

**REPORT ON THE FIRST INTERNATIONAL SYMPOSIUM
ON SELF-TESTING FOR HIV**

**THE LEGAL, ETHICAL, GENDER, HUMAN
RIGHTS AND PUBLIC HEALTH IMPLICATIONS
OF HIV SELF-TESTING SCALE-UP**

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List of Acronyms

AIDS	Acquired immune deficiency syndrome
MC	Male circumcision
ANC	Antenatal care
ART	Antiretroviral therapy
FDA	United States Food and Drug Administration
FGD	Focus group discussion
GBV	Gender-based violence
HIV	Human immunodeficiency virus
HIVST	HIV self-testing
HTC	HIV counselling and testing
HW	Health worker
IDI	In-depth interview
MATCH	Multi-country African testing and counselling for HIV
MSM	Men who have sex with men
PEP	Post-exposure prophylaxis
PMTCT	Prevention of mother-to-child transmission of HIV
PrEP	Pre-exposure prophylaxis
PWID	People who inject drugs
RDT	Rapid diagnostic test
TB	Tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization

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1. Background

Effective HIV prevention and care requires both increasing access to HIV testing and knowledge of HIV serostatus. Although access to and uptake of HIV testing and counselling (HTC) has increased significantly over the past decade, many people, including many of those at high risk, still do not know their status. The use of HIV rapid diagnostic tests (RDTs) for HIV self-testing (HIVST) allows individuals to screen for HIV infection in private, but does not provide a definitive diagnosis. Rather, HIVST is a screening test for HIV-1/2 antibodies and/or HIV-1 p24 antigen and requires a confirmatory test in accordance to the national algorithm. Nevertheless, HIVST does have the potential for early identification of HIV infected individuals in order to facilitate timely treatment initiation, and to augment the public health approach to HIV testing services in high prevalence countries.

HIVST was first considered over 20 years ago, but has not been widely implemented formally in health or alternative settings. However, in many countries HIVST is performed informally by health workers (HWs) and other lay users in an unregulated manner and, in some cases, with poorly regulated test kits through pharmacies and internet sales. Sale of the over-the-counter (OTC) OraQuick® in-home HIV test in the United States (USA) was approved by the U.S. Food and Drug Administration (FDA) in 2012 and two recent reviews discussed the limited experience with potential uses for HIVST (1, 2, 3). In 2011, two pilot studies were conducted by providing HIVST kits to HWs and their partners in Kenya (4), and to community members in Malawi (5). In both pilots, HIVST scale-up was driven by a need to reach individuals and couples not accessing current HTC approaches, and to find more acceptable and cost-effective ways of expanding access to testing. These pilot studies, and others, have begun to change thinking and debate around HIVST. Yet, HIVST remains a concern for many policymakers and implementers due to the associated ethical, legal, and social issues. For example, there have been reports of poor test sensitivity in the hands of the intended users and disconnection of testing from larger health system support, including counselling, treatment and care.

The incorporation of HIVST into national HIV programmes in high prevalence countries has started. HIVST was included in national policy in Kenya in 2009 and Zambia in 2011, and a number of other countries including Malawi and South Africa are considering including it in policy and practice. Despite rapid policy changes, there is limited data on distribution, uptake, and outcomes of HIV RDTs for HIVST. Further, no published studies address the possible ethical, human rights and social implications of HIVST.

For many policymakers, HIVST remains a contentious issue. HIVST is discussed in current World Health Organization (WHO) policy documents on HIV testing (6), but formal WHO guidance on HIVST has not yet been developed. There is increasing recognition that HIVST, if implemented carefully and with the meaningful involvement of communities, may provide an opportunity to increase knowledge of status whilst maintaining the five Cs of HTC as outlined by WHO: consent, confidentiality, counselling, correct results and linkage to care. However, before international guidance for national programmes can be developed, more research is needed to provide the evidence that HIVST is a viable option at the national level.

Experts from 14 different countries across the Americas, Europe, Africa and Asia (see Appendix 2 for list of participants) gathered at the Brocher Foundation near Geneva, Switzerland, to discuss the legal, ethical, gender, human rights and public health implications of HIVST scale-up. This symposium focused on high-prevalence and resource-poor settings and brought together ethicists, policymakers, practitioners, researchers, activists and donors to present their experiences and research findings on HIVST, in order to stimulate debate and pave a way forward for research and practice. The aim of the meeting was to develop a consensus statement and to publish a framework and series of papers to catalyse and support policy change regarding HIVST.

The specific objectives of the symposium were to:

- engage international experts in the debate around HIVST, including ethical, human rights, gender and public health implications;
- review evidence from existing and planned public health approaches to HIVST;
- examine and discuss programmatic opportunities, challenges and policy concerns for scale-up of HIVST;
- identify knowledge gaps to influence the operational research agenda;
- identify "priority niches" for HIVST;
- foster support from donors on HIVST– including operational research/feasibility studies;
- explore potential for WHO normative guidance development.

These objectives were covered throughout the meeting. For the purposes of this report, information discussed as part of the formal presentations is outlined in blue boxes and any discussion by participants follows.

