Hepatitis B Market Intelligence Webinar

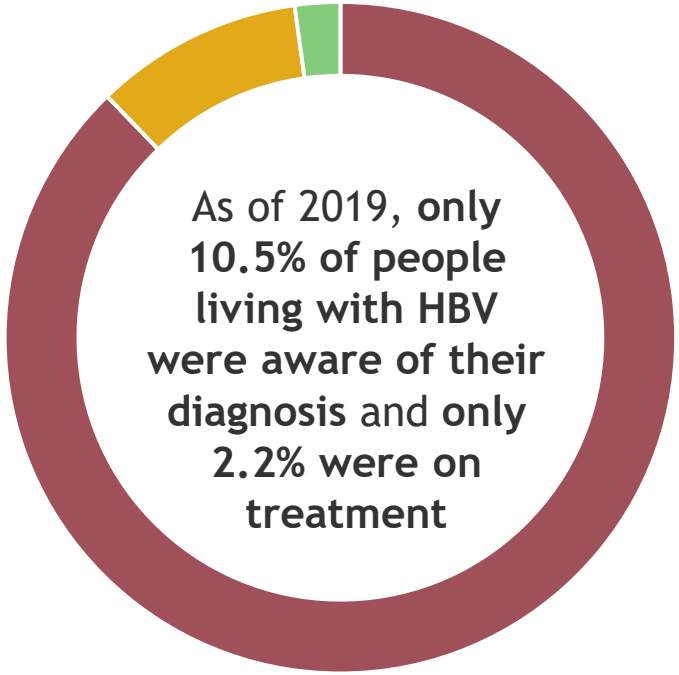
January 31st, 2023

HBV infection remains a major cause of liver disease globally, with significant testing and treatment gaps globally

296M
People living with chronic HBV as of 2019

820k
HBV-related deaths, mostly from cirrhosis and hepatocellular carcinoma

1.5M
New infections per year mostly driven by vertical transmission from mother-to-child at delivery

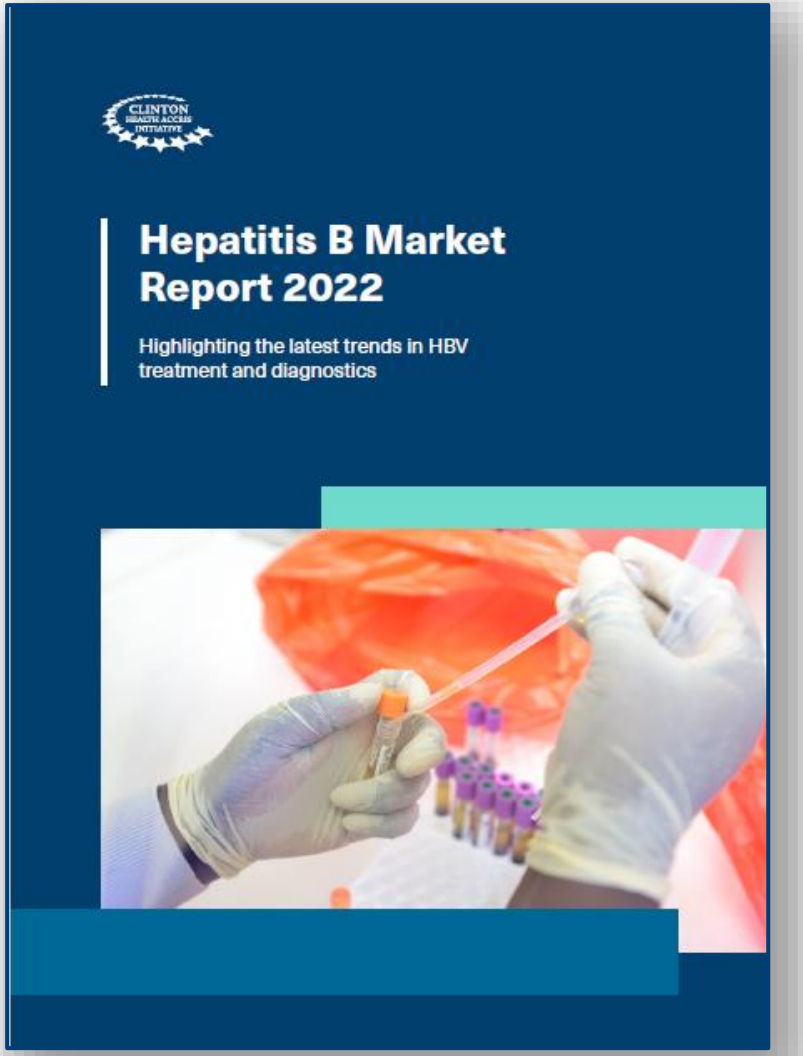


Global Burden

- WHO estimates burden of HBV infection is highest in the Western Pacific (116 million) and in Africa (81 million)
- 60 million chronically infected in Eastern Mediterranean, 18 million in Southeast Asia, 14 million in Europe, and 5 million in the Americas

Due to limited awareness and limited funding, there are **few LMICs which have public programs that provide comprehensive HBV testing and treatment services**

CHAI is excited to share the HBV Market Report 2022 which provides product, volume, and pricing trends in HBV Market



Topics Covered in the Report

- Supplier Landscape for HBV commodities
- Volume & Pricing for TDF
- Finding from TDF scoping Exercise
- Recommendations HBV programs to access TDF at price parity with HIV programs
- Pricing, Supply, and Volume Trends for HBV Rapid Diagnostic Tests (RDT) & HBV viral load (VL)
- Hepatitis B e-Antigen (HBeAg) Market
- Combination RDT Market

Webinar Agenda

Welcome Remarks & Introduction	**Ms. Oriel Fernandes,** Senior Director, Hepatitis Program, CHAI	5 mins
HBV Treatment Highlights	**Ms Navya Sharma,** Senior Analyst, Global Markets Team, CHAI	35 mins
Ethiopia Case Study	**Mr. Wegene Adugna** , HIV & Viral Hepatitis Officer, Ministry of Health, Ethiopia **Mr. Melese Jorge,** Quantification & Market Shaping Team Leader, Ethiopian Pharmaceutical Supply Service	
India Case Study	**Dr. Sandhya Kabra,** Deputy Commissioner, NVHCP, & Additional Director, NCDC, MoH&FW, India	
Uganda Case Study	**Ms. Viola Kasone,** Program Officer Viral Hepatitis/Advanced HIV Disease, Uganda National Health Laboratory Services, Ministry of Health	
Key Learnings & Recommendations	**Ms. Navya Sharma,** Senior Analyst, Global Markets Team, CHAI	
HBV Diagnostics Highlights	**Ms. Robia Islam,** Associate, Global Diagnostics Team, Hepatitis, CHAI	10 mins
Community Perspective	**Mr. Kenneth Kabagambe,** Executive Director, The National Organization for People Living with Hepatitis B	10 mins
Looking Forward	**Dr. Philippa Easterbrook,** Global HIV, Hepatitis and STI Programme, World Health Organization (HQ)	10 mins
Q&A	**Ms. Emi Okamoto,** Associate Director, Hepatitis/HIV Diagnostics, Global Diagnostics Team, CHAI	15 mins
Closing Remarks	**Ms. Oriel Fernandes,** Senior Director, Hepatitis Program, CHAI	5 mins

7 mins

HBV Treatment Highlights

Ms. Navya Sharma, Senior Analyst, Global Markets Team, CHAI

Treatment Guidelines and Supplier Landscape For HBV Treatment Market

Treatment Guidelines

- WHO recommends the use of Tenofovir Disoproxil Fumarate (TDF) or Entecavir (ETV) for the treatment of HBV infection in all individuals aged 12 years or older for whom antiviral therapy is indicated
- Tenofovir prophylaxis is recommended for pregnant women with high viral load from 28 weeks of pregnancy until at least birth, to prevent mother-to-child transmission of HBV
- Some countries have also included TAF in their National Treatment Guidelines for HBV

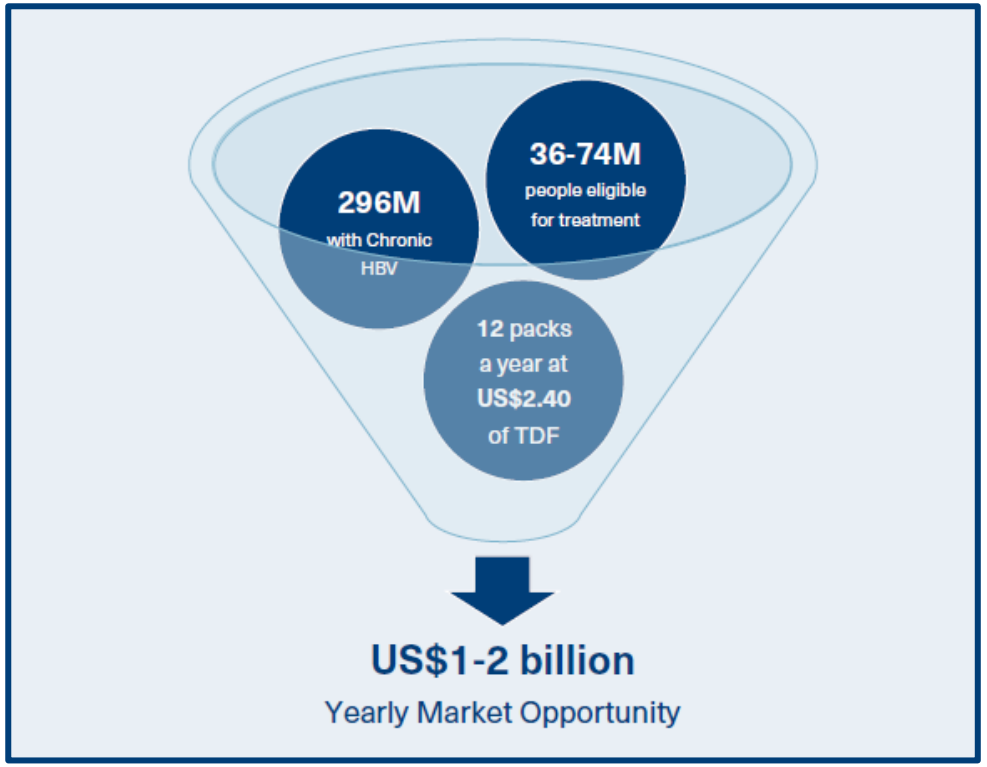
Supplier Landscape

- **TDF**, which **has been a mainstay for HIV treatment**, **has the same dosage approved for HBV treatment** (300 mg/day)
- TDF has a broad supplier base - WHO PQ'd suppliers for TDF are **Aurobindo, Cipla, Viatris, Macleods, Strides, Laurus Labs**
- The only WHO PQ's supplier for ETV is **BrightGene Bio-Medical Technology**

