Elimination of Mother-to-child transmission of Hepatitis B

Management of the HBV-Exposed Infant

Leandro Sereno, MD, MPH

Department of Communicable Diseases Prevention, Control and Elimination

March 2026

Pan American Health Organization

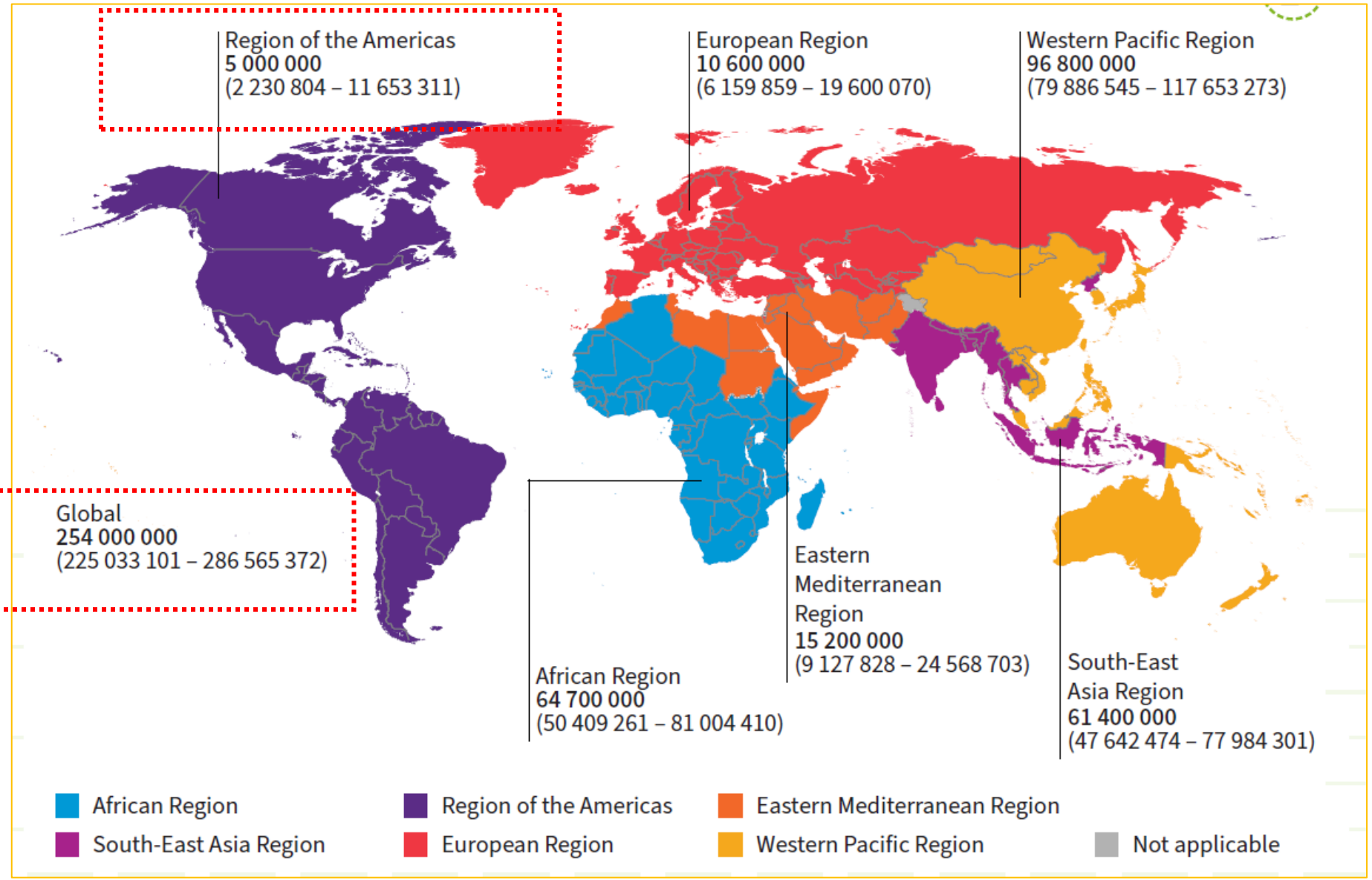
World Health Organization

Americas Region

Hepatitis B Prevalence by WHO Region, 2022

Global Viral Hepatitis Progress Report

an estimated **254 million people are living with hepatitis B**

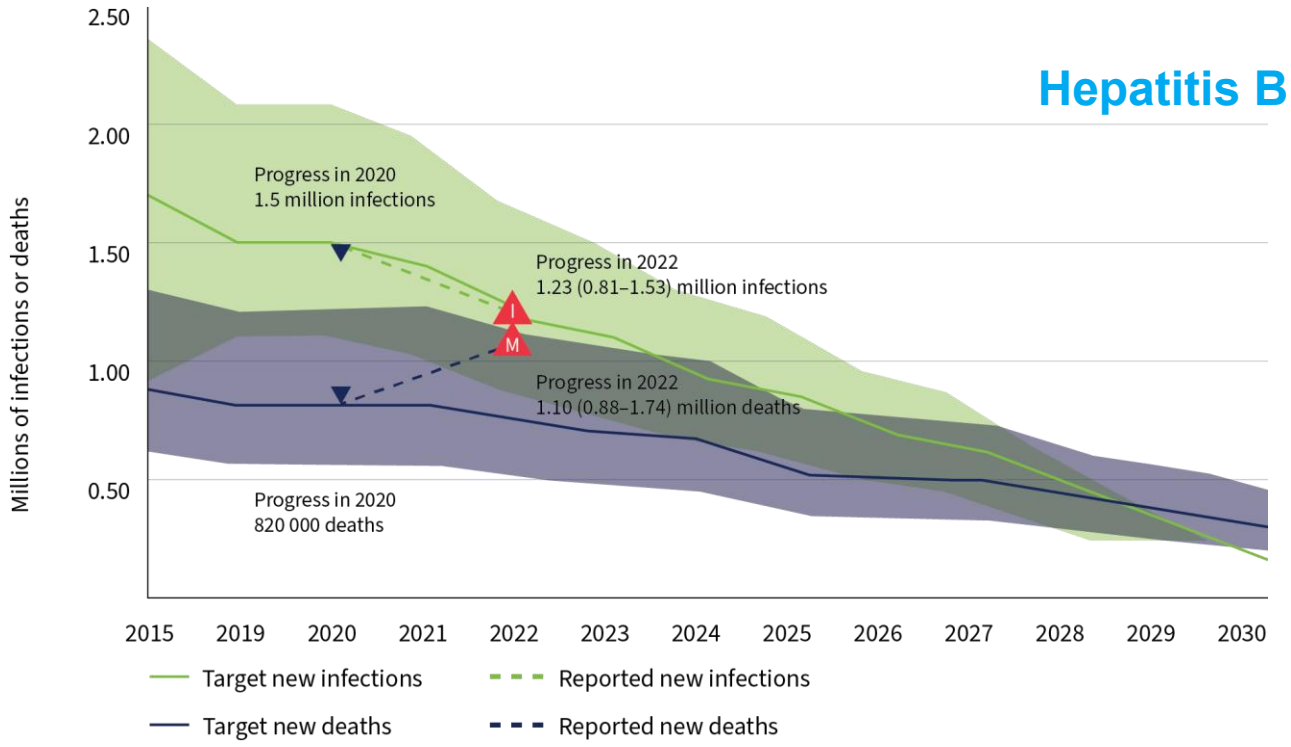


Source: WHO, Global hepatitis report 2024: action for access in low- and middle-income countries, 2024 https://www.who.int/publications/i/item/9789240027077 ;

Global Trends in Hepatitis B Incidence and Mortality, 2015-2030

- **Incidence:** The estimated number of people newly infected with hepatitis B decreased from 1.5 million in 2019 to 1.2 **million in 2022**

- **Increasing mortality** and a major cause of death from infectious diseases (along with TB and COVID).
- **HBV mortality increased** from an estimated 0.8 million deaths in 2019 to 1.1 million in 2022



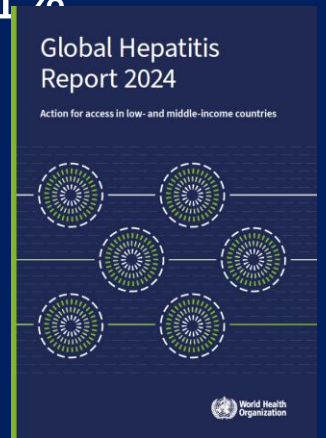
Trends in hepatitis B incidence and mortality, 2015–2030

Source: WHO, Global hepatitis report 2024: action for access in low- and middle-income countries, 2024 https://www.who.int/publications/i/item/9789240027077 ;

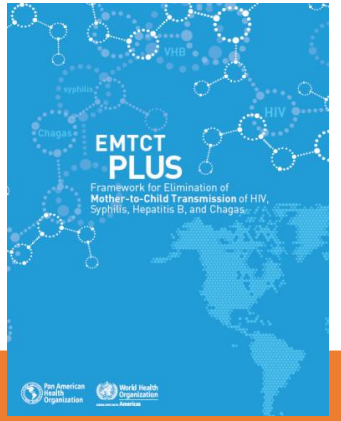
Hepatitis B in the Region of the Americas, 2022

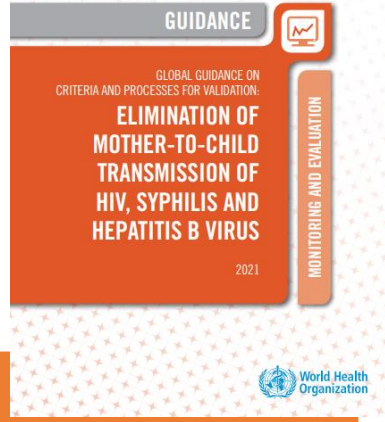
Hepatitis B in the Americas, 2022

- **5.0 (0.5%) million people with chronic infection**
  - 2.5 million in Latin America
  - **720,000 in the Caribbean**
  - Prevalence in 5-year-olds: <0.1%
- 8,000 new infections
- 20,000 deaths



Criteria for Validation of EMTCT of HIV, syphilis & HBV





	ELIMINATION		
	HIV	Syphilis	HBV
IMPACT criteria	• MTCT < 2% OR < 5% in breastfeeding populations	• Case rate ≤ 0.5 per 1000 live births	• ≤0.1% prevalence HBsAg in ≤5-year-olds *Additional criteria for countries using targeted Birth Dose:* • MTCT rate of ≤ 2%
PROCESS criteria	• ANC1 coverage ≥ 95% • Testing coverage ≥ 95% • ART coverage ≥95%	• ANC1 coverage ≥ 95% • Testing coverage ≥ 95% • Treatment coverage >95%	• ≥90% HepB3 vaccine coverage • ≥90% HepB-BD coverage *Additional criteria:* • >90% coverage of maternal HBsAg testing • ≥90% coverage with antivirals for those eligible • ≥85% coverage of vaccine in all **provinces** [***supporting indicator***] • ≥80% coverage of **HBIG** to exposed neonates ***[supporting indicator]***

EMTCT of HIV and Syphilis

13 Countries and Territories Validated (2024)

Anguilla	Antigua and Barbuda	Belize	Bermuda	Cayman Islands	Cuba
Dominica	Montserrat	St. Kitts y Nevis	Saint Vincent and the Grenadines	Jamaica	Brazil
The Bahamas					

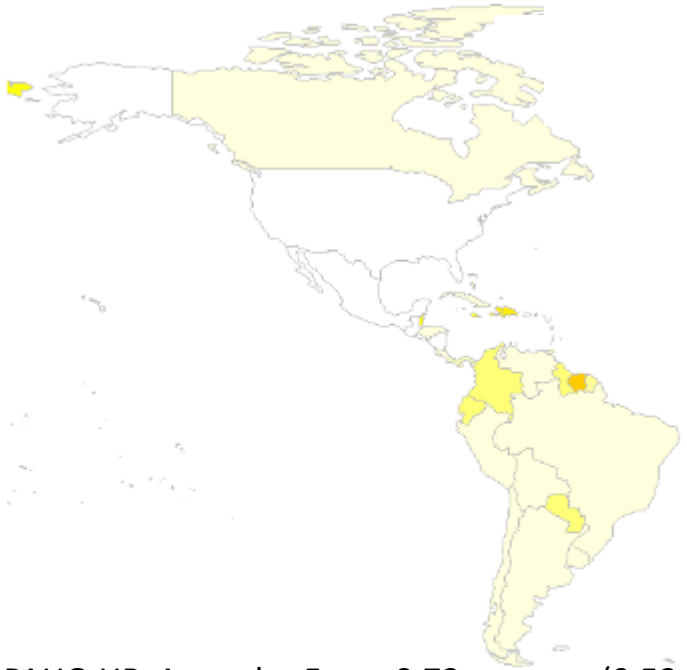
Lessons learned:

- **Interprogrammatic** coordination and implementation
- High-level political **commitment**
- Maternal and Child Health **quality marker**
- Leveraging the successes and experience of robust **immunization programs**

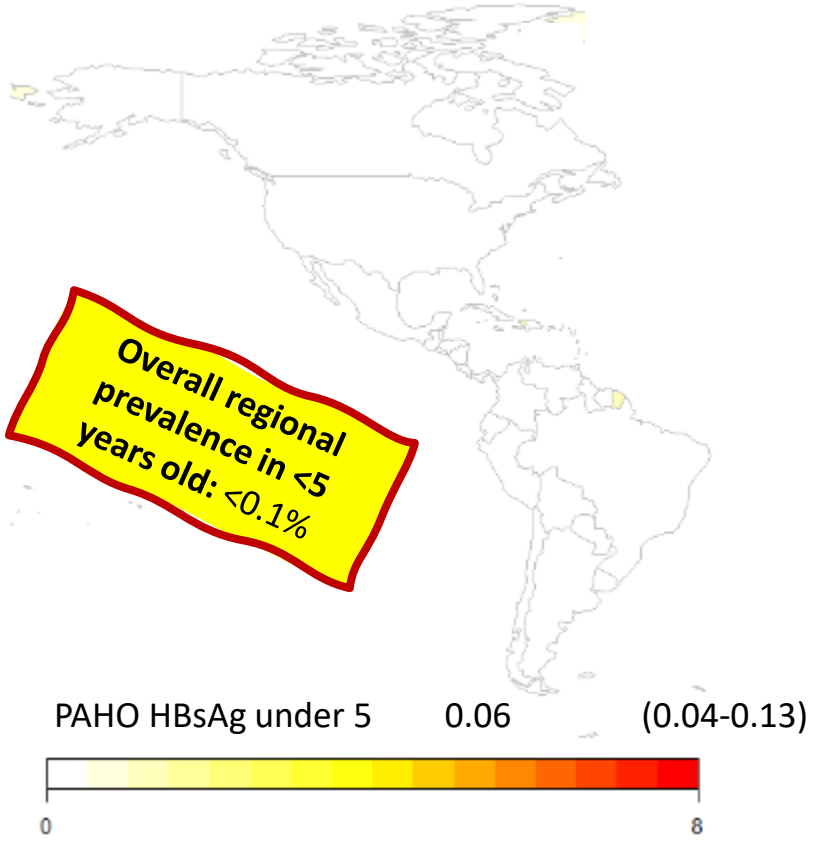
Impact of Immunization Programs Towards HBV EMTCT

Prevalence of HBsAg among children under five years of age, pre- and post- introduction of HBV vaccine

PRE-VACCINATION (~1990)



POST-VACCINATION (2020)

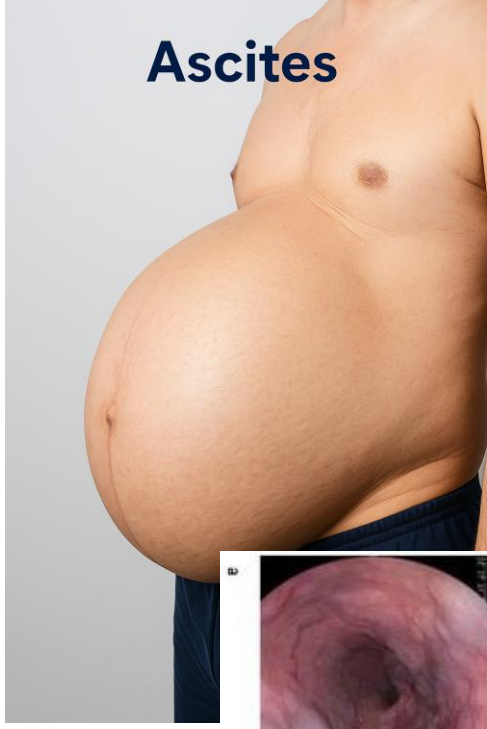


Countries with estimated prevalence of HBsAg among children below 0.1%:

1. Argentina
2. Brazil
3. Chile
4. Costa Rica
5. Cuba
6. Dominican Republic
7. Ecuador
8. El Salvador
9. Guatemala
10. Honduras
11. Mexico
12. Nicaragua
13. Panama
14. Peru
15. Saint Kitts and Nevis
16. Suriname
17. United States of America

Sources: World Health Organization. Hepatitis B surface antigen (HBsAg) prevalence among children under 5 years. The Global Health Observatory. 2024. •

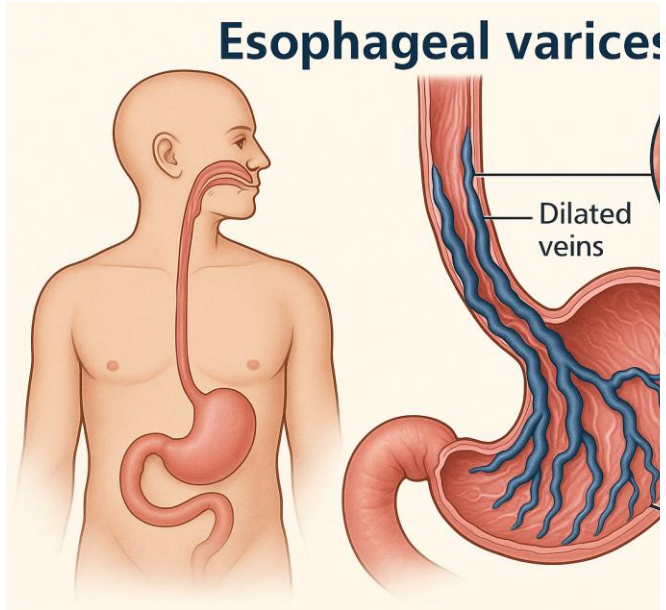
Chronic Viral Hepatitis

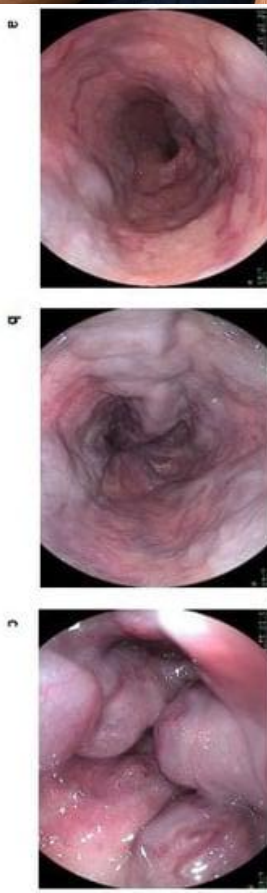


- Chronic inflammation of the liver lasting more than 6 months due to persistent infection with **HBV, HCV, or HDV.**
- Represents ongoing hepatocyte injury, with gradual healing through fibrosis formation.

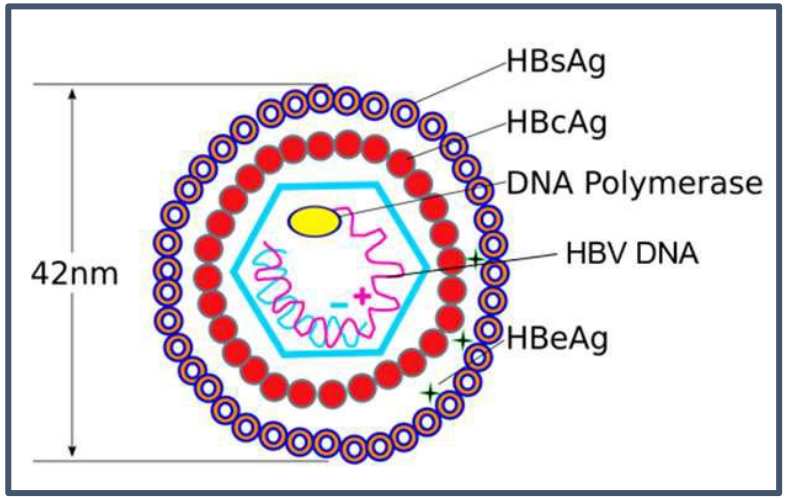
Clinical Characteristics:

- **Asymptomatic** or mildly symptomatic for years.
- **ALT/AST elevation**
- Progressive **fibrosis → cirrhosis → liver failure**.
  - signs of **liver failure**: jaundice, coagulopathy, encephalopathy
  - signs of **portal hypertension**: splenomegaly, Esophageal and gastric varices, ascites
  - fatigability, nausea, vomiting, weight loss, low-grade fever, abdominal fullness or pain.
  - **Other physical signs**: Palmar erythema, spider angiomas, dark skin pigmentation, gynecomastia, xanthomas, and subcutaneous bruising.





Structure of HBV viral particle and Serological Markers



Antigen-antibody		Nucleic acid
Antigen	Antibody	
HBsAg (Hepatitis B surface Antigen)	Anti-HBs (HB surface antibody)	HBV DNA (qualitative or quantitative)
HBcAg (Hepatitis B core Antigen) Does not appears in blood	IgM anti-HBc (HB core antibody IgM)	
	Total anti-HBc (IgM plus IgG)	
HBeAg (Hepatitis B e Antigen)	Anti-HBe (Hepatitis B e antibody)	