2. Field experience with self-testing

HIV self-testing: Definition

The test is collected, performed and interpreted in private by the individual who wants to know about their HIV status.

HIV self-testing does not confer “knowledge of status” or provide a definitive diagnosis. HIVST involves a screening test that provides an individual with information upon which to base further action—confirmatory testing, access to post-test counselling, care, treatment and prevention. Written and/or pictorial instructions should be provided with the self-test kits to support their correct use. Information kits should also include contact details for peer support groups (e.g. networks of people living with HIV), information hotlines and other services (e.g. legal aid).

There are many different approaches where self-testing can be provided with various levels of additional support. In some research settings pre-test support is given, outlining the benefits and implications of HIVST, demonstrating how to perform HIVST, and providing information about what post-test support services are available. In other approaches where HIV RDTs used for self-testing are provided or purchased, there may be options for the provision of face-to-face or telephone support from a trained counsellor or HWs.

Examples of HIVST include:

In the Malawi community self-testing programme, the test procedure was demonstrated by a community volunteer trained in self-testing (5, 7, 8). The RDT was then provided to the individual to take home, performed and interpreted by the individual who wanted to know their HIV status. The individual could then seek further contact with the community volunteer for on-going support and a referral for confirmation of the result and further care as required. A “self-referral card” was provided at the time of testing, enabling participants to use an alternative option of direct self-referral into local clinics providing confirmatory HTC and care services.

In the Kenya HIVST programme for HWs (4), HIV self-testing was demonstrated by a trained user and the HWs were then provided with RDTs for themselves and their partners to perform and interpret at home. A hotline was available to provide support and advice about performing and interpreting the tests, as well as for post-test counselling and referral, if required.

3. Day One—Presentations

Session One: Accuracy and Efficacy

Session Chair: Dr Miriam Taegtmeier

ELLIOT COWAN¹—FIRST OVER-THE-COUNTER HOME-USE RAPID HIV TEST IN THE UNITED STATES (1, 9)

This presentation summarised the regulatory framework and FDA processes over eight years, culminating in the first FDA approval of an HIVST RDT for sale over-the-counter (OTC) in the USA. The speaker emphasised that RDTs sold for the purpose of HIVST should be evaluated as a test system (i.e. in the hands of the intended users, in the intended use settings, with informational materials as part of the test system).

In the FDA review of the OraQuick® in-home HIV test, the performance evaluations showed the performance in the clinical trials was 92.98% (95% CI 86.6-96.92%), whereas sensitivity was expected to be at least 95% as the lower bound of the 95% confidence interval. Though one study participant was in the window period, the remaining misclassified results were attributed to operator error (including test interpretation errors) (9).

In evaluating the safety and effectiveness of the test, FDA conducted a benefit:risk analysis to understand the public and individual health implications of approving this particular oral fluid-based RDT for HIVST at a lower sensitivity than expected. The analysis projected a net public health benefit for HIV infections newly identified in the first year of use and a significant number of potential transmissions averted. FDA concluded that despite the lower than anticipated sensitivity of the HIVST, the public health benefit was potentially significant and outweighed the individual health risk. This was an important factor in the subsequent approval.

Messages to mitigate individual health risk that need to accompany HIVST

In the packaging of the OraQuick® in-home HIV test, now available in the USA, additional information was developed to help users understand how to test themselves, to help users interpret their test results, and to educate users with prevention messaging.

In the approved OraQuick® packaging, it is stated that any antibody-detecting RDT used for HIVST may have a “window period” of up to three months².

¹ The presenter was not speaking on behalf of the FDA.

² The “window period” refers specifically to the time period between a potential exposure to HIV and appearance of HIV-1/2 antibodies. Following initial exposure, it may not be possible to conclusively determine their HIV status, as individuals may be undergoing seroconversion (i.e. developing HIV-1/2 antibodies). All HTC programmes which utilise HIV RDTs need to remain cognisant of the window period.

Re-testing is recommended for anyone who tests negative and has had a recent risk exposure or has on-going risk of HIV infection. A negative result does not imply it is safe to engage in risky behaviour and information about HIV prevention needs to be available. The results of an HIVST RDT should not be used as a basis for deciding to engage in behaviour that increases the risk of transmitting HIV infection. A reactive result always needs to be confirmed with additional testing in a medical setting.

For scale-up in resource-limited settings

The presenter recommended that clear instructional materials should be designed with the target population in mind, and that the test kit, including the instructional materials, must be adapted for the market in which it is intended to be used.

Key outstanding questions discussed include:

- What will be done with the test result?
- How can confirmation of reactive test results and linkage to care be supported?
- How will questions be addressed and counselling provided if needed?

ANITA SANDS—WHO PREQUALIFICATION AND EVALUATION OF ORAL TESTING

The WHO prequalification of diagnostics programme fills a niche for products that are currently not stringently regulated and which are intended for sale and use in countries that have non-existent or poor regulatory processes for approving diagnostics. The WHO prequalification assessment focuses on the quality, performance, safety and use of diagnostics in resource-limited settings. It also assesses suitability for use by non-laboratory personnel in remote, hot and humid localities.

