

# Self-testing implementation toolkit for HIV, viral hepatitis and sexually transmitted infections (STIs)

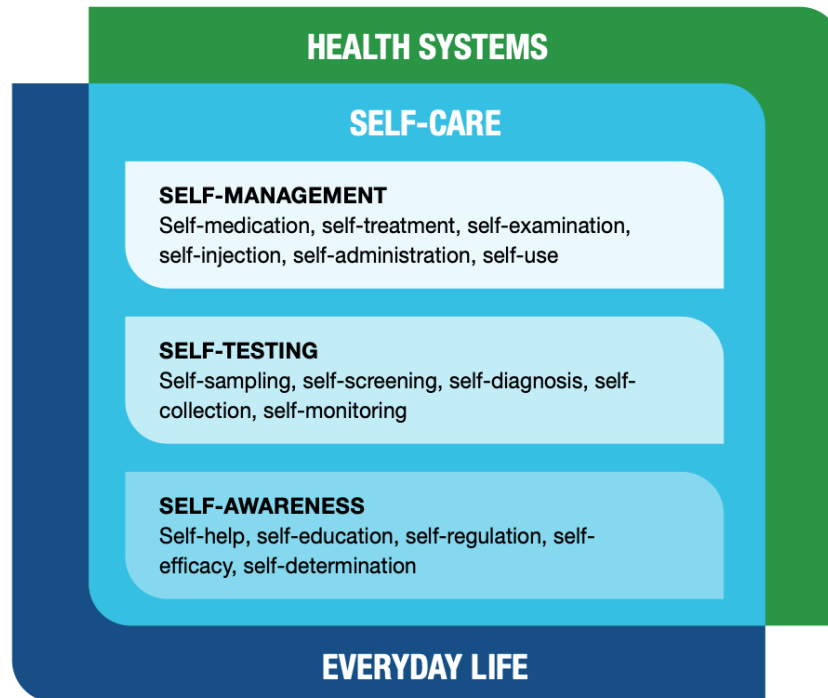
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# The self-care revolution: Why self-care?

**Self-care** is the ability of individuals, families and communities to promote health, prevent disease, maintain health and cope with illness and disability with or without the support of a health worker.



**Self-testing** is a process in which an individual collects their specimen using a simple RDT, performs the test, and interprets their result, when and where they want.



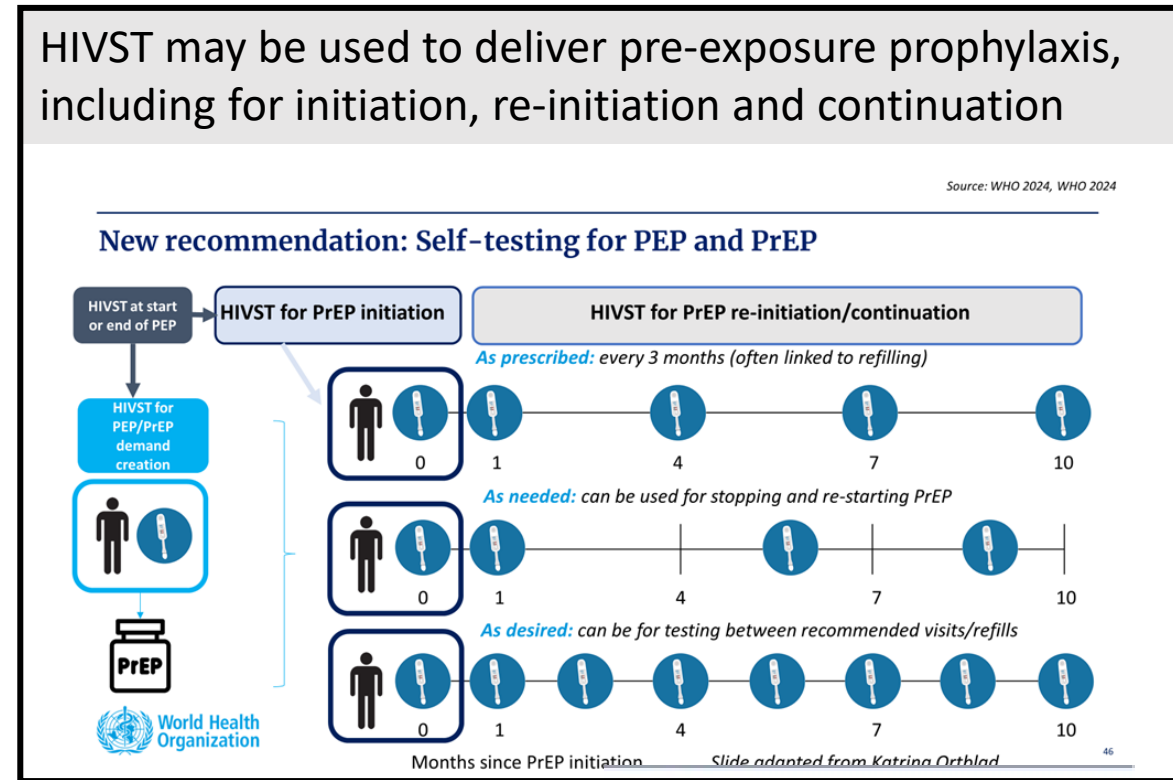
# WHO self-testing recommendations for HIV, HCV and syphilis

