World Health Organization

GUIDELINES

RECOMMENDATIONS AND GUIDANCE ON

HEPATITIS C VIRUS SELF-TESTING

JULY 2021

HEPATITIS TESTING SERVICES

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Recommendations and guidance on hepatitis C virus self-testing

ISBN 978-92-4-003112-8 (electronic version)
ISBN 978-92-4-003113-5 (print version)

Suggested citation. Recommendations and guidance on hepatitis C virus self-testing. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

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Design and layout: 400 Communications Ltd.

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ACKNOWLEDGEMENTS

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Belen Dinku and **Laurent Poulain** provided administrative support. **Yann Siegenthaler** provided communication support.

Mary Henderson and **Jura Editorial Services** edited the publication.

Funding

Unitaid provided funding to support this work, including the systematic reviews of evidence and evidence compilation and the development, editing and both print and electronic publication of these guidelines.

ABBREVIATIONS AND ACRONYMS

CDC	United States Centers for Disease Control and Prevention
FIND	Foundation for New Innovative Diagnostics
GDG	Guideline Development Group
HCV	hepatitis C virus
HCV cAG	HCV core antigen
HCVST	hepatitis C virus self-testing
HIV	human immunodeficiency virus
HIVST	HIV self-testing
IVD	in-vitro diagnostic
PICO	population, intervention, comparison, outcome
RCT	randomized controlled trial
RDT	rapid diagnostic test
RNA	ribonucleic acid
STI	sexually transmitted infection
UHC	universal health coverage
USAID	United States Agency for International Development
WHO	World Health Organization

GLOSSARY

Chronic hepatitis C virus (HCV) infection

The presence of viraemic HCV ribonucleic acid (RNA) or HCV core antigen (HCV cAg) in association with positive serology for HCV antibody.

HCV antibody

Antibody to HCV, which can be detected in the blood usually within two or three months of HCV infection or exposure.

HCV cAG

Nucleocapsid peptide 22 of HCV, which is released into the plasma during viral assembly and can be detected early on and throughout the course of infection.

HCV RNA

HCV viral genomes that can be detected and quantified in the blood by nucleic acid testing.

HCV self-testing (HCVST)

HCVST is a process in which an individual collects their own specimen (blood or oral fluid), performs a rapid diagnostic test for the presence of HCV antibodies, and then interprets the result, often in a private setting, either alone or with someone they trust.

HCV testing services

The term "HCV testing services" encompasses the full range of services that should be provided when diagnosing HCV infection. These include: HCV antibody and confirmatory testing (detection of HCV RNA or HCV cAG), brief pre-test information and post-test counselling, linkage to appropriate disease staging as well as care and treatment services and other support services, and coordination with laboratory services to support quality assurance.

Key populations

Groups of people who, due to specific high-risk behaviours and additional stigma and discrimination, are at increased risk for human immunodeficiency virus (HIV), HCV and other infectious diseases irrespective of the epidemic type or local context. Key populations often face legal and social issues related to their behaviours that increase their vulnerability to HIV, HCV and hepatitis B virus infection. These guidelines refer to the following groups as key populations: men who have sex with men, people who inject drugs, people in prisons and other closed settings, transgender people and sex workers.

Rapid diagnostic test (RDT)

Immunoassays that detect antibodies or antigens and can give a result in less than 30 minutes. Most RDTs can be performed with capillary whole blood collected by finger-stick sampling, but now also oral fluid sampling.

Vulnerable populations

Groups of people who are particularly vulnerable to HCV infection in certain situations or contexts. These may include mobile/migrant populations from high or intermediate endemic countries, certain indigenous populations, HIV-infected persons, persons with a history of certain health care procedures (such as reception of blood products or haemodialysis).

EXECUTIVE SUMMARY

Less than a quarter of people with chronic HCV infection know their status.

Despite recent advances in highly effective and affordable hepatitis C virus (HCV) treatment, many people with HCV infection do not know their status. The World Health Organization (WHO) estimates that 58 million people had chronic HCV infection globally in 2019, and only 21% of them were diagnosed. Lack of awareness, poor access to testing and treatment services, stigma, discrimination and other structural barriers contribute to such low uptake of HCV testing services.

WHO has set a global goal to eliminate HCV as a public health problem by 2030. Meeting this goal requires innovative approaches and service delivery models for reaching the people who remain unaware of their HCV infection and linking them to treatment and care services. Self-testing is one such approach. The COVID-19 pandemic has demonstrated the value of self-care and self-testing options in situations where direct contacts with health care providers are limited, thus often enabling programmes to continue essential services.

WHO developed the first comprehensive guidelines on testing for hepatitis B and C infection in 2017. These guidelines recommended facility- and community-based HCV testing approaches and highlighted HCV self-testing (HCVST) as a potential future approach to reduce the gap in HCV diagnosis. Building on the experiences and lessons learned from HIV self-testing (HIVST) implementation, these new guidelines address a specific gap by providing a recommendation and new guidance on HCVST. The guidelines will support countries to make decisions about strategic implementation and scale up of HCVST.

