World Health Organization

Guidelines for the prevention, diagnosis, care and treatment for people with chronic hepatitis B infection

Policy brief

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Acronyms and abbreviations

ALT	alanine aminotransferase
APRI	aspartate aminotransferase-to-platelet ratio index
CHB	chronic hepatitis B
CHD	chronic hepatitis D
CrCl	creatinine clearance
ELISA	enzyme-linked immunosorbent assay
EMTCT	elimination of mother-to-child transmission
GFR	glomerular filtration rate
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HBeAg	hepatitis B e antigen
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCC	hepatocellular carcinoma
HDV	hepatitis D (delta) virus
HepBD	hepatitis B vaccine given within 24 hours of birth
HepB3	three doses of hepatitis B vaccine given in infancy
NAT	nucleic acid testing
POC	point of care
PMTCT	prevention of mother-to-child transmission
ULN	upper limit of normal

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Guidelines development group

The chairs of the Guidelines Development Group were Wendy Spearman (University of Cape Town, South Africa) and Saeed Sadiq Hamid (Aga Khan University, Karachi, Pakistan). Roger Chou (Oregon Health and Science University, Portland, United States of America) was the guidelines methodologist.

The following experts served on the Guidelines Development Group:

Danjuma K. Adda (World Hepatitis Alliance, Nigeria), Suna Balkan (Médecins Sans Frontières, France), Ajeet Singh Bhadoria (All India Institute of Medical Sciences Rishikesh, India), Yap Boum (Institute Pasteur of Bangui, Central African Republic), Vladimir Chulanov (National Medical Research Center for Infectious Diseases, Russian Federation), Chari Cohen (Hepatitis B Foundation, United States of America), Naranjargal Dashdory (Onom Foundation, Mongolia), Manal Hamdy El-Sayed (Ain Shams University, Egypt), Jordan Feld (Toronto Centre for Liver Disease, Canada), Jin-Lin Hou (Nanfang Hospital, Southern Medical University, China), Saleem Kamili (United States Centers for Disease Control and Prevention), Patrick Kennedy (Queen Mary University of London, United Kingdom of Great Britain and Northern Ireland), Giten Khwairakpam (Treat Asia, Thailand), Sulaiman Lakoh (Ministry of Health, Sierra Leone), Maud Lemoine (Imperial College, United Kingdom), Hailemichael Desalegn Mekonnen (St. Paul's Hospital Millennium Medical College, Ethiopia), David Handojo Muljono (Indonesian Academy of Sciences, Indonesia), Wongani Mzumara (Ministry of Health, Malawi), Edith Okeke (Jos University Teaching Hospital, Nigeria), Janus Ong (University of the Philippines, Philippines), Christian B. Ramers (Clinton Health Access Initiative, United States of America), Lewis Roberts (Mayo Clinic, United States of America), Cao Thi Thanh Thuy (Medical Centre, Hospital of Hanoi Medical University, Viet Nam) and Su Wang (Cooperman Barnabas Medical Center, United States of America).

The following experts served on the Guidelines Development Group subgroup on treatment for children: Alasdair Bamford (Great Ormond Street Hospital, United Kingdom), Mei Hwei Chang (National Taiwan University and Children's Hospital, Taiwan, China), Geoffrey Dusheiko (King's College Hospital, United Kingdom), Manal Hamdy El-Sayed (Ain Shams University, Egypt), Giuseppe Indolfi (University of Florence, Italy), Simon C. Ling (Hospital for Sick Children, Toronto, Canada), Fatima Mir (Aga Khan University, Pakistan) and Tammy Meyers Morris (University of New South Wales, Australia).

The following experts served on the Guidelines Development Group subgroup on hepatitis D virus testing: Segolene Brichler (Avicenne Hospital, Assistance Publique, France), William L. Irving (University of Nottingham, United Kingdom), Cirley Maria de Oliveira Lobato (Universidade Federal do Acre, Brazil), Francesco Negro (University Hospital of Geneva, Switzerland), Hong You (Beijing Friendship Hospital, Capital Medical University, China) and Cihan Yurdaydin (University of Ankara, Türkiye).

WHO steering group

WHO headquarters: Philippa Easterbrook, Sahar Bajis, Diana Faini, Olufunmilayo Lesi, Niklas Luhmann, Myat Sandi Min, Wole Ameyan, Nathan Ford, Robert Luo, Morkor Newman, Marco Victoria, Lara Vojnov, Meg Doherty (Department of Global HIV, Hepatitis and Sexually Transmitted Infections Programmes). Martina Penazzato (Global Accelerator for Paediatric Formulations (GAP-f)), Mark Lanigan (Regulation and Prequalification), Shalini Desai (Immunization, Vaccines and Biologicals).

WHO regional and country offices and other United Nations organizations: Doroux Aristide Charles Billy (WHO Regional Office for Africa), Polin Chan (WHO Country Office in India), Catherine de Martel (International Agency for Research on Cancer), Franck Fwamba (WHO Country Office in Chad), Kiyohiko Izumi (WHO Regional Office for the Western Pacific), Muhammad Jamil (WHO Regional Office for the Eastern Mediterranean), Casimir Mingiedi Manzengo (WHO Regional Office for Africa), Marcelo Naveira (WHO Regional Office for Europe), Van Thi Thuy Nguyen (WHO Country Office in Viet Nam), Muhammad Pasha (WHO Country Office in Pakistan), Leandro Sereno (WHO Regional Office for the Americas).

Overall coordination and writing

Philippa Easterbrook provided overall coordination and drafting of the guidelines. Sahar Bajis and Niklas Luhmann (Department of Global HIV, Hepatitis and Sexually Transmitted Infections Programmes) drafted the chapters on hepatitis D virus testing. Additional input on specific chapters with reference review was provided by Geoffrey Dusheiko (King's College Hospital London, United Kingdom), Simon Ling (Hospital for Sick Children, Canada), Catherine de Martel (International Agency for Research on Cancer), Emmanouil Tsochatzis (UCL Institute of Liver and Digestive Health, United Kingdom), Gibril Ndow (Hepatitis Research Group, MRC Unit The Gambia at London School of Hygiene and Tropical Medicine, United Kingdom), Maud Lemoine (Imperial College, United Kingdom) and Lewis Roberts (Mayo Clinic, United States of America). Myat Sandi Min and Megan Wilson-Jones provided contributions on referencing, web annexes and summaries of declarations of interest. Jasmin Leuterio and Lydia Kawanguzi provided administrative support. David Breuer edited the text, and 400 undertook design and layout.

