

UNITAID • PSI



HIV SELF-TESTING AFRICA

## WHAT IS STAR?

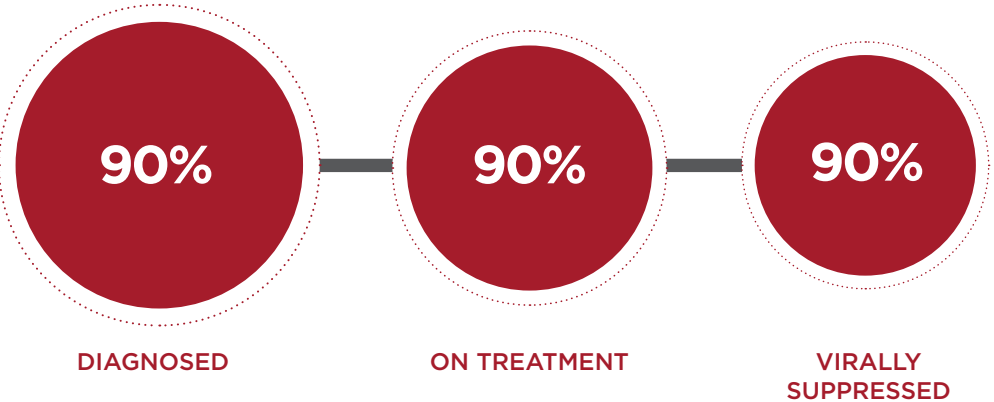
The Unitaid-funded HIV Self-Testing Africa (STAR) Initiative is a five-year project to catalyze the market for HIV self-testing (HIVST). The first phase (2015-2017) has generated crucial information about how to distribute HIVST products effectively, ethically and efficiently. The project generated multi-country public health evidence to inform WHO normative guidance and supported the development of national-level policy on HIVST. The evidence generated by the STAR Initiative informed estimates of the market size, encouraged market entry among potential HIVST manufacturers and informed the future scale up of HIVST globally.

With funding support from Unitaid, 4.8 million HIV self-test kits will be distributed across Malawi, Zambia, Zimbabwe, South Africa, Lesotho and Swaziland by 2020.



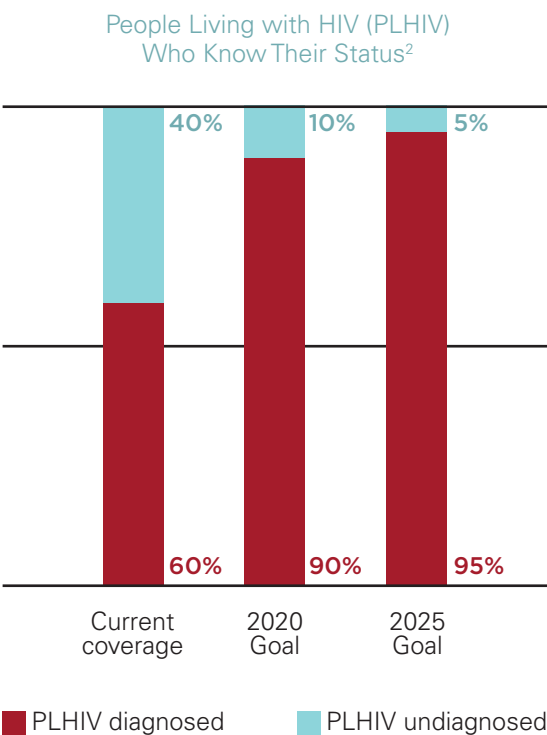
# WHY HIV SELF-TESTING?

In 2014, the United Nations set bold new targets, calling on the global community to ensure that by 2020, 90% of all people living with HIV will know their HIV status, 90% of all people diagnosed with HIV will receive sustained antiretroviral therapy and 90% of all people receiving antiretroviral therapy will have durable viral suppression.<sup>1</sup>



However, today, only an estimated 60% of people living with HIV globally know their status.

Increased uptake and frequency of HIV testing is crucial to reaching the 90-90-90 goal – particularly the first 90. Self-testing will play an important role in achieving these goals, as its discreet and convenient nature can address many of the barriers which hinder access to and uptake of HIV testing services. These include stigma, discrimination, privacy concerns, and structural barriers such as long distances to testing sites, long lines and health worker shortages. By addressing these barriers, HIVST may reach populations that are at high risk for HIV and may not otherwise test. These populations include men, young people, key populations and other vulnerable populations.



