

What is new in treatment and diagnostics guidelines

HIV, Viral Hepatitis and Sexually Transmitted Infections

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HIV what's new



What's new in HIV testing guidance ?

1 Expanding self-testing

Self-testing is safe, effective and empowering

- Recommended across conditions and diseases including HIV, hepatitis C and syphilis – including dual HIV/syphilis self-tests
- Affordable and WHO prequalified self-tests increasingly available (\$1) and in the pipeline
- ST used in facilities, communities, pharmacies and through partners, peers and networks in +100 countries
- Check out the new self-testing tool kit for more resources: <https://www.who.int/tools/self-testing-implementation-toolkit-for-hiv-hcv-and-syphilis> (**launched October 2024**)

HIVST now recommended more broadly in facilities (**New recommendation**)

- Increases coverage when needed
- Replaces risk-based screening tools which miss too many undiagnosed PLHIV

HIVST now recommended for expanding prevention access (**New recommendation**)

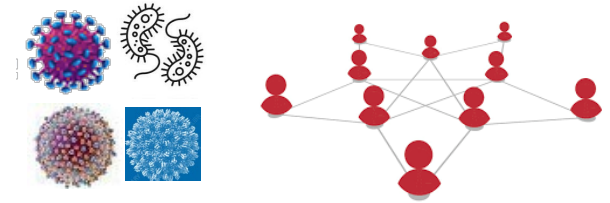
- PEP delivery – at start and completion
- Initiation, re-initiation and continuation of PrEP (oral & ring w/ ongoing research needed for LA-PrEP)
- Greater access, many benefits, lower costs
- No risks of increasing drug resistance at population-level
- Oral and blood-based ST both acceptable

Consolidated guidelines
on differentiated
HIV testing services

What's new in HIV testing guidance ?



2 Prioritize network-based testing services



Partner services (**New and updated recommendation**)

- New recommendation on STI partner services
- Provider-assisted partner services should be encouraged as still most effective strategy
- Provide options based on client needs (partner referral, provider-assisted, expedited partner therapy*)
- Services must always be voluntary

Social network testing now for all with risk (**New and updated recommendation**)

- ST, community-led, multiple rounds, virtual or in-person
- Do not need incentives or in-depth training
- More opportunities and work to optimize with AI

Prioritize and integrate services

- Prioritize and integrate based on capacity and resources
- Strategic opportunities with ANC, male partners, KP
- Consider dual HIV/syphilis RDT/ST and HBV within family and household outreach
- **WHO tool kit on network-based testing planned for Q1 2025**

What are network-based testing services?

Range of approaches (Partner services, social network, family/household testing) that extend testing by supporting individuals to disclose to, refer for testing, and/or distribute self-tests to partners, families, and other members of their social networks.

Recommended across HIV, viral hepatitis and STIs

**EPT is only an option for curable STIs*

3 Deprioritize recency testing in routine HTS programmes

WHO guidance recommends **against** recency testing in routine HTS

Findings from evidence review:

- No study showed evidence of effectiveness or clinical benefit
- Variable acceptability, with many finding intervention unacceptable
- Effects on social harm were uncertain.
 - Concerns about social harms such as stigma, conflict among community members, dissatisfaction with services and increased intimate partner violence were reported by providers and clients.
- Need to prioritize limited HTS resources toward impactful approaches
 - Very limited feasibility due to requirements for substantial resources, time, planning, training and monitoring.
 - High costs as does not replace diagnostic testing and requires additional tests and service costs (test kits, VL, implementation).
 - Concerns about reduced equity due to diversion of funds

What is recency testing?

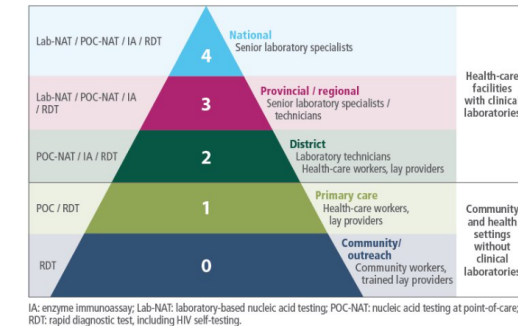
Assay used within an algorithm to estimate if HIV infection occurred in past 1-year

No WHO PQ recency assays

Guidance on recency for surveillance still supported and guidance unchanged

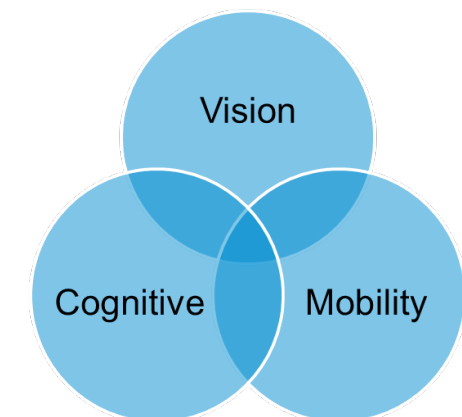
What's coming in 2025 on HIV testing and diagnostics?