The primary audience for these guidelines is policy-makers, programme managers, implementers and health care providers responsible for planning and implementing viral hepatitis testing, prevention, care and treatment services, particularly those in low- and middle-income countries. These guidelines also will be a resource for donor and development agencies, international organizations, nongovernmental organizations and civil society and community-based organizations, including those working with or led by key populations and affected communities.

These guidelines were developed in accordance with procedures established by the WHO Guidelines Review Committee. The recommendation in these guidelines is based on the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach to reviewing evidence and formulating recommendations. A guideline development group (GDG) reviewed the evidence, including systematic review findings and additional information on values and preferences, feasibility and cost-effectiveness of the intervention, and made the new recommendation on HCVST (Box 1).

Box 1. NEW WHO recommendation on hepatitis C virus self-testing (HCVST)

HCV self-testing should be offered as an additional approach to HCV testing services *(strong recommendation, moderate-certainty evidence)*.

Remarks

- HCVST 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 HCVST 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 HCVST programmes.

These guidelines present key implementation considerations. HCVST is a private and convenient option for reaching people with HCV who do not otherwise test using existing services and who may prefer self-care options. These may include key populations and other vulnerable groups as well as those with a high burden of HCV infection, such as men and migrant populations from high burden settings, according to the local epidemiology and context. Also, HCVST can be a valuable addition to expand access to HCV testing in the general population in high burden settings. HCVST implementation should be focused on priority populations and regions with the greatest gaps in testing coverage.

HCVST can reach people with HCV who do not otherwise test using existing services and who may prefer self-care options.

Countries introducing HCVST need to adapt national testing policies and update product regulation, registration and related policies to ensure the availability of affordable quality-assured test kits. Programmes should provide potential users with accurate and accessible information about HCVST use and where and how to obtain stigma-free confirmatory testing, as well as how to access prevention, treatment, care and support services after HCVST. Service delivery models and support options for HCVST should be adapted to the local epidemic context and community preferences. Offering users choices in service delivery models and support tools is desirable. Health care workers, including lay providers, key population networks and peer-led organizations, can play important roles in supporting the development, implementation and monitoring of HCVST programmes and should be engaged meaningfully and effectively throughout the design and implementation of programmes.

1. INTRODUCTION

1.1 Background and rationale

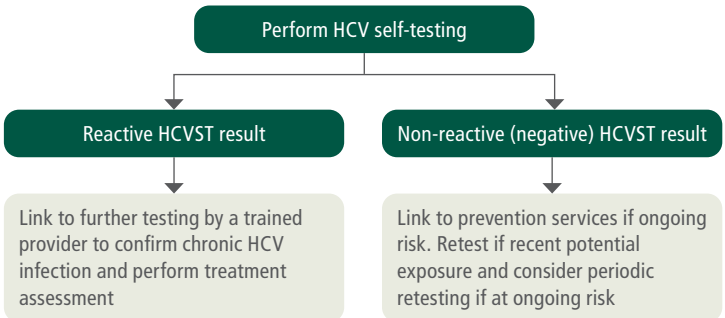
The World Health Organization (WHO) has set a global goal to eliminate hepatitis C virus (HCV) as a public health problem by 2030, with targets to diagnose 90% of those with chronic HCV and treat 80% of those eligible for treatment. The past five years have seen great advances in highly effective and affordable HCV treatment. However, due to lack of awareness and limited access to testing and treatment services, many people with chronic HCV are not diagnosed and not able to access treatment. WHO estimates that 58 million people globally had chronic HCV infection in 2019, but only 21% of those were diagnosed. Between 2015 and 2019, a total of 9.4 million (62%) of those diagnosed with chronic HCV infection were treated, using direct-acting antivirals *(1)*. Despite strong national programmes in some countries focused on elimination of HCV, testing uptake has plateaued over time or they have faced challenges reaching key and vulnerable populations. New and innovative approaches are needed to accelerate progress toward the HCV elimination targets. Self-testing is one such approach.

New and innovative approaches are required to accelerate progress toward the HCV elimination goals. Self-testing is one such approach.

HCV self-testing (HCVST) is a process in which an individual collects their specimen (blood or oral fluid), performs a simple rapid diagnostic test (RDT), and then interprets their result, often in a private setting, either alone or with someone they trust. Like HIV self-testing (HIVST), HCVST does not provide a diagnosis but requires additional testing. All reactive HCVST results need to be followed by further testing by a trained provider according to the national algorithm for testing and diagnosis to confirm HCV infection and the need for treatment (Fig. 1). WHO recommends a ribonucleic acid (RNA) or HCV core antigen (HCV cAG) test to confirm viraemic infection as well as further clinical assessment before starting treatment *(2)*.

A reactive HCVST result requires further testing by a trained provider to confirm the diagnosis.

Fig. 1. HCVST testing strategy



The first WHO guidelines on hepatitis B and C testing were published in 2017 *(2)*. Those guidelines focused on facility- and community-based testing approaches and highlighted HCVST as a potential future approach to reduce the gap in HCV diagnosis. The WHO-recommended testing approaches are based on different epidemiological contexts and include considerations on where to apply focused approaches for specific geographies or priority populations with the greatest HCV burden and gaps in diagnosis, such as key populations,[1] or more general population approaches in high HCV burden settings. The guidelines recommend the use of a single, quality-assured serological in vitro diagnostic (IVD) test – either a laboratory-based immunoassay or an RDT – for detecting HCV antibodies. A reactive HCV antibody test result is followed by a quantitative or qualitative molecular RNA test as the preferred option to diagnose viraemic infection. In settings with limited access to RNA testing, HCV cAG testing can be considered as an alternative *(3)*. These new 2021 guidelines address a gap in the 2017 guidelines and recommend HCVST as an additional approach to HCV testing services.