Time course and interpretation of serological markers of HBV infection

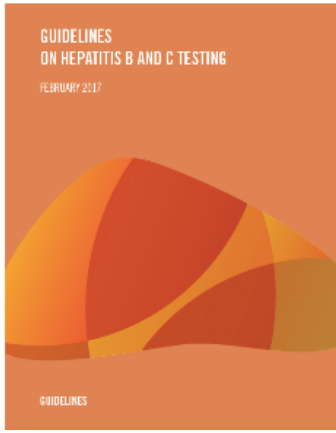


FIG. 4.2 Acute HBV infection with recovery

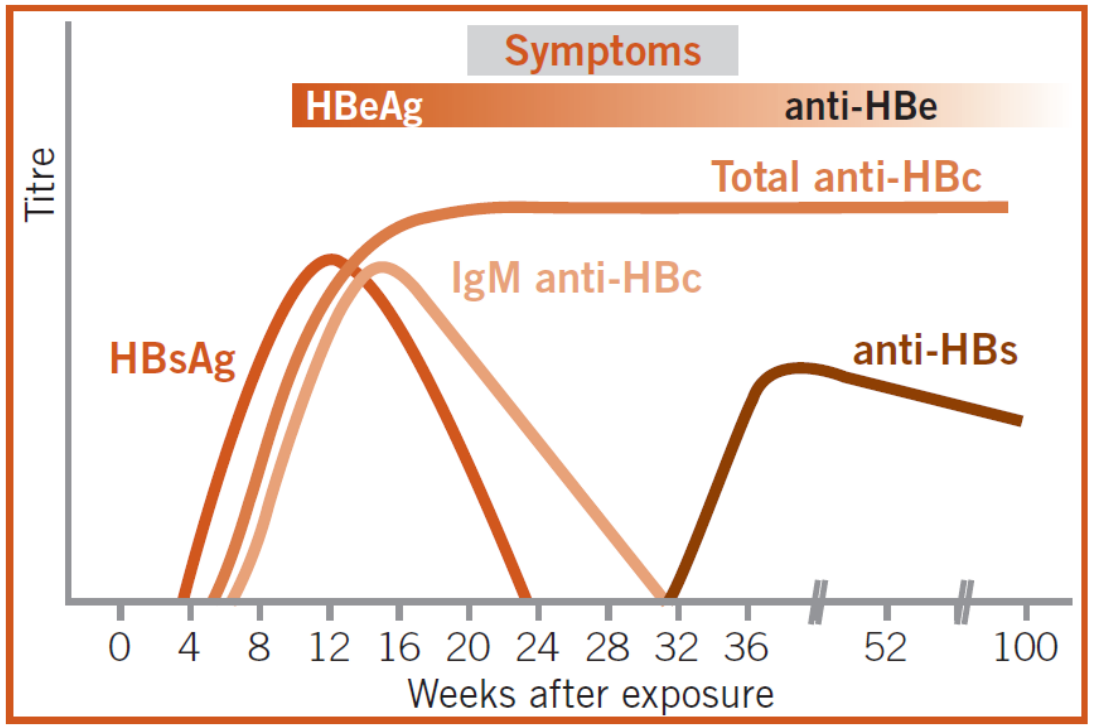
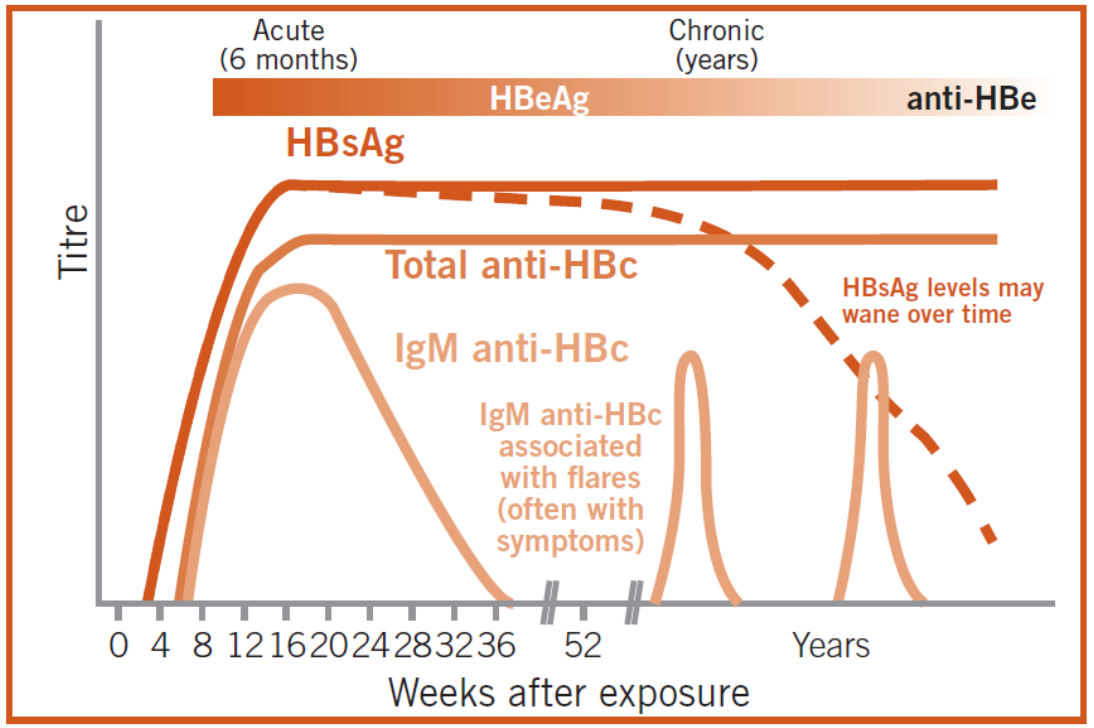
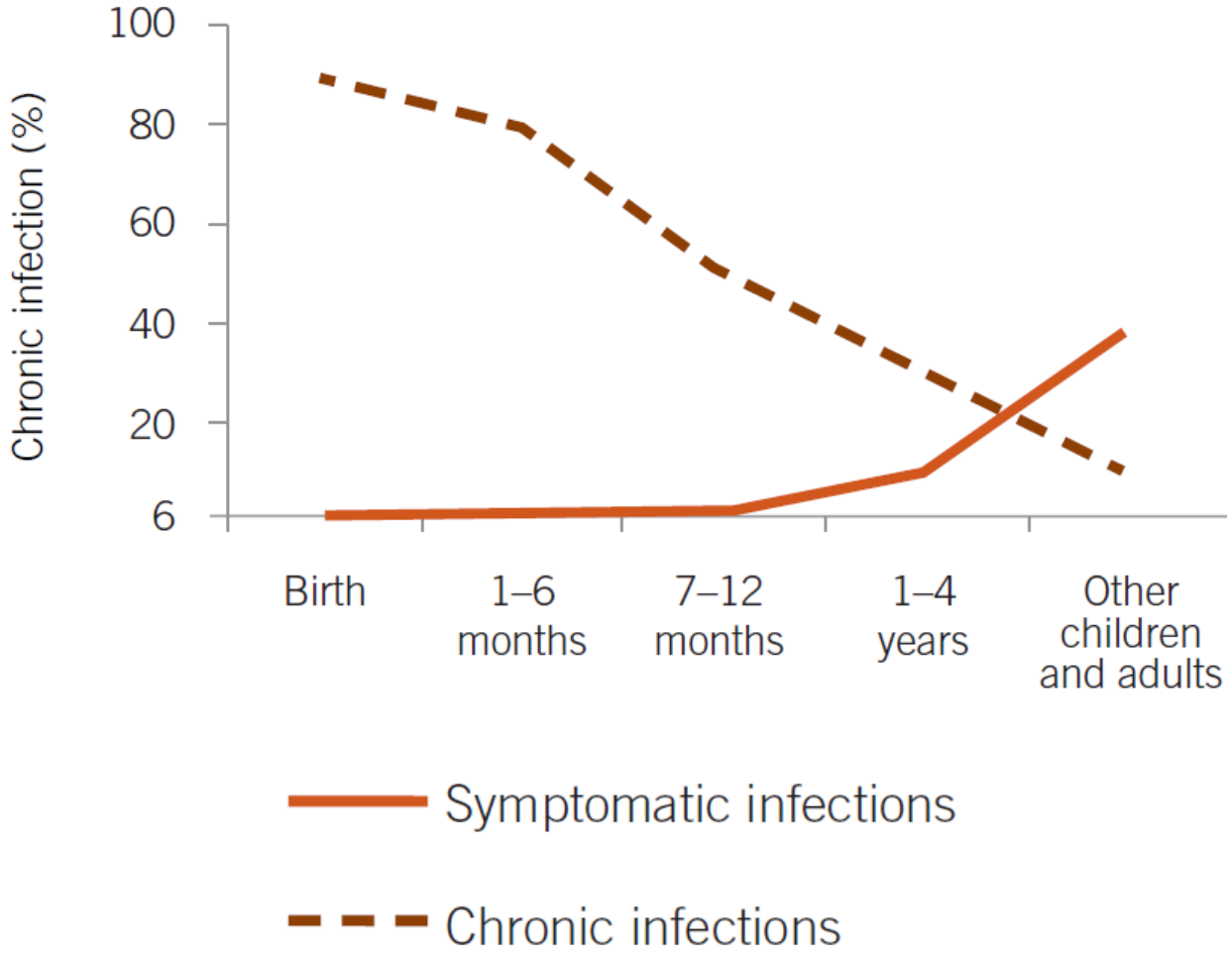


FIG. 4.3 Chronic HBV infection



Hepatitis B virus infection outcomes by age at time of infection



Incremental approach to the prevention of HBV infection at birth and in the first years of life

Number of countries and territories with adopted interventions:

10 countries

Antiviral treatment for pregnant women

23 countries

HBIg for children born to mothers with HBsAg+

26 countries

HBsAg testing in ANC, linkage to care, baby follow-up

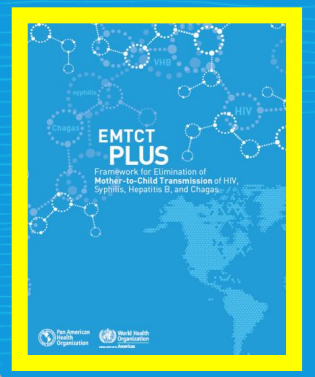
33 countries (BD)
51 countries (B3)

At least 3 doses **of hepatitis B vaccine**, including a timely **birth dose** within 24 hours

Risk of Hepatitis B mother-to-child transmission and protective effect of recommended interventions

Interventions	Women with high viral load	Women with high viral loads, receiving antiviral treatment
No vaccination	100% (90.3 – 100)	5.6% (4.5 – 5.6)
Vaccine – 24h dose only	90% (81.3 – 100)	5.1% (4.1 – 5.6)
Complete vaccination, without the 24-hour dose.	32.7% (29 – 35)	1.6% (1.5 – 1.8)
Full vaccination without HBIG	13.8% (9.6 – 41.3)	0.7% (0.5 – 2.1)
Full vaccination with HBIG	7.7% (1.5 – 20.7)	0.4% (0.1 – 1.0)

Source: Razavi-Shearer et al. The Global Prevalence, cascade of Care, and Prophylaxes Coverage of Hepatitis B in 2016: A modelling study. The lancet Gastroenterology, 2018



Development of the first vaccine (plasma)

1982

1986

Recombinant vaccines (surface protein)

PAHO: Universal Vaccination in Infants in the First Year of Life **(HepB3)**

1999

- Universal vaccination for infants
- Vaccination campaigns
- Health personnel
- Monitoring vaccination coverage
- Combined Vaccines
- 3 to 4 doses in the first year of life

2011

PAHO: Universal Vaccination for Newborns: In the First 24 Hours **(HepB-BD)**

EMTCT plus: elimination of mother-to-child transmission of HIV, syphilis, hepatitis and Chagas disease

2017

Hepatitis B vaccines: WHO position paper – July 2017

2017, 92, 369–392 No 27

World Health Organization
Organisation mondiale de la Santé

Weekly epidemiological record
Relevé épidémiologique hebdomadaire

7 JULY 2017, 92th YEAR / 7 JUILLET 2017, 92e ANNÉE
No 27, 2017, 92, 369–392
http://www.who.int/wer

Contents

369 Hepatitis B vaccines: WHO position paper – July 2017

Sommaire

369 Vaccins anti-hépatite B: note de synthèse de l'OMS – juillet 2017

Hepatitis B vaccines: WHO position paper – July 2017

Introduction

In accordance with its mandate to provide guidance to Member States on health policy matters, WHO issues a series of regularly updated position papers on vaccines and vaccine combinations against diseases that have an international public health impact. These papers are concerned primarily with the use of vaccines in large-scale immunization programmes. They summarize essential background information on their respective diseases and vaccines, and conclude with the current WHO position concerning their use in the global context.

The papers are reviewed by external experts and WHO staff, and reviewed and endorsed by the WHO Strategic Advisory Group of Experts (SAGE) on immunization (http://www.who.int/immunization/sage/en/). The GRADE methodology is used to systematically assess the quality of available evidence. The SAGE decision-making process is reflected in an evidence-to-recommendation table.[1] A description of the process followed for the development of vaccine position papers is available at: http://www.who.int/immunization/position_papers/position_paper_process.pdf.

The position papers are intended for use mainly by national public health officials and managers of immunization programmes. They may also be of interest to international funding agencies, vaccine advisory groups, vaccine manufacturers, the medical community, scientific media and the general public.

Vaccins anti-hépatite B: note de synthèse de l'OMS – juillet 2017

Introduction

Conformément à son mandat, qui prévoit qu'elle conseille les États Membres en matière de politique sanitaire, l'OMS publie une série de notes de synthèse régulièrement mises à jour sur les vaccins et les associations vaccinales contre les maladies ayant une incidence sur la santé publique internationale. Ces notes, qui portent essentiellement sur l'utilisation des vaccins dans les programmes de vaccination à grande échelle, résument les informations essentielles sur les maladies et les vaccins associés et présentent en conclusion la position actuelle de l'OMS concernant l'utilisation de ces vaccins dans le contexte mondial.

Ces notes sont examinées par des experts externes et des membres du personnel de l'OMS, et évaluées et approuvées par le Groupe stratégique consultatif d'experts sur la vaccination (SAGE) de l'OMS (http://www.who.int/immunization/sage/fr). La méthodologie GRADE est utilisée pour évaluer de manière systématique la qualité des données disponibles. Le processus de décision du SAGE est reflété dans un tableau des données à l'appui des recommandations.[1] La procédure suivie pour élaborer les notes de synthèse sur les vaccins est décrite dans le document: http://www.who.int/immunization/position_papers/position_paper_process.pdf.

Les notes de synthèse de l'OMS s'adressent avant tout aux responsables nationaux de la santé publique et aux administrateurs des programmes de vaccination. Toutefois, elles peuvent également présenter un intérêt pour les bailleurs de fonds internationaux, les groupes consultatifs sur la vaccination, les fabricants de vaccins, le corps médical, les médias scientifiques et le grand public.

WORLD HEALTH ORGANIZATION Geneva
ORGANISATION MONDIALE DE LA SANTÉ Genève

Annual subscription / Abonnement annuel
Sw. fr. / Fr. s. 346.–
07.2017
ISSN 0049-8114
Printed in Switzerland

[1] SAGE guidance for the development of evidence-based vaccine-related recommendations. Available at http://www.who.int/immunization/sage/Guidelines_development_recommendations.pdf, accessed July 2017.

[1] SAGE guidance for the development of evidence-based vaccine-related recommendations. Disponible sur http://www.who.int/immunization/sage/Guidelines_development_recommendations.pdf, consulté en juillet 2017.

