

HIV self-testing among health workers

**A REVIEW OF THE LITERATURE AND DISCUSSION OF CURRENT PRACTICES,
ISSUES AND OPTIONS FOR INCREASING ACCESS
TO HIV TESTING IN SUB-SAHARAN AFRICA**

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SUMMARY

Health workers in sub-Saharan Africa are often at high risk from HIV infection both in their personal lives and because of occupational exposure. However many health workers are currently reluctant to seek HIV testing and therefore do not access HIV treatment and prevention services. There is also increasing evidence that self-testing is practiced among health workers. Reasons for self-testing are various, and exploring how to better address concerns around access, privacy, confidentiality and quality of HIV testing and counselling for health workers should be explored to enable them to benefit from earlier diagnosis, treatment and care.

Until very recently, a cautionary approach to self-testing has been adopted in all countries. Though it is more than 20 years since the idea of self-testing was first considered, HIV self-testing continues to be a source of controversy and debate, many policymakers have reservations about the introduction of self-testing and it is not currently widely available.¹

The general global trend towards liberalization of policies relating to the link between counselling and testing, and technological advances in HIV test kit development, indicate the need for further research and guidance on self-testing, as it is widely practiced in some settings and over-the-counter tests are available in a number of countries.

This paper examines the particular issues of self-testing among health workers in sub-Saharan Africa, where high levels of interest and motivation for self-testing among health workers has been reported and informal self-testing already practiced. Health workers may benefit in a number of ways from formalized self-testing, however there are concerns which also need to be addressed. Many health workers perceive benefits in self-testing due to their daily experience of HIV issues through testing and counselling and clinical care of patients, but are reluctant to seek testing for themselves because of fears confidentiality and stigma within their health services where they work. As it may be difficult to discourage informal self-testing, formalizing access to self-testing or improving conditions for accessing confidential and quality HIV testing could improve outcomes and minimize adverse consequences. Informal self-testing, usually conducted in secrecy, carries a number of potential risks: inaccurate results, unsafe disposal of sharps, limited or no access to counselling and inadequate onward referral for care. A well-implemented and regulated self-testing programme could be an effective way of maximizing HIV prevention and ensuring early entry into HIV care for health workers, potentially at a lower cost and with fewer human resource requirements than alternative approaches.

Self-testing is only one of the possible options for expanding access to testing among health workers.² Other approaches to increasing access to testing by health workers will also be discussed but the authors give specific consideration to self-testing because it falls outside the most recent international policy recommendations on HTC.³

Further research is needed to explore ways of supporting increased access to testing for health workers and before definitive guidance on whether to promote or discourage self-testing can be given.

Acronyms and abbreviations

AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
CARE	computer-assisted risk assessment and education
CDC	Centers for Disease Control and Prevention
CLIA	Clinical Laboratory Improvement Amendments
CITC	client-initiated voluntary testing and counselling
CTR	counselling, testing and referral
DALY	disability-adjusted life year
DBS	dried blood spot
ELISA	enzyme-linked immunosorbent assay
FDA	United States Food and Drug Administration
FGD	focus group discussion
HIV	human immunodeficiency virus
HTC	HIV testing and counselling
MSM	men who have sex with men
NGO	nongovernmental organization
OTC	over-the-counter
PCR	polymerase chain reaction
PEP	pre-exposure prophylaxis
PITC	provider-initiated testing and counselling
PMTCT	prevention of mother-to-child transmission (of HIV)
STI	sexually transmitted infection
TB	tuberculosis
TTR	Treat, Train, Retain
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNGASS	United Nations General Assembly Special Session
USAID	United States Agency for International Development
VCT	voluntary counselling and testing
WHO	World Health Organization

1. Introduction

Shortage of health workers

Human resources for health-care delivery are essential for attaining global health and development goals. There is a strong correlation between density of the health workforce, service coverage and positive health outcomes,^{4,5,6} and a shortage of health workers has been widely and consistently identified as a barrier to the delivery of health services.^{7,8,9,10,11,12} Fifty-seven countries have been identified as having shortages in their health workforce,¹³ and the World Health Organization (WHO) estimates that the global shortage of health workers is over 4 million.¹⁴ No region faces as severe a shortage of trained health workers as sub-Saharan Africa, where 36 countries have a critical shortfall.¹⁴ An estimated 1.5 million health workers need to be trained to meet the current shortfall,¹⁵ and the current output of health worker training programmes in Africa is only 10% of what is needed.⁶

The HIV epidemic has increased the demand for health workers, and efforts to scale up HIV prevention, treatment and care rely on the size and capacity of national health workforces. At the same time, the increased global commitment to HIV puts more pressure on bottlenecks created by health workforce shortages, especially in sub-Saharan Africa where HIV intervention targets remain unmet.^{16,17,18} In light of this, strengthening and expanding the health workforce has been identified as a global challenge to scaling up HIV services,^{19,20} and the commitment to meeting this challenge has been renewed.

Low coverage of HIV testing

The importance of increasing access to HIV testing is widely acknowledged. People who are unaware of their HIV infection cannot access effective treatment and there is evidence that people who are aware of their HIV status can adopt practices to reduce HIV transmission.^{21,22,23,24,25} Knowledge of HIV status remains inadequate: based on 10 population-based surveys conducted in 2007–2009, the median percentage of people living with HIV who know their status is estimated at below 40%.²⁶

Treat, Train, Retain

In 2006, the United Nations General Assembly Special Session (UNGASS) on HIV/AIDS announced a plan to scale up comprehensive HIV prevention, treatment, care and support programmes in an effort to attain universal access to these services by 2010.²⁷ Recognizing the additional demand that would be generated by this and other global health goals, WHO launched “Treat, Train, Retain” (TTR) as a strategy under the Global Health Workforce Alliance to strengthen human resources for health.⁶ Focused primarily on high HIV prevalence sub-Saharan Africa, the strategy is intended to serve as a “menu of options” that addresses both the causes and effects of HIV as they relate to health workers. “Treat” refers to a package of HIV prevention, care and support strategies for health workers; “Train” involves increased pre-service and in-service training, task-shifting and expansion of the health workforce; and “Retain” emphasizes retention of health workers in places where they are needed most. TTR is part of WHO efforts to promote universal access to HIV services, but is also a strategy for strengthening human resources to attain broader health and development goals.

A consensus principle of TTR is the support of alternative models of health care, with one priority being the removal of barriers to access to HIV and TB prevention, treatment and care for health workers. This report aims to inform the “Treat” component of TTR through exploration of HIV self-testing as a strategy for enhancing HIV prevention and care among health workers.

2. Background

Impact of HIV on health care workers

WHO estimates that 2.5% of HIV infections among health workers are a result of needle-stick injury. However, the majority of HIV infections among health workers are acquired through unprotected sex.¹³ Health workers have the same social and economic pressures as the general population; and they are vulnerable to HIV in the workplace^{28,29} and in their personal lives outside the workplace.^{28,29}

There is evidence that health workers do not have priority access to effective HIV prevention and treatment services. In Botswana, an estimated 17% of the health workforce was lost to HIV from 1999 to 2005 and, without intervention, it was projected that 40% will be lost between 1999 and 2010.¹³ Data from Zimbabwe, Mozambique, Malawi, Kenya and Ethiopia indicate that 43% of deaths or medical retirement were suspected or known to be caused by HIV.³⁰ In Swaziland, 3–4% of nurses are lost to HIV infection annually,³¹ and in Kenya, HIV incidence among health workers is twice the national average.^{31,32} In Kenya, Lesotho and Malawi, death is the leading cause of attrition among health workers.^{13,32} In addition to the high attrition rate due to death or medical retirement, these statistics do not take into account absence from work due to HIV-related illness, which can be up to 50% of the expected time in the last year of life.¹³

The high rate of health workforce attrition in sub-Saharan Africa attributable to HIV of the health workforce implies low uptake of HIV services among this group. Health workers usually know where to access services, usually at their own workplaces. However, this knowledge is often not enough to promote widespread uptake of services among health workers.

Increasing uptake of testing

One of the major imperatives for increasing uptake of regular HIV testing is to protect HIV-positive health workers from their high risk of developing tuberculosis (TB).^{33,34,35,36,37,44} HIV-related TB has a high mortality even when diagnosed, but can be prevented by early diagnosis of HIV infection followed by a combination of measures to reduce ongoing exposure to *M. tuberculosis*, including provision of isoniazid preventive therapy and ART.^{38,39} Institutional rates of *M. tuberculosis* transmission are high in high HIV-prevalence settings, and most TB in health workers is due to occupationally acquired infection.^{31,32,44} It is the employer’s responsibility to reduce this risk, and there are therefore ethical, personal and public health reasons to support access to HIV testing to prevent morbidity and mortality, and retain health workers within the workforce.

Health workers are also at risk from occupational exposure to HIV through needle stick and other injuries/accidents, and early post exposure prophylaxis (PEP) is recommended.⁴⁰ However uptake of PEP is reported as being low. A study in Kenya found that only 4% of health workers accessed PEP following needle stick injuries and 'fear of testing' was cited as an important barrier to accessing PEP.⁴¹ Similarly, 'reluctance to test' was reported as a barrier to accessing PEP from a small study

from Malawi.⁴² It is possible that greater access to self-testing could be an important factor to help health workers access PEP following occupational exposure.

