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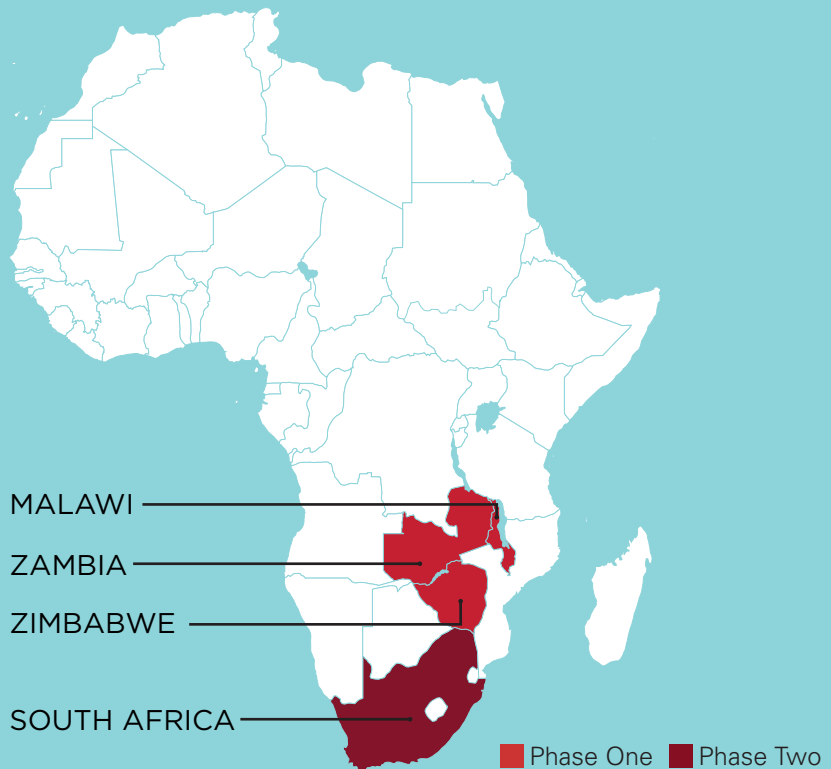


HIV SELF-TESTING AFRICA

WHAT IS STAR?

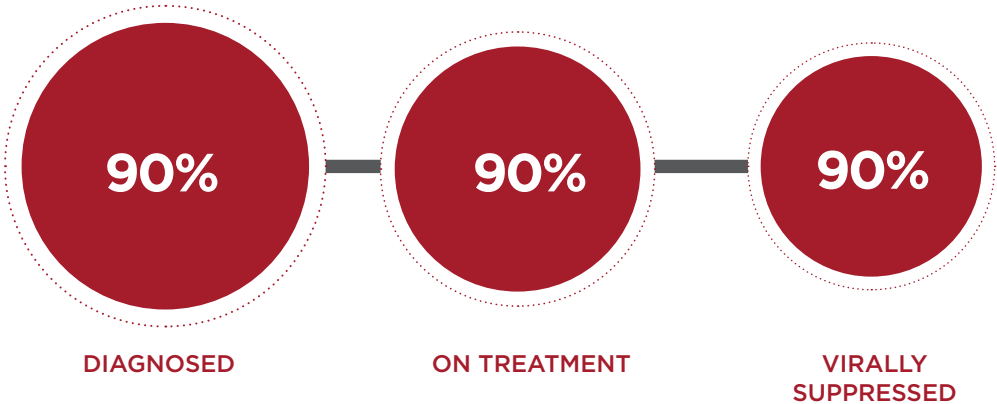
The UNITAID/PSI HIV Self-Testing Africa (STAR) Project is a four-year initiative to catalyze the market for HIV self-testing (HIVST). The project will be implemented in two phases, each lasting two years. Phase One (2015-2017) will generate crucial information about how to distribute HIVST products effectively, ethically and efficiently. The project will generate multi-country public health evidence to inform WHO normative guidance and support development of national-level policy on HIVST. The evidence generated by the project will inform estimates of market size, encourage market entry among potential HIVST manufacturers and inform the future scale up of HIVST globally.

With funding support from UNITAID, nearly 750,000 HIV self-tests will be distributed across Malawi, Zambia and Zimbabwe in Phase One of the project. Phase Two of the project (2017-2019) will scale up successful distribution models and demonstrate the population-level health impact of HIVST.



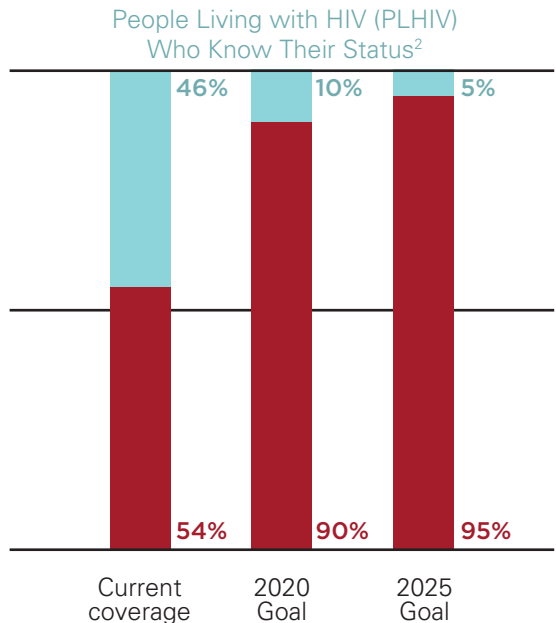
WHY HIV SELF-TESTING?