These guidelines build on HIVST evidence and implementation experiences. HIVST has been successfully implemented in a range of settings and has proved effective in increasing access to and uptake of testing, particularly for populations that may not otherwise test, including key populations. In 2016 WHO first recommended HIVST as an additional approach to HIV testing services. In 2019 WHO updated the recommendation based on a review of 32 randomized controlled trials (RCTs) and provided guidance and operational considerations on service delivery models *(4)*. As of July 2020, 88 countries had developed national policies supporting HIVST, and nearly half of these are implementing them *(5)*. HIVST is now a routine approach in many national HIV programmes *(6)*. The service disruptions caused by the COVID-19 pandemic have further highlighted the potential of HIVST to support continuity of services when opportunities to visit facilities and see providers are limited *(7)*.

These guidelines provide evidence-based recommendations on HCVST and highlight considerations for successful and sustainable implementation of HCVST as an additional testing approach.

1.2 Objectives

The primary objective of these guidelines is to supplement the existing WHO guidelines on hepatitis testing services *(2)* and to support countries and national programmes in reaching 2030 HCV elimination goals by helping them reach people who may not otherwise test.

1.3 Intended audience

The primary audience for these guidelines is national and subnational programme managers and policy-makers, ministries of health and related agencies that are responsible for the national health sector response to viral hepatitis, particularly in low- and middle-income countries. The recommendation and guidance are also important for clinicians, health care providers, including lay providers and community health workers, who are the first points of contact for patients and laboratory staff. These guidelines will be relevant for implementers of viral hepatitis services, nongovernmental organizations and community-based organizations, including those working with or led by key populations. This document also can serve donors, development agencies and international organizations to support planning, implementation, and monitoring and evaluation of HCV testing programmes.

[1] WHO defines key populations as men who have sex with men, people in prisons or other closed settings, people who inject drugs, sex workers and transgender people.

The recommendations are also important for persons with or at risk of acquiring HCV and other infections (hepatitis B, HIV, tuberculosis, sexually transmitted infections (STIs)) and members of key populations and other vulnerable population groups.

1.4 Guiding principles

The following principles have informed the development of these guidelines and should guide the implementation of the recommendations:

- HCV testing must be delivered within a public health and universal health coverage (UHC)[2,3] framework that promotes equity and respects human rights.
- HCV testing services need to be accessible to the populations most affected in a stigma free and non-discriminatory environment.
- All HCV testing services should adhere to WHO's five core principles for HIV and viral hepatitis testing, namely Consent, Confidentiality, Counselling, Correct test results and Connection (linkage to prevention, treatment and care services).
- HCV testing services should always be voluntary. Coercive or forced testing is never warranted. An enabling environment that removes barriers such as stigma, discrimination and criminalization and empowers the communities is important for increasing access to and uptake of HCV testing services, especially among those at high ongoing risk and members of key populations.

[2] UHC means that all people have access to the health services they need, when and where they need them, without financial hardship. It includes the full range of essential health services, from health promotion to prevention, treatment, rehabilitation and palliative care. A WHO fact sheet provides further information: https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-(uhc).

[3] Hepatitis is a specific programme area of the UHC Compendium developed by WHO. The UHC Compendium is a database of health services and intersectoral interventions designed to assist countries in making progress towards UHC. It is accessible at: https://www.who.int/universal-health-coverage/compendium.

2. METHODS FOR GUIDELINES DEVELOPMENT

These guidelines were developed in accordance with procedures established by the WHO Guidelines Review Committee *(8)*. The recommendation in these guidelines is based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to reviewing evidence and formulating recommendations *(9)*. Consistent with previous WHO guidelines, these guidelines are based on a public health approach that considers effectiveness, acceptability, feasibility and resource needs across a variety of settings.

All external contributors to the guidelines, including members of the Guideline Development Group (GDG) and the External Review Group, completed a WHO declaration of interests form in accordance with WHO policy for experts (Web Annex B).

The systematic reviews on HCVST and HIVST followed a research question in population, intervention, comparator, outcome (PICO) format (Web Annex C). The systematic review findings and evidence-to-decision-making tables were prepared in accordance with the GRADE process, and they were shared in advance and presented at the GDG meetings, where an independent methodologist facilitated the discussions.

Web Annex A details the method for developing these guidelines. All Web Annexes are available on the WHO Website.

3. REVIEW OF THE EVIDENCE AND RECOMMENDATION

3.1 Systematic review of effectiveness: benefits and harms

Evidence on the effectiveness of the intervention was derived from systematic reviews on HCVST and HIVST (Web Annex C). No eligible studies were identified in the systematic review on HCVST. A decision was made *a priori* with the GDG that, in the absence of HCVST evidence, HIVST evidence would be used as indirect evidence. In the systematic review on HIVST, 27 RCTs were included that compared HIVST with standard facility-based HIV testing. These RCTs represented a wide range of populations and countries. No RCTs were conducted among people who inject drugs; however, one observational study among people who inject drugs was included.

