

KNOWING YOUR STATUS—THEN AND NOW REALIZING THE POTENTIAL OF HIV SELF-TESTING

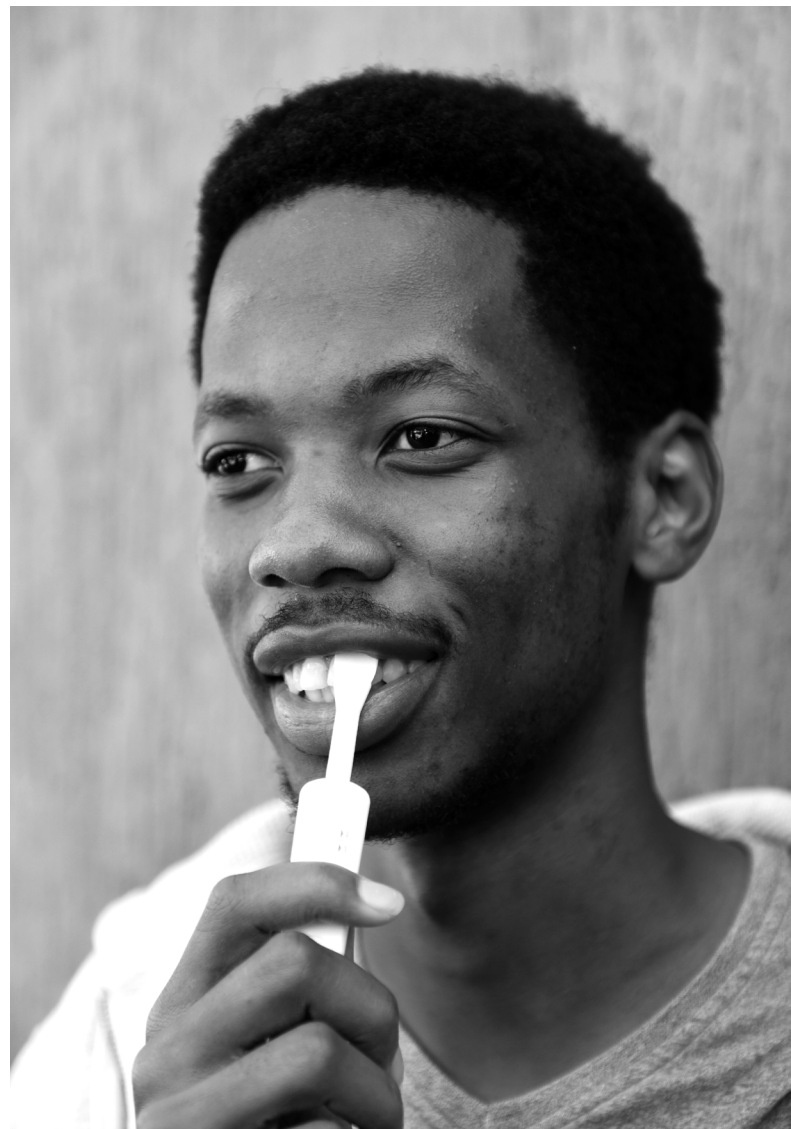


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EXECUTIVE SUMMARY

Globally, an estimated 36.9 million people were living with HIV in 2017 (1). With 1.8 million new cases and nearly 1 million deaths each year, the HIV epidemic remains one of the world's toughest public health challenges. To combat the epidemic, ministries of health around the world have adopted the United Nations 90–90–90 targets: By 2020, 90% of people living with HIV will know their status, 90% of those people will be receiving treatment, and 90% of people on treatment will have an undetectable viral load – the indicator of successful treatment.

Thirty years ago HIV testing was one of the few interventions available to people with HIV, but in the absence of treatment its benefits were limited. Today, however, due to the extensive scale-up of HIV testing and treatment, knowing one's HIV status – including by means of an HIV self-test – is a first step toward HIV treatment and prevention and a healthy life. While this shift has resulted in tremendous progress toward controlling the epidemic, significant gaps remain. More than four decades into the epidemic, even with a large and growing number of HIV tests performed each year, key populations, men and young people are still being missed.

HIV self-testing offers a discreet and convenient way to test, with the potential to reach individuals in need of HIV testing services but who may not otherwise test. For many years informal HIV self-testing was common, particularly among health workers, but its potential as a strategy for reaching the first 90 target had yet to be explored. In 2015 the Unitaid Self-Testing Africa (STAR) Initiative began the largest evaluation of HIV self-testing. The STAR Initiative's first phase generated crucial information about how to distribute HIVST products effectively, ethically and efficiently. Implemented initially in Malawi, Zambia and Zimbabwe, the first phase of the STAR Initiative was designed to address critical challenges to the development of the HIVST market. The STAR Initiative's second phase built on the evidence generated in the first phase to scale access to HIVST across sub-Saharan Africa and expanded implementation to three additional countries, Eswatini, Lesotho and South Africa with the aims of generating large-scale experience and evidence, contributing to reaching the first 90 target, creating an enabling environment and catalysing a global market.

By November 2018 STAR Initiative had distributed 2.3 million HIV self-test kits in Eswatini, Lesotho, Malawi, South Africa, Zambia and Zimbabwe. As a result HIV testing coverage has increased, with HIV self-testing reaching many men, young people and first-time testers. At end 2014, just before the STAR Initiative began, it was estimated only 45% of people with HIV in sub-Saharan Africa knew their status (2). Now it is estimated 81% of people with HIV in sub-Saharan Africa are aware of their status (1).

The STAR Initiative has used various delivery models to reach those in greatest need. Models range from clinic-based distribution to reach patients who would have been missed otherwise, workplace and partner-delivered approaches to reach first-time male testers, to community outreach to sex workers and the general population in hotspots. These various approaches have led to considerable success and taught many lessons. For instance, offering HIV self-testing through clinics increases testing coverage among patients – including female sex workers - while saving health workers' time. Focused distribution through workplaces, to the partners of people with HIV and to postpartum women also fosters high rates of uptake, particularly among high-risk men. Support tools introduced as part of the service delivery package improve linkage to treatment or prevention after self-testing. And people who self-test see it as an empowering and beneficial option. To date, there have been no incidents of suicide or self-harm.

The evidence and experience produced by the STAR Initiative has directly led to the development of policy and regulations that have made HIV self-testing more widely available. In July 2015, just before STAR Initiative began, only two countries had national policies on HIVST and were implementing – both in high income settings. As of July 2018, 59 countries now have policies and 28 are actively implementing; with an additional 53 reporting that a policy is under development. Such gains are largely due to the development of the 2016 World Health Organization (WHO) guidelines on HIV self-testing, which strongly recommend HIV self-testing as an additional testing approach, as well as the WHO prequalification of the first HIV self-test in 2017. By end November 2018 several quality-assured HIVST products have been registered, and there are now two WHO prequalified tests. Also, Four STAR Initiative countries have drafted regulations governing in vitro diagnostics, including HIV self-test kits. With enabling policies and regulations in place, donor procurement of HIV self-test kits has increased rapidly, and market forecasting estimates 16 million kits will be procured by 2020.

Through the STAR Initiative, HIV self-testing is continuing to change what it means to know your status. Distinct models for distributing HIV self-test kits have been developed to reflect the needs, preferences and expectations of various groups of populations. In addition to providing a first step toward treatment and prevention services, self-testing offers an empowering and client-centred way to reach the remaining people with HIV who do not know their status and those at high ongoing risk and in need of HIV prevention services. Now, for many, testing for HIV does not have to mean travelling long distances, taking time from work, waiting in long lines or worrying about who might see them going for testing.

There have been many achievements, but much work remains. The STAR Initiative is continuing to generate evidence on sustainable, effective and cost-effective strategies to deliver HIV self-testing until mid-2020. By that time 5 million self-test kits will have been distributed through the STAR Initiative alone. Moving forward, the STAR Initiative, governments and communities will be taking HIV self-testing to scale and identifying the most effective, efficient and sustainable models for mobilization, distribution and linkage to prevention and care. With investment from Unitaid, three other projects are expanding access to HIVST in synergy with the STAR Initiative: (1) the ATLAS project – Autotest, Libre d'Accéder à la connaissance de son Statut VIH – implemented by Solthis, which will bring HIVST to West Africa; (2) mass media demand-creation campaigns in South Africa and Côte d'Ivoire developed by the MTV Staying Alive Foundation; and (3) the Fiotec ImPreP project, implementing HIV self-testing as a strategy to increase demand for pre-exposure prophylaxis in Brazil, Mexico and Peru.

The STAR Initiative provides a strong foundation for other countries in Africa and globally to introduce HIV self-testing and allow for rapid scale-up based on the rich evidence already gathered. Learning from efforts to date, and with sustained coordination and acceleration of market development, HIV self-testing can help address the testing gap and provide a focused and cost-effective means to expand access to treatment and prevention services. HIV self-testing will play a crucial role in ensuring the achievement of global HIV treatment and prevention goals.

1983

1983 1st WHO meeting on HIV global AIDS situation and begins international surveillance

1985 1st HIV test for HIV approved

1986 HIV self-testing and home specimen collection first discussed

1987 WHO launches global programme on HIV/AIDS

1988 WHO's 1st World AIDS Day; first application for self-test submitted to a regulatory authority



1997

1997 WHO establishes high and low prevalence testing strategies all using rapid tests

1999 WHO announces HIV biggest killer in Africa (4th biggest killer in the world)

2005

2005 WHO launches 3x5 focused on HIV. Estimated 10% PLHIV diagnosed and 700,000 on ART by the end of 2004

2006 1st African country (Botswana) starts routine HIV testing in all facilities

2006 WHO announces 1 million Africans with HIV diagnosed and on ART

2007 WHO Recommends routine (opt out) provider initiated HIV testing and male circumcision for 14 priority countries in Africa

2008 Kenya is first country to include HIVST in national guidelines, however not implemented due to absence of available products

2012

2012 WHO recommends couples and partner testing (including index testing); US FDA approves first HIVST kit

2013 WHO recommends community-based testing—focus on key populations, men and young people; WHO hosts first global consultation on HIVST

2014 90-90-90 testing and treatment targets set; estimated 45% of people with HIV in sub-Saharan Africa diagnosed

2014 WHO calls for countries to explore HIVST; issues policy statement and includes HIVST into guidelines

2015

JUL WHO recommends lay provider HIV testing; as well as PrEP and treat all.

AUG Unitaid partners with PSI and WHO to establish the STAR Initiative

DEC Unitaid/WHO release the 1st ed. of Market landscape for rapid diagnostic tests for HIV self-testing



2016

MAY PSI distributes 8,000 HIVST kits in a pilot distribution in Zimbabwe

OCT PSI release of HIVST market sizing in 9 African countries supported by the Gates Foundation

NOV WHO recommends HIV self-testing and assisted partner notification

2017

MAR CIFF investment in private sector market in Kenya

MAR Expert review panel for diagnostics (ERPD) approves first HIVST; allowing donor procurement of HIVST

APR WHO-led HIVST guidelines regional dissemination meeting in Nairobi, followed by STAR workshop

JUN Subsidization of OraQuick® HIVST by BMGF and CIFF; product available for US\$ 2 in 50 low- and middle-income countries

JUL WHO PQ first HIVST; STAR Initiative phase 2 approved

JUL PEPFAR commits to procuring at least 1 million HIVST kits

NOV Start of HIVST implementation in 3 additional countries under STAR Initiative



2018

NOV ERPD approval of BioSure SureCheck, INSTI and Atomo HIVST

APR South Africa starts developing investment case

APR Unitaid's approval of MTV SAF and Solthis ATLAS grants. April and July respectively

JUL Unitaid/WHO release HIVST market forecast; 59 countries report having HIVST policy-of which 28 are fully implementing

NOV HIVST Regulations for in vitro diagnostics established in 3 STAR countries; operational guidelines for HIVST in place in 5 STAR countries

NOV WHO PQ second HIVST kit.