Volume Trends For HBV Treatment Market

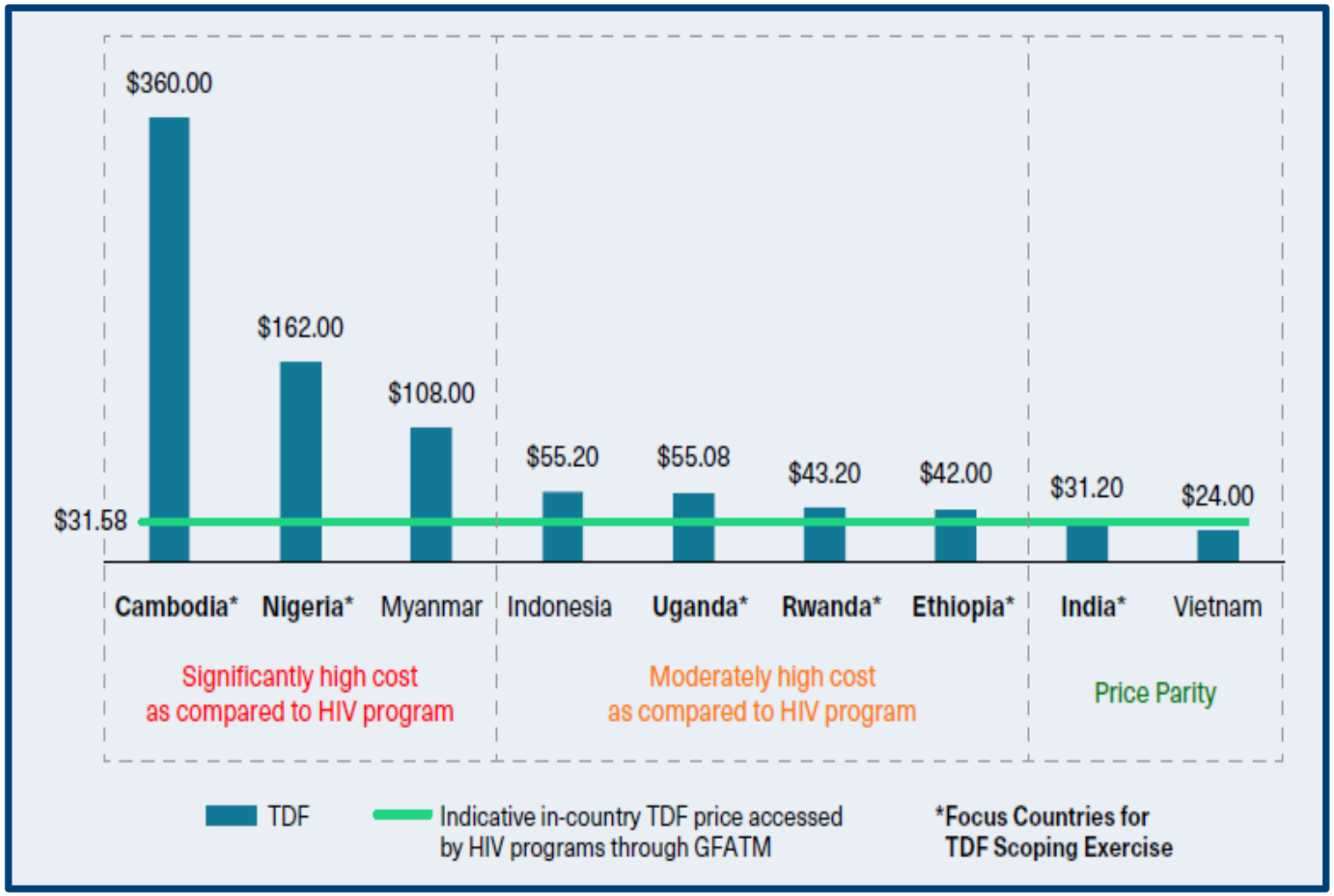
- In 2021, approximately **3 Mn packs** of TDF singles were exported by Indian generics to LMICs - **150% increase from the previous year.**
- During the same period, 108K packs of ETV were exported by Indian Generics to LMICs

Only 2.2 percent of chronic HBV-infected patients are estimated to be on treatment, leaving more than **29 to 67 million** patients worldwide eligible but not on treatment.



TDF Pricing Trends

Price for one-year HBV treatment course in 2022 (US$)

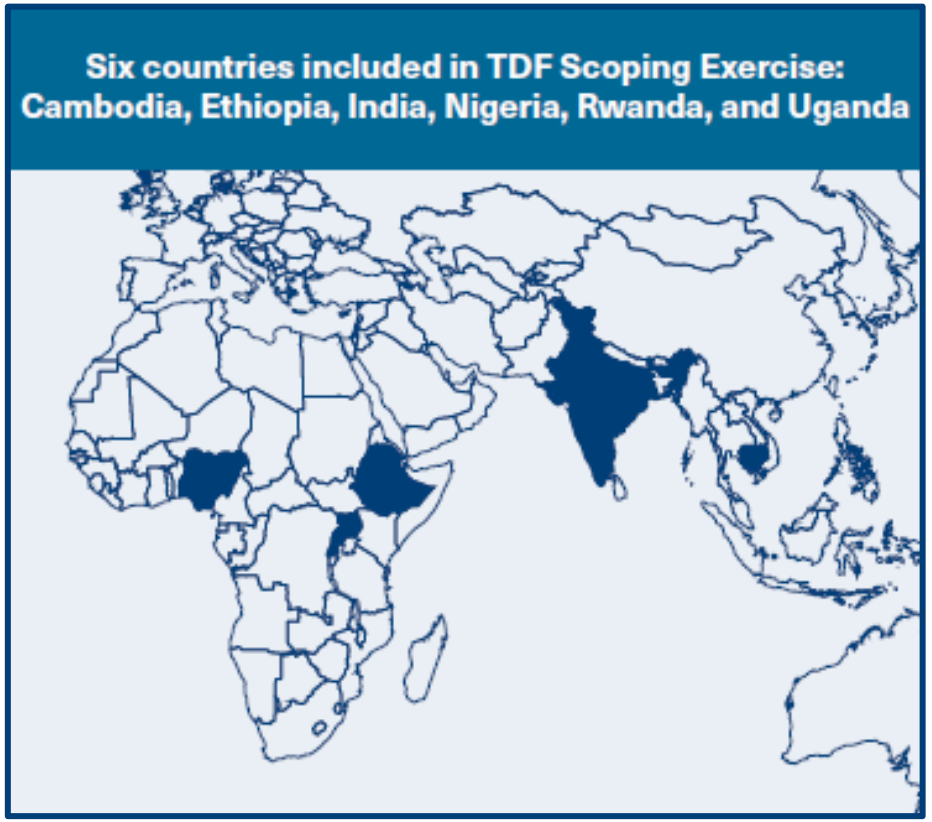


- Price of TDF has been driven down over the past two decades due to its wide use in HIV treatment.
- However, several programs/ hospitals report procuring TDF at significantly higher prices for HBV mono-infection and there is significant variability across LMICs
- HBV patients in Cambodia pay the highest at approximately US$360 for a year of TDF treatment
- In countries such as Nigeria and Myanmar, a one-year TDF course for HBV Tx costs over US$100, while countries such as India procure TDF at prices similar to the HIV program

TDF Scoping Exercise: Objectives, Methodology and Countries of Focus

The TDF scoping exercise was undertaken with three broad objectives:

- Collect pricing for TDF for mono-infected HBV and HIV programs in focus countries to determine price differential.
- Identify key factors that are driving the price differential by examining volumes, suppliers, and procurement and distribution mechanisms utilized by viral hepatitis and HIV programs.
- Evaluate whether there is a potential market-shaping strategy to catalyze TDF price reductions for HBV programs.



