Strategic testing services for HIV, hepatitis and STIs

A focus on rapid testing and self-testing technologies and cost-effectiveness

Global HIV, Hepatitis and STIs Programmes

WHO, Geneva, Switzerland

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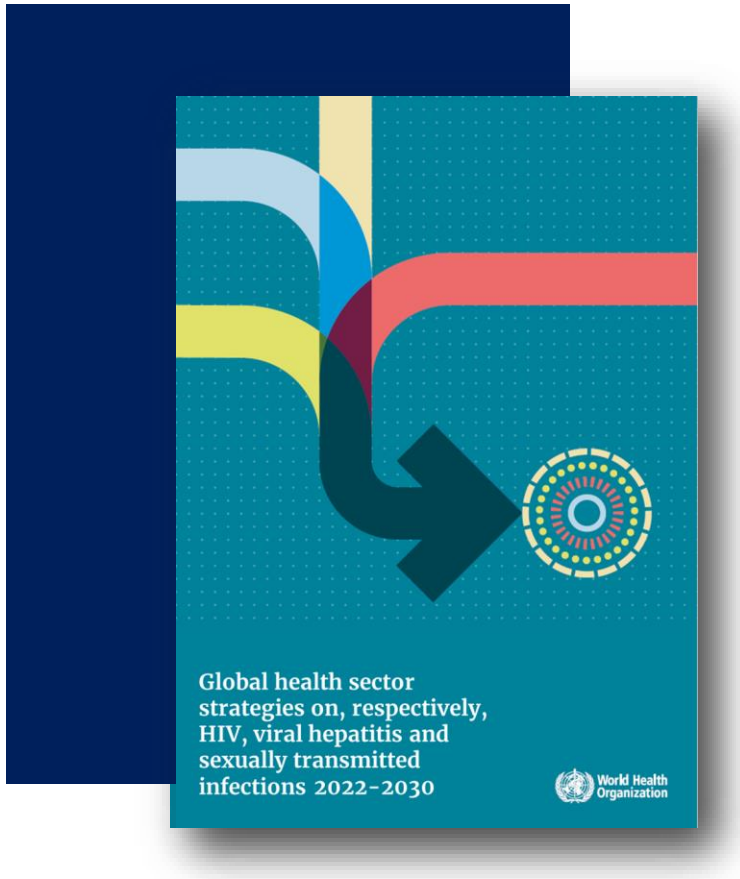
World Health Organization

CORE
Community Response to End Inequalities

Global health sector strategy on HIV, viral hepatitis and STIs



Key targets across HIV, viral hepatitis and sexually transmitted infections

Disease area	Impact indicator	Baseline 2020[b]	2025 target	2030 target
Shared	Reduced incidence • Number of new HIV and viral hepatitis cases per year • Number of new cases of syphilis, gonorrhoea, chlamydia and trichomoniasis[c] among people 15–49 years old per year	4.5 million 374 million	<1.5 million < 300 million	<500 000 <150 million[d]
	Healthy lives – reduced mortality and cancers • Number of people dying from HIV, viral hepatitis and sexually transmitted infections[a] per year • Number of new cases of cancer from HIV, viral hepatitis and sexually transmitted infections per year	2.3 million 1.2 million	<1.7 million <900 000	<1 million <700 000
HIV	Number of people newly infected with HIV per year	1.5 million	370 000	335 000
	Number of people newly infected with HIV per 1000 uninfected population per year	0.19	0.05	0.025
	Number of children 0–14 years old newly infected with HIV per year	150 000	20 000	15 000
	Number of people dying from HIV-related causes per year	680 000	250 000	<240 000
	Number of people living with HIV dying from TB, hepatitis B and hepatitis C	210 000	110 000	55 000

Disease area	Impact indicator	Baseline 2020[b]	2025 target	2030 target
Viral hepatitis	Hepatitis B surface antigen prevalence among children 0–4 years old[f]	0.94%	0.5%	0.1%
	Number of new hepatitis B infections per year	1.5 million new cases 20 per 100 000	850 000 new cases 11 per 100 000	170 000 new cases 2 per 100 000
	Number of new hepatitis C infections per year	1.575 million new cases 20 per 100 000	1 million new cases 13 per 100 000	350 000 new cases 5 per 100 000
	Number of new hepatitis C infections among persons who inject drugs per year	8 per 100	3 per 100	2 per 100
	Number of people dying from hepatitis B per year	820 000 deaths 10 per 100 000	530 000 deaths 7 per 100 000	310 000 deaths 4 per 100 000
	Number of people dying from hepatitis C per year	290 000 deaths 5 per 100 000	240 000 deaths 3 per 100 000	140 000 deaths 2 per 100 000
Sexually transmitted infections	Number of new cases of syphilis among people 15–49 years old per year	7.1 million	5.7 million	0.71 million
	Number of new cases of gonorrhoea among people 15–49 years old per year	82.3 million	65.8 million	8.23 million
	Number of congenital syphilis cases per 100 000 live births per year	425	<200	<50
	Percentage of girls fully vaccinated with human papillomavirus vaccine by 15 years of age	14%	50%	90%

a The proposed impact indicators and targets are in accordance with target 3.3 and indicators 3.3.1 and 3.3.4 of the Sustainable Development Goals.
b Some targets are based on data from 2019 because of COVID-19-related service disruptions in the data reported for 2020. All data will be disaggregated by age, sex and, where relevant, key and focus populations specific to the disease.
c Curable sexually transmitted infections.
d Includes the target of 90% reduction in the number of new cases of syphilis and gonorrhoea as well as 50% reduction in the number of new cases of chlamydia and trichomoniasis by 2030.
e The mortality data will be further disaggregated to assess the urgent need to tackle the drivers and causes of deaths. For HIV, these include cryptococcal meningitis, tuberculosis and severe bacterial infections; for viral hepatitis, they include other types of cancer and harmful use of alcohol.
f Please note that the targets in this table are global targets and should be adapted by Member States according to the national context when setting country targets. For example, in some countries a target for the prevalence of hepatitis B surface antigen among children younger than five years old may be less than 0.1% or 0.2%, although the overall global target is 0.1%.

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Fostering access to diagnostic innovations for action is key

HIV

New HIV diagnostics technologies and testing approaches for earlier and more accurate HIV diagnosis

New options for antiretroviral-based prevention. Expand effective antiretroviral-based HIV prevention options (**including long-acting and MPT approaches**)

Optimized use of antiretrovirals - optimal doses & formulations of ARVs that minimize toxicity & drug-drug interactions & reduce costs; **ensure safer ARVs for pregnant and lactating women.**

HIV vaccines Promote HIV vaccine agenda by encouraging investments and visibility in efforts to secure a viable HIV vaccine, including through strengthened collaboration with R&D based partnerships, private sector & communities

HIV cure. Encourage investments and visibility in efforts to secure a viable HIV cure through strengthened collaboration with R&D development-based partnerships, communities and private sector.

Partnerships for innovation. Optimize the potential for innovation through market analyses and strengthening research- and development-based partnerships, including strengthened engagement with the private sector.

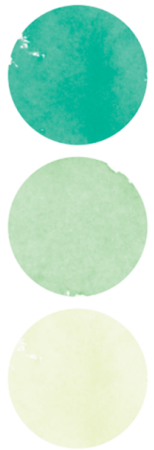
Viral Hepatitis

New viral hepatitis diagnostics technologies and testing approaches. Continue to improve diagnostics technologies and testing approaches for simplified, timely and accurate hepatitis B and hepatitis C virus diagnosis and strengthened patient monitoring.

Optimized antivirals for hepatitis B and C virus. Support research on optimal doses and formulations of antivirals for hepatitis B and C virus.

New viral hepatitis vaccines. Promote the hepatitis C and hepatitis E virus vaccine agenda by promoting investments and visibility in efforts to secure a viable hepatitis C vaccine, including through strengthened collaboration with research and development-based partnerships, the private sector and communities.

Hepatitis B virus cure. Promote investments and visibility in efforts to secure a viable hepatitis B virus cure through strengthened collaboration with research- and development-based partnerships, the private sector and communities.



Partnerships for innovation. Optimize the potential for innovation through market analyses and strengthening research- and development-based partnerships, including strengthened engagement with the private sector.

Sexually Transmitted Infections

Innovations in STI prevention - support the development and evaluation of prevention products for STIs.

Innovations in STI diagnostics - support the development and evaluation of new PoC and near PoC diagnostics for STIs; promote integration of NAAT based test and multiplex diagnostic approaches

Innovations in STI treatment - support the development and clinical testing of new treatments for STIs and their complications and sequelae; minimize toxicity, drug-drug interactions and reduce costs; **ensure safer STI drugs for pregnant and lactating women**

Public-private partnerships for STIs - develop and support public-private partnerships to catalyze the development of new STIs technologies.

Partnerships for innovation. Optimize the potential for innovation through market analyses and strengthening research- and development-based partnerships, including strengthened engagement with the private sector.

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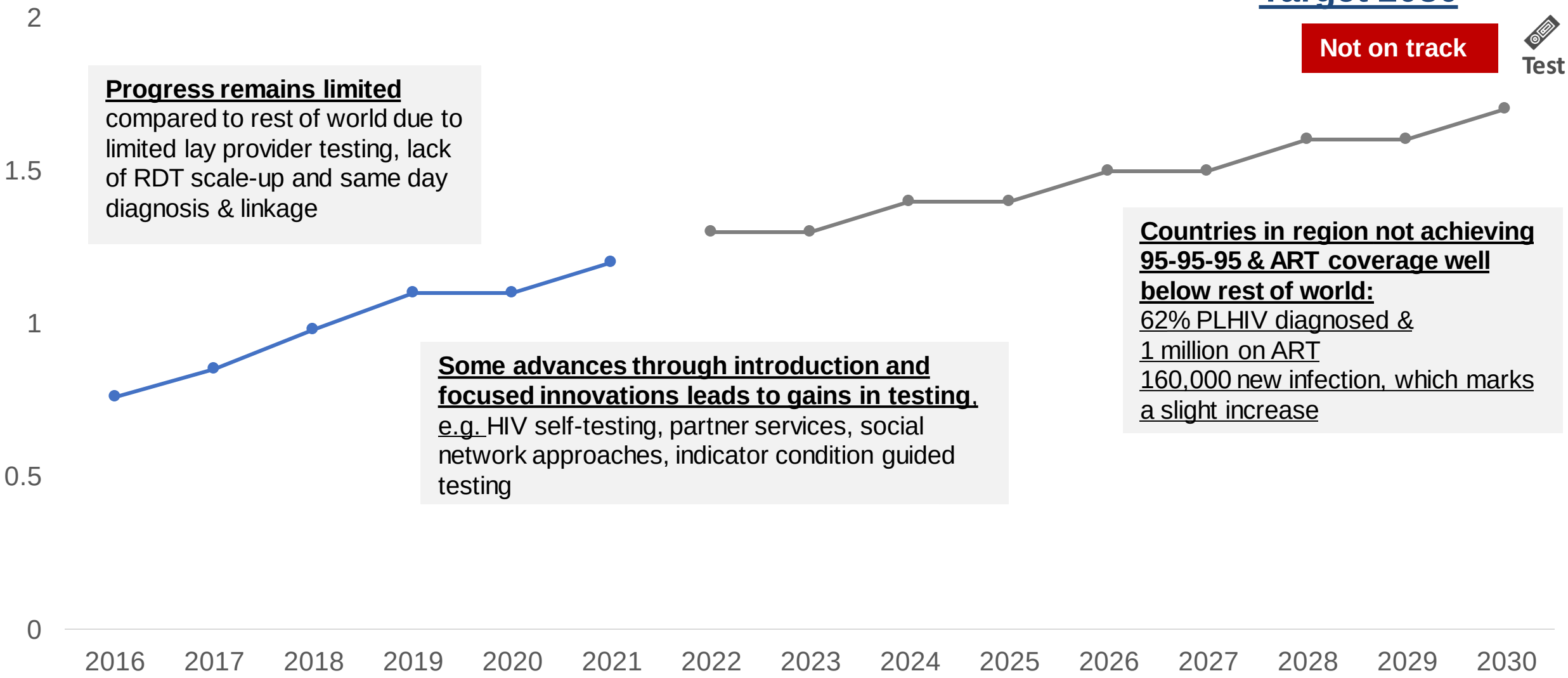
Progress toward EECA HIV testing goals