The evidence reviewed showed that HIVST consistently increased uptake of HIV testing among both key populations and the general population. A meta-analysis found an overall 77% higher uptake of HIV testing with HIVST than with standard facility-based testing services. In one observational study among people who inject drugs, HIV testing more than tripled after the engagement of peers and the offer of assisted self-testing and optimized HIV case finding through a social network approach *(10)*.

Data from seven RCTs showed that a pooled proportion of 65% (range: 25%–100%) of those with reactive HIVST results reported confirmatory testing within two weeks to five months. Overall, rates of HIV positivity and linkage following HIVST among those randomized were comparable to those with standard facility-based HIV testing services. A greater number of people were diagnosed and linked to treatment or care with HIVST than with standard HIV testing services.

Misuse, adverse events and social harms associated with HIVST (including coercion and partner violence) were rare. There was no difference in occurrence of social harm or adverse events following HIVST when compared with standard testing services. Adverse events, especially relationship breakdown, were often temporary and resolved within days. Studies suggest harms related to HIVST are sometimes exacerbated by pre-existing conditions within a couple, such as alcohol abuse and history of gender-based violence *(11)*. No suicides were reported in any of the RCTs.

Box 2 summarizes key evidence from the systematic reviews. The GDG assessed the applicability and relevance of HIVST evidence to HCVST and determined that:

- priority population groups for both HIV and HCV overlap in many settings, namely key populations, including men who have sex with men and people who inject drugs;
- interventions and follow-up steps after self-testing are sufficiently similar;
- the outcomes from the HIVST review are highly relevant and applicable to HCVST.

In view of these similarities, the GDG determined that further downgrading of HIVST evidence was not necessary.

The GDG determined that the overall benefits of HCVST outweigh any potential harm. The GDG also noted large gaps in existing HCV testing coverage globally in many settings and that HCVST could contribute to closing these gaps.

Box 2. Key findings from the systematic reviews

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. No suicides were reported.

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.

3.2 Values and preferences

Values and preferences were identified from HCVST and HIVST systematic reviews and community-led studies on HCVST. In the HCVST systematic review, five studies were identified that presented findings relevant to values and preferences. Four of these studies took place in Europe and involved people who use drugs, hepatology/infectious disease outpatient clinic attendees and young people *(12-15)*. The one remaining study was conducted in the general population in South Africa *(16)*.

Two studies reported that participants valued HCVST for its simplicity, rapid results and the ability to learn their own status in private and then make their own decisions about seeking care *(14, 16)*. Some participants expressed concerns about instructions for use and potential for user errors. Participants desired a clear pathway to additional testing and to care and treatment. They also wanted messages and instructions accompanying HCVST kits that would suggest steps to take after obtaining self-test results.

Three studies reported on self-collection for HCV testing (only collection of own specimens, and not running the test) *(12, 13, 15)*. In two of these studies, self-collected fingerstick specimens and preparation of dried blood spot specimens were found to be acceptable and feasible *(12, 15)*. In one study among trained nurses, self-collection using oral fluid tests was found to be acceptable and feasible *(13)*.

The above findings from HCVST review are similar to those reported previously for HIVST *(4)*. In summary, HIVST is found to be highly acceptable in a range of settings and populations. Users value high quality test kits with clear and simple instructions and discreet packaging. People want HIVST kits at an affordable price. They had no clear preference for oral fluid or blood-based self-test kits *(4, 17)*. Many users expressed a desire for a choice in service delivery models for accessing self-test kits, the type of self-test kits and support options.

WHO coordinated with the Foundation for New Innovative Diagnostics (FIND) to conduct values and preferences studies on HCVST across 10 low- and middle-income countries with communities most affected by HCV, including people who inject drugs, men who have sex with men, the general population in certain settings and health care workers (total sample=920) (Web Annex D). Participants from all population groups, including key populations, the general population and health care workers, considered the benefits and advantages of HCVST to outweigh potential harms or disadvantages.

Overall, participants in values and preferences studies felt that the benefits and advantages of HCVST outweighed potential harms and disadvantages.

Participants saw HCVST as an innovative tool that could motivate users to access testing, demand treatment and modify risk behaviours. Participants noted low awareness in the communities regarding HCV and that HCVST could help raise awareness if accompanied by awareness campaigns and appropriate messaging. The perceived benefits of HCVST included privacy, confidentiality and the ability to make their own decisions about when and how to seek treatment and care. The perceived barriers to HCVST use included negative attitudes and discrimination by providers, the need for confirmatory testing (although participants acknowledged that this applies to any initial HCV testing at facilities or in the community), the lack of established HCV referral and care pathways, the potential for errors, the lack of in-person pre-/post-test support and the potential risk for psychosocial harms. Participants did not perform HCVST in these studies.

Overall, participants supported the availability of HCVST, ideally free of charge or at affordable pricing, with distribution and promotion approaches suited to the local context. Participants said that HCVST should be distributed in ways that reduce stigma and discrimination for vulnerable and marginalized groups. Health care workers, too, saw value in HCVST availability and felt it could be a safe way to increase early diagnosis and access to HCV treatment.