Barriers to testing

Stigma and fear of disclosure may be major obstacles to health worker access to HIV testing and counselling (HTC) and other HIV services.⁶ Being infected with HIV can be a source of personal and professional shame for a health worker, and may also invoke fear of losing one’s job and damaging future career prospects.^{6,43} To access HIV services, health workers may have to attend with the people that they serve, which may undermine the relationship of trust and authority that they have with clients. Furthermore, being tested and/or treated for HIV by a colleague might compromise confidentiality, and the service provider may also feel burdened by the knowledge of their colleague’s HIV status.⁴⁴ Regardless of the outcome, it has been documented that having an HIV test can be stigmatizing, and health workers are sometimes assumed to be HIV positive if they are known to have been tested.⁴⁴ Specific factors that may influence the uptake of HTC by health workers should be considered when developing services.^{6,44}

Table 1: Facilitators and barriers to HIV testing in all populations and health workers^{44,78, ,45,46,47,48,49,50,51}

Facilitators	Barriers	Comments
All populations		
Convenient access to testing services	Fear of HIV positive diagnosis.	
Direct offer of immediately available test	Fear of being unable to cope with knowledge of positive status.	Convenience of direct offer of immediate test appears to outweigh fears and related concerns for most people.
Same day results	Fear of adverse events if positive result received e.g. partner violence, abandonment or marginalization.	
Confidentiality	Observed stigmatization of others.	
Respect for HCT service providers		Preference for mature counsellors of similar or higher professional standing than self.
Access to HIV care		
Belief in HIV as cause of AIDS		
Belief in effectiveness of ART		Shown to affect adherence and likely to affect willingness to test as well.

	Adverse experiences in health facilities such as lengthy queuing or perceived staff insensitivity.	Common finding in qualitative studies investigating delayed use of available health services.
Health workers		
Greater knowledge and understanding of HIV	Heightened sense of shame and tendency to self-stigmatize because of HIV status.	Overall levels of testing are higher in health workers than in general population, implying that facilitators predominate.
Easy access to HIV testing in workplace	Observed stigmatization of patients by colleagues.	
High levels of belief in effectiveness of ART	Observed discrimination against HIV positive colleagues.	
Witnessing supportive management of HIV positive colleagues	Lack of knowledge or confidence in HIV anti-discrimination legislation.	
Experience counselling others about HIV	Personally knowing HIV test provider.	Concerns over familiarity with test provider and subsequent contact a significant disincentive, especially if provider is junior to self. Seeking HIV test at another facility and informal self-testing commonly reported.
Easy access to HIV care through workplace	Being senior to HIV counsellors.	Anticipation of preferential and convenient treatment appears to outweigh confidentiality concerns for most individuals: may be related to seniority and access to private health care (with more senior cadres seeking private care elsewhere).
Personal knowledge of HIV care providers	Personal knowledge of HIV care providers.	

Global HTC policy

There has been a change in international policy away from recommendations that prioritized individualized in-depth counselling towards a simplified approach to support wider access to HIV testing linked to greater access to prevention and care including ART. HTC policies have become increasingly public-health oriented, emphasizing the need for convenience, better integration into routine health services, and prioritizing wide coverage through sustainable strategies rather than in-depth pre- and post-test counselling.^{52,53,54} Human rights dialogue has also changed the approach to HTC, from a cautionary position to an issue of right to access to HTC, treatment and care. With this shift has come an expanded range of HTC models (See Annex 1). The UN General Assembly adopted the Declaration of Commitment on HIV/AIDS in 2001, which stated that prevention of HIV infection must be the mainstay of the response to the epidemic and this should include commitment to expanded access to HTC.⁵⁵ This was reaffirmed in the Political Declaration on HIV/AIDS in 2006.⁵⁶ In 2004, UNAIDS and WHO issued a revised Policy Statement on HIV testing, which emphasized that HIV testing is the gateway to expanded prevention, treatment and care.³ Current WHO policy supports this public health approach,^{54,57,58} recognizing the importance of knowing one's HIV status

and promoting expanded access to HIV testing through, for example, routine facility-based PITC. PITC uptake rates of 50–95% have been reported if it is integrated into routine care, thus minimizing the additional inconvenience and waiting time.^{59,60,61}

The 2004 UNAIDS/WHO Policy Statement on HTC states that HIV testing must be confidential, accompanied by counselling and with informed consent.³ Though pre- and post-test counselling is recommended, for PITC, pre-test counselling may be minimal, providing only enough information to ensure that the patient is able to provide informed consent.³ However this does not negate the need to provide in-depth post test counselling for those who may benefit from it to support access to ongoing prevention, emotional and treatment care and support.⁶² UNAIDS/WHO do not support coercive or mandatory HIV testing as these are neither effective nor ethical for public health purposes.⁶²

See Annex 1 for table of different approaches to HIV testing

Self-testing

HIV self-testing allows an individual to collect their own sample and perform a simple rapid laboratory HIV test, thus being the first to know their result. The primary considerations for effective HIV self-testing include:

- Accuracy of testing;
- Availability of counselling and onward referral to prevention, care and treatment services.

Other considerations for the implementation of an effective HIV self-testing system include:

- Adherence to confirmatory testing protocols;
- Disclosure and partner notification;
- Monitoring access to and use of test kits.

Current HIV self-testing policy and practice

Self-testing has not been addressed in UNAIDS/WHO documents on HTC. However, several countries have addressed the issue, and it is useful to consider the range of thinking on this issue while maintaining a focus on the particular context and needs of developing countries.

Kenya was one of the first countries to develop and implement public health policies to support and achieve a high coverage of HIV testing.

Box 1: Excerpt from the National Guidelines for HIV Testing and Counselling in Kenya, 2009¹⁰³

Excerpt from the National Guidelines for HIV Testing and Counselling in Kenya, 2009

Self-testing for HIV

The basic principle of self-testing has been used before for other non-invasive tests, such as in pregnancy tests. Clients can access test kits from pharmacies and other approved suppliers. Self-testing is different from the traditional HTC strategies as the client does not receive basic education, or pre-test counselling. But in order to strengthen support systems for self-testing, there is a need for basic standards. These standards include:

- Test kits must be evaluated and approved for use in Kenya;
- Test kits must be used before the expiry date;
- Storage conditions must be adequate;
- Test kits must pass quality control standards in Kenya;
- Pharmacists must be trained and approved to dispense, counsel and demonstrate the use of the test kit to clients and patients as the need arises;
- Follow-up and referral services, including confirming positive test results, must be accessible for clients.

The vendor should be able to provide the client with step-by-step instructions for

1. How to conduct the test;
2. How to correctly interpret the test results; and
3. Where to access follow-up and support services in the surrounding area.

Persons must also be informed that the results are not confirmed until a second, confirmatory test is conducted. This information should also be made available on a package insert, to be included on all HIV tests sold or distributed in Kenya, along with the minimum standards mentioned above.

Pharmacists and other suppliers of self-test materials should undergo HTC training and be certified by the Ministry of Health. They must provide a private room for clients who may need further information, counselling and social support. Utmost care should be taken to avoid cases of misuse of test kits, as well as to prevent negative social outcomes.

The 2009 revised Kenyan Ministry of Health National Guidelines for HIV Testing and Counselling¹⁰³ supports a broad approach to HTC and includes guidelines that cover new strategies, including oral fluid test kits for HIV self-testing. Kenya is the first country in Africa to develop policy guidelines on access to OTC self-testing kits for the general public although at the time of writing, no kit had yet been granted OTC status.

In the USA, unsupervised self-testing and sale of OTC HIV test kits is not legal. This may be revised, as collaboration between oral self-test kit manufacturers and government agencies, including the Centers for Disease Control and Prevention (CDC), is currently underway to carry out post-marketing surveillance and product development with the aim of meeting the accuracy and ease-of-use requirement for OTC sales. European legislation concerning diagnostic devices has recently been changed to provide uniform standards across most of the European Union and to make OTC sales of HIV test kits illegal unless approved specifically for this purpose. This has resulted in the withdrawal of OTC kits in some countries where such sales had previously been permitted (for example, the sale of self-testing kits through pharmacies in Holland and Germany).⁶³ A number of Asian and Middle Eastern countries allow unrestricted OTC sales of HIV test kits for self-use, including China and Thailand. There are, however, few data on demand or post-marketing surveillance.

Advocacy on HIV self-testing

There has been some advocacy for increased access to home- and self-testing from groups in high-income countries. The National AIDS Trust in the United Kingdom released a position paper in 2008

calling for more accessible HIV testing.¹⁰² They urged the piloting of home sample collection for HIV in the UK, and called for an amendment to permit and regulate self-testing, with careful monitoring and research to evaluate the impact on risk reduction behaviour and improved access to care. The Blood Products Advisory Committee of the US Food and Drug Administration (FDA) includes representation from patient groups and HIV activists, and has been supportive of the principle of home self-testing.

The *Canadian Medical Association Journal* has also issued a statement calling for home testing in Canada.⁶⁴ In the United States, there was strong objection to home HIV testing when the FDA held the first public hearings in 1989, with people citing fears of inaccuracy and increased rates of suicide. By 1996, however, the concerns previously cited were never realized and the first home sample collection kits were issued.

3. Method

A literature review was undertaken. Of the 70 available databases, those most likely to contain relevant citations were selected for systematic review. Due to the limited amount of published data on HIV self-testing in any populations, grey literature from additional electronic resources and an extensive Google search also produced useful information. A broad search was conducted for any citation with reference to HIV self-testing or home-based testing. References from all relevant studies were examined for any additional citations. Authors of pertinent studies were contacted to explore any further available data on HIV self-testing, and individuals thought to have conducted unpublished work related to self-testing were also contacted for further information.