369

https://www.who.int/publications/i/item/WER9227

- A **comprehensive approach to eliminating HBV transmission** must address prevention of infections acquired **perinatally** and during **childhood**, as well as prevention of infections acquired by **adolescents** and **adults**.
- Experience from the field:
  - 60.1% decrease in incidence of HCC,
  - 76.3% decrease in mortality from fulminant hepatic failure,
  - 92% decrease in mortality from chronic liver disease over
- **Cost-effective**, particularly as part of triple elimination strategy to eliminate mother-to-child transmission of HIV, hepatitis B and syphilis.
- Excellent safety profile: minimal adverse reactions (local pain, myalgia, mild fever)

Hepatitis B vaccines: WHO position paper

- Hepatitis B vaccination is recommended for **all children worldwide**
- National schedules should include a monovalent **dose of hepatitis B vaccine at birth, ideally within 24 hours**.
  - **Late birth dose**: effectiveness declines progressively in the days after birth but can still prevent horizontal transmission.
  - **Low birth weight**: birth dose is safe for premature infants, but the first dose should not count as part of the 3-dose series.
- Followed by 2 additional doses of monovalent HBV vaccine or **3 doses of penta-/hexavalent HBV-containing vaccine.**
  - At least 4 week between doses
  - No evidence to support booster dose
- Consider **catch-up campaigns** with priority for young people, if resources are available.

https://www.who.int/publications/i/item/WER9227

Hepatitis B vaccines: WHO position paper – July 2017

- **Vaccination of populations at higher risk of HBV infection:**
  - frequent use of blood products
  - Dialysis *(double dose)*,
  - chronic diseases (diabetes)
  - liver diseases, including HCV infection
  - prisons
  - PWID
  - sexual contacts of people living with HBV
  - health workers
  - PLHIV *(double dose)*
  - immunocompromised people *(double dose)*
  - key populations
  - indigenous population

- Vaccination is safe for **pregnant and breastfeeding women**

https://www.who.int/publications/i/item/WER9227

Hepatitis B vaccines: WHO position paper – July 2017

- Hepatitis B Vaccine is to be administered by intramuscular injection into the **anterolateral face of the thigh for infants** or into the **deltoid muscle for older children and adults**. (gluteal muscle not recommended)
- The hepatitis B vaccine may be co-administered at **different anatomical** sites with other vaccines.
- Available hepatitis B vaccines may be used **interchangeably** within immunization programs
- In any age group, interruption of the vaccination schedule does not require restarting the vaccination series.
- Usually, transported and stored at **2–8 °C to maintain potency**. (avoid freezing), but evidence indicate that the monovalent hepatitis B vaccine is **thermostable** and could be used **out-of-cold-chain where needed.**

https://www.who.int/publications/i/item/WER9227

Hepatitis B vaccines: WHO position paper – July 2017

- Protective efficacy of hepatitis B vaccine depends on the presence of anti-HBs (≥10 mIU/mL) measured 1–2 months after administration of the last dose

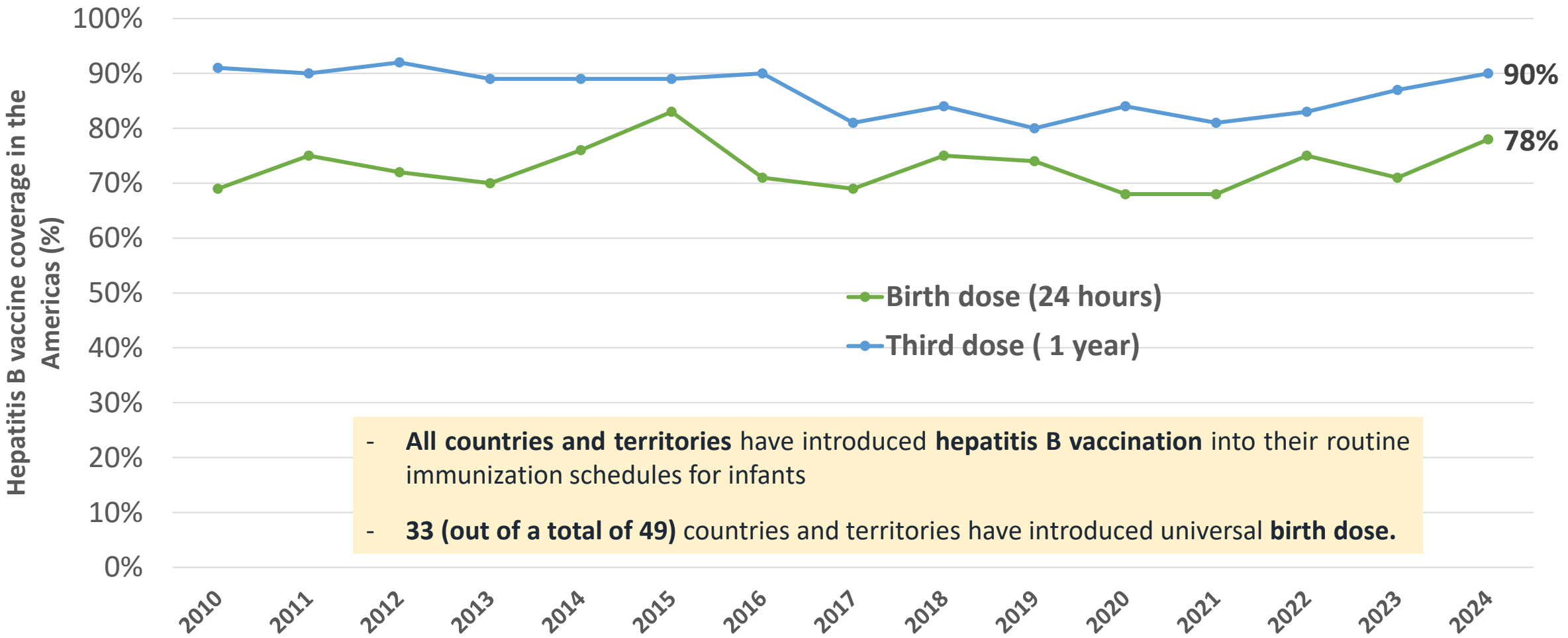
- 90% (range 74%–100%) of vaccinated persons remained protected for at least 30 years, irrespective of the presence or absence of measurable anti-HBs antibody, even levels <10 mIU/mL

- booster doses are not necessary in immunologically competent persons who had received a full primary course

- Routine post-vaccination testing for immunity is not necessary, but it is recommended for high-risk individuals:
  - Risk of occupational exposure to HBV infection
  - Immunocompromised patients
  - **Infants born to HBsAg-positive mothers**
  - Chronic hemodialysis patients
  - PLHIV and immunocompromised persons
  - Sex partners of persons who are HBsAg-positive

https://www.who.int/publications/i/item/WER9227

Hepatitis B Vaccination Coverage in the Region of the Americas, 2010-2023

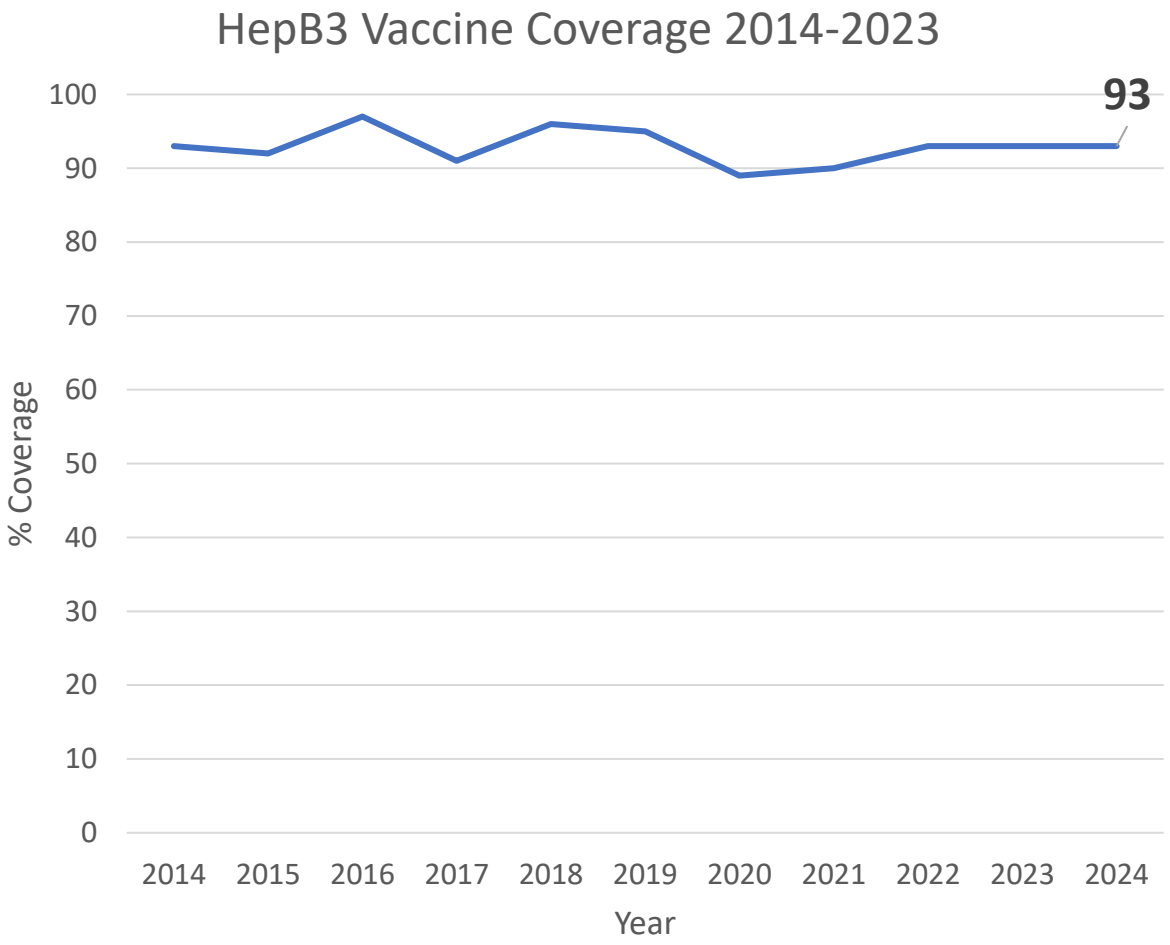


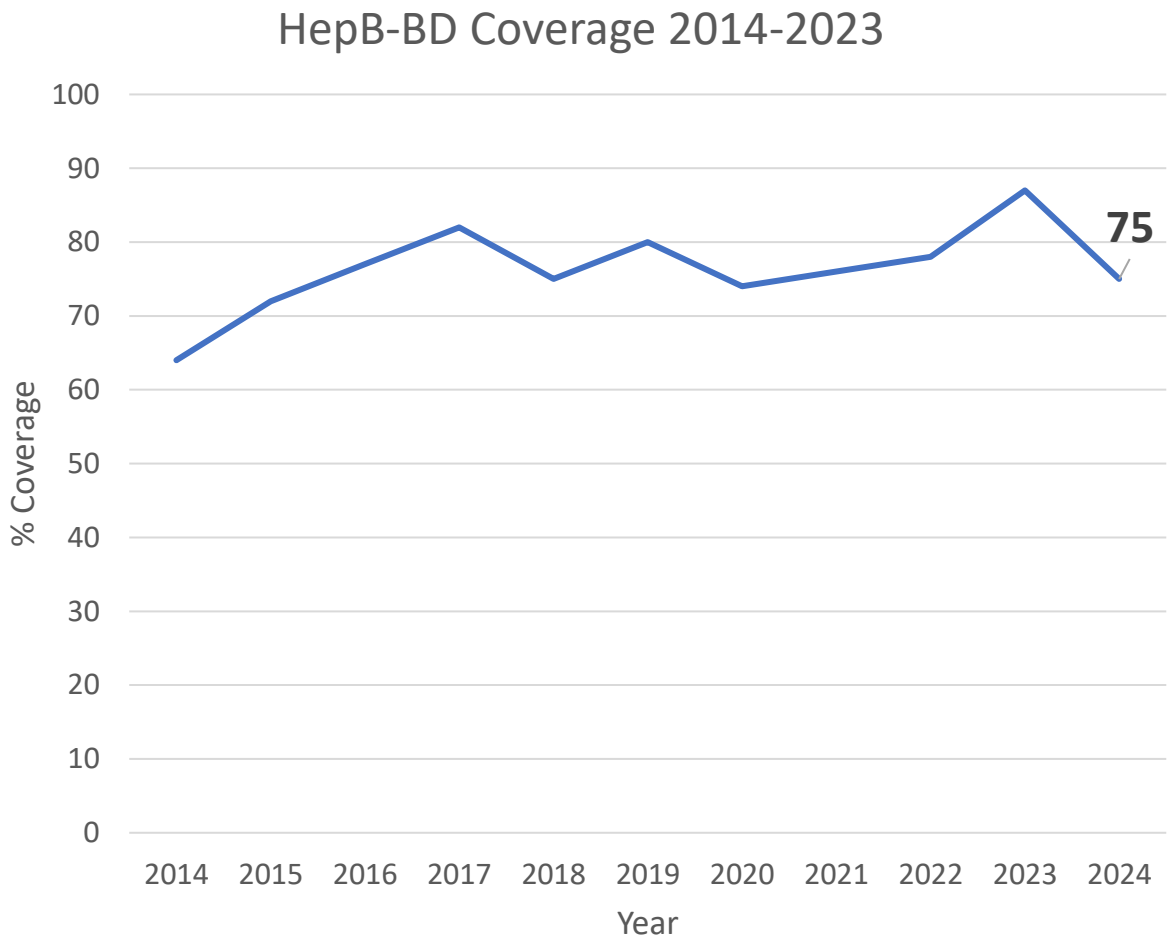
- **All countries and territories** have introduced **hepatitis B vaccination** into their routine immunization schedules for infants
- **33 (out of a total of 49)** countries and territories have introduced universal **birth dose.**