Background

Hepatitis B virus (HBV) infection is a major public health problem and cause of chronic liver disease that led to an estimated 1.1 million deaths in 2022, mainly due to cirrhosis and liver cancer. In 2022, WHO estimated that 253 million people were chronically infected and living with hepatitis B, of whom 63% are in the African and Western Pacific Asian region *(1)*. Most of the global burden of chronic hepatitis B (CHB) can be attributed to mother-to-child transmission at the time of or shortly after birth, and such perinatal infections lead to a high rate of chronicity. Considerable progress has been made towards eliminating the perinatal transmission of HBV through universal infant HBV immunization, including the timely hepatitis B birth-dose (HepBD), which has been highly effective in reducing new infections among children. However, HepBD coverage is only 45% globally, with lowest coverage (18%) in the WHO African Region *(2)*. For people with CHB infection, nucleoside analogue treatment with currently recommended tenofovir and entecavir is highly effective and can reduce progression of liver disease and incidence of hepatocellular carcinoma (HCC) and improve long-term survival. However, a major testing and treatment gap remains. In 2022, only 13% of the estimated 253 million people with CHB had been diagnosed and 3% had been treated *(1)*. Scaling up testing and treatment towards the elimination goals will require a radical simplification of treatment criteria, diagnostic approaches and service delivery models to overcome barriers in access to hepatitis B testing and treatment.

In 2015, WHO issued the first comprehensive guidelines on prevention, care and treatment for people with CHB *(3)*, followed in 2017 with WHO guidelines on testing for viral hepatitis B and C *(4)* and in 2020 with WHO guidelines on preventing the mother-to-child transmission of HBV using antiviral prophylaxis in pregnancy *(5)*. Several significant developments have occurred since the 2015 guidelines were published. These include new study data in several areas:- diagnostic performance of non-invasive tests for staging of liver disease and cut-off thresholds for diagnosing significant fibrosis or cirrhosis; natural history of CHB in different regions and antiviral therapy effectiveness according to different HBV DNA and ALT levels; comparison of the effectiveness and safety of dual combination of tenofovir + lamivudine or emtricitabine and also tenofovir alafenamide (TAF), a prodrug of tenofovir compared to tenofovir; diagnostic performance and impact of HBV DNA point-of-care viral load testing technologies; testing for hepatitis D virus (HDV) infection (who to test and how to test), and impact of reflex testing approaches for HBV DNA and hepatitis D virus infection; and impact of different service delivery models for care and treatment of CHB on outcomes across the cascade of care.

Scope of new guidelines

The objective of the 2024 guidelines is to provide updated evidence-informed recommendations on key priority topics. These include expanded and simplified treatment criteria for adults but now also for adolescents; expanded eligibility for antiviral prophylaxis for pregnant women to prevent mother-to-child transmission of HBV; and improving HBV diagnostics through use of point-of-care HBV DNA viral load and reflex approaches to HBV DNA testing; and who to test and how to test for HDV infection.

The 2024 guidelines include 11 updated chapters with new recommendations:

Expanded treatment and antiviral prophylaxis

- use of non-invasive tests for staging of liver disease (Chapter 4);
- who to treat among people with CHB (Chapter 5);
- first-line antiviral therapies for CHB (Chapter 6);
- preventing mother-to-child transmission of HBV using antiviral prophylaxis (Chapter 7);
- treatment of adolescents and children with CHB (Chapter 8);

HBV DNA and HDV infection diagnostics

- measurement of HBV DNA level to guide treatment eligibility and monitor treatment response (Chapter 10);
- HBV DNA reflex testing (Chapter 11);
- HDV testing – who to test and how to test, including reflex testing (Chapters 12–14); and

HBV service delivery

- Eight approaches to promote access and delivery of high-quality health services for CHB (no new recommendations but includes existing recommendation on strategies to promote linkage to care) (Chapter 15).

There are also five existing chapters relating to monitoring with unchanged recommendations from the 2015 guidelines, but these have been updated with new context, additional studies and new research gaps. These chapters are:

- second-line antiviral therapies for managing treatment failure (Chapter 9);
- monitoring for treatment response, and for treatment side effects (Chapters 16–17);
- surveillance for HCC (Chapter 18);
- when to stop and restart antiviral therapy (Chapter 19).

Target audience

These guidelines are addressed primarily to clinicians and national hepatitis programme managers and other policy-makers in health ministries, especially in low- and middle-income countries, who are responsible for developing national hepatitis testing and treatment plans, policy and guidelines. Implementation of the recommendations in these guidelines should be informed by local context, including hepatitis B epidemiology and prevalence of other comorbidities, availability of resources, the organization and capacity of the health system and anticipated cost–effectiveness.

Guidelines methodology

The development of these guidelines was conducted in accordance with procedures established by the WHO Guidelines Review Committee. Clinical recommendations were formulated by a regionally representative and multidisciplinary Guidelines Development Group at a meeting held in May 2023. The GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach was used to formulate and categorize strength of recommendations (strong or conditional) and was adapted for diagnostic tests. This includes assessing the certainty of evidence (high, moderate, low or very low), consideration of overall balance of benefits and harm (at individual and population levels), patient and health-care worker values and preferences, resource use, cost–effectiveness and consideration of feasibility and effectiveness across a variety of resource-limited settings, including when access to laboratory infrastructure and specialized tests is limited. The process also identified key gaps in knowledge that will guide the future research agenda.

Fifteen systematic reviews and meta-analyses were undertaken to address the key research questions, in addition to two modelling and cost–effectiveness analyses on the impact of expanded treatment eligibility criteria at the global, regional and country levels and the impact of expanding antiviral prophylaxis for preventing mother-to-child transmission to include all hepatitis B surface antigen (HBsAg)-positive women and girls. In addition, WHO commissioned various partner organizations to undertake four key surveys among populations affected by hepatitis B, health-care workers and national hepatitis programme managers to assess the acceptability of potential recommendations relating to topics covered in the guidelines.

Topics with new recommendations

Expanded eligibility for treatment:

The updated recommendations provide four options for meeting treatment eligibility that apply to all adults with CHB and now also adolescents (aged 12 years or older). Only one of the four options requires access to HBV DNA testing, which has been considered one of the major barriers to accessing treatment. Overall, these four options will capture a much higher proportion (at least 50%) of all HBsAg-positive people (depending on the region) compared to about 8–15% previously. They include:

1. Treat all with significant fibrosis (previously only cirrhosis) based on revised thresholds of non-invasive tests for staging of liver disease (APRI score >0.5 or transient elastography (if available) >7KPa), regardless of HBV DNA or ALT levels. This recommendation will capture an estimated 20–25% of all HBsAg-positive people.
2. Treat all with HBV DNA>2000 IU/mL (previously >20,000 IU/mL) and ALT above the upper limit of normal (ULN). This recommendation will capture an estimated 20-35% of all HBsAg-positive people.
3. Treat all with coinfections (such as HIV, hepatitis D or hepatitis C); family history of liver cancer or cirrhosis; immune suppression (such as long-term steroid use, solid organ or stem cell transplants); comorbidities (such as diabetes or metabolic dysfunction–associated steatotic liver disease); or extrahepatic manifestations (such as glomerulonephritis or vasculitis), regardless of HBV DNA or ALT levels. This recommendation will capture an estimated 5–8% of HBsAg-positive people.
4. An additional conditional recommendation (where there is no access to HBV DNA) to treat those with CHB based on persistently abnormal ALT levels alone. This recommendation, which is maintained from the 2015 WHO hepatitis B guidelines, will capture an estimated 20% of all HBsAg positive people.