RDTs that are used for HIVST need to be as, or more, robust as and easier to perform than a those used by professionals. This is because lay users are not trained, tests may be stored before use in more adverse environmental conditions than intended and testing is more likely to be performed in uncontrolled conditions.

Implications for users

There were discussions over where RDTs used for HIVST will be sold, and what the role and responsibility of sellers (including those in the private sector) and distributors should be for training, trouble-shooting, referral and reporting complaints.

There was consensus that the instructions-for-use (IFU) for HIVST RDTs must be clear and uncluttered, with less complexity than those developed for professional use, e.g. more pictures, fewer words. Different and more innovative training approaches may also be used (e.g. supervised HIVST, demonstration at point-of-sale/distribution, YouTube videos).

LIZ CORBETT—ACCURACY OF TESTING AND LINKAGE TO CARE

This presentation shared interim results of a cluster-randomised trial in Malawi using a hybrid

model of HIVST combined with tuberculosis (TB)/ HIV prevention.

Interim findings show that 81% of the 16,660 adult residents offered access to HIVST have taken kits, of which 89% have returned kits, 98% would recommend HIVST to friends and family and private (in-home) HIVST was generally the preferred method for “next test” for most men and women.

Initially sensitivity of RDTs, as reported on client feedback forms, was low (84.4%: self-reported results compared to lab read of returned kits), but has improved to 91.8% over time after changes to reporting processes. Formal re-testing quality assurance (QA) shows a sensitivity of 99.6%, and a specificity assessed with both of these approaches of 100%.

Who was testing?

Highest uptake of HIVST was among the youngest age groups, men, and those who had tested for HIV before. Twenty-one percent of participants were less than 20 years of age. Forty-two percent of participants were male. Two-thirds of participants had an HIV test before. Only 14% of participants engaged in couples testing. In Malawi, HIV prevalence was less than anticipated due to increased uptake of testing among younger age groups, among whom HIV prevalence is relatively low.

Linkage to care

Sixty-seven percent of HIVST users disclosed results to a counsellor. The majority of patients accessed care through counsellors; few bypassed the counsellor and accessed care on their own.

Linkage to care was three times higher when clients were provided with the option of antiretroviral therapy (ART) initiations done at home. HIVST did not increase initiation of ART, but was comparable to traditional HTC.

In the first six (6) months of the home-initiation arm, 2.2% of all resident adults (~46% eligible) started ART, while in the facility-care arm, 0.7% of all resident adults (~15% eligible) started ART (risk ratio: 2.94, 95% CI: 2.10-4.12).

Session One Discussion: Accuracy and Efficacy

Lower sensitivity and accuracy of oral testing in the hands of the intended user

All reactive test results must be confirmed with a second test due to the possibility of a false positive result. This is especially true if the reactive test was conducted with a HIV RDT that has a low specificity, which increases the risk of a false positive. In low prevalence settings, the positive predictive value, which is linked to the false positivity rate, will be lower. An investigation into poor specificity (greater false positive results) of oral fluid HIV RDTs used by HWs in the USA reported that user error was the usual cause, citing factors such as: poor vision, poor lighting and not reading the results within the specified time period (i.e. reading before 20 minutes or after 60 minutes) (10).

At this time there are little data available from post-market surveillance on the accuracy of test

results. Since FDA approval of OraQuick® in-home HIV test as a self-test in the USA, FDA is considering how to address the need for post-market surveillance data. Key challenges for collecting such data are the confidentiality of HIV test results and the non-requirement to report results, which makes subsequent QA difficult to assess.

Linkage

Linkage to confirmatory testing following a reactive test result

The linkage of those who have an initial reactive HIVST result to confirmatory testing and counselling is of paramount concern. HIVST, by design, places responsibility in the hands of the individual performing the test.

Linkage to HIV prevention, support, care and treatment services

Linkage to care following a positive HIV test is known to be suboptimal in many models of HTC. For self-testing, this is a critical issue that needs to be more fully understood and addressed effectively. Similarly, linkage to prevention and other follow-up services for both those with reactive and non-reactive test results is also a concern.

Linkage to HIV care and treatment: who is responsible?

The question of who takes responsibility for follow-up was discussed. For instance, should the responsibility for follow-up rely on the provider of the HIVST, as described in the current USA approach, or rely on the self-tester to seek confirmation of their test result and care? Although a hotline is available to provide information on follow-up support, this is largely used by individuals seeking advice on how to use the test. While further research is needed, preliminary results from a community-based HIVST research study in Malawi suggest proactive efforts to support linkage and follow-up may be effective when HIVST is introduced to a new community through community worker support.

Session Two: Public Health and Health Systems

Session Chair: Ms Annrita Ikahu

NICOLA DESMOND—SOCIAL IMPACTS OF HIVST IN MALAWI

The study design presented will make this the first study in a developing country looking at the social impact of HIVST and aiming to explore how people come to make testing decisions. Pre-testing, household dynamics, disclosure post-testing, risk behaviours, gender based violence (GBV) and couple commitment to partnership post-testing will be examined. The methods that will be used to explore the social issues and impacts associated with HIVST will include longitudinal diary studies, critical incident interviews, in-depth interview (IDIs) and focus group discussions (FGDs). Data collection will start in May 2013.