Progress remains limited compared to rest of world due to limited lay provider testing, lack of RDT scale-up and same day diagnosis & linkage

Some advances through introduction and focused innovations leads to gains in testing, e.g. HIV self-testing, partner services, social network approaches, indicator condition guided testing

Countries in region not achieving 95-95-95 & ART coverage well below rest of world:
62% PLHIV diagnosed &
1 million on ART
160,000 new infection, which marks a slight increase

Source: WHO forecast 2022; UNAIDS 2022

Progress toward EURO viral hepatitis testing goals

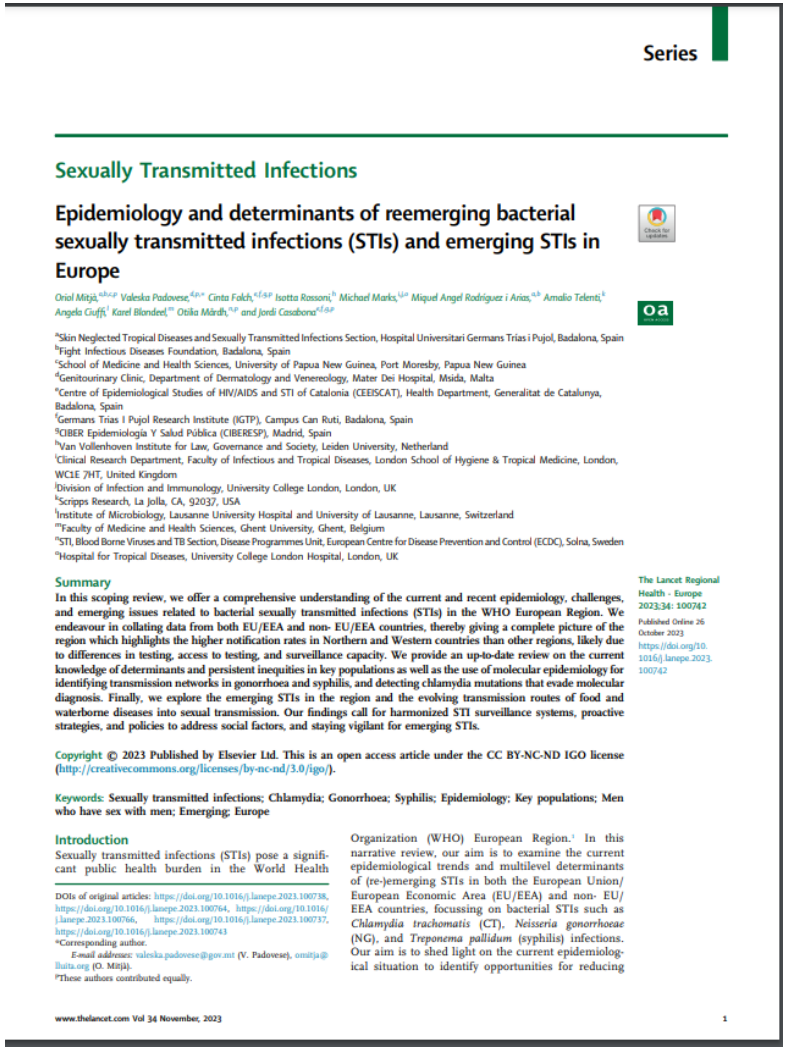
Indicator	
Number of people living with hepatitis C infection	8.6 million
Number of new hepatitis C infections per year	126 000
Number of deaths caused by hepatitis C infection per year	21 000
Percentage of people living with hepatitis C who are diagnosed	29%
Percentage of people living with hepatitis C who receive treatment (among all people with hepatitis C)	9%

Indicator	
Number of people living with hepatitis B infection	10.6 million
Number of new hepatitis B infections per year	18 000
Number of deaths caused by hepatitis B infection per year	32 000
Percentage of people living with hepatitis B who are diagnosed	15.7%
Percentage of people living with hepatitis B who receive treatment (among those diagnosed)	12.2%
Percentage of people living with hepatitis B who receive treatment (among all people with hepatitis B)	1.9%

Report highlights gaps in access to quality diagnostics for viral hepatitis and only 1 country in the region has HCVST available and there are no WHO PQ products available

Source: WHO 2024, https://www.who.int/publications/i/item/9789240091672

Progress toward EURO STI testing goals



Series

Sexually Transmitted Infections

Epidemiology and determinants of reemerging bacterial sexually transmitted infections (STIs) and emerging STIs in Europe

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Summary

In this scoping review, we offer a comprehensive understanding of the current and recent epidemiology, challenges, and emerging issues related to bacterial sexually transmitted infections (STIs) in the WHO European Region. We endeavour in collating data from both EU/EEA and non- EU/EEA countries, thereby giving a complete picture of the region which highlights the higher notification rates in Northern and Western countries than other regions, likely due to differences in testing, access to testing, and surveillance capacity. We provide an up-to-date review on the current knowledge of determinants and persistent inequities in key populations as well as the use of molecular epidemiology for identifying transmission networks in gonorrhoea and syphilis, and detecting chlamydia mutations that evade molecular diagnosis. Finally, we explore the emerging STIs in the region and the evolving transmission routes of food and waterborne diseases into sexual transmission. Our findings call for harmonized STI surveillance systems, proactive strategies, and policies to address social factors, and staying vigilant for emerging STIs.

Keywords: Sexually transmitted infections; Chlamydia; Gonorrhoea; Syphilis; Epidemiology; Key populations; Men who have sex with men; Emerging; Europe

Introduction

Sexually transmitted infections (STIs) pose a significant public health burden in the World Health Organization (WHO) European Region.[1] In this narrative review, our aim is to examine the current epidemiological trends and multilevel determinants of (re-)emerging STIs in both the European Union/European Economic Area (EU/EEA) and non- EU/EEA countries, focussing on bacterial STIs such as *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and *Treponema pallidum* (syphilis) infections. Our aim is to shed light on the current epidemiological situation to identify opportunities for reducing

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- Trends show increases in the case notification rate for *Chlamydia trachomatis* (CT), alongside a considerable increase for *Neisseria gonorrhoeae* (NG) and syphilis in EU/EEA countries, as opposed to decreasing trends in non- EU/EEA countries.
- Enabling environments is a key driver affecting STIs among key and vulnerable populations in the region, including differences in STI testing policies and access to testing, as well as different levels of access to testing approaches and diagnostics.

> ECDC Director Andrea Ammon, expressed deep concern over the rising STI rates, saying, "Addressing the substantial increases in STI cases demands urgent attention and concerted efforts. Testing, treatment and prevention lie at the heart of any long-term strategy. We must prioritise sexual health education, expand access to testing and treatment services, and combat the stigma associated with STIs. Education and awareness initiatives are vital in empowering individuals to make informed choices about their sexual health. Promoting consistent condom use and fostering open dialogue about STIs can help reduce transmission rates."

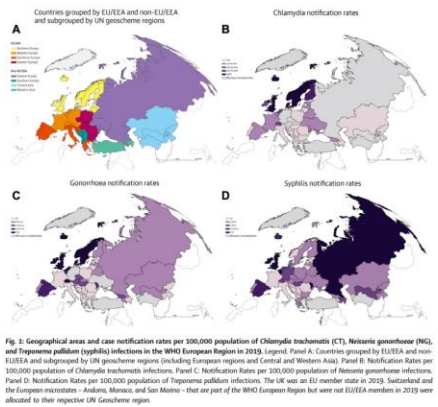
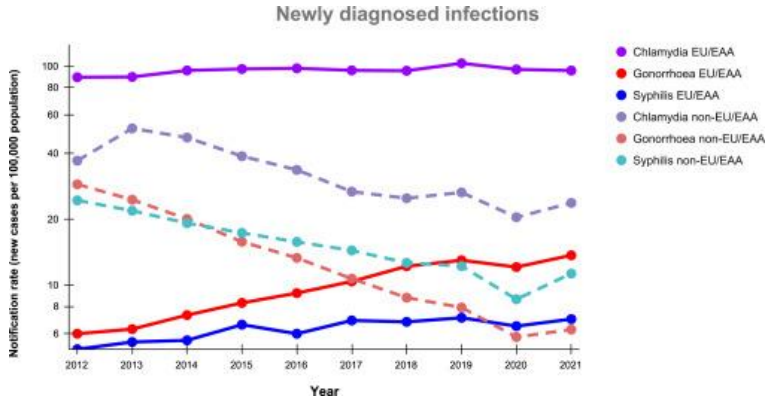
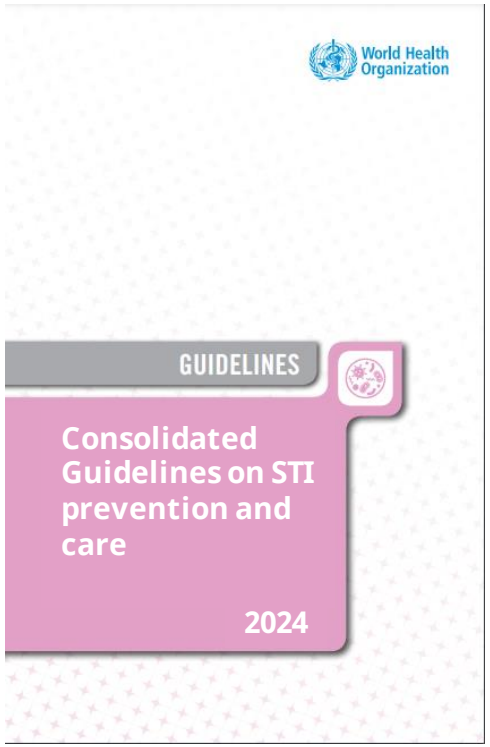