**HIV self-testing (HIVST)** is recommended as an approach to HIV testing services

**HCV self-testing (HCVST)** should be offered as an additional approach to HCV testing services

**Syphilis self-testing (SST)** is suggested as an additional approach to syphilis testing services. SST may include products such as dual HIV/syphilis self-tests, treponemal self-tests and dual treponemal/non-treponemal self-tests.

HIVST may be used to deliver pre-exposure prophylaxis, including for initiation, re-initiation and continuation



Source :<https://iris.who.int/bitstream/handle/10665/378162/9789240096394-eng.pdf?sequence=1>  
<https://www.who.int/publications/i/item/9789240031128>



# About the toolkit


- Provides **practical guidance, tools, and resources to support countries in implementing self-testing for HIV, viral hepatitis and STIs.**
- Focuses on HIV self-testing (HIVST), HCV self-testing (HCVST) and syphilis (SST)
- Follows a **modular framework** providing guidance and resources for the process of implementing self-testing services including:
  - **understanding self-testing: principles, guidance**
  - **policy and planning**
  - **product selection and procurement**
  - **Implementation: demand generation, distribution models**
  - **monitoring and evaluation**
- **Main document plus web-page with modules and resources**

## Audience

- Policymakers
- National and subnational programme managers
- Implementing partners, and communities responsible for strategic planning, development and implementation of guidelines and services.