All information contributing to knowledge of HIV self-testing in any population is included in this review, with a focus on data collected among health workers. Assessments of good practice and applicability to specific contexts may be required once sufficient evidence is available. Sources of information include surveys and focus group discussions (FGDs) evaluating acceptability, feasibility, current practices and barriers to self-testing, as well as intervention studies on self-testing. Due to the heterogeneity of populations and data collection methods, it is not possible to synthesize the data in a meta-analysis, and the data are presented by study with results divided into relevant categories.

A total of 17 studies on HIV self-testing were identified. They included eight peer-reviewed publications (three publications report different analyses among the same population, thus constituting one study), two draft manuscripts, four reports, three abstracts (one abstract and draft manuscript represented the same study), data from one online media source and two unpublished studies.^{44,77,78, 63,65,66,67,68,69,70,71} preliminary data from one ongoing study implementing HIV self-testing among health workers in Kenya.⁷⁹

Few published data on self-testing among health workers exist, and all are from Africa. Data on self-testing in non-health worker populations are also limited and most studies are from the USA and Europe. The studies vary in their aims, design and outcomes so it is difficult to make comparisons and draw conclusions. The health worker studies assess current levels of informal self-testing and explore the acceptability of a formal self-testing service. The non-health worker studies describe a range of scenarios, including pilot studies where various models of self-testing are offered.

Data are limited on the possible adverse emotional and social consequences of self-testing. Data are also limited on the potential benefits of self-testing, for example, to increase access and adherence to ART for people who test positive, promote behaviour change to prevent HIV transmission, etc. All the studies were cross-sectional, and therefore do not provide any indication of the possible risks or benefits of self-testing in the longer term.

See Annex 2 for summary of references included in HIV self-testing review

4. Overview of studies and key issues

Health-worker studies

Six of the 17 studies focused on health workers, all in Africa.^{44,77,78,70,43,79}

Study A, the 2005 Kenyan Health Workers Survey, was carried out by the Ministry of Health. This survey was conducted among 1897 health workers of various disciplines, who work directly with patients and are involved in HIV testing.⁷⁸

Health workers from different types of health facilities in all eight provinces of Kenya participated in the survey designed to examine the preparedness of the Kenyan health system to implement the Ministry of Health guidelines for scaling up HIV testing and access to treatment.

Study B was a situational analysis focused on health workers in five sub-Saharan African countries – Ethiopia, Kenya, Malawi, Mozambique and Zimbabwe.⁴⁴ Interviews were conducted with 938 health workers from 50 facilities. Thirty facilities were selected through random cluster sampling and 20 were selected as “best practice” facilities. Best practice facilities tended to be facilities with known HIV or TB services and good human resource management, and not based on the perceived strength of their staff services. A broad range of health-worker disciplines was included in the survey, from front-line health providers to support service employees. The objective of this analysis was to understand current policy and practice concerning health worker access to HIV/TB prevention, testing, care and support, and to evaluate the extent to which these differ from those in “best practice” facilities.

Study C among health workers was also conducted in Kenya.⁷⁷ The study comprised a series of FGDs among 161 doctors, clinical officers, pharmacists, laboratory technologists and counsellors in 10 district-level health facilities. These FGDs were designed to determine the feasibility and acceptability of HIV self-testing in this population, and to inform optimal service delivery models for the afore-mentioned ongoing study implementing an HIV self-testing programme with health workers in Kenya.

Study D was a two-part study to describe occupational burnout among health workers, as well as utilization of HIV services among 483 health workers from 13 public primary care centres in Zambia.⁷⁰ The study included physicians, clinical officers, nurses, midwives and pharmacy staff. Health workers also participated in six FGDs and four in-depth interviews.

Study E was conducted in Malawi in 2009.⁴³ The researchers used qualitative data obtained through interviews with health workers in two districts and a survey of 906 health workers in eight districts to explore the enablers and barriers to HTC and antiretroviral therapy by health workers.

Study F presents the results of a pre-pilot conducted in two hospitals in Kenya as a preliminary assessment of the acceptability and feasibility of a free home-based HIV self-testing intervention for health care workers. This assessment is meant to serve as the formative stage for a full evaluation to be conducted in seven district hospitals in Kenya.⁷⁹

Box 2: Kenya Pilot Study

Kenya Pilot Study

Only preliminary results are available, the Kenyan model being piloted in two hospitals with funding from Population Council and Horizons is of relevance from the perspective of the design of the model programme.

The strategy incorporates findings from FGDs and feedback from health workers in the pilot programme. Group training for health workers on how to use self-test kits is provided, followed by the opportunity to participate in self-testing. Counselling is available through a telephone system, and there are defined links with existing external CIRC sites where health workers can go for confirmation of results. Spouses of health workers may also self-test if they wish, in which case they are obliged to attend the self-testing training course.

Participants are asked to bring their test kit back to the hospital for proper disposal. While it is too early to determine if this system will be successful, the idea of implementing the programme was met with interest. Of the 295 health workers invited to use the service, 70% attended the pre-self-testing session and 93% accepted self-testing kits, but few used the counselling hotline, and those who did mostly called for clarification on proper sample collection.

One of the negative outcomes reported is that there is still some stigma associated with attending the training, particularly if a spouse also works at the hospital.

Informal and formal self-testing among health workers

In a study from 5 countries in sub-Saharan Africa⁷², informal HIV self-testing was reported as being high among health workers, with 41% reporting self-testing in Mozambique. Rates of reported informal self-testing vary widely across and within countries. Self-testing is not condoned in any health setting, and reported uptake of self-testing may therefore be underestimated.

A few health workers who had self-tested expressed regret. Those who regretted their decision to self-test reported that they were unprepared to cope with the results.⁷²

Reported disclosure following self-testing was high. In one study, 85% of those who self-tested reported that they had disclosed their results to at least one person. However, in the same study, many health workers said that they were not aware of the HIV status of their partners.⁷²

Confirmation of self-test results is an important concern. Only 46% of health workers said that they had sought confirmatory testing, but the majority reported that the self-test was not their last HIV test.⁴⁴ This may imply that confirmatory or follow-up testing is generally conducted, but ensuring confirmation of a single self-test will be a major concern if self-testing is to be formally introduced.

Rates of formal testing were also high among health workers and varied according to health worker discipline and type of health facility. Uptake of testing may be influenced by access to HIV testing services, as the highest rates of HIV testing were in maternity centres where PITC is standard, whereas the lowest were in dispensaries without integrated HIV services.

In a qualitative study from Malawi, researchers found that 76% of health workers surveyed reported having accessed HIV testing and counselling services, with 74% reporting a repeat test. Nearly half (49%) of the health workers noted that they tested because they “just wanted to know” while 22%

tested due to concerns about occupational exposure and 11% because of ill health. Eleven per cent of health workers surveyed reported self-testing while 41% of respondents believe that their colleagues have self-tested.⁴³

Interest in and acceptability of self-testing

Surveys indicate a high interest in self-testing, and there is widespread informal self-testing among health workers in health facilities in five countries.^{44,77,78} Data from health workers and general populations suggest that HIV self-testing is perceived to be an acceptable option.^{44,73,74,75,76} Self-testing was acceptable in other US and European populations as well.^{63,65,66}

Acceptability data were collected from health workers in Kenya, Ethiopia, Malawi, Mozambique and Zimbabwe, Malawi.^{44,77,78,72} show high levels of unregulated self-testing (20-41%) and high levels of interest in self-testing among health workers, ranging from 72% to 80%. Interest in self-testing was also reported among at-risk populations in the US, especially among those who had never tested before.^{71,80} This finding may indicate that provision of a self-testing service may be an effective means of encouraging testing in this target population.

Preliminary data from a pilot study providing self-testing for health workers in two hospitals in Kenya showed a high uptake of HIV self-testing following pre-testing information sessions. This self-testing programme is being scaled up to seven other hospitals in Kenya.⁷⁹

Information collected during focus group discussions (FGDs) confirmed that self-testing was common practice and often carried out repeatedly, in secret, as it was not sanctioned by their health institution.⁷²

Some health workers view self-testing as an opportunity to also have family members tested, which would be an important consideration while implementing a self-testing programme. This might be a particularly effective way to increase couples testing. Health workers thought that introducing self-testing would reduce or eliminate stigma around HIV testing, which has been shown to be a formidable barrier to testing in this population.

Perceived HIV risk of health workers

In one study, a large percentage of health workers stated that they had not taken an HIV test because they did not feel at risk, yet the occupational and societal risk for HIV among health workers in sub-Saharan Africa is well documented, and 94% of participants in one study reported being “very concerned” about becoming HIV infected at work.⁷⁸ It is well documented that a major barrier to HIV testing is refusal to acknowledge being at risk, even among those who are.

Lack of confidentiality as a barrier to testing

Reported concerns about the lack of confidentiality in HIV testing were low in the health workers surveyed, yet in FGDs fear of colleagues and the community knowing their status was a prominent theme. Furthermore, perceived lack of confidentiality was consistently cited as one of the top reasons for interest in self-testing. It is possible that though health workers feel the results of their

HIV test will not be disclosed, simply the act of testing for HIV can be stigmatizing, as those who test are often assumed to be positive.

