HBsAg Test (SD Biosensor, Inc., Republic of Korea). **HBsAg immunoassay** • ARCHITECT HBsAg Qualitative II (Abbott Ireland Diagnostics Division, Ireland) • Monolisa HBsAg ULTRA assay (Bio-Rad Laboratories, France) • Elecsys HBsAg II (Roche Diagnostics GmbH). • HBsAg Hepatitis B Surface Antigen (Shenzhen Mindray Bio-Medical Electronics Co., Ltd, China).	**HbeAg immunossays** • Elecsys HBeAg (Roche Diagnostics GmbH). • HBeAg (CLIA) - (Shenzhen Mindray Bio-Medical Electronics Co., Ltd, China) **HBV DNA** • Alinity m HBV (Abbott Molecular Inc, Des Plaines IL, USA) • Generic HBV Charge Viral Version 2.0 (Biocentric, France) • COBAS Quantitative HBV Test for use with 4800/5800/6800/8800 (Roche Diagnostics) • ExiStation Universal Molecular Diagnostic System (Bioneer Corporation, Republic of Korea). **Point-of-care HBV DNA** • Xpert HBV Viral Load (Cepheid Inc., Sweden).

Annex 5

Overview of available hepatitis C IVDs as of October 2024

	Serological testing to screen for HCV antibodies and to aid in diagnosing viraemic HCV infection	Confirming HCV viraemia to initiate treatment and monitor sustained virological response at 12 weeks after the end of treatment
WHO guidelines *(1-3)*	**RDT** Laboratory-based immunoassay Self-testing	**HBV viral load** Laboratory-based HCV RNA (qualitative or quantitative) NAT Point-of-care HCV RNA NAT HCV core antigen assays
Assay types listed in WHO Model List of Essential In Vitro Diagnostics	**Community settings and health facilities without laboratories**	
	Anti-HCV RDT	
	Clinical laboratories	
	Anti-HCV RDT Anti-HCV immunoassay Combined anti-HCV and HCVcAg anti-HCV immunoassay Combined anti-HCV and HCVcAg immunoassay for use in blood screening.	HCVcAg immunoassay Qualitative or quantitative HCV NAT.
Products with WHO pre-qualification[1]	**Anti-HCV RDT** • Bioline HCV (Abbott Diagnostics Korea Inc.) • OraQuick HCV Rapid Antibody Test Kit (OraSure Technologies, Inc.) • Rapid Anti-HCV Test (InTec Products, Inc.) • STANDARD Q HCV Ab Test (SD Biosensor, Inc.) • First Response HCV Card Test (Premier Medical Corporation Pvt Ltd) • HCV Hepatitis C Virus Rapid Test Device (ABON Biopharm). **Anti-HCV immunoassay** • INNO-LIA HCV Score (Fujirebio Europe NV) • INNOTEST HCV Ab IV (Fujirebio Europe NV) • Monolisa HCV Ag-Ab ULTRA V2 (Bio-Rad).	**HCV viral load NAT** • Abbott RealTime HCV (Abbott Molecular Inc.) • Alinity m HCV (Abbott Molecular Inc.) • Cobas HCV (quantitative NAT for use on Cobas 5800/6800/8800 systems) (Roche Diagnostics GmbH). **Point-of-care HCV RNA NAT** • Xpert HCV Viral Load (Cepheid AB) + Xpert HCV VL Fingerstick (Cepheid AB) – the only prequalified assay that can be used at or near point-of-care. **HCVcAg** • ARCHITECT HCV Ag assay (Denka Seiken Co., Ltd, Kagamida Factory).
HCV self-test product with WHO pre-qualification [1]	**OraQuick HCV Rapid Antibody Test Kit for self-test** (OraSure Technologies, Inc.)	
Benchmark prices	**HCV RDT** prices paid by countries: US$ 0.21 to US$ 2.42 per test **Benchmark price:** US$ 0.80–1.10 per test ex works (Global Fund Pooled Procurement Mechanism).	**HCV viral load** test prices paid by countries: US$ 6.12 to US$ 56.40 per test **Benchmark price:** Several HCV viral load test suppliers offer global access pricing at US$ 8-15 per test.
Products on the Global Fund list that are not WHO prequalified[1]	**Anti-HCV RDT** • INSTI HCV Antibody Test (bioLytical® Laboratories Inc. France) • OnSite HCV Ab Plus Combo Rapid Test (CTK Biotech Inc, USA) **Anti-HCV immunoassay** • Murex anti-HCV Version 4 (DiaSorin, South Africa) • Elecsys® Anti-HCV II (Roche Diagnostics GmbH) • Anti HCV Antibody to Hepatitis C Virus (Shenzhen Mindray Bio-Medical Electronics Co., Ltd, China)	**HCV viral load NAT** • Genedrive HCV ID Kit (Genedrive Diagnostics Ltd., United Kingdom) • Aptima HCV Quant Dx Assay Kit (Hologic, Inc. USA) • ExiStation Universal Molecular Diagnostic System (Bioneer Corporation, Republic of Korea).