KNOW YOUR STATUS TIMELINE



HIV SELF-TESTING AFRICA INITIATIVE



KNOWING YOUR STATUS, THEN

Thirty years ago, on 1 December 1988, the World Health Organization (WHO) held the first World AIDS Day. At the time there were few options for people diagnosed with HIV. Although HIV treatment had started to become available in high-income countries in 1987, it would be many more years until it became more widely available in resource-limited settings (3).

HIV testing was one of the first interventions in the global HIV response, starting in 1985 with the first approved test (4). Early testing programmes began in blood donation centres and special laboratory settings. Efforts to extend testing to health-care facilities and community settings were met with caution (5, 6), even as rapid testing offering same-day diagnoses became available (7) and the possibility of self-testing was raised (8). With no treatment or vaccine available, as well as limited information and knowledge, the benefits of testing were limited, and stigma against those who tested was widespread.

Initial efforts focused on protecting client privacy and rights, particularly from mandatory or coercive testing. To address these concerns, in the late 1980s and early 1990s programmes began “voluntary counselling and testing (VCT)”, providing HIV testing to those who requested it in confidential stand-alone sites with pre- and post-test counselling to support those newly diagnosed. Counselling emphasized prevention, using “knowing one’s status” to encourage behaviour change that would reduce risk of transmission (9). Despite these programmes, implementation and uptake of testing were limited, and significant gaps remained (10). With the VCT-only approach, in 2005, only 12% of people who wanted to test for HIV were able to do so (11). As of 2005 population-based surveys in high burden African countries estimated that 10% of people with HIV had been diagnosed (11).

Despite VCT programmes, in the late 1980s and early 1990s implementation and uptake of testing were limited

As HIV treatment became more widely available in resource-limited settings, in 2007 WHO recommended offering opt-out provider-initiated testing and counselling (PITC), particularly in high HIV burden settings (12). This approach offers HIV testing routinely to all patients in health facilities, to normalize testing and reduce stigma and to diagnose as many people with HIV as early as possible (13). Early success in Botswana and Uganda showed that PITC in clinical settings reached more people and diagnosed a high proportion of people with HIV (14-16). In 2007 and 2008 rapid HIV testing was scaled up through PITC and more than doubled the number of HIV tests performed in 39 low- and middle-income countries. In the same period the number of HIV testing sites in 66 high-burden countries increased by 35% (17). Integrating HIV testing into antenatal care had particularly high impact (18-20); this was largely responsible for increasing testing coverage from 7% to 44% among pregnant and postpartum women globally between 2004 and 2013 (17, 21).

By 2013, 95% of countries had policies on PITC, and 71% had policies on community-based testing (21). In addition to VCT and PITC, programmes were now offering a variety of differentiated HIV testing approaches, including door-to-door, mobile and workplace outreach, to further expand services. Strategies to reach key populations, families and couples also were actively promoted through a mixture of models (22, 23).

Increased availability and normalization of HIV testing, as well as scale-up of treatment and more prevention options, changed the HIV epidemic and the HIV response. WHO no longer recommended pre-test counselling; counselling became one element of a broader package of services focused on linkage to prevention and care (24). At the same time, voluntary medical male circumcision (VMMC), which had been shown to reduce men's risk of HIV acquisition by 60%, was being scaled up in 14 priority countries (25). By 2011 studies demonstrated the preventive effect of antiretroviral treatment (ART) (26) and the potential of pre-exposure prophylaxis (PrEP) to reduce HIV transmission (27).

As a result of treatment scale-up, HIV-related mortality rates steeply declined, and people with HIV on treatment began to live longer and healthier lives. Knowing one's status was now considered an important gateway to effective HIV treatment and prevention options.

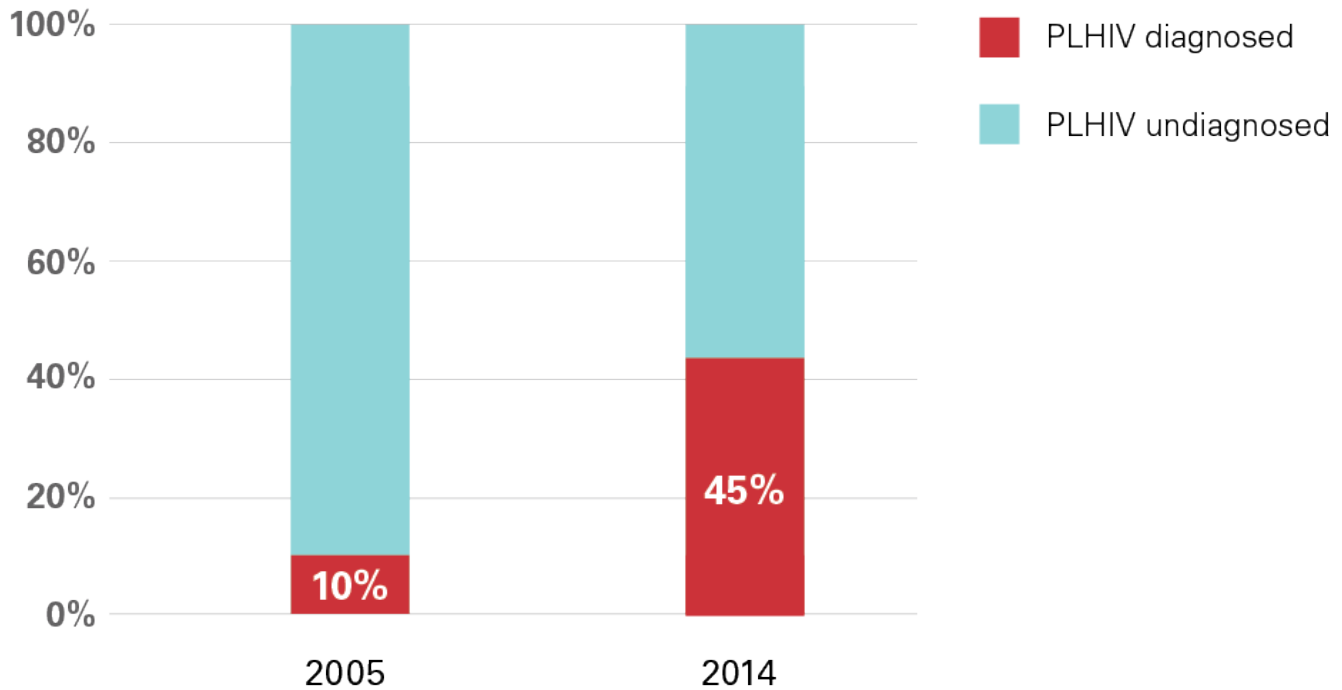
Despite this tremendous progress and considerable investment, ongoing efforts to increase testing were not reaching all those in need. Between 2010 and 2014, more than 600 million people (age 15 and older) in 122 low- and middle- income countries had been tested for HIV (28). (Fig. 1 compares data for sub-Saharan Africa in 2005 and in 2014.) While this represented a great increase in testing coverage, by 2014 still only 54% of all people with HIV had been diagnosed, and only 3% of tests performed were positive in 81 reporting low- and middle-income countries (28).

More than twenty years into the epidemic, even with a large and growing number of HIV tests performed each year, key populations, men and young people were – and are – still being missed (3). Key populations and their sexual partners remain disproportionately affected, contributing to nearly half of new HIV infections, but they are still largely unreached, due to stigma, discrimination and criminalization (21, 23). And in 2014 only 30% of tests were among men (28). Growing evidence showed that men were being missed or tested late and so were contributing disproportionately to the number of HIV-related deaths. Similarly, fewer than one of every five young women (ages 15–19) in sub-Saharan Africa were aware of their HIV status (29), and barriers such as age of consent laws hindered their access to testing (30).

Knowing one's status became an important gateway to the new effective HIV treatment and prevention options.

FIGURE
01

Estimated proportion of people with HIV (PLHIV) in sub-Saharan Africa diagnosed between 2005 and 2014



Sources: WHO (11), UNAIDS (31)

Such gaps highlighted the fact that, although increasing numbers of tests were being performed, the positivity rate was often low; testing services were not reaching those at higher HIV risk. A change in the focus of HIV testing was needed.

With the announcement in 2014 of the United Nation’s 90–90–90 targets – to diagnose 90% of people with HIV, treat 90% of people diagnosed and achieve viral suppression for 90% of people treated by 2020 (31) – global and national programme focus and HIV testing priorities shifted. Instead of pursuing targets to increasing numbers of tests performed, programmes began to focus on identifying the most effective and efficient approaches to reach the largest number of people with undiagnosed HIV infections, especially those being left behind, by current testing approaches. The need for this redirection was underscored by static donor investment and by mathematical modelling highlighting increasing costs and the inability to reach targets without more strategic and focused HIV testing (32–34).

Priorities shifted: Programmes began to focus on identifying the most effective and efficient approaches to reach the largest number of people with undiagnosed HIV infections.



MAKING SELF-TESTING A REALITY: THE UNITAID STAR INITIATIVE

HIV self-testing (HIVST) – in which individuals perform the test and interpret the results by themselves – addresses key barriers to the uptake of HIV testing services. These barriers include people’s concerns about confidentiality, stigma, discrimination and, in some contexts, criminalization

(35). HIVST also can reduce opportunity costs that are common to conventional testing services, including inconvenience, missed work and cost (36).

HIVST is not new. As self-testing promised a discreet and convenient option, discussions of its potential role started early in the epidemic (37). Informal self-testing was documented among health workers between 2000 and 2010 (38), and in some settings products were available in private sector pharmacies (39). In 2008 Kenya became the first country to release a national policy on HIVST (40). However, no products intended for self-testing were available outside research settings. Worldwide, lack of regulation and policy to permit HIVST limited the development of products for self-testing until 2012, when the United States Food and Drug Administration approved the first such product (41, 42).

In 2013 WHO and partners held the first global consultation on HIVST, which outlined the process for developing guidelines and prequalification of products and specified the evidence and experience that would be needed for this – for example, whether HIVST would:

- be acceptable and feasible
- increase uptake and frequency of testing among high-risk groups who might not test otherwise
- lead to the diagnosis of new HIV-positive cases
- facilitate linkage to prevention and treatment
- not lead to social harm or other adverse events
- increase health system efficiencies and be more cost-effective (or at least cost-neutral) (43).

In 2015 Unitaid started to fund the STAR Initiative, a five-year project to catalyse the market for HIV self-testing. The first phase generated crucial evidence on the feasibility and acceptability of HIVST, and information about how to distribute HIVST products effectively, ethically and efficiently. Implemented in Malawi, Zambia and Zimbabwe, phase 1 was designed to address challenges to the development of the market. The second phase of STAR is building on the evidence generated by the first phase, adding Eswatini, Lesotho and South Africa, to create a market for HIVST and evaluate optimal distribution models for scale up across sub-Saharan Africa, helping to make HIV self-testing a reality.