Alternative antiviral regimens for treatment:

The existing recommendation for use of two nucleoside analogues with a high genetic barrier to resistance - tenofovir disoproxil fumarate (TDF) or entecavir (ETV) as preferred first-line regimens was retained from the 2015 WHO hepatitis B guidelines. The new recommendation is for use of dual regimens of tenofovir + lamivudine or tenofovir + emtricitabine as alternative regimens in settings where access to tenofovir monotherapy is lacking but where there is ready access to the dual regimens at low-cost (as component of HIV antiretroviral or pre-exposure prophylaxis regimens) through existing ARV drug procurement. The use of tenofovir alafenamide (TAF) is reserved for special circumstances for those with existing or at risk of renal impairment or osteoporosis.

Expanding access to antiviral prophylaxis for prevention of mother-to-child transmission (PMTCT):

The existing recommendation for use of TDF prophylaxis for HBsAg-positive pregnant women with HBV DNA levels ≥200 000 IU/mL or a positive HBeAg, in settings where there is ready access to these assays, is maintained from the 2020 WHO hepatitis B antiviral prophylaxis guidelines for PMTCT. To address the continued significant challenge in accessing HBV DNA or even HBeAg serology testing to determine eligibility for antiviral prophylaxis, a new conditional recommendation provides the option of using antiviral prophylaxis for all HBsAg-positive pregnant mothers. Use of prophylaxis is in addition to hepatitis B infant vaccination, including hepatitis B birth dose for HBV PMTCT. It provides the option to continue TDF for mothers who meet the criteria for antiviral therapy for their own health and among women of childbearing age planning additional pregnancies.

Point-of-care and reflex HBV DNA testing:

The use of POC HBV DNA nucleic acid testing (NAT) assays is now recommended as an alternative approach to laboratory-based HBV DNA testing to assess treatment eligibility and to monitor treatment response. Reflex HBV DNA testing in those with a positive HBsAg test result is recommended as an additional strategy to promote linkage to care and treatment. This can be achieved either through automatic laboratory-based reflex HBV DNA testing using a specimen already held in the laboratory, or clinic-based reflex testing in a health facility through immediate specimen collection for HBV DNA testing following a positive rapid HBsAg test result, avoiding the need for a second visit and further blood sample.

HDV infection testing - who to test and how to test, and use of reflex Delta antibody serology and HDV RNA NAT testing:

The guidelines now include recommendations for who to test and how to test for chronic hepatitis D (CHD), a major contributor to more rapid progression and HBV liver-related morbidity and mortality. For who to test - WHO recommends a universal HDV antibody testing approach among people with CHB, or where this approach may not be feasible because of limited laboratory capacity - for testing to be prioritised in specific HBsAg-positive populations or settings with well-established higher prevalence of HDV infection. These include people born in HDV-endemic countries and regions; people at higher risk of acquiring HDV (people who inject drugs, men who have sex with men, sex workers, people living with HCV or HIV and haemodialysis recipients); children and family members of people with HDV infection; people with advanced liver disease; and those already receiving HBV treatment. For how to test - WHO recommends a serological assay to detect total anti-HDV followed by a NAT to detect HDV RNA and active (viraemic) infection among those who are anti-HDV positive. Reflex testing is recommended 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, as an additional strategy to promote diagnosis, and improve care and monitoring.

Key approaches for delivering high-quality services for hepatitis B care:

Hepatitis B still has a very limited direct evidence base to guide formal recommendations on service delivery. Eight key approaches are promoted for high-quality health service delivery for hepatitis B care applied from similar principles in HIV and HCV care. These include: strategies to promote uptake of testing and strengthen linkage to care, treatment and prevention; strategies to promote and sustain adherence to long-term antiviral therapy; strategies to promote retention in care and track and re-engage those disengaged from care; 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; decentralization of testing and treatment services at primary health facilities to promote access to care supported through task-sharing and a differentiated care strategy; and community engagement and peer support.

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4. World Health Organization. Guidelines on hepatitis B and C testing. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/handle/10665/254621, accessed 5 February 2024).
5. World Health Organization. Prevention of mother-to-child transmission of hepatitis B virus: guidelines on antiviral prophylaxis in pregnancy. Geneva: World Health Organization; 2020 (https://apps.who.int/iris/handle/10665/333453, accessed 5 February 2024).

Summary of recommendations

Non-invasive assessment of liver disease stage at baseline and during follow-up	
Existing and maintained recommendation (2015 hepatitis B guidelines)	APRI (aspartate aminotransferase-to-platelet ratio index) is recommended as the preferred non-invasive test to assess for the presence of significant fibrosis or cirrhosis among adults in resource-limited settings. Transient elastography (FibroScan®) may be a preferable non-invasive test in settings where it is available and cost is not a major constraint. *(strong recommendation, moderate-certainty evidence)*
New recommendation (for non-invasive test thresholds to establish the presence of significant fibrosis (≥F2) or cirrhosis (F4)	Evidence of significant fibrosis (≥F2) should be based on an APRI score of >0.5 or transient elastography value of >7.0 kPa,[a] and cirrhosis (F4) should be based on clinical criteria[b] (or an APRI score of >1.0 or transient elastography (FibroScan®) value of >12.5 kPa [a]). *(adults: strong recommendation, moderate-certainty evidence; adolescents: strong recommendation, low-certainty evidence)*

a These cut-offs apply to FibroScan® – other elastography techniques do not necessarily have the same cut-offs.

b Clinical features of decompensated cirrhosis: portal hypertension (ascites, variceal haemorrhage and hepatic encephalopathy), coagulopathy, or liver insufficiency (jaundice). Other clinical features of advanced liver disease/cirrhosis may include: hepatomegaly, splenomegaly, pruritus, fatigue, arthralgia, palmar erythema or oedema.