MOSES KUMWENDA—PARTNERSHIP DYNAMICS AND CARE-SEEKING TRAJECTORIES AMONG COUPLES AFTER HIVST IN BLANTYRE

This presentation covered the preliminary findings of a qualitative longitudinal research study on immediate impacts of HIVST on partnership and care-seeking for self-testers in relationships.

Preliminary findings report four key themes regarding motivators for couples testing are emerging from the data :

- **Confirmation**—to re-check previous test result, test the “power of prayer to heal” or dispel a notion that prolonged ART eliminates HIV;
- **Disclosure**—to disclose previously withheld known HIV-positive status to sexual partners;
- **Mistrust/risk behaviour**—perceived mistrust of a sexual partner or recent risk behaviour;
- **Peer influence**—individuals influenced by experiences of neighbours, friends or community counsellors to test for HIV.

HIVST is potentially a powerful tool for promoting HIV status disclosure among partners and adoption of HIV protective behaviour.

The preliminary research suggests that, regardless of whether the woman is the positive or negative partner in a serodiscordant couple, the socio-cultural norms where a woman is “disempowered” within a household often limit the level of adjustments that couples can make in a relationship after a discordant result.

The study recognises that gender disparities between men and women are often normalised in Malawi, as elsewhere, and violence is also seen as acceptable in certain situations. In this setting, men appear more hesitant than women to access HIV related services following a positive HIV result.

Coercion can be seen as a normal behaviour in some settings where power imbalances are the norm—largely accepted or unchallenged—and where partners (usually female) or ‘junior family members’ (such as daughter-in-laws or children and adolescents) have little choice in decision-making processes. Although participants acknowledged that coercion to test is not acceptable, a partner reporting that they had been coerced to test or persuaded to test may not regret testing or may be grateful that s/he had been influenced to test. The difference between coercion and persuasion is often blurred.

Couples “self-testing” together in the LSTM “HIT TB” study (11), in which this study is nested, was lower than anticipated; only 14% reported HIVST use. However, it is possible that couples self-testing may be higher than reported because individuals may bring a test to their partner and may test separately, or the two people in a couple may accept HIVST individually and share their results at a later stage. Key questions discussed regarding couples HIVST include:

- How is couples HIVST defined?
- Do couples have to test together?
- If one tests after the other, is it still considered partner testing?

Any guidelines developed for couples HIVST will need to begin with a clear working definition appropriate to particular national contexts and HIVST delivery models.

FRANCOIS VENTER—POTENTIAL MODELS FOR HIVST

This presentation proposed that the paternalistic attitudes of some HWs responsible for providing HTC are a barrier to accessing testing. Unlike other tests for clinical conditions, HWs can emphasise undue caution and require over-elaborate pre-test counselling which may deter some people from seeking testing or re-testing. Counselling is only mandatory for testing in public health facilities in South Africa; meanwhile, testing in the private sector is often available without counselling. Patient autonomy is an important consideration that should be respected in decisions concerning the provision of HIVST programmes.

The unsubstantiated, but sometimes cited, concern that knowledge of HIV status could lead to “disinhibition” should not be overemphasised and proposed as a barrier to supporting HIVST. The HTC programme in South Africa has been successful in increasing the number of people tested, but effective linkage to care remains a challenge.

RDTs are widely available to the public in South Africa and used for HIVST, despite policies which limit the ability of pharmacists to sell RDTs over-the-counter. The quality of these RDTs is unknown. Three (3) models for HIVST were suggested by the presenter:

1. **Clinically restricted-clinical counsellor**—HIVST kits given by HWs in specific situations, for example:
 - as part of post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP);
 - couples testing may be more likely to happen with HIVST. Perhaps there is a role for women to bring HIVST RDTs to male partners;
 - high risk groups: sex workers, truck drivers and men who have sex with men (MSM) could be targeted for HIVST programmes.

If this approach were to be used, it would only be for a relatively small group.

2. **Semi-restricted (public health programmes)**—Linked with other programmes, such as TB programmes and tests in the workplace.
3. **Open access**—As part of the progression of “know your status”, normalising HTC will increase the desire for HIVST. HWs who are currently reluctant to test in facilities where their co-workers could access their result are a deterrent. HIVST could be a more discrete approach for HWs to find out their HIV status. The open access model could potentially have a large market, particularly in middle-income countries like South Africa.

Within the discussed models, there remains potential for intimate partner abuse among couples. While most often abuse related to HIV status and disclosure occurs in relationships that are already abusive, there is no data which suggests that HIVST will change these relationships or increase the risk of violence. Nevertheless, concerns regarding abuse remain, particularly regarding potential mandatory testing of domestic workers by their employers.

It was proposed that HIVST should be widely available and that linkage to care must be locally facilitated. Community-based monitoring combined with complaint and redress mechanisms are also important for maintaining a protective and enabling environment.

