

WHO HEPATITIS B GUIDELINES



Community Briefing

WHAT ARE THE GUIDELINES?

The World Health Organization published new guidelines for the prevention, diagnosis, care and treatment for people with chronic hepatitis B in March 2024.ⁱ The new guidelines:

- Recommend simplified global standards of care for testing and treatment of hepatitis B.
- Aim to increase testing and case finding for hepatitis B, update national guidelines, improve opportunities for cost reduction of hepatitis B medications, and promote wide access to training and capacity building of healthcare workers.
- Update recommendations for treatment eligibility and delivering high-quality services for hepatitis B, which will increase the number of people who can access treatment from 8-15% to 50%.



While the guidelines are targeted at clinicians, national hepatitis programme managers and policy makers, they can also be a key advocacy tool for civil society.

To support advocates, the World Hepatitis Alliance (WHA) has developed this community briefing summarising the guidelines' new recommendations and why these are important to improve access.

i. World Health Organization. Guidelines for the prevention, diagnosis, care and treatment for people with chronic hepatitis B infection [Internet]. 2024 [Accessed 1 May 2024]. Available from: <https://www.who.int/publications/i/item/9789240090903>

KEY TERMSⁱⁱ

ALT

An enzyme found in your liver. ALT is released to your bloodstream when your liver is damaged, so a blood test checking for ALT levels can detect signs of liver disease.

APRI

An index for estimating hepatitis fibrosis based on a formula derived from concentrations of another enzyme found in the liver, aspartate aminotransferase (AST), and platelets.

This mathematical calculation can be done without specialist equipment and by various medical professionals.

Fibroscan

A non-invasive technique to measure liver stiffness using sound waves, performed similarly to an ultrasound.

Hepatitis B DNA test

Also known as a viral load test, it measures hepatitis B DNA levels in blood. The presence of viral load is detected using nucleic acid testing (NAT) technology, which determines if the infection is active and if the individual would benefit from antiviral treatment. It is also used to confirm effective suppression of hepatitis B. The units of measurement used are IU/mL.

Hepatitis B surface antigen test (HBsAg)

This tests for the presence of the virus. A positive test means that the person is infected with hepatitis B, which can be an 'acute' or 'chronic' infection.

Hepatitis B surface antibody test (anti-HBs or HBsAb)

A positive test indicates the person has successfully responded to the hepatitis B vaccine or has recovered from an acute hepatitis B infection. This means they are immune to hepatitis B and are not contagious.

Reflex testing

Refers to a testing principle where a healthcare professional will automatically perform a second test, if the result of the first test meets specific criteria. Reflex testing requires only one specimen.

ii. World Hepatitis Alliance. Diagnosing hepatitis [Internet]. 2024 [Accessed 1 May 2024]. Available from: <https://www.worldhepatitisalliance.org/missing-millions/diagnosing-hepatitis/#glossary>

WHAT HAS CHANGED?

Expanded eligibility to treatment (page 35)

The guidelines broaden eligibility for treatment of all adults with chronic hepatitis B and, importantly, adolescents aged 12 years or older, including pregnant women and girls and women of reproductive age, across four categories:

- 1.** Treat all with evidence of significant fibrosis based on non-invasive tests (APRI or transient elastography using Fibroscan), regardless of hepatitis B viral load or ALT levels;
OR
- 2.** Treat all with hepatitis B viral load of greater than 2000 IU/mL (previously greater than 20,000 IU/mL) and ALT above the upper limit of normal;
OR
- 3.** Treat all with coinfections, such as HIV, hepatitis D or hepatitis C; family history of liver cancer or cirrhosis; immune suppression; and/or comorbidities, such as diabetes or vasculitis, regardless of hepatitis B viral load or ALT levels;
OR
- 4.** Treat those with persistently abnormal ALT levels (in the absence of access to hepatitis B viral load testing).

Why it matters

The guidelines no longer require hepatitis B viral load testing to decide treatment eligibility. Instead, other, more readily available testing options can be used to make treatment decisions.

This is particularly relevant in places where viral load testing is often unavailable. Anyone that falls within one of these categories is now eligible for treatment, and this will increase the number of people receiving treatment by at least 35%.

Where an individual does not fall into any of the above categories, however, the guidelines state that providers should help them through a patient-centred approach.

This is important, as it means people living with hepatitis B who wish to start treatment should feel empowered to have those conversations with their healthcare providers.

The guidelines highlight that, in circumstances where individuals do not meet any of the four options for treatment eligibility, a patient-centred approach with discussion between individuals and their healthcare professional can be helpful when considering beginning treatment.

Non-invasive tests for liver disease (page 26)

The guidelines now recommend APRI as the preferred non-invasive test to assess for the presence of significant liver disease or cirrhosis among adults in resource-limited settings.ⁱⁱⁱ

In settings where cost is not a major constraint, the guidelines recommend transient elastography (Fibroscan) as a preferable non-invasive test when available.

Why it matters

In places where hepatitis B viral load testing is required for treatment, but is not available or affordable, many people have been prevented from accessing treatment.

Recommending APRI and Fibroscan as non-invasive tests to assess for liver disease will expand eligibility for hepatitis B treatment, as the guidelines no longer require viral load testing. The use of APRI and Fibroscan will allow for flexibility and ensure greater access to treatment.