- **Multiplex and integrated testing services in primary and self care models**
 - WHO policy brief on integration in development for 2025
 - WHO guidelines expected for late 2025/early 2026
- **Simplified and multi-disease quality management systems for testing in non-lab settings to capacitate countries and enable future programme sustainability**
 - WHO tool kit launch for Q1 2025
 - WHO & Global Fund Next Gen SI to support global quality and market strategy for sustainability
 - Important to leverage emerging financing to move on QA for local production as part of this
- **WHO promoting universal design principles to make testing accessible to all users**
 - Addressing lack of accessibility among people with disabilities – end users and providers
 - And contribute to the broader mandate for the WHA Diagnostics Resolution
- **What to expect market-wise for 2025-2026?**
 - More self-testing and self-care diagnostics in the space
 - More multiplex product demand and introduction
 - More integration, coordination and push toward sustainability and affordability to the market



+95% of all HIV testing worldwide is done at level 0 or 1 (health centres & community)

RDTs (including self-tests) are most commonly used for HIV and an increasingly important for STIs and viral hepatitis



Guidelines and guidance for HIV prevention through the use of antiretrovirals: PrEP and PEP

Pre-exposure prophylaxis (PrEP)

Daily **oral PrEP** for individuals at substantial risk of acquiring HIV (TDF/FTC or TDF/3TC).

PrEP through **dapivirine vaginal ring (DVR)** for cisgender women at substantial risk of acquiring HIV.

2019

2022

2015

2021

Event-driven, **on-demand**, or "2+1+1" PrEP, targeting gay men, bisexual men, and other men who have sex with men.

Injectable PrEP (**long-acting cabotegravir**) can be used as an additional option for preventing HIV in individuals at substantial risk of acquiring HIV.

Post-exposure prophylaxis (PEP)

2016: Use of 3-antiretroviral regimens (TDF/XTC/DTG) to prevent HIV acquisition following potential exposure.

2024: Updated guidelines for the implementation of PEP in community settings - **NEW**

WHO implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection

Provider module for oral and long-acting PrEP



World Health Organization

Guidelines for HIV post-exposure prophylaxis



World Health Organization

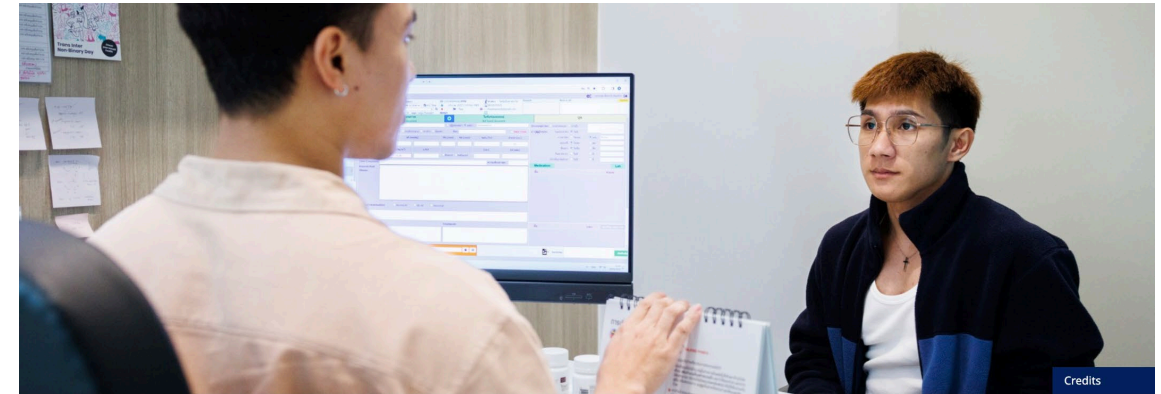
WHO next steps with Lenacapavir

Lenacapavir, a new long-acting PrEP product, was included in the Expression of Interest (EOI) for **WHO Pre-qualification list of medicines** in November 2024, which invites product applications from manufacturers.

WHO is convening a **Guideline Development Group** on LEN for HIV prevention, 28-30 January 2025, with guidelines launched by July 2025 at the latest.

