BRIEFING NOTE: OPERATIONAL RESEARCH TO IMPROVE IMPLEMENTATION AND UPTAKE OF HIV SELF-TESTING

PURPOSE

Current guidance from the World Health Organization (WHO) encourages countries to pilot and explore how HIV self-testing (HIVST) can be used to scale up HIV testing (1, 2), especially among people not reached by existing HIV testing services. These pilot programmes will provide the experiences needed to deliver HIVST in an effective, ethical and acceptable way and inform country implementation and policy.

In accordance with this WHO guidance, the Global Fund is supportive of countries including operational research on HIVST in their HIV applications or reprogramming requests as a way to increase access to and uptake of HIV testing among populations at high risk for HIV infection and who may not test otherwise. In this note operational research is defined as pilot programmes which utilize a scientific process to identify solutions to problems that limit program quality, efficiency and effectiveness, or to determine which alternative service delivery strategy would yield the best outcomes.

This note seeks to inform grants recipients or applicants who are preparing applications or reprogramming requests for submission to the Global Fund about key implementation considerations regarding HIVST and guide the inclusion of HIVST pilot programmes in reprogramming or new applications.

INTRODUCTION

Diagnosing 90% of all people with HIV is the first of three global goals set by the United Nations to end the HIV epidemic by 2030 (3). Despite scale-up of HIV testing services, 46% of all people with HIV are unaware of their status (4), testing coverage is low in most settings, and late diagnosis and linkage to prevention, care and treatment persists (5). Meanwhile, the level of internal and external investment in the HIV response is flat or declining in many countries (6–8). HIVST has been proposed as a way to address these challenges by efficiently and effectively reaching people at risk for or with an undiagnosed HIV infection who may not test otherwise (2).

Self-testing for HIV and for other diseases and conditions, such as pregnancy, bowel cancer and diabetes through blood glucose monitoring, is not new, and such tests are increasingly available and used. HIVST refers specifically to a person testing him- or her-self and reading the result to learn his or her HIV status, generally using an HIV rapid diagnostic test (RDT) adapted and packaged for self-use. HIVST does not provide a definitive diagnosis; all reactive self-test results require confirmation by a health worker (2).

HIVST has many possible advantages, including those listed below.

- Self-testing is a discreet and convenient approach that is empowering and appealing to individuals who may not test otherwise, such as adolescents, men and people from key populations and other vulnerable groups (2, 9, 10).
- It is highly acceptable among various users in various settings (11–32).
- It increases access to and the uptake and frequency of HIV testing (33–35).
- It facilitates HIV case-finding in some settings (33, 34, 36–40), while potentially being low cost to users and providers (41).
- RDTs used for HIVST can be accurate – as high as 98.9% sensitivity and 100% specificity – when they are quality products with clear, validated instructions (42).
- There can be good linkage to care post-HIVST, using a proactive intervention such as home-based initiation of treatment and follow-up through a community network (43).

See the Consolidated guidelines on HIV testing services for more information on HIVST (2).

IMPLEMENTATION OPPORTUNITIES AND CONSIDERATIONS

WHO guidance outlines approaches for implementing HIVST that vary in the level of support provided to the user and where and how the self-test is distributed (2). Various approaches to reach people with HIVST should be explored through different distribution models, for example, community health workers, facilities, kiosks, pharmacies and the Internet. In addition, different models of linkage into prevention, treatment and care for self-testers will need to be explored and evaluated, for example, hotlines, package inserts, mobile phones, videos, computer-based programs, follow-up support and referral by a community health worker, and offer of home-based care (2). See HIVST.org for examples and information on various approaches being utilized globally.

Further considerations for implementing HIVST pilot programmes are detailed below.