In 2014, UN 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.¹



However, today, only an estimated 54% of people living with HIV globally know their status.

Increased use of HIV testing is crucial to reaching the 90-90-90 goal. By addressing key barriers to uptake, self-testing could play an important role in increasing access to and frequency of testing, while still ensuring linkage into care. Barriers could include privacy concerns and limited access to HIV testing services (HTS). Self-testing may be particularly useful in reaching populations with low testing uptake, including men, young people, key populations and other vulnerable populations.



¹UNAIDS. "90-90-90: An ambitious treatment target to help end the AIDS epidemic", 2014

²http://www.unaids.org/en/resources/documents/2015/MDG6_15years-15lessonsfromtheAIDSresponse

■ PLHIV diagnosed ■ PLHIV undiagnosed



WHAT MARKET ISSUES LIMIT THE INTRODUCTION OF HIV SELF-TESTING?

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
- Concerns about potential social harm
- Lack of information about how HIVST should be implemented, distributed and monitored
- Lack of information on optimal procurement and supply channels
- Lack of policies and guidance supportive of HIVST (including national policies and WHO normative guidance)
- Absence of a low-cost and WHO pre-qualified HIV self-test product.

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

WHAT WILL STAR ACHIEVE?

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

WHO WILL STAR REACH?

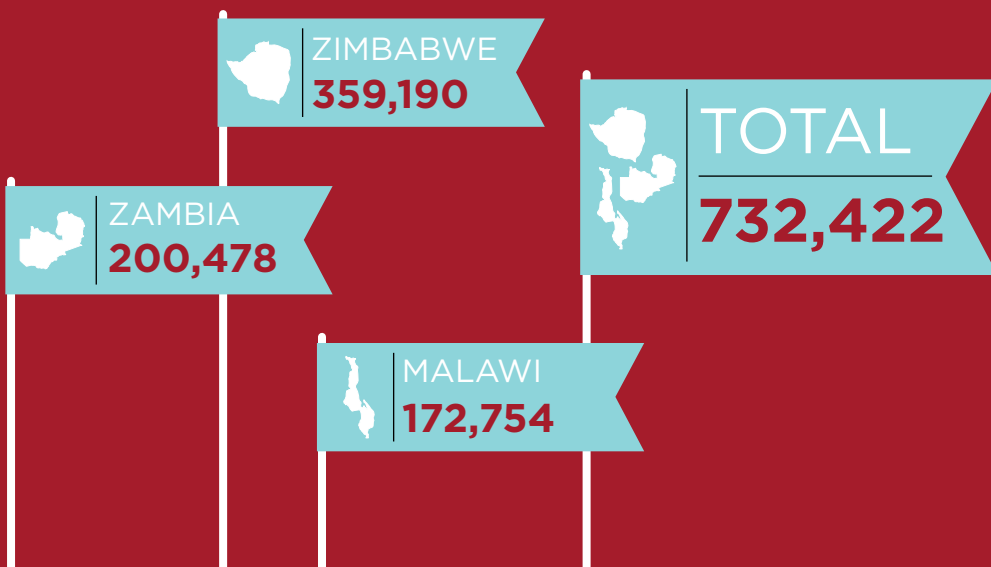
The STAR Project is designed to reach people with limited access to HIV testing and low rates of testing uptake, including populations in rural and peri-urban areas. Within the project, Zimbabwe and Malawi will also target key populations, including female sex workers and men who have sex with men.

WHAT HIVST DISTRIBUTION MODELS ARE INCLUDED IN THE STAR PROJECT?

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



HOW MANY HIV SELF-TESTS WILL BE DISTRIBUTED UNDER THE STAR PROJECT IN PHASE ONE (2015-2017)?



WHAT RESEARCH QUESTIONS WILL BE ANSWERED BY THE STAR PROJECT?

Research under the first phase of the STAR Project is designed to answer questions about how to deliver HIVST, how to generate HIVST demand and the potential public health impact of HIVST.

Increased Anti-Retroviral 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 HTS in the Priority Population

- 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 Population

- 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)?

WHO ARE THE MEMBERS OF THE STAR CONSORTIUM?

Population Services International (PSI) heads the STAR consortium, in close collaboration with the World Health Organization. WHO will lead on development of policy and normative guidance. London School of Hygiene and Tropical Medicine, Liverpool School of Tropical Medicine, and University College London lead the overall research agenda. PSI leads implementation of HIV self-test distribution in each country, including all marketing and demand creation activities. In-country HIVST research activities will be implemented by local research institutions (Malawi-Liverpool-Wellcome Trust Clinical Research Programme, ZAMBART, and the Centre for Sexual Health and HIV/AIDS Research Zimbabwe), in collaboration with PSI's country teams. The program is funded by UNITAID, an international organization based in Geneva that is finding new ways with partners to prevent, treat and diagnose HIV/AIDS, tuberculosis and malaria more quickly, more cheaply and more effectively.

WHO ARE OUR KEY PARTNERS?

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



PSI

1120 19th St. NW
Washington, DC 20036
www.psi.org

DR. KARIN HATZOLD

Director UNITAID/PSI
HIV Self-Testing Africa (STAR) Project
khatzold@psi.org

November 2015



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