WHO is participating in the **EMA Medicines4All mechanism** to obtain a positive opinion for lenacapavir, enabling a streamlined assessment under WHO PQ.

WHO, alongside Global Fund, PEPFAR, UNAIDS and Unitaid, are conveners for [Coalition to Accelerate Access to Long-Acting PrEP](#)



Long-acting injectable lenacapavir continues to show promising results for HIV prevention

26 September 2024 | Departmental update | Reading time: 2 min (586 words)

WHO welcomes the latest findings from the PURPOSE-2 trial on long-acting injectable lenacapavir (LEN) for HIV prevention. An interim analysis, announced on 12 September 2024, demonstrated the drug's remarkable efficacy in preventing HIV. LEN, an HIV-1 capsid inhibitor delivered by subcutaneous injection twice a year, was shown to be highly effective in preventing HIV among cisgender men, transgender men, transgender women,

Related

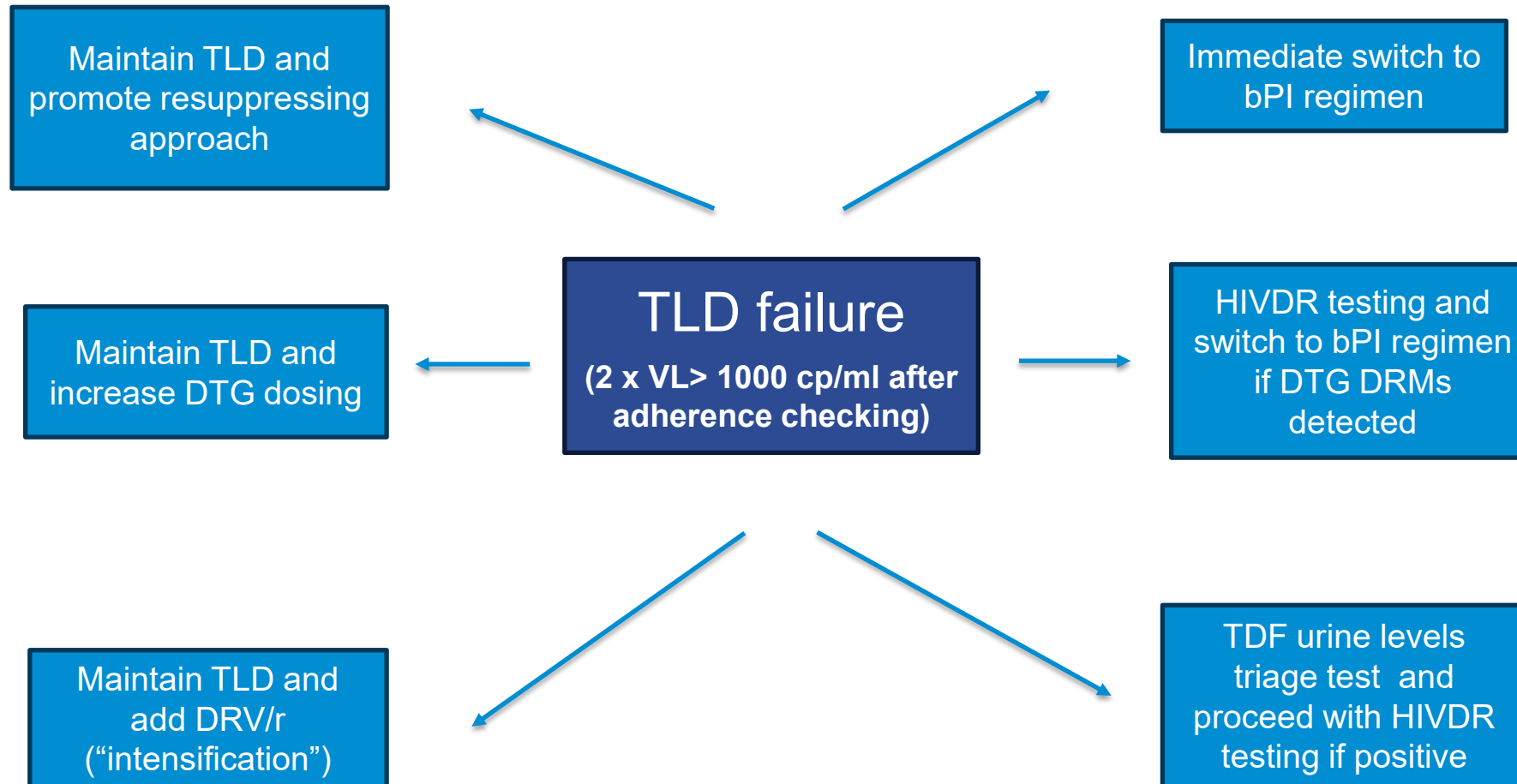
[Pre-exposure prophylaxis \(PrEP\)](#)