<sup>1</sup>UNAIDS. “90-90-90: An ambitious treatment target to help end the AIDS epidemic”, 2014

<sup>2</sup>UNAIDS Prevention Gap Report, 2016



## WHAT WILL STAR ACHIEVE?

The STAR Initiative is designed to answer key public health questions about HIVST and to increase the effective use of HIVST, including ensuring adequate linkage to treatment and prevention services. To achieve this, the STAR Initiative will:



### **INCREASE ACCESS AND USE OF HIVST**

Establish and optimize distribution models for quality-assured HIV self-tests in each project country, including effective linkage into prevention, treatment and care services.



### **INCREASE INFORMED DEMAND**

Increase informed demand for quality-assured HIVST, including definition of the best marketing strategies and consumer packaging.



### **REDUCE POLICY AND REGULATORY BARRIERS**

Reduce policy barriers to market entry for quality-assured HIVST products, including release of WHO normative guidance, and integration of HIVST into national policies and algorithms in project countries.



### **REMOVE STRUCTURAL BARRIERS**

Reduce structural barriers to market entry for quality-assured HIVST products by generating routine market intelligence, supporting manufacturers pursuing WHO prequalification and facilitating establishment of a harmonized regional regulatory framework.

# WHAT MARKET ISSUES LIMIT THE INTRODUCTION OF HIVST?

Despite its potential, the market for HIVST is currently limited. Key challenges to the development of a healthy HIVST market include:

- Uncertain levels of consumer demand
- Limited data on the public health impact and cost effectiveness of HIVST
- Lack of information about how HIVST should be implemented, distributed and monitored
- Lack of information on optimal procurement and supply channels
- Concerns about potential social harm
- Lack of policies and guidance supportive of HIVST (including national policies and WHO normative guidance)
- Absence of low-cost and quality-assured (WHO pre-qualified, Global Fund or USAID approved) HIV self-test products for procurement in resource-limited settings

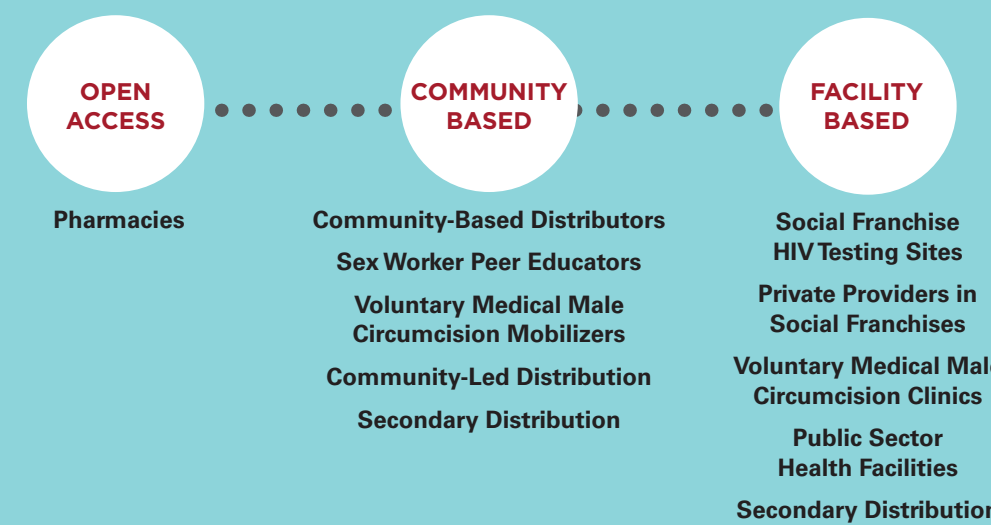
The STAR Initiative is designed to address these barriers and catalyze further HIVST market development.

# WHO WILL STAR REACH?

STAR is designed to reach people with limited access to HIV testing and low rates of testing uptake. This includes populations in rural and peri-urban areas, as well as young people, men and key populations, including female sex workers and men who have sex with men (MSM).

# WHAT HIVST DISTRIBUTION MODELS ARE INCLUDED IN THE STAR INITIATIVE?

STAR tests and optimizes distribution models across the continuum of self-testing delivery. The models used vary in the level of support provided to testers, as well as where tests are made available.



# WHAT RESEARCH QUESTIONS WILL BE ANSWERED BY THE STAR INITIATIVE?

Research under STAR is designed to answer questions about how to optimize HIVST delivery to priority populations, ensure linkage to HIV care and prevention, and maximize public health impacts at minimal cost.