Specific target populations for HIVST

**Men**

Uptake and coverage of HIV testing among men is lower than among women in most countries (2). HIV testing has been identified as a barrier to uptake of voluntary male medical circumcision (VMMC) (44). HIVST could reach men who are reluctant or unable to see a health worker for HIV testing services and so could facilitate uptake of VMMC. This approach is currently being evaluated in Zimbabwe as part of the PSI/UNITAID STAR Project and is proposed as part of other initiatives focused on reaching adolescent boys and men, such as offering HIVST through community and sports events. To reach men, HIVST could be offered through workplace programmes, community-based outreach and other non-facility based settings such as pharmacies, kiosks, vending machines and through the Internet. Where relevant, HIVST projects should include linkages and integration with VMMC programmes. Other approaches to support linkage to prevention, treatment and care should be evaluated.

**Couples and partners**

Rates of HIV testing uptake and coverage among women are high, particularly in antenatal care and reproductive health settings (2). However, globally, testing uptake among male partners is low, and health workers do not routinely offer couples and partner testing (45). HIVST could make it easier for women to encourage their partners to test (23, 33, 46). To reach male partners, HIVST could be offered to women coming to antenatal care and drop-in centres, who can then give the test to their partners and encourage them to self-test (25). Also, HIVST could be offered in community outreach and in home-based settings to reach couples who can then test together. As with all partner HIV testing, programmes should include information and tailored messaging on mutual disclosure to mitigate risk of social harm and to help couples cope with a reactive self-test result or discordant test results, with linkages to services for domestic abuse and gender-based violence (2). Approaches to support linkage to prevention, treatment and care should be evaluated.

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2 Social harm is defined as the intended or unintended cause of physical, economic, emotional, or psychosocial injury or hurt. It can be from one person to another, a person to themselves, or an institution to a person. It can occur before, during or after self-testing for HIV. It may be the result of the threat of or actual force or power.
Key populations

Key populations\(^3\) are disproportionately affected by HIV (47), but uptake of HIV testing is low due to poor coverage and barriers such as discriminatory and judgmental service providers, self-perception of low risk and fear of stigma and potential criminal prosecution (47). HIVST can facilitate uptake and increase frequency of HIV testing among key populations (34, 48–50). It could be offered through peer outreach, nongovernmental organization clinics or other services for key populations such as harm reduction and screening for other sexually transmitted infections. The offer of HIVST through the Internet and via mobile phones (already used in many countries both formally and informally) is appealing in settings where these services are widely available, as it provides privacy and convenience (32). Sales through vending machines in or near clinics, bars, clubs, gyms and bathhouses frequented by people from key populations could also be considered (51). Programmes focusing on key populations should identify strategies to support linkage to further testing and HIV prevention, treatment and care and mitigate risk of misuse of HIVST and possible social harm. This is critical in settings with legal barriers and restrictive environments may limit key populations’ access to services or where misuse of HIVST could potentially result in stigma, discrimination and/or criminalization.

Other populations at high ongoing risk of HIV infection

In addition to key populations, serodiscordant couples and country-specific vulnerable populations at high ongoing risk for HIV require a special focus and frequent retesting, at least annually (2). HIVST is particularly relevant to country-specific high-risk groups who are hard to reach, for example, migrant workers, truck drivers or miners. It could also reduce the burden on facilities imposed by frequent retesting among serodiscordant couples, some key populations, the sex partners of key populations (i.e. commercial sex clients) and people using pre-exposure prophylaxis (PrEP) (2, 52). HIVST could be distributed through mobile outreach, facilities offering PrEP and workplace and corridor programmes. Programmes should explore linking with existing workplace and corridor programmes and PrEP implementation projects where relevant. Linkage to care may be particularly challenging for mobile populations, for example in some settings migrants diagnosed with HIV-infection are not eligible for treatment due to restrictive laws and policies. Strategies to support linkage and to mitigate risk of misuse of HIVST and possible social harm for such groups will need to be identified and evaluated.