SAM KALIBALA—TARGETING HEALTH WORKERS IN KENYA

This presentation shared findings from a feasibility and acceptability study of HIVST among HWs in Kenya. Findings showed that HIVST was highly acceptable (89% took the RDT test kit). Of those who took the RDT test, 85% tested, of which 94% said the RDT was very easy to conduct and 96% said the instructions on the leaflet were very easy to follow. FGD participants reported that HIVST is more confidential than voluntary counselling and testing and that the oral fluid RDT was easier to conduct than the whole blood-based RDT. There is potential for HIVST to facilitate PEP in this population, as HIV testing has been reported as a barrier to accessing PEP.

Telephone hotline—used by few people in this study to clarify test procedure; however it was not used to seek post-test counselling.

Couples testing—of those who took a test kit for their partner, 64% of partners took the test kit, of which 85% used the test and 88% discussed the test results.

Adverse events—while HWs expressed concerns about abuse of the test kit, during the study no such incident, nor adverse event, was reported.

Lessons learned:

- on-site coordinators for supplying test kits are essential;
- hotline for post-test counselling should ensure anonymity, and therefore should not be linked to a local facility;
- a “high level counsellor” for HWs (e.g. psychologist) could offer more in-depth support for those who need it.

Session Two Discussion: Public Health and Health Systems

Gender and couples self-testing

The relationship between gender and HIV is complex. Women are often more often aware of their HIV status than are men (14, 15). When discussing gender and HIV testing, consideration of how to increase uptake among men is essential. HTC and health service utilisation by men is relatively low, and efforts to increase partner testing through antenatal clinics have had variable success (16, 17). Other ways to reach them are needed. Therefore, it is critical to promote HIVST through alternative means, e.g. workplaces which are more accessible to men.

Key gender related considerations include:

- Men report “coercion” in relation to HIV testing, as do women, though in the case of men it tends to be viewed positively (e.g. as “encouragement”). It is generally seen as beneficial if a female partner can persuade a male partner to test.
- Men are often made to feel like outsiders in health systems focused on maternal and child health.
- Outcomes are lower for men than women, in terms of accessing HTC and treatment.
- There is a need to ensure equity for men, so that those in need of HIV testing and

services are reached, such as those of lower socio-economic status.

HTC approaches like couples testing serve as avenues to reach both men and women. Preliminary results of qualitative analyses of data from the MATCH study suggest (12):

- The definition of couples must be described carefully. Within the study there was a difference between those who identified as couples, i.e. cohabitating and those who referred to partners. The qualitative data that refer to partners confirm that there are many more individuals with partners than cohabiting couples. Interpretation of the data suggests the terminology and concept of couples may need to be modified to account for a more fluid notion of partnership.
- Among those who mention partners and testing, just over 10% refer to “encouragement” from a spouse or a joint decision to test. This stands in contrast to the quantitative data, which indicated approximately 25% of respondents had discussed testing with their partner. These findings suggest very different interactions are subsumed under the heading of “discussion with partner”. There was also evidence that lack of trust, uncertainty and general relationship factors could represent obstacles to testing.

Violence and testing

There are direct linkages between violence and HIV. Although there are successful examples of integrating screening for intimate partner violence in HTC services, violence is not directly related to HTC. Generally, gender based violence (GBV) related to testing is thought to occur as a result of disclosure in a partnership with pre-existing violence. Studies that report GBV in relation to testing often do not have a baseline of underlying GBV in the communities of study. In the case of self-testing, it is possible that GBV may be exacerbated through situations where one partner forcibly tests another partner. How GBV may specifically take place within self-testing is an area for further research, as well as community level monitoring so that appropriate action can be taken to handle and refer individual cases.

Suicide and self-harm after testing has generally become less of a concern for counsellors now that treatment is widely available. However, there are still risks and there is a need to provide adequate messaging and information to prevent potential harm and facilitate linkage to care among users. Within the context of HIVST, the risk for potential self-inflicted harm should be considered and assessed by implementers, programme managers and policymakers.

Models of HIVST

Different models that include both reaching people of low socio-economic status and those who can afford to purchase tests at multiple price points needs to be considered by those planning to implement HIVST as part of a national HTC strategy. Three models were presented and discussed in relation to adopting a model similar to condom marketing/distribution. Condoms are widely available OTC in a variety of packaging and at different costs for different groups alongside social marketing programmes; likewise programmes demonstrating how to use condoms properly and where condoms can be found are widely distributed.

It was also discussed that an open market scenario would allow for HIVST immediately before a sexual encounter (i.e. ‘point-of-sex’ or ‘pre-sex’ testing). In the USA, among MSM engaging in high risk behaviour, this has been shown to prevent HIV exposure (13). There was discussion over whether point-of-sex testing could possibly be adapted to other populations such as heterosexuals, e.g. HIVST in bars and with sex workers. However, there were concerns and cautions about the possibility of screening potential sex partners. This approach has serious limitations because of the inability to detect infection during the “window period” when individuals may be at increased risk of transmission. Considerable concerns were voiced by meeting participants about the potential for coerced testing of sex workers by clients or brothel owners. Overall, there was consensus that innovative models need to be carefully considered and piloted with the meaningful involvement of people who are most at risk of acquiring HIV.