Non-health worker studies

Self-testing among non-health worker populations was also reviewed. Three of the non-health worker studies were surveys among high-risk persons and/or clients of HIV testing facilities, with the objective of determining preferred methods of testing, reasons for the preference, and identifying attributes associated with acceptability of HIV testing.^{67,68,69,71,80} Study G was a survey among 354 clients (49% MSM) of four public testing facilities in San Francisco, USA.⁸⁰ Participants were asked about their preferences for HIV testing using various analytical methods, and to rank the importance of eight pre-defined testing attributes; 24% chose home self-testing as their preferred option. Study H was a large state-representative survey among 2964 people in California, USA to identify general behavioural risk factors.^{67,68,69} A series of questions in this survey examined willingness to use home HIV tests and preferences for HIV test characteristics. Study I was conducted among 460 at-risk participants in Seattle, USA. This study used formative research to develop an extensive list of possible barriers to HIV testing, and targeted high-risk groups who were not currently seeking HIV testing. The study then determined participant preferences from a broad range of possible HTC strategies; 20% indicated that self-testing was their preferred method and, among those who had never tested, 30% reported that they would prefer this method.⁷¹

Four studies directly evaluated the feasibility of HIV self-testing through participant self-testing and three included confirmation of results.^{73,74,75,76} The first of these (Study J) was conducted at two HIV testing centres in Singapore among 350 known HIV-positive and at-risk individuals of unknown status.⁷³ The feasibility of self-testing was assessed by the level of agreement between results obtained by self-testing and by trained personnel; 89% indicated that they would prefer to take an HIV test in private, by themselves. Participants were also presented with four sample rapid tests and asked to interpret the results based on the information provided in the instructions. Study K⁷⁴ was among 240 HIV-positive participants in Seattle, USA.⁷⁴ Participants conducted a self-test using both the oral fluid and finger-stick HIV rapid tests. Testing was conducted in seven waves of 20 participants each and, after each wave, instruction sheets and testing procedures were modified based on participant feedback. A final 100 participants were evaluated using the final set of instructions. Information was collected on difficulties with specimen collection, performing the test and interpretation of results. Over 60% cited that they would have preferred to find out their status using a self-test. Study L piloted the current oral fluid test kit for self-testing.⁷⁵ This study was conducted among 246 patients in an urban emergency department in the United States. Patients did not have a prior diagnosis of HIV, and were approached to participate in self-testing after health workers collected a sample for HIV rapid testing. Two hundred eighteen (89%) agreed to self-testing using only a visual instruction template. The results were 100% concordant with those of health workers. The majority of participants trusted the self-test results, found the test easy to perform, and reported they would both test at home and recommend self-testing to a friend.

Project Masiluleke, or “Project M” in South Africa (Study M) is a nationwide, cross-sector collaboration using mobile technology as a tool to fight HIV and TB.⁷⁶ The objective of Project M is to promote widespread scale up of HIV testing through the introduction of HIV self-test kits in the context of severe shortages of health-care professionals. A mobile telephone system is used for providing counselling and information. We have not been able to confirm whether or not self-testing has actually been piloted yet. Early responses from leaders in health care as well as the

community have been enthusiastic, and community members indicated a preference for telephone counselling. Accuracy data are not yet available.

Two studies looked at the acceptability and feasibility of computer-assisted self-testing. The first, Study N, a small study with 27 participants conducted in the USA, assessed the acceptability and usability of Computer-assisted Risk assessment and Education (CARE), an interactive HIV counselling tool, with HIV rapid self-testing among staff at a drug treatment centre where HIV testing is not currently offered.⁶⁶ The second, Study O, evaluated the acceptability and feasibility of CARE at community internet centres in India.ⁱ Eight FGDs were conducted with four to eight people each, including internet centre staff and potential participants such as single women, single men, married women, married men and couples.

We briefly report the results from two operational evaluations: Study P is a report of the demographics and motives for testing, and experience of testing, collected by online survey conducted in 2006 and 2007 of 1113 purchasers of an HIV Home Test.⁶³ This is a blood-based rapid HIV self-test kit that was sold over-the-counter (OTC) in pharmacies and through internet sales in the Netherlands and several other European countries between 1999 and 2005.⁶³ The kit was withdrawn following a new European Directive on in vitro diagnostics. Finally, Study Q was a small pilot study among 40 participants, carried out in Amsterdam, the Netherlands, by a nongovernmental organization (NGO) “Checkpoint” in which a proportion of users attending community-based HIV testing services were offered the option of self-testing.⁶⁵

Accuracy of self-testing

There are little data on the accuracy of self-testing. Four studies evaluated this. There was an unacceptably high level of invalid results (56%) with a finger-stick blood sampling test, which is designed for analysis by a laboratory technician. Participants performed better with an oral fluid test, which has fewer steps. Evaluation of another oral fluid-based test demonstrated much higher levels of accuracy, with 100% ($N=201$) concordance between patients and trained health-care professionals in one study.

See Annex 3 for summary of findings from HIV self-testing review.

Limitations of studies

Only 13 studies that examined self-testing were identified. The studies were conducted among heterogeneous populations and had varying data collection methods, making comparability across studies difficult. Four studies were conducted among clients of testing facilities. These results are not generalizable, as this group had already made the decision to test for HIV at a standard facility, and therefore were not necessarily representative of the majority of people who have never had an HIV test. Four of the thirteen studies targeted high-risk populations including MSM, injection drug users and HIV-positive persons.

Four of the studies were conducted among health workers. These included data from five sub-Saharan African countries.^{44,77,78,70} Two of the four studies had large sample sizes, and were conducted across a number of disciplines and types of health facilities, making these results more generalizable.^{44,78}

ⁱ Personal communication, Spielberg 2010

5. Discussion

Advocates for self-testing cite the potential for an increase in knowledge of HIV status, earlier diagnosis of HIV infection and earlier access to treatment and care, popularizing HIV testing and potentially de-stigmatizing it. Self-testing can also offer increased privacy and confidentiality, convenience and empowerment of individuals by offering greater autonomy over the timing and circumstances of HIV testing.^{81,82,83,84,85,86} Precluding individuals this choice on the grounds that they need to be protected from their own decisions could be argued as being restrictive or paternalistic.^{1,87,88} Self-testing is also potentially less resource-intensive, and so may allow rapid scale-up of testing activity without overburdening health facilities.

Arguments against self-testing mainly concern the risks of inaccurate results, psychological problems posed by decoupling HIV testing from adequate counselling, insufficient HIV prevention measures for sexual partner/s and the potential legal consequences of failure to disclose HIV status to sexual partner/s if disclosure is not encouraged (although there can be similar problems with partner disclosure with most testing and counselling models), and greater difficulty of ensuring referral to treatment and care for positive individuals. Concerns have also been raised about the potential for unethical use of HIV self-testing, such as testing partners without their consent, or test kits being used in other coercive situations.^{89,90,91} Another concern that has been raised is self-testing immediately prior to sexual relations, using the results as a justification for unprotected sex despite the risk of HIV transmission during the diagnostic “window period” due to acute HIV infection.¹ Finally, ensuring the safe disposal of sharps can be an issue for blood-based self-testing.

Box 2. Arguments for and against self-testing^{92,93,94,95,96,97,98,99}

Arguments for and against self-testing

Arguments for:

- Potential for increase in knowledge of HIV status
- Potential for earlier diagnosis of HIV infection and access to treatment and care
- Increased confidentiality
- Increased convenience
- Increased autonomy and empowerment
- Potential to reduce stigma associated with HIV
- Potentially less resource intensive

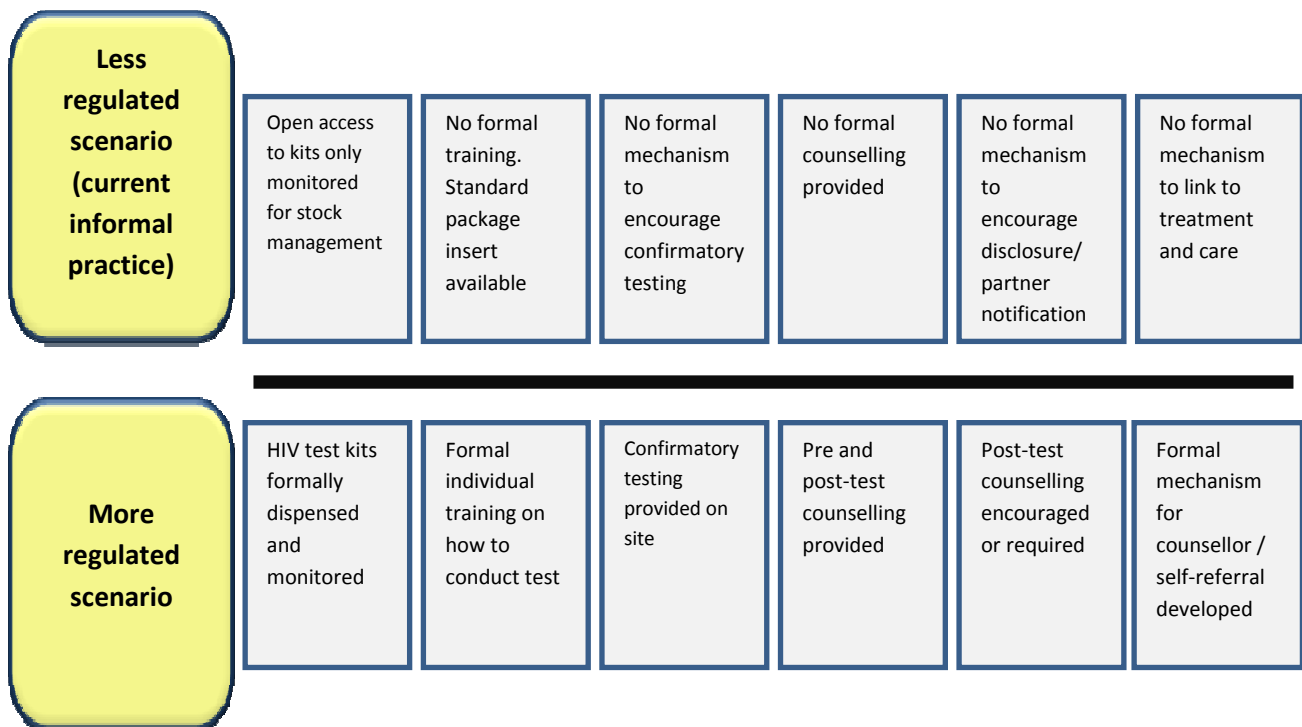
Arguments against:

- Potential for inaccurate results (lack of confirmatory test and quality issues)
- Psychological problems when decoupling testing and counselling
- Difficulty in ensuring referral to prevention, treatment and care services
- Potential unethical use of HIV self-testing
- Self-testing as justification for unprotected sex
- Concern for safe disposal of biohazardous material

Previously, some of these arguments against self-testing carried more weight than they do now. Rapid point-of-care HIV tests have improved sensitivity and specificity.^{100,101} Options for rapid testing include tests based on oral fluids, which are less technically demanding than blood-based tests and do not pose problems for sharps disposal. Knowledge about HIV, its transmission and prevention is now more widespread, especially among health workers. There is also much greater access to effective ART in many resource-poor settings. This may lessen the need for in-depth counselling for health workers who are aware of these HIV-related issues. However, it is not yet known whether increasing access to testing for health workers through approaches such as regulated self-testing will lead to a greater and earlier uptake of HIV prevention services.

Currently, the un-regulated self-testing system involves confidential and unmonitored access to HIV testing kits, allowing health workers to test themselves when and where they choose. A more regulated self-testing system could be similar to standard HTC with a trained counsellor present to provide pre- and post-test counselling, coupled with training on performing HIV rapid testing. The HIV test would then be self-conducted and the result read confidentially; thus, the client would be the first to know their results. There are a number of key elements that must be considered in a self-testing service delivery system. Examples of some key elements for the less and more regulated self-testing scenarios are presented in Figure 1.

Figure 1: Examples of key elements in two possible self-testing service delivery systems, representing less and more regulated systems^{102,103}



Implementation considerations

Global policy on HTC has evolved.¹⁰⁴ There has been a change from CIRC models with pre- and post-test counselling to PITC in health facilities, which is now being implemented on a large scale, with less emphasis on pre-test counselling. HIV testing algorithms have also changed to include the highly sensitive, specific and easy-to-use rapid tests now available. Kenya has already taken the new technology forward into a pilot programme of self-testing for health workers and included self-testing in its new HTC guidelines for the general population.⁷⁹

This review suggests that self-testing programmes may be one of the options to meet the need for a confidential and accessible HIV testing service for health workers, and may have the further advantage of allowing countries to discourage the practice of informal self-testing without affecting test uptake. If implemented with steps to ensure the accuracy of tests, confirmation of positive test results and onward referral for counselling and care as appropriate, self-testing may be safe and well received.

Maximizing benefits and reducing potential for harm

As informal self-testing is currently widely practised, it is important to minimize the current risks associated with informal self-testing. The risk of an increase in incorrect results or greater psychological distress may be counterbalanced by the potential for positive behaviour change and earlier access to treatment by those who might not have otherwise tested. Discouraging self-testing without providing acceptable, safe alternatives could be costly, administratively cumbersome and potentially ineffective. Options include formalizing self-testing and/or expanding other testing opportunities, and implementing measures to create a safe environment that promotes the uptake of HIV testing and links to other HIV services.

Models for self-testing programmes

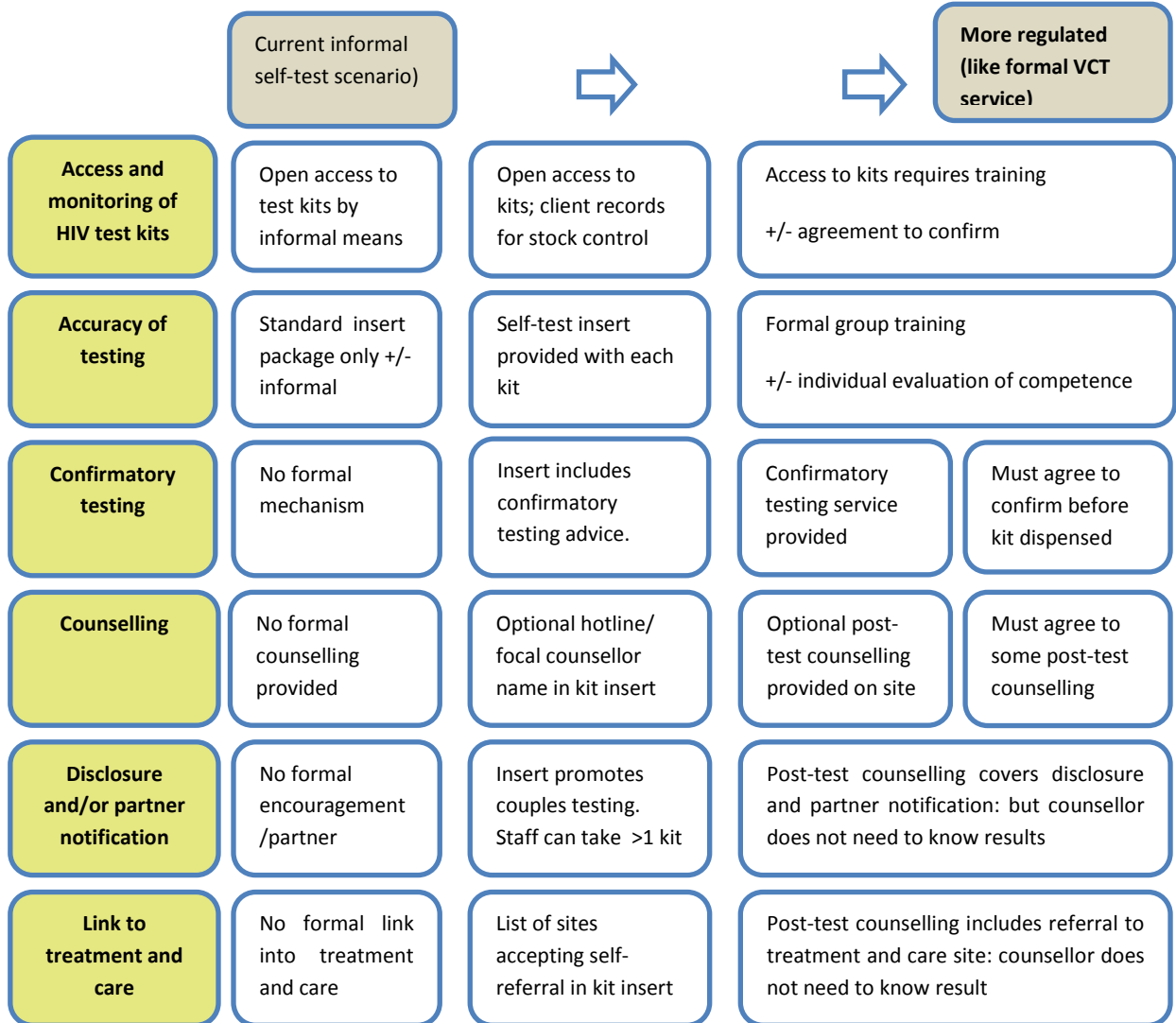
The most important consideration in an HIV self-testing programme is whether it can be provided in a way that is safe and acceptable to all stakeholders, including policy-makers, implementers and health workers. The interest in self-testing and evidence of current practice presents an important argument for evaluating models of self-testing in the health worker population. However, this does not mean that a formal self-testing service could be provided which continues to satisfy health workers' needs while also meeting key requirements.

Essential elements of a formal self-testing service delivery model, which will require development, provision, monitoring and evaluation, will include the following:

- Access to HIV test kits
- Ensuring the accuracy of testing;
- Utilization of confirmatory testing;
- Provision of HIV prevention and counselling services;
- Provision of HIV treatment and care services;
- Disclosure and partner notification.

For each of the elements, a range of approaches can be taken, influenced by barriers to HIV testing, desired coverage levels, resources available and level of monitoring and regulation desired. Figure 2 shows options for each of these key elements ranging from a less to a more regulated scenario.

Figure 2: Options for addressing each of six key elements in a self-testing service delivery model



A formal self-testing programme will also need to be tailored to the intended target population. This could, for example, be for all health workers or only for clinical cadres, and for employees only or their families and partners as well.

Accuracy and safety issues

An essential requirement of any HIV testing service is the accuracy of test results. Addressing this concern begins with consideration of which test kit would be most appropriate for self-testing. The ideal kit would have a simple method of specimen collection, a limited number of steps to perform the assay, and high sensitivity and specificity, including high sensitivity for acute HIV infection. For self-testing, the ease with which the test can be performed and interpreted correctly is of paramount importance.

Disposal of biohazard material is an important safety concern, with oral fluid tests having significantly less biohazard risk than other tests. Limiting self-testing opportunities to health facilities rather than extending them to the home environment would minimize this risk. Improper disposal of used sharps is likely to be of greater concern when test kits are used informally than in a formal self-testing system.