Alternative antiviral regimens for treatment (page 53)

The guidelines expand the number for treatments recommended for hepatitis B. It recommends tenofovir disoproxil (TDF) or entecavir (ETV) as the preferred treatment regimens for hepatitis B. However, when TDF is not available, WHO recommends the combination therapy of TDF and lamivudine (3TC) or TDF and emtricitabine (FTC) in settings where there is access to these treatments through existing HIV programme procurement.

The guidelines also recommend that use of tenofovir alafenamide fumarate (TAF) is reserved for special circumstances of those with risk of, or existing renal impairment or osteoporosis.

Why it matters

In many countries, limited access to TDF has been a significant barrier to treatment for people living with hepatitis B.

Some formulations such as 3TC and FTC are currently available for HIV PrEP. Expanding the number for treatment options will allow many more people to access treatment for hepatitis B through existing HIV programmes.

Procurement of TDF may also become easier, as more treatments can be used through combination therapy.

iii. The new recommendation for evidence of significant fibrosis should now be based on an APRI score of >0.5 or transient elastography >7 kPa, and cirrhosis should be based on clinical criteria, or an APRI score of >1.0 or transient elastography value of > 12.5 kPa.

Expanding access to treatment as prevention of mother-to-child transmission (PMTCT) (page 63)

The guidelines recognise significant challenges in accessing hepatitis B viral load and/or hepatitis B e antigen (HBeAg) testing in some countries. It therefore recommends:

- In settings where hepatitis B DNA or HBeAg testing is available, pregnant women with hepatitis B DNA greater than 200,000 IU/mL or who test positive for hepatitis B surface antigen (HBsAg) should receive prophylaxis with TDF.
- In settings when hepatitis B DNA or HBeAg testing is not available, all women who test positive for HBsAg should receive prophylaxis with TDF.

The guidelines also note that women who are planning multiple pregnancies can remain on treatment between pregnancies if they choose.

Point-of-care and reflex hepatitis B viral load testing (pages 97 and 108)

The guidelines recommend the use of POC hepatitis B NAT as an alternative to laboratory hepatitis B viral load testing to assess eligibility for treatment. Reflex testing following a positive HBsAg test is also recommended to assess treatment eligibility and linkage to care.

Why it matters

In many settings, limited access to hepatitis B viral load or HBeAg testing has been a barrier to treatment for pregnant women living with hepatitis B. The new recommendations now only require a simple point-of-care (POC) testing for pregnant women to begin treatment for hepatitis B.

The implementation of POC testing will ensure testing is delivered in a more convenient and accessible way for pregnant women living with hepatitis B. POC testing will also further expand PMTCT, as many more pregnant women will be able to access treatment for hepatitis B.

Why it matters

In many settings, hepatitis B viral load testing is not available or is unaffordable, which has proven a significant barrier to treatment for people living with hepatitis B. POC testing will help address this by ensuring people can access testing in community settings.

Furthermore, reflex testing will ensure people are not being asked to return for confirmation testing – a key point in the care cascade where people can be lost during follow-up. The implementation of both POC and reflex testing will ensure testing is delivered in a more convenient and accessible way for people living with hepatitis B.

Hepatitis delta (page 113)

WHO has expanded the guidelines to include recommendations for hepatitis delta testing. The guidelines recommend a universal hepatitis delta antibody testing approach among people living with chronic hepatitis B.

When there is limited laboratory and resource capacity, the guidelines recommend prioritising testing in specific hepatitis B populations, including people at higher risk of acquiring hepatitis delta (people who inject drugs, men who have sex with men, sex workers, people living with hepatitis C or HIV, and haemodialysis recipients), children and family members of people with hepatitis delta, and those already receiving treatment for hepatitis B.

The guidelines also include reflex testing for hepatitis delta, which tests for hepatitis delta following a positive hepatitis B test. It also recommends reflex hepatitis delta RNA testing where available, to improve monitoring and care.

Why it matters

There is a considerable lack of data on hepatitis delta, driven in large part through limited testing.

These new recommendations will help improve our understanding of the prevalence of hepatitis delta and ensure that people living with hepatitis B will know their hepatitis delta status.

This is critical, as those co-infected with hepatitis B and hepatitis delta will progress to liver disease faster and should be carefully monitored and linked to relevant care as a priority.

Delivering high-quality services (page 137)

The guidelines promote key approaches to delivering high-quality services for hepatitis B care, similar to principles from HIV and hepatitis C care. These include:

1. Strategies to promote increased testing and improve linkage to care, treatment and prevention.
2. Strategies to promote and sustain long-term access to antiviral treatment.
3. Strategies to promote retention in care, and track and re-engage those disengaged from care.
4. Integration of hepatitis testing, care and treatment with other services, such as HIV and primary care.
5. Decentralisation of testing and treatment services at primary health facilities to promote access to care.
6. Community engagement and peer support.

Why it matters

Implementation of the new hepatitis B recommendations requires healthcare systems that are structured to support them. The above approaches will facilitate this, increasing access to effective testing, treatment and care. Advocates should ensure national strategies include them.

**Find the full WHO
hepatitis B guidelines
HERE**



www.worldhepatitisalliance.org | contact@worldhepatitisalliance.org