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Who to treat among people with CHB (adults and adolescents)	
New recommendations	Treatment is recommended for all adults and adolescents (aged ≥12 years) with chronic hepatitis B (CHB)[a] (including pregnant women and girls and women of reproductive age) with: 1. Evidence of significant fibrosis (≥F2[b]) based on an APRI score of >0.5 or transient elastography value of >7 kPa or evidence of cirrhosis (F4) based on clinical criteria[b,c] (or an APRI score of >1 or transient elastography value of >12.5 kPa[b]), regardless of HBV DNA or ALT levels. *(adults: strong recommendation, moderate-certainty evidence; adolescents: strong recommendation, low-certainty evidence)* **OR** 2. HBV DNA >2000 IU/mL and an ALT level above the upper limit of normal (ULN) (30 U/L for men and boys and 19 U/L for women and girls). For adolescents, this should be based on ALT>ULN on at least two occasions in a 6- to 12-month period.[d] *(adults: strong recommendation, high-certainty evidence [HBV DNA >20 000 IU/mL] and low-certainty evidence [HBV DNA 2000–20 000,]; adolescents: conditional recommendation, low-certainty evidence)* **OR** 3. Presence of **coinfections** (such as HIV, hepatitis D or hepatitis C); family history of liver cancer or cirrhosis; **immune suppression** (such as long-term steroid use, solid organ or stem cell transplant); **comorbidities** (such as diabetes or metabolic dysfunction–associated steatotic liver disease); or **extrahepatic manifestations** (such as glomerulonephritis or vasculitis), regardless of the APRI score or HBV DNA or ALT levels. *(adults: strong recommendation, moderate-certainty evidence; adolescents: conditional recommendation, low-certainty evidence)* **OR** **In the absence of access to an HBV DNA assay:** 4. Persistently abnormal ALT levels alone (defined as two ALT values above the ULN at unspecified intervals during a 6- to 12-month period), regardless of APRI score.[e] *(adults and adolescents: conditional recommendation, very-low-certainty evidence)*

a Defined as the presence of HBsAg on at least one occasion, in adults and for adolescents and children, persistence of HBsAg for six months or more.

b The thresholds of non-invasive tests (APRI and transient elastography) for diagnosis of significant fibrosis or cirrhosis and treatment recommendation are based on extrapolating data from adults and have not yet been fully validated for adolescents or children.

c Clinical features of decompensated cirrhosis: portal hypertension (ascites, variceal haemorrhage and hepatic encephalopathy), coagulopathy or liver insufficiency (jaundice). Other clinical features of advanced liver disease and cirrhosis may include: hepatomegaly, splenomegaly, pruritus, fatigue, arthralgia, palmar erythema and oedema.

d The ULN for ALT have been defined as <30 U/L for men and boys and <19 U/L for women and girls for consistency. Some guidelines use different ULN ALT levels for adolescents and children (<22 U/L for girls and women and <25 U/L for boys and men). Raised ALT may normalize in pregnancy and is therefore not a good marker for deciding about long-term treatment in pregnancy. Pregnant women should be reassessed after delivery.

e Persistently normal or abnormal may be defined as two ALT values below or above the ULN at unspecified intervals during a 6- to 12-month period. ALT levels fluctuate with CHB and require longitudinal monitoring to determine the trend.

First-line antiviral therapies for CHB (adults, adolescents and children)	
Existing and maintained recommendations (from the 2015 hepatitis B guidelines)	Nucleoside analogues with a low genetic barrier to resistance (lamivudine, adefovir or telbivudine) can lead to drug resistance and are not recommended. *(strong recommendation, moderate-certainty evidence*
Updated recommendation	For all adults, adolescents and children (two years or older) for whom antiviral therapy is indicated, the nucleos(t)ide analogues that have a high genetic barrier to drug resistance – tenofovir disoproxil fumarate (TDF) or entecavir (ETV) are recommended as preferred regimens. TDF + lamivudine (3TC) or TDF + emtricitabine (FTC) are recommended as alternative regimens (where TDF monotherapy is not available). *(strong recommendation, moderate-certainty evidence)*
New recommendation	Entecavir (ETV) or tenofovir alafenamide (TAF)[a] (if available) are recommended for people with established osteoporosis and/or impaired kidney function, and for children (ETV for those aged two years or older) or adolescents (TAF for those aged 12 years or older) as alternative regimens, for whom antiviral therapy is indicated. *(strong recommendation, moderate-certainty evidence)*
a TAF is not recommended if eGFR is <15mL/min	

Second-line antiviral therapies for managing treatment failure	
Existing and maintained recommendation (2015 HBV guideline)	Among people with evidence of treatment failure due to confirmed or suspected antiviral resistance[a,b,c] (based on history of previous exposure or primary non-response) to lamivudine, entecavir, adefovir or telbivudine, switching to tenofovir disoproxil fumarate is recommended. Tenofovir alafenamide may be considered as an alternate regimen, if available. *(strong recommendation, low-certainty evidence)*

a Treatment adherence should be reinforced for all people with confirmed or suspected antiviral resistance. See also Box 15.2.

b Some countries and health-care providers may consider switching people to TDF (or TAF, if available) from existing antiviral regimens with a low barrier to resistance before evidence of treatment failure, but these guidelines make no formal recommendations.

c To date, there are only isolated case reports of TDF or TAF resistance when used for hepatitis B treatment. If there is primary non-response, then treatment adherence should be reinforced and monitored. At present, there is therefore no indication to switch to an alternative drug regimen.

Preventing mother-to-child transmission of hepatitis B and use of antiviral prophylaxis	
Existing and maintained recommendations (2017, Strategic Advisory Group of Experts)	**Immunization** a) All infants should receive their first dose of hepatitis B vaccine as soon as possible after birth, preferable within 24 hours. b) Delivery of hepatitis B vaccine within 24 hours of birth should be a performance indicator for all immunization programmes, and reporting and monitoring systems should be strengthened to improve the quality of data on the birth dose. c) The birth dose should be followed by two or three additional doses to complete the primary immunization series.
Existing and maintained recommendation (2019 guidelines on HIV testing)	**HBsAg testing among pregnant women and adolescent girls** All pregnant women should be tested for HIV, syphilis and hepatitis B surface antigen (HBsAg) at least once and as early as possible during their pregnancy. *(strong recommendation, low-certainty evidence)*
Updated recommendation (2020 guidelines on antiviral prophylaxis)	**Antiviral prophylaxis among pregnant women and adolescent girls** **In settings where HBV DNA or HBeAg testing is available**, prophylaxis with tenofovir disoproxil fumarate (TDF)[b] is recommended for all HBV-positive (HBsAg-positive) pregnant women with HBV DNA ≥200 000 IU/mL or positive HBeAg[a] (preferably from the second trimester of pregnancy until at least delivery or completion of the infant HBV vaccination series), to prevent the mother-to-child transmission (MTCT) of HBV. *(strong recommendation, moderate-certainty evidence)*
New recommendation	**Antiviral prophylaxis among pregnant women and adolescent girls** **In settings where neither HBV DNA nor HBeAg testing is available,** prophylaxis with tenofovir disoproxil fumarate (TDF)[b] is recommended for all HBV-positive (HBsAg-positive) pregnant women (preferably from the second trimester of pregnancy until at least delivery or completion of the infant HBV vaccination series), to prevent the mother-to-child transmission (MTCT) of HBV. *(strong recommendation, moderate-certainty evidence)* All interventions should be given in addition to at least three doses of hepatitis B vaccination for all infants, including a timely birth dose. Note: All pregnant women and girls of reproductive age should be assessed first for eligibility for long-term treatment for their own health. For women and adolescent girls of childbearing age planning additional pregnancies, TDF prophylaxis can also be maintained after delivery and during subsequent pregnancies, according to women's choice.

a The use of the HBeAg recommendation represents an additional option for determining eligibility, but HBeAg RDTs have poor diagnostic performance, which limits their routine use in low- and middle-income countries.

b TAF may be considered for people (including pregnant women) with impaired kidney function and/or osteoporosis but is not yet approved for hepatitis B treatment in pregnancy. TAF is not recommended if eGFR is <15 ml/min.