3.3 Feasibility

WHO also coordinated with FIND to conduct a multi-country usability and feasibility study of HCVST among a total of 1066 participants in China (men who have sex with men), Egypt (the general population), Georgia (people who inject drugs and men who have sex with men), Kenya (people who inject drugs), Pakistan (the general population), Rwanda (the general population) and Viet Nam (people who inject drugs and men who have sex with men). Web Annex E presents details.

Overall, this study found that HCVST was highly acceptable. More than 94% of participants in five of the six countries would recommend HCVST to friends and family, except for China, where 74% would recommend it. Most participants were able to use HCVST kits correctly. However, some user errors did occur. These errors seldom led to wrong results, as indicated by inter-operator agreement of >95% (that is, agreement between the self-test result and the result of a professional-use test performed by a trained provider). Most participants successfully completed all steps of the self-test procedure independently. However, people who inject drugs often asked for assistance (Viet Nam: 67%; Kenya: 77%). Between 42% and 96% of participants in different settings (42% in Pakistan, 44% in Egypt, 66% in Kenya and >80% in the other sites) found the self-test kit easy or very easy to use. In Rwanda similar

More than 94% of participants in five of the six countries would recommend HCVST to friends and family.

proportions of participants found oral fluid (86%) and blood-based (83%) kits easy or very easy to use. Support options that include an in-person demonstration or assistance or video instructions may be considered during early implementation, particularly for people with low literacy levels and highly marginalized communities such as people who inject drugs.

Most participants were able to use HCVST kits correctly. Some user errors did occur, but these errors seldom led to wrong results.

Widespread use of HIVST and additional published literature on self-collection of oral fluid or fingerstick blood specimens for dried blood spot testing and rapid testing by community workers and peers attest to the feasibility of this intervention *(13, 15, 18-22)*.

3.4 Cost and cost-effectiveness

The systematic review identified no studies assessing cost or cost-effectiveness of HCVST. WHO coordinated with FIND and the University of Bristol to conduct a multi-country cost-effectiveness modelling analysis of HCVST in priority populations. Settings and populations studied included: men who have sex with men in China, men ages 40–49 years in Georgia and people who inject drugs in Kenya and Viet Nam (Web Annex F).

HCVST costs more per diagnosis than facility-based testing, but more cases would be diagnosed.

The analysis showed that cost per diagnosis with HCVST was greater than with standard facility-based testing, but that more people would be diagnosed and cured with the introduction of HCVST. HCVST is likely to be cost-effective in settings with high HCV burden or when focused on those with the greatest gaps in diagnosis. The cost would be reduced if the price of HCVST were decreased and if a greater proportion of HCVST users were linked to confirmatory testing and treatment and referral pathways were optimized. The model did not consider opportunity cost to users, accessibility and equity issues and the cost of identifying additional HCV infections with standard approaches, which is likely to be substantial. The model did not include the potential impact of HCVST over a longer horizon in terms of benefits of treatment and reduction in transmission. The overall costs of HCVST programmes were often driven by local treatment costs.

Similar findings are reported in HIVST literature, which suggests that HIVST is cost-effective in high HIV burden settings and when focused on populations with the greatest gaps and low treatment coverage.

3.5 Equity and human rights

In light of the evidence reviewed and its discussions, the GDG noted the potential for HCVST to increase equity by reaching those who prefer self-testing or have difficulties accessing standard facility- and community-based testing services. This includes members of key populations and vulnerable populations, who are disproportionally affected by HCV and yet often have low testing and treatment coverage. The GDG also noted the impact that HCVST can have on maintaining essential services in the COVID-19 context as a potential strategy to improve equitable access. The GDG concluded that HCVST can likely improve equity by reaching those who may not otherwise test.

3.6 Recommendation

Considering the evidence on effectiveness of HCVST, its acceptability to stakeholders, feasibility to implement and potential for cost-effectiveness and improved equity, the GDG deemed that the overall benefits of HCVST outweigh the potential harms and risks. By consensus, the GDG decided to recommend HCVST as an additional approach to HCV testing services, with additional remarks (Box 3). The strength of the recommendation and the quality of evidence were determined through the GRADE approach *(23)*.

Box 3. NEW WHO recommendation on hepatitis C virus self-testing (HCVST)

HCV self-testing should be offered as an additional approach to HCV testing services *(strong recommendation, moderate-certainty evidence)*.

Remarks

- HCVST 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 HCVST 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 HCVST programmes.

4. IMPLEMENTATION CONSIDERATIONS

4.1 Considerations for successful implementation and strategic planning

Globally, the public health response to HCV is evolving, with important differences across countries and regions. Increasingly, countries are developing national viral hepatitis programmes and plans. However, these are often not sufficiently costed and funded. In many countries awareness of HCV and access to testing services, diagnostics for confirmation of viraemic infection, as well as prevention and treatment access, remain low. These gaps need to be addressed to improve the demand for HCV testing generally. HCVST should be strategically implemented to support achievement of the overall goal of HCV elimination.