Oral fluid tests are easy to use, do not involve sharps disposal and have low technical demands of specimen collection which make these potentially attractive choices, but currently oral fluid test kits are more expensive than other rapid test kits[†].

Theft of tests kits for informal for-profit service provision outside the facility must also be guarded against and a stock-keeping system should be developed and implemented.

Training in reading self-testing kits

In a formalized service, training can be provided to ensure that all health workers using the service have the necessary skills to use test kits correctly. Extending service access to families of health workers could be done through facility-based training as in the current Kenyan model, outreach training provided at home or through information pamphlets, with health workers then acting as trainer-of-trainers for their own partners.

Counselling and confidentiality

HIV counselling has a beneficial behavioural impact that contributes to HIV prevention. Research among discordant couples and HIV-positive individuals supports this, though among HIV-negative persons the evidence is less certain. Currently, WHO/UNAIDS and CDC policies on HTC require HIV testing to be linked with counselling, but more flexible approaches are being considered. In the revised guidelines from CDC, there is a greater emphasis on making HTC widely available even when pre-test counselling is not feasible. Post-test counselling has the potential for enhancing HIV prevention, supporting disclosure to sexual partners, and enabling those who test seropositive to be referred for appropriate care and treatment. Post-test counselling also ensures that positive tests can be confirmed where necessary and appropriate steps for repeating serodiscordant results and addressing re-testing issues can be considered. The provision of post-test counselling is, therefore, an important factor to consider while implementing a self-testing service.

[†] In 2004, WHO performed an evaluation of the OraQuick HIV-1/2 – Rapid HIV-1/2 antibody test (not be confused with the FDA-approved test from OraSure). It performed well and is currently listed on the WHO WebBuy for procurement.

Health workers may face a special challenge to confidentiality posed by their knowing counselling staff. However, efforts to protect privacy and confidentiality need to be balanced against concerns regarding inadequate availability of counselling, how to promote confirmatory testing and disclosure of status, and how to create links to treatment and care services. Leaving individuals to face HIV test results on their own without any provision of pre- or post-test counselling or referral routes would not be recommended, even for health workers, who are better informed than others about the availability of services.

The health workforce includes large numbers of non-clinical support staff, with different needs for psychosocial support; services will need to offer a broad range of counselling options. Modified pre-test information for experienced front-line health workers would ideally include a reminder that they have a legal right to protection against HIV discrimination at the workplace, knowledge of which is poorly disseminated at present, and information about their high occupational risk for TB. As face-to-face counselling from a colleague will almost certainly be a disincentive for some health workers, this could be optional with alternatives such as telephone counselling, periodic health information provided at facility level to all employees, informational pamphlets, or interactive computer counselling. These same methods could be used for onward referral to HIV care.

A number of ethical concerns have been raised about HIV self-testing. A commonly expressed fear is that testing without face-to-face counselling could increase the risk of serious psychological consequences including suicide. However, the limited data on this do not support this view. In developing countries, some studies have shown that women who disclose their HIV status have a small but appreciable risk of experiencing violence and adverse life events.^{105,106} Self-testing might reduce this risk by providing women with greater confidentiality and autonomy, but it may also put more women at risk in a poorly supported post-test environment.

Finally, the possibility of coercive testing by a partner or employer is a concern. There is no information on this aspect. Mechanisms to monitor coercive testing and safeguards to prevent it should be put in place in any proposed formal self-testing programme.

Cost-effectiveness

Client-initiated testing and counselling is thought to be a cost-effective HIV prevention strategy in developing countries.^{50,107} HIV self-testing could also have the potential to be a cost-effective strategy, where indirect gains may include reduction in illness or death from late HIV diagnosis and late access to ART, and loss of productivity due to ill-health. At present, there are no data on the cost or cost-effectiveness of self-testing. Cost studies will be needed as part of pilot programmes.

The resources required to implement a self-testing programme will depend on the service delivery model employed. Available resources will be a factor in deciding which service delivery model is the most appropriate. Self-testing programmes may require fewer resources than other HIV testing methods, and could be a cheaper way of increasing HIV testing for health workers.

Confirmatory testing and quality assurance

Health workers should be informed that self-testing is a screening tool and confirmation of results is required. They will need to understand the possibility of a false-positive or false-negative test result, and the diagnostic window period. This information should be included in all HIV self-testing user training packages.

The effectiveness of strategies to encourage confirmation of the results should be evaluated. Strategies could include establishing links to private services for health workers to confirm results,

counselling to encourage the use of existing PITC or CITC services, or making a second rapid self-test available for confirmation.

Implementation

Due to the limited experience with self-testing, before considering the implementation of a service delivery model, a baseline assessment should be carried out to gauge the views of health workers and service providers, map the existing services and resources, and discuss with a range of policy-makers to ensure that any proposed self-testing programme is in line with existing HIV policies and guidelines of the implementing country.

Self-testing programmes should be integrated into existing programmes where possible, and comply with existing quality assurance standards and practices.

The service delivery model selected should have the human, financial and material resources necessary to ensure adequate long-term support for health workers following testing.

As self-testing is only one option for increasing access to HIV testing for health workers, other approaches as described below should also be explored and comparisons made so that recommendations can be made as to which approach is the most effective.

Monitoring and evaluation

Indicators of progress should include the level of uptake (first, repeat and couples testing); accuracy of testing; uptake of counselling, prevention, care and treatment services; adverse events; cost analysis and cost-effectiveness; and periodic assessment of the level of residual informal testing.

Other outputs that may be appropriate or informative to measure include the number of health workers being trained in self-testing, the profile of those self-testing (gender, discipline, etc.), burden and stage of HIV diagnosed through the self-testing programme, and treatment choices and outcomes.

Evaluation of HIV self-testing programmes is essential for developing strategic, evidence-based guidance for programme planning, sustainability, quality and effectiveness, and to ensure accountability of programme partners. At present, there is very little information on the acceptability, uptake, reliability, outputs, outcomes and overall impact of a formalized programme of self-testing for health workers. Pilot programmes should be undertaken, and monitoring these factors will be essential.

Impact

The ultimate goal of a self-testing programme would be to decrease the HIV-associated morbidity and mortality of health workers and improve their well-being and quality of life to strengthen human resources for health.

Indicators that would be appropriate for measuring the impact of HIV self-testing include: number of health workers who know their status; number of health workers accessing treatment and other HIV services; number of health workers accessing HIV prevention; extent of access to and utilization of PEP; measures of HIV-associated stigma in the workplace; days of work missed due to illness; and HIV-related health worker attrition.

Setting goals for policy and practice

The goals of HIV testing for health workers should be to enable all health workers to access HIV testing and re-testing as appropriate (i.e. following occupational exposure for those with ongoing exposure or a new incident of exposure).¹⁰⁸ Reduced HIV incidence and HIV-related morbidity including from TB would then be the secondary goals.

With sensitive and rapid HIV assays and the availability of effective treatment, the historical view that HIV is an exceptional illness has become increasingly inappropriate. For health workers to agree to HIV testing, the benefits must outweigh the perception of risks. Self-testing may normalize, and therefore destigmatize, HIV testing. Efforts to reduce the stigma associated with HIV testing could have far-reaching implications for expanding the acceptability and uptake of HIV testing among health workers as well as the general population. Understanding the obstacles to HIV testing among health workers and increasing the number of testing options may increase uptake. Self-testing could be a relatively simple and potentially low-cost option that addresses some of the barriers to testing.

Alternative approaches for providing increased access to HTC for health workers

There are several *theoretical* alternative approaches that could be considered to increase access to testing for health workers. As these are largely theoretical approaches pilot testing with evaluation will be required before recommendations could be given.

- **Occupational testing programme**

An occupational HTC programme for health workers, with a recommendation to test and a direct offer of immediately available testing and counselling could be considered. This could be implemented in a way that would ensure provision of an accessible testing option directed at health workers, which falls outside the public services. Easy access to services could be maintained while potential discomfort associated with queuing with clients could be avoided. A systematic, opt-out testing service for all health workers would challenge the stigma associated with presenting for an HIV test, and reduce potential discrimination towards service users. Potential disadvantages of PITC for health workers are the possibility of increasing stigma around HIV in the workplace and creating a heightened sense of job-related stress, but this could be overcome by a health worker education programme highlighting the particular benefits for health workers of knowing their status and providing confidential counselling services. The potential for health workers to feel coerced into testing or subject to speculation and discrimination if they decline to be tested could be a disadvantage of this approach.

- **Support to attend HTC sites**

Lack of perceived risk rather than lack of confidentiality was reported as a major reason for health workers not seeking testing.^{72,43} Some health workers may be motivated to seek HTC if they are provided with adequate information on the benefits of knowing their HIV status and the various HTC sites available to them, such as stand-alone HTC sites or private provider facilities not directly linked to the health facility where they work. Time off for attending and funds/token to cover costs could help to overcome logistic and financial concerns.

- **Service provider exchange**

Health workers may be more inclined to present for HIV testing to service providers they do not know personally or work with regularly. A service provider exchange programme could be arranged to provide increased access to HTC for health workers. In this type of programme, health workers could take advantage of CIRC provided conveniently at their own facilities, without being tested by

colleagues. If such an option is to be implemented, it would be important to consider how HIV testing would be brought to health facilities that do not currently provide HIV testing.