Support and counselling

In Kenya, the telephone hotline provided to HWs taking part in the pilot was poorly accessed for counselling (4). This was largely attributed to the inability to provide anonymity as the hotline counsellor was the onsite testing coordinator. In the USA, hotlines reported greater use, although still relatively low, and mainly for clarification questions (9). This suggests a potential role for hotlines outside of counselling. There was a discussion that counselling hotlines should not be ruled out as a support mechanism/alternative counselling model, but that careful planning to ensure anonymity must be undertaken. Novel models for alternatives to face-to-face counselling and hotlines need to be explored, especially for users without access to a telephone.

Session Three: Ethics, Gender and Human Rights

Session Chair: Mr Jason Sigurdson

ANNE SCOTT—AUTONOMOUS CHOICES AND RELATIONAL RESPONSIBILITIES

This presentation covered the role of autonomy and the ethical issues related to HIVST. In particular, it was suggested that introducing HIVST in resource-poor environments could enhance public health efforts. If integrated into national screening programmes, self-testing will move from the arena of “personal health care” to the public health arena. HIVST may have positive implications for consent, privacy and confidentiality by removing intermediaries from the testing process.

The presentation suggested that the principle of non-maleficence (“do not harm”) may be a more congruent driving principle when considering the ethical issues related to the use of RDTs for HIVST in various contexts, particularly given the current state of knowledge about the impact of HIVST. Therefore, from an ethics perspective, the active promotion of HIVST with no follow-up/linkage to care is not reasonable. Key areas of discussion included:

- **HIVST is not a “neutral” activity**—if those with a reactive test link to care, the benefits are obvious. Apart from linkage to care, the benefits and harms of HIVST remain relatively unknown; there may be limited benefits and significant potential for harm. A

clear understanding of risks and benefits of HIVST is needed.

- **Autonomy is important**—but not absolute. If autonomy is examined as a continuum, varying degrees become apparent. Through the lens of a continuum, one's ability to exercise autonomy (for instance, enabling informed consent) may require adequate support, assistance and protection. Therefore, it is important to consider what the exercise of autonomy means in a particular context and what support is needed to enable individuals to act autonomously.
- **Relational issues are central.** Responsibilities related to HIV are relational, as are the consequences of testing. In the context of HIVST as part of a national screening programme (as opposed to a publically available over-the-counter programme), it is suggested that the duty of clinicians and policymakers will be to consider the implications of their interventions, seek adequate consultation with populations who will potentially be involved in/exposed to HIVST and allow for the provision of adequate follow-up care and protection.
- **Context is important**—studies in one context may not be directly relevant to another context.
- **Informed consent, privacy and confidentiality**—are important and continued dialogue is needed to ensure that the rights of the individual remain central.

MARK HEYWOOD—HIVST AND HUMAN RIGHTS

This presentation suggested that meeting attendees should examine why HIVST is being considered, and then determine if HIVST is being considered because it is possible or because it is needed.

Autonomy—HIVST can increase autonomy, recognise autonomy or can be used against vulnerable people to limit autonomy—for example, in communities where there is high violence against women and children or where rights of workers are undermined.

Access—Is HIVST linked to the right to access healthcare services? If so, by making OTC HIVST available, is it providing a service which individuals may not otherwise have access to? While increased HIV testing could lead to increased access to care, effective counselling services cannot be ensured (e.g. PITC).

The right to the “highest available standard of physical and mental health”—Is access to HIVST also access to quality health services? Is HIVST the highest available standard?

For scale-up in resource-limited settings—It is important to consider that many resource-limited settings have low levels of literacy, poor access to information, low access to quality health systems, high stigma and high incidence of violations linked to stigma. The question of whether resources ought to be invested in improving the potentially poor quality of existing services, rather than in a new and risky approach, was discussed.

Dr Heywood recommended:

- against the widespread use of HIVST in the general population;
- possible use among particular populations (e.g. nurses, vulnerable groups), which must

be accompanied by accessible public information campaigns and promotion of health care services for people who test positive and negative;

- proper regulation for quality and review of the legal implications;
- need for systems to report violations and protect human rights.

Session Three Discussion: Ethics, Gender and Human Rights

Should ethical concerns prevent HIVST scale-up?

It was generally considered that the ethical issues which have been raised are not risks identified by participants and do not rise to the level of being arguments that should prevent access to block the introduction or expansion of HIVST. However, context-specific analyses are needed to assess risk of widespread misuse—e.g. against domestic workers, coerced testing of spouses or children—accompanied by measures to mitigate potential risks. Some meeting participants noted that it is not realistic to place the burden of advancing human rights on the licensing and availability of a new medical technology. Since a guarantee of linkage to care is not normally required to licence a new medication or diagnostic, it was determined that this would be an unreasonable standard of justification.