Adolescents and young people

Adolescents and young people,\(^4\) especially girls and young women, are at increased risk of HIV in many settings. Uptake of HIV testing is low in settings with high incidence, however, often due to low coverage, structural barriers to services including stigma, poor quality services, discrimination, and restrictive laws and policies (53). HIVST with community-based support can be an effective way to reach young people (33). Implementation could include distribution through community outreach and integration with adolescent reproductive health services for young women and girls in high-burden settings. Approaches focusing on young people must consider age of consent for HIV testing and other medical services, including treatment in each particular country/setting. This should be taken into account where considering the appropriate age for offering HIVST. These approaches should also provide clear messages, information and linkages to HIV testing services, prevention, treatment and care, including comprehensive sexuality education and contraceptive. Internet and mobile phone schemes could be useful for distributing HIVST and supporting implementation with, for example, instructional videos and psychosocial support. Options to support linkage to prevention, treatment and care should be evaluated.

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\(^3\) WHO defines key populations as groups who, due to specific higher-risk behaviours, are at increased risk for HIV irrespective of the epidemic type or local context. Key populations include men who have sex with men, people in prisons and other closed settings, people who inject drugs, sex workers and transgender people.

\(^4\) Adolescents are defined as individuals 10–19 years of age. Young people are defined as individuals 15–24 years of age.
Health workers

Health workers often delay or do not access HIV testing due to fear of stigma and discrimination by their employer or other colleagues, and they often opt to self-test informally (54, 55). HIVST could be integrated into workplace wellness and occupational health initiatives and offered to health workers, their partners and family members to facilitate uptake of HIV prevention – for example, post-exposure prophylaxis following occupational or other exposure (24). Programmes should provide information on HIV prevention, treatment and care, including where and how health workers can discreetly obtain these services. Approaches to supporting linkage to prevention, treatment and care should be evaluated.

Linkage to further testing, prevention, treatment and care

Monitoring and evaluation of linkage to further testing, prevention, treatment and care following HIVST is critical. Among those who self-test for HIV, knowledge of linkage to further testing, prevention, treatment and care following HIVST is often limited. The following list outlines some approaches that could be utilized and evaluated.

- **Home-based treatment initiation with support and active follow-up by community-based networks** has been shown to be an effective way to support linkage to care (13, 14).
- **Package inserts** can be included in HIVST kits that explain the importance of further testing, and where and how to obtain prevention, treatment and care services.
- **Telephone hotlines** can be set up that people can call before or after self-testing to obtain information, including psychosocial and technical support as well as referrals and linkage to prevention, treatment and care and other non-medical services (i.e. legal support, redress for violence).
- **Mobile phone services**, which can operate like hotlines, can also provide reminders, videos and other messages and information to encourage linkage to prevention, treatment and care.
- **Internet and computer-based programs** can support self-testers. Some approaches have included online two-way audio or video counselling services and programs that offer step-by-step instructions on what to do following a reactive self-test result and describe where and how to obtain further testing, prevention, treatment and care.
- **Vouchers, coupons, rebates or referral slips** can assist linkage to further HIV testing, prevention, treatment and care, particularly among populations that face structural barriers to accessing services, such as long distance and costly transportation.
- **Partner HIVST** may increase linkage to care and encourage male involvement. Offering HIVST within **partner notification services** also may promote linkage to prevention, treatment and care.

Monitoring and partner notification services

There are currently no published reports of serious social harm or adverse events resulting from HIVST. However, as with all types of HIV testing services, it is important that it is voluntary, that clear messages and information are provided to mitigate the risk for misuse, social harm and/or adverse events, as well as monitoring and reporting systems, if and when they occur. In some contexts, special attention may also be needed to safeguard key population groups who may experience stigma, discrimination and criminalization.

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5 Adverse experience or adverse event is any undesirable experience associated with the use of a HIV rapid diagnostic test for self-testing by an individual. This could include pain or discomfort resulting from testing, any breakage of the diagnostic test, sale, use of an expired test kit, and any long- or short-term emotional distress resulting from a false reactive prior to confirmation or false nonreactive results after receiving false results before confirmatory testing.
for their behaviour and other vulnerable groups who may be particularly susceptible to misuse of HIVST by family members, partners, clients, employers, or institutions. Additionally, as noted above, where HIVST is being promoted for couples and partner testing attention should also be paid to ensure links to violence prevention, treatment and care services.