[Global HIV Programme](#)

Future Trends in Global HIV Treatment: Key Messages

WHO Treatment policy	Current status	Future trends/expected changes
Use of DRV/r	<p>For those failing to 1st line DTG containing regimen, boosted PI containing regimens are recommended, with ATV/r and LPV/r as preferred PI options.</p> <p>DRV/r is an alternative 2nd line option, preferred in third-line regimens.</p>	<p>For those failing to 1st line DTG-containing regimen, DRV/r is expected to be the preferred PI option for either 2nd or 3rd line regimens (generic coformulation available)</p> <p>Considerations on dosing of DRV/r in PW (OD vs BD)</p>
Recycling tenofovir/abacavir and use of TAF	<p>If tenofovir was used in the failing first-line regimen, it is recommended to switch to AZT in the second-line regimen, and vice versa (box 4.3)</p> <p>No recommendation on abacavir recycling</p> <p>TAF recommended as an alternative option in children and could be used in certain clinical circumstances in adults (limited safety data at the time of the guidelines review)</p>	<p>Tenofovir (TDF or TAF) or abacavir (in children), can be recycled in 2nd line regimens, even if part of the failed 1st line treatment (NADIA , CHAPAS 4, ODISSEY)</p> <p>Choice between TDF and TAF should consider clinical and programmatic parameters (expanding use of TAF as an alternative option to mitigate TDF renal /bone effects but need to balance with TAF cardiometabolic & weight gain effects). Considerations on peds dosing</p> <p>If tenofovir is combined with a boosted-PI, renal function should be monitored more frequently. For patients using TAF and boosted PIs, TAF dosage should be adjusted</p>
Use of dual therapies as simplification strategy	No recommendation	Use of dual regimens (oral and injecting) can be considered in special circumstances, as simplification for PLHIV stable on ART or for those with severe adherence challenges with standard oral daily regimens

Potential strategies to manage TLD failure we need evidence



Where next for advanced HIV disease?

Q2 2024:
CD4 Donor Alignment meeting

Q3 2024:
AHD Satellite at AIDS2024, AMDS 2024 - AHD session

Q3 2024
- AIDS Vs AHD Delphi Process - 1st stakeholder meeting
- AMDS/Manufacturers meeting - AHD diagnostics forecast

Q4 2024:
- Systematic reviews on AHD prevalence, hospitalisations, deaths.
- New AHD indicators - CD4 and cryptococcal disease in GAM
- 2nd round of DELPHI process for AIDS Vs AHD

2025:
- New WHO recommendations on CD4, post-discharge, Kaposi Sarcoma and LAM, update of Chapter 5 of consolidated guidelines 2021
- Introduction of new WHO PQ processes for AHD, new estimates of prevalence, hospitalisation and death causes
- Framework for antimicrobial resistance and integration of AHD programming into PHCs

Viral Hepatitis what's new



2024 Global Hepatitis report:

Increasing mortality and slow decline in incidence of viral hepatitis

Need to increase coverage of prevention, diagnosis and treatment through a public health approach