Countries that have a well-developed national HCV response and elimination programme with well-functioning pathways for confirmatory testing, prevention, treatment and care services should consider inclusion of HCVST to accelerate progress and to reach those being missed with standard approaches. Countries that are still developing their national HCV programmes and testing plans should carefully consider the optimal positioning of HCVST in their settings. In addition to introducing HCVST, they should also expand facility- and community-based testing, rapid testing with lay providers and optimal referral pathways as part of a strategic mix of testing approaches.

As for any HCV testing, HCVST should be focused on areas and populations with the greatest burden and gaps in testing and treatment coverage. Thus, it is important first to analyse and evaluate the existing national HCV testing programme to identify gaps so that HCVST can be best positioned to complement existing services and address these gaps.

HCVST is a particularly attractive option for reaching people with HCV who are unable to access or have difficulty accessing existing services or who prefer self-care options. This includes populations at ongoing risk such as key populations (including men who have sex with men and people who inject drugs) and other vulnerable populations (such as mobile/migrant populations from high burden countries, certain indigenous populations and people with HIV). Depending on the epidemiological context, HCVST also can be a valuable addition that can expand access to HCV testing in the general population, such as in certain age groups, and among men or other priority groups with low access, including persons with a history of exposure to certain repeated health care procedures involving receipt of blood products or haemodialysis.

Integrating HCVST with existing self-testing or self-care interventions may be useful in certain epidemiological contexts and may improve efficiency. For example, in some countries HIVST programmes are well established and can support introduction and opportunities for funding HCVST programmes.

Fig. 2 summarizes key implementation considerations for programmes, policy-makers and implementers to consider when introducing HCVST.

Fig 2. Summary of implementation considerations when introducing HCVST

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 products[4] and use of WHO collaborative registration procedures[5] 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 surveillance[6] for HCVST kits.

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[4] WHO prequalified in vitro diagnostics. https://extranet.who.int/pqweb/vitro-diagnostics/vitro-diagnostics-lists

[5] Collaborative procedure for accelerated registration. https://extranet.who.int/pqweb/medicines/collaborative-procedure-accelerated-registration

[6] Post-market surveillance for prequalified in vitro diagnostics. https://extranet.who.int/pqweb/vitro-diagnostics/post-market-surveillance

4.2 Policy and regulatory frameworks

To support implementation of HCVST, certain national policies and regulations may need to be developed or adapted. Legal and regulatory barriers to the sale, distribution, promotion and use of IVDs for self-testing will need to be addressed or removed. Countries should provide clear pathways for national registration of HCVST kits and support the availability of quality-assured products at an affordable price. WHO prequalification and the Unitaid/Global Fund Expert Review Panel for Diagnostics processes provide pathways for countries to ensure access to quality-assured products. WHO's Collaborative Regulatory Procedure for IVDs can be utilized to accelerate national registration of forthcoming WHO-prequalified HCVST products *(24)*.

Distribution of HCVST kits should be accompanied by appropriate instructions for use, messages and materials (for example, brochures, peer-led messages and videos in local languages). This communication should support correct use of HCVST kits and appropriate actions to take after HCVST as well as seek to prevent misuse or harm (such as coercive testing, violence or discrimination). Community members, lay providers and peers can play a role in developing and disseminating messages to raise awareness and encourage appropriate use of HCVST. It is important to develop channels, such as community-based monitoring systems *(25)*, to report, monitor and address any misuse or harm. In addition, post-market surveillance systems may need to be established and/or adapted to identify and report product problems and/or adverse events related to HCVST.

Existing policy frameworks and implementation strategies for HIVST programmes can be utilized to accelerate the introduction and scale-up of HCVST. In countries where HIVST has not yet been implemented, a harmonized approach may be considered to develop or adapt regulations and registration, policies and quality assurance systems for both HIVST and HCVST.

4.3 Service delivery approaches for HCVST

It is important to identify optimal approaches to deliver HCVST based on disease burden, identified testing gaps, available resources and the populations that are prioritized for HCVST programmes. Service delivery models should be adapted to suit the local context and community preferences. Fig. 3 presents details and considerations for different service delivery models for HCVST. Offering different models and choice in type of test kits (both oral fluid and blood-based) may improve uptake.

Fig 3. HCVST service delivery models

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.

4.4 Support options for HCVST

Many people can independently self-test accurately using manufacturer's instructions for use and without any additional support. Some may need support, and they can be supported with a variety of options ranging from Internet/video-based instructions, in-person instructions (training, demonstration or observation either one-on-one or in group settings) or virtual real-time support. These options need to match community needs and preferences. Where possible, offering a range of support options is desirable.

Populations with disabilities (for example, visual impairment), low literacy levels, language barriers (for example, ethnic minorities, migrants), people in rural communities, and certain key populations (for example, people who inject drugs) may require assistance. Other support options include telephone hotlines, text message services and digital tools such as mobile applications. Some other populations such as those with higher literacy levels, as well as frequent or repeat testers may not need assistance.

Peer support models, particularly when working with key populations or vulnerable populations and those with low education or literacy levels, may be considered for first-time testers and when first introducing HCVST. Over time, as users gain experience with self-testing and awareness increases, sustainable and less intensive support options may be sufficient.