A range of human rights may be impacted both positively and negatively by HIVST. Despite the potential for widespread benefit, it must be weighed against the potential harms. Community engagement is essential to generate a better sense of what is more important—and how HIVST can be used to not only increase knowledge of status but also expand uptake of treatment and care. Efforts to move forward with scale-up should integrate monitoring for potential adverse consequences, which can be addressed in real time and documented. Such contextually appropriate, supportive and protective programming around HIVST is important.

There needs to be greater understanding of how HIVST is linked into care and prevention, but this should not prevent movement forward as learning can occur alongside scale-up. Ethical discussions of HIVST are needed to develop a better sense of the importance of linkage to care and knowledge of status. Additionally, measuring the effectiveness of HIVST by using linkage to care as an indicator should be considered by stakeholders and those implementing HIVST as part of a national HTC programme.

The scale-up of HIVST, why and how?

A key question that was discussed was “Why HIVST scale-up”? Discussions assessed if HIVST is being explored because it is possible (“the technology is there”), or if there was a compelling reason for it in public health, human rights or ethics—e.g. to reach those who are not well-served by tradition models of HTC. It was suggested that once the potential benefits of expanding HIVST have been identified, countries/programmes need to consider if there is a

better, risk-free way to reach those objectives (e.g. increased cost-efficacy, lower risk, higher acceptability). It was noted that in the context of strained resources, there is an argument for improving existing interventions rather than introducing HIVST, unless there is evidence of HIVST filling a gap.

Discussion took place over whether it is justified to limit availability of HIVST to certain groups when there are potential risks involved in making RDTs for self-testing more widely available. Many noted that to answer this question, a stepwise approach to expanding availability may be desirable, depending on the context. Possible models may involve, for example, workplace programmes where employees participate in education sessions and are sent home with a test kit to use in the privacy of their home, or integration of HIVST into stand-alone HTC programmes, where people testing HIV negative are provided with a kit so that they can re-test at a future date without the inconvenience of travel to a clinic, delays in a waiting room or repeat counselling.

Overall, demand for HIV testing is significantly higher now than before the wide availability of ART. However, it remains a public health imperative to reach the millions of people who have not yet learned their status, particularly those most marginalised and criminalised. Without access to HTC people will continue to become symptomatic and die, despite the availability of treatment. Although in principle the sale of HIV RDTs for self-testing in pharmacies and other retail outlets may potentially increase access to testing, this was characterised as a “middle class” idea of HIVST, as the majority of people of low-economic status in low-income countries will not be able to access tests from pharmacies. Therefore, HIVST scale-up efforts should also focus on approaches that will expand access to testing to reach people from lower socio-economic groups. This will generally require more proactive distribution through national HIV programmes.

Power dynamics

Power dynamics, in addition to those implicit to gender roles, within relationships need to be considered in relation to HIVST. For example, older women in a family structure may exert significant power over younger daughter-in-laws.

The possible HIVST strategy for sex workers to require clients to test was discussed. However, this strategy remains a questionable approach since sex workers (a) would be unlikely to have the power to make this request and (b) could potentially test negative in the window period and be highly infectious.

Coercive testing among vulnerable populations and groups, e.g. domestic workers was also raised by meeting attendees as a concern that needs to be tackled proactively.

The importance of context

Context influences one's ability to give informed consent and determines if there is a real chance of maintaining privacy and confidentiality. In a home environment, the context may dictate that one person has the ability to give consent for the whole family, potentially limiting individual autonomy.

The importance of ethics and human rights moving forward

Many questions raised in the course of the discussion focused on ethics and human rights. Despite a high level of concern and consideration, there was widespread consensus that these human rights arguments should not create a gridlock. Rather, it was suggested that the ethical and human rights questions raised must be considered when moving forward with the scale-up of HIVST. The active engagement of civil society in national discussions will be an essential element in any such scale-up efforts.

Session Four: Discussion on HIVST experiences from the field

Panel: Dr Paul Semugoma, Dr Peter Cherutich and Dr Sally Theobald

Context has been identified as a key consideration when thinking about expanding HIVST. This session focused on experiences from the field and a discussion about contextual issues surrounding HIVST.

The Kenyan Experience

This presentation reported on the experience of integrating HIVST into national guidelines in Kenya in 2007. Door-to-door testing had already been implemented in Kenya in an attempt to expand access to HTC, and HIVST was proposed as an option to fill gaps for people who do not access HTC through currently available approaches. HIVST was approved for use in Kenya in 2006; however since 2007, HIVST has not been widely implemented or used in Kenya because:

- lack of clarity about whether HIVST or oral fluid testing were being promoted and if the two should be de-linked;
- unresolved operational issues such as what would be the confirmatory testing strategy and how this should be supported;
- HIVST has been included in the national guidelines, but there is no clear implementation plan on how it can be best utilised in programmes;
- task shifting to lay counsellors to provide HTC has been a successful policy shift in Kenya, but “task shifting to the individual” has yet to be appreciated and realised.

The Asia-Pacific region

The Asia-Pacific region has a concentrated HIV epidemic among key populations. Although the populations of countries in this region are large, testing rates are low. There is vast potential for HIVST in this region, but there is concern about operational feasibility. Current approaches to HTC have not been successful outside clinical settings, such as antenatal clinics (ANC), and linkage to care is often a significant barrier, particularly for key populations due to high levels of stigma and discrimination. Throughout Asia, HIV RDTs are still performed in laboratories and without any task-shifting.