- **Home-based testing programme**

Home-based HTC has been employed with moderate to high levels of uptake in other populations,¹⁰⁹ and is a possibility for increasing uptake of HIV testing in health workers. This method may provide added convenience and confidentiality, particularly as it takes HIV testing out of the workplace and away from colleagues. However, there is also the potential for creating additional problems of marginalization and stigma if home visits target only health workers. Costs and personnel requirements may be high with this approach.

- **Mobile testing**

A mobile HIV testing unit could potentially visit health facilities and offer outreach HTC for health workers. This could provide the convenience of easily accessible testing services, and employs service providers who do not normally work at the facility. It has the added benefit of being a unique service for health workers, so they would not have to queue up with patients. Mobile HIV testing units can be very expensive to implement and maintain. The mobile testing service could also provide other screening opportunities such as tuberculosis screening blood pressure monitoring, diabetes screening, etc. as has been piloted for general populations in other settings⁷⁹ and therefore allow health workers to attend without being seen by colleagues to be specifically seeking HIV testing.

- **Home sample collection**

Home sample collection is another theoretical possibility. Samples could be collected at home, and brought to the laboratory for analysis. This would improve the accuracy of test results, as well as provide additional privacy and convenience. As with other self-testing approaches, a system would have to be devised for providing counselling and referral services.

6. Issues and action points for operational research

There remain a number of unanswered questions and key issues that need to be addressed before self-testing guidance can be developed and endorsed. Operational research and pilot programme analysis could provide opportunities to examine these issues.

Uptake of self-testing.

High levels of interest in self-testing and high rates of “informal” self-testing are reported among health workers surveyed in five countries, highlighting an unmet need for HIV testing. Prior to implementation of any HIV testing programme, an evaluation should be conducted of uptake of HIV testing among those who have never tested, ever tested and recently tested and what, if any, improvement in uptake might be gained over conventional testing strategies for first-time and regular repeat testing. This should then be monitored at the workforce level. Alternative strategies to increase access to testing for health workers should also be explored. This may discourage informal, unregulated use of test kits for self-testing by health workers.

Action point 1: *A high level of testing among health workers is an achievable goal. Efforts to maximize and monitor uptake should be a government responsibility. Countries with generalized HIV epidemics could consider developing and evaluating pilot programmes that provide access to alternative HIV testing approaches such as self-testing for health workers as part of an occupational health programme.*

Formalizing self-testing.

Formalizing self-testing may potentially increase the uptake of HIV testing and minimize the potential for harm associated with informal self-testing. Formalizing self-testing may also reduce the frequency of unregulated, informal self-testing. However, without adequate data, the impact of implementing formalized self-testing on the current informal self-testing system is unclear.

Action point 2: *Operational research should be conducted to establish the extent to which informal self-testing continues through monitoring in pilot and operational research projects.*

Accuracy of self-testing.

The limited data on the accuracy of self-testing gives mixed results. Preliminary data suggest that some oral fluid tests are accurate and easy to use and could be used for self-testing. Finger-prick blood tests can be used if self-testing is conducted in a supervised setting. It is essential that any testing method/test kit used is supported by national HIV testing policies, strategies and quality assurance programmes.

Action point 3: *The accuracy of self-testing with different types of tests and in different settings should be monitored carefully. Evaluation of accuracy is required for safe and effective implementation of self-testing for health workers.*

User training.

User training will be necessary for self-testing to ensure accuracy and minimize potential harm. Different training methods should be explored. Development of special instruction sheets, provision of face-to-face training on test kit use, or video-recorded instructions are some options. Ways of modifying instructions for low literacy audiences should be explored so that self-testing might be extended to all clinic staff and/or to family members. Whether one method is significantly more effective than another is unclear and each has implications for cost and confidentiality, which must be considered. Overall, it will be important to define and determine the most effective way of providing the bare essentials of training, information, counselling and referral, which would minimize the potential for harm and, at the same time, not be an obstacle or disincentive to HIV testing.

Action point 4: *Strategies should be explored for provision of training on the use of test kits in ways that are effective and not a disincentive to testing. Such strategies should take into consideration varying levels of education and understanding.*

Confirmation of test results.

All HIV testing strategies recommend confirmation of HIV-positive test results and re-testing for some categories of people who test negative. UNAIDS and WHO HIV-testing algorithms currently recommend confirmatory testing for positive results. Systems and strategies must be developed,

implemented and monitored to maximize confirmation of test results and support and promote re-testing where appropriate, and prevent re-testing when it is not needed.

Action point 5: *Operational research should be conducted on different strategies to encourage confirmation of results. Current recommendations for confirmatory testing for positive results should remain in place.*

Counselling and coping following self-testing.

Risks associated with self-testing have not been explored in depth, such as psychological trauma or greater likelihood of inaccurate results due to user error, and the psychosocial impact of self-testing over the longer term. Health workers indicated fear of coping with a positive result, and that counselling should be available. However, there is little information on how to provide counselling support services; the training, information and counselling needed to minimize the potential for harm; and what the uptake of counselling services would be if they were provided for people accessing self-testing. Options for alternative methods of counselling could include telephone counselling and computer-assisted counselling, both of which have demonstrated encouraging results (Spielberg F, Foundation G. Acceptability of self-testing for STIs in India, 2010).

Action point 6: *Counselling support services should be available to minimize the potential for harm. Monitoring and evaluation of pilot programmes should assess uptake of onward referral for counselling and evaluate the effectiveness of different counselling models.*

Accessing services following self-testing.

Information about the ability and willingness to enter into prevention, care and treatment following a positive self-test result is largely unavailable. Qualitative research among health workers suggests willingness and ability to accept results and seek entry into care.

Action point 7: *Onward referral and access to prevention (including prevention of mother to child transmission (PMTCT) services), care and treatment services following testing is essential and must be encouraged and facilitated. Strategies should be explored to ensure acceptable provision of these services following self-testing and the effectiveness of programmes in supporting uptake of prevention, care and treatment services assessed .*

Couples counselling and disclosure.

The confidentiality, autonomy and convenience that self-testing features could be a suitable platform for targeting couples. Levels of serodiscordancy are high and knowledge of the HIV status of partners low, and represents the main risk for HIV transmission. As many health workers are in stable partnerships⁴³, couples counselling should be encouraged. Although the Kenyan model encourages testing of health workers' partners, it is not known if this will be an acceptable or effective strategy.

Action point 8: *In order to maximize HIV prevention, HIV self-testing programmes should specifically accommodate and encourage testing of couples and partner disclosure. The uptake and acceptability of couples testing and disclosure should be assessed.*

Possible benefits of self-testing.

The possible health benefits of increased access to self-testing models could be increased rates of reporting of occupational exposure and uptake of post-exposure prophylaxis (PEP); increased uptake of and adherence to ART; decreased rates of health worker absenteeism due to health problems and decreased rates of TB among health staff. The potential for secondary benefits of self-testing include personal empowerment, increased job satisfaction, diminished HIV-related stigma and favourable group dynamics around knowing one's status.

Action point 9: *The possible health benefits of increased access to self-testing models should be monitored, such as increased rates of reporting of occupational exposure and uptake of post-exposure prophylaxis (PEP); increased uptake of and adherence to ART; decreased rates of health worker absenteeism due to health problems and decreased rates of TB among health staff. Potential secondary benefits such as personal empowerment and diminished HIV-related stigma should be assessed in representative and pilot research.*

Possible harmful effects of self-testing

A less-regulated self-testing environment has the potential for harmful effects due to greater user error and increased psychological trauma from decoupling testing and counselling. There is very little information on the greater likelihood of adverse outcomes, and no clear evidence of worse outcomes from self-testing than with other HIV testing methods.

Action point 10: *Systems to report adverse outcomes of self-testing should be considered in future pilot or representative self-testing programmes.*

Cost and cost-effectiveness.

Though self-testing has the potential to be a less expensive testing option than currently available models, there is little information on cost and cost-effectiveness of self-testing (for example, by preventing HIV transmission and increasing uptake of ART), particularly in relation to other HIV testing models.

Action point 11: *Evaluation of the cost and cost-effectiveness of different service delivery methods should be conducted if self-testing programmes are to be piloted or implemented, and should be compared with other HIV testing options.*

Annex 1 Different approaches to HIV testing

Approach	Setting	Target populations	Comments
Voluntary counselling and testing	Free-standing services.	General public; can accommodate regular repeat testers.	Counselling and links with care and support services provided. Testing is anonymous. Potentially stigmatizing to access free-standing services. Low income and vulnerable groups may not access
	Integrated into existing health services.	General medical, ANC, STI family planning, TB service clients; others.	Lower-cost than free-standing. Potentially less stigmatizing. Can be integrated into a range of existing services. Can target high-risk service users. Counselling and links with care and support provided
	Private sector.	Private practice clients; employees with workplace clinics.	Often little information or counselling. Cost may limit access. Potentially less confidentiality. Potential for coercive testing in some cases such as workplace clinics. Care may be available onsite.
Community outreach	Often mobile, may be linked to NGO outreach services for most at risk groups	Targeted communities or high-risk groups; often directed at those “hard-to-reach”; general public.	Accessible and anonymous services. Can provide referral to care and support services. Follow up maybe difficult. Potential lack of confidentiality and stigma to access unique service.
Home-based, campaigns	Door to door testing and HIV testing campaigns	Targeting general populations	Has potential to reach groups who do not attend health facilities. Follow up and linking to care may be limited.
Provider-initiated counselling and testing	Integrated into existing health services.	Widespread in ANC as part of PMTCT now being integrated into a range of health services, e.g. TB, general medical	Offered to all patients. High uptake and potential to reduce stigma as all clinic users targeted. Counselling and links with care and support provided. Counselling may be limited in some settings.
Self-testing / home sample collection	OTC HIV tests for use by general population; home sample collection tests; unapproved HIV tests available over the internet.	General public in certain countries and settings. Informally used among health care workers. Can accommodate regular repeat users.	Increased privacy and autonomy. Less expensive for health care system. Limited counselling and referral to care. Unapproved test kits available online. Informal self-testing carries higher risk of adverse outcomes, particularly with unapproved test kits.
Blood and tissue screening	Blood and organ donor services.	Blood or organ donors.	Screening for infectious diseases in donated blood and tissue is always recommended. Information may or may not be provided to the donor, and results are typically given. Counselling and referral may not be offered.
Mandatory testing	Unusual, but practiced in some places for military recruitment, immigration, specialized employment or by court order.	Military personnel, private sector employee, prospective immigrants to certain countries, other special legal considerations.	Mandatory testing is rare and considered unethical and therefore not recommended.