Source - PAHO Immunization Data - https://paho-cim.shinyapps.io/immunization-dashboard/

Hepatitis B vaccination coverage in the Caribbean, 2013-2023

*Among countries with Hep-BD introduced





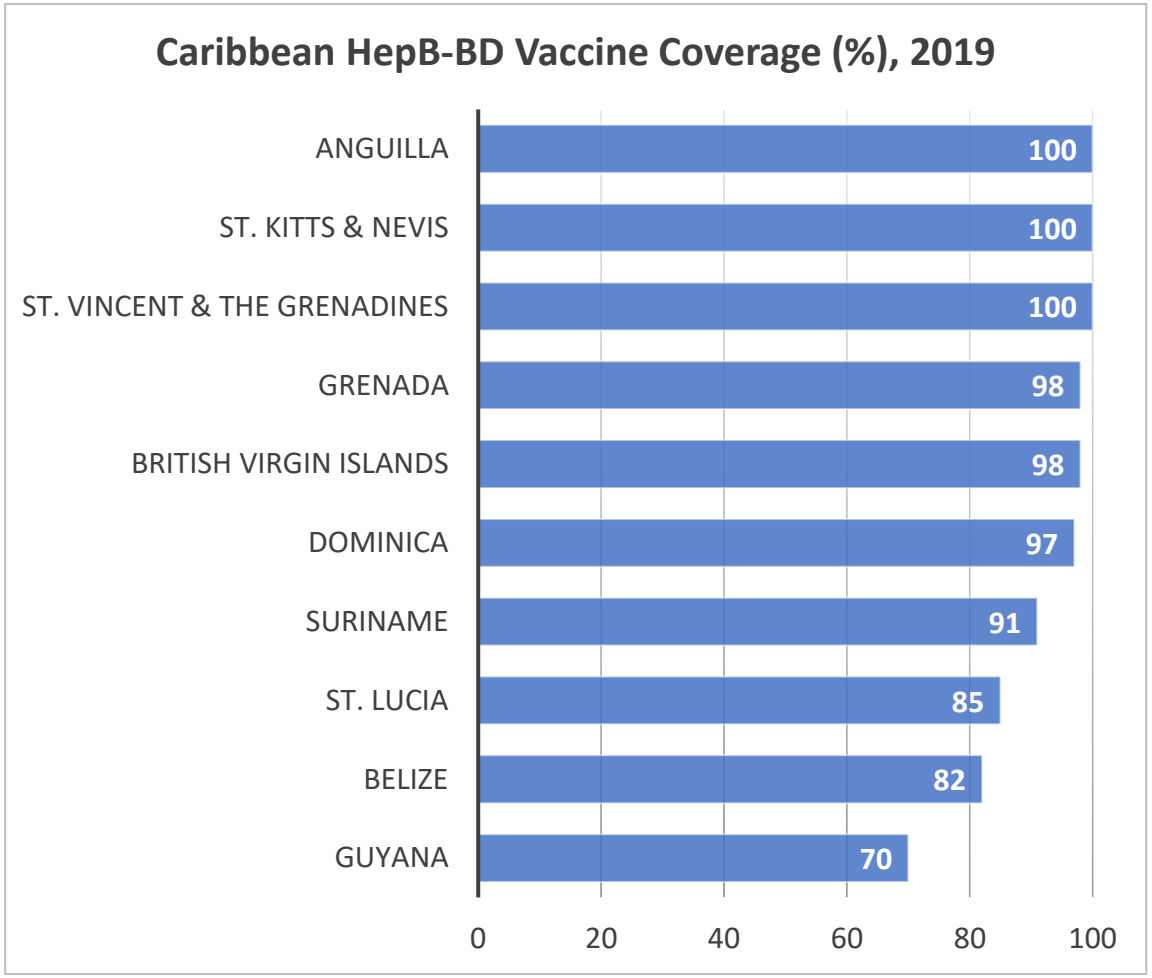
Source - PAHO Immunization Data - https://paho-cim.shinyapps.io/immunization-dashboard/

Hepatitis B birth dose introduction in The Caribbean, 2024

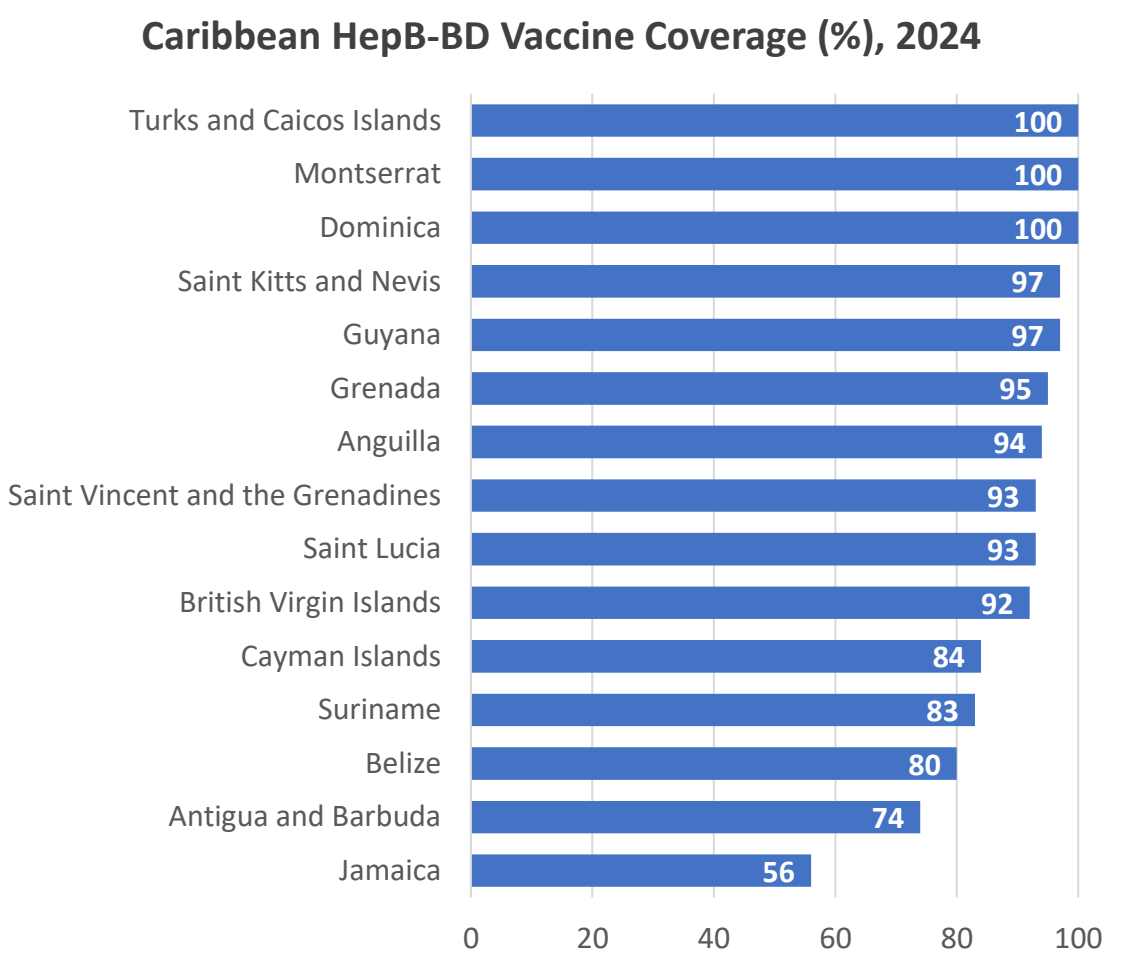
Country (16/22)
Anguilla
Antigua & Barbuda
Aruba
Bahamas
Barbados
Belize
Bermuda
British Virgin Islands
Cayman Islands
Curaçao
Dominica
Grenada
Guyana
Jamaica
Montserrat
Sint Maarten
St. Kitts & Nevis
St. Lucia
St. Vincent & the Grenadines
Suriname
Trinidad & Tobago
Turks and Caicos

Source: Country reports through the electronic PAHO-WHO/UNICEF Joint Reporting Form (eJRF), 2024.
Data as of 17 March 2025.

Hepatitis B Birth Dose Coverage in the Caribbean 2019/2023



- 10 countries reported



- 15 countries reported

Source: Country reports through the electronic PAHO-WHO/UNICEF Joint Reporting Form (eJRF), 2023.

Hepatitis B vaccines: WHO position paper

2017, 92, 369–392 No 27

World Health Organization
Organisation mondiale de la Santé

Weekly epidemiological record
Relevé épidémiologique hebdomadaire

7 JULY 2017, 92th YEAR / 7 JUILLET 2017, 92e ANNÉE
No 27, 2017, 92, 369–392
http://www.who.int/wer

Contents

369 Hepatitis B vaccines: WHO position paper – July 2017

Sommaire

369 Vaccins anti-hépatite B: note de synthèse de l'OMS – juillet 2017

Hepatitis B vaccines: WHO position paper – July 2017

Introduction

In accordance with its mandate to provide guidance to Member States on health policy matters, WHO issues a series of regularly updated position papers on vaccines and vaccine combinations against diseases that have an international public health impact. These papers are concerned primarily with the use of vaccines in large-scale immunization programmes. They summarize essential background information on their respective diseases and vaccines, and conclude with the current WHO position concerning their use in the global context.

The papers are reviewed by external experts and WHO staff, and reviewed and endorsed by the WHO Strategic Advisory Group of Experts (SAGE) on immunization (http://www.who.int/immunization/sage/en/). The GRADE methodology is used to systematically assess the quality of available evidence. The SAGE decision-making process is reflected in an evidence-to-recommendation table.[1] A description of the process followed for the development of vaccine position papers is available at: http://www.who.int/immunization/position_papers/position_paper_process.pdf.

The position papers are intended for use mainly by national public health officials and managers of immunization programmes. They may also be of interest to international funding agencies, vaccine advisory groups, vaccine manufacturers, the medical community, scientific media and the general public.

Vaccins anti-hépatite B: note de synthèse de l'OMS – juillet 2017

Introduction

Conformément à son mandat, qui prévoit qu'elle conseille les États Membres en matière de politique sanitaire, l'OMS publie une série de notes de synthèse régulièrement mises à jour sur les vaccins et les associations vaccinales contre les maladies ayant une incidence sur la santé publique internationale. Ces notes, qui portent essentiellement sur l'utilisation des vaccins dans les programmes de vaccination à grande échelle, résument les informations essentielles sur les maladies et les vaccins associés et présentent en conclusion la position actuelle de l'OMS concernant l'utilisation de ces vaccins dans le contexte mondial.

Ces notes sont examinées par des experts externes et des membres du personnel de l'OMS, et évaluées et approuvées par le Groupe stratégique consultatif d'experts sur la vaccination (SAGE) de l'OMS (http://www.who.int/immunization/sage/fr/). La méthodologie GRADE est utilisée pour évaluer de manière systématique la qualité des données disponibles. Le processus de décision du SAGE est reflété dans un tableau des données à l'appui des recommandations.[1] La procédure suivie pour élaborer les notes de synthèse sur les vaccins est décrite dans le document: http://www.who.int/immunization/position_papers/position_paper_process.pdf.

Les notes de synthèse de l'OMS s'adressent avant tout aux responsables nationaux de la santé publique et aux administrateurs des programmes de vaccination. Toutefois, elles peuvent également présenter un intérêt pour les bailleurs de fonds internationaux, les groupes consultatifs sur la vaccination, les fabricants de vaccins, le corps médical, les médias scientifiques et le grand public.

WORLD HEALTH ORGANIZATION Geneva
ORGANISATION MONDIALE DE LA SANTÉ Genève

Annual subscription / Abonnement annuel
Sw. fr. / Fr. s. 346.–
07.2017
ISSN 0049-8114
Printed in Switzerland

[1] SAGE guidance for the development of evidence-based vaccine-related recommendations. Available at http://www.who.int/immunization/sage/Guidelines_development_recommendations.pdf, accessed July 2017.

[1] SAGE guidance for the development of evidence-based vaccine-related recommendations. Disponible sur http://www.who.int/immunization/sage/Guidelines_development_recommendations.pdf, consulté en juillet 2017.