Major gaps in testing and treatment of hepatitis B and C

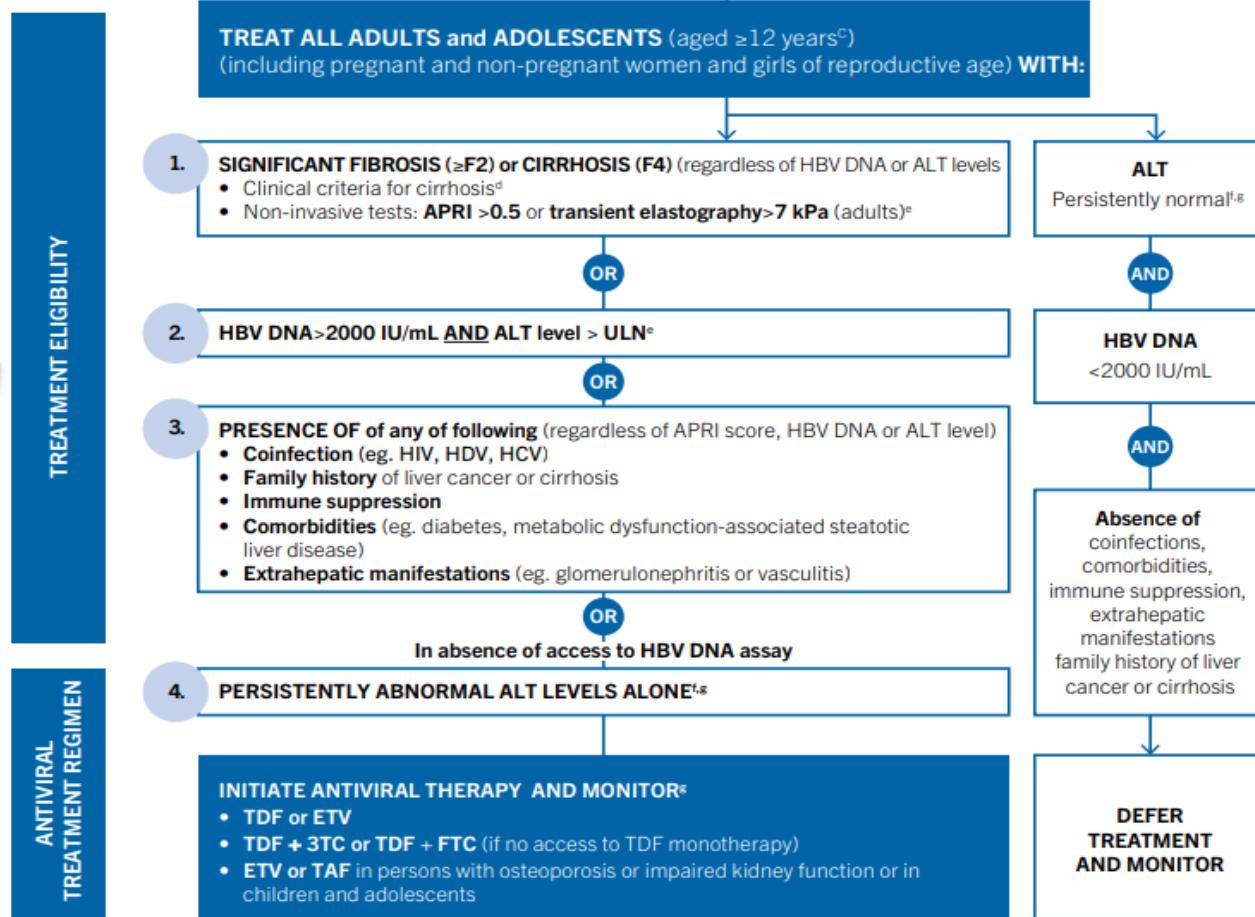
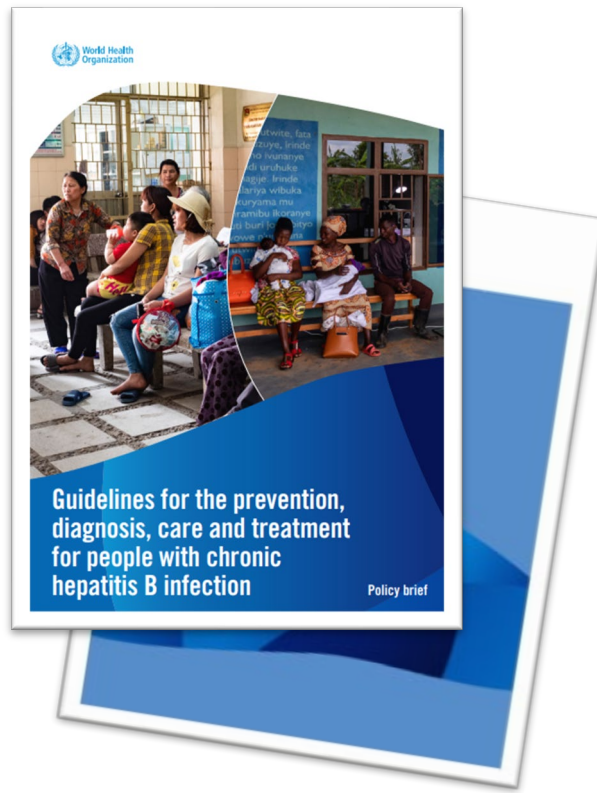
Without expansion in access, the world will face increasing cases of liver cancer in the next generation, with associated increasing care costs and hepatitis-related deaths

Getting on track to achieve (SDG)

- Requires **treating 40 million people with hepatitis B** and providing **curative treatment to 30 million people with hepatitis C** by the end of 2026.