## Increased Antiretroviral Therapy and Voluntary Medical Male Circumcision Coverage

- How effectively do individuals link into HIV care and VMMC after HIVST?
- Are interventions to improve linkage into post-test services effective and cost-effective?
- What are user preferences for the delivery of post-test services and how can demand for services be maximized?

## Improved Design of HIVST Models for Target Populations

- What level of accuracy can be achieved by HIVST users?
- How can social harm from introducing HIVST to individuals and key populations be anticipated and reported best?
- What are the delivery costs of adding HIVST?
- What are users' preferences and how can demand for HIVST be maximized?

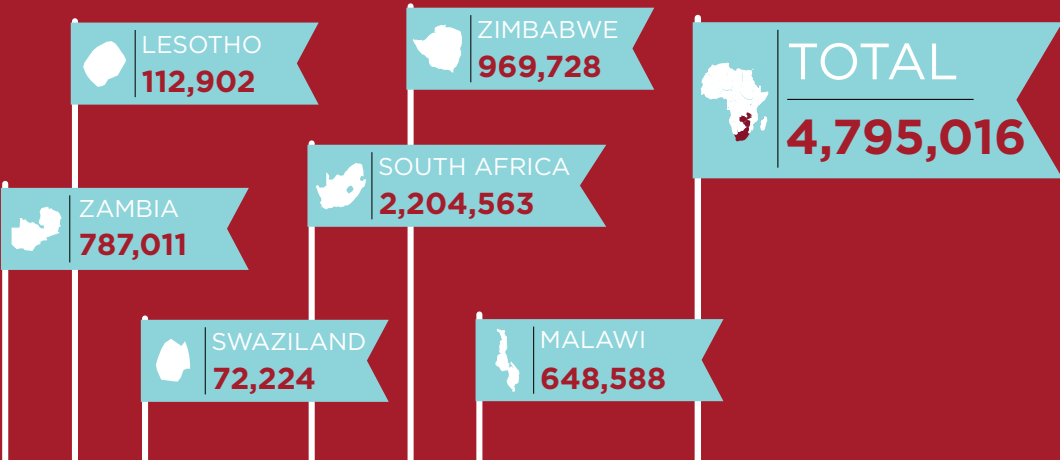
## Increased Coverage of HIV Testing Services (HTS) in the Priority Populations

- Does HIVST increase HTS frequency/coverage compared to current testing strategies?
- What is the population-level cost effectiveness of introducing HIVST?

## Increased Uptake of HIVST in the Priority Populations

- What is the estimated market size of HIVST?
- Is HIVST reaching people who are currently not accessing HTS (key populations, men, adolescents and other vulnerable populations)?

# HOW MANY HIV SELF-TESTS WILL BE DISTRIBUTED UNDER THE STAR INITIATIVE?



## STAR ACHIEVEMENTS 2015-2017

- STAR generated public health evidence on safety, acceptability, feasibility and cost effectiveness.
- 7 different distribution models are being investigated for cost, client preferences, and linkage to care and prevention.
- STAR distributed 466,000 tests between May 2015 and June 2017.
- Rapid accumulation of multi-country data has led to:
  - WHO guidelines for HIV self-testing released in 2016.
  - Price reductions for HIV self-test kits.
  - Updated country policies and regulations that include HIV self-testing.

## EARLY RESULTS INDICATE THAT HIV SELF-TESTING IS EFFECTIVELY REACHING MANY PEOPLE WHO DO NOT SEEK HIV TESTS IN HEALTH FACILITIES

- Among users of self-tests, 23% in Zimbabwe, 21% in Zambia and 26% in Malawi were first-time testers.
- Preliminary results also indicate that self-tests are helping to close knowledge-of-status gaps for young people and men.
  - Over the first year, young people comprised 28% of self-test users in Zimbabwe, 21% in Zambia and 26% in Malawi. Testing coverage among young people (aged 16–24 years) in the project areas increased by 24% in Malawi, by 17% in Zambia and by 39% in Zimbabwe.
  - Men accounted for 44% of self-test users in Zimbabwe, 51% in Zambia and 49% in Malawi. Testing coverage among men in the project areas increased by 24% in Malawi, by 21% in Zambia and by 28% in Zimbabwe.

## WHO ARE THE KEY PARTNERS?

STAR consortium partners will be working closely with Ministries of Health in Malawi, Zambia, Zimbabwe, Lesotho, Swaziland and South Africa. Civil society at the global and country level will play a key role in informing project design, dissemination of results and HIVST-related advocacy with key donors.



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