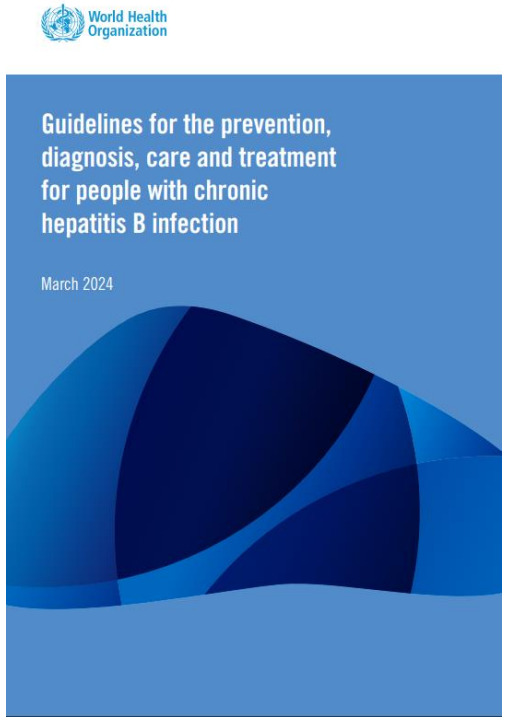
Fig. 1: Geographical areas and case notification rates per 100,000 population of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and *Treponema pallidum* (syphilis) infections in the WHO European Region in 2019. Legend: Panel A: Countries grouped by EU/EEA and non-EU/EEA and subgrouped by UN geoscheme regions (including European regions and Central and Western Asia). Panel B: Notification Rates per 100,000 population of *Chlamydia trachomatis* infections. Panel C: Notification Rates per 100,000 population of *Neisseria gonorrhoeae* infections. Panel D: Notification Rates per 100,000 population of *Treponema pallidum* infections. *The UK was an EU member state in 2019. Switzerland and the European microstates – Andorra, Monaco, and San Marino – that are part of the WHO European Region but were not EU/EEA members in 2019) were allocated to their respective UN Geoscheme region.*

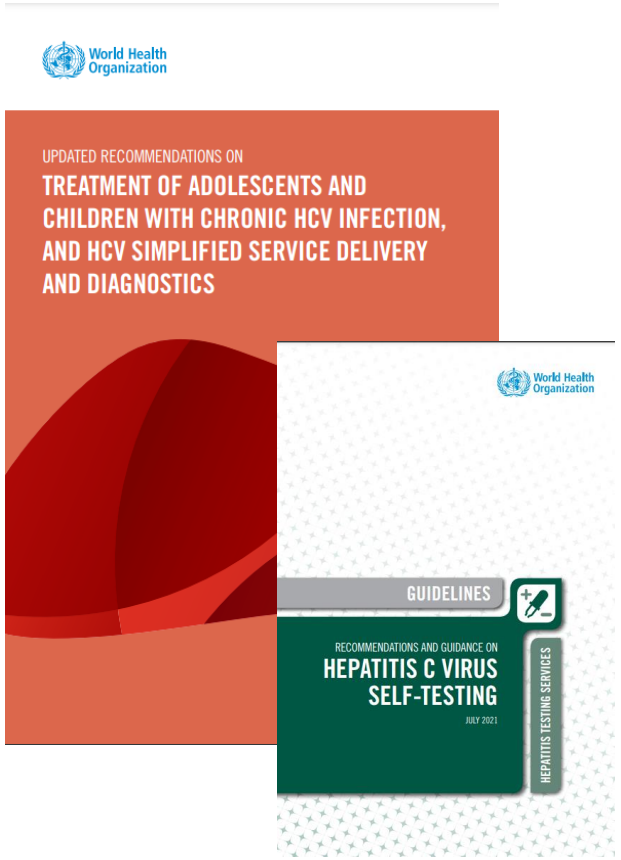


Source: ECDC 2024; Mitjà 2023

WHO guidance for testing across HIV, viral hepatitis and STIs







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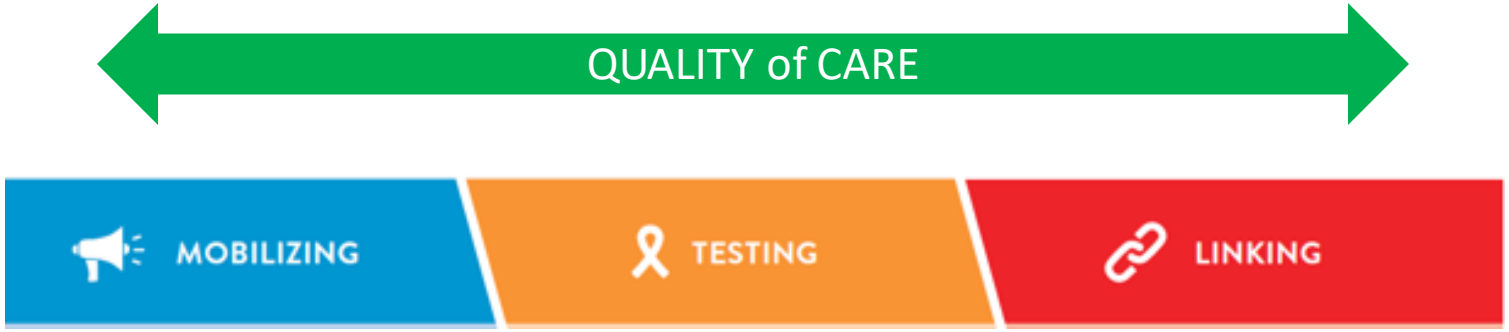
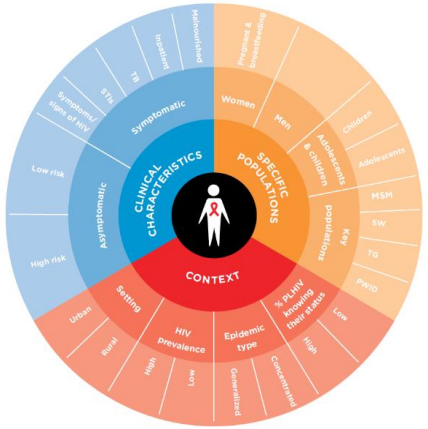
Strategic principles for testing services

Testing approaches need to consider three dimensions for implementation:

1. Mobilizing and creating demand for testing
2. Testing service delivery
3. Linkage to post-test services



Approaches are then adapted based on the context, population and epidemic



	Mobilizing and creating demand	HTS implementation	Linkage to care
When	Continuous, intermittent or focused	Time of day and frequency	Time period for linking and frequency of monitoring
Where	Location of mobilization activities	Health facility, other facility, community	Location of linkage activities
Who	Who does the mobilizing? Who is the focus for messages and mobilization?	Who does the testing? Who is the focus for testing?	Who supports linkage to prevention or treatment?
What	What package of services and demand creation interventions?	What testing approach?	What linkage intervention?

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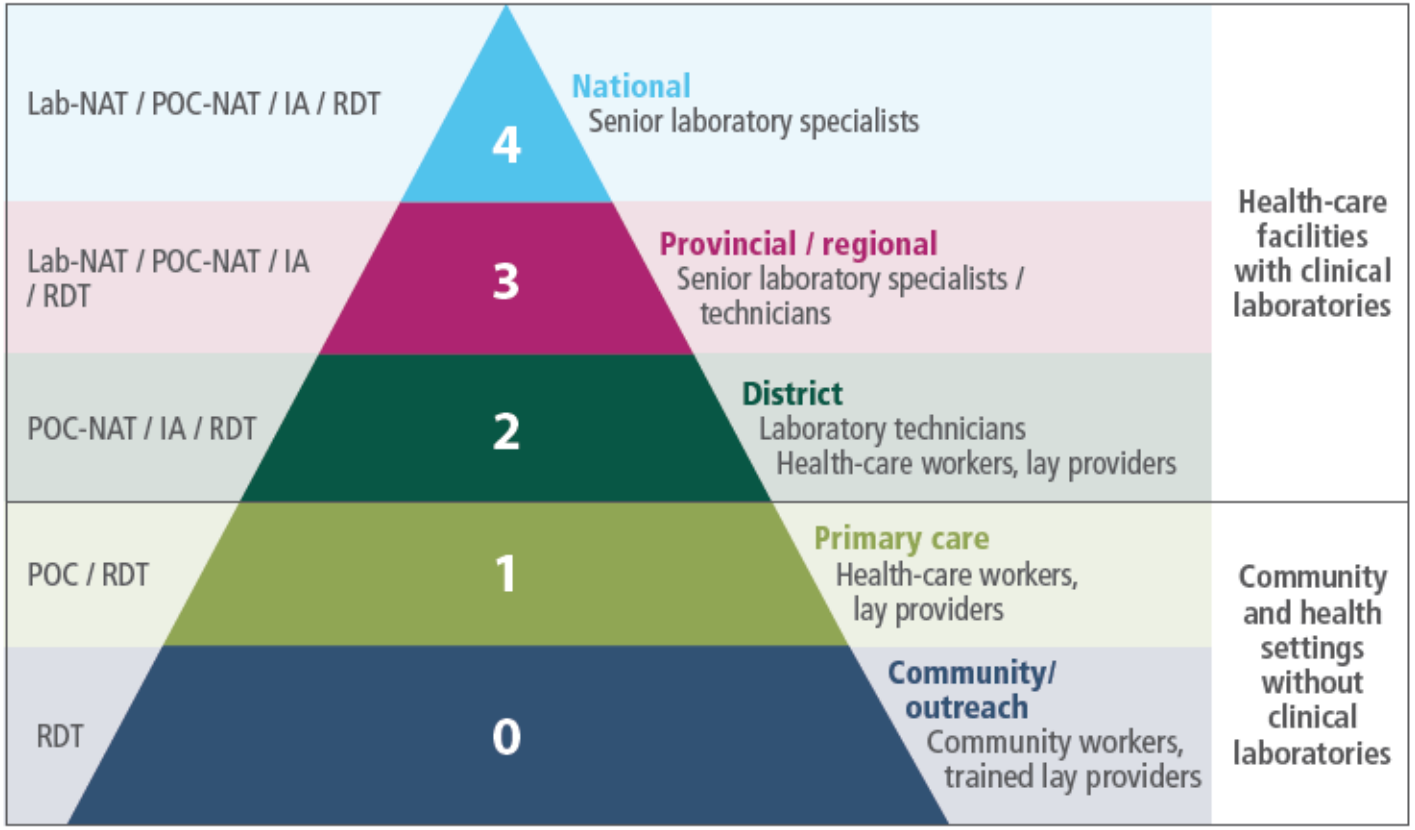
Source: WHO 2019; IAS 2018

Understanding testing services: a cross-cutting programme perspective

- **Different purposes for testing**
  - **Case-finding focused testing**: Implementation focused on reaching undiagnosed individuals and facilitating linkage to care. Generally, includes specific targeted testing outreach.
  - **Prevention focused testing**: Ensuring those people stay negative and identifying HIV early in those with high ongoing risk. Core services e.g. PMTCT/ANC, KP, AGYW, VMMC, PrEP/PEP
  - Aim is to achieve a strategic mix that is person-centered and contributes to larger treatment and prevention goals.
- **Different scale and providers**
  - Diagnosis with rapid tests and includes range of cadres often lay providers, community workers as well as self-testing and self-sampling
  - Testing providers have many tasks including mobilizing, testing, linking; often integrating work with other disease
  - Testing sites vary widely (mobile & fixed, big & small, high & low throughput). In some settings testing in ANC/PHC settings and lower-level sites without clinical labs and limited staff capacity

Source: WHO, https://www.who.int/publications/i/item/978-92-4-155058-1

Tiers of testing services



IA: enzyme immunoassay; Lab-NAT: laboratory-based nucleic acid testing; POC-NAT: nucleic acid testing at point-of-care; RDT: rapid diagnostic test, including HIV self-testing.