While WHO encouraged countries to start exploring HIVST and provided advice for operational research, normative guidance was not yet available (24, 44). In July 2015 only two high-income countries were actively implementing HIVST – with two products, both of which were limited primarily to the private sector (45).

Starting in August 2015, Unitaid funded the STAR Initiative, which is led by Population Services International (PSI), in partnership with London School of Hygiene and Tropical Medicine (LSHTM), ministries of health, local research partners and implementers, and with WHO providing technical support for the research as well as for the policy development at country (and global) level, to undertake a comprehensive evaluation and implementation of HIVST in southern Africa to provide the evidence and experience needed to help to make HIVST a reality. The STAR Initiative’s first phase generated crucial information about how to distribute HIVST products effectively, ethically and efficiently. Implemented initially in Malawi, Zambia and Zimbabwe, the first phase of the STAR Initiative was designed to quickly generate evidence which would lead to the development and implementation of guidelines for HIVST at the national and global level. The STAR Initiative’s second phase built on the evidence and experience generated in the first phase to scale access to HIVST across sub-Saharan Africa and expanded implementation to three additional countries, Eswatini, Lesotho and South Africa. As with the first phase, the second phase of the STAR Initiative focuses on generating large-scale experience and evidence, contributing to reaching the first 90 target, creating an enabling environment and catalysing a global market.

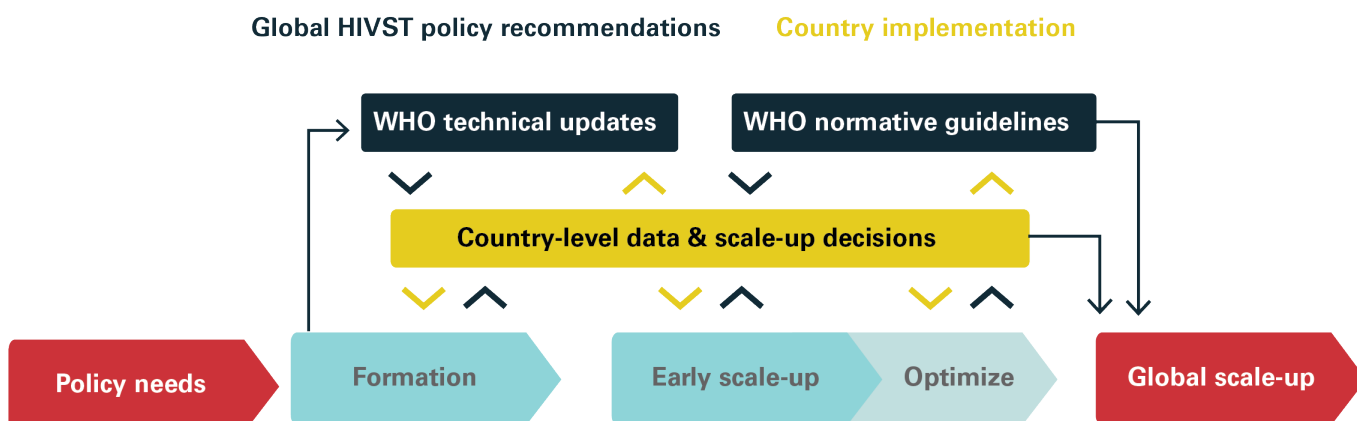
In collaboration with a diverse network of organizations and market players, the STAR Initiative identified three key tasks needed to facilitate the growth of HIVST:

1. creating an enabling environment
2. generating diverse demand and financing
3. accelerating market entry

From the outset the pace of change was rapid (Fig. 2). The STAR Initiative began with establishing the evidence base and product introduction (formation), moved to inclusion of HIVST in national plans and guidelines (early scale-up), and then optimized service delivery and the start of global scale-up.

To mark the 30th World AIDS Day, we report here on the key achievements of the STAR Initiative and how HIVST has changed what “knowing your status” means today.

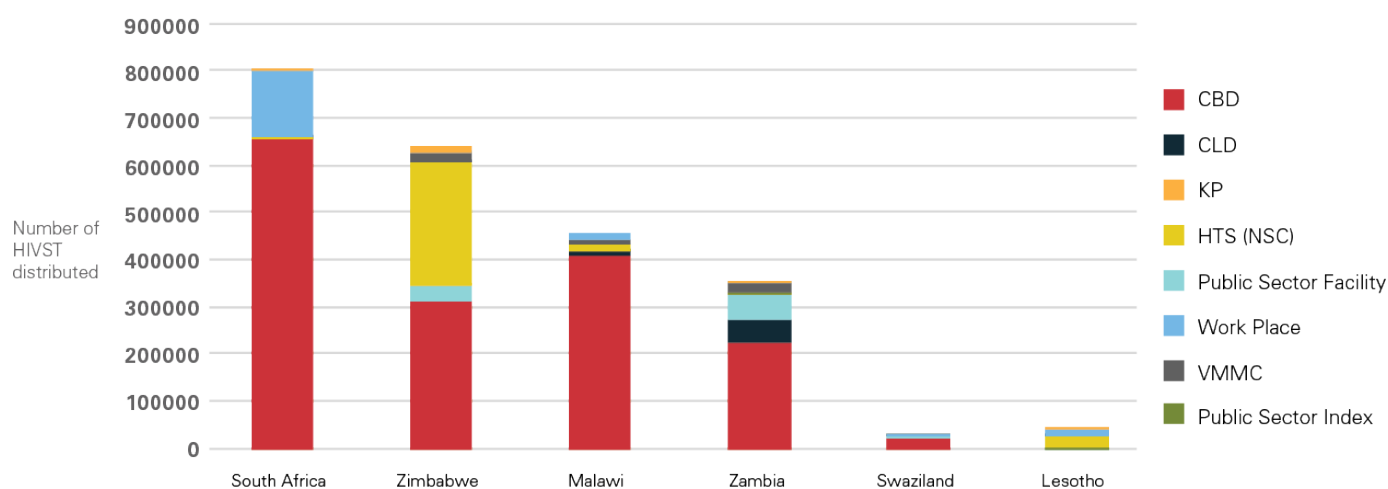
FIGURE 02 | STAR Initiative policy, implementation and research strategy



2.1 COUNTRY IMPLEMENTATION FOR IMPACT

Taking HIV self-testing to scale. From June 2015 through October 2018, the STAR Initiative distributed 2.3 million HIVST kits across six African countries. The greatest number of kits was distributed in South Africa, which started distribution in November 2017, followed by Zimbabwe, Malawi, Zambia, Eswatini and finally Lesotho (Fig. 3). The predominant model of distribution has been the community-based model, followed by HIV Testing Services integrated approaches and distribution at workplaces. Both approaches to reach key populations and distribution at public sector health facilities have started to gain momentum in all six countries since early 2018. Distribution at public sector facilities has included direct distribution or secondary distribution by people with HIV to their sexual partners and by pregnant women and postpartum women seen at antenatal care clinics to their partners.

FIGURE 03 | Number of HIVST kits distributed through the STAR Initiative, by country and distribution model, June 2015 – October 2018 (N = 2,349,858)



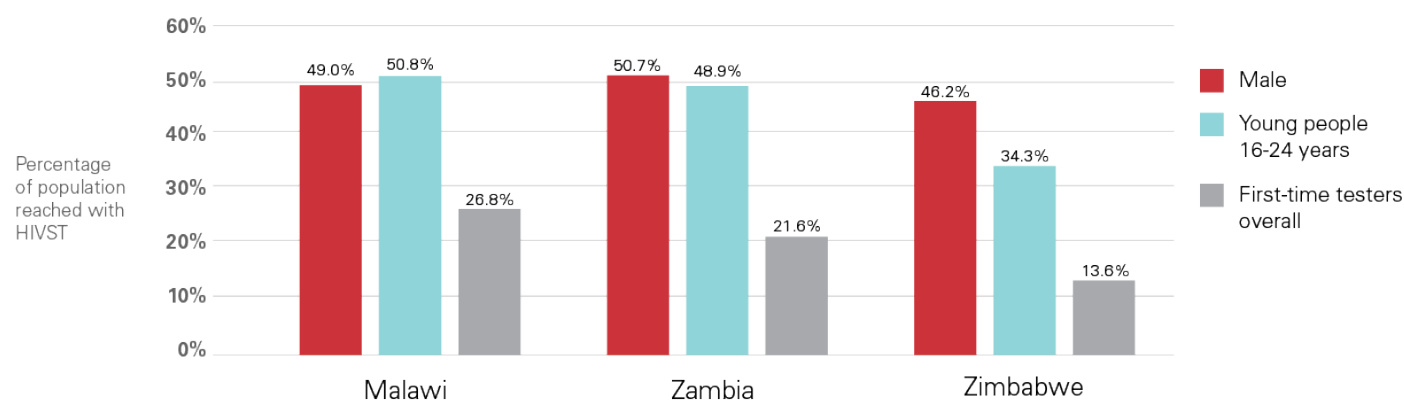
Abbreviations: ANC = antenatal care; CBD = community-based distribution; CLD = community-led distribution, KP = key populations; HTS (NSC) = HIV testing services (New Start clinic network). See definitions and descriptions of models in Table 2.

Increasing coverage. Findings of population surveys before 2015 in Malawi, Zambia and Zimbabwe showed gaps in testing coverage of men and young people and highlighted the need to encourage retesting once or twice a year among key populations and those at continuing high risk (46-49). Between June 2015 and July 2017, 628 708 HIVST kits were distributed in these three countries – 172 830 in Malawi, 190 787 in Zambia and 265 091 in Zimbabwe. During this period, the STAR Initiative programme data showed that HIVST reached a high proportion of men, young people and first time testers. Across all three countries close to half of all self-testers were men; one-third or more of all self-testers were between 16 and 24 years of age, and between 14% and 27% were first time testers (Fig. 4).

In Malawi, Zambia and Zimbabwe, HIVST distribution increased the reach of testing among men and young people between 16 and 24 years of age.

A higher proportion of male self-testers (65,577; 22.3%) were first-time testers than women (54,096; 17.1%). This pattern was consistent in all three countries – Malawi: 27.9% of men who were first-time testers chose HIVST versus 25.9% of women; Zambia: 25.4% versus 17.7%; and Zimbabwe: 16.2% versus 11.4%. Data collected through population-based surveys before and after community-based distribution also showed that HIVST increased testing coverage (as indicated by testing within the previous 12 months) among both men and women as well as young people (Figs. 5 and 6). Evidence from the STAR Initiative trials in Malawi and Zimbabwe also showed that community-based HIVST increased coverage and the number of ART initiations compared with standard testing services (50, 51).