Country Categorisation

Countries with coordinated public HBV programs providing free care

India, Rwanda, Uganda

Countries with no publicly funded services

Ethiopia, Cambodia, Nigeria

8 mins

Case Study: Ethiopia

Mr. Wegene Adugna,
HIV & Viral Hepatitis Officer,
Ministry of Health, Ethiopia

Mr. Melese Jorge
Quantification & Market Shaping
Team Leader, EPSS, Ethiopia

Ethiopia has been scaling HBV care over the years

Burden

Ethiopia has an estimated 11 million people living with HBV

Current Service Access

Ethiopia has scaled up HBV testing in all hospitals & health centers and treatment sites from 13 to 90 health facilities

Patients pay OOP for HBV testing except for pregnant women, & treatment

Program Overview

Program Objective

Government annually allots around **US$ 1 million** for hepatitis programming, including procurement of commodities

Government Policy

The government is currently implementing the **2nd five-year strategic** plan spanning from 2021 - 2025

Also developed **first national triple elimination-focused strategic plan** spanning from 2021 - 2025

Program Allocation

Ethiopia is committed to halting transmission by providing access to safe and affordable care to people with HBV

Treatment & Diagnostics Trends in Ethiopia

Diagnostics Trends

Hepatitis B Surface Antigen Procurement

- HBsAg RDTs procured at a cost of **US$ 1.85 - 2.75 per test**
- **HBsAg is available at 343 hospitals and 3,587 health centers**:
  - Free-of-cost for pregnant women and OOP for other clients
- EPSS has **procured around 3.7 million test kits in a year**, across 3 different suppliers

TDF Procurement Practice

Volume-based Pricing through RDF

Use of **revolving drug fund** to aggregate demand and procure centrally. Revenue from commodities is used to replenish RDF

Use of International Competitive Bidding

EPSS purchases TDF through International Competitive Bidding which ensures large supplier participation and competition

Moderately High Cost Compared to the HIV Program

Ethiopia procured 197,000 packs of TDF in 2021-22 for the HBV program

Hospitals procured TDF via the RDF between US$3.50-4.00

Best Practice

Use of an alternative financing mechanism (RDF) has enabled the affordability and accessibility of TDF

8 mins

Case Study: India

Dr. Sandhya Kabra
Deputy Commissioner, NVHCP, & Additional Director, NCDC, MoH&FW, India

India provides HBV care under a centrally coordinated, domestically funded National Viral Hepatitis Control Program (NVHCP)

Burden

India has an HBV seroprevalence of 0.95% (0.89-1.01)

NVHCP launched in 2018, offers free care & support to patients with hepatitis B and/or C

Program Scale

The program offers care across 868 facilities nationwide. **NVHCP is in the process of scaling up these facilities**

National AIDS Control Program | Reproductive & Child Health | Immunization | Surveillance | Blood Safety → INTEGRATION

Program Overview

Who is Covered?	What Services are covered?	What patients have to pay?
Entire population is covered. Active outreach to vulnerable groups including pregnant women, Incarcerated population, PWIDs, PLHIVs and other HRGs	Diagnostic and management services Preventive (HBIG and Vaccination)	All services provided are offered free to the patients NVHCP allocates ~US$ 12 Mn for Tx and Dx commodities

Towards Universal Health Coverage

India was the only country in the TDF scoping exercise that accessed TDF at a price parity with benchmark price

Diagnostic Trends

- Diagnostic commodities are procured at the state level
- The program has been able to procure the HBsAg RDT for as low as US$ 0.09 and HBV viral load for US$15
- India has screened over 14 Mn individuals for HBV in the last year

Key Findings from TDF Scoping

Procurement at Price Parity

India procured **20,000** patient courses of TDF for approximately **US$2.60 per month** in 2021 for the HBV program

Pooled Procurement

India uses a centralized procurement mechanism that enables pooled procurement

Large Supplier Base

Through Open tendering India has also encouraged a large supplier base, enabling competition

Over **15 suppliers** took part in the last TDF tender

Best Practice

The use of competitive tendering and pooled procurement has enabled effective market shaping

8 mins

Case Study: Uganda

Ms. Viola Kasone
Program Officer Viral Hepatitis/Advanced HIV Disease, Uganda National Health Laboratory Services, Ministry of Health, Uganda

Since beginning five-year HBV mass testing and vaccination campaign in 2015, more than 5 million of the target population have been tested to date

In Uganda, an estimated 4.1% (800,000) of the population is living with chronic hepatitis B infection[1]

Access to Screening and HBV Viral Load

- Established laboratory and diagnostic capacity with widespread provision of HBsAg rapid diagnostic test kits
- **52% of facilities** nationally are also **hepatitis testing centers**
- HBV viral load testing is conducted at the **Central Public Health Laboratory (CPHL)**, leveraging **National Sample and Results Transport Network (NSTRN)**
- Opportunities to scale HBV VL by leveraging existing point-of-care platforms

Funding Efforts

- Government of Uganda allocates around 3 million USD annually to support implementation of HBV program
- Funding **for HBsAg tests** have been provided with **support from the Ministry of Health and PEPFAR**
- **HBV VL** testing has been provided with **support from the Global Fund**

Triple Elimination & Integrated Screening

- **Triple elimination strategy starting in 2020**, focused attention on prevention of perinatal and early childhood HBV transmission through
- Uganda has rolled out screening for pregnant mothers for HIV, syphilis, and hepatitis B as part of the strategy
- Dual HIV/syphilis tests kits and single Hepatitis B test kits being used; **MoH exploring other opportunities to integrate testing into one combination test kit as a one shop stop model**

[1] Uganda Population-based HIV Impact Assessment survey (UPHIA 2016) survey

Since the program's inception in 2015 until April 2022, nearly 433,000 patients have been enrolled in treatment

KEY FINDINGS FROM TDF SCOPING

Treatment Pricing

- The current price of the TDF singles for HBV from the local supplier to the central warehouse at NMS is US$4.59 per pack.
- The price is **moderately high** cost as compared to the HIV program
- This price was negotiated referencing the GFATM pricing for ARVs used for both HIV and HBV programs, a best practice.

Procurement

- TDF is available at no cost at the district, regional and national referral hospitals.
- The National Medical Stores (NMS), has established a framework contract through a national competitive bidding process that allows only in-country manufacturers to bid. This is inline with the Buy Uganda Build Uganda (BUBU) policy.

Best Practice

The use of benchmark pricing allows NMS to negotiate better and access TDF at an affordable cost

5 mins

HBV Treatment Highlights: Recommendations

Ms. Navya Sharma, Senior Analyst, Global Markets Team, CHAI

Key Takeaways from TDF Scoping Exercise

1. Centrally financed programs procuring via pooling demand could enable affordable procurement of TDF

2. Nigeria and Cambodia grapple with high TDF prices due to fragmented demand and low order quantities

3. TDF emerged as the preferred treatment for chronic HBV

4. Fixed dose combinations are used for HIV treatment

5. Alternative financing mechanisms such as RDF are potential methods to combat high OOP

6. Leveraging volume-based pricing via pooled procurement and competitive bidding can optimize prices

Recommendations for HBV Programs

Pool demand and procure centrally at a national **or state level to leverage volume-based pricing**

Implement tendering mechanisms to get **competitive quotes**

Implement alternative financing mechanisms such as revolving drug funds for programs where patients pay OOP

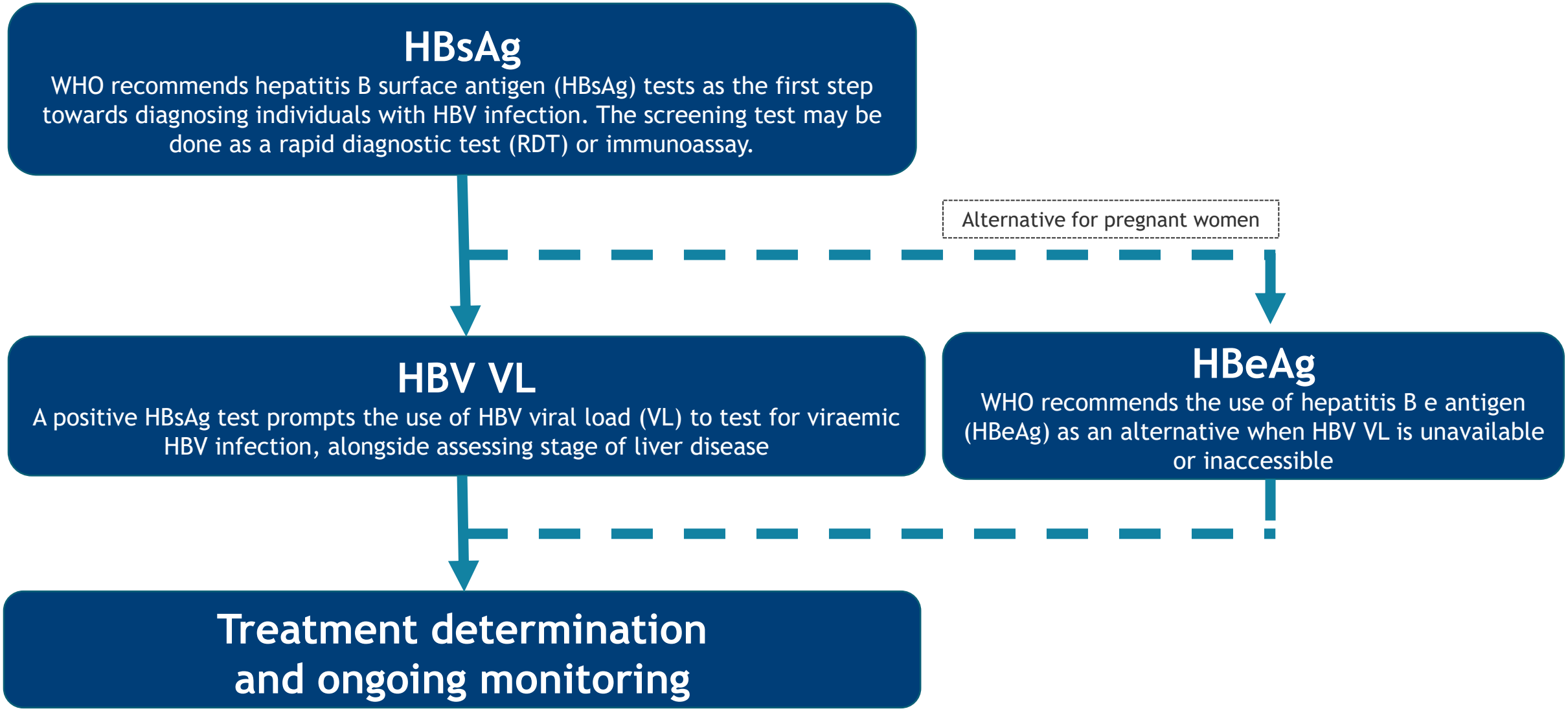
Leverage pricing negotiated by international procurement mechanisms as a benchmark