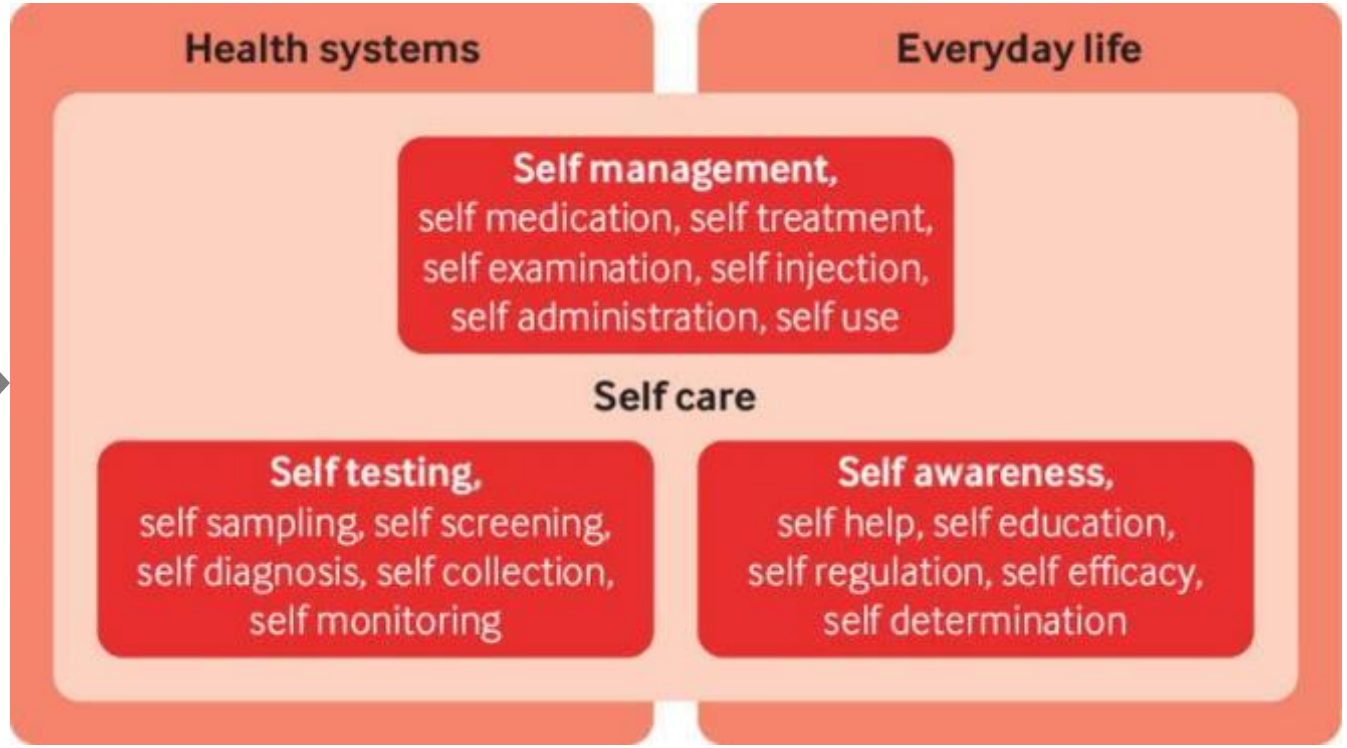
+95% of all HIV testing worldwide is done at level 0 or 1 (health centres & community)

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

Self-care and self-testing

Self-care

The ability of individuals to promote health, prevent disease, maintain health, and cope with illness and disability with or without support of a healthcare provider.



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Source: WHO, 2019, https://www.who.int/reproductivehealth/self-care-interventions/access-health-services/en/

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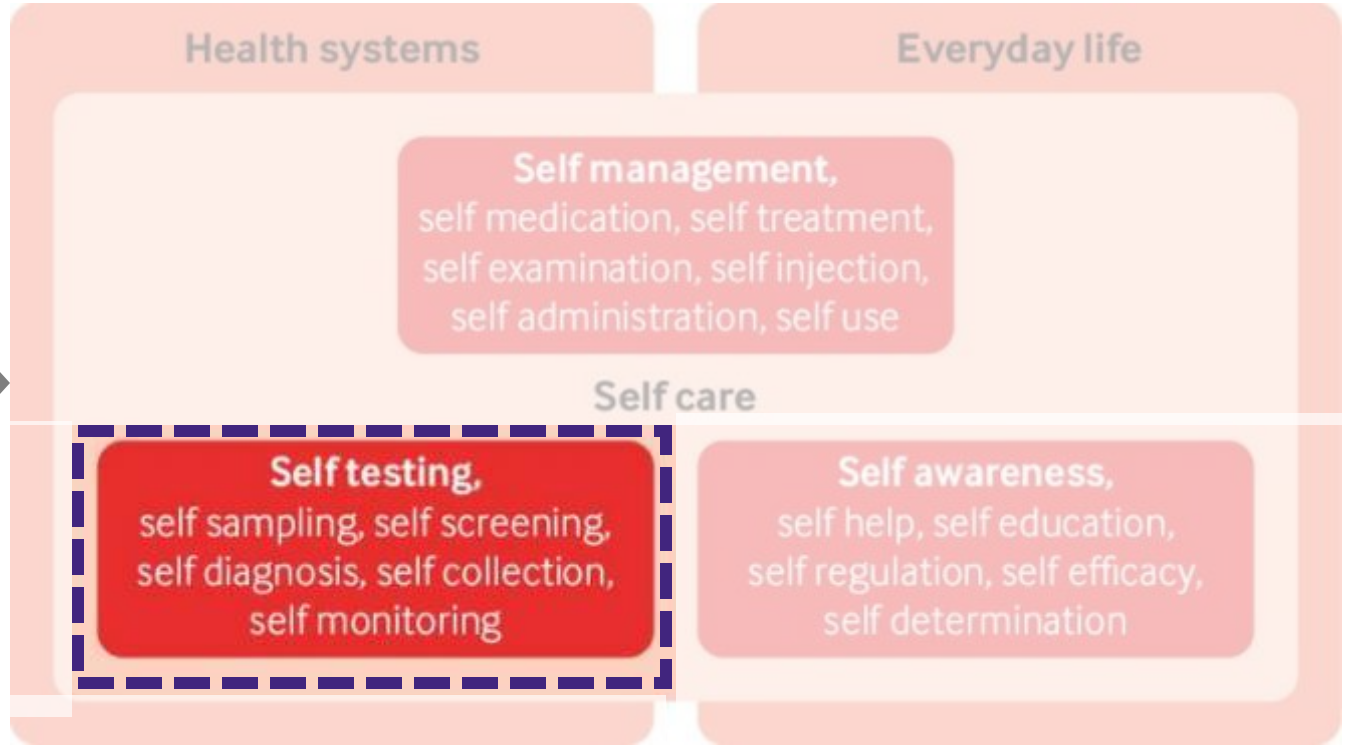

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Source: WHO, 2019, https://www.who.int/reproductivehealth/self-care-interventions/access-health-services/en/

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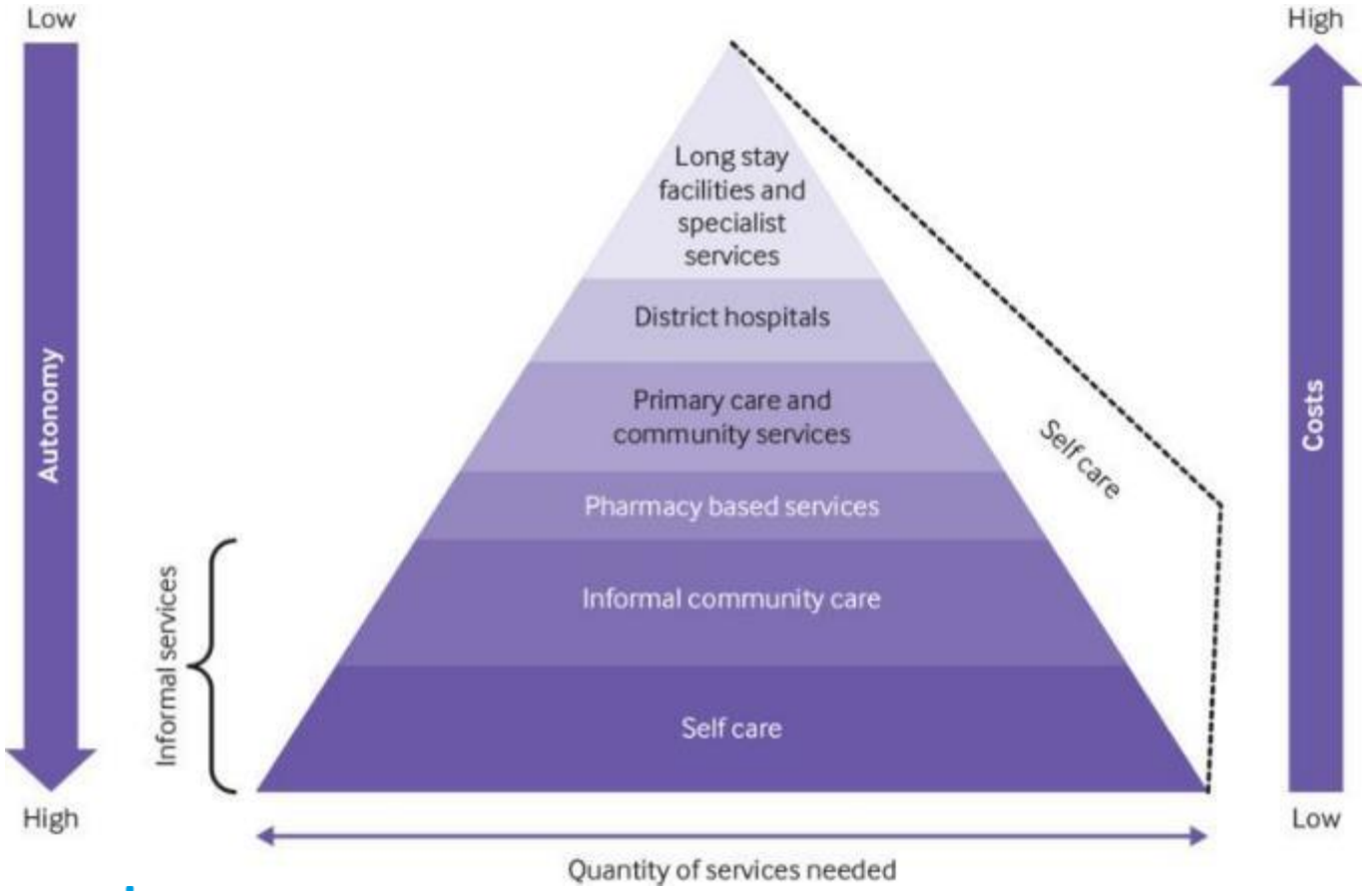
Self-care and self-testing: critical to health system



- Increase engagement and autonomy
- Increase access and equity
- Improve quality of care
- Increase efficiency
- Reduce costs to health system and individuals
- Expand UHC efforts

Source: Remme 2019, https://www.bmj.com/content/365/bmj.l1228

Self-testing framework

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PREPARATION

Demand generation

Support package

Accessible & affordable

Uptake among at-risk groups

DIRECT ACTION

Link to treatment

Re-link to Tx

Disclosure/Shared knowledge of status

Link to Prevention

Triaged out of Health System

DIRECTIMPACT

Health: Reduced Morbidity & Mortality

Reduced Transmission & Infections Averted

Cost and Time Savings (Health System & Users)

