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.¹

HIV self-testing will play an important role in achieving these goals. Today, only an estimated 70% of people living with HIV globally know their status. Long distances to testing facilities, long lines to access services and fear of stigma and discrimination act as barriers to HIV testing, especially among men, adolescents and key populations. Self-testing can play an important role in addressing these barriers and achieving the first and second 90s by providing a discreet and convenient way to test for HIV. By increasing testing uptake, self-testing also contributes to HIV prevention goals by generating demand for and improving linkage to voluntary medical male circumcision (VMMC) and pre-exposure prophylaxis (PrEP) services.

¹UNAIDS. “90-90-90: An ambitious treatment target to help end the AIDS epidemic”, 2014
²UNAIDS Prevention Gap Report, 2016
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. The Initiative is designed to address key market challenges that limit access to HIV self-testing, make a measurable contribution to achievement of the UN’s 90-90-90 treatment target and global HIV prevention goals, and reduce morbidity and mortality among people living with HIV.

STAR INITIATIVE FOCUS COUNTRIES

The STAR Initiative is being implemented in six sub-Saharan countries.
WHAT WILL STAR ACHIEVE?

The STAR Initiative’s first phase generated crucial information about how to distribute HIVST products effectively, ethically and efficiently. Implemented in Malawi, Zambia and Zimbabwe, Phase 1 was designed to address critical challenges to the development of the HIVST market.

<table>
<thead>
<tr>
<th>KEY MARKET CHALLENGES</th>
<th>TARGET OUTPUTS PHASE 1</th>
<th>PHASE 1 ACHIEVEMENTS</th>
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<tr>
<td>Limited data on public health impact and cost-effectiveness of HIVST.</td>
<td>Established and optimized distribution models for quality-assured HIV self-tests, including effective linkage into prevention, treatment and care services.</td>
<td>7 distribution models investigated for cost, client preferences and linkage to care and prevention. Testing coverage increased 21-35% among men and 22-28% among women in communities reached.</td>
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<td>Lack of information on how HIVST should be implemented, distributed and monitored.</td>
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<td>+ 750,000 HIV self-tests distributed across 3 countries (August 2015 - September 2017) Estimated HIV market size in 9 sub-Saharan African countries.</td>
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<td>Increased informed demand for quality-assured HIVST, including definition of the best marketing strategies and consumer packaging.</td>
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<td>Uncertain levels of consumer demand.</td>
<td>Reduced policy barriers to market entry for quality-assured HIVST products.</td>
<td>41 countries with HIVST policies. Release of WHO normative guidance on HIVST in 2016.</td>
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<td>Lack of policies and guidance supportive of HIVST.</td>
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<td>Absence of low cost and quality-assured HIV self-test products for procurement in resource-limited settings.</td>
<td>Reduced structural barriers to market entry for HIVST products by generating market intelligence, supporting manufacturers pursuing WHO prequalification and facilitating establishment of regulatory frameworks.</td>
<td>1 HIV self-test pre-qualified by the WHO in July 2017. 3 low-cost HIVST products eligible for procurement by the Global Fund or PEPFAR.</td>
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WHO WILL STAR REACH?

The STAR Initiative is designed to reach people with limited access to HIV testing and low rates of testing uptake. This includes young people, men and key populations, including female sex workers and men who have sex with men. Phase 1 found significant increases in the uptake of HIV testing in these populations after the introduction of HIVST—between 22% and 28% of self-testers had never tested before.

WHAT HIVST DISTRIBUTION MODELS ARE INCLUDED IN THE STAR INITIATIVE?

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

OPEN ACCESS

- Pharmacies
- Community-Based Outlets

COMMUNITY BASED

- Door-to-Door Distribution
- Peer Educators
- Voluntary Medical Male Circumcision Mobilizers
- Community-Led Delivery
- Secondary Distribution Through PLHIV
- Workplace Distribution

FACILITY BASED

- HIV Testing Clinics
- Public Sector Facilities
- Clinics for Key Populations
- VMMC Clinics
- Secondary Distribution Through Pregnant and Post-Partum Women and Newly Diagnosed PLHIV
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.

**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?
- How can HIVST be integrated into routine programmatic services? Can accuracy, linkage to care, and prevention be adequately estimated using routine program M&E?
- Can community-led distribution models be used to maximizing benefits and reduce costs?

**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 can we further reduce the cost of HIV self-testing (market shaping strategy for the medium to long term horizon)?

**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 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?
WHO ARE THE KEY PARTNERS?

The STAR Initiative will work closely with Ministries of Health in Malawi, Zambia, Zimbabwe, Lesotho, Swaziland and South Africa. In addition, active community and civil society participation is a critical component of ensuring successful achievement of the STAR Initiative’s goals. STAR will be engaging with civil society organizations and communities in all STAR countries in order to advocate and achieve policy goals, mobilize investment and establish strong supply and demand of HIVST. Engagement with communities and civil society will also be integral in the design of marketing strategies and distribution models.

HOW MANY HIVST WILL BE DISTRIBUTED UNDER THE STAR INITIATIVE?

- **Lesotho**: 114,000
- **Zambia**: 787,000
- **Zimbabwe**: 970,000
- **Swaziland**: 72,000
- **South Africa**: 2,205,000
- **Malawi**: 649,000

**Total**: 4,796,000