<https://www.who.int/publications/i/item/9789240091672>

New WHO HBV guidelines (2024): Transforming the hepatitis B response to a public health response



Key recommendations

- Non invasive fibrosis assessment
- Who to treat
- First-line treatment
- PMTCT
- Simplifying diagnosis
- Simplifying service delivery

- When implemented will support earlier treatment and capture **(at least 50%)** of all HBsAg-positive people versus about 8–15% previously
- Options for those without access to HBV DNA testing,

Preventing mother to child transmission of HBV using antiviral prophylaxis (new 2024 recommendation)

Updated 2020 recommendation

In settings where HBV DNA or HBeAg testing is available,

*Prophylaxis with TDF is recommended for **all HBV-positive** (HBsAg-positive) pregnant women with **HBV DNA** $\geq 200\ 000$ IU/mL **or positive HBeAg**

(strong recommendation, moderate-certainty evidence)

New 2024 recommendation

In settings where neither HBV DNA nor HBeAg testing is available,

*Prophylaxis with TDF for **all HBV-positive** (HBsAg-positive) pregnant women may be considered

(conditional recommendation, low-certainty evidence)



Rationale: HBV DNA or HBeAg Available

- TDF prophylaxis for HBsAg-positive pregnant women with high HBV DNA viraemia or positive HBeAg supported by most clinical trials

Not available

- Modelling analysis suggested that prophylaxis all strategy would have great impact with about **4.9 million neonatal infections averted** (95% CI: 4.7 million–5.1 million)

Simplified service delivery

Implementing the public health response for hepatitis C

Simplified criteria (Who to treat?): HCV treatment for all infected people above 12 years of age (pregnant women excepted)

RECOMMENDATIONS

Decentralization, Integration and Task-shifting *Moving treatment and care out of speciality clinics*

Decentralization:

We recommend delivery of HCV **testing** and **treatment** at peripheral health or community-based facilities, and ideally at the same site, to increase access to diagnosis, care and treatment.

These **facilities** may include primary care, harm reduction sites, prisons and HIV/ART clinics as well as community-based organizations and outreach services.

Integration:

We recommend integration of HCV **testing** and **treatment** with existing care services at peripheral health facilities.

These **services** may include primary care, harm reduction (needle and syringe programme (NSP)/opioid agonist maintenance therapy (OAMT) sites), prison and HIV/ART services.

Strong recommendation/ moderate certainty of evidence (PWID/prisoner) low (general population, PLHIV)

Task-sharing: We recommend delivery of HCV **testing, care and treatment** by trained non-specialist doctors and nurses to expand access to diagnosis, care and treatment.

Strong recommendation/ moderate certainty of evidence

<https://www.who.int/publications/i/item/9789240052697>

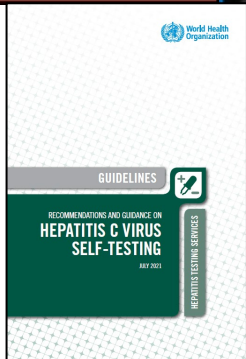
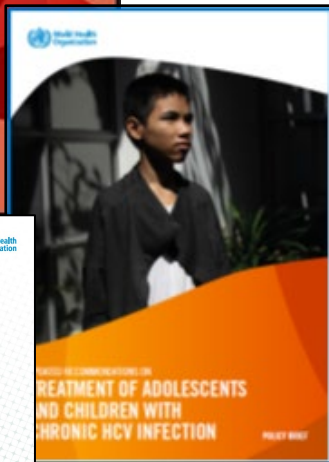
Treatment

Without cirrhosis

- Sof/Vel for 12 weeks or
- Sof/Dac for 12 weeks or
- G/P for 8 weeks²

With compensated cirrhosis

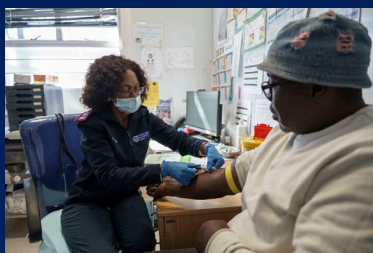
- Sof/Vel for 12 weeks or
- Gl/P for 12 weeks² or
- Sof/Dac 24 weeks



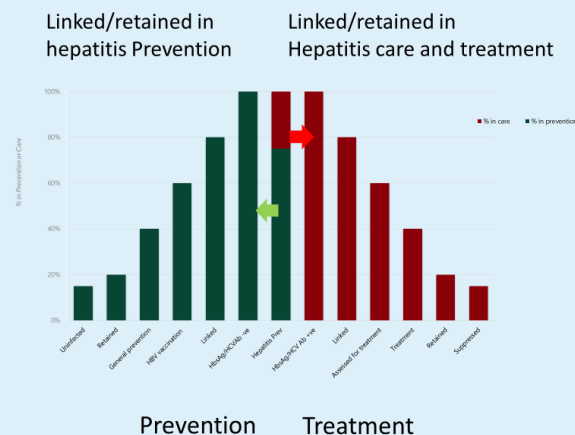
Planning person-centred hepatitis B and C testing services:

Operational guide. Priorities in designing and integrating testing approaches

Coming
soon
December 2025



Testing is the critical entry point into hepatitis B and C prevention, care and treatment continuum



Source: Modified from Frits van Griensven, 2014 Thailand 25

About the guide

To support countries operationalizing WHO recommendations for hepatitis B and C testing by **developing a strategic mix of testing approaches tailored to each country's unique context**

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

Emphasizes integration and **differentiated service delivery models based on 4 building blocks (When, where, by who and what) for:**

- a) mobilizing and creating demand
- b) Testing implementation
- c) linkage to care

Country case studies from England, Georgia, Morocco and Uganda demonstrating key enablers and good practices in implementing testing approaches

Annexes (recommendations and products), tools and further guidance

Looking ahead

Norms and standards

Simplification and consolidation of existing HBV/HCV guidance on prevention, testing, treatment and monitoring

- ❑ Consolidated **treatment** recommendations and guidelines
 - ❑ Existing HBV guidelines 2015 → Revised HBV update 2024,
 - ❑ Revised HCV update-including service delivery & paediatrics 2022,
 - ❑ HBV PMTCT 2020
 - ❑ New recommendations on who to treat and patient monitoring
 - ❑ Revised cascade of care monitoring for HBV and HCV
- ❑ Consolidated **testing** recommendations and guidelines
 - ❑ HBV and HCV testing 2017,
 - ❑ HCV self test 2021 → now HDV testing 2024
 - ❑ Priorities in designing and integrating testing approaches
 - ❑ Planning person-centered hepatitis B and C testing services
- ❑ Promote the need to strengthen routine data systems for monitoring trends over time



STIs what's new



15 November 2024
Enhanced Gonococcal Antimicrobial Surveillance Programme (EGASP):... surveillance report 2023
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10 November 2024
List of key WHO-recommended maternal and newborn health... commodities
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25 October 2024
Eliminating HIV, viral hepatitis, sexually transmitted infections and... tuberculosis as public health
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22 July 2024
Implementing the global health sector strategies on HIV, viral hepatitis and... sexually transmitted
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18 July 2024
Framework for monitoring sexually transmitted infections and strengtheni... surveillance
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17 July 2024
Updated recommendations for the treatment of Neisseria gonorrhoeae,... Chlamydia trachomatis, and
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16 July 2024
Recommendations for the treatment of Trichomonas vaginalis, Mycoplasma... genitalium, Candida
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11 July 2024
Mobilize for action on sexually transmitted infections - Berlin meeting... report, October 2023
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1 July 2024
Recommended package of enabling and health interventions for HIV, viral... hepatitis and STI
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27 June 2024
Antimicrobial Resistance Diagnostic Initiative
Download Read More

Comprehensive STI case management guidelines

Service delivery – access to service, integration, operational issues

Non-infected: Primary prevention

Infected

Asymptomatic

Symptomatic

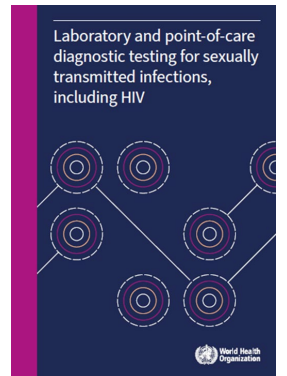
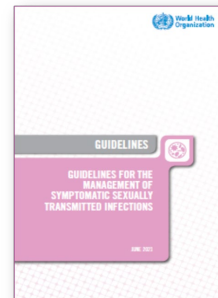
Partner mgt.

Effective treatment

Monitoring and evaluation



Screening-NG/CT: FSW, MSM, Adolescent, PW - GRC approved



Updated treatment guidelines in STIs

- ***N. gonorrhoeae***: ceftriaxone 250 mg to **ceftriaxone 1 gram** → delay the development of resistance to last-line treatment options.
- ***C. trachomatis***: **Doxycycline 100mg x2/d x7 days**, while reserving azithromycin for emerging infections, such as *Mycoplasma genitalium*.
- **Syphilis: BPG** > alternative treatment regimens, especially to prevent vertical transmission during **pregnancy**.

Additional testing recommendations:

1. Offering **syphilis self-testing** to increase testing coverage
2. Offering **RDTs for both treponemal and non-treponemal components** to support the differentiation between current/active syphilis and previously treated/cured infection (high-prevalence settings).

