

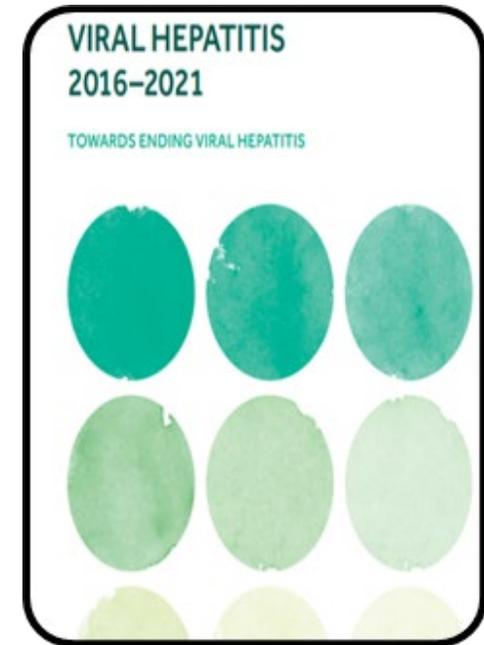
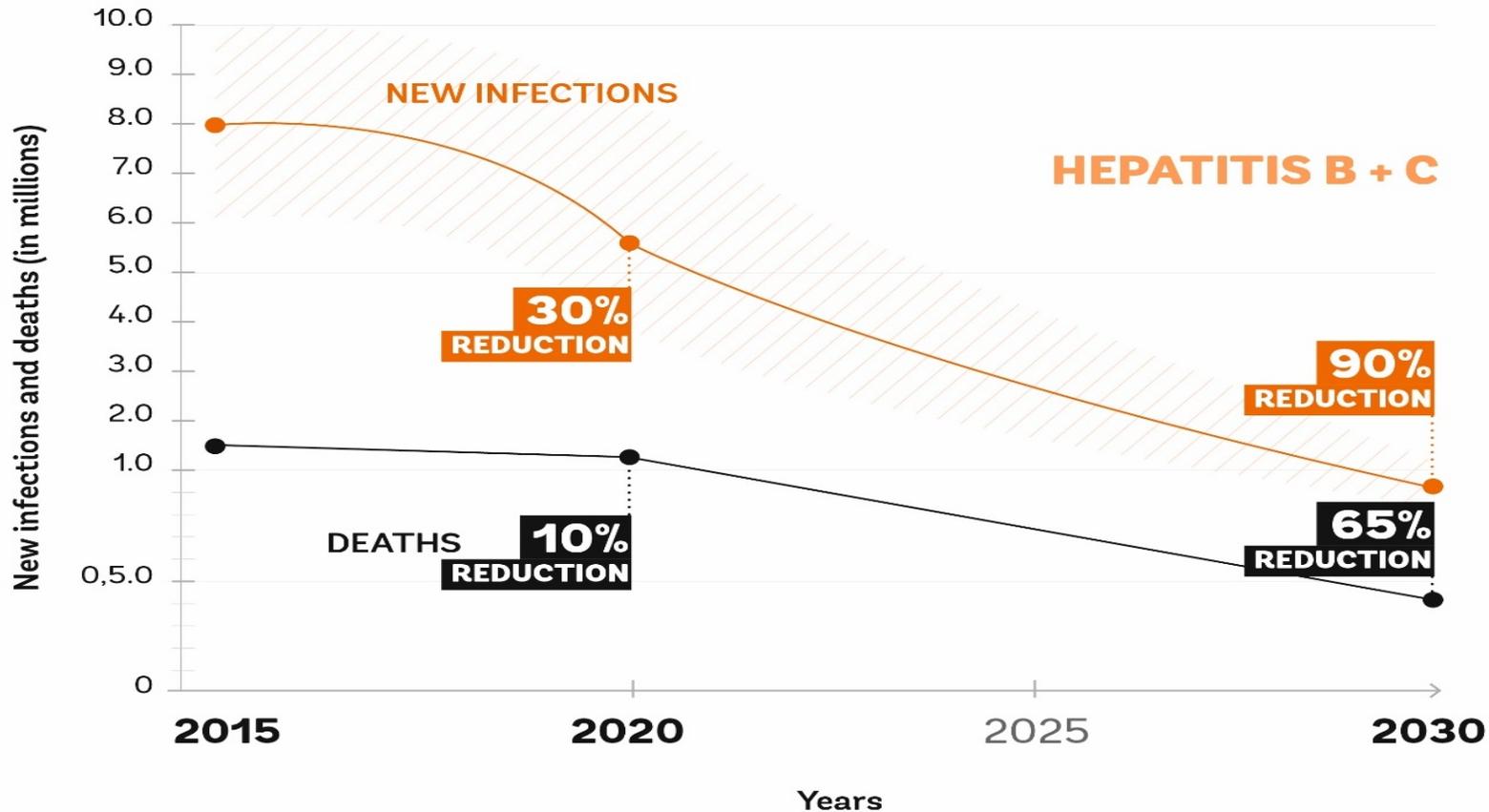
WHO recommendations and evidence on HCV self-testing