ADDITIONAL IMPACT

Social & Economic

Population Productivity & Growth

Social Benefit Social Harm

Health Systems

Efficiency

Expanded Coverage

Equity of Health

**Adapted framework based on BMGF & UNITAID HIVST Meeting in January 2017*

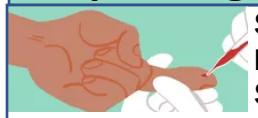
DIFFERENT POPULATIONS

DIFFERENT CONTEXTS

DIFFERENT GEOGRAPHIES

In vitro diagnostic medical devices (IVDs) for testing services

1 Rapid diagnostic tests



Steps: Minimal
Results: 1-20 min, same day results
Specimen: Fingerprick blood & oral fluid

Throughput: 5-10 per 5-15 min
Price per test: ~$0.82-$5.00
Performance: WHO PQ standards across HIV, STIs, Hepatitis
Where: Virtually anywhere (PHC & Community level, as well as higher level facilities and labs)
Who: Virtually anyone (trained lay providers, HCW, lab techs etc)
Storage: Generally no electricity or refrigeration needs

2 Self-test

Steps: Minimal
Results: 1-20 min, same day results
Specimen: Fingerprick blood & oral fluid

Throughput: Vast, but variable by distribution approach
Price per test: ~$1.00-5.00
Performance: WHO PQ standards across HIV, STIs, Hepatitis
Where: Virtually anywhere (PHC & community level etc)
Who: Most anyone (videos/demonstrations can help users)
Storage: No electricity or refrigeration needs

3 Other simple assays & Immunoassays

Steps: Moderate to complex
Results: ~30 min–3hrs, turnaround time varies by setting generally next day
Specimen: Serum, plasma

Throughput: 9 per 15-30 min to 90 per hr (varies with batching)
Price per test: Variable (>$1.00)
Performance: WHO PQ standards across HIV, STIs, Hepatitis
Where: Health facilities (some PHC, but mostly higher level facilities and labs as some assays need automation
Who: Trained facility staff and lab techs only etc
Storage: Electricity and refrigeration needs

4 Nucleic acid techniques (NAT)

Steps: Moderate to Complex
Results: ~1hrs–4hrs, turnaround up to 35 days (varies by setting), turnaround time not same day
Specimen: Plasma & DBS (RNA and TNA)

Throughput: Widely variable by device (8-384 per 8hr shift)
Price per test: $8-25 (not including $$$ device)
Performance: Data must support Mx claim (%PA)
Where: Health facilities (some PHC, higher level facilities & labs
Who: Trained facility staff and lab techs only etc)
Storage: Electricity and (mostly) refrigeration needs

Factors for product selection

Operational characteristics for consideration:

- Test purpose (aid for diagnosis, monitoring)
- Specimen type
- Detection type
- Time to result
- Storage and stability
- Staff and skill level
- Equipment and consumables required
- Quality control (internal/external)

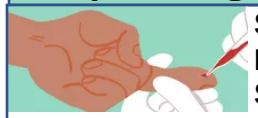
Additional considerations

- Aims and population
- Contributing to best algorithm and programme need
- Programme & public health impact
- Implementation and feasibility
- Price and service costs
- Training needs
- Support and supervision

Source: WHO, 2019: https://apps.who.int/iris/bitstream/handle/10665/335902/9789240011809-eng.pdf

In vitro diagnostic medical devices (IVDs) for testing services

1 Rapid diagnostic tests



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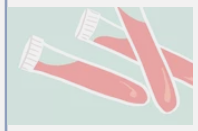
Results: ~30 min–3hrs, turnaround time varies by setting generally next day
Specimen: Serum, plasma

Throughput: 9 per 15-30 min to 90 per hr (varies with batching)
Price per test: Variable (>$1.00)
Performance: WHO PQ standards across HIV, STIs, Hepatitis
Where: Health facilities (some PHC, but mostly higher level facilities and labs as some assays need automation
Who: Trained facility staff and lab techs only etc
Storage: Electricity and refrigeration needs

4 Nucleic acid techniques (NAT)



Steps: Moderate to Complex
Results: ~1hrs–4hrs, turnaround up to 35 days (varies by setting), turnaround time not same day
Specimen: Plasma & DBS (RNA and TNA)

Throughput: Widely variable by device (8-384 per 8hr shift)
Price per test: $8-25 (not including $$$ device)
Performance: Data must support Mx claim (%PA)
Where: Health facilities (some PHC, higher level facilities & labs
Who: Trained facility staff and lab techs only etc)
Storage: Electricity and (mostly) refrigeration needs

Factors for product selection

Operational characteristics for consideration:

- Test purpose (aid for diagnosis, monitoring)
- Specimen type
- Detection type
- Time to result
- Storage and stability
- Staff and skill level
- Equipment and consumables required
- Quality control (internal/external)

Additional considerations

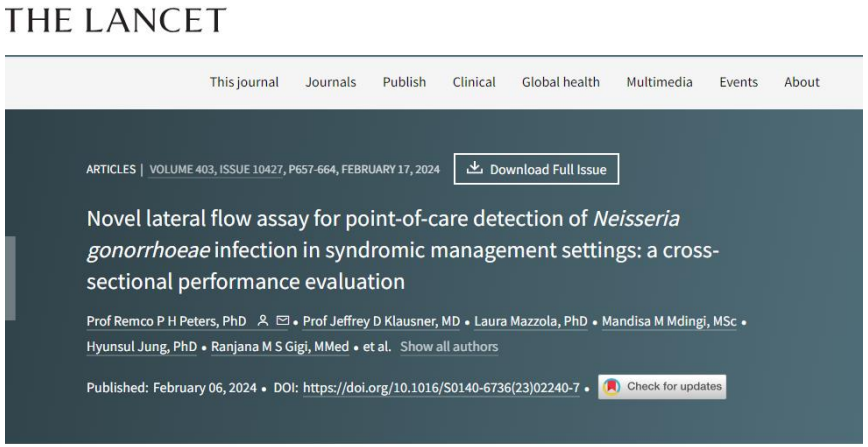
- Aims and population
- Contributing to best algorithm and programme need
- Programme & public health impact
- Implementation and feasibility
- Price and service costs
- Training needs
- Support and supervision

Source: WHO, 2019: https://apps.who.int/iris/bitstream/handle/10665/335902/9789240011809-eng.pdf

Rapid diagnostic tests available and in the pipeline

RDTs with WHO PQ

- ~15 HIV RDTs
  - 1 under assessment & 3 for self-testing
- 3 HIV/syphilis RDTs & 2 syphilis RDTs
  - 1 syphilis RDT under assessment
- 1 HBV RDT & 5 HCV RDTs
  - 3 HCV RDT under assessment
- WHO PQ introducing other STI diagnostics starting in 2025 broadening possibilities
  - New LFAs emerging for STIs
- Several others in pipeline, including additional multiplex RDTs
  - 1 HIV, HBV, syphilis panel under assessment
  - Additional coming into the pipeline



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Source: WHO PQ:, https://extranet.who.int/prequal/vitro-diagnostics/prequalification-reports/whopr; Peters 2024 https://www.sciencedirect.com/science/article/abs/pii/S0140673623022407

Cost-effective testing service delivery considerations

AIDS CARE, 2017
VOL. 29, NO. 12, 1473–1479
https://doi.org/10.1080/09540121.2017.1317710

Routledge
Taylor & Francis Group

OPEN ACCESS

Should trained lay providers perform HIV testing? A systematic review to inform World Health Organization guidelines

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ABSTRACT

New strategies for HIV testing services (HTS) are needed to achieve UN 90-90-9 diagnosis of 90% of people living with HIV. Task-sharing HTS to trained lay pro health worker shortages and better reach target groups. We conducted a s studies evaluating HTS by lay providers using rapid diagnostic tests (RDTs). Pe were included if they compared HTS using RDTs performed by trained lay p health professionals, or to no intervention. We also reviewed data on en preferences around lay providers preforming HTS. Searching was conducted databases, reviewing reference lists, and contacting experts. Screening and da conducted in duplicate using systematic methods. Of 6113 unique citations were included in the effectiveness review and 6 in the values and preferenc based randomized trial found patients' uptake of HTS doubled with lay prov percent difference: 30, 95% confidence interval: 27-32, $p < 0.001$). In Malaw showed increases in HTS sites and tests after delegation to lay provi Cambodia, Malawi, and South Africa comparing testing quality between laboratory staff found little discordance and high sensitivity and specificity preferences studies generally found support for lay providers conducting non-hypothetical scenarios. Based on evidence supporting using trained lay expert panel recommended lay providers be allowed to conduct HTS using this recommendation could expand HIV testing to more people globally.

POLICY BRIEF

WHO RECOMMENDS COUNTRIES MOVE AWAY FROM THE USE OF WESTERN BLOTTING AND LINE IMMUNOASSAYS IN HIV TESTING STRATEGIES AND ALGORITHMS

NOVEMBER 2019

World Health Organization

Introduction

The first of the United Nation's 90–90–90 global HIV targets is to diagnose 90% of people with HIV globally (UNAIDS, 2014a). Achieving this goal will require a range of approaches to delivering HIV testing services (HTS) tailored toward different epidemic contexts, groups most at risk for HIV, and people who remain undiagnosed and underserved (WHO, 2015). Rapid diagnostic tests (RDTs) can facilitate this by providing HIV test results in minutes rather than days. However, in many settings, a critical shortage of healthcare providers hampers expansion, and traditional testing approaches may poorly reach key populations and other high-risk groups (UNAIDS, 2014b).

Task-sharing – the rational redistribution of tasks from higher-level health provider cadres to lower-level cadres –

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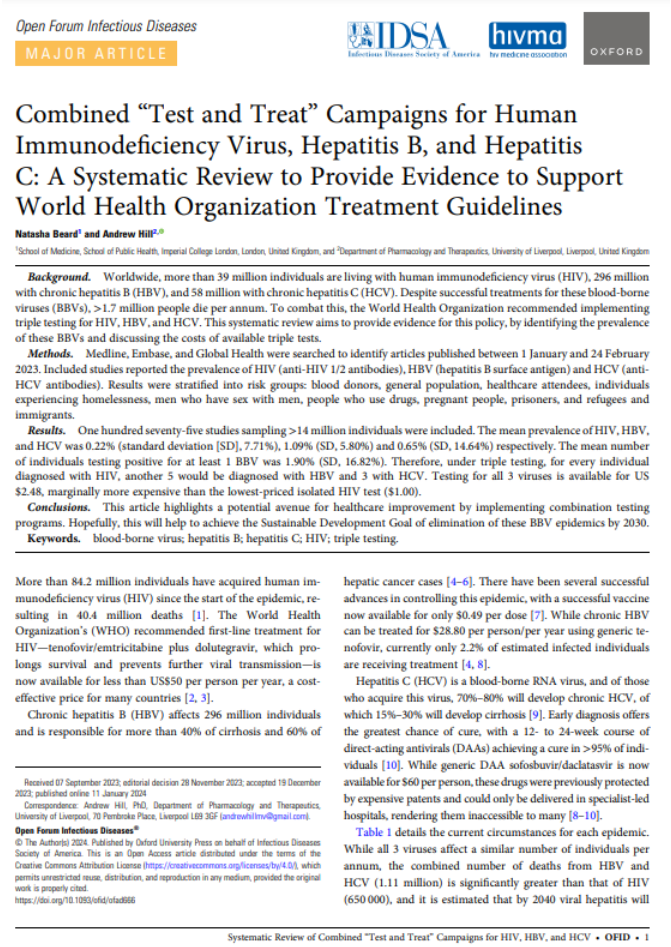
Supplemental data for this article can be accessed 10.1080/09540121.2017.1317710

- Community outreach and network-based testing can be highly cost-effective when targeted – particularly among key populations and groups
- Lay provider testing (WHO recommended) found to be cost-effective
  - 1 RCT reported that in addition to achieving greater testing uptake overall, lay provider testing was more affordable than standard testing
    - Estimated HIV testing costs in the healthcare provider and lay provider arms averaged US $8.10 and $31.00 per result received.
    - The healthcare provider strategy ICER of $58,700/ QALY and lay provider strategy (compared to the health-care provider strategy) a ratio of $64,500/QALY.
- Shifting away from laboratory testing was also found to be more affordable and cost-effective, such as moving to RDT/EIA based testing algorithms and discontinuing western blotting.
  - In 2019, one country reported that shifting away from WB to a new strategy the turnaround time between testing and receiving final HIV diagnoses reduced from 4-6 weeks to 1-2 weeks. And cost of HIV testing services reported by the national programme have also considerably decreased.