HBV DNA testing

Measuring HBV DNA to guide treatment eligibility and monitor the response	
Existing and maintained recommendation (2017 guidelines on hepatitis testing)	**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[a]) is recommended as the preferred strategy to assess viral load level for treatment eligibility and to monitor treatment response. *(strong recommendation, moderate-certainty evidence)*
New recommendation	**Point-of-care (POC) HBV DNA assays:** POC 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. *(conditional recommendation, low-certainty evidence)*

a Assays should meet minimum quality, safety and performance standards.

HBV DNA reflex testing	
New recommendation	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 through either laboratory-based reflex HBV DNA testing using a sample already held in the laboratory or clinic-based reflex testing in a health-care facility through immediate sample collection following a positive HBsAg rapid diagnostic test (RDT). *(conditional recommendation, low-certainty evidence)*

Hepatitis Delta virus (HDV) testing

Who to test for HDV infection	
New recommendations	For people with CHB, serological testing for anti-HDV antibodies may be performed for all individuals who are HBsAg positive, as the preferred approach to scale up access to HDV diagnosis and linkage to care. *(conditional recommendation, very-low-certainty evidence)* In settings in which a universal anti-HDV antibody testing approach is not feasible because laboratory capacity or other resources are limited, testing for anti-HDV may be given priority in specific populations of HBsAg-positive individuals, including the following: • 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); and • people considered to have increased risk of HDV infection, including haemodialysis recipients, people living with hepatitis C or HIV, people who inject drugs, sex workers and men who have sex with men. *(conditional recommendation, very-low-certainty evidence)*

How to test for HDV infection: testing strategy and choice of serological and NAT assays	
New recommendation	People with CHB (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. Assays should meet minimum quality, safety and performance standards.[a] *(conditional recommendation, low- certainty evidence)*

a The NAT for detecting HDV RNA should be harmonized with the WHO HDV RNA standard and the results reported in IU/mL. The assays should have a limit of detection of 100 IU/mL or better. Primers used in in-house assays should target the ribozyme region, which is the most conserved region of the HDV genome, for genotype inclusivity.

How to test for HDV infection: laboratory-based reflex testing	
New recommendation	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. *(conditional recommendation, low-certainty evidence)*

Monitoring

Monitoring for treatment response among people with CHB receiving treatment or not yet receiving treatment	
Existing and maintained recommendations (2015 hepatitis B guidelines)	**Monitoring for people receiving treatment** For people receiving treatment, the following are recommended to be monitored at least annually: • non-invasive tests (APRI score or transient elastography) to assess stage of disease and progression of fibrosis or cirrhosis; and • ALT levels[a] (and AST for APRI), HBV DNA levels (when HBV DNA testing is available), HBsAg[b] and HBeAg/anti-Hbe.[c] • Treatment adherence should be monitored regularly and at each visit. *(strong recommendation, moderate-certainty evidence)* More frequent on-treatment monitoring (every 3–6 months for the first year) may be performed for: people with more advanced disease (compensated or decompensated cirrhosis);[d] during the first year of treatment to assess treatment response and adherence; where treatment adherence is a concern; in HIV-coinfected people; and for people with renal impairment. *(conditional recommendation, very-low-certainty evidence)*
Existing and maintained recommendations (2015 hepatitis B guidelines)	**Monitoring for people not yet receiving treatment** People who do not currently meet the criteria for antiviral therapy (persistently normal serum aminotransferase results and HBV DNA levels below 2000 IU/mL (when HBV DNA testing is available) or who have expressed a desire to defer treatment may be monitored annually for disease progression and ALT and HBV DNA levels (where HBV DNA testing is available). *(conditional recommendation, low-certainty evidence)*

a ALT levels fluctuate among people with CHB, and longitudinal monitoring is required to determine the trend. The ULN for ALT has been defined as below 30 U/L for men and boys and 19 U/L for women and girls. Persistently abnormal or normal may be defined as two ALT determinations above or below the ULN at unspecified intervals during a 6- to 12-month period or predefined intervals during a 12-month period.

b Among people receiving treatment, monitor for HBsAg loss (although this occurs rarely) and for seroreversion to HBsAg positivity after discontinuing treatment. Quantitative HBsAg, if available, can be used to determine whether HBsAg concentrations are declining, or more rarely, seroclearance.

c Monitoring of HBeAg and anti-HBe mainly applies to those who are initially HBeAg positive. However, those who have already achieved HBeAg seroconversion and are HBeAg negative and anti-HBe positive may subsequently serorevert.

d Decompensated cirrhosis is defined by the development of portal hypertension (ascites, variceal haemorrhage and hepatic encephalopathy), coagulopathy or liver insufficiency (jaundice). Other clinical features of advanced liver disease or cirrhosis may include: hepatomegaly, splenomegaly, pruritus, fatigue, arthralgia, palmar erythema and oedema.

Monitoring the safety of nucleoside analogues	
Existing and maintained recommendations (2015 hepatitis B guidelines)	Before initiating antiviral therapy, people's baseline risk for renal dysfunction[a] and measurement of baseline renal function[b] may be performed. People receiving long-term tenofovir disoproxil fumarate therapy may be monitored annually for renal function and growth monitored carefully in children. *(conditional recommendation, very-low certainty evidence*

Note: In the 2021 WHO consolidated HIV guidelines, baseline measurement of creatinine is not required before initiating ART for people living with HIV with the preferred tenofovir-based regimen.

a Factors associated with a higher risk of renal dysfunction include: decompensated cirrhosis, CrCl <50 mL/min, older age >60 years, body mass index (BMI) <18.5 kg/m^2 (or body weight <50 kg), poorly controlled hypertension, proteinuria, uncontrolled diabetes, active glomerulonephritis, concomitant use of nephrotoxic drugs or a boosted protease inhibitor for HIV and solid organ transplantation.

b Measurement of baseline renal function includes: serum creatinine levels and calculation of CrCl/estimated glomerular filtration rate (eGFR) using the Cockcroft–Gault (CG) or MDRD formulas. An online calculator is available at http://nephron.com/cgi-bin/CGSI.cgi. For children, the Schwartz or similar formula can be used: http://nephron.com/bedsidepedsnic.cgi.

CG formula: eGFR = (140 – age) Í (weight in kg) Í 0.85 (if female)/(72 Í Cr in micromol/l)

MDRD formula: eGFR = 175 Í serum Cr$^{-1.154}$ Í age$^{-0.203}$ Í 1.212 (if the person is Black) Í 0.742 (if the person is female).