Dr Niklas Luhmann, WHO HQ

ETW Webinar; Self-testing for Hepatitis C; 8 November 2021

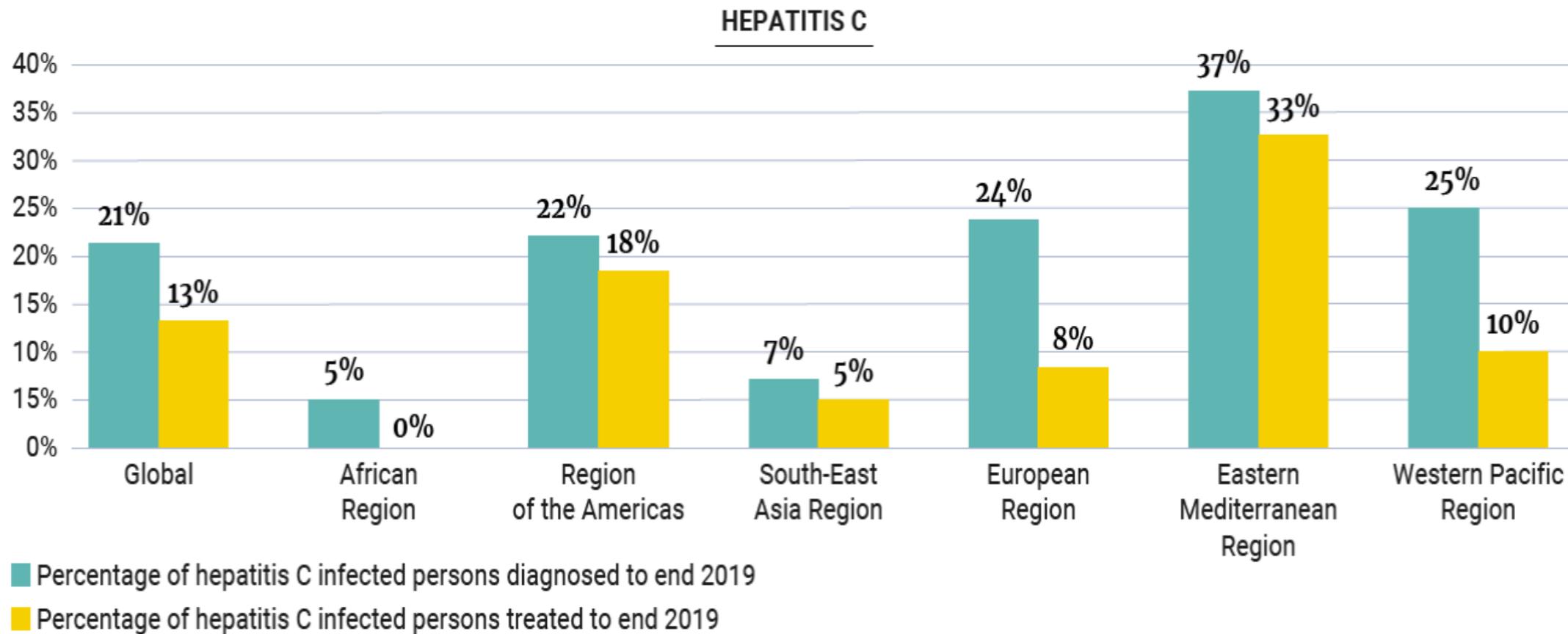
WHO's goal is to eliminate viral hepatitis as a major public health problem by 2030



Target: 90% of those with chronic HCV infection diagnosed

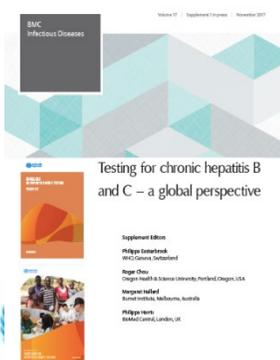
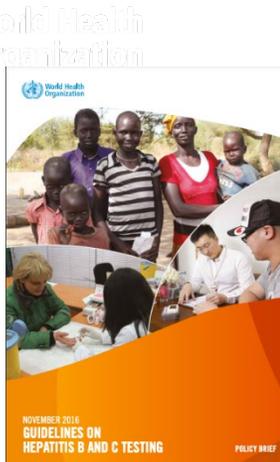
Target: 80% of eligible persons with chronic hepatitis C virus infection treated