10 mins

HBV Diagnostics Highlights

Ms. Robia Islam, Associate, Global Diagnostics Team,
Hepatitis, CHAI

WHO-recommended HBV Diagnostic Tests

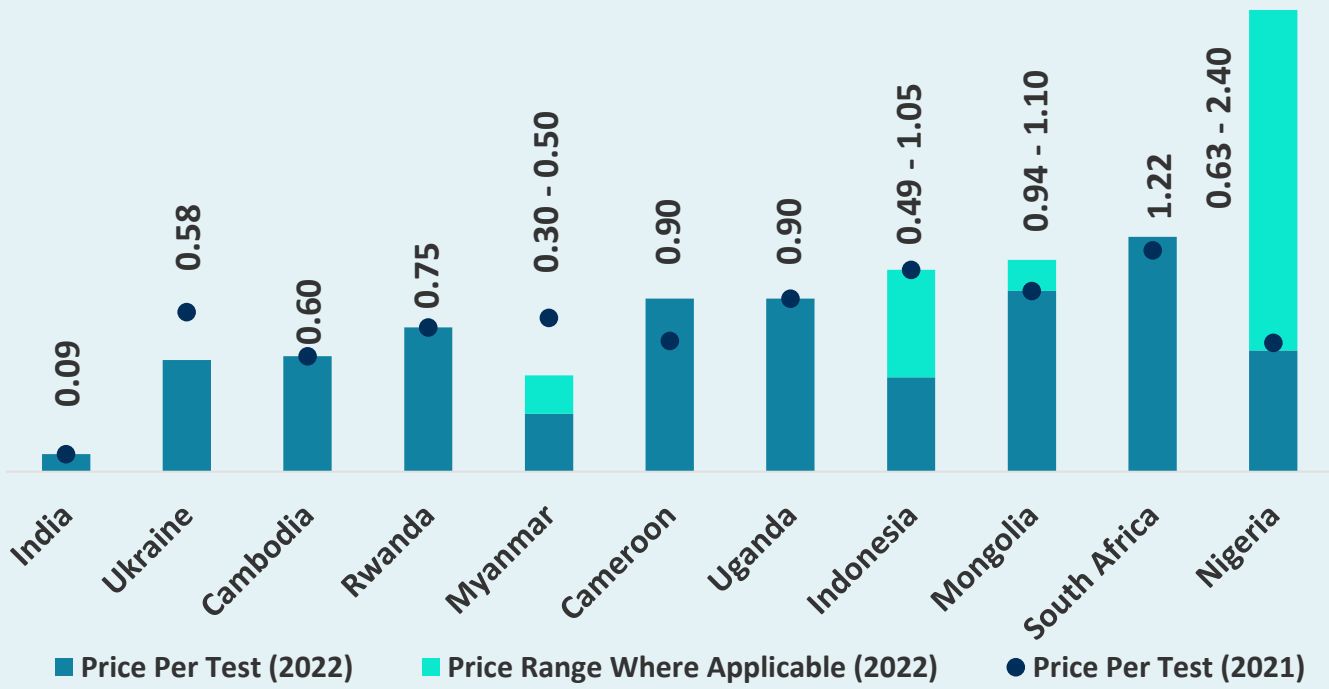


Supply-Side Landscape and Pricing Trends of the Hepatitis B Surface Antigen (HBsAg) Market

Supply Trends

- Four HBsAg products have WHO prequalification—two RDTs and two lab-based immunoassays
- Additionally, several other HBsAg products have approvals from other regulatory bodies such as CE-Mark or ERPD
  - These products have been approved for procurement through major global funders such as the Global Fund

Pricing Trends (US$)



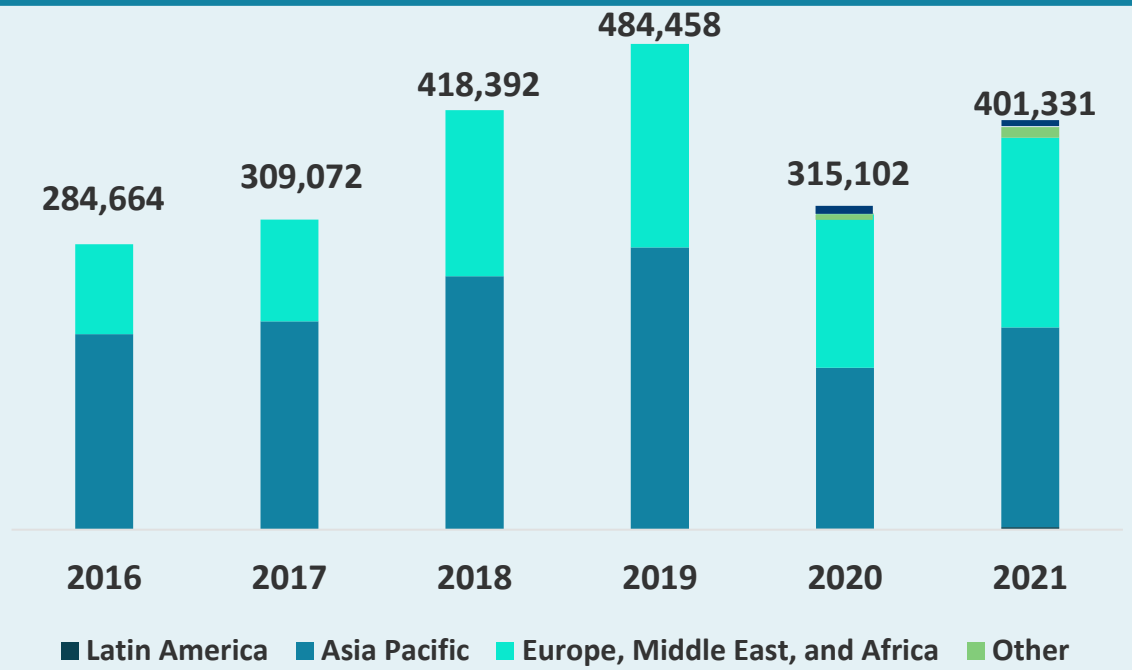
Global prices for HBsAg RDTs are generally comparable with those of RDTs across other disease areas, with **most LMICs procuring the test at around US$ 1**

Supply-Side Landscape, Pricing, and Volume Trends of HBV VL

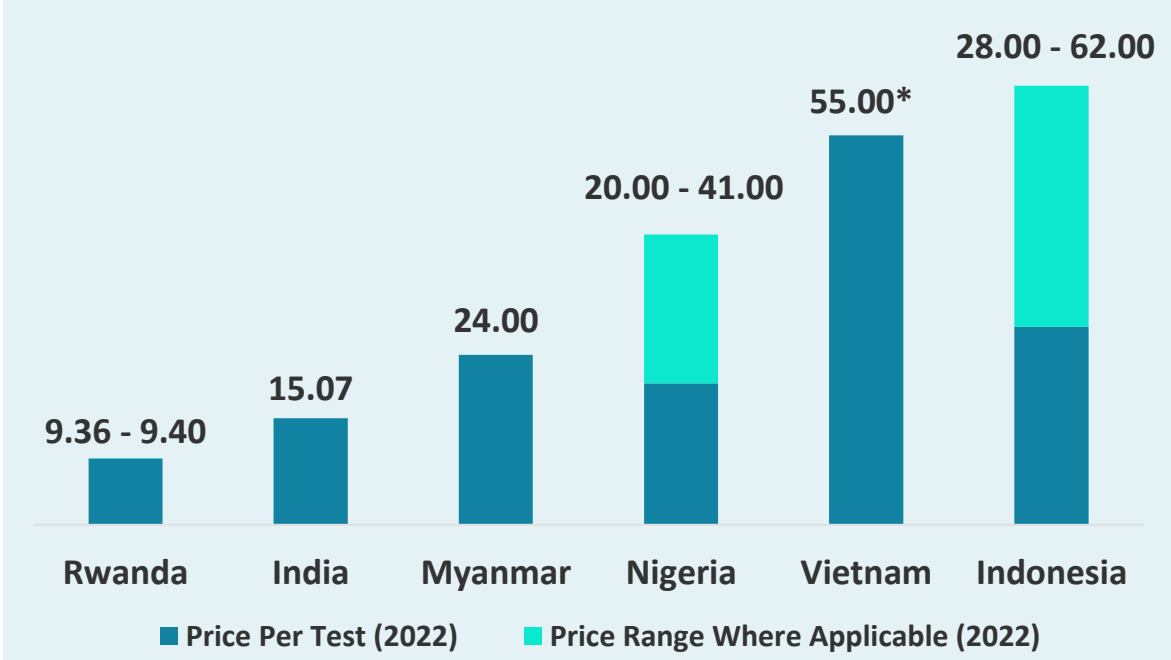
Supply Trends

- Multiple manufacturers have HBV VL products with stringent regulatory authority (SRA) approvals
- **Recent Update:** WHO PQ process recently extended to include HBV VL products
- Most manufacturers with HIV and HCV molecular tests also have HBV DNA, including two with near POC products