## Using the toolkit

Become familiar with self-testing concept and guidance

  
**Start here...**  
**Module 1:**  
Understanding self-testing as part of self-care for HIV, HCV and syphilis

Based on requirement and relevance, select thematic area

**Module 2:**   
Planning and preparing for self-testing implementation

**Module 3:**   
Product selection, registration, procurement, and supply chain

**Module 4:**   
Implementation of self-testing

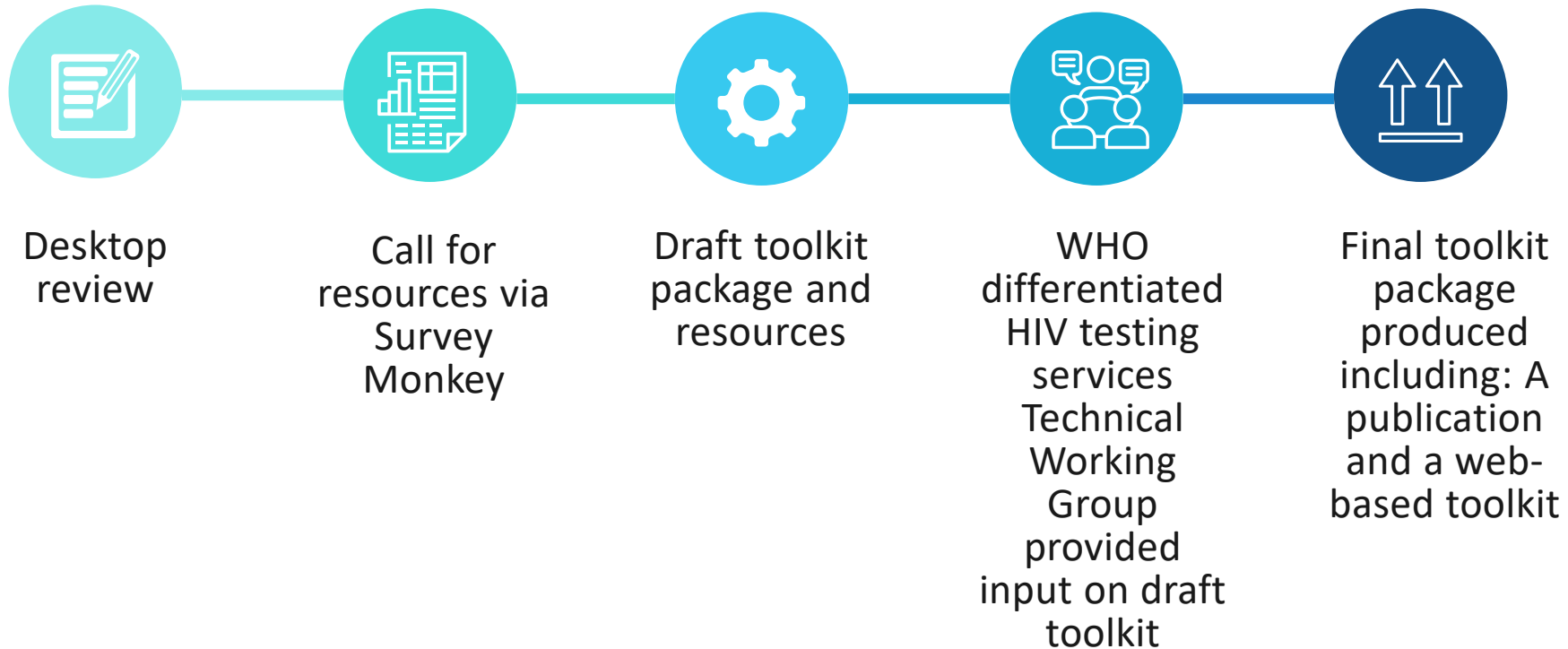
**Module 5:**   
Monitoring and evaluation

Find technical resources according to needs and context

Find relevant resources;

1. Overview of self-testing including algorithms
2. SOPs for planning and preparations
3. Demand creation for self-testing including awareness raising material
4. Distribution models
5. WHO prequalified products

# Toolkit development process



# Modules / Key Messages

## Module 1- Understanding self-testing as part of self-care for HIV, HCV and syphilis

- Self-testing increases access to and uptake of testing, prevention, and treatment services
- Self-testing can also increase patient autonomy and help decentralize services. Most people are willing and able to self-test
- Self-testing is safe, accurate, and feasible, among diverse populations (particularly key populations) and across settings
- Reactive self-test results require follow-up and further testing.
- Self-testers need to be provided with how to interpret their self-test results and, if needed, where to go for further testing and treatment

## Module 4 - Implementing HIV, HCV and syphilis self-testing

- Implementing self-testing services should be based on gaps and needs identified in national HIV, HCV, and STI programmes through the country-specific situational analysis
- A range of self-testing approaches and should replace risk-based screening tools and can also be used as part of PEP and PrEP implementation
- Differentiated service delivery models for self-testing
- Establishing linkage to prevention and treatment pathways
- Training and education of healthcare workers and communities
- Meaningful community engagement
- Demand generation strategies and raising awareness

## Module 2 - Planning and preparing for implementation of HIV, HCV and syphilis self-testing

- **Conducting a situational analysis** of self-testing services
- **Integrating self-testing into national policy and regulations**
- **Selection and registration of products** is a critical step that ensures that a clear and transparent national registration pathway is established for HIVST, HCVST and SST
- **Identifying service delivery approaches and distribution models**
- The planning process has to incorporate quality assurance systems and monitoring and evaluation.
- Developing SOPs for implementation

## Module 3 - Product selection, registration, procurement and supply chain

- When selecting HIVST, HCVST and SST products for procurement, **it is recommended that national programmes first determine if any of these products are listed by relevant national regulatory authorities**
  - PQ products
  - Global Fund list
- **Supply chain management**

## Module 5 – Monitoring and Evaluation

- Essential to understanding implementation progress and allows for optimization of service delivery models and adaptation to support scale-up to achieve national goals
- Because of the discreet and private nature of self-testing, routine collection of HIVST, HCVST and SST 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
  - type and numbers of kits distributed
  - populations reached by HIVST, HCVST and SST distribution; and
  - number of patients coming to facilities for confirmatory testing who report prior HIVST, HCVST or SST use.