Only 21% of estimated 58 million people with chronic HCV infection were diagnosed in 2019 – *Variation by regions*



Source: Global progress report on HIV, viral hepatitis and sexually transmitted infections, 2021

WHO Hepatitis testing guideline recommendations 2017



Topic	Recommendation
Who to test?	<ul style="list-style-type: none"> ▪ Focused testing for most affected populations*, those with a clinical suspicion of chronic viral hepatitis, family members/children, and sexual partners (HBV), healthcare workers. ▪ General population testing: In settings with $\geq 2\%$ or $\geq 5\%$ (intermediate/high) HBsAg or HCV Ab prevalence. ▪ Birth Cohort testing (HCV): where specific identified birth cohorts of older persons at higher risk of HCV infection <p>* PWID, people in prisons, MSM, sex workers, HIV-infected, tattoos, transfusions, some migrant pops from endemic countries, some indigenous populations, children of HBV/HCV +ve mothers</p>
How to test?	<ul style="list-style-type: none"> ▪ A single serological assay (EIA or RDT) that meets minimum performance standards with prompt NAT testing + linkage to care
Confirmation of HCV viraemia	<ul style="list-style-type: none"> ▪ Nucleic acid testing (NAT) (quantitative or qualitative RNA) or core HCV antigen assay, with comparable clinical sensitivity
Promoting uptake and linkage	<ul style="list-style-type: none"> ▪ Use of DBS specimens for virology \pm serology ▪ On-site or immediate RDT testing with same day results ▪ Trained peer and lay health workers ▪ Clinician reminders to prompt provider initiated, facility-based testing ▪ Testing as part of integrated services at a single facility

WHO recommendation on HCV self-testing (2021)



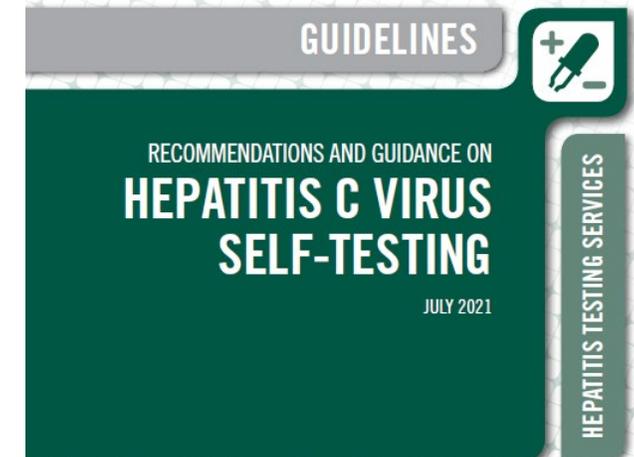
Hepatitis C virus (HCV) self-testing should be offered as an additional approach to HCV testing services

(strong recommendation, moderate-certainty evidence)



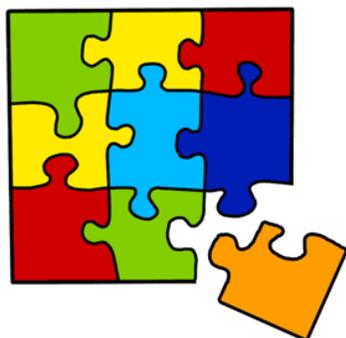
Remarks:

- HCV self-testing needs to be followed by **linkage to appropriate post-test services**, including confirmation of viraemic infection, treatment, care and referral services, according to national standards.
- It is desirable to **adapt HCV self-testing service delivery and support options** to the national and local context, which includes community preferences.
- **Communities, including networks of key and vulnerable populations and peer-led organizations, need to be meaningfully and effectively engaged** in developing, adapting, implementing and monitoring HCV self-testing programmes.



Approach to guidelines update – multiple sources and use of HIVST evidence for effectiveness

Used multiple complementary sources of evidence to provide a complete picture



Benefits/Harms

HCVST systematic review

HIVST systematic review (indirect evidence)

Values and Preferences, acceptability

HCVST systematic review

Community-led V&P studies

HIVST V&P Review (indirect evidence)

Feasibility

HCVST systematic review

Special usability & acceptability studies

HIVST policies, programs, implementation

Resource Use

HCVST costs and cost-effectiveness (HCVST systematic review and mathematical modeling analysis)

Equity – Discussion by the Guideline Development Group

Key findings and summary of evidence



No direct evidence on HCVST effectiveness was identified.