369

https://www.who.int/publications/i/item/WER9227

Post-exposure prophylaxis and passive immunization (Hepatitis B Immune Globulin (HBIG)

- HBIG should be used as an adjunct to hepatitis B vaccine
- Beneficial for:
  - **newborn infants whose mothers are HBsAg-positive**
  - people who have had percutaneous or mucous membrane **exposure to HBsAg-positive blood or body fluids** (health workers)
  - unvaccinated people who have been **sexually** exposed to an HBsAg-positive person; and
  - patients who need protection from recurrent HBV infection following **liver transplantation**
- Owing to concerns related to supply, safety and cost, the use of **HBIG may not be feasible in many settings.**

Recommendations for the screening and diagnosis of hepatitis

How to test?

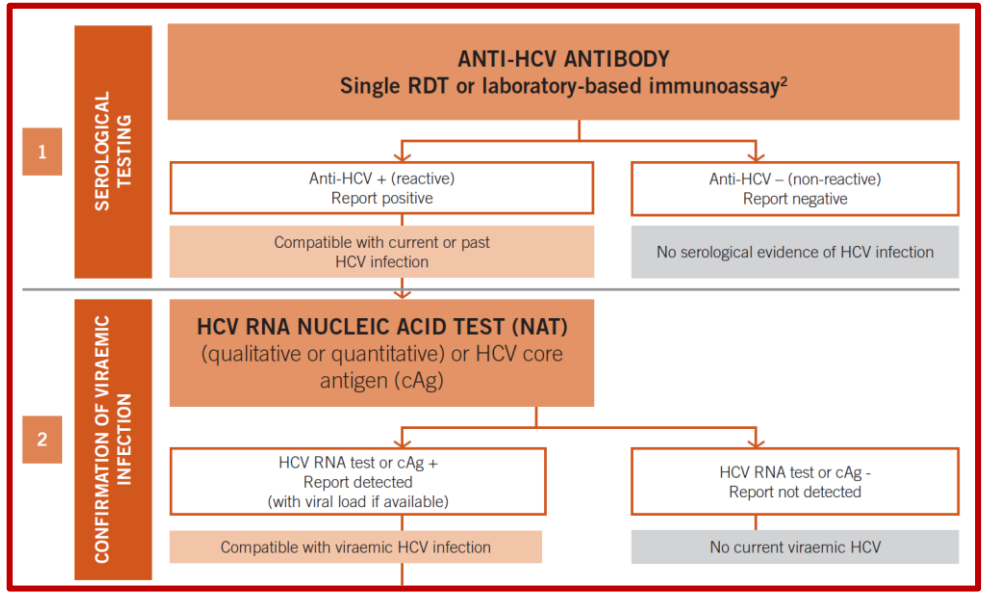
1. **A serological test HBsAG (EIA or RDT)**

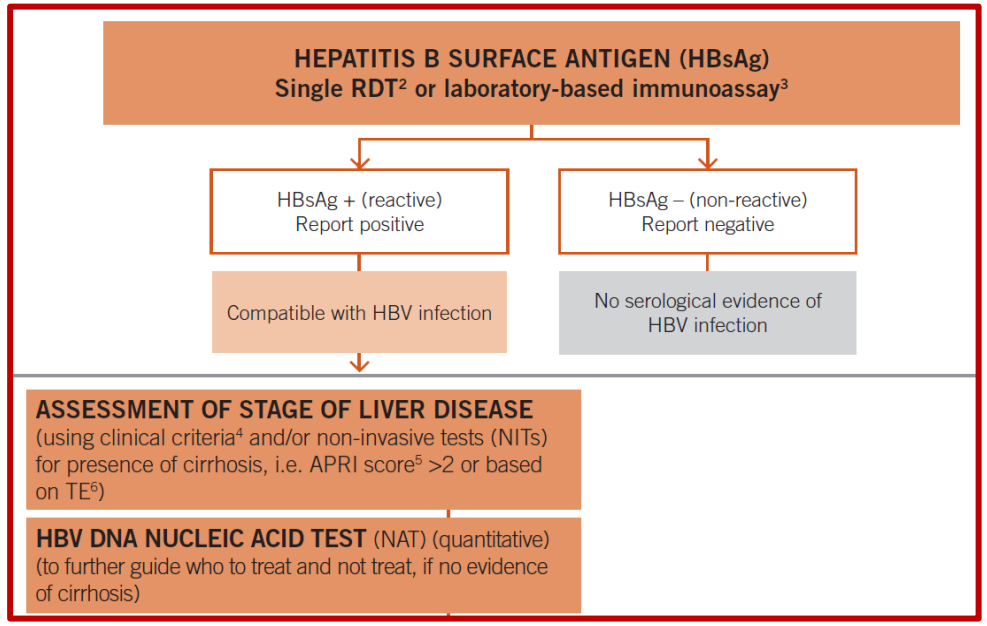
2. Followed by molecular testing (viral load)
   - **HBV DNA** to **guide treatment.**

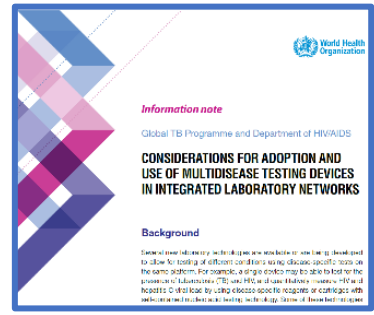
3. **Linkage to care**

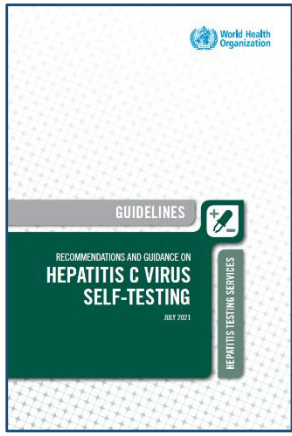
Considerations for Expanding Access

- **Rapid tests for point-of-care screening**
- Point-of-Care (PoC) Viral Load **- GeneXpert** and Other Multi-Diagnostic Platforms
- Using paper-based dried blood samples **(DBS)** for virology
- ***Reflex Viral load in laboratories***
- **Self Test**
- **Outreach activities**









Prevention of mother-to-child transmission of HBV through **antiviral prophylaxis**

1) In settings where HBV DNA or HBeAg testing is available:

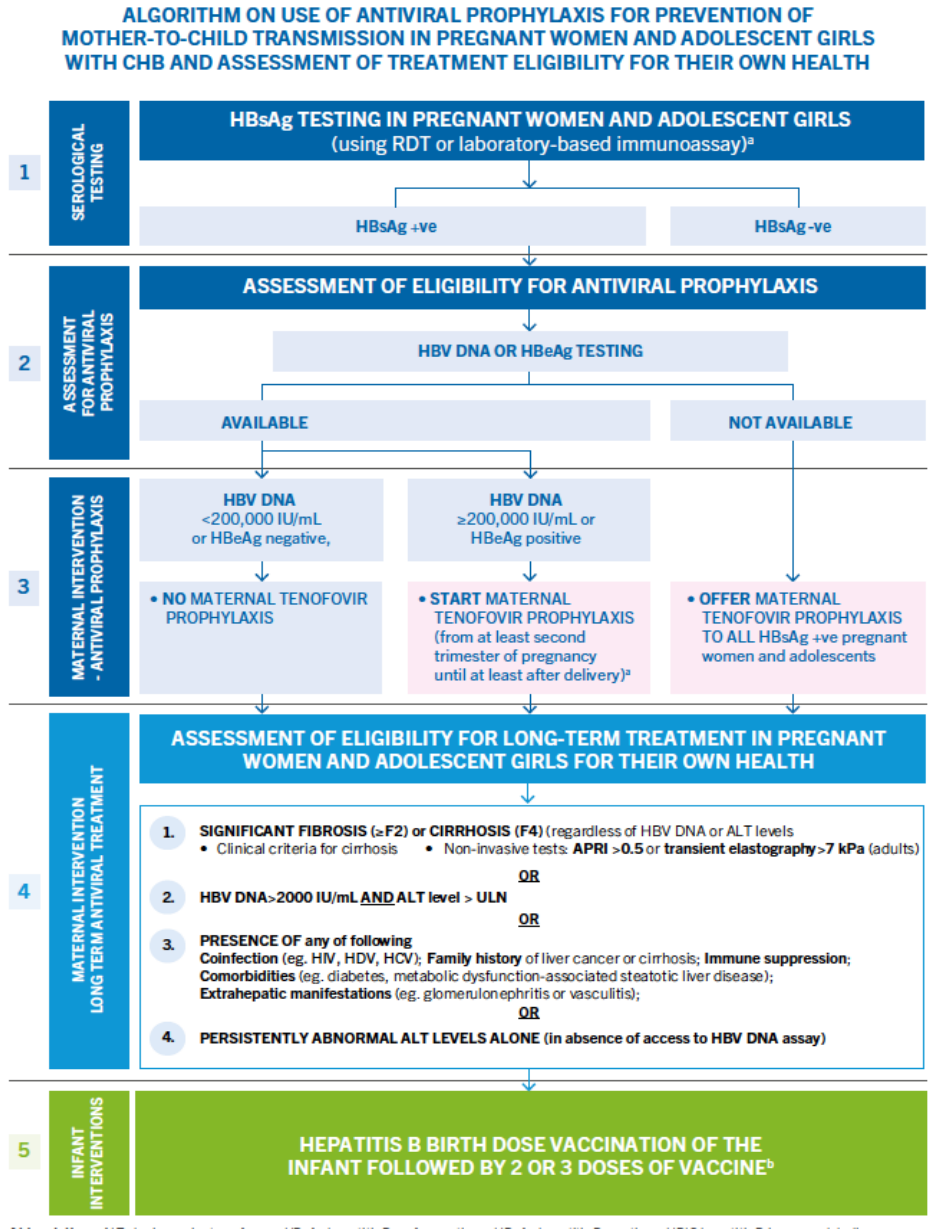
TDF prophylaxis is recommended for HBsAg-positive pregnant women with

- **HBV DNA ≥200,000 IU/mL or**
- **HBeAg-positive**

2) In settings where HBV and HBeAg DNA testing are not available:

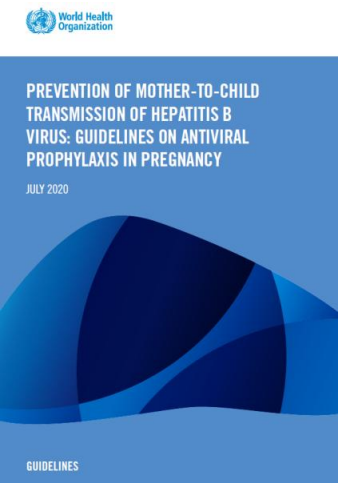
TDF prophylaxis may be considered for **all HBsAg-positive** pregnant women

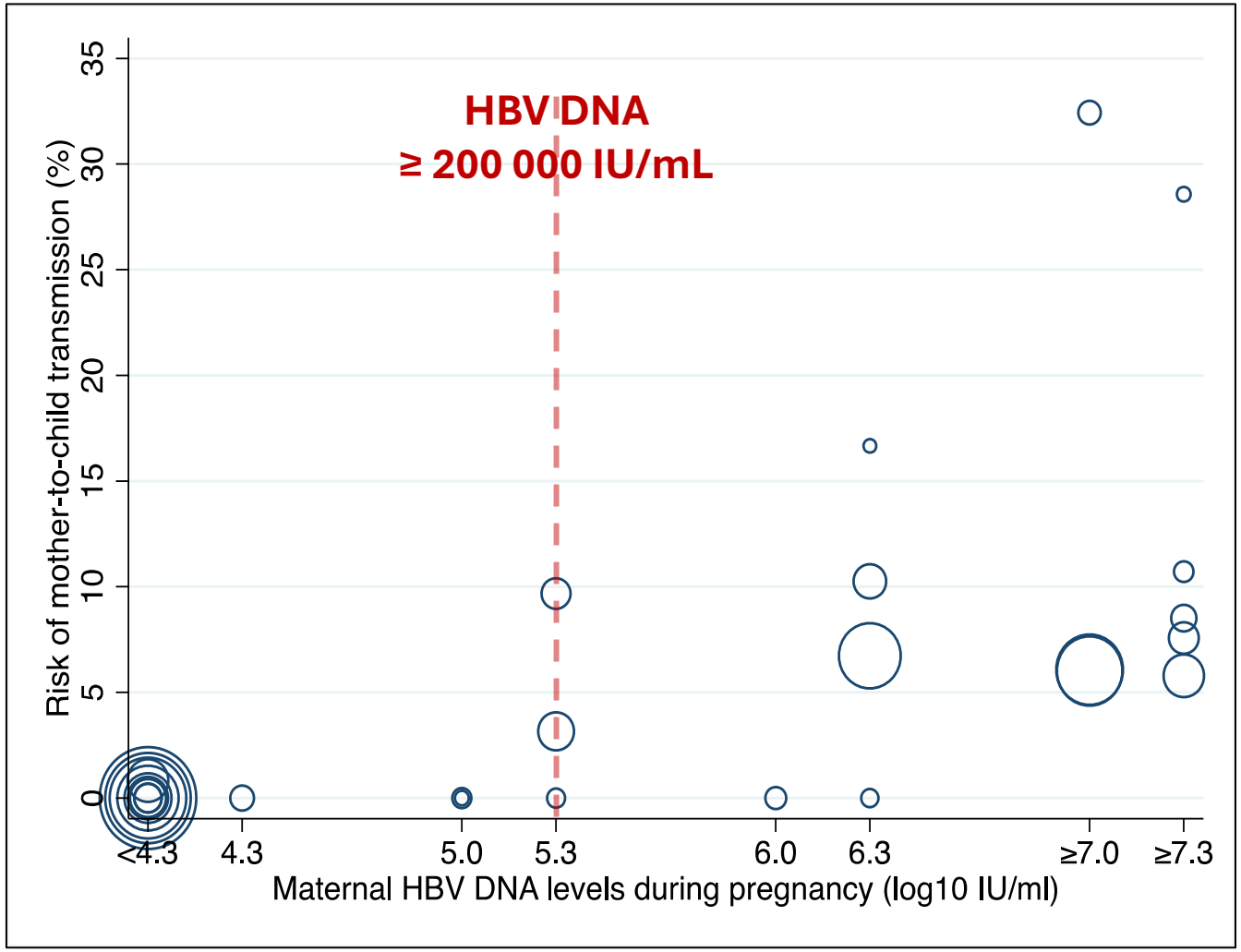
3) Prophylaxis preferably **from the second trimester** of pregnancy until at least delivery or completion of the HBV childhood vaccination series.