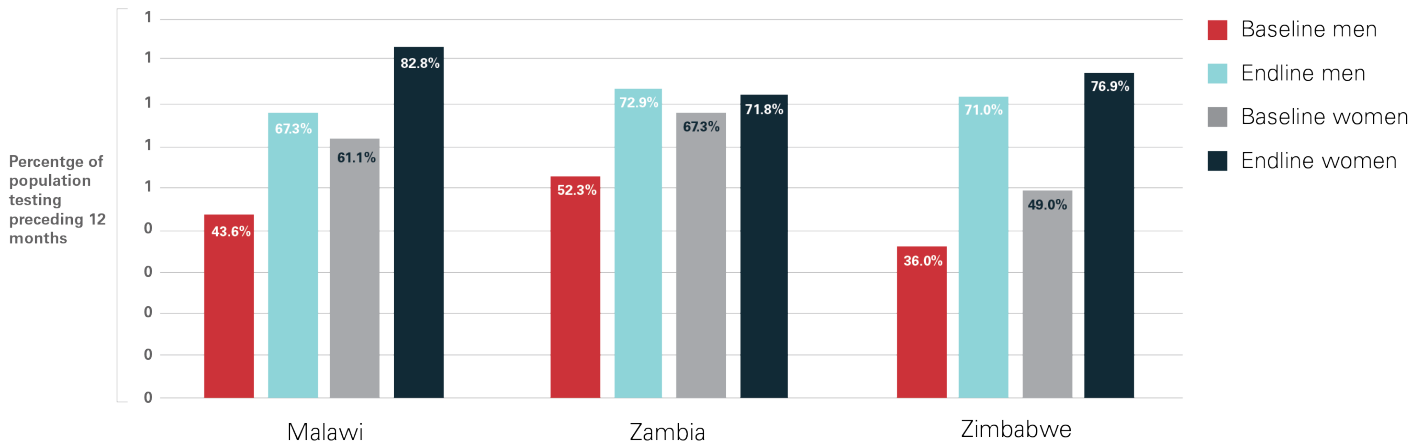
FIGURE 04 Proportion of young people, men and first-time testers reached through HIVST by the STAR Initiative in three countries, between June 2015 and July 2017



Total n = 628 705; Malawi = 172 830, Zambia = 190 787; Zimbabwe = 265 091. Total male = 294 508; total young people = 263 073; total first-time testers = 119 673

FIGURE
05

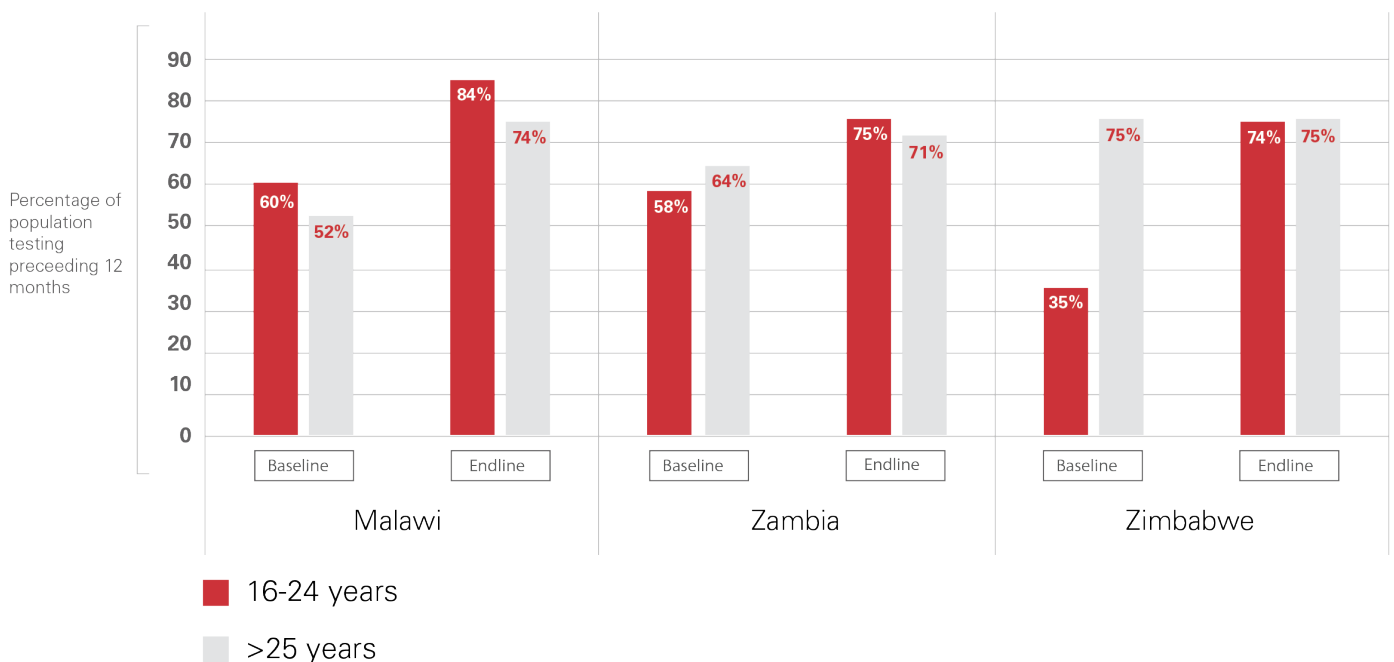
Testing within preceding 12 months by sex, Malawi, Zambia and Zimbabwe, before and during HIVST implementation, baseline and midline surveys, 2015 – 2017



Malawi: n=1387 (baseline) and n=541 (midline); Zambia: n=1043 (baseline) and n=273 (midline); Zimbabwe: n=17 995 (baseline) and N=2646 (midline)

FIGURE
06

Testing within preceding 12 months by age, Malawi, Zambia and Zimbabwe, before and during HIVST implementation, baseline and midline surveys, 2015 – 2017

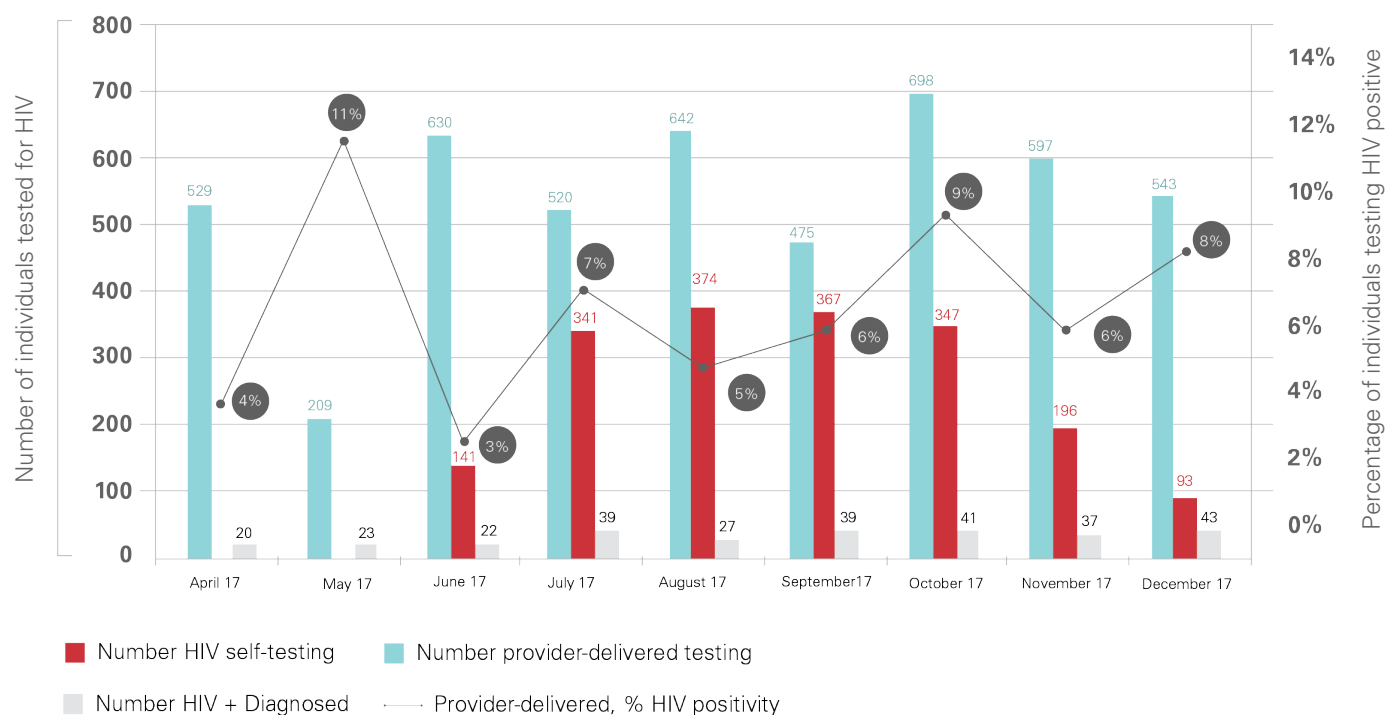


Malawi: n=1387 (baseline) and n=541 (midline); Zambia: n=1043 (baseline) and n=273 (midline); Zimbabwe: n=17 995 (baseline) and n= 2646 (midline)

Reaching people at greatest HIV risk. Using a variety of delivery models (Table 2), the STAR Initiative has reached many people in need of testing services. Integrating HIVST into health facilities has had significant impact. In Zimbabwe, HIVST was offered as an alternative option to provider-delivered HIV testing services to individuals accessing other health services at outpatient departments of 42 clinics, who had not recently tested for HIV or were unaware of their status. Following the introduction of HIVST at public sector health facilities, the number of patients tested for HIV more than doubled. Approximately 30% of all those tested at the facility opted for self-testing over provider-initiated testing. Prior to HIVST introduction, the HIV positivity rate was between 3% and 4% within the facilities. Between June and December 2017, during HIVST implementation, HIV positivity was consistently higher than before HIVST was made available and number of HIV-positive cases identified increased by 80% (Fig. 7). When HIVST was introduced for screening of sexual partners of people with HIV, who had tested at 10 PSI managed health care facilities in Zimbabwe, the overall number of sexual partners accepting HIV testing increased two-fold. The total number of positive cases identified among sexual partners also doubled, when compared to before HIVST was introduced as an option for partner testing (Fig. 8).

Focused HIVST delivery in male-dominated workplaces in South Africa, where undiagnosed HIV burden is high, reached men previously untested or not retested in the last 12 months. Four percent of men who self-tested and shared their result were diagnosed with HIV, and more than half of these men started treatment (Table 1). HIVST has also increased testing among female sex workers. In Zimbabwe uptake of HIVST in clinics was high among sex workers, and 12% of those self-testing were newly diagnosed with HIV (Fig. 9). Preferences for HIVST varied among the countries, with sex workers in Malawi preferring peer distribution and sex workers in Zimbabwe preferring clinic-based HIVST.