From **HIVST systematic reviews**, evidence from 27 RCTs showed that:

- HIVST increases the uptake of HIV testing.
- Proportion of people diagnosed with HIVST is greater than facility-based testing.
- Proportion linked to care with HIVST is comparable to facility-based testing.
- Misuse of HIVST and social harms associated with HIVST are rare.



HCVST values and preferences, usability and cost-effectiveness studies in a range of settings and populations showed that:

- Many people are willing and able to perform HCVST with minimal support.
- HCVST is acceptable and feasible in a range of populations and settings.
- HCVST has the potential to increase equity by reaching those who may not otherwise test.
- HCVST may cost more per diagnosis than facility-based testing, but more cases would be diagnosed.

Implementation considerations

- Enabling policy environment
- Quality assured products
- Choice of service delivery models and support tools
- Linkage pathway
- Monitoring to optimize implementation
- Community engagement

Planning

Strategic planning: review of programme data, understanding testing gaps and identifying priority populations.

Enabling policy environment: review of national policies and updating of existing policies or development of new policies that are supportive of HCVST. Development of standard operating procedures and training manuals as needed.

Regulatory framework and quality-assured products: review of national IVD regulatory and registration policies and removing barriers to availability of quality-assured HCVST products. Review of available WHO-prequalified products⁴ and use of WHO collaborative registration procedures⁵ for expedited national registration of products. Consider procurement, logistics and supply chain solutions.

Community engagement throughout the design, implementation and monitoring approaches, including development of appropriate and context-specific messages, information materials, resources and job aides.

Demand generation and mobilization activities: Social marketing and promotion to raise awareness and generate demand. Mobilization of staff including peers and lay workers to support implementation.

Resource considerations: consider available human and financial resources for sustainable implementation.

Implementation

Design service delivery models*: match models to focus populations. Consider **who** are the intended users (members of key populations or populations from specific age groups, social and/or sexual contacts); **where** are kits distributed (facilities, other fixed sites, communities, mobile outreach services); **when** and **how** are kits distributed (timing and frequency – ongoing, occasional, or event-/campaign-based); **who** distributes kits (in-person – providers, peers, clients; automated – vending machines; home delivery).

Optimized support tools and options*: define a minimum support package for self-testers during and after self-testing (in-person, videos, virtual, hotlines).

Referral pathways: develop efficient and effective pathways for confirmatory testing and linkage to services including prevention, treatment and care.

Training of providers and distributors

Integration with other services such as HIV self-testing programmes (depending on epidemiology) may reduce costs.

* Offering choice is desirable.

Monitoring and evaluation

Data collection: decide on indicators and data collection systems for programme monitoring and evaluation. Use and enhance existing data collection systems where feasible and appropriate. Triangulation of data sources and information is key.

Strategies to mitigate risk, harms and adverse events with the use of appropriate messaging. Approaches to monitor harm and redress where necessary.

Regular review of data to refine programmes and optimize implementation.

Post-market surveillance⁶ for HCVST kits.

Many service delivery models can be used and adapted



Facility-based

Distribution from facilities or other fixed sites for use within the facilities or for later use. Kits can be given to clients for secondary distribution (see below).

Potential facilities for distribution include public and private viral hepatitis services, such as general practitioners and primary health care, HIV testing and prevention services. Other options include distribution through key population clinics or drop-in centres – for example, harm reduction services for people who inject drugs, such as needle and syringe programmes and opioid substitution therapy.



Community-based

Distribution in the community during periodic campaigns, events, mobile outreach or home-based (door-to-door) distribution. Community health care workers, lay providers or peers can distribute HCVST kits and support self-testers in the community.

Integration with existing community-based testing programmes can improve efficiency and optimize resources. Community-led models can be considered.



Secondary distribution

Secondary distribution includes distribution to partners, social contacts or peers. It may involve HCVST distribution through social or sexual contacts, households, drug injecting partners and networks, including by those who are diagnosed HCV-positive. In high HCV burden settings distributing HCVST kits through antenatal care clinics or other health services to partners of women clients can be considered.



Online, digital and other virtual distribution models

This typically involves online ordering through websites or other platforms and home delivery or in-person collection. A range of online platforms such as websites, social media, dating apps, and other digital media can be used. HCVST kits can be provided for free, at a cost or with coupons/vouchers for reduced cost.

Such models have the potential to reach populations that do not use conventional services and in the COVID-19 context. Such options may be more attractive for young people and members of key populations.



Retail outlets, pharmacies and vending machines

Through these models, kits are typically provided at a cost to users but price can be reduced or subsidized through public-private partnerships and distribution of coupons or vouchers.