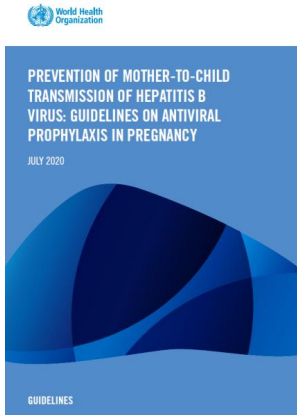
Results of the DNA viral load threshold assessment for vertical transmission

- When the timely dose of vaccine and immunoglobulin is used, no breakthrough infection was reported when maternal HBV DNA viral load was less than **5.3 log IU/mL (200,000 IU/mL)**

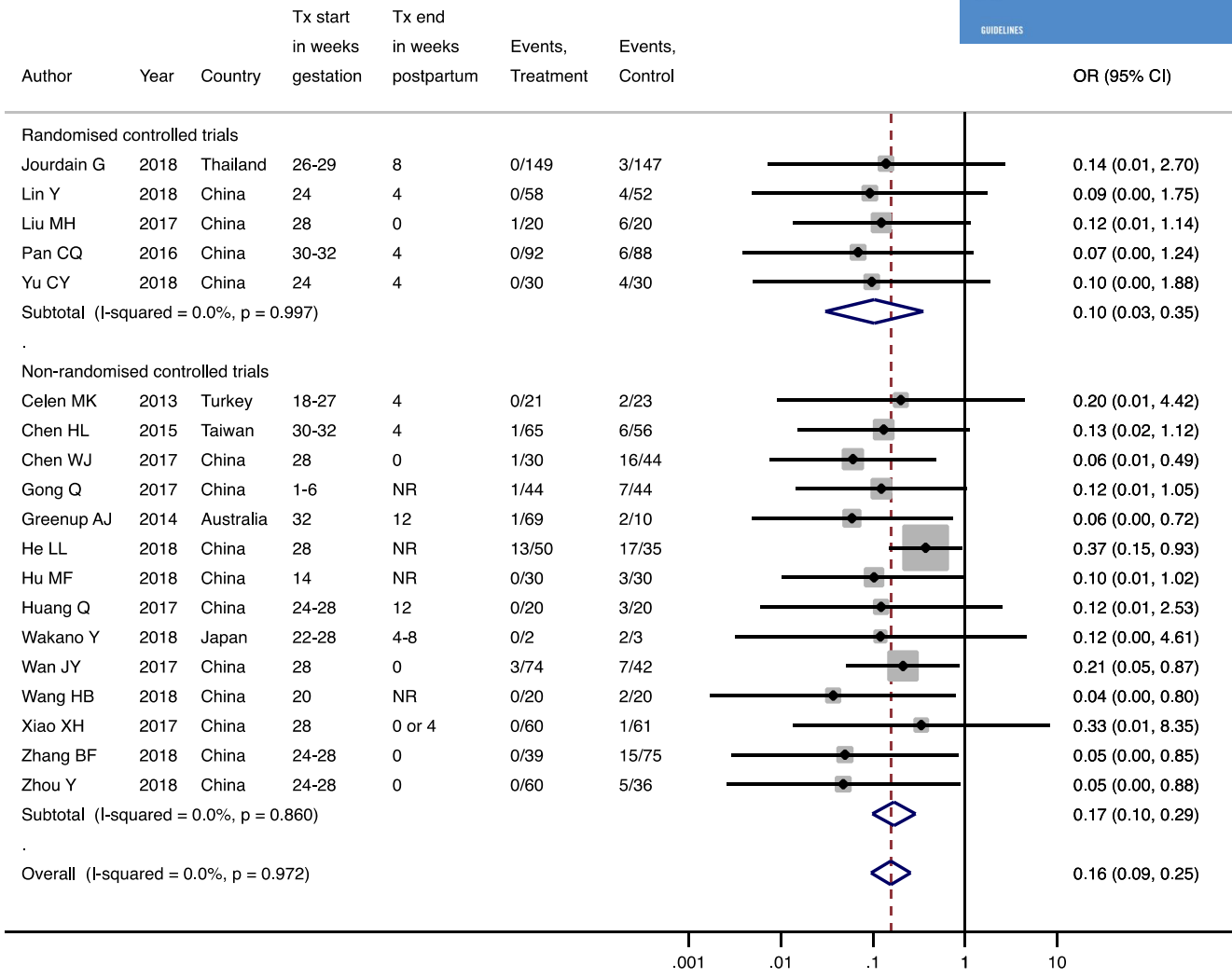




Efficacy of TDF for the prophylaxis of mother-to-child transmission of HBV



- 19 studies included
- Recruitment: 2007 - 2018
- Countries:
  - China (Mainland, n=14 & Taiwan, n=1)
  - Japan (n=1)
  - Australia (n=1)
  - Thailand (n=1)
  - Turkey (n=1)
- Meta-analysis:
  - **TDF 300mg: OR 0.16 (95% CI: 0.10-0.26)**



Integrated ANC HBV pathway

Screen all pregnant women

HBsAg test (RDT or laboratory assay)

HBsAg negative

Prevention package

- Risk-reduction counselling
- Vaccinate mother and susceptible contacts (if indicated)
- Plan for timely birth dose

HBsAg positive

Assess maternal treatment eligibility

- Fibrosis/cirrhosis (APRI or elastography)
- ALT and HBV DNA when available
- Coinfection, immunosuppression, family history, comorbidities

Treatment eligible

- **Start treatment**
- Monitor ALT/HBV DNA
- Monitor renal function
- HCC surveillance if indicated

Not treatment eligible

Consider prophylaxis:

- HBV DNA ≥200,000 IU/mL or
- HBeAg+ or
- HBsAg+ (all)

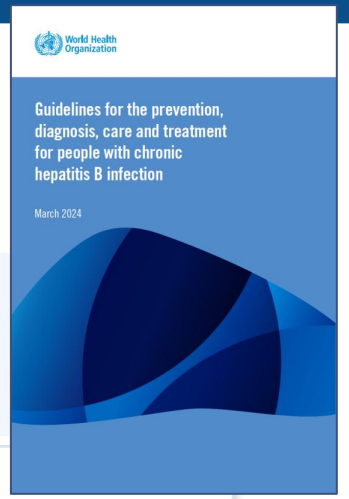
maternal TDF from 2nd trimester through delivery/postpartum

Exposed Infant:

- **Immunoglobulin (HBIG),**
- **hepatitis B birth dose (preferably ≤24h) + complete vaccine series +**
- **HBsAg testing at 9-12 months**

All Infants: hepatitis B birth dose (preferably ≤24h) + complete vaccine series

Chronic Hepatitis B — Initial assessment



HBsAg positive

Assess treatment eligibility

Disease stage + labs + clinical context

1 Stage liver disease severity

Use **non-invasive assessment** (e.g., APRI or transient elastography) to estimate fibrosis/cirrhosis risk.

2 Check ALT/AST and HBV DNA

Interpret ALT relative to the lab ULN and review viral load to guide treatment decisions.

3 Medical history & risk modifiers

- Coinfections (HIV/HDV/HCV),
- Comorbidities,
- Immunosuppression,
- Extrahepatic disease,
- Family history of cirrhosis/liver cancer.

General care measures

Risk reduction + readiness + prevention

1 Lifestyle counselling

Address **alcohol** use, **diet** quality, and physical activity; tailor to metabolic and liver risk profile.

2 Prepare for treatment

Assess **adherence** support needs; evaluate renal risk factors and **baseline renal function** relevant.

3 Prevent transmission

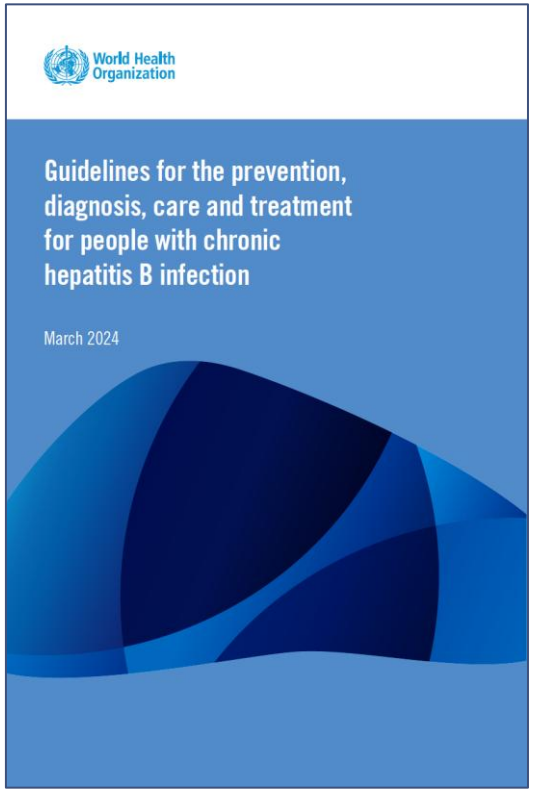
Screen **household/sexual contacts** (HBsAg) and **vaccinate** those who are HBV negative.

Non-invasive tests for liver fibrosis

- **Liver biopsy** considered **impracticable** in low-income settings

- **APRI (aspartate aminotransferase-to-platelet ratio index)**
  - **>0.5** suggests significant fibrosis; **>1.0** suggests cirrhosis.
  - **recommended as the preferred non-invasive test**

$$\text{APRI} = \left(\frac{\text{AST (U/L)}}{\text{Upper Limit of Normal AST (U/L)}} \right) \div \text{Platelet count } (10^9/\text{L}) \times 100$$



- **Transient Elastography (FibroScan®):**
  - Measures liver stiffness (kPa).
  - **>12 kPa** suggests cirrhosis.
  - Preferred in settings **where it is available and cost is not a major constraint**.

- **Others (specialized):**
  - FIB-4 Index; FibroTest, FibroSure, HepaScore, ELF test (combination of serological markers);
  - Shear-Wave or Acoustic Radiation Force Elastography (Ultrasound-based);
  - Magnetic Resonance Elastography (MRE).

WHO Recommendations: When to treat **chronic hepatitis B**

Treat adults and adolescents (≥12 years) with chronic hepatitis B, including pregnant women, if ANY of the following apply

Quick rule

- Treat if there is evidence of **liver damage**, active **viral replication with liver inflammation**, or important **clinical risk factors.**

- If HBV DNA is not available, persistently abnormal ALT can support treatment.

1 **Significant fibrosis (≥ F2) or cirrhosis (F4)**

APRI >0.5 or elastography >7 kPa; treat **regardless of ALT or HBV DNA**.

2 **HBV DNA >2,000 IU/mL + ALT above Upper Limit of Normal: 30(M) and 19(F) U/L**

Adolescents: persistent ALT elevation rather than a single abnormal value (6-12 months)

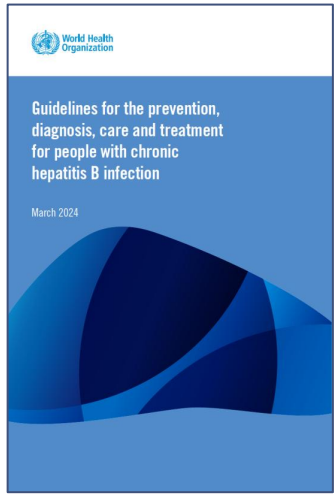
Raised ALT may normalize in pregnancy (reassess after delivery)

3 **Special situations**

Coinfection, family history of liver cancer/cirrhosis, immunosuppression, comorbidities, or extrahepatic manifestations.