Key messages

In 2022, viral hepatitis was one of the leading causes of death among communicable diseases globally, with deaths rising from 1.1 million in 2019 to 1.3 million.

Testing is the critical first step in accessing hepatitis B and C prevention, care and treatment services.

Countries should develop policies that define a strategic mix of hepatitis B and C testing approaches, based on their unique country situation and priorities.

Most people with hepatitis B and C remain undiagnosed and untreated. By the end of 2022, only 13% of the estimated 254 million people living with hepatitis B had been diagnosed, and less than 3% had received antiviral treatment. Of the estimated 50 million people living with hepatitis C, 36% had been diagnosed between 2015 and 2022, and 20% had received curative treatment.

Key enablers in implementing hepatitis B and C testing services

- political commitment
- enabling policy, regulatory and legal environment
- data-driven decision-making
- community engagement and awareness raising
- access to quality-assured products and establishment of quality management systems at testing sites
- decentralization and integration of HBV and HCV testing with existing services and other disease programmes
- integrated education and training of the health workforce.

A five-step framework for planning person-centred hepatitis B and C testing approaches

1 Conducting a situational analysis to enable the development of testing approaches according to a country's epidemiological situation, programmatic response and gaps, health system and availability of resources.

2 Defining "who to test" based on country's epidemiology and priority populations and on WHO recommendations on routine testing of certain populations, general population testing approaches and focused testing of most-affected populations.

3 Building differentiated models for hepatitis B and C testing based on four building blocks – "when, where, who is providing services, and what" – for implementing testing services, mobilizing and creating demand, and linkage to care

4 Prioritizing and operationalizing a strategic mix of testing approaches using information from the situational analysis, building differentiated models of testing services and defining priority populations.

5 Monitor and evaluate key indicators: Use existing data and strengthen hepatitis B and C surveillance to monitor testing approaches and results and to adapt them over time.

a. In all settings: routinely test pregnant women and health care workers for HBV and routinely test blood donors and those with clinical suspicion of chronic viral hepatitis for HBV and HCV.
b. In all settings: Test most-affected populations through focused testing as a priority (key populations; sexual partners, children and household contacts of those with HBV infection; certain indigenous populations and migrant and mobile population groups from ≥2% HBV or HCV prevalence countries; people living with HIV, TB or STIs; populations exposed to HBV or HCV in health care settings or outside the health care system).
c. General population testing: i) Birth cohorts with higher prevalence of HCV may be tested as a priority. ii) Geographical areas with higher HBV or HCV prevalence than the general population could be prioritized in all settings, before expanding to other areas through a stepwise approach. iii) All adults and adolescents should be offered HBV and/or HCV serological testing in settings with ≥2% HBV and/or HCV seroprevalence.

Country case examples

From England (United Kingdom), Georgia, Morocco and Uganda offer compelling examples of how testing approaches and strategies were developed and implemented. These cases highlight the use of various key enablers, a phased implementation and integration to achieve scale-up and the ongoing challenges that need to be addressed.

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