Many programmes are using a combination of the following approaches:

- **Monitoring and analysis** of messages and calls to **hotlines** or **SMS**, which can identify reports of test kit failures, adverse events or social harm;
- **Community-based surveillance systems** and **household/population-based surveys** that are designed to document and assess social harm and adverse events;
- **Internet and mobile phone surveys and tools** that encourage users to provide feedback on their experiences, including test kit failures and other social harm or adverse events.
- Adapt existing **post-market surveillance systems** to identify and report problems related to the RDTs used for HIVST.

**ADDRESSING HIVST IN OPERATIONAL RESEARCH IN FUNDING REQUESTS**

Pilot programmes are an important and essential step for countries and programmes to gain experience with HIVST before beginning wider implementation and national rollout. Recipients and applicants should take advantage of WHO guidance and Global Fund support and include HIVST pilot programmes in their funding requests, particularly as a way to scale up access to and uptake of HIV testing among populations at high ongoing risk of HIV infection and those who are underserved and unreached by existing services.

This section outlines key attributes of HIVST pilot programmes that should be addressed in funding requests to the Global Fund, at the time of new applications or through reprogramming requests during the implementation of existing grants.

**Rationale for HIVST pilot programmes**

Recipients and applicants should develop a clear rationale for an HIVST pilot programme and describe this rationale in their requests.

Requests should specifically address the rationale for the HIVST programme and how the pilot programme will be able to explore implementation issues and answer specific questions, including:

- What are the gaps and challenges with existing HIV testing services, for example, the testing gap (estimate the number of people with HIV who do not know their status) and populations and geographic settings with poor testing coverage and uptake?
- How could HIVST address these gaps and challenges, that is, improve access to and uptake of HIV testing services among at-risk and underserved populations and in “hotspots” with high HIV prevalence and/or incidence?
- How will the programme address likely barriers and potential users’ concerns about HIVST?
- What will be done to prevent and address potential social harm or adverse events, if and when they occur? And how will possible social harm and adverse events be monitored and reported?
- Are there any laws and policies that may be a barrier to or a facilitator to implementing HIVST? Are their existing laws and policies which safeguard key populations, adolescents and other vulnerable groups from coercive or mandatory HIV testing?
- Where will HIVST be implemented? Which populations will be served?
- What HIVST approaches will be implemented? How will these approaches provide and encourage linkage to further testing, prevention, treatment care and other support services? How will linkage be monitored?
• What results and information are needed for decision-making to support broader implementation and scale-up of HIVST? How will these results be collected?
• How will the overall HIVST pilot programme be evaluated?
• How will results and findings be disseminated to key stakeholders and policy-makers and used to inform decision-making on how HIVST will be implemented and scaled-up more broadly?

Partnerships for success

HIVST pilot programmes are most successful when planned and carried out in partnership with a team that includes civil society, community-based organizations and networks and organisations representing key and vulnerable populations, technical agencies, implementing partners, policy-makers and research institutions. These partnerships are essential to ensure that programmes are developed using local knowledge and up-to-date epidemiological information and are aligned with the latest WHO guidance. Such partnerships should be described in funding requests.

Involvement of Country Coordination Mechanisms and country dialogue

The Global Fund requires participation of people living with HIV and key populations in Country Coordination Mechanisms (CCMs). Financial resources are available from the Global Fund Secretariat to support strengthening this outreach and participation. The CCM Funding Policy is available on the Global Fund website.

Community response

Many of the most effective responses to HIV, including HIVST, are delivered at the community level by peers or lay providers. However, community organizations often lack the resources needed to be effective partners. Recipients and applicants should seek to strengthen and build the capacity of civil society, community organizations and networks of key and affected vulnerable populations to support HIVST, such as capacities for sharing information and messages, distributing RDTs for self-testing, providing counselling and support, facilitating linkage to prevention, treatment and care, monitoring programmatic outcomes, documenting adverse consequences and liaising for further support and organizing community surveillance systems.

Further information is included in the Community systems strengthening framework and the Community systems strengthening guidance note on the Global Fund's website.