Volume Trends



Pricing Trends (US$)



Most major suppliers offer **global access pricing (GAP) for LMICs ranging from US$ 9-15** with variable terms, conditions, and country inclusion

Multiple HBeAg tests in the market, some of which have been SRA-approved

Supply Trends

- **Multiple products in the market have SRA-approvals** including several RDTs; no WHO PQ process for HBeAg

Pricing Trends

- Prices for RDT range from **US$ 0.30 USD to 4.50**
- Prices for lab-based assays can range from **US$ 2.00 to 40**

Barriers to Market Uptake

Variable Test Performance

As demonstrated by studies across multiple countries in the Asia Pacific (Thailand and Cambodia) region and Africa

Limited Implementation Knowledge

A few countries, such as Cambodia and Thailand, have shared experiences on the implementation of HBeAg in vertical transmission algorithms

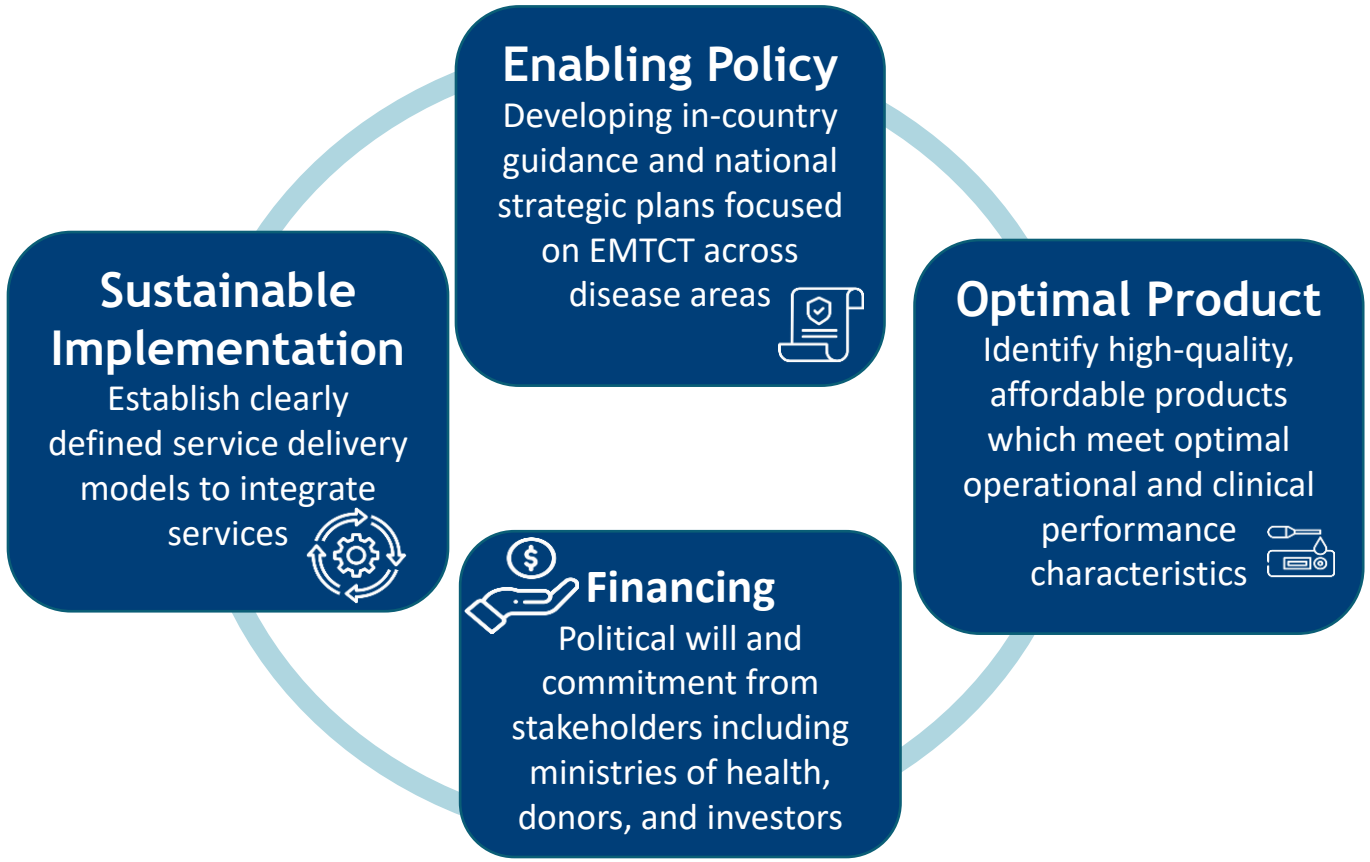
This demonstrates a larger need for **countries to consider validating HBeAg testing in settings considering use** and **share lessons learned across settings**

As countries prioritize the triple elimination of HIV, syphilis, and HBV, there are increasing integration opportunities for a person-centered approach to diagnosis

Combination RDT Supply Trends

- A non-exhaustive list of **combination rapid diagnostic tests (RDTs)** demonstrates quality-assured test kits which can provide comprehensive diagnosis of all three disease areas
  - Four combination tests which include testing for other disease areas such as HCV, **one of which have SRA-approvals**
  - Suppliers include Abbott, CTK Biotech, Wondfo, Accubio Limited/Orient Gene
  - No WHO PQ process
- **Prices range from US$ 1.45 – 2.00**, comparably priced to purchasing several single disease RDTs.

Considerations for Integrated ANC Screening



Introduction of the dual HIV/syphilis RDT demonstrates **opportunity for suppliers to develop similar products which include test options for HBV**

10 mins

Access to HBV Testing & Treatment

Community Perspective

Mr. Kenneth Kabagambe

Founding Executive Director of the National Organization for People Living with Hepatitis B (NOPLHB)

10 mins

Looking Forward

Dr. Philippa Easterbrook
Global HIV, Hepatitis and STIs Programmes
World Health Organization (HQ)

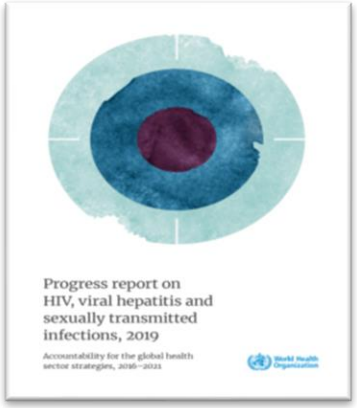
Looking forward on the HBV Market – New directions for WHO HBV guidelines

Philippa Easterbrook
Global Hepatitis Programme
Global HIV, Hepatitis and STIs Programmes
World Health Organization HQ

Outline

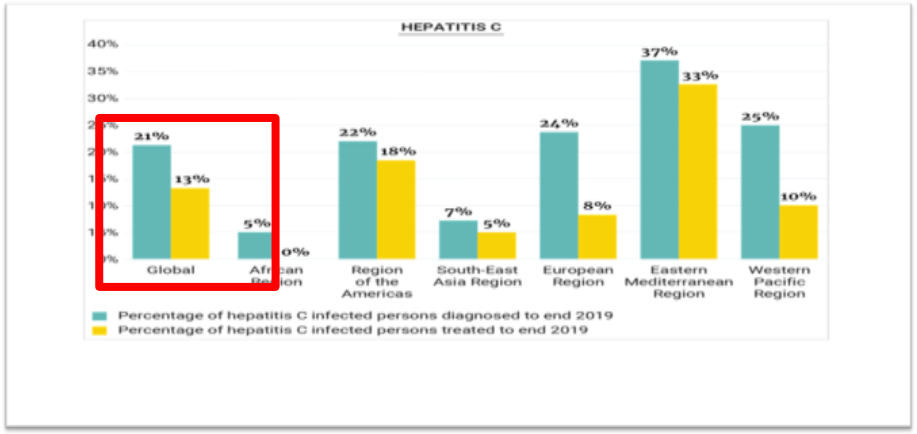
- **Progress on path to elimination of viral hepatitis – major gaps in testing and treatment**
- **Progress in 2022 on simplification of WHO HCV guidelines**
- **Overview of planned topics for 2023 WHO HBV Guidelines update**
- **Major opportunities**
  - Opportunities for integration
  - New 2021 guidance for countries on validation of elimination of viral hepatitis
  - New 2022 Global health sector strategy for HIV, viral hepatitis and STIs
- **Challenges**

2019 status on global and regional progress toward elimination of viral hepatitis



Data shows major gaps in testing and treatment uptake

21% of estimated 58 million people with chronic HCV infection were diagnosed in 2019 with variation by regions

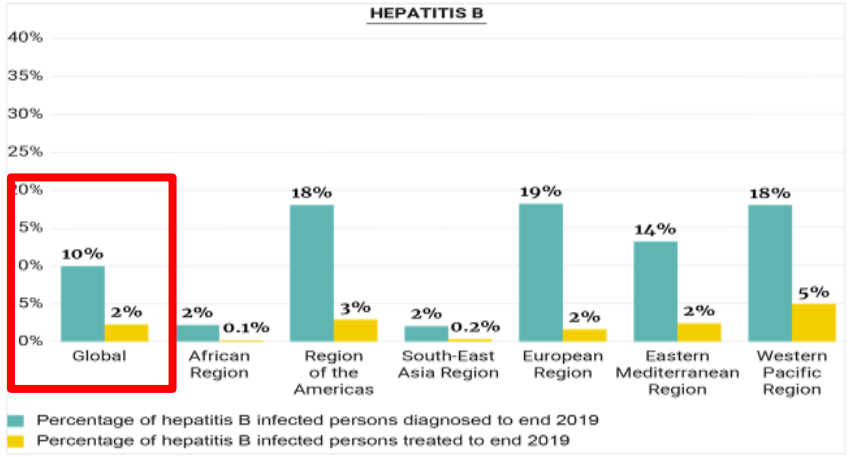


Data shows major gaps in path towards universal health access and public health elimination