Surveillance for hepatocellular carcinoma (HCC) among people with CHB	
Existing and maintained recommendations (2015 hepatitis B guidelines)	Routine surveillance for HCC with abdominal ultrasound and alpha-fetoprotein testing every six months is recommended for: • people with cirrhosis, regardless of age or other risk factors; *(strong recommendation, moderate-certainty evidence)* • people with a family history of HCC; and *(strong recommendation, moderate-certainty evidence)* • if there is no family history of HCC or evidence of cirrhosis, people older than 40 years (a lower age may apply depending on the regional incidence of HCC[a]) and with HBV DNA level >20,000 IU/mL (if HBV DNA testing is available). *(conditional recommendation, low-certainty evidence)*

a The GLOBOCAN project of the International Agency for research on Cancer (IARC) (http://globocan.iarc.fr/ia/World/atlas.html) provides current estimates of the incidence of, mortality and prevalence of major types of cancer, including HCC, at the national level, for 185 countries. The GLOBOCAN estimates are presented for 2020, separately for each sex. One-, three- and five-year prevalence data are available for adults only (15 years and older).

When to stop and restart antiviral therapy	
Existing and maintained recommendations (2015 hepatitis B guidelines)	**Lifelong nucleos(t)ide analogue therapy** All people with cirrhosis[a] based on clinical evidence (or APRI or transient elastography score) require lifelong treatment with nucleos(t)ide analogues and should not discontinue antiviral therapy because of the risk of reactivation, which can cause an acute hepatitis flare. *(strong recommendation, moderate-certainty evidence)*
Existing and maintained recommendations (2015 hepatitis B guidelines)	**Discontinuation** Antiviral therapy is lifelong. Discontinuation of nucleos(t)ide analogue therapy may be considered exceptionally for: • people without clinical evidence of cirrhosis (or presence of advanced fibrosis based on a non-invasive test score – APRI or transient elastography); and • who can be followed carefully after discontinuation and long term for reactivation; and • if there is evidence of HBeAg loss and seroconversion to anti-HBe (for people initially HBeAg-positive) and after completion of at least one additional year of treatment; and • in association with persistently normal ALT levels[b] and persistently undetectable HBV DNA levels (if HBV DNA testing is available). **If HBV DNA testing is not available:** discontinuing nucleos(t)ide analogue therapy may be considered for people who have evidence of persistent HBsAg loss and after completion of at least one additional year of treatment, regardless of previous HBeAg status. *(conditional recommendation, low-certainty evidence)*
Existing and maintained recommendations (2015 hepatitis B guidelines)	**Retreatment** Relapse is common after stopping therapy with nucleos(t)ide analogues. Retreatment is recommended if there are consistent signs of reactivation: HBsAg or HBeAg becomes positive, ALT levels increase or HBV DNA becomes detectable again (if HBV DNA testing is available) *(strong recommendation, low-certainty evidence)*

a Clinical features of decompensated cirrhosis: portal hypertension (ascites, variceal haemorrhage and hepatic encephalopathy), coagulopathy or liver insufficiency (jaundice). Other clinical features of advanced liver disease or cirrhosis may include: hepatomegaly, splenomegaly, pruritus, fatigue, arthralgia, palmar erythema and oedema.

b The ULN for ALT has been defined as <30 U/L for men and boys and <19 U/L for women and girls. Persistently normal or abnormal may be defined as two ALT values below or above the ULN at unspecified intervals during a 6- to 12-month period. ALT levels fluctuate with CHB and require longitudinal monitoring to determine the trend.

Summary of existing recommendations on who to test and how to test for chronic hepatitis B infection (from the 2017 guidelines on testing for viral hepatitis B and C infection)

Who to test for CHB	
Testing approach and population	**Recommendations**
General population testing	In settings with a ≥2% or ≥5%[a] 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. General population testing approaches should make use of existing community- or health facility-based testing opportunities or programmes such as at antenatal clinics, HIV or TB clinics. *(conditional recommendation, low-certainty of evidence)*
Routine testing for HIV, HBsAg and testing among pregnant women	• All pregnant women should be tested for HIV, syphilis and hepatitis B surface antigen (HBsAg) at least once and as early as possible during their pregnancy. *(strong recommendation, low-certainty evidence)* • Couples and partners in antenatal care settings should be offered HBV testing services. *(strong recommendation, low-certainty evidence)*
Focused testing in most affected populations	In all settings (and regardless of whether delivered through facility- or community-based testing), 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[b] (who are either part of a population with high HBV seroprevalence or who have a history of exposure and/or high-risk behaviour for HBV infection); • adults, adolescents and children with a clinical suspicion of chronic viral hepatitis[c] (symptoms, signs, laboratory markers); • sexual partners, children and other family members, and close household contacts of those with HBV infection;[d] and • 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 (adapted from existing guidance on hepatitis B vaccination). *(strong recommendation, low-certainty evidence)*
Blood donors	In all settings, screening of blood donors should be mandatory with linkage to care, counselling and treatment for those who test positive.

a A threshold of ≥2% or ≥5% seroprevalence was based on several published thresholds of intermediate or high seroprevalence. The threshold used will depend on other country considerations and the epidemiological context.

b Includes those who are either part of a population with higher seroprevalence (such as some mobile and migrant populations from high and intermediate endemic countries and certain indigenous populations) or who have a history of exposure or high-risk behaviour for HBV infection, such as people who inject drugs, people in prisons and other closed settings, men who have sex with men, sex workers, people living with HIV, partners, family members and the children of people with hepatitis B.

c Features that may indicate underlying CHB 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.

d In all settings, it is recommended that HBsAg serological testing with hepatitis B vaccination of those who are HBsAg negative and not previously vaccinated be offered to all children with parents or siblings diagnosed with HBV infection or with clinical suspicion of hepatitis, through community- or facility-based testing.

How to test for CHB	
Topic	**Recommendations**
Which serological assays to use	For the diagnosis of CHB in adults, adolescents and children (>12 months of age[a], a serological assay (in either RDT or laboratory-based immunoassay format[b]) that meets minimum quality, safety and performance standards[c] (with regard to both analytical and clinical sensitivity and specificity) is recommended to detect hepatitis B surface antigen (HBsAg). • In settings where existing 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. *(strong recommendation, low-certainty evidence)*
Serological testing strategies	• In settings or populations with an HBsAg seroprevalence of ≥0.4%,[d] a single serological assay for detection of HBsAg is recommended, before further evaluation for HBV DNA and staging of liver disease. • In settings or populations with a low HBsAg seroprevalence of <0.4%,[d] 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.[e] *(conditional recommendation, low-certainty evidence)*

a A full vaccination schedule including birth dose should be completed in all infants in accordance with the WHO position paper on hepatitis B vaccines from 2017. Testing of exposed infants is problematic within the first six months of life since HBsAg and hepatitis B DNA may be inconsistently detectable in infected infants. Exposed infants should be tested for HBsAg between 6 and 12 months of age to screen for evidence of hepatitis B infection. In all age groups, acute HBV infection can be confirmed by the presence of HBsAg and IgM anti-HBc. CHB is diagnosed if there is persistence of HBsAg for six months or more.

b Laboratory-based immunoassays include enzyme immunoassay, chemoluminescence immunoassay, and electrochemiluminescence assay.

c Assays should meet minimum acceptance criteria of either WHO prequalification of in vitro diagnostics or a stringent regulatory review for in vitro diagnostics. All in vitro diagnostics should be used in accordance with manufacturers' instructions for use and, where possible, at testing sites enrolled in a national or international external quality assessment scheme.