HIV testing for research

Research settings.

Research participants.

Carried out only after appropriate ethical approval. Typically requires written informed consent. Except in rare circumstances, results will be provided. All HIV testing in a research setting should be accompanied by counselling and referral services.

Annex 2

Summary of references included in HIV self-testing review

Study	Year	Description	Location	Population	Sample size	Primary outcomes
(A) MoH, Kenya [78]	2006	Cross-sectional KAP survey on HTC, treatment and care and impact on HCWs. FGDs also conducted with health care providers and district management teams.	Kenya	Doctors, clinical officers, lab techs, pharmacists, VCT counsellors	1897	64% of HCWs ever tested for HIV; 43% tested in last year and 50% of partners had ever tested. 73% of HCWs interested in self-testing if available.
(B) Corbett [44]	2007	Situational analysis re current policy and practice on HCW access to HIV/TB prevention, testing, care and support. Comparison of results with 'best practice' facilities.	Ethiopia Kenya, Malawi Mozambique Zimbabwe	Range of disciplines from front line providers to support staff.	938	70% of HCWs ever tested for HIV; 80 % interested in self-testing if available; 31 % already self-tested.
(C) Kiragu et al. [77]	2007	FGDs and in-depth interviews around feasibility and acceptability of HIV self-testing in this population	Kenya	Doctors, clinical officers, pharmacists, lab techs and VCT counsellors	161	Many HCWs avoid formal testing services due to fear of stigma; great demand for self-testing if available. Many HCWs report they have already self-tested, but note the need for adequate counseling and referral services.
(D) Kruse et al. [70]	2009	Cross-sectional survey, FGDs and in-depth interviews to evaluate HCW burnout and utilization of health services	Zambia	Physicians, clinical officers, nurses, midwives and pharmacy staff	483	
(E) Namakhoma et al. [43]	2010	Semi-structured in-depth interviews and a quantitative survey used to explore enablers and barriers to HIV counseling and testing and ART among HCWs in 8 districts in Malawi	Malawi	Nurses, Health Surveillance Assistants and medical officers	906	76% ever tested for HIV, and 75% of those had repeat tested. Fifty-five per cent of those who had ever tested had done so at their own facilities; 45% had last tested elsewhere. Reasons for testing

						included “just wanting to know” (49%), possible occupational exposure (22%) and ill health (11%). Reasons for never having tested included not feeling ready (32%) and fear of a positive result (22%).
(F) Kalibala et al. [79]	2009	Preliminary assessment of acceptability and feasibility of a free home-based HIV self-testing intervention for HCWs. Informational group sessions were conducted at the respective hospitals to provide information about the HST kits, the benefits of HST, and instruction on how to use and dispose of the kits. HST kits distributed and follow-up FGDs and IDIs conducted.	Kenya	Doctors, nurses, lab techs, counselors, and social workers.	245	At both hospitals involved in the preliminary assessment, there was a high level of attendance at informational sessions (91%) and a high level of acceptance of HST kits (94%). In general, HCWs felt that the HST offers more privacy than VCT, and they stated that if offered they would take the kit again. There was also a general view that HCWs should regularly test for HIV. Results suggest a high demand for HST and a view that kits should be available on a larger scale.
(G) Skolnik et al. [80]	2001	Cross-sectional survey to determine preferences for HIV testing using various methods of analysis and. Survey also ranked 8 testing attributes.	USA	Clients at two stationary and two mobile public HIV testing facilities; 49% MSM	354	
(H) Phillips et al. [67-69]	2002, 2003	Cross-sectional survey to identify behavioural risk factors; questions examined willingness to use home test kits and preferences for HIV test characteristics.	USA	State-representative survey	2964	
(I) Spielberg et al. [71]	2003	Cross-sectional survey to determine preferences for possible HIV testing and counseling strategies.	USA	At-risk participants from a needle exchange; 2 bathhouses	460	

				and 1 sex venue for MSM, and an STI clinic		
(J) Lee et al. [73]	2007	Cross-sectional survey to determine knowledge and attitudes around HIV self-testing. Feasibility evaluated by determining agreement between participant self-test results and results from trained personnel testing.	Singapore	HIV-positive and high risk individuals of unknown status; clients of two HIV testing centres.	350	89% preferred self-testing but thought confidential counseling necessary. 85% failed to use self-test kit properly and 56% had invalid results. 12% unable to correctly interpret results.
(K) Spielberg et al. [74]	2003	Evaluation of interest in and feasibility of self-testing using OraQuick fingerstick and oral fluid sample assays. Seven waves of participants conducted self-testing with instructions modified after feedback from each wave.	USA	HIV-positive individuals	240	
(L) Gaydos et al. [40]	2009	Evaluation of acceptability and accuracy of OraQuick Advance and Uni-Gold rapid tests performed by untrained patients with results compared with those of trained health workers.	USA	Patients from urban emergency department with no diagnosis of HIV	218	
(M) Project Masiluleke [41]	2009	Pilot research from a nationwide programme for unsupervised HIV self-testing with mobile telephone counselling	South Africa	General population from KwaZulu Natal	N/R	
(N) Bui et al. [66]	2010	Computer-assisted counselling and rapid HIV testing in chemical dependency treatment settings	USA	Staff from chemical dependency treatment centres	3 FGDs, 27 individuals	

(O) Spielberg (personal communication)	2010	Acceptability and feasibility of computer-assisted HIV self-testing at community internet centres.	India	Internet centre staff and potential participants (adult internet centre users)	8 FGDs of 4-8 people each	
(P) MiraTes [63]	2008	Evaluation of motivation for and experience with home testing using blood-based MiraTes HIV Home Test	Germany, Netherlands, UK, Belgium, Austria, Switzerland	General population, aged 13-76 years (50% reporting unprotected sex and large proportion of MSM)	1112	
(Q) Checkpoint [65]	2007	Annual report of Checkpoint HIV testing facility, including data captured on DIY testers for possible HIV testing and counselling strategies	Netherlands	General population, sex venue for MSM and an STI clinic	40	

Annex 3

Summary of findings from HIV self-testing review

Study	Interested in HIV self-testing	Ever self-tested	Confirmation / disclosure of self-test results	Concerns	Cost
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A	73%	FGD indicate many have self-tested		Fears about coping with positive result	
B	79%	31%	85% disclosed to at least one person; 46% sought confirmatory testing.	4% expressed regret over self-testing	
C	FGDs indicate many welcome self-testing.	FGDs indicate self-testing already common	FGDs indicate disclosure is important.	Fears of coping with a positive result	Self-test should be less than \$0.65.
D	52%	FGDs indicate some have self-tested without counselling.			
E	Most respondents note that they would prefer to self-test or to go to a facility other than their own in order to avoid judgment of junior colleagues and potential violation of confidentiality. Forty-one per cent of respondents believe that colleagues have self-tested.	11%		Hierarchy in the workplace inhibits uptake of testing, specifically due to concerns around confidentiality among junior colleagues and concerns about role model status	
F	Of eligible HCWs, 91.1% attended pre HST (home-based HIV self-test) sessions. Of those, 94% accepted test kits.			HCWs reported feeling more comfortable carrying a test kit home than walking into a VCT centre for a test; concerns over privacy addressed with access to HST. Some concerns expressed about accuracy of test results with HCWs feeling that they can trust HST results more than clinic results.	NA
G	24%				Only 5% thought cost was not important.
H	37%		Concern around user error and lack of counselling.		
I	20%				8% decided on testing method based on cost.
J	89%				Willing to pay \$7-13.

K	61% prefer to test at home; 88% thought self-testing should be made available.				70% willing to pay \$15; 40% willing to pay \$20.
L	80% agreed to self-test.				
M	Enthusiastic support from both community and health care workers.				
N	Staff thought their clients would be interested in computer-assisted counseling and in self-testing; thought self-testing would empower their clients.		Staff expressed concern for dealing with a positive result and ability to follow instructions accurately.		
O	Participants asked if they wanted computer counselling and rapid self-testing programme in internet kiosks – on a scale of 1-10, mean score was 9.8 (mode 10). 86% would rather test themselves than have staff test them.				
P	67% of self-testers would have a clinic-based test if home self-tests were not available.		98% would go to a doctor if they tested positive; 23% conducted self-test with another person present.	3% reported that taking a self-test did not “put their mind at ease” (91 % reported it did).	
Q	40/40 opted for self-testing, but only 1% knew it was an option prior to arrival at facility.	Of 40 clients, 13 returned to facility within a month; 16 returned 1-24 months later; 10 returned >24 months after self-test.			

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