# Main SOP Templates

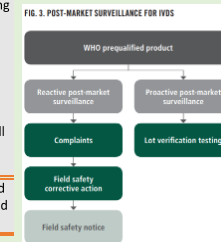
SOP Template: Conducting a situational analysis for self-testing HIV, viral hepatitis, syphilis
<b>A needs assessment will help determine where the gaps are between testing services provide and what the community needs</b>
<b>Key Considerations when introducing ST</b>
<ul style="list-style-type: none"> <li>Can you demonstrate the value of ST from the situational analysis of existing testing services?</li> <li>Can resources be mobilized to support ST implementation and scale-up?</li> <li>Are there laws/policies regulating the marketing, distribution, use of ST kits?</li> <li>Have communities been consulted and engaged, do they understand ST?</li> <li>Are HIV testing services accessible for further testing to confirm any reactive (positive) self-test results? (facility and community-based services)</li> <li>Are treatment services accessible for those diagnosed with the disease?</li> <li>Is relevant prevention information available and accessible for those with a negative self-test result?</li> <li>Is the country able to procure quality-assured ST products (WHO prequalified)?</li> <li>Are quality assurance systems in place or does it have plans to adapt or develop such systems</li> <li>Is there post-market surveillance system to monitor social harm, adverse events or complaints or does the country have plans to develop one?</li> </ul>
<b>Key steps in situational analysis</b>
<ul style="list-style-type: none"> <li>This process should be rapid and led by the Ministry of Health (working with key stakeholders)</li> <li>Identify key documents to be reviewed (policies, strategies, reports, surveys, studies etc) and key programmatic data sources (DHIS etc) for HIV/Hep/Syphilis</li> <li>The analysis should examine progress and gaps across national and subnational HIV epidemiology and programmatic data, including HIV testing coverage, testing frequency/retesting, knowledge of status among people with HIV, positivity rate, linkage to prevention and treatment, and HIV testing costs</li> <li>Identify populations missed by current testing programs or those at high risk of HIV/HCV/STI who require more frequent testing</li> <li>Determine how existing services would be adapted when introducing ST</li> <li>Establish if there are ST-kits that are already available (informally, unregulated, unregistered)</li> <li>Do a stakeholder mapping of partners who will support implementation. Also include advocac for other potential stakeholders</li> <li>Ensure the process is consultative and addresses concerns, share information, and learn how NOT to implement ST</li> <li>Determine the extent of sustainable funding sources for ST which should inform implementatic decisions.</li> <li>Define gaps and challenges and establish populations targeted,</li> <li>Integrate ST into existing working groups and add a ST-focused subgroup to guide the development of ST policies, guidelines, M&amp;E tools, SOPs, research</li> </ul>

SOP Template 1 for conducting a situational analysis for self-testing HIV, viral hepatitis and syphilis