4.5 Linkage to service following HCVST

Effective linkage to appropriate prevention, treatment and care services after self-testing is critical to achieve the benefits of HCVST. Programmes need to decide on the optimal approaches to facilitate and support linkage to post-test services for those who receive reactive HCVST results, as well as for those who test negative and are at ongoing risk. This will include clear referral pathways to confirmatory testing and treatment for those with reactive results and to prevention services for those who test negative and are at ongoing risk. Depending on the context and setting, programmes can decide whether, after a reactive HCVST result, to use another HCV antibody RDT or to go directly to confirmatory testing for viraemic infection using RNA or core antigen assays. Lessons on referral pathways learned during early implementation can inform development of optimal pathways for scale-up.

Instructions, information materials and tools accompanying HCVST kits should clearly identify steps for further testing and linkage to treatment specific to the setting. Additional tools may also be useful, such as email, social media or messaging platforms, community or social media influencers, appointment cards, hotlines and community-based follow-up.

Peer navigators, who can support and guide individuals through the necessary steps after their self-test result, and clinical assessment or treatment initiation at home or in a community setting have proved effective in improving linkages after HIVST when compared with HIVST alone *(4, 26-28)*. Where resources are available, similar approaches can be adapted for HCVST. Linkage options and support for key and vulnerable populations should be prioritized, as these people may face additional barriers that need to be addressed to improve linkage to care following HCVST.

4.6 Monitoring and reporting

As for any testing approach, it is important to routinely monitor and evaluate HCVST implementation, including review of outcomes and impact. Through operational research, pilot programmes and early implementation experiences, programmes can identify the most effective, feasible and acceptable models for different settings and populations. These models can be optimized over time through routine monitoring and ongoing adaptation to support scale-up to achieve national programme goals.

Programmes need to develop a monitoring plan and related indicators to assess programme effectiveness. Because of the discreet and private nature of HCVST, routinely collecting in-depth information on HCVST use, results and linkage can be challenging and could discourage use. However, existing data collection systems and triangulation of data sources can be useful for routine monitoring. At a minimum, programmes should routinely collect data on the type and numbers of kits distributed, the populations reached by HCVST distribution and the number of patients coming to facilities for confirmatory testing who report prior HCVST use. Virtual platforms, including websites and applications, as well as digital tools, can also be used for voluntary self-reporting of self-test use, results and linkage *(29)*.

Routine national or population-specific representative surveys may be useful to track country progress and trends in HCVST awareness, interest and use. In settings where HCVST is available in the private sector, sales data from pharmacy councils and Internet-based providers may be collected to help track access and availability. At the same time, countries should monitor, report and respond to adverse events, even though they are generally rare.

Community health care workers, pharmacists, networks of key and vulnerable populations and peer-led organizations can play important roles in supporting monitoring of HCVST programmes.

5. PRIORITY RESEARCH GAPS

The GDG identified several areas for future operational research to inform implementation and scale-up decisions on HCVST (Table 1). For any HCVST research, it is important to partner with communities and networks of populations affected by HCV to identify priorities and to inform the design, implementation and monitoring of research efforts and outcomes.

Table 1 Operational research priorities for HCVST

Operational research area	Key objectives and outcomes
Product optimization (in coordination with manufacturers)	Improving product design and usability Optimizing instructions for use, tools and messages to support appropriate actions according to test results
Service delivery and support	Identifying and optimizing cost-effective, non-discriminatory and inclusive service delivery and support models for different populations and settings
Integration	Exploring opportunities and appropriate models for integrating HCVST into existing HIV self-testing and other self-care programmes
Linkage pathways	Design client-centred and cost-effective pathways to confirmatory testing and treatment after reactive HCVST results, including direct linkage to RNA testing options and strategies to improve these linkages
Positioning in national programmes and plans	Optimal positioning of HCVST in national programmes and national testing plans Costing and budget impact analyses to plan high-impact scale-up

REFERENCES

1. 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 (https://www.who.int/publications/i/item/9789240027077, accessed 29 June 2021).
2. Guidelines on hepatitis B and C testing. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/handle/10665/273174, accessed 29 June 2021).
3. Guidelines for the care and treatment of persons diagnosed with chronic hepatitis C virus infection. Geneva: World Health Organization; 2018 (https://apps.who.int/iris/handle/10665/273174, accessed 15 May 2021).
4. Consolidated guidelines on HIV testing services, 2019. Geneva: World Health Organization; 2020 (https://apps.who.int/iris/handle/10665/336323, accessed 15 May 2021).
5. Global AIDS Monitoring Online Reporting Tool. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2021 (https://aidsreportingtool.unaids.org/, accessed 27 April 2021).
6. Prevailing against pandemics by putting people at the centre. World AIDS Day Report. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2020 (https://aidstargets2025.unaids.org/assets/images/prevailing-against-pandemics_en.pdf, accessed 17 May 2021).
7. Maintaining essential health services: operational guidance for the COVID-19 context: interim guidance, 1 June 2020. Geneva: World Health Organization; 2020 (https://apps.who.int/iris/handle/10665/332240, accessed 29 June 2021).
8. WHO handbook for guideline development, 2nd ed. Geneva: World Health Organization; 2014 (https://apps.who.int/iris/handle/10665/145714, accessed 29 June 2021).
9. Guyatt GH, Oxman AD, Kunz R, Falck-Ytter Y, Vist GE, Liberati A et al. Going from evidence to recommendations. BMJ. 2008;336:1049-51.
10. Kravchenko N, Denisiuk O, Kuznetsova J, Jayaraj J, Zachariah R, Smyrnov P. Engaging people who inject drugs and their peers in HIV testing and harm reduction in Ukraine: do they make a difference? J Infect Dev Ctries. 2019;13:118S-25S.
11. Mulubwa C, Hensen B, Phiri MM, Shanaube K, Schaap AJ, Floyd S et al. Community based distribution of oral HIV self-testing kits in Zambia: a cluster-randomised trial nested in four HPTN 071 (PopART) intervention communities. Lancet. 2019;6:e81-e92.
12. Abou-Saleh MT, Rice P, Foley S. Hepatitis C testing in drug users using the dried blood spot test and the uptake of an innovative self-administered DBS test. Addict Disord Their Treat. 2013;12:40-9.