World Health Organization

Kennedy 2015 https://doi.org/10.1080/09540121.2017.1317710 , Walensky 2011: https://pubmed.ncbi.nlm.nih.gov/21684391/, WHO 2019: https://iris.who.int/bitstream/handle/10665/329915/WHO-CDS-HIV-19.30-eng.pdf?sequence=1, WHO 2019 https://www.who.int/publications/i/item/978-92-4-155058-1 , Choong et al https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4519559

Cost-effectiveness of integrated testing



Open Forum Infectious Diseases
MAJOR ARTICLE

Combined "Test and Treat" Campaigns for Human Immunodeficiency Virus, Hepatitis B, and Hepatitis C: A Systematic Review to Provide Evidence to Support World Health Organization Treatment Guidelines

Natasha Beard[1] and Andrew Hill[2,©]

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Background. Worldwide, more than 39 million individuals are living with human immunodeficiency virus (HIV), 296 million with chronic hepatitis B (HBV), and 58 million with chronic hepatitis C (HCV). Despite successful treatments for these blood-borne viruses (BBVs), >1.7 million people die per annum. To combat this, the World Health Organization recommended implementing triple testing for HIV, HBV, and HCV. This systematic review aims to provide evidence for this policy, by identifying the prevalence of these BBVs and discussing the costs of available triple tests.

Methods. Medline, Embase, and Global Health were searched to identify articles published between 1 January and 24 February 2023. Included studies reported the prevalence of HIV (anti-HIV 1/2 antibodies), HBV (hepatitis B surface antigen) and HCV (anti-HCV antibodies). Results were stratified into risk groups: blood donors, general population, healthcare attendees, individuals experiencing homelessness, men who have sex with men, people who use drugs, pregnant people, prisoners, and refugees and immigrants.

Results. One hundred seventy-five studies sampling >14 million individuals were included. The mean prevalence of HIV, HBV, and HCV was 0.22% (standard deviation [SD], 7.71%), 1.09% (SD, 5.80%) and 0.65% (SD, 14.64%) respectively. The mean number of individuals testing positive for at least 1 BBV was 1.90% (SD, 16.82%). Therefore, under triple testing, for every individual diagnosed with HIV, another 5 would be diagnosed with HBV and 3 with HCV. Testing for all 3 viruses is available for US $2.48, marginally more expensive than the lowest-priced isolated HIV test ($1.00).

Conclusions. This article highlights a potential avenue for healthcare improvement by implementing combination testing programs. Hopefully, this will help to achieve the Sustainable Development Goal of elimination of these BBV epidemics by 2030.

Keywords. blood-borne virus; hepatitis B; hepatitis C; HIV; triple testing.

More than 84.2 million individuals have acquired human immunodeficiency virus (HIV) since the start of the epidemic, resulting in 40.4 million deaths [1]. The World Health Organization's (WHO) recommended first-line treatment for HIV—tenofovir/emtricitabine plus dolutegravir, which prolongs survival and prevents further viral transmission—is now available for less than US$50 per person per year, a cost-effective price for many countries [2, 3].

Chronic hepatitis B (HBV) affects 296 million individuals and is responsible for more than 40% of cirrhosis and 60% of hepatic cancer cases [4–6]. There have been several successful advances in controlling this epidemic, with a successful vaccine now available for only $0.49 per dose [7]. While chronic HBV can be treated for $28.80 per person/per year using generic tenofovir, currently only 2.2% of estimated infected individuals are receiving treatment [4, 8].

Hepatitis C (HCV) is a blood-borne RNA virus, and of those who acquire this virus, 70%–80% will develop chronic HCV, of which 15%–30% will develop cirrhosis [9]. Early diagnosis offers the greatest chance of cure, with a 12- to 24-week course of direct-acting antivirals (DAAs) achieving a cure in >95% of individuals [10]. While generic DAA sofosbuvir/daclatasvir is now available for $60 per person, these drugs were previously protected by expensive patents and could only be delivered in specialist-led hospitals, rendering them inaccessible to many [8–10].

Table 1 details the current circumstances for each epidemic. While all 3 viruses affect a similar number of individuals per annum, the combined number of deaths from HBV and HCV (1.11 million) is significantly greater than that of HIV (650 000), and it is estimated that by 2040 viral hepatitis will

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https://doi.org/10.1093/ofid/ofad666

- Systematic review found integrating HIV and Hepatitis B and C testing was not only effective in increasing case identification but affordable
- Under triple testing, for every individual diagnosed with HIV, another 5 would be diagnosed with HBV and 3 with HCV.
- Testing for all 3 viruses was found to be available for US$2.48, marginally more expensive than the lowest-priced isolated HIV test ($1.00).
- Maximizing opportunities for integration and using rapid tests can achieve impact and be affordable as part of efforts to expand access

World Health Organization

Beard & Hill 2024: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10863549/

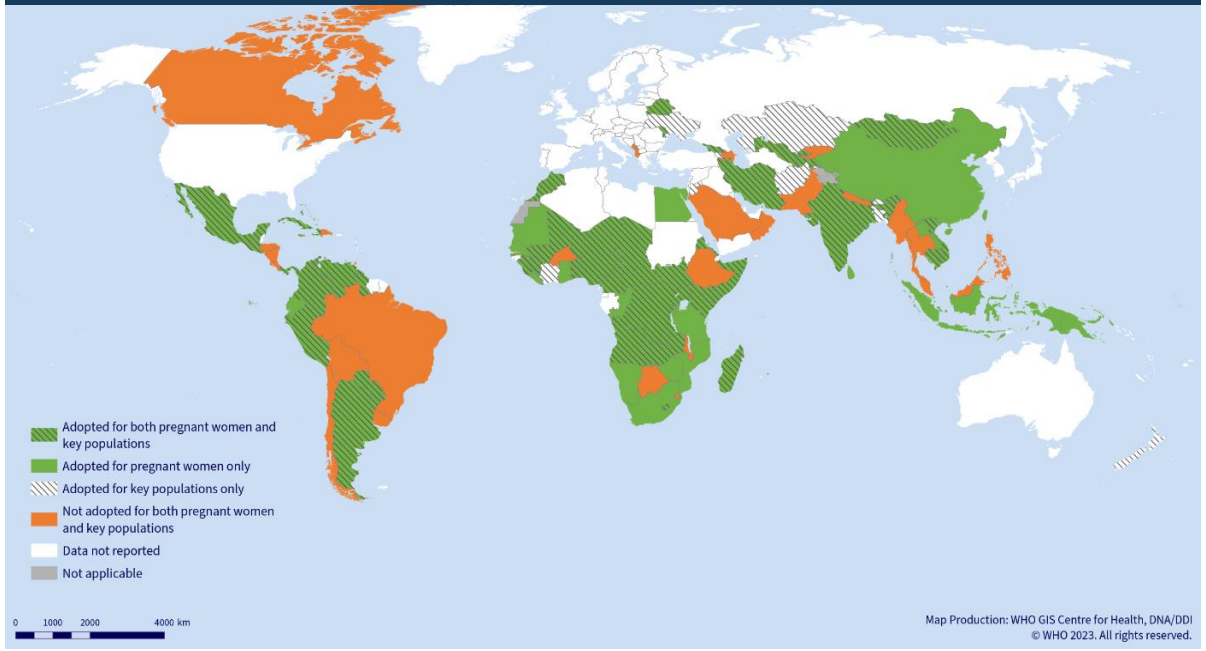
Dual HIV/syphilis testing services

- ✓ Prices range from $0.95 to $1.50 per test
- ✓ Can be procured through WHO, Global Fund, PEPFAR/USAID: opportunities for pooled procurement
- ✓ Revitalized collaboration with US CDC on serology proficiency testing

Year PQed	Product Name	Manufacturer	WHO evaluation Final sensitivity	WHO evaluation Final specificity
Oct 2015	Bioline HIV/Syphilis Duo	Abbott Diagnostics Korea Inc (Republic of Korea)	HIV: 100% **Syphilis: 87%**	HIV: 99.5% **Syphilis: 99.5%**
June 2019	First Response HIV 1+2/Syphilis Combo Card Test	Premier Medical Corporation Pvt Ltd (Gujarat, India)	HIV: 100% **Syphilis: 99%**	HIV: 99.5% **Syphilis: 100%**
May 2020	Standard Q HIV/Syphilis Combo Test	SD Biosensor Inc (Republic of Korea)	HIV: 100% **Syphilis: 95.5%**	HIV: 99.5% **Syphilis: 99.5%**

https://extranet.who.int/pqweb/vitro-diagnostics/vitro-diagnostics-lists

National policies on dual HIV/syphilis rapid tests, **July 2023**



67 (63%) countries reported having policies and/or using dual HIV/syphilis test use in ANC (GAM, 2023) – but uptake in Europe is low despite increasing syphilis rates

Cost-effectiveness of integrated testing

Articles

Cost-effectiveness of dual maternal HIV and syphilis testing strategies in high and low HIV prevalence countries: a modelling study

Patricia J Rodriguez, D Allen Roberts, Julianne Meisner, Monisha Sharma, Morkor Newman Owiredu, Bertha Gomez, Maeve B Mello, Alexey Babrik, Arkadii Vodianyk, Andrew Storey, George Githuka, Thato Chidarikire, Ruanne Barnabas, Magdalena Barr-Dichiara, Muhammad S Jamil, Rachel Baggaley, Cheryl Johnson, Melanie M Taylor, Alison L Drake

Summary

Background Dual HIV and syphilis testing might help to prevent mother-to-child transmission (MTCT) of HIV and syphilis through increased case detection and treatment. We aimed to model and assess the cost-effectiveness of dual testing during antenatal care in four countries with varying HIV and syphilis prevalence.

Methods In this modelling study, we developed Markov models of HIV and syphilis in pregnant women to estimate costs and infant health outcomes of maternal testing at the first antenatal care visit with individual HIV and syphilis tests (base case) and at the first antenatal care visit with a dual rapid diagnostic test (scenario one). We additionally evaluated retesting during late antenatal care and at delivery with either individual tests (scenario two) or a dual rapid diagnosis test (scenario three). We modelled four countries: South Africa, Kenya, Colombia, and Ukraine. Strategies with an incremental cost-effectiveness ratio (ICER) less than the country-specific cost-effectiveness threshold (US$500 in Kenya, $750 in South Africa, $3000 in Colombia, and $1000 in Ukraine) per disability-adjusted life-year averted were considered cost-effective.