Human rights and gender responsive programming

Funding requests require applicants to identify human rights and gender-related barriers to accessing health services. To ensure an enabling environment, Global Fund-supported health programmes and applicants are strongly encouraged to address barriers to access and to ensure that HIVST is provided in an ethical and responsible manner. Although there are many existing programmes which could be adapted to address barriers to accessing health services, it is particularly important for funding requests to address the following issues:

1. Legal environment assessment. Review national policies and regulatory frameworks to identify barriers and facilitators to HIVST, and then develop a costed and time-bound plan to reform policies and laws (such as those concerning the age of consent to self-test, criminalisation of HIV non-disclosure, exposure and transmission for example) in order to improve access to HIVST. In addition, conducting gender assessment may also be useful to identify harmful gender norms and develop appropriate interventions to address gender-related barriers to health.

2. Health education and literacy as well as access to justice for communities. Educate communities about HIVST, including messages and information to prevent misuse, mandatory or coercive testing and possible social harm. These activities provide important community support systems and an opportunity

6 http://www.theglobalfund.org/en/ccm/funding/
to increase uptake of HIV testing services and linkage to prevention, treatment and care. Providing access to justice is also an important component of efforts to reduce barriers to services, including HIVST, and to provide redress to people who may be coerced into testing.

3. **Training for officials and health workers.** Training of and communication with those who implement laws and policies can help to create a more enabling environment for the health response. The understanding of officials and health workers is key to ensuring that messages about HIVST are communicated correctly and that HIVST is offered ethically and appropriately.

4. **Community-based monitoring.** Monitoring and reporting on rights violations following HIVST are essential. These violations include, among others, discrimination, intimate partner violence, mandatory or coercive testing, social harm and other misuse or abuses, and violations of medical confidentiality.

**Considerations for procurement of HIV RDTs for HIVST**

Diagnostic products procured with grant funds are required to comply with the Global Fund’s *Quality assurance policy for diagnostic products*.

The Global Fund maintains in its website non-exhaustive lists which indicate Finished Pharmaceutical Products known to the Global Fund to be compliant with above requirements. Such lists which include HIV RDTs for self-testing are updated regularly and are available in the *List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy*.

Products currently listed raise issues of affordability and as well as whether the RDT, including instructions for use, has been adapted and validated in the hands of self-testers in low- and middle-income settings. Thus, when planning procurement countries and programmes should take into account HIV RDTs for self-testing in the pipeline for WHO prequalification and those assessed by Global Fund’s External Review Panel for Diagnostics (ERP-D) which will be more promising in terms of price and which will also provide better assurance on performance, such as sensitivity and specificity, stability and robustness among self-testers in low- and middle-income settings. Diverse interventions are underway, including those funded by partners (for example, UNITAID), to improve affordability and the market for HIVST, as well as interventions to adapt, validate and optimize HIV RDTs for self-testing in low- and middle-income settings.

More information on the pipeline and pricing of RDTs for HIVST is available in *WHO/UNITAID market landscape on HIV rapid diagnostic tests used for self-testing*. Also, the Global Fund has invited manufacturers to submit an *expression of interest for HIV RDTs for self-testing for product evaluation by its ERP-D*.

The Global Fund is developing a procurement strategy for HIV RDTs, including self-testing. Countries and programmes seeking assistance related to procurement for such tests should review the current List of HIV diagnostic test kits available on the Global Fund website and contact their Global Fund Country Team, particularly the Health Product Management Specialist. WHO HIV Department and in-country offices can also provide additional technical support for selecting appropriate HIV RDTs for self-testing.

**Submission of funding requests**

During grant implementation, the CCM and the recipient can directly contact the Fund portfolio manager to assess the possibility of a reprogramming of existing funds.7

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The applicant can also envisage introducing this activity in its next application to the Global Fund. Materials and how to apply will be communicated early 2017.

TECHNICAL RESOURCES

Technical assistance can be obtained through WHO, the Global Fund and from the following publications:


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REFERENCES