FIGURE 07 | Number of patients tested and newly diagnosed with HIV at public sector health care facilities in Zimbabwe where HIVST was offered as alternative to provider testing, by month, April – December 2017*

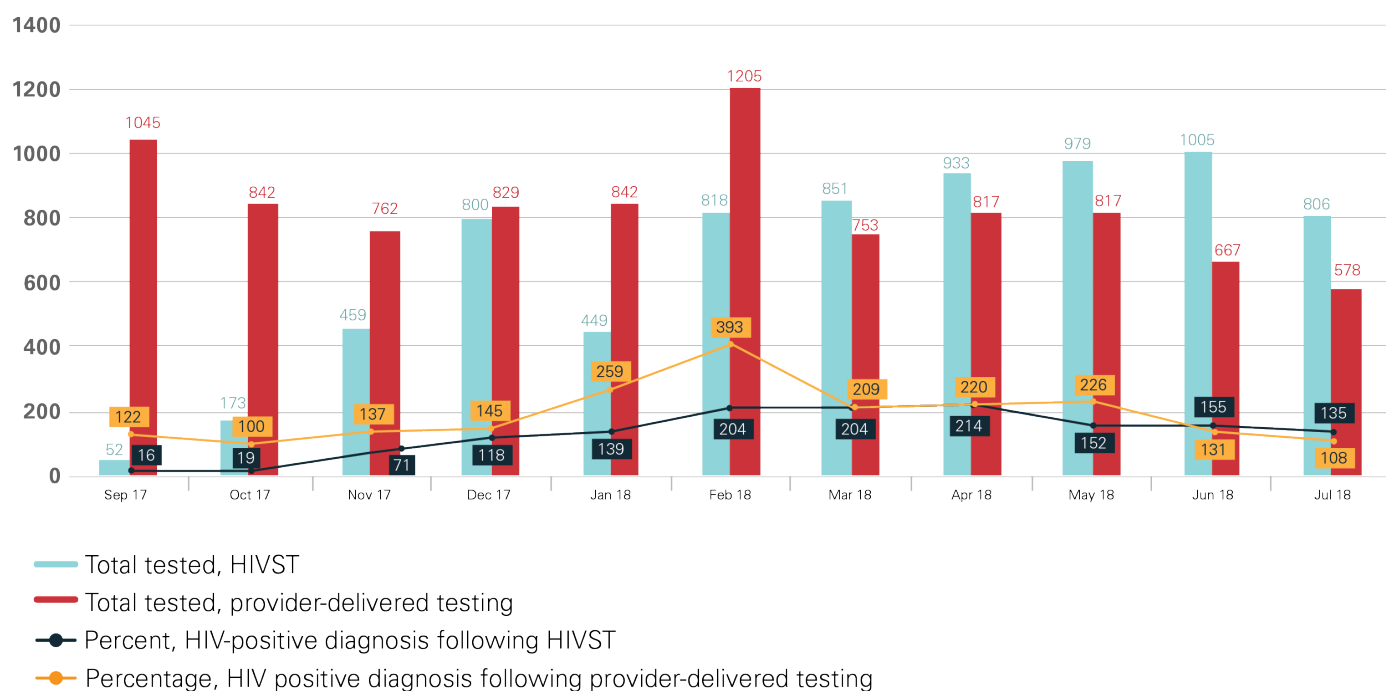


*HIVST was introduced into clinics starting in June 2017

Source: WHO (52)

FIGURE
08

Numbers of sexual partners of people with HIV tested and diagnosed with HIV using provider referral and HIVST, by approach, 10 clinics and mobile teams in Zimbabwe, September 2017 – July 2018



Total tested, HIVST: 8987; Total tested, provider referral: 7495; Total HIV-positive cases, HIVST: 1614; Total HIV-positive cases, provider referral: 1863

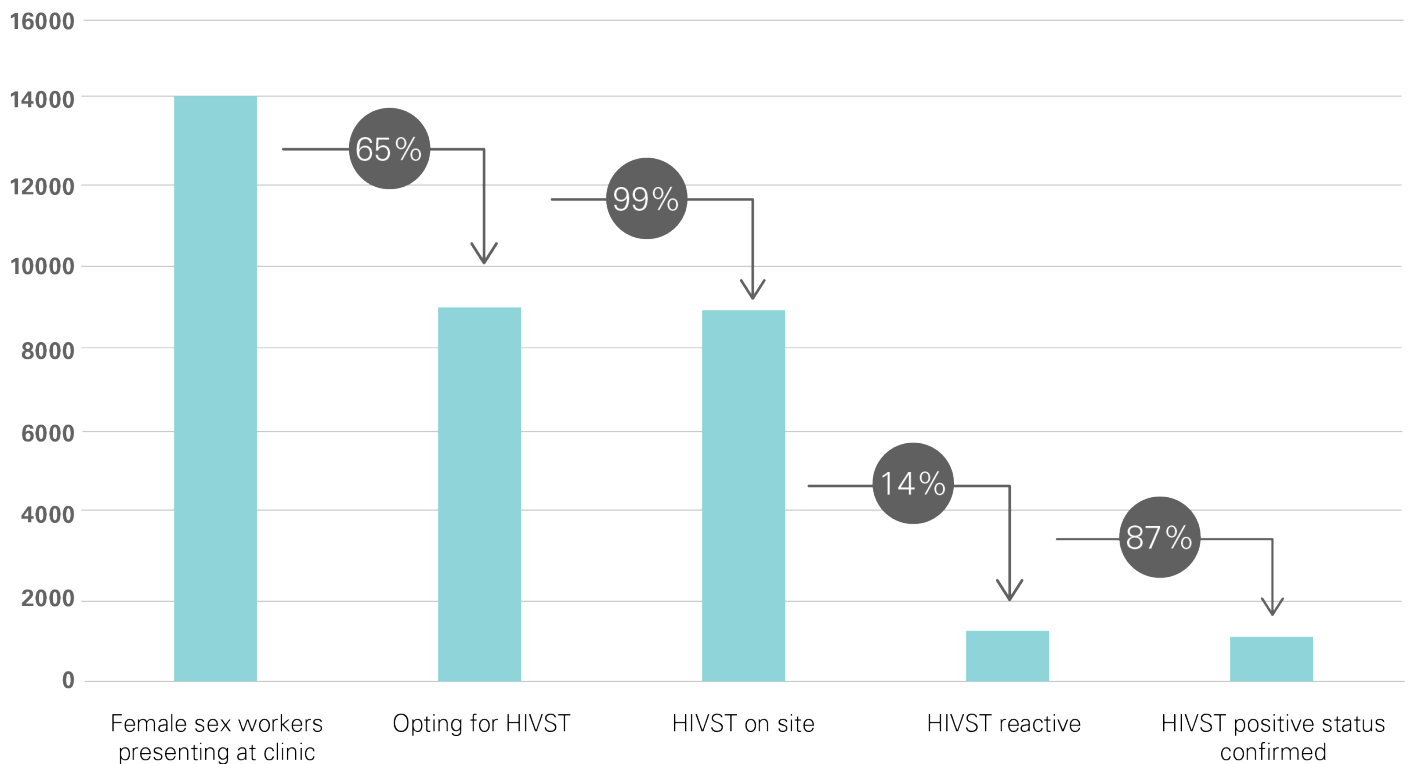
TABLE
01

HIVST among employees at workplaces in three provinces in South Africa (Gauteng, Mpumalanga, North West Province), January – July 2018

	HIVST use	HIVST reactive	HIV positivity rate	Confirmed positive, initiating ART	% HIV-positive initiating ART
Total who reported self-testing for HIV	6101	251	4.1%	135	53.8%
Self-testers reporting their last HIV test was more than 12 months ago	2227	86	3.9%	50	58.1%
Self-testers reporting never testing before	614	27	4.4%	12	44.4%

FIGURE
09

Results of distribution of HIVST kits at six female sex worker clinics in Zimbabwe, October 2016 – July 2017



Enabling prevention. As in previous studies, HIVST through the STAR Initiative has increased uptake and frequency of HIV testing in key population groups, which is key to prevention as well as to case-finding. Secondary distribution of HIVST kits to sexual partners of pregnant and breastfeeding mothers has the potential to lead to earlier diagnosis and uptake of antiretroviral therapy among sero-discordant partners, thereby reducing mother to child transmission.

Many men at high ongoing risk who had a negative self-test result were linked to HIV prevention services – including voluntary male medical circumcision (VMMC). HIVST can increase willingness to take up VMMC, particularly among those who perceive that HIV testing, which is offered as part of the minimum package of VMMC, is mandatory. In the STAR Initiative HIVST was integrated into VMMC services by offering it as part of routine mobilization for VMMC. As a result, data from one VMMC site in Harare showed that 26% of those reporting a negative self-test result received circumcision, and 76% of all those circumcised reported that they had self-tested prior to the VMMC (Fig. 10). Within the STAR Initiative several studies are assessing the impact of HIVST on prevention, including saving health workers’ time and facilitating uptake of pre-exposure prophylaxis (PrEP). Results are expected in mid-2019.



FIGURE
10

Uptake of voluntary male medical circumcision (VMMC) following HIVST at the PSI VMMC clinic in Harare, Zimbabwe, January–April 2018

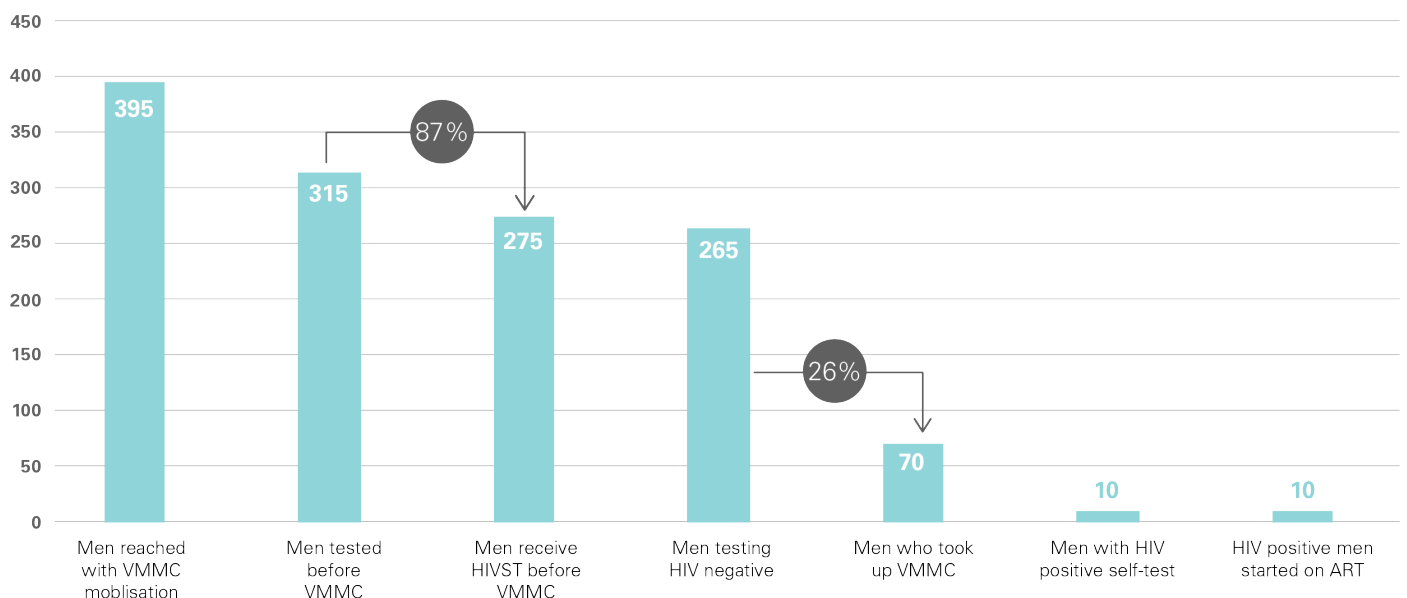


TABLE
02

HIVST distribution models used by the STAR Initiative

**Models for high HIV prevalence setting.*

Model	Description	Target population	Mobilization strategy	Linkage strategy	Rationale
Community-based (mainly door-to-door)	HIVST kits offered at households for clients to test on own or with assistance.	Rural populations, especially adult men and young people unable to access conventional testing services.	Mobilization through community sensitization by community-based distributors and community leadership.	Referral notes, linking self-testers to prevention and treatment services, provided at delivery of the test kit together with information on where and how to link.	Increases testing in populations who would otherwise not seek or have access to testing services, including in rural areas.
HIVST integrated into mobile services or HIVST fixed sites	<p>Distribution at urban and rural community hotspots.</p> <p>Confirmatory testing and in some cases ART on site.</p> <p>People can test themselves in a cubicle at the distribution point or HTS clinic (with assistance available) or take kit home.</p>	High-risk adults, adult men, adolescents, especially girls and young women.	Mobilization and demand creation for HIVST at community level.	Confirmatory testing offered at site; referral to treatment with referral note after confirmed HIV positive status.	<p>Fast-track pre-screening, triaging out those who self-test HIV– unless confirmatory testing desired.</p> <p>Providers can shift attention to those most in need – for example, index testing and assisted partner notification, confirmatory testing, initiation of ART.</p> <p>Increase in demand for HTS if mobile or fixed HTS clinic services are promoted as outlets for HIVST kits.</p>
	HIVST kit offered to PLHIV to take to sexual partner(s). Follow-up with partner for confirmatory testing.	Sexual partners of PLHIV diagnosed through HTS (secondary distribution).	PLHIV clients offer HIVST to sexual partners.	Referral form included in information materials when HIVST kit is handed to sexual partner. Referral information provided via PLHIV client.	Increases likelihood of sexual partner testing. (A high proportion of sexual partners of PLHIV are testing positive.)