Findings Routinely offering testing at the first antenatal care visit with a dual rapid diagnosis test was cost-saving compared with the base case in all four countries (ICER: −$26 in Kenya,−$559 in South Africa, −$844 in Colombia, and −$454 in Ukraine). Retesting during late antenatal care with a dual rapid diagnostic test (scenario three) was cost-effective compared with scenario one in all four countries (ICER: $270 in Kenya, $260 in South Africa, $2207 in Colombia, and $205 in Ukraine).

Interpretation Incorporating dual rapid diagnostic tests in antenatal care can be cost-saving across countries with varying HIV prevalence. Countries should consider incorporating dual HIV and syphilis rapid diagnostic tests as the first test in antenatal care to support efforts to eliminate MTCT of HIV and syphilis.

Funding WHO, US Agency for International Development, and the Bill & Melinda Gates Foundation.

Introduction

Dual elimination of mother-to-child transmission (MTCT) of HIV and syphilis is a public health priority. Worldwide, 1·4 million maternal HIV infections and 988 000 maternal syphilis infections occur annually.[1] Although maternal treatment is highly effective at preventing MTCT of both HIV and syphilis, gaps in maternal testing and treatment coverage lead to 180 000 infant HIV infections, 355 000 adverse congenital syphilis birth outcomes, and 306 000 non-clinical congenital syphilis cases every year.[1,2] WHO has set goals to reach elimination of MTCT of HIV and syphilis, including at least 95% of pregnant women receiving antenatal care, 95% tested for HIV and syphilis, and 95% treated for their infection(s).[3,4] Yet, by 2020, only 14 countries had received validation by WHO for achieving the elimination of paediatric HIV or congenital syphilis.[5,6] Globally, as HIV testing coverage has increased, more pregnant women with HIV are aware of their status, of whom 85% have accessed treatment; whereas, only 66% of pregnant women are tested for syphilis, of whom 78% receive treatment.[1,7] Global efforts for prevention of MTCT (PMTCT) of HIV have led to substantial reductions in new paediatric HIV infections, but PMTCT of syphilis has received considerably less attention and success.[1]

Integrating syphilis testing and treatment into existing HIV PMTCT programmes might avert additional syphilis morbidity and mortality. 57% of congenital syphilis cases resulting in adverse birth outcomes were attributed to an absence of syphilis screening for women attending antenatal care.[1] Testing coverage for HIV is often several times higher than for syphilis, suggesting that integrated testing could improve syphilis test coverage.[4] Although

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The Comparative Health Outcomes Policy & Economics Institute (P J Rodriguez MPH), Department of Epidemiology (D A Roberts MPH, J Meisner BVM&S), Department of Global Health (M Sharma PhD, R Barnabas DPhil, A L Drake PhD), and Department of Medicine (R Barnabas), University of Washington, Seattle, WA, USA; Global HIV, Hepatitis and Sexually Transmitted Infections Programme, WHO, Geneva, Switzerland (M N Owiredu MBChB, M Barr-Dichiara MPH, M S Jamil PhD, R Baggaley MBBS, C Johnson MA, M M Taylor MD); Pan American Health Organization and WHO, Colombia Office, Bogotá DC, Colombia (B Gomez MD); Department of Communicable Diseases and Environmental Determinants of Health, Pan American Health Organization and WHO, Washington DC, USA (M B Mello PhD); Global Fund to Fight AIDS, Tuberculosis and Malaria, Grand-Saconnex, Switzerland (A Babrik MD); Department of Infectious Diseases, Ukraine Country Office, WHO, Kiev, Ukraine (A Vodianyk MD); Maternal and Neonatal Health, Clinton Health Access Initiative, Boston, MA, USA (A Storey MBA); Ministry of Health, Nairobi, Kenya (G Githuka MBChB); HIV Prevention Programmes, National Department of Health, Pretoria, South Africa (T Chidarikire PhD); Clinical Research Department, London School of Hygiene & Tropical Medicine, London, UK (C Johnson); and Division of

Open access Original research

BMJ Open

Cost-effectiveness of implementing HIV and HIV/syphilis dual testing among key populations in Viet Nam: a modelling analysis

David Coomes ,[1,2] Dylan Green,[1,2] Ruanne Barnabas,[2,3] Monisha Sharma,[2] Magdalena Barr-DiChiara,[4] Muhammad S Jamil,[4] R Baggaley,[4] Morkor Newman Owiredu,[4] Virginia Macdonald,[4] Van Thi Thuy Nguyen ,[5] Son Hai Vo,[6] Melanie Taylor,[4,7] Teodora Wi,[4] Cheryl Johnson,[4,8] Alison L Drake [1,2]

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ABSTRACT

Objectives Key populations, including sex workers, men who have sex with men, and people who inject drugs, have a high risk of HIV and sexually transmitted infections. We assessed the health and economic impacts of different HIV and syphilis testing strategies among three key populations in Viet Nam using a dual HIV/syphilis rapid diagnostic test (RDT).

Setting We used the spectrum AIDS impact model to simulate the HIV epidemic in Viet Nam and evaluated five testing scenarios among key populations. We used a 15-year time horizon and a provider perspective for costs.

Participants We simulate the entire population of Viet Nam in the model.

Interventions We modelled five testing scenarios among key populations: (1) annual testing with an HIV RDT, (2) annual testing with a dual RDT, (3) biannual testing using dual RDT and HIV RDT, (4) biannual testing using HIV RDT and (5) biannual testing using dual RDT.

Primary and secondary outcome measures The primary outcome is incremental cost-effectiveness ratios. Secondary outcomes include HIV and syphilis cases.

Results Annual testing using a dual HIV/syphilis RDT was cost-effective (US$10 per disability-adjusted life year (DALY)) and averted 3206 HIV cases and treated 27 727 syphilis cases compared with baseline over 15 years. Biannual testing using one dual test and one HIV RDT (US$1166 per DALY), or two dual tests (US$5672 per DALY) both averted an additional 875 HIV cases, although only the former scenario was cost-effective. Annual or biannual HIV testing using HIV RDTs and separate syphilis tests were more costly and less effective than using one or two dual RDTs.

Conclusions Annual HIV and syphilis testing using dual RDT among key populations is cost-effective in Vietnam and similar settings to reach global reduction goals for HIV and syphilis.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Our model parameters are informed by empiric data including demographic, behavioural and biological data from government sources, surveys, surveillance, publicly available reports, databases and peer-reviewed literature.
- ⇒ We assess the impact of five testing scale up scenarios using both HIV rapid diagnostic test (RDT) and dual HIV/syphilis RDT and conduct sensitivity analyses to evaluate uncertainty in model results.
- ⇒ Due to limited data, we make assumptions regarding the timing and uptake of HIV and syphilis testing among key populations that may be inaccurate.
- ⇒ Our model conservatively assumes that increased syphilis testing and treatment will not impact syphilis prevalence, which is currently unknown.

INTRODUCTION

Key populations, including people who inject drugs (PWID), men who have sex with men (MSM), sex workers (SW) and transgender populations, are at higher risk of acquiring both HIV and syphilis. HIV incidence is significantly higher among key populations compared with the general population in all geographical regions; however, differences vary substantially by region and by key population.[1] While key populations and their sexual partners represent approximately 25% of new HIV cases in sub-Saharan Africa, they represent 80% of new HIV cases in the rest of the world.[2] Recent data suggests that syphilis incidence, while generally remaining stable in low-income and middle-income countries (LMICs), is increasing among key populations, particularly MSM.[1 3 4] WHO HIV testing guidelines recommend HIV retesting at least annually for key populations and more frequent testing (3–6 months) for those with high ongoing risk.[5] WHO guidelines for syphilis screening depend on population and setting. Laboratory-based syphilis testing remains common, however rapid diagnostic tests (RDTs) for syphilis are increasingly

- Cost-effectiveness modelling on use of dual HIV/syphilis RDTs found use in ANC and KP was cost-effective
  - In ANC: Cost-saving in all scenarios, including in Ukraine, and cost-effective with retest in 3rd trimester in all settings including Ukraine
  - In KP: Annual testing using a dual HIV/syphilis RDT was cost-effective in KP-driven epidemic. And biannual testing using one dual test was cost-effective. Using dual RDTs was less costly than single HIV RDTs and separate syphilis RDTs.
  - Similar strategies to integrate and use multiplex tests could have similar results but require careful planning to achieve true benefit at clinical level

World Health Organization

Beard & Hill 2024: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10863549/

Cost-effectiveness of self-testing

frontiers | Frontiers in Public Health

How much does HIV self-testing cost in low and middle income countries? A systematic review of evidence from economic studies

PLOS MEDICINE

Expanding syphilis test uptake using rapid dual self-testing for syphilis and HIV among men who have sex with men in China: A multiarm randomized controlled trial

PLOS GLOBAL PUBLIC HEALTH

Cost-effectiveness of Hepatitis C virus self-testing in four settings

PREVENTION RESEARCH

Estimating the Cost-Effectiveness of HIV Self-Testing in the United States Using Net Benefit Regression

Islam, Md Hafizul PhD[a]; Shrestha, Ram K. PhD[a]; Hoch, Jeffrey S. PhD[b]; Farnham, Paul G. PhD[a]

Author Information

JAIDS Journal of Acquired Immune Deficiency Syndromes 95(2):p 138-143, February 1, 2024. | DOI: 10.1097/QAI.0000000000003325

World Health Organization

- Multiple studies have shown self-testing across HIV, HCV and syphilis can be cost-effective
  - **HIVST** is affordable and cost-effective in LMICs. A recent systematic review found variability but that all implementation cost-effective and estimated:
    - Cost per person tested ranged from $1.09–155.
    - Cost per case diagnosed ranged from $20–1,277.
    - Cost-utility estimates ranged from cost-saving to $1846 per DALY averted.
    - Higher cost-effectiveness estimates were associated with more expensive testing algorithms with increased support for linkage to care and post-test counseling.
  - In HIC settings like the USA where private sector options or more costly testing options are supported also found HIVST likely to be cost-effective
    - **Need to adapt models for Europe to support policy change**
  - **HCVST** was more cost-effective when used in high prevalence populations and overall would increase the number of people tested, diagnosed, and cured (though at a higher cost than existing services).
  - **HIV/syphilis ST** was cost-effective among MSM in China and reported the cost per person tested was US$27 for SST which substantially less than the cost of standard testing (US$66)
- Cost drivers need to be addressed and implementation through virtual interventions, secondary distribution, coordinated procurement and support on access to quality and affordable products can help maximize benefits and reduce costs

WHO 2019, Empringham 2023, Hanzul 2024, Walker 2023, Wang 2022, PloS Med,

Cost-effectiveness of self-testing

Articles

Impact of HIV self-testing for oral pre-exposure prophylaxis scale-up on drug resistance and HIV outcomes in western Kenya: a modelling study

Sarah N Cox*, Linxuan Wu*, Rachel Wittenauer, Samantha Clark, D Allen Roberts, Ifechukwu Benedict Nwogu, Olga Vitruk, Alexandra P Kuo, Cheryl Johnson, Muhammad S Jamil, Anita Sands, Robin Schaefer, Christine Kisia, Rachel Baggaley, Joanne D Stekler, Adam Akullian, Monisha Sharma

Summary

Background Community-based oral pre-exposure prophylaxis (PrEP) provision has the potential to expand PrEP coverage. HIV self-testing can facilitate PrEP community-based delivery but might have lower sensitivity than facility-based HIV testing, potentially leading to inappropriate PrEP use among people with HIV and subsequent development of drug resistance. We aimed to evaluate the impact of HIV self-testing use for PrEP scale-up.