SOP Template: Developing self-testing policies
<b>Establishing Self-testing policies</b>
<ul style="list-style-type: none"> <li>Relevant HIV planning committees or processes should consider the adaptation of national policies and regulations for self-tests.</li> <li>Clear, supportive policies and regulations are needed for effective scale-up of ST and access to quality-assured ST products to achieve impact</li> <li>National guidelines are often a pre-requisite for implementation, scale-up, development of regulations, procurement, and importation of products</li> <li>When reviewing policies, minimize the gap between policy development and product availability</li> </ul>
<b>What should be included in the Self-testing Policy</b>
<ul style="list-style-type: none"> <li>A clear definition of self-testing and emphasize that it is about testing yourself</li> <li>Include the message that current evidence on HIVST shows that social harm is very rare</li> <li>Describe your priority populations for Self-testing</li> <li>Clearly articulate the legal age of consent for the self-testing strategy</li> <li>Clear ST strategy and diagram that links to the national testing strategy</li> <li>For HIV, indicate ST is considered a test for triage and cannot replace the first test within the validated national testing algorithm</li> <li>Nonreactive (negative) self-test results should be considered negative with no need for immediate further testing to confirm a negative diagnosis</li> <li>Include re-testing frequency guidance for various categories of individuals based on risk</li> <li>Outline the ST distribution models to be used in the country</li> <li>Develop a minimum communication package with key messages for all self-testers and community</li> <li>Those officially distributing ST kits require a well-established minimum training package</li> <li>Minimum standards and requirements for procurement and distribution of ST kits</li> <li>System for quality assurance and post-market surveillance</li> <li>Monitoring and evaluation indicators and plans, including a reporting system for complaints, adverse events, and cases of social harm.</li> </ul>
<b>National Registration and Regulations</b>
<ul style="list-style-type: none"> <li>Have a clear and transparent national registration pathways for ST</li> <li><b>Market authorization</b> (registration) – this is a process through which a test kit is released onto the market after its quality, safety and performance has been assessed.</li> <li><b>Premarket controls</b> - The system a manufacturer should employ once the product is on the market to ensure monitoring continues with the aim of identifying and addressing potential complaints, including adverse events.</li> <li><b>Market control.</b></li> <li><b>Post-market surveillance</b></li> <li><b>Market surveillance/control</b></li> </ul>

SOP Template for developing self-testing policies

SOP Template: Selecting and procuring self-testing products
<b>Selecting and procuring HIVST products</b>
<ul style="list-style-type: none"> <li>Ensure products are quality-assured and have acceptable specifications</li> <li>Plan to procure more than one type of ST kit for back-up options</li> <li>There are many quality-assured ST products, both blood-based and oral fluid-based tests, that have WHO prequalification, some meet the requirements of the Global Fund Quality Assurance Policy and/or are approved by one of the founding members of the Global Harmonization Task Force on Medical Devices.</li> <li>When selecting ST products for procurement - first determine if there are any products for self-testing listed by relevant national regulatory authorities</li> <li>If no such products exist, or do not meet minimal standards - select from those listed by WHO and the Global Fund (to enable the country to forgo in-country performance evaluations)</li> <li>Note that from a programmatic perspective, studies have shown that packaging, components, and instructions for use impact a user's ability to correctly perform and interpret self-test results</li> <li>The unit cost per self-test is an important factor as governments and donors support most procurement, and a lower-cost HIVST kit may be key to achieving scale-up.</li> </ul>
<b>Quality assurance and post-market surveillance for ST products</b>
<ul style="list-style-type: none"> <li>Integrate quality assurance for ST products into existing monitoring, assessment, and quality improvement processes.</li> <li>A risk-based approach to validating new lots of ST kits entering the country may be considered to ensure commodities meet national quality and regulatory standards.</li> <li>Post-market surveillance of ST can be implemented through reactive and active approaches</li> <li><b>Reactive approaches</b> - include the use of WHO complaint reporting systems</li> <li>can be used to issue HIVST product-related complaints as well as to routinely check for WHO in vitro diagnostic (IVD) field safety notices related to HIVST products.</li> <li>Active post-market surveillance can be periodically conducted by an authorized government agency to assess the quality and performance of the HIVST kits in use</li> </ul>