World Health Organization

Progress report on HIV, viral hepatitis and sexually transmitted infections 2021: accountability for the global health sector strategies, 2016–2021: actions for impact. Geneva: World Health Organization; 2021

10% of estimated 296 million people with chronic HBV infection were diagnosed in 2019 with variation by regions



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World Health Organization

Continued Evolution of WHO HCV Guidelines Towards simplified Treatments + Simplified HCV Service Delivery

Topic	2014	2016	2018	2022
Who to treat?			Treat All	Treat All
Genotyping	Yes	Yes	No	No
Regimens	PEG-IFN+RBV	DAAs preferred	Pan-genotypic DAAs	Pan-genotypic DAAs
	8 options - PEGIFN+RBV - SOF+RBV - SIMP or TELAP or BOCEP /PEGIFN+RBV -	6 options DAAs preferred by GT or cirrhosis	3 options SOF/DAC SOF/VEL G/P PEGIFN phase out	3 options SOF/DAC SOF/VEL G/P Paeds formulations
Age group	Adults ≥18yrs	Adults≥ 18yrs	Adults ≥18yrs and adolescents ≥12 yrs	Adults, adolescents and children≥3 yrs
Service Delivery			8 Good Practice Principles for Simplified Service	Decentralization Integration Task-shifting
HCV NAT diagnosis		Laboratory-based NAT	Core Ag	-HCV Self-testing (2021) -POC NAT assay -Reflex NAT testing (lab or clinic-based)

SIMPLER TREATMENTS

TREATMENT OF CHILDREN AND ADOLESCENTS

SIMPLIFIED SERVICE DELIVERY

DIAGNOSTIC INNOVATIONS

NEW

CHAPTER 6. SIMPLIFIED SERVICE DELIVERY FOR A PUBLIC HEALTH APPROACH TO TESTING, CARE AND TREATMENT FOR HCV INFECTION

Box 6.1. Good practice principles for health service delivery

1. **Comprehensive national planning for the elimination of HCV infection** based on local epidemiological context, existing health-care infrastructure, current coverage of testing, treatment and prevention, and available financial or human resources
2. **Simple and standardized algorithms** across the continuum of care from testing, linkage to care and treatment
3. **Strategies to strengthen linkage from testing to care,** treatment and prevention
4. **Integration of hepatitis testing, care and treatment with other services** (e.g. HIV services) to increase the efficiency and reach of hepatitis services
5. **Decentralized** testing and treatment services at primary health facilities or harm reduction sites to promote access to care. This is facilitated by two approaches:
   - **5a. task-sharing,** supported by training and mentoring of health-care workers and peer workers;
   - **5b. a differentiated care** strategy to assess level-of-care needs, with specialist referral as appropriate for those with complex problems.
6. **Community engagement and peer support** to promote access to services and linkage to the continuum of care, which includes addressing stigma and discrimination
7. **Strategies for more efficient procurement and supply management** of quality-assured, affordable medicines and diagnostics
8. **Data systems to monitor the quality of individual care and coverage** at key steps along the continuum or cascade of care at the population level.

Strong community support for simplified service delivery – HCV testing and treatment at decentralised sites

If it were possible to conduct the viral load test outside the hospital, respondents preferred:

- community-based organization (45%)
- primary care (GP) clinic (44%)

88% would like to conduct the initial and confirmatory tests on the **same day**

- possibility to be treated more quickly (76%)
- possiblity to confirm status more quickly (81%)

92% would like to conduct the initial and confirmatory tests at the **same place**

- community-friendly site (60%)
- convenience (70%)

85% would like to **start treatment on the same day if they had positive viral load**

- avoid exposing family and friends to hepatitis C (28%)
- continued follow-up from testing to treatment (27%)

92% would like to be tested and treated in the same place

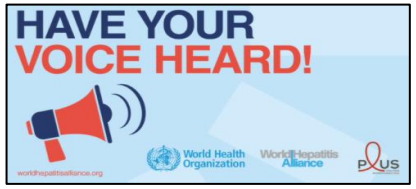
- convenience (34%)
- continued follow-up from testing to treatment (32%)

"I struggle to do doc appointments so the less places and times I have to go the better and more likely that I get them done"

– Respondent X

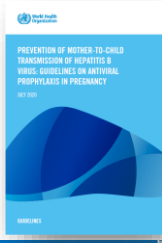
Same site means clear continuity of care, avoiding having to repeat personal story / issues and build trust with new clinician or worker"

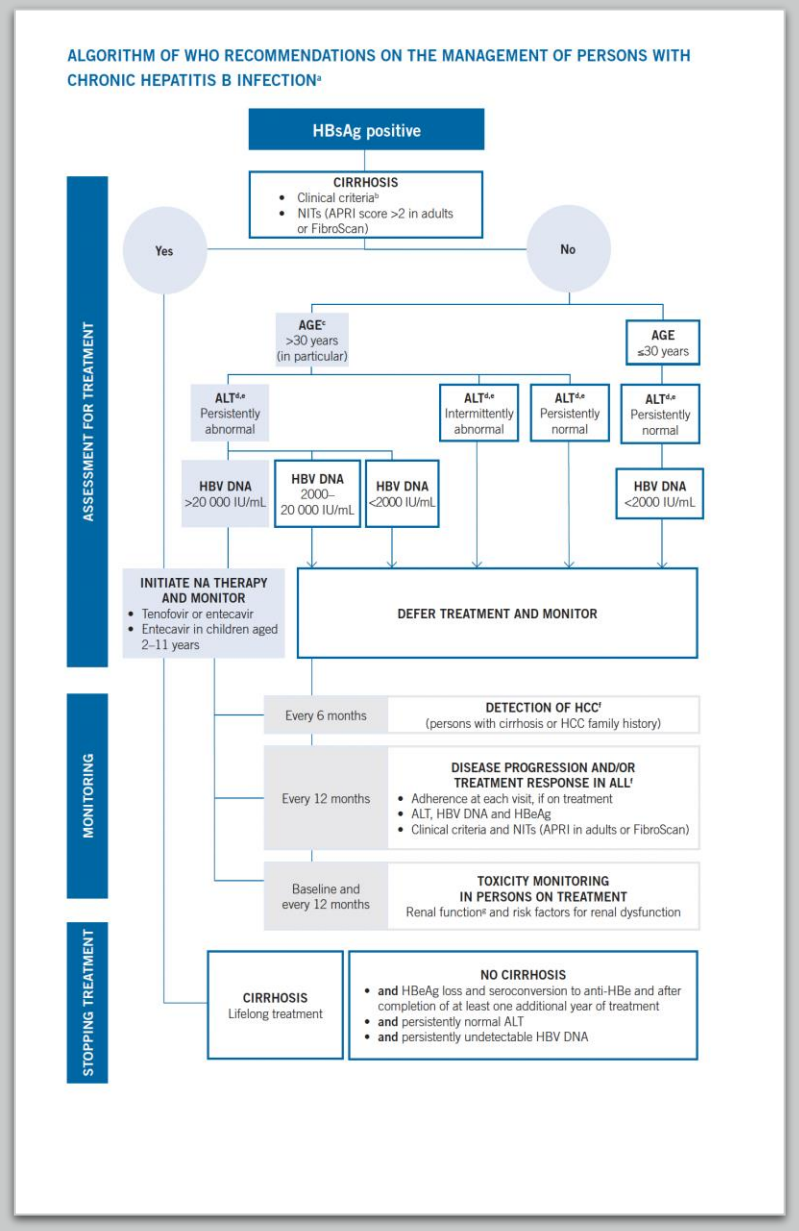
– Respondent Y



Available in: https://cdn.who.int/media/docs/default-source/hq-hiv-hepatitis-and-stis-library/hcv-guidelines-2022-presentations_25-7-2022.pdf?sfvrsn=733703ef_3

HBV Guideline Recommendations (2015) and PMTCT update (2020)