Methods We parameterised an agent-based network model, EMOD-HIV, to fumarate and emtricitabine PrEP scale-up in western Kenya using four te nucleic acid testing, provider-administered rapid diagnostic tests detecting ar or oral fluid HIV self-testing. Scenarios were compared with a no PrEP count with one or more heterosexual partners who screened HIV-negative were elig health impact of rapid PrEP scale-up with high coverage over 20 years, and various HIV testing modalities.

Findings PrEP coverage of 29% was projected to avert approximately 54% of deaths among adults aged 18–49 years over 20 years; health impacts were sim to deliver PrEP. The percentage of HIV infections with PrEP-associated nu (NRTI) drug resistance was 0·6% (95% uncertainty intervals 0·4–0·9) in th 0·8% (0·6–1·0) in the oral HIV self-testing scenario, compared with 0·3% (0· testing scenario and 0·2% (0·1–0·2) in the nucleic acid testing scenario. Accou we found similarly low proportions of drug resistance across scenarios. The using HIV self-testing and provider-administered rapid diagnostic tests were approximately 50% more costly.

Interpretation Scaling up PrEP using HIV self-testing has similar health impac as provider-administered rapid diagnostic tests. Policy makers should conside PrEP access among those at HIV risk.

Funding The Bill and Melinda Gates Foundation.

Lancet HIV 2024; 11: e167–75
Published Online January 29, 2024
https://doi.org/10.1016/S2352-3018(23)00268-0

Introduction

Despite the high efficacy of oral pre-exposure prophylaxis (PrEP) and availability in clinics,[1] uptake is below global targets in sub-Saharan Africa.[2] Barriers to clinic-based PrEP uptake include privacy concerns, lost wages due to long wait and travel times to clinics, stigma, limited clinic hours, and understaffing.[3] Community-based PrEP provision (eg, via pharmacies, mobile sites, home delivery, or telehealth) is a promising strategy to overcome barriers associated with facility-based PrEP and expand coverage.[4] Sub-Saharan Africa has a growing network of remote and community-based health services, which expanded Kenya Ministry of community HIV UNAIDS target particularly in re western Kenya.

Community-bas HIV testing appr necessary before to support PrEP facilitate PrEP de easily enabling

Current HIV/AIDS Reports (2022) 19:394–408
https://doi.org/10.1007/s11904-022-00617-x

THE SCIENCE OF PREVENTION (R HEFFRON AND K NGURE, SECTION EDITORS)

Examining the Use of HIV Self-Testing to Support PrEP Delivery: a Systematic Literature Review

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Abstract

Purpose of Review HIV self-testing (HIVST) has the potential to expand access to and uptake of HIV pre-exposure prophylaxis (PrEP) delivery. We conducted a systematic literature review to understand the evidence on HIVST use for PrEP delivery.

Recent Findings After screening 1055 records, we included eight: three randomized trials and five values and preferences studies. None measured PrEP initiation. Most studies occurred in Sub-Saharan Africa (7/8) and included different populations. One trial found that HIVST use between quarterly clinic visits as part of an adherence package with biofeedback slightly increased adherence; the other two trials found that HIVST use between or in lieu of quarterly clinic visits had no significant or non-inferior effects on adherence. HIVST to support PrEP delivery was acceptable, feasible, and preferred.

Summary HIVST use for PrEP continuation largely resulted in similar outcomes to standard-of-care delivery and was perceived acceptable and feasible. Further research is needed to optimize HIVST use within PrEP programming.

Keywords Systematic literature review · HIV self-testing · PrEP delivery · HIV prevention · Implementation science · Sub-Saharan Africa

Introduction

Pre-exposure prophylaxis (PrEP) use has been increasing steadily since it was first recommended by the World Health Organization (WHO) for HIV prevention in 2015 [1]; however, many individuals that could benefit from PrEP lack access [2]. Common barriers to PrEP initiation and continuation in high HIV prevalence settings include long wait times at often overcrowded healthcare facilities [3] and the need for frequent clinic visits for HIV testing and PrEP refills which lead to high client opportunity costs [4], as well as stigma associated with PrEP access and use [5]. Simplified and novel models of PrEP delivery are needed to increase the reach and access of PrEP to populations at HIV risk not currently engaged in PrEP care [6].

HIV self-testing (HIVST), which has been recommended as an effective HIV testing approach since 2016, has the potential to simplify and support PrEP delivery [7]. Currently, the WHO recommends that individuals using PrEP should test for HIV every 3 months to detect potential breakthrough infections [8], and that HIVST can be used as a way to maintain PrEP programs in the context of the COVID-19 pandemic [9]. Currently, PrEP initiation is generally linked to clinic-based HIV testing services, followed by quarterly testing that accompanies PrEP refills. HIVST could enable individuals taking PrEP to test routinely, by replacing or complementing existing testing intervals with providers, which could potentially increase access and adherence to PrEP services [10]. Additionally, HIVST could enable

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- Emerging evidence showing the HIVST may also be helpful and reduce PrEP costs through:
  - Simplifying delivery systems
  - Reducing health worker time
  - Reducing facility visits
  - Creating flexibility for users (reducing opportunity costs, travel) increase cost-effectiveness of PrEP
  - Enabling virtual implementation models–e.g. tele-PrEP, online and app-based
- Modelling study using available data found HIVST-supported PrEP scale-up would have simliar costs, and low risk of drug resistance, when compared with provider-administered rapid testing which does not offer same user benefits of efficiencies.

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Kiptiness 2023; Cox 2024

Self-testing products with WHO PQ, ERPD or IMDRF* approval

HIVST		
Test (manufacturer)	**Specimen**	**Approval**
Mylan HIV Self Test (Atomo Diagnostics, Australia)	Blood	WHO PQ
autotest VIH® ** (AAZ Labs, France)	Blood	CE mark
BioSURE HIV Self Test ** (BioSURE , United Kingdom Ltd)	Blood	CE mark ERPD
Exacto® Test HIV (Biosynex, France)	Blood	CE mark ERPD
INSTI® HIV Self Test ** (bioLytical Lab., Canada)	Blood	WHO PQ
OraQuick® In-Home HIV Test (OraSure Technologies, USA)	Oral fluid	FDA, CE Mark
OraQuick® HIV Self Test (OraSure Technologies, USA)	Oral fluid	WHO PQ
SURE CHECK® HIV Self Test (Chembio Diagnostic Systems Inc., USA)	Blood	WHO PQ
Check Now HIV Self-Test (Abbott Rapid Diagnostics, Jena GmbH, Germany)	Blood	WHO PQ
Wondfo HIV self-test (Guangzhou Wondfo Biotech Co., Ltd.)	Blood	WHO PQ

- WHO PQ products available for US$0.95-3.10 through Global Fund
- Private sector availability in Europe
- Pipeline for products remains strong
- Blood and oral both WHO PQed

HCV self-testing
- 2 products in the pipeline
- 1 advanced in PQ pathway

Syphilis self-testing
- 2 dual HIV/syphilis product in pipeline
- 1 single syphilis product in pipeline
- WHO PQ making amendment to TSS in August 2024 to start accepting submissions

HIC, high-income countries; **FDA**, Food and Drug Administration; **ERPD,** Expert Review Panel for Diagnostics; **Gen,** test generation; **LMIC**, low- and middle-income countries, **MRSP**: maximum suggested retail price; **NA**, not available.
* Includes products prequalified by WHO, approved by a regulatory authority in one of founding-member countries of the International Medical Device Regulators Forum or eligible for procurement on recommendation of Unitaid/Global Fund Expert Review Panel for Diagnostics. ** These products sold in more than one packaging format.
Note: Product details based on information provided by the manufacturers at the time of report preparation.

WHO-Unitaid 2022

Self-testing product journey

How can these lessons be applied to Europe more broadly and beyond HIV?

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Products emerge in some European markets €20-30

Some LMIC private sector markets HIVST pricing $10-15; LMIC public sector price $3.00

Unitaid investment results in additional LMIC public sector product price reduction $1.99
Global Fund tender via Wambo 1.99-3.10 for all procurement

Unitaid

The Global Fund
To Fight AIDS, Tuberculosis and Malaria

Efforts to pool procurement increase as shipping costs and delivery increase

2012/13 | **2014/15** | **2016/17** | **2018/19** | **2020/21** | **2022/23**

HIVST available in USA for $40-50
LMIC research price $4-5

LMIC research price $3.15

Buy down on 1 product reaches $2 in LMIC public sector market; LMIC private sector expands with minimal price change $5-15

New lost cost products come into the market $0.95 for LMIC public sector

BILL & MELINDA GATES foundation

Self-testing evidence, implementation and policy scale-up

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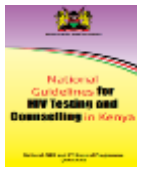
1st HIVST kit discussed

1986



2008

FDA

2005

FDA

First HIVST kit under review by FDA

2011

2012

2014

2015 – 3 countries with policies and 1 HIVST product

2013

WHO review on HIVST in health workers

WHO convenes 1st International Meeting on HIVST

2015

2016

WHO recommends HIVST

WHO HIVST scale-up guides

2018

2017

HIVST comes to Europe: 2 products CE marked and on sale in UK and France

Unitaid PSI-WHO-LSHTM STAR project kick-off Zimbabwe November 2015

1st WHO PQed kit & real world implementation

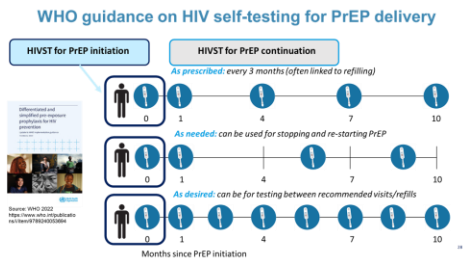
2019

WHO Self-Care and Updated HIVST guidelines on optimized service delivery

2020

HIVST & ST embraced as a key COVID adaptation

ST for syphilis (including dual test) and for PrEP recommended



2023

Multiplex self-tests and different combinations now a priority

2024

2021

Self-testing studies for HCV &C19 (WHO, 3ACP, FIND)

WHO guidance July 2021 & March 2022

HIVST: 102 countries, 6 PQ kits, market size > 20 million & price < $1

C19ST: 101 countries, market and use transitioning as pandemic evolves, price <$1

HCVST: 2 products in pipeline, price $1-4

SST: New, pipeline include 3+ products

NG/CT-ST: Emerging

7 WHO GL products, 20 systematic reviews, 12 modelling studies, 58 original research studies, 20 policy, consultation, V&P reports all showing strong evidence and support for ST

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- **Focus on effective service delivery apporaches that**:
  - Achieve greatest impact
  - Increase access and equity
  - Reach the right people
  - Are affordable
  - Use quality-assured tests
  - Use public health approach

- **Integration is high impact and cost-effective** – clear opportunities through service delivery and multiplex tests
  - Prepare service delivery systems and countries for new products coming

- **Important to advocate for investment in strategic testing approaches to achieve impact**
  - Community services need funding in the long-term. Outreach - especially testing with lay providers and rapid tests is worth it and needs expansion particularly for KP
  - Self-testing is lacking in Euorpe and need to support policy changes and ways to broaden financing and effort to use across disease areas
  - Self-testing for PrEP/PEP may be a strategic opportunity for Europe

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For more information on HIV testing services

WHO HIV Testing Services Dashboard

WHO HIV Testing Services Info App

WHO HTS GL

Questions?

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