- **Recommendations for the treatment of other STIs**

Updated recommendations for the treatment of *Neisseria gonorrhoeae*, *Chlamydia trachomatis* and *Treponema pallidum* (syphilis), and new recommendations on syphilis testing and partner services

Recommendations for the treatment of *Trichomonas vaginalis*, *Mycoplasma genitalium*, *Candida albicans*, bacterial vaginosis and human papillomavirus (anogenital warts)

World Health Organization

Explore the full findings in EGASP's 2023 report.

Antimicrobial resistance in gonorrhoea, risks turning a treatable infection into a **major global health threat**, highlighting the urgent need for continuous surveillance.

EGASP data is vital for guiding effective treatment strategies and containing the spread of drug-resistant gonorrhoea.

Management of asymptomatic STIs

GRC approved guidelines

In settings where prevalence is high, and resources and capacity are available, WHO suggests to screen for *N. gonorrhoeae* and/or *C. trachomatis*:

Pregnant women accessing health care services for antenatal visits.

Sexually active adolescents and young people (10–24 years) accessing health care services (when balancing resources and benefits of screening, female adolescents may be prioritized).

Sex workers accessing health care services.

Men who have sex with men accessing health care services.

Remarks: Screening with high quality molecular assay or rapid point of care

STI partner services

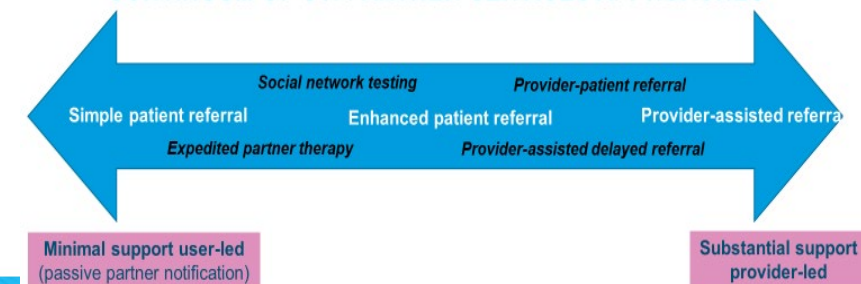
WHO recommends that **STI partner services** should be offered to people with STIs as a range of options that are based on their needs and preferences and are within a voluntary comprehensive package of STI testing, care and prevention (*strong recommendation, low certainty in evidence*).

Remarks:

- **Human rights:** STI partner services must always be voluntary and never mandatory. Coercive or forced testing is never warranted. All consenting clients should have their privacy protected and personal information should be kept confidential.
- **Important to offer options:** There are a range of STI partner services which should be offered based on client preferences, feasibility and resources available.
- **Linkage:** Linkage to STI management services for sexual partners is an essential component of STI services.
- **Integration:** STI partner services should be based within a broader programme and package of services.



CONTINUUM OF STI PARTNER SERVICES APPROACHES



Thank you

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STIs guidelines

HIV, hepatitis & STIs cross-cutting guidelines

Guidelines on HIV, viral hepatitis and sexually transmitted infections

The Department of Global HIV, Hepatitis and Sexually Transmitted Infections Programmes leads the development of guidelines in the area of [HIV](#), [viral hepatitis](#) and [sexually transmitted infections \(STIs\)](#), as well as guidelines focusing on key aspects of the public health response [across the 3 infectious disease areas](#).

Recommendations in WHO guidelines are based on sound scientific evidence. Fundamental steps in the process for guideline development include formulating key questions, evidence retrieval and synthesis, and appraisal of the quality of the evidence. But the methods used in these steps were originally conceived for the development of clinical interventions as part of the evidence-based medicine movement.

WHO develops guidelines on a broad array of clinical, public health, health system, health promotion and implementation strategies. These interventions are often highly context-specific, with multiple factors that directly and indirectly impact the health and societal outcomes.

Hepatitis guidelines

19 July 2024

Consolidated guidelines on differentiated HIV testing services

9 April 2024

Consolidated guidelines on person-centred viral hepatitis strategic...

29 March 2024

Guidelines for the prevention, diagnosis, care and treatment for people with...

17 October 2022

Updated recommendations on treatment of adolescents and children...

All hepatitis guidelines

Technical information on hepatitis

HIV guidelines

22 July 2024

Guidelines for HIV post-exposure prophylaxis

19 July 2024

Consolidated guidelines on differentiated HIV testing services

17 July 2024

Updated recommendations for the treatment of Neisseria gonorrhoeae...

29 July 2022

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29 July 2022

Consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis...

All STIs guidelines

Technical information on STIs

<https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/guidelines>