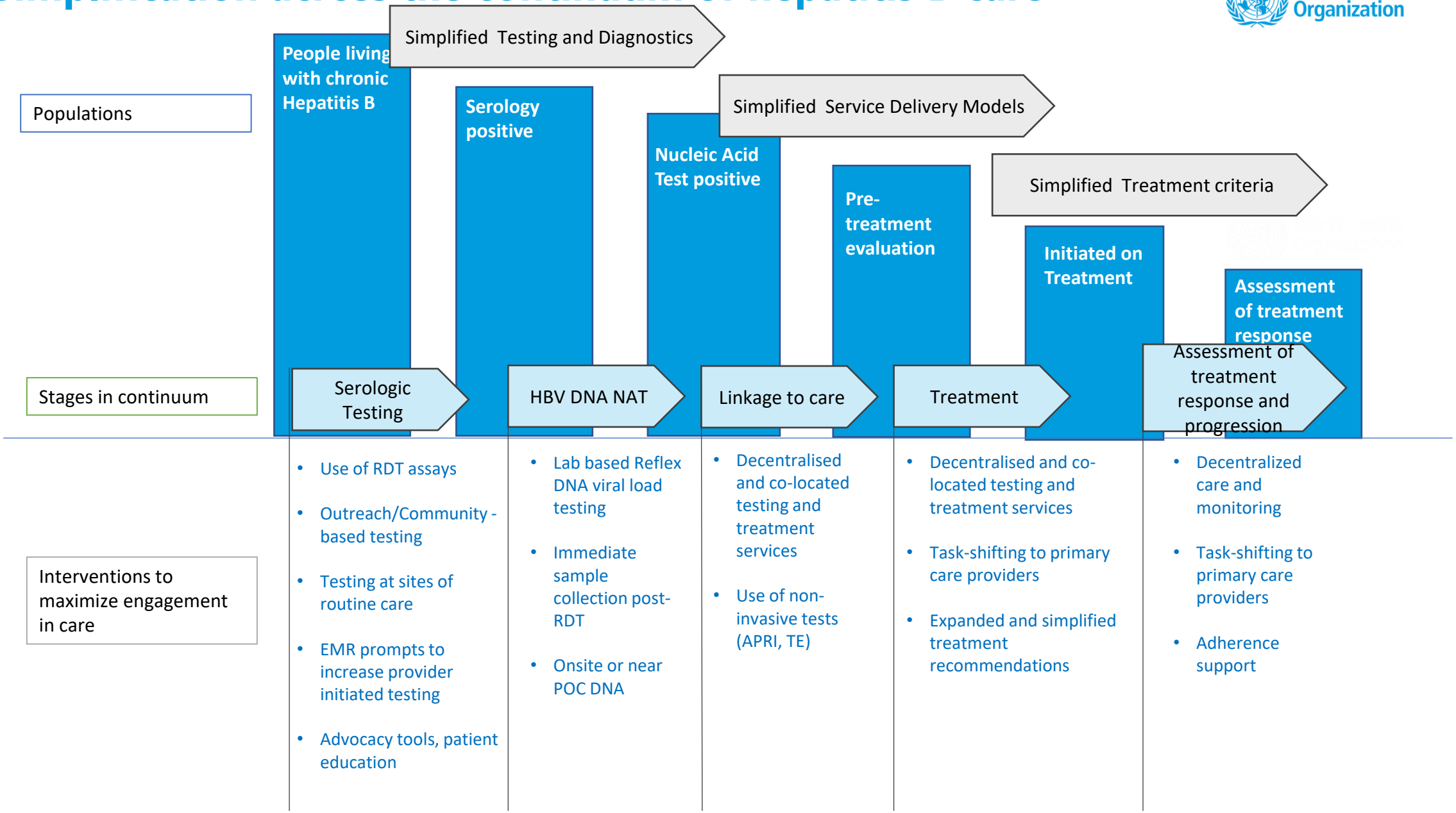
TOPIC	RECOMMENDATION
Staging/ non-invasive test (NIT)	▪ APRI preferred NIT to assess for the presence of cirrhosis
Who to treat	▪ Decompensated cirrhosis or cirrhosis (clinical criteria or APRI score >2), regardless of ALT levels, HBeAg, or HBV DNA. ▪ No cirrhosis but persistently abnormal ALT levels +/- ongoing HBV replication, (HBV DNA >20,000 IU/mL *or* HBeAg +ve).
First line treatment	▪ Drugs with a high barrier to resistance (TAF vs. TDF or ETV). ▪ ETV in children aged 2-11 years.
Treatment failure	▪ Switch to TDF if evidence of resistance to 3TC, ETV, ADF, TBV.
Treatment discontinuation	▪ Never discontinue in persons with cirrhosis. ▪ If no cirrhosis, discontinuation on case-by-case basis (persistent HBeAg and/or HBsAg loss or undetectable HBV DNA)
Monitoring (treatment response/toxicity)	▪ *On or pre-treatment:* ALT + HBV DNA (HBsAg, HBeAg + APRI pre-treatment) annually. More frequent monitoring with cirrhosis. ▪ Assessment of baseline renal function prior to treatment initiation.
Monitoring for HCC	▪ Ultrasound + AFP every 6 months in persons with cirrhosis and/or family history of HCC.
PMTCT antiviral prophylaxis (2020)	▪ TDF prophylaxis in those with HBV DNA >200,000 IU/mL from 3rd trimester or HBeAg positive (if HBV DNA not available)

World Health Organization

Why the need for expanded treatment criteria and updated simplified WHO HBV guidelines?

- Still very low testing and treatment coverage globally (10% those infected diagnosed, and 2% treated), esp SSA
- HBV guidance is perceived as complex
  - Need age, HBV DNA, and ALT to determine treatment eligibility
  - AASLD and EASL had already lowered HBV DNA threshold for treatment eligibility to >2000 IU/ml
  - APRI threshold >2 for diagnosis of cirrhosis – missing cases of cirrhosis
- Existing guidelines lack data from Sub-Saharan Africa – regional differences eg. low HBeAg positivity and high HCC rates
- Increasing evidence on ongoing integration of HBV during infection and oncogenicity of HBV
- Ongoing horizontal and vertical transmission in those not on treatment
- HBV Cure agenda opportunities sets direction for expanded treatment
- Lack of simplified care models for HBV – Recent WHO HCV guidelines update with a focus on simplified service delivery (“one-stop shops” and “test and treat” approach)

What do we mean by simplify?
Simplification across the continuum of hepatitis B care



New Directions - Updating WHO hepatitis B guidelines 2023

- **Who to treat?**
  - Expanding criteria for treatment (lower APRI score >1 and HBV DNA threshold >200 IU/ml)
  - Expanding treatment for adolescents and children (immune tolerant)
- **First-line treatment**
  - TAF and dual therapy vs. TDF
- **PMTCT**
  - Expanding criteria for use of antiviral prophylaxis to all HBsAg positive pregnant women
- **Simplifying diagnosis and service delivery**
  - Use of PoC HBV DNA viral load and reflex viral load testing
  - Delta virus testing
  - Decentralisation, integration and task-sharing

World Health Organization

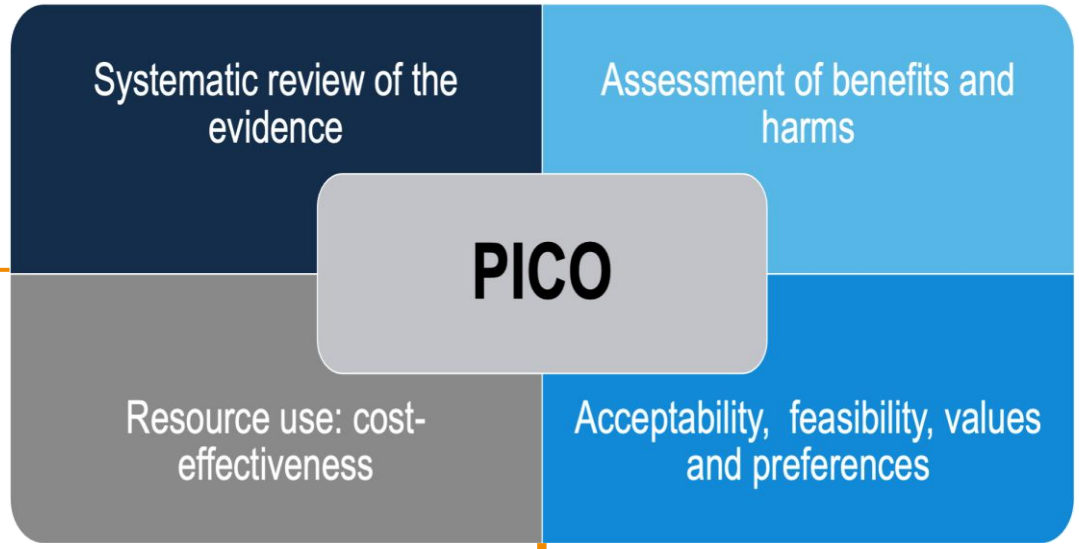
The WHO Guidelines process and GRADE

PICO QUESTION

PICO 1

Can HCV care and treatment be delivered effectively and safely in lower level health facilities (decentralisation)?

POPULATION:	Adults and adolescents (PWID, prisoners, PLHIV, general population).
INTERVENTION:	HCV testing, care and treatment outside of hospital-based facilities (harm reduction sites, prisons, ART clinics, primary care). Full decentralisation (and integration) of testing and treatment at the same site. Partial decentralisation (and integration) of testing at decentralised site, and referral for treatment.
COMPARISON:	HCV testing, care and treatment in hospital-based facilities (i.e. no decentralisation or integration).
MAIN OUTCOMES:	Uptake of testing, viral load confirmation, linkage to care, treatment initiation, SVR12 cure assessment, SVR12. Patient satisfaction. Stratified according to population and setting.