Faith based

Distribution from faith-based settings may be useful in high HCV burden settings.



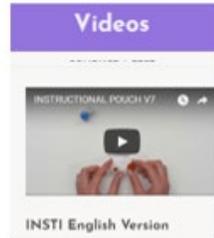
Workplace programmes

Distribution to workers for testing themselves and/or for their partners. Consider sustainable models such as through public-private partnerships and/or insurance packages to cover or reduce the cost.

Variety of support tools for HCVST – can be adapted for local context and community preferences



1. **In-person** demonstration, training or observation (one-on-one, with partners or in groups). Consider peer support/led options for key populations.
2. **Video** instructions or demonstration (including online links to videos, QR codes, virtual real time support).
3. **Telephone hotline** (can be integrated into existing national hotline services).
4. **Messaging platforms** (short message service through telephone, Internet, social media).
5. **Educational information** via radio, television, leaflets, brochures, the Internet, social media and applications for smartphones/tablets.
6. **Local information and resources** (for example, on counselling services, testing sites, treatment centres and where to access prevention services).



Next Steps on HCVST

Product pipeline

- No product with stringent regulatory approval yet
- Promising prototypes for oral and blood based HCVST
- TSS published in Q1 2021 (awaiting PQ submissions and approvals)
- The assessment phase of [ERP Round 18](#) is underway and the outcome of the initial review will be shared with manufacturers late October-early November.



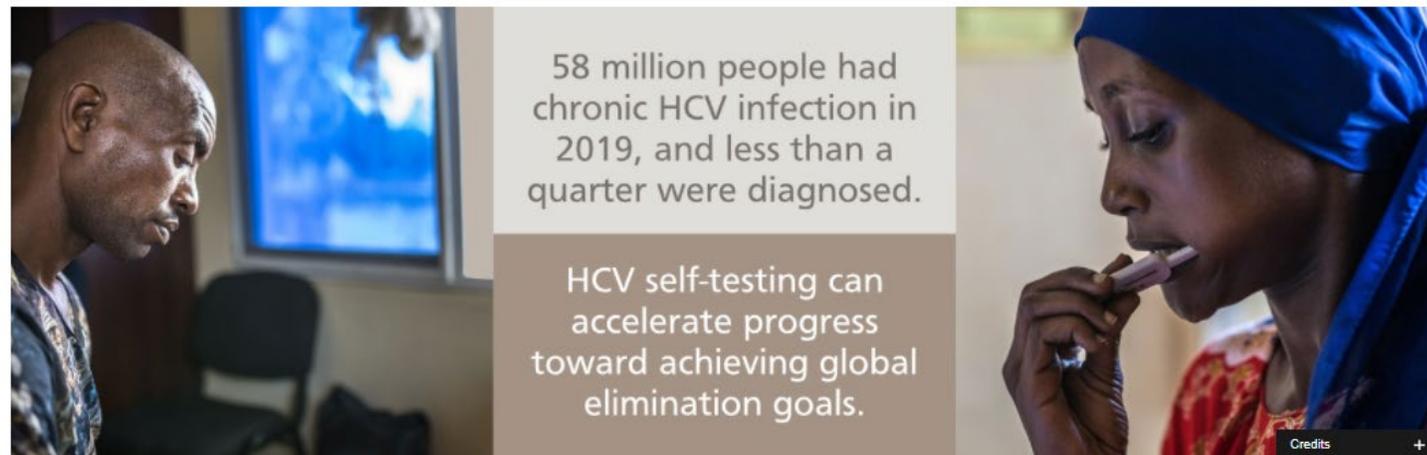
Pilot projects

- STAR-Unitaid partners discussing pilot projects in 5 countries looking mainly at modalities of integration into HIVST in different populations: [India](#), [South Africa](#), [Cameroon](#), [Nigeria](#) and [Vietnam](#).
- FIND research in [Georgia](#), [Pakistan](#) and [Malaysia](#) – piloting distribution models and assessing effectiveness through 3 RCTS
- [Georgia](#): CDC/WHO/FIND pilot in general population with 2 distribution models : secondary distribution in cancer screening sites and pharmacy based

Resources



[Home / News / WHO releases first guidelines on hepatitis C virus self-testing](#)



[WHO releases first guidelines on hepatitis C virus self-testing](#)

[Community perspectives on HCV self-testing – Video](#)

[PowerPoint slides](#)

[Recommendations and guidance on hepatitis C virus self-testing](#)

[Guidelines on hepatitis B and C testing](#)

[Guidelines for the care and treatment of persons diagnosed with chronic hepatitis C virus infection](#)



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WHO Steering Group

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Thank You!