Model	Description	Target population	Mobilization strategy	Linkage strategy	Rationale
HIVST offered at men's workplaces	HIVST kits are offered to employees at workplaces employing mostly men after buy-in and agreement by employer. Employees can perform HIVST in a private space provided at the workplace where assistance is available or take the HIVST kit home.	High-risk adults, men.	Peer educators and counsellors at workplaces promote HIVST.	Referral form included in information materials given when HIVST kit.	Increases testing in populations that would otherwise not seek testing services. Rapidly and greatly increases testing coverage.
Integrated with public sector facility	Facility-based counsellors and health care workers directly promote HIVST at entry points of the health delivery system – for example, outpatients, in-patients.	Individuals accessing health-care facilities in both urban and rural areas.	Health-care providers actively promote HIVST at health facilities, option of individuals to take test kit for partner home testing.	Self-testers with reactive result receive confirmatory testing on site, initiation on ART (test and treat).	Test-for-triage approach. HTS clinic can shift attention to other tasks. Increases numbers tested and more targeted provider-initiated testing to maximize HIV+ diagnoses, ART initiation and uptake of prevention service.
	HIVST kit offered to PLHIV to take to sexual partner(s). Follow-up with index or partner for confirmatory testing.	Sexual partners of PLHIV diagnosed at HTS (secondary distribution).	PLHIV clients offer HIVST to sexual partners.	Referral form included in information materials when HIVST is handed to sexual partner. Referral information provided via PLHIV client.	Increases likelihood that sexual partner will test.
	HIVST kit is offered to all pregnant women regardless of HIV status to take to male partner.	Partners of pregnant women using public sector maternity services (secondary distribution).	Pregnant women offer HIVST to sexual partners.	Referral form included in information materials when HIVST is handed to sexual partner. Referral information provided via PLHIV client.	Increases opportunity for partners of pregnant women to test for HIV and link to care, treatment or prevention.

Model	Description	Target population	Mobilization strategy	Linkage strategy	Rationale
Demand creation for and uptake of VMMC	HIVST offered to men mobilized for VMMC to use at home before VMMC.	Men considering VMMC services.	Mobilizers for VMMC offer HIVST as option to conduct pre-screening before VMMC.	VMMC mobilizers may directly follow up with clients on successful referral for HIVST.	May reduce fear of testing that discourages men from taking up VMMC services.
HIVST integrated with HTS services for key populations, e.g. FSW and MSM	HIVST offered as alternative to HTS To clients accessing sex worker clinics or health services for MSM. HIVST distribution through social networks of FSW or MSM.	FSW and MSM.	Health-care providers actively promote HIVST at health facilities. Peers of key populations are promoting HIVST.	Self-testers with reactive result receive confirmatory testing on site, immediate initiation of ART. Referral form included in information materials given with HIVST kit.	Test-for-triage approach. HTS clinic can shift attention to other tasks. Increases numbers tested and more targeted provider-initiated testing to maximize HIV-positive diagnoses, ART initiation and uptake of prevention service. Increases uptake and frequency of testing among key populations.

ART: Anti-retroviral therapy; FSW: Female sex worker; HIVST: HIV self-testing; HTS: HIV testing services; PLHIV: People living with HIV; MSM: Men who have sex with men; and VMMC: Voluntary male medical circumcision



HIV self-testing is empowering. Throughout the STAR Initiative social harm was rigorously monitored using community-based reporting systems, telephone hotlines and short message services. Since the beginning of STAR, reports of social harm following the distribution of HIVST kits have been very rare. There have been no incidents of suicide or social harm.

In Malawi detailed analysis of six years of reporting found less than one report of social harm per 8000 events. Of these the few instances reported were generally not related to self-testing but the challenges of being diagnosed with HIV, sero-discordant partnerships (in which one partner is HIV-positive and the other is HIV-negative) or a history of intimate partner violence. The majority of people see HIVST as encouraging discussion between sexual partners and bolstering mutual trust, fidelity and joint reduction of sexual risks. Communities continue to report HIVST is highly acceptable and that the benefits outweigh potential risks (53).

HIV self-testing is cost-effective and affordable if targeted. Through STAR, modelling and investment scenarios are making the case for using HIVST to better focus programmes, reach the remaining people who do not know their status, and reach those who would benefit most from prevention services. The impact and cost-effectiveness of HIVST is sensitive to the prevalence of undiagnosed HIV in the sub-population to be reached and the overall costs of HIVST service delivery. Analyses of community-based distribution of HIVST (CB-HIVST) at hotspots in Malawi, Zambia and Zimbabwe has compared epidemiological impact and cost-effectiveness in different target populations. This analysis showed that the greatest epidemiological impact, in terms of HIV infections and deaths averted, as well as the most cost-effective use of scarce resources, can be achieved when CB-HIVST focuses on adult men – particularly when HIV-negative male self-testers are linked to VMMC – and when targeted at women having transactional sex (54).

When the STAR Initiative began, products for HIVST were costly compared with standard HIV rapid diagnostic tests (45). The STAR Initiative initially procured products for US\$ 3.15 apiece. But as of 2017 STAR Initiative has been able to procure kits for US\$ 2.00 apiece, due largely to an agreement negotiated by the Bill and Melinda Gates Foundation (BMGF) and the Children’s Investment Fund Foundation, which set the price for 50 low- and middle-income countries.

Increasing the number of affordable and available WHO prequalified HIVST products could potentially reduce the unit price through competition. The STAR Initiative consortium partner University of Witwatersrand Reproductive Health and HIV Institute simultaneously conducted studies in South Africa to support and inform submissions for WHO prequalification for several HIVST products, including blood-based self-tests. With the support of BMGF, the STAR Initiative conducted consumer usability studies on four blood-based HIVST products, optimizing instructions for use, and piloting the use of the most suitable blood-based HIVST products. By end of November 2018, one additional blood based HIVST product had received WHO prequalification. This is an important step toward a competitive market, which may lead to end-user price reductions, more affordable products and greater access to HIVST.

The majority see HIVST as encouraging discussion between sexual partners and bolstering mutual trust, fidelity and joint reduction of sexual risks.

2.2 POLICY AND REGULATION FOR IMPACT

Moving to policy and practice. When the STAR Initiative began in late 2015, there were no WHO recommendations, no products that donors could buy, and only two countries (both high-income) had policies and were implementing HIVST (45). Lessons learned by the STAR Initiative informed WHO's first guidelines, which strongly recommended that countries offer HIVST as an additional testing approach (35, 55). By mid-2018, 59 countries had HIVST policies, and 28 of these countries were actively offering services (Figs. 11 and 12). All six STAR Initiative countries have now developed and implemented national policy on HIVST. Nine low- or middle-income countries, five of which are STAR Initiative countries, have also developed detailed operational guides (56).

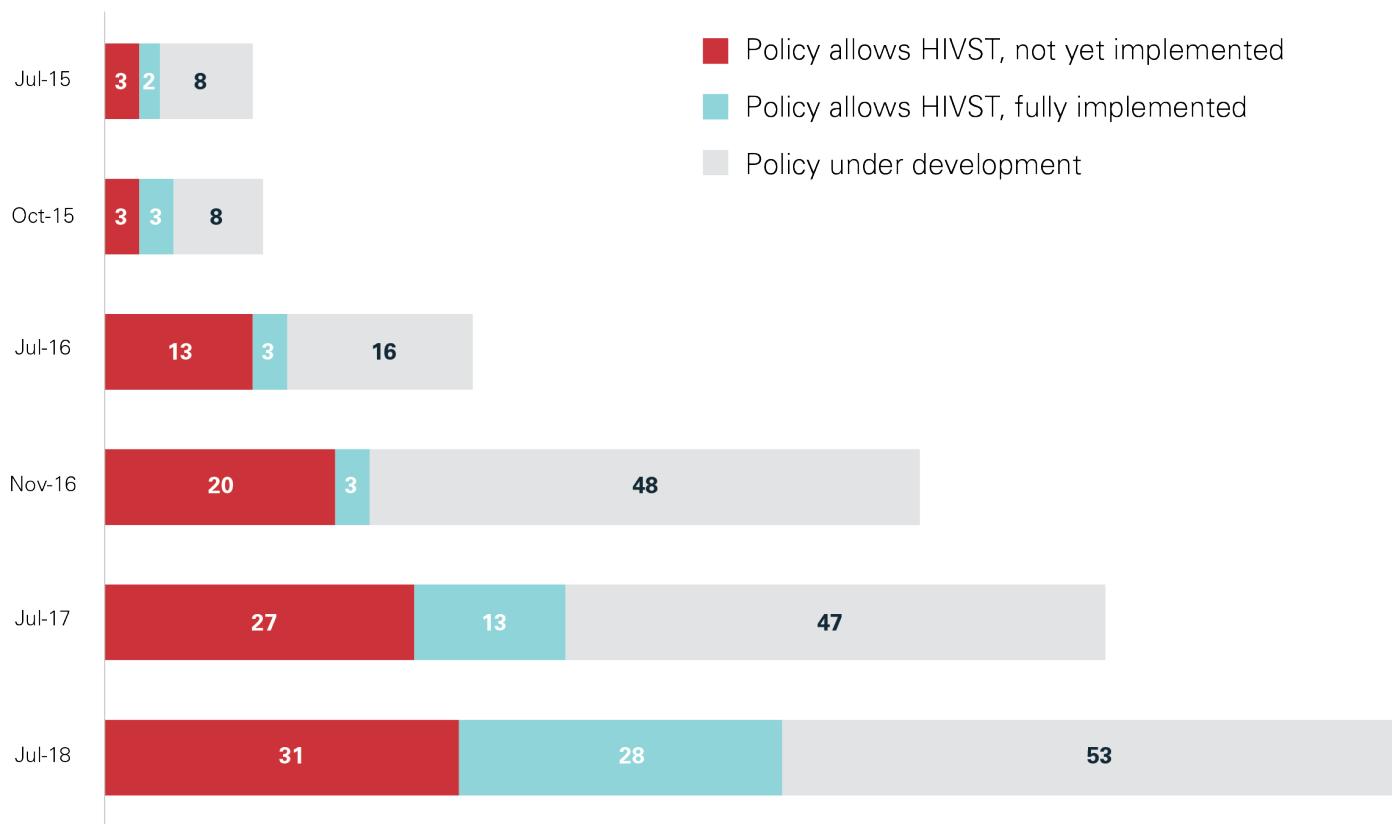
Using the WHO framework for in vitro diagnostics (IVD) regulations, the STAR Initiative provided ongoing support in all six countries ensuring a clear legal mandate, linking government policies and priorities for HIVST to regulation of IVDs, developing and implementing medical device guidelines and regulations for IVDs. By October 2018, South Africa was actively implementing IVD regulations with Malawi, Zambia and Zimbabwe expected to start implementation by early 2019 (Fig 13).