4 **If HBV DNA is unavailable**

Persistently abnormal ALT levels alone can support treatment.



**** Children 2-11 Years:** treatment is generally offered on a case-by-case basis: cirrhosis or advancing liver fibrosis stage ≥F2, persistent HBV DNA >2000 IU/mL, comorbidities.

**** Children <2 Years:** Treatment not recommended

RECOMMENDATIONS– HOW TO TREAT

1. **Preferred regimens:**
   - Tenofovir disoproxil fumarate (TDF) or
   - Entecavir (ETV)

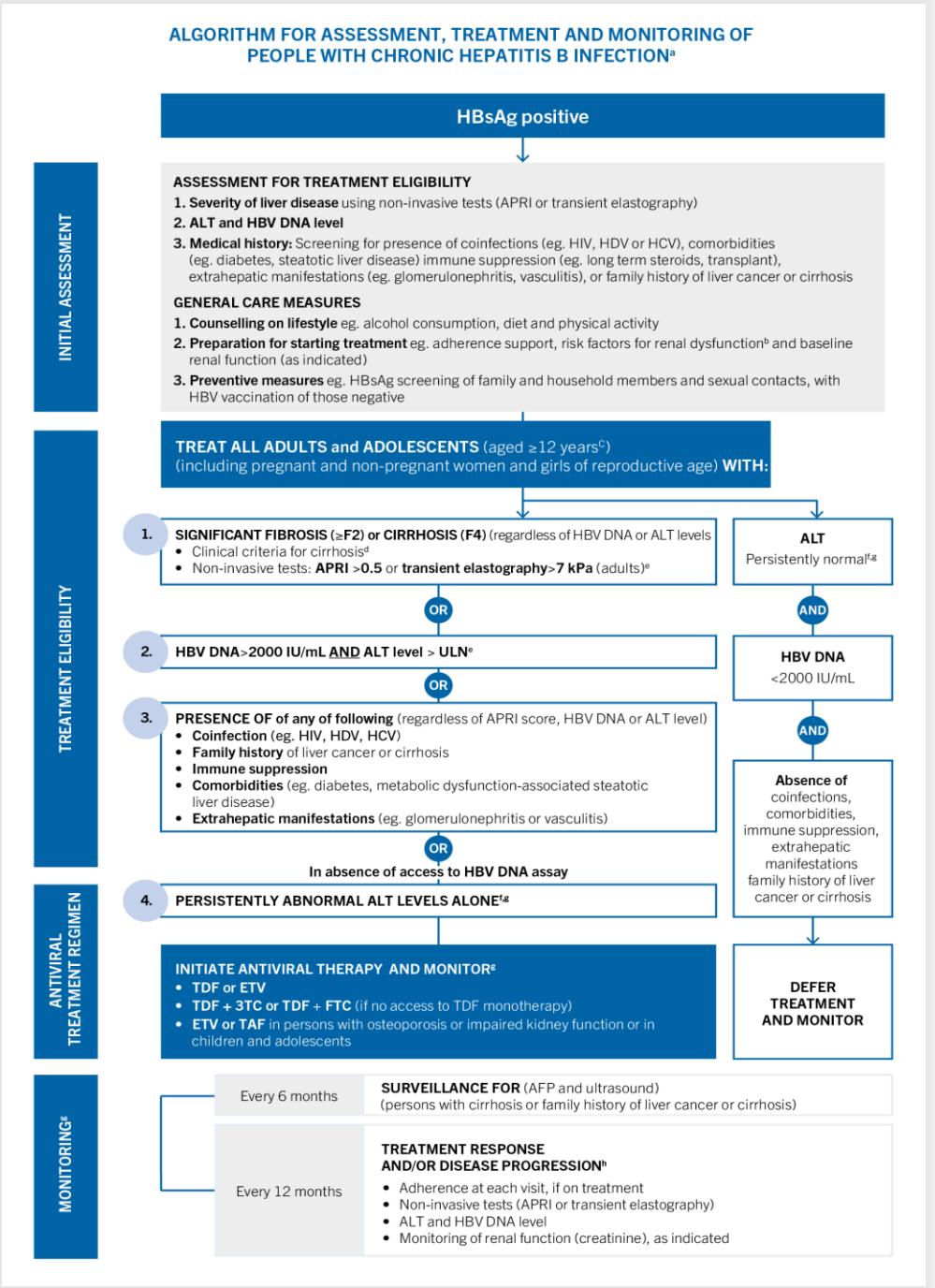
2. **Alternative regimens** (where TDF monotherapy is not available)
   - TDF + lamivudine (3TC)
   - TDF + emtricitabine (FTC)

3. **Osteoporosis and/or impaired kidney function:**
   - Entecavir (ETV) or
   - Tenofovir alafenamide fumarate (TAF)

4. **Children or adolescents**
   - aged ≥2 years: similar regimens (TDF, ETV, TDF+3TC, TDF+FTC)
   - TAF only for children aged ≥12 years
   - Ages <2 years: treatment not recommended

(strong recommendation, moderate-certainty evidence)

World Health Organization



Chronic hepatitis B: treatment monitoring

FOLLOW-UP PLAN

1 HCC surveillance — EVERY 6 MONTHS

- Abdominal ultrasound + Apha-fetoprotein (AFP) for patients with
  - Cirrhosis
  - Family history of liver cancer or cirrhosis
  - age >40 years and HBV DNA >2,000 IU/mL without cirrhosis

2 Monitor all patients — AT LEAST ANNUALLY

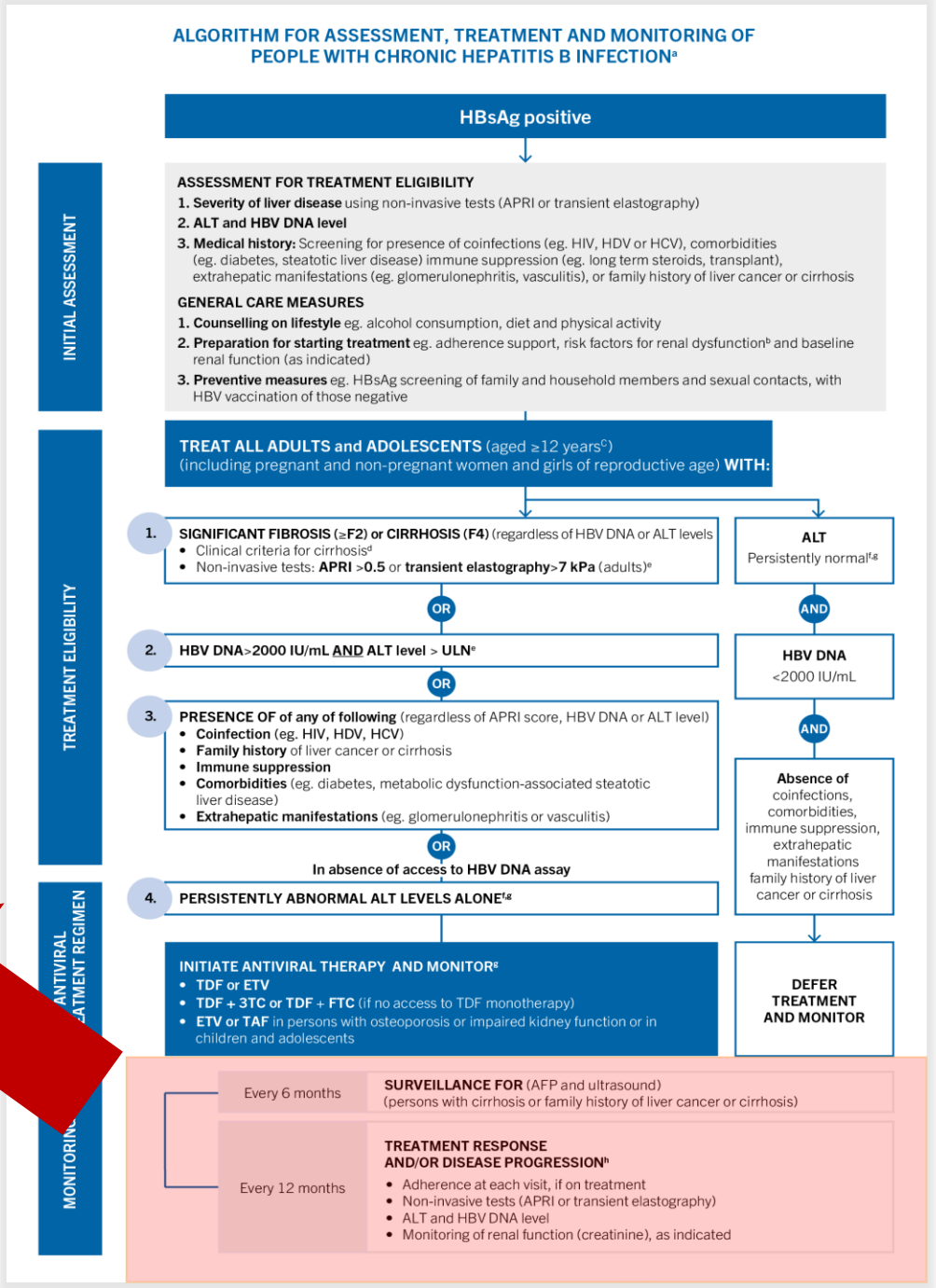
- **ALT** (and AST for APRI), HBsAg, HBeAg, **HBV DNA**
- **Non-invasive fibrosis assessment** if no cirrhosis at baseline
- Assess **adherence** at each visit if on treatment

3 Renal safety and Growth — BEFORE TREATMENT AND THEN ANNUALLY

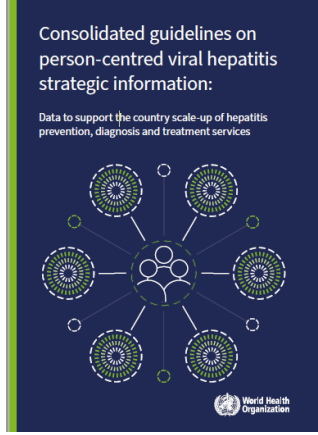
- Baseline renal function and baseline risk assessment
- **Annual renal monitoring** on long-term tenofovir or entecavir

  Children: Monitor growth when using TDF

Use the right half of the slide for narrative, treatment pathway, or speaker notes visual.



Monitoring and Evaluation (M&E) Framework for HBV and HCV



10 basic indicators

Initial assessment

Prevention indicators

Cascade of care and healing

Impact

PREVALENCE

Vaccination

EMTCT

Injection Safety

Harm Reduction

Diagnosis

Treatment

Viral Suppression/ Cure

INCIDENCE

MORTALITY

Monitoring of EMTCT of Hepatitis B

1. Overall HBV EMTCT indicators

- Prevalence of HBsAg among 5 years-old
- MTCT rate of Hepatitis B
- Coverage of HepB-BD and HepB-3D
- ANC coverage
- HBsAg screening coverage in pregnancy
- HBsAg positivity among pregnant women
- Eligibility assessment among HBsAg-positive pregnant women (HBV DNA or HBeAg)
- Antiviral treatment/prophylaxis initiation among eligible women
- Timely HepB birth-dose coverage among exposed newborns
- HBIG coverage among exposed newborns
- Completion of infant HepB vaccine series among exposed infants
- Post-vaccination testing among exposed infants
- HBV infection among exposed infants

2. Key case-based data for line listing of exposed infants

- Case ID, year, region/facility
- Date and gestational age of maternal HBsAg screening
- Maternal HBsAg result
- Date and result of maternal HBV-DNA or HBeAg (eligibility for treatment/prophylaxis)
- Date of treatment initiation and treatment used
- Date of delivery
- Timely Birth dose given and date
- HBIG given and date
- Dates of infant vaccine doses (1st, 2nd and 3rd doses)
- Infant post-vaccination test done, date, and result
- Final infant outcome
- **Assessment**: Comments on protocol breaches / likely reason for transmission

Recommendations for the Caribbean to accelerate progress towards viral hepatitis elimination

Verticality of programs

EMTCT Plus requires **inter-programmatic work** focused on strengthening MCH and PHC and **leveraging national political commitment**.

Expand birth dose coverage

- Ensure timely administration in the first 24 hours
- Availability in public and private delivery wards
- Raise awareness among pregnant women, families, and the community
- Exposed infants: complete vaccine series and HBIG when indicated

Expand ANC hepatitis B services

- Universal HBsAg screening early in pregnancy
- Use of point-of-care rapid tests
- Service integration and linkage to care and treatment/prophylaxis of HBsAg-positive persons

Demonstrate impact

Strengthen data reporting systems for

- vaccine and HBIG coverage
- testing and treatment among pregnant women
- post-vaccination testing of exposed infants.

Conclusions

Pan American Health Organization

World Health Organization

Americas Region