SOP Template 3: selecting and procuring self-testing products

SOP Template: Pre-test information for self-testing	
<b>Purpose</b>	This template is designed for counselors, outreach workers, and healthcare providers to facilitate the introduction of self-testing kits for HIV, hepatitis C (HCV), and syphilis to individuals. It guides the pre-test information session to ensure consistency in messages provided to testers.
<b>Key Messages</b>	<p><b>Pre-test information may be offered through</b></p> <ul style="list-style-type: none"> <li>individual or group information sessions</li> <li>posters, brochures, websites, and short video clips shown in waiting rooms</li> <li>information should be age-appropriate for children and adolescents.</li> <li>Face-to-face during distribution of self-test kit – advise client where to get further information – such as IFU</li> </ul> <p>Introduce self-testing for HIV, HCV, and syphilis as an option available for screening. Share the benefits of self-testing (empowers the user to exercise choice, gives accurate results, can be done at a convenient place and time, easy to use and interpret the result, ensures privacy and non-discrimination)</p> <p><b>Emphasize</b></p> <ul style="list-style-type: none"> <li>those using self-tests with reactive results should always get further testing by a trained provider</li> <li>test results must be read only in the read time suggested.</li> <li>Self-testers should be advised to dispose of kits after interpreting their results and should not re-read results after the read window has elapsed</li> </ul>
<b>Content</b>	<p><b>Introduction</b></p> <ul style="list-style-type: none"> <li>When distributing ST kits, users should be provided with appropriate and high-quality pre-test information and demonstrations</li> <li>Information must include <ul style="list-style-type: none"> <li>how to collect the specimen</li> <li>how to conduct the test</li> <li>how to interpret the result of the ST (reactive, non-reactive, or invalid)</li> <li>where to get confirmatory testing if the result is reactive</li> <li>how to link to prevention, treatment and other related services</li> </ul> </li> </ul> <p><b>Information must include the following:</b></p> <ul style="list-style-type: none"> <li>benefits of HIV/Hep/Syph testing and implications of undiagnosed disease</li> <li>meaning of a reactive self-test, and that it requires further testing by a trained provider</li> <li>meaning of a non-reactive result, and information about prevention options.</li> <li>for HIV, highlight the potential for incorrect results if one is on ART</li> <li>for viral hepatitis, highlight the differences between acute and chronic disease</li> <li>include information on the benefits of treatment as prevention – that is, U=U</li> <li>include modes of transmission and address common myths.</li> </ul>

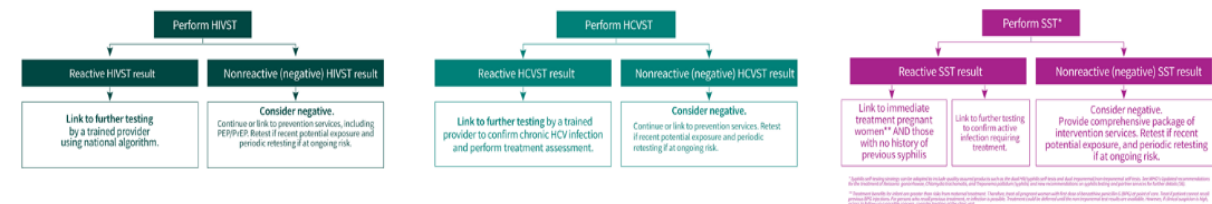
SOP Template 4: pre-test information for self-testing



## Key messages

- \* **Self-testing is a process in which an individual collects their specimen using a simple rapid diagnostic test, performs the test, and interprets their result, when and where they want.**
- \* **Self-testing increases access to and uptake of testing, prevention, and treatment services.** Self-testing can also increase patient autonomy, help decentralize services, and alleviate the burden of testing at facilities. Most people are willing and able to self-test.
- \* **Self-testing has been shown to be safe, accurate, acceptable, and feasible, among diverse populations (particularly key populations) and across settings in various regions.**
- \* **Reactive self-test results require follow-up and further testing.** HIVST and HCVST do not provide a diagnosis but require further testing by a trained provider using the national testing algorithm to confirm HIV or HCV infection and link individuals to care. A reactive SST result can be used to link to immediate treatment among pregnant women and those with no report of previous syphilis infection, however further testing is still needed to confirm an active infection in need of treatment.
- \* **Self-care approaches recognize the central and active role that people play in managing their own health care** and is increasingly becoming important as an additional strategy in expanding access to and utilization of health services, across various disease areas and conditions.

## Self-testing strategies



## Modules



### Planning and preparation

When considering HIVST, HCVST or SST introduction, developing a plan that will guide implementation, policy and regulatory development is important.

[More information and resources](#)



### Demand creation

Demand generation strategies for self-testing involve community mobilization, social media campaigns, digital marketing, and coordination mechanisms with stakeholders to integrate self-testing.

[More information and resources](#)



### Distribution models for self-testing

A range of service delivery and distribution models are effective in increasing the uptake of testing for HIV, HCV and syphilis and reaching people with the disease who are undiagnosed or those at ongoing risk.

[More information and resources](#)

## Live demonstration

<https://www.who.int/tools/self-testing-implementation-toolkit-for-hiv-hcv-and-syphilis>



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