Formulating Recommendations

GRADE-ing recommendations

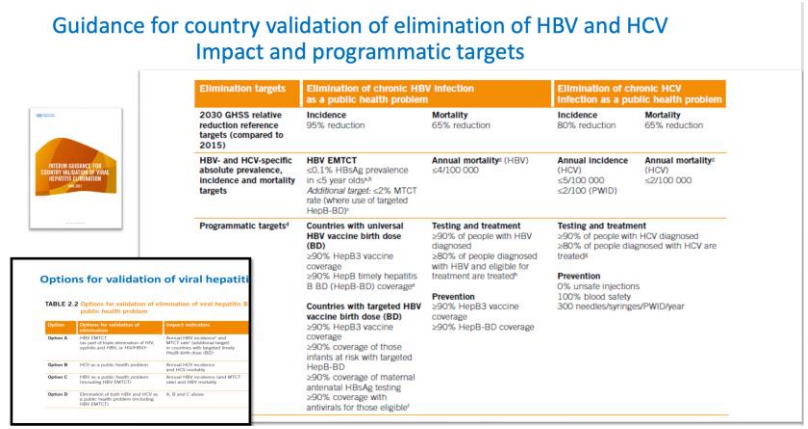
- Strength of recommendation
  - Strong=do in most circumstances
  - Conditional=different choices may be appropriate under certain conditions
- Good practice statements: Can apply to recommendations that are "obvious" and for which certainty is high—even though this is difficult to prove directly

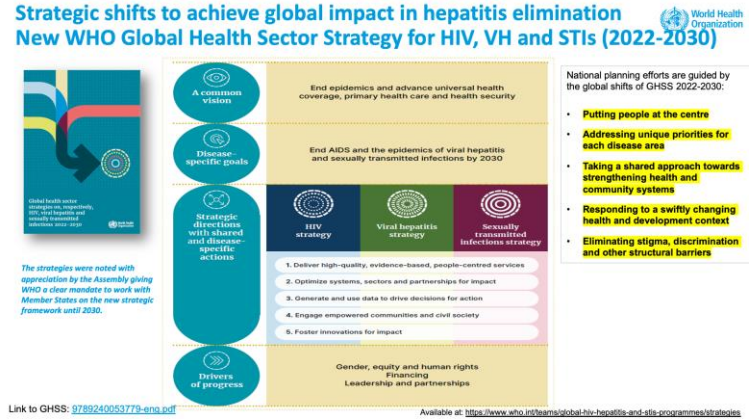
Strength of Recommendation	Quality of Evidence			
Strong	**High**	**Moderate**	**Low**	**Very Low**
Conditional	**High**	**Moderate**	**Low**	**Very Low**

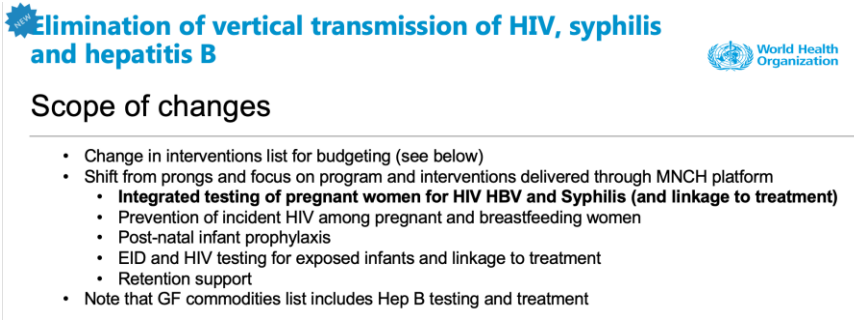
Available in: https://cdn.who.int/media/docs/default-source/hq-hiv-hepatitis-and-stis-library/hcv-guidelines-2022-presentations_25-7-2022.pdf?sfvrsn=733703ef_3

Key opportunities

1. Low cost tenofovir widely available in LMICs
2. Strong support from community and health workers towards expanding treatment eligibility and access
3. Key global initiatives
    1. WHO elimination guidance for countries
    2. New integrated HIV/hepatitis/STI global strategies
    3. Global Fund support option for testing and as part of triple elimination
4. Opportunities for decentralisation of HBV care at HIV clinic and integration in primary care sites;Telemedicine to support decentralisation





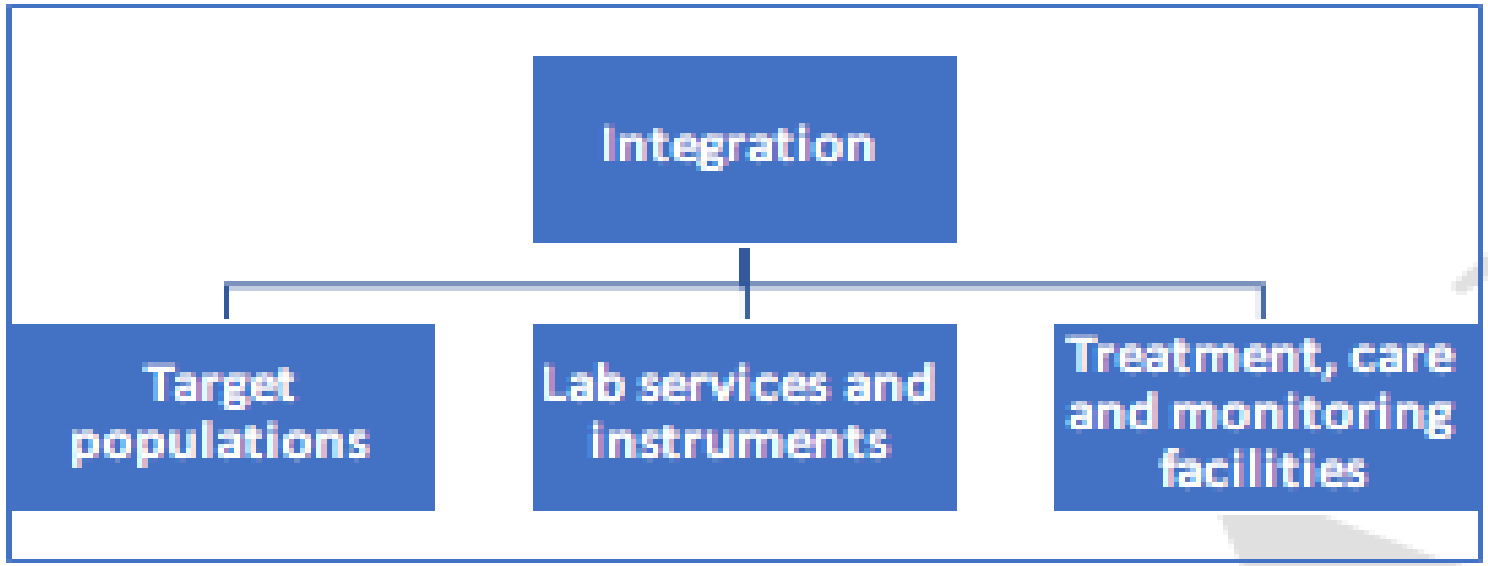


The need for simplification in hepatitis B care pathway to achieve elimination

1. **Simple and standardised algorithms** for testing, care and treatment
2. **Case-Finding plan: Who to test and where to test?**
3. **Strengthening the linkage** from testing to care.
4. **Moving treatment out of speciality clinics – Decentralized** testing and treatment
5. **Integration** of hepatitis testing, care and treatment with other services, and integrated multi-disease diagnostic platforms.
6. **Task-shifting to non-specialist health workers** to support decentralized care.
7. **Engagement with community.**
8. **Efficient procurement + supply management of quality medicines/diagnostics**

Evolving opportunities for HBV Integration

World Health Organization



- Integration with other testing services or opportunities eg. HIV, antenatal or TB

- Integrated combo serology (HIV/HBV RDTs), including self-testing
- Use of integrated lab and POC multi-disease platforms for HBV DNA (centralised or decentralised)

- HBV care in primary care
- HBV care at HIV/ART clinics
- Integrated triple elimination (HIV/HBV/syphilis) in antenatal clinics

Build on substantial existing HIV/TB/COVID capacity

Integrated information systems

Feasibility and acceptability of integrating hepatitis B care into routine HIV services: a qualitative study among health care providers and patients in West Nile region, Uganda

Joan Nankya Mutyoba[1*], Claude Wandera[2], David Ejalu[1], Emmanuel Seremba[3], Rachel Beyagira[4], Jacinto Amandua[2], Kaggwa Mugagga[5], Andrew Kambugu[2], Alex Muganzi[2], Philippa Easterbrook[5] and Ponsiano Ocama[3]

A training for health care workers to integrate hepatitis B care and treatment into routine HIV care in a high HBV burden, poorly resourced region of Uganda: the '2for1' project

Integrating hepatitis B into HIV programs in sub-Saharan Africa: pilot clinic experience in Zambia

Wamundila Kawana [2], Michael Vinikoor [2], Sombo Fwoloshi [1,2], Lloyd Mulenga [1,2], Rokaya Ginwalla[1], Faith Kunda Mwila[1], Robert Chirwa[1], Eslone Chama[1], Annie Kanunga[1], and Edford Sinkala [2,4]

1. University Teaching Hospital HIV AIDS Programme.
2. University Teaching Hospital, Ministry of Health, Lusaka, Zambia
3. University of Alabama at Birmingham, Birmingham, Alabama, USA. School of Medicine
4. University of Zambia, School of Medicine

COLDA 2022

TRI-MOM (Gambia & Burkina Faso)

The TRIple elimination Model Of Mother-to-child transmission study

TRI MOM

Key challenges for updated guidelines and expanded treatment eligibility

1. More limited evidence-base to support recommendations
2. Existing biomarkers do not fully correlate with molecular and immunological status of disease
3. Significant proportion show minimal disease progression and indications for treatment for own health
4. Few public sector programmes for hepatitis B, and coverage through national insurance schemes

Acknowledgements

WHO- Global Hepatitis Programme
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Partner Collaborations

15 mins

Q&A

CHAI

Panelists

- Ms. Oriel Fernandes, Senior Director, Hepatitis Program, CHAI
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- Ms. Viola Kasone, Program Officer Viral Hepatitis/Advanced HIV Disease, Uganda National Health Laboratory Services, Ministry of Health
- Ms. Robia Islam, CHAI Global Diagnostics Team, Hepatitis
- Mr. Kenneth Kabagambe, Founding Executive Director of the National Organization for People Living with Hepatitis B (NOPLHB)
- Dr. Philippa Easterbrook, Global HIV, Hepatitis and STIs Programmes, World Health Organization (HQ)
- Ms. Emi Okamoto, Associate Director, Hepatitis/HIV Diagnostics, Global Diagnostics Team, CHAI

5 mins

Closing Remarks

Ms. Oriel Fernandes, Senior Director,
Hepatitis Program, CHAI