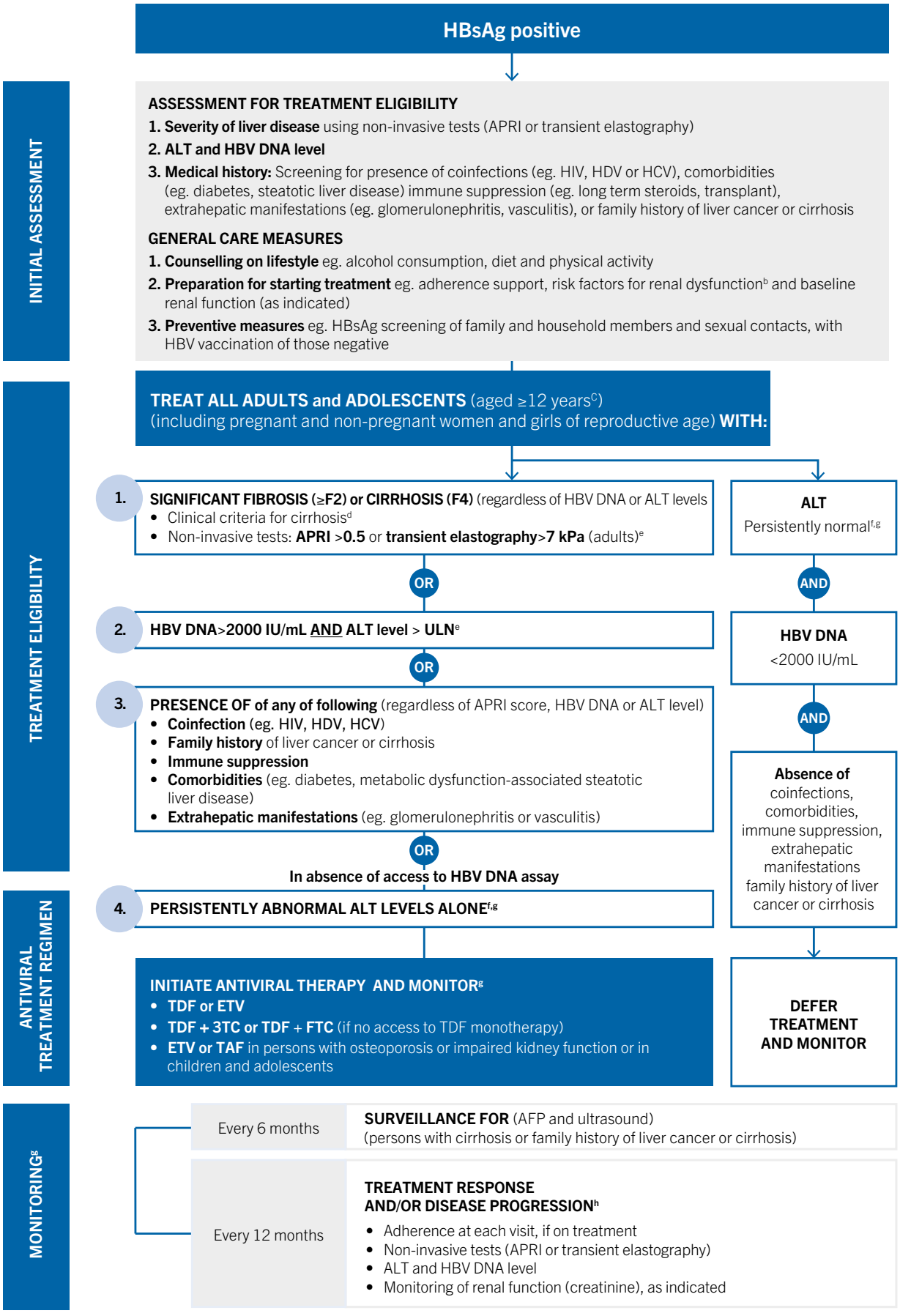
d Based on the results of predictive modelling of positive predictive values according to different thresholds of seroprevalence in populations to be tested and assay diagnostic performance.

e A repeat HBsAg assay after six months is also a common approach used to confirm the chronicity of HBV infection.

Eight approaches to promote access to and delivery of high quality health services for chronic hepatitis B

1. **Strategies to promote uptake of testing and strengthen linkage to care, treatment and prevention:** This includes adopting existing recommendations from the 2017 WHO hepatitis testing guidelines for using dried blood spots for serological and virological testing; peer and lay health worker support in community-based settings; electronic reminders and clinician prompts for facility-based testing; and providing testing as part of integrated services.
2. **Strategies to promote and sustain adherence to long-term antiviral therapy.** This includes adopting and adapting existing recommended strategies from the 2021 WHO consolidated HIV guidelines for using peer counsellors, mobile text reminders, cognitive behavioural therapy, behavioural skills training and medication adherence training.
3. **Strategies to promote retention in care and track and re-engage those disengaged from care.** This includes adopting and adapting existing recommended strategies from 2021 WHO consolidated HIV guidelines for using lay adherence counsellors, peer and family support and adherence clubs.
4. **Integrating hepatitis testing, care and treatment with other services** (such as HIV services and primary care) to increase the efficiency and reach of hepatitis services. This includes adopting and adapting existing recommended strategies for integration from the updated 2022 WHO HCV guidelines.
5. **Decentralized testing and treatment services at primary health facilities or HIV and ART clinics to promote access to care.** This is facilitated by task-sharing and a differentiated care approach. This includes adopting and adapting existing recommended strategies for decentralization from the updated 2022 WHO HCV guidelines.
6. **Task-sharing.** This is supported by training and mentoring health-care workers and peer workers and includes adopting and adapting existing recommended strategies for task-sharing from the updated 2022 WHO HCV guidelines.
7. **Differentiated care strategy.** Various care needs need to be assessed with referral to specialists as appropriate for those with complex problems. This includes adopting and adapting existing recommended strategies for differentiated care from the updated 2022 WHO HCV guidelines.
8. **Community engagement and peer support.** These promote access to services and linkage to care, which includes addressing stigma and discrimination.