In addition to informing the WHO Strategic framework on HIVST (52), the STAR Initiative has also developed an implementation guide for countries and programmes on regulatory pathways for HIVST and addresses issues related to post-market surveillance. This tool kit will be released in early 2019.



FIGURE
11

Progress on HIVST policies and implementation, numbers of countries, 2015–2018



Source: Unitaaid (57), WHO country intelligence tool, July 2018



FIGURE
12

National policies on HIVST,
July 2018

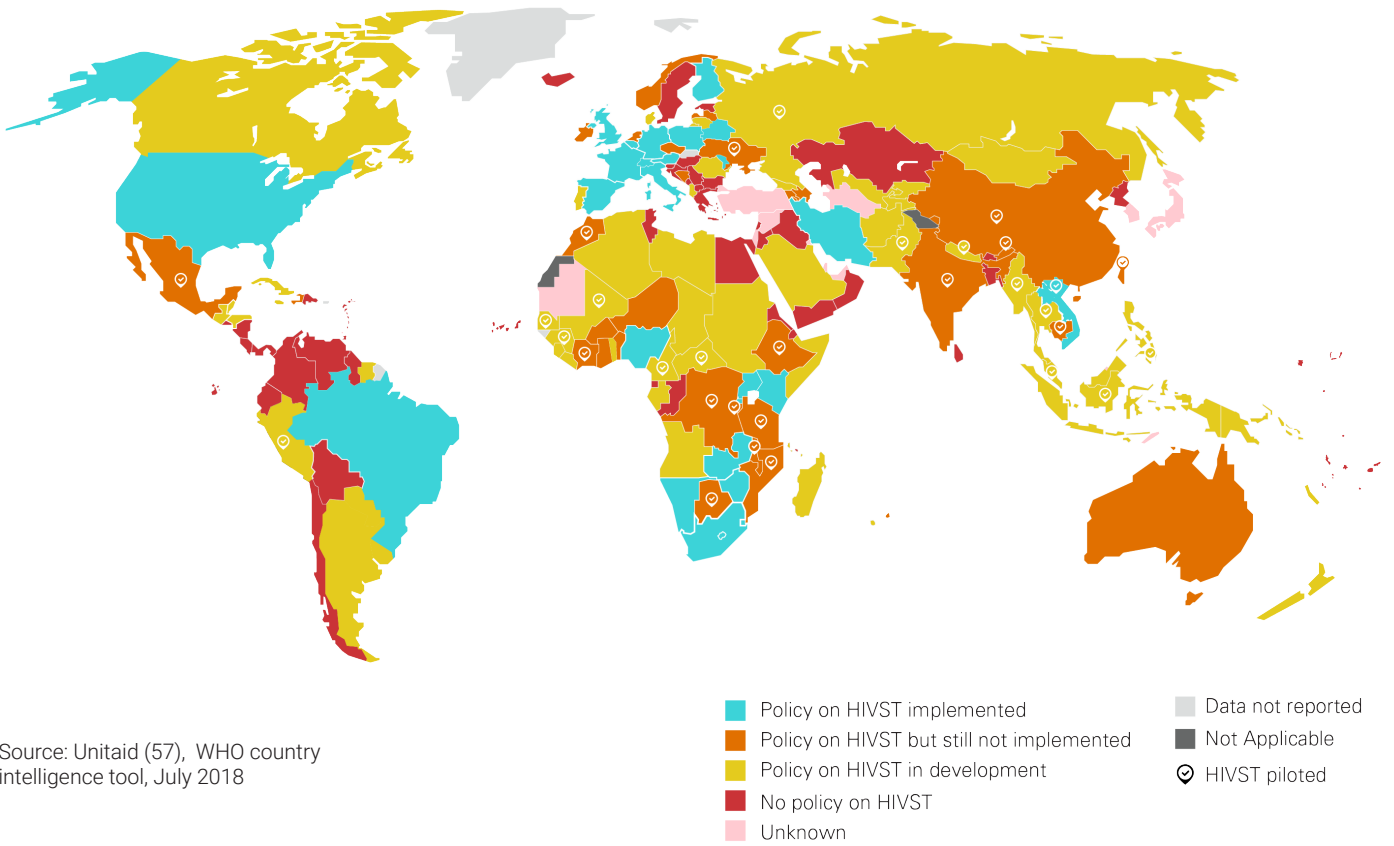
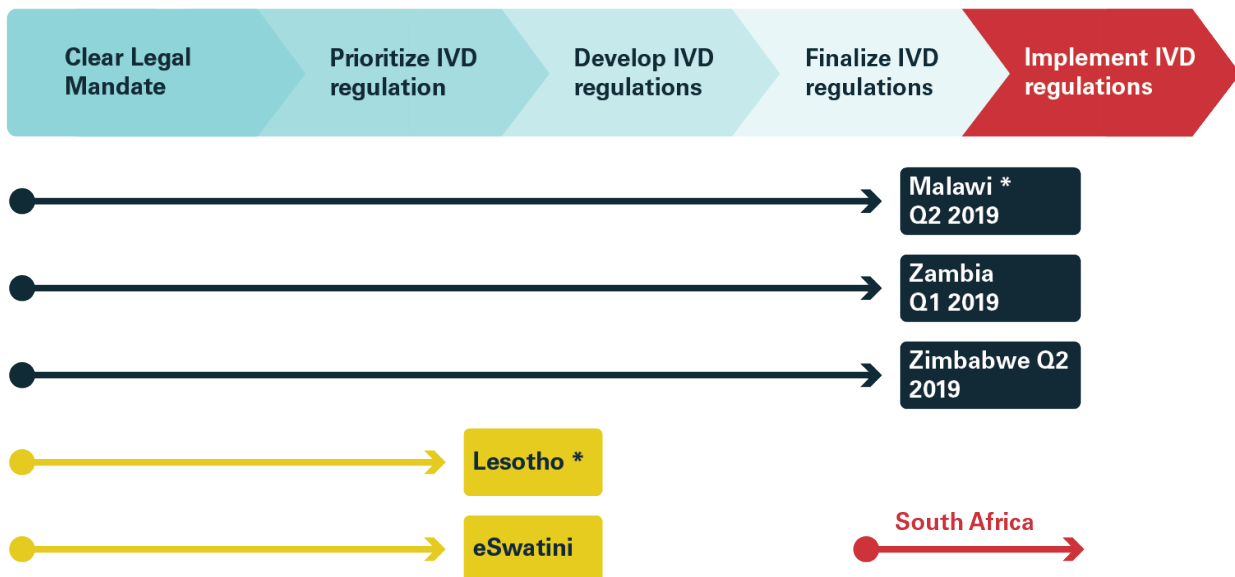


FIGURE
13

Progress towards the implementation of IVD regulations in STAR Initiative countries



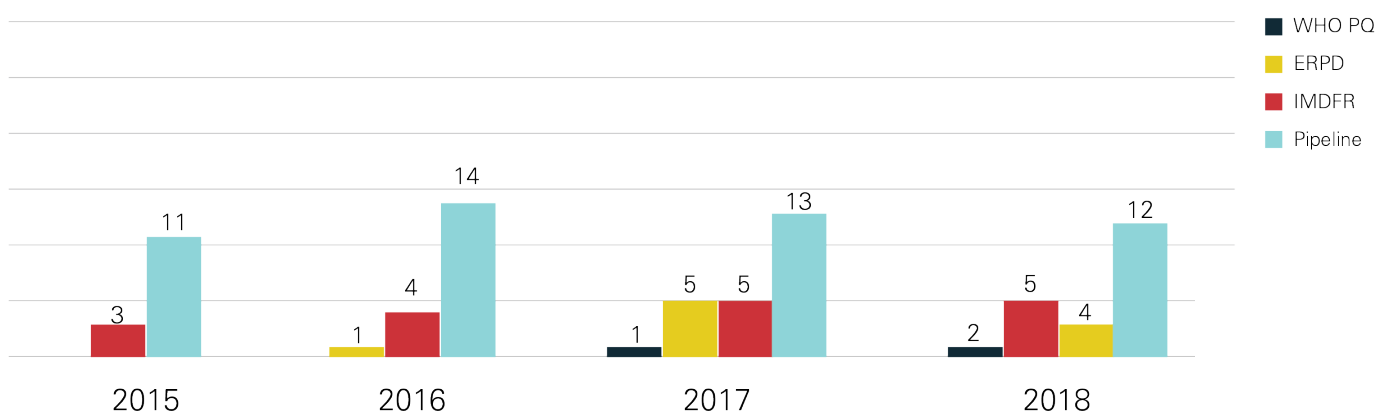
*awaiting regulatory act to be passed

2.3 MARKET FOR IMPACT

Accelerating supply. Soon after release of the guidelines on HIVST, WHO prequalified the first HIV self-test product. At the end of November 2018, a second product also received WHO prequalification. Three other products have also become available for donor procurement under the Unitaid/Global Fund Expert Review Panel for Diagnostics (ERPD), which is hosted by WHO. Several other products have received approval from one of the founding members of the International Medical Device Regulators Forum (Fig. 14). A number of manufacturers also report that they have products under development (57).

As the numbers of policies and products have grown, procurement of HIV self-test kits has increased rapidly. It was estimated that major donors would procure close to 5 million HIV self-test kits in 2018. Forecasting based primarily on current donor investment suggests that the market will grow to 16 (11-19) million kits by 2020 (Fig. 15) (57). Modelling for nine African countries estimated the market would reach between 3.3 million and 5.7 million or between 11 million and 15 million tests per year by 2020, depending upon whether conservative or moderate assumptions about investments are applied.