13. Candfield S, Samuel MI, Ritchie D, McDonald C, Brady M, Taylor C. Use and acceptability of salivary hepatitis C virus testing in an English Young Offender Institution. Int J STD AIDS. 2017;28:1234-8.

14. Guise A, Witzel TC, Mandal S, Sabin C, Rhodes T, Nardone A et al. A qualitative assessment of the acceptability of hepatitis C remote self-testing and self-sampling amongst people who use drugs in London, UK. BMC Infect Dis. 2018;18:1-8.

15. Prinsenberg T, Rebers S, Boyd A, Zuure F, Prins M, van der Valk M et al. Dried blood spot self-sampling at home is a feasible technique for hepatitis C RNA detection. PloS One. 2020;15:e0231385.

16. Majam M, Fischer A, Reipold EI, Rhagnath N, Msolomba V, Lalla-Edward ST. A lay-user assessment of hepatitis C virus self-testing device usability and interpretation in Johannesburg, South Africa. Diagn. 2021;11:463.

17. Figueroa C, Johnson C, Verster A, Baggaley R. Attitudes and acceptability on HIV self-testing among key populations: a literature review. AIDS Behav. 2015;19:1949-65.

18. Brouard C, Saboni L, Gautier A, Chevaliez S, Rahib D, Richard J-B et al. HCV and HBV prevalence based on home blood self-sampling and screening history in the general population in 2016: contribution to the new French screening strategy. BMC Infect Dis. 2019;19:1-14.

19. Jamil LH, Duffy MC, Fakhouri M, Jamiil HJ. Prevalence of antibodies to the hepatitis C virus among Arab and Chaldean Americans in southeast Michigan, USA. Ethn Dis. 2013;23:18-21.

20. Kimble MM, Stafylis C, Treut P, Saab S, Klausner JD. Clinical evaluation of a hepatitis C antibody rapid immunoassay on self-collected oral fluid specimens. Diagn Microbiol Infect Dis. 2019;95:149-51.

21. O'Brien JM, Kruzel KE, Wandell MG, Vinogradov IV, Sheagren JN, Frank AP. Detection of hepatitis C antibody with at-home collection kits using an innovative laboratory algorithm. Infect Dis Clin Pract. 2001;10:474-80.

22. Quoilin S, Hutse V, Vandenberghe H, Claeys F, Verhaegen E, De Cock L et al. A population-based prevalence study of hepatitis A, B and C virus using oral fluid in Flanders, Belgium. Eur J Epidemiol. 2007;22:195.

23. Guyatt GH, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso-Coello P et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ. 2008;336:924-6. doi: 10.1136/bmj.39489.470347.AD

24. Collaborative procedure for accelerated registration [web page]. Geneva: World Health Organization; 2021 (https://extranet.who.int/pqweb/medicines/collaborative-procedure-accelerated-registration, accessed 15 May 2021).

25. Kumwenda MK, Johnson CC, Choko AT, Lora W, Sibande W, Sakala D et al. Exploring social harms during distribution of HIV self-testing kits using mixed-methods approaches in Malawi. J Int AIDS Soc. 2019;22:e25251.

26. Sibanda E, Neuman M, Tumushime M, Hatzold K, Watadzaushe C, Mutseta M, et al. Linkage to care after HIV self-testing in Zimbabwe: a cluster-randomised trial. Conference on Opportunistic Infections and Retroviruses; 3-6 Mar; Boston, USA; 2018.

27. MacPherson P, Lalloo DG, Webb EL, Maheswaran H, Choko AT, Makombe SD et al. Effect of optional home initiation of HIV care following HIV self-testing on antiretroviral therapy initiation among adults in Malawi: a randomized clinical trial. JAMA. 2014;312:372-9.

28. Nichols B, Cele R, Chasela C, Siwale Z, Lungu A, Long L. Cost and impact of community-based, assisted HIV self-testing amongst youth in Zambia. Conference on Retroviruses and Opportunistic Infections; Seattle, Washington, USA, 4–7 March 2019.

29. Tahlil KM, Ong JJ, Rosenberg NE, Tang W, Conserve DF, Nkengasong S et al. Verification of HIV self-testing use and results: a global systematic review. AIDS Patient Care STDS. 2020;34:147-56.

LIST OF WEB ANNEXES

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ISBN 978-92-4-003112-8