ALGORITHM FOR ASSESSMENT, TREATMENT AND MONITORING OF PEOPLE WITH CHRONIC HEPATITIS B INFECTION[a]



ALT: alanine aminotransferase, APRI: aspartate aminotransferase-to-platelet ratio index.

a Defined as the presence of HBsAg for adults and persistence of HBsAg for six months or more for adolescents and children.

b Before initiation, consider assessing renal function: serum creatinine level, estimated glomerular filtration rate, urine dipsticks for proteinuria and glycosuria and risk factors for renal dysfunction (decompensated cirrhosis, creatinine clearance <50 mL/min, poorly controlled hypertension, proteinuria, uncontrolled diabetes, active glomerulonephritis, concomitant nephrotoxic drugs, solid organ transplantation, older age, BMI <18.5 kg/m2 (or body weight <50 kg), concomitant use of nephrotoxic drugs or a boosted protease inhibitor for HIV). Monitoring should be more frequent for those at higher risk of renal dysfunction.

c Age groups: these guidelines use the following definitions for the purpose of implementing treatment recommendations for adolescents and children aged three years and older. An adult is a person aged 18 years or older; an adolescent 12–17 years old inclusive; and a child is 2–11 years old. Countries may have other definitions under national laws.

d Clinical features of decompensated cirrhosis: portal hypertension (ascites, variceal haemorrhage and hepatic encephalopathy), coagulopathy or liver insufficiency (jaundice). Other clinical features of advanced liver disease and cirrhosis may include: hepatomegaly, splenomegaly, pruritus, fatigue, arthralgia, palmar erythema and oedema.

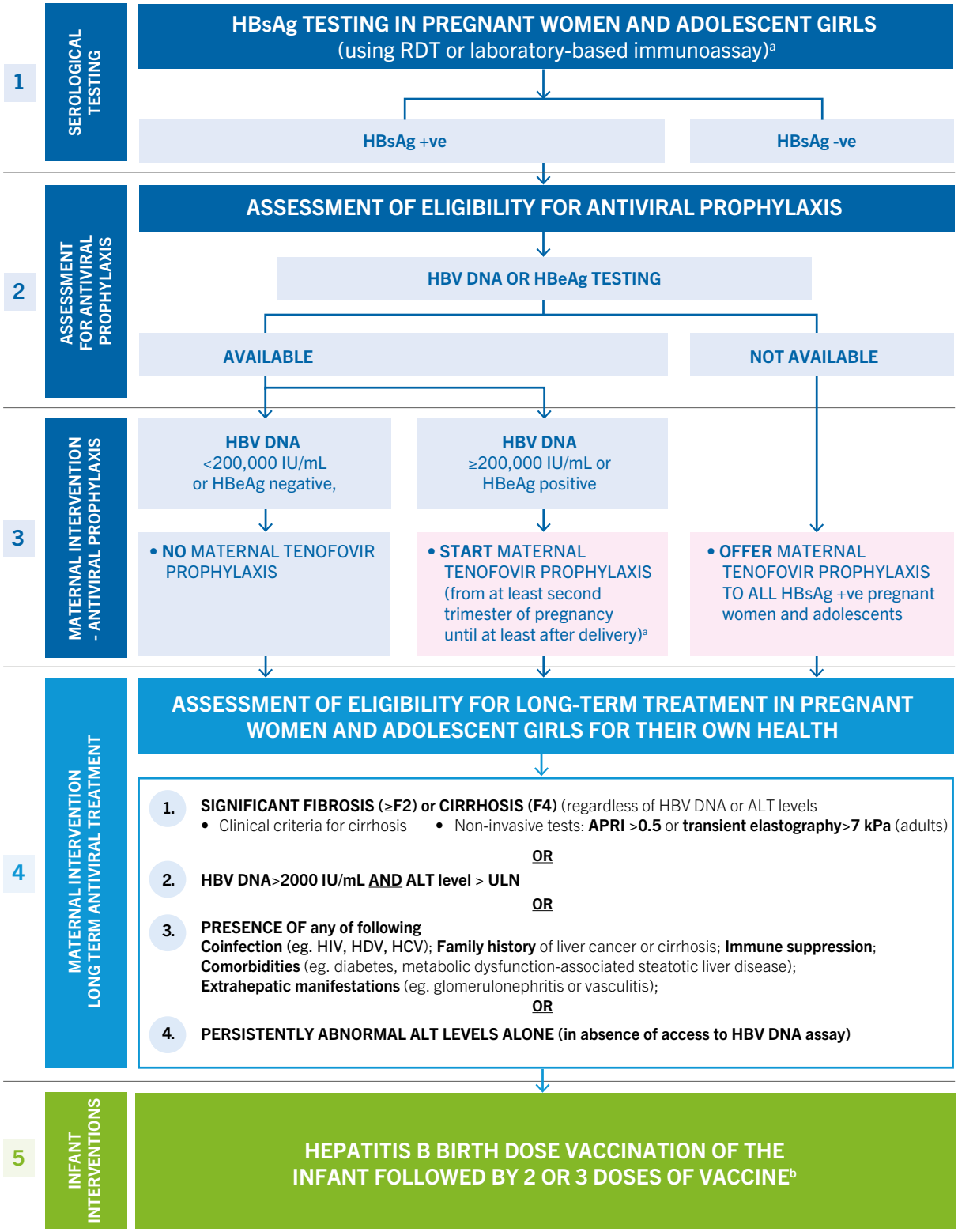
e Non-invasive tests including APRI and transient elastography have not yet been validated for children and adolescents.

f The ULN for ALT have been defined as <30 U/L for men and boys and <19 U/L for women and girls. Persistently normal or abnormal may be defined as two ALT values below or above the ULN at unspecified intervals during a 6- to 12-month period. ALT levels fluctuate with CHB and require longitudinal monitoring to determine the trend.

g Raised ALT may normalize in pregnancy and is therefore not a good marker for deciding about long-term treatment in pregnancy. Pregnant women should be reassessed after delivery.

h All people with CHB should be monitored regularly for disease activity and progression and detection of HCC and after stopping treatment for evidence of reactivation. More frequent monitoring may be required for those with more advanced liver disease, during the first year of treatment or if adherence is a concern.

ALGORITHM ON USE OF ANTIVIRAL PROPHYLAXIS FOR PREVENTION OF MOTHER-TO-CHILD TRANSMISSION IN PREGNANT WOMEN AND ADOLESCENT GIRLS WITH CHB AND ASSESSMENT OF TREATMENT ELIGIBILITY FOR THEIR OWN HEALTH



Abbreviations: ALT alanine aminotransferase, HBsAg hepatitis B surface antigen, HBeAg hepatitis B e antigen, HBIG hepatitis B immune globulin

[a] At least once and as early as possible in the pregnancy. HBsAg testing should be undertaken as part of triple testing for HIV, syphilis and HBsAg toward triple elimination initiative.

[b] Hepatitis B timely (within 24 hours) birth dose vaccination of the infant followed by 2 or 3 doses of hepatitis B vaccine should be given regardless of HBsAg status of the pregnant mother. HBIG (if available) is also offered mainly in high income settings for infants born to HBsAg positive mothers, especially with high HBV DNA.

Global Hepatitis Programme
World Health Organization
Department of Global HIV,
Hepatitis and Sexually Transmitted
Infections Programme

20, avenue Appia
1211 Geneva 27
Switzerland

E-mail: hepatitis@who.int

www.who.int/health-topics/hepatitis

9789240091368