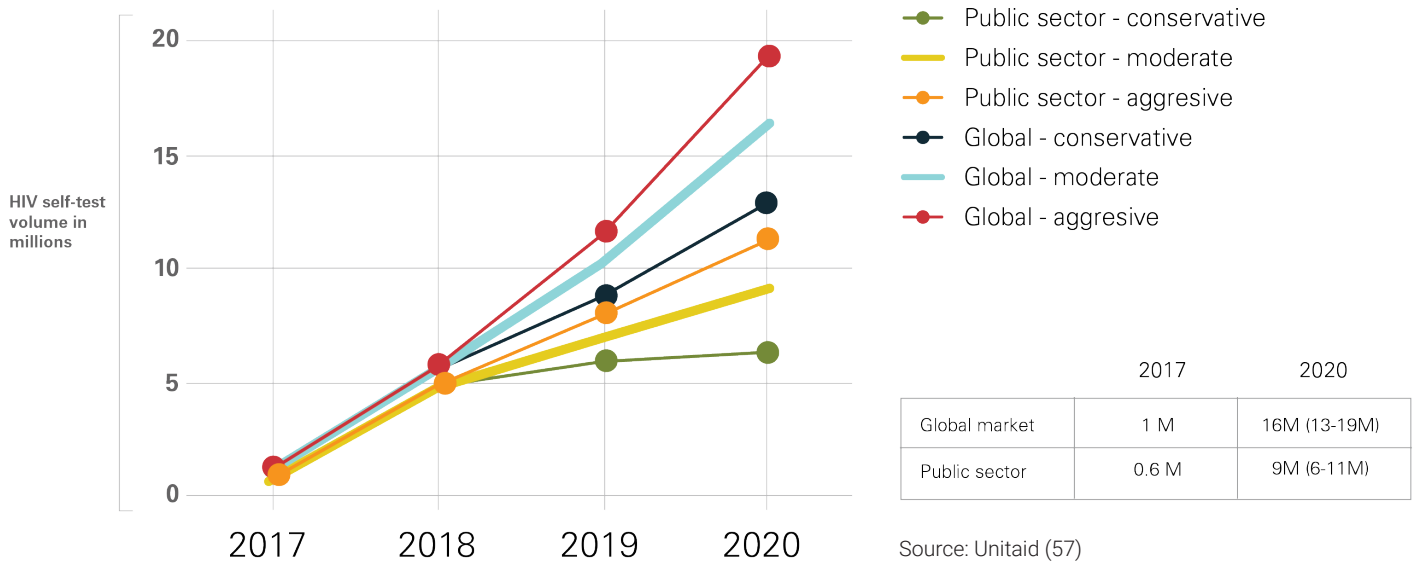
FIGURE 14 | Number of products for HIV self-testing with WHO prequalification, Expert Review Panel for Diagnostics or approval by a founding member of the International Medical Device Regulators Forum, by year



Source: Unitaid (57)

FIGURE
15

Global HIV self-testing procurement forecast, July 2018



Going to scale. Recognizing the need to fund and scale up HIVST beyond the STAR Initiative countries, Unitaid, together with PSI and their partners, has engaged ministries of health, the Global Fund and the U.S. President’s Emergency Fund for AIDS Relief (PEPFAR) to integrate HIVST into both budgetary and programmatic plans. Global Fund concept notes and PEPFAR country operational plans address HIVST, and the STAR Initiative routinely disseminates its findings to key technical leaders in both organizations. In 2018 PEPFAR included HIVST in country guidance as a dedicated testing strategy and increased funding for HIVST. (Table 3 shows countries which have included HIVST into national procurement plans).

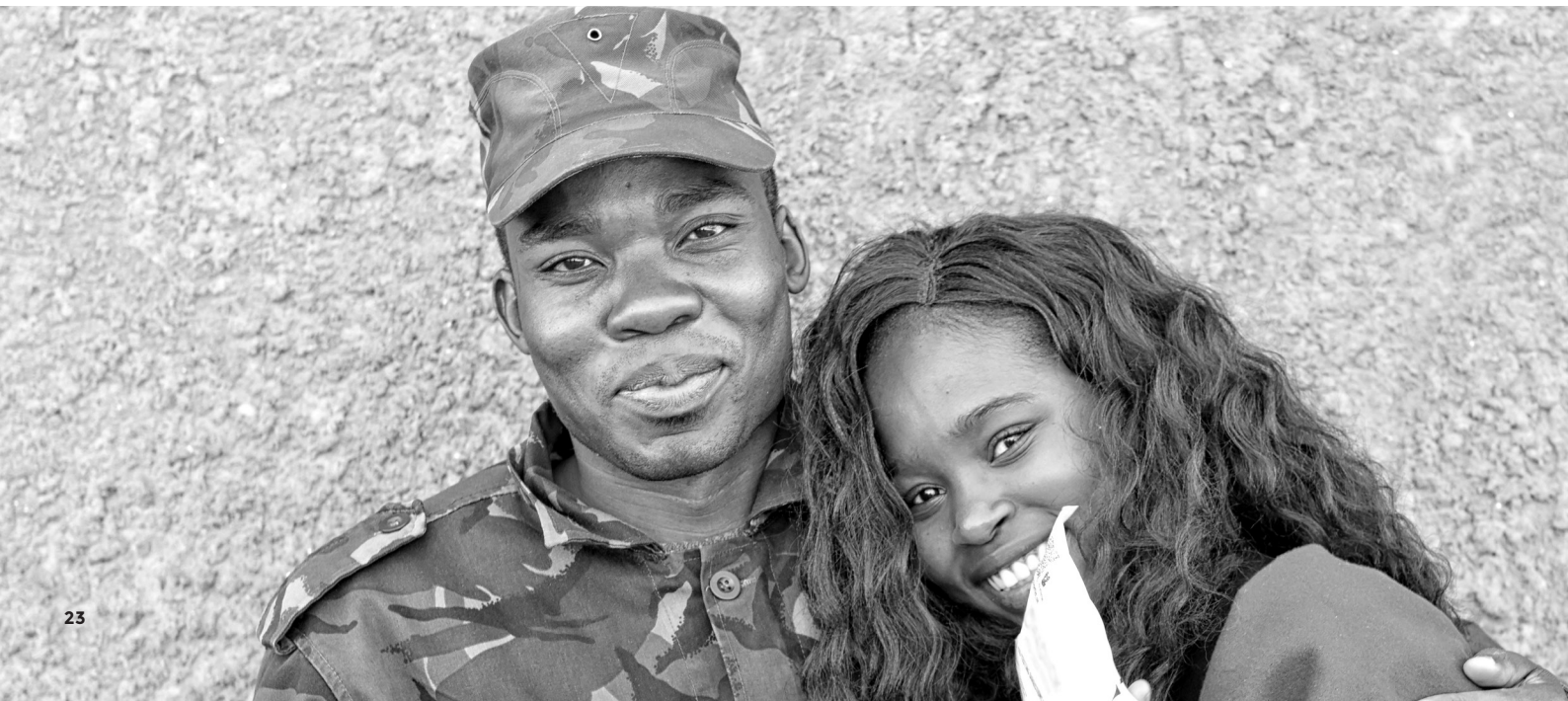


TABLE
03

List of countries with HIVST included in procurement plan, including funding from PEPFAR and Global Fund, as of April 2018

African Region	Algeria Angola Benin Botswana Burkina Faso Burundi Cameroon Central African Republic Chad Congo, Democratic Republic of Côte d'Ivoire Eritrea Zambia	Zimbabwe Eswatini Ethiopia Gabon Ghana Guinea Kenya Lesotho Malawi Mali Mauritius Morocco Mozambique	Namibia Niger Nigeria Rwanda Senegal Sierra Leone Somalia South Africa South Sudan Sudan Tanzania, United Republic of Uganda
Region of the Americas	Bolivia Brazil Colombia Cuba Dominica	El Salvador Guatemala Haiti Jamaica Mexico	Paraguay Peru Surinam Venezuela
South-East Asia Region	India Indonesia	Myanmar Nepal	
Eastern Mediterranean Region	Afghanistan Iran, Islamic Republic of Lebanon	Libya Pakistan	
European Region	Albania Armenia Azerbaijan Belarus	Bulgaria Georgia Kosovo Kyrgyzstan	Moldova, Republic of Tajikistan Ukraine Uzbekistan
Western Pacific Region	Cambodia China Cook Islands Fiji	Kiribati Lao People's Democratic Republic Mongolia	Niue Philippines Vietnam

Total countries: 83

Source: Unitaaid (57)

3

KNOWING YOUR STATUS – NOW AND IN THE FUTURE

It is currently estimated that 81% of people with HIV in sub-Saharan Africa have been diagnosed (1). Between 2015 and 2017, the global number of people with HIV who are unaware of their status and in need of testing services has decreased from 17.1 million to 9.4 million (58, 59). Over this period HIV self-testing through the STAR Initiative has contributed to changing what it means to know your status.

Thirty years ago HIV testing was one of the few interventions available to people with HIV, but the absence of treatment limited its benefits. Today, however, due to the extensive scale-up of HIV testing and treatment, knowing one's HIV status – including by means of an HIV self-test – is a first step toward HIV treatment and prevention and a healthy life. HIV self-testing now offers an additional empowering, safe and effective way to reach those in need of testing but who may not test otherwise. Now for many, testing for HIV does not have to mean travelling long distances, taking time from work, waiting in long lines or worrying about who might see them going for testing.

Through the STAR Initiative, effective and efficient models to deliver HIVST have been identified, policy and regulation have been developed, products have become more affordable and accessible, and countries are now going to scale. As countries and the world move closer to and surpass the first 90 target, efforts to reach concrete prevention goals will become an increasingly important priority. There is also a growing opportunity to use HIVST to avoid new infections and reach those who would most benefit from HIV prevention services by integrating HIVST into VMMC, PrEP and sexual and reproductive health services.

The lessons learned from self-testing are also not just for HIV. Many other disease areas may also benefit from approaches that use self-testing. Although it is still early, there are burgeoning efforts to implement self-testing for hepatitis C, malaria and sexually transmitted infections as well as self-collection for human papilloma virus testing. For several of these, the same devices and platforms used for HIVST may be usable and may significantly increase their market potential (57).

While there have been many achievements, much work remains to be done. The STAR Initiative is continuing to roll out HIVST and expects to distribute an additional 2.6 million kits by 2020. Moving forward, STAR, WHO, governments and communities will be taking HIVST to scale and identifying the most effective, efficient and sustainable models for mobilization, distribution and linkage to prevention and care. Over the next year, the STAR Initiative will be completing several research studies focused on optimising and increasing affordability and cost-effectiveness of HIVST and facilitating linkage to both treatment and prevention. Study results have been aligned with the

There is a growing opportunity to use HIVST to reach those who would most benefit from HIV prevention services.

update of the WHO guidelines which will be released in December 2019. To support scale-up, WHO and the STAR Initiative are providing technical assistance at the country level and are producing a suite of tool kits to guide implementation and scale-up of HIVST, such as the WHO Strategic Framework on HIVST (52). Additional tools are in development and will also be released in early 2019.

WHO and Unitaid have also expanded existing market and technology forecasting and landscaping for HIVST to explore other disease areas and strategic opportunities that could address concerns about pricing and increase the affordability of HIVST.

With further investment from Unitaid, three additional projects will further catalyse and expand HIVST, including: (1) the ATLAS project – Autotest, Libre d'Accéder à la connaissance de son Statut VIH – implemented by Solthis, which will bring HIVST to West Africa; (2) the mass media demand-creation campaigns in South Africa and Côte d'Ivoire created by the MTV Staying Alive Foundation; and (3) the Fiotec ImPrEP project, implementing HIVST as a strategy to increase demand for PrEP in Brazil, Mexico and Peru.

The STAR Initiative provides a strong foundation for other countries in Africa and globally to introduce HIVST and allow for rapid scale-up based on the rich evidence already gathered. Building on this work, both national programmes and donors, such as PEPFAR and Global Fund, have begun to scale-up HIVST. To achieve the first 90 target – and realise the full potential of HIVST – continued effort will be needed at a global scale.

Learning from efforts to date, and with sustained coordination and acceleration of market development work, HIVST can help address the testing gap and provide a focused and cost-effective means to expand access to treatment and prevention services. HIVST will play a crucial role in ensuring the achievement of global HIV treatment and prevention goals.



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