Some countries in the Asia-Pacific region are considering the use of oral fluid testing in a programmatic context rather than HIVST. Cost of programming is a key factor in this region because the people who could most benefit from HIVST are often from the poorest and most marginalised communities. For example, transgender people are among the most at-risk for HIV infection in the Asia-Pacific region, yet they have the least amount of access to HTC and other health services (18).

HIVST for frequent re-testers

Meeting participants heard a passionate personal testimony from a gay African man living in a serodiscordant relationship. He described HIVST as an important addition to current testing approaches. For people with on-going risk, e.g. those in a serodiscordant relationship where re-testing is recommended, HIVST could be considered. However, unequal power relationships could result in coercion and abuse of the test. It was acknowledged that empowering someone with the knowledge of their positive HIV status may cause them to be depressed for some time, but it may also link them to life-saving care. It was suggested that re-testers are often tired of “the ritual of testing” and HIVST offers a way for them to access testing without the lectures from HWs. In the speaker’s opinion, withholding the HIVST RDTs is paternalistic and having the test may empower individuals to take action for their own health.

The need for community involvement

It was clearly stated that involving, understanding and addressing the concerns and priorities of affected communities is key. In the past, the involvement of communities in discussion around key policy and implementation issues has often been tokenistic. As policy issues on HIVST are considered, it will be critical to include community consultation. This needs to involve a wider range of stakeholders, including those from key populations, to ensure that HIVST is not imposed on particular groups and that issues around human rights violations are considered. Human rights issues require careful deliberation and will need to be addressed by community groups before HIVST programmes are considered. Without such consideration, there is significant potential for abuse and misuse of HIVST. For example:

- What are the legal implications and protections needed that can be provided to sex workers, other key populations and those who test positive, especially in the context of criminalisation of HIV non-disclosure, exposure and transmission?

- How can we provide linkages to care for people who inject drugs (PWID) and other people from key populations?

How can community-based interventions link people to care and support their retention in care, as well as help to mitigate the impact of adverse consequences?

Cost

It was noted that the US model is largely consumer driven, i.e. “middle class model”. Through this approach the informed middle class can access OTC HIVST, many of which may be part of the “worried well” (i.e. relatively low-risk, but seeking confirmation in relation to a possible exposure to HIV). In this context, perhaps this approach is appropriate, as it has no cost to the public health system. However, the idea of having different HIVST models should be supported. Overall, there was support for differentiated approaches that expand access and have price points adapted to ability to pay.

The OraQuick® in-home HIV test is marketed in the USA in a well-designed, attractive package with a supporting telephone hotline for the cost of approximately US\$ 40. For resource-constrained settings, it should be possible to develop a lower cost version. However, a less expensive version would still likely be beyond the reach of most, but could be an option for a small minority of those with higher incomes. Subsidised or socially marketed versions could make HIV RDTs for self-testing more widely accessible. HIVST using RDTs with fingerstick whole blood specimen is also an option, which is at this time likely to be cheaper to manufacture. It is important to encourage manufacturers to develop RDTs suitable for the intended use of HIVST.

Regulation

HIV RDTs used for self-testing should be regulated appropriately, and at the very least should be registered by national authorities. All test kit users need to be advised on confirmatory testing as outlined in the national testing algorithm.

4. Day Two—Working groups

Updates from the field

Update from 3ie’s HIVST work

The International Initiative for Impact Evaluation (3ie) is currently supporting a programme of formative research and pilot projects on HIVST to increase evidence-based policy making. This programme consists of supporting a range of pilot implementation projects pertaining to accuracy, packaging and labelling, demand, supply, linkage to care and evidence on harm of HIVST in various communities/populations by various approaches in Kenya. Further pilot projects are planned for two other high prevalence settings in sub-Saharan Africa.

Update from UNAIDS

UNAIDS is motivated by a principle objective of supporting HIVST to help ensure that people do not die

of AIDS without a diagnosis or are diagnosed too late to treat. Secondary objectives include:

- HIVST being available in contexts where it can help people make the change from “seroguessing” in relation to behaviour to “serosorting”, i.e. point-of-sex testing;
- potential health systems savings if people with the ability to pay buy tests and screen themselves, rather than testing at publically funded health facilities (i.e. money spent on the “worried well”);
- people choosing when to access testing and when to access counselling and/or treatment (Consumerist perspective: control over testing and convenience);
- reaching populations where options are “self-test or no test”.

UNAIDS focus is on:

- Countries where the lack of knowledge of HIV status is the limiting factor to getting people on treatment. These countries include: Chad, Democratic Republic of Congo (DRC), Ghana, Haiti, Nigeria and Uganda.
- Countries where lack of knowledge of HIV status for men is an issue. These countries include: Mozambique, Swaziland and Zambia.
- Countries where lack of knowledge of HIV status for key populations, (e.g. sex workers, MSM, PWID), is an issue of focus. These countries include: Brazil, Iran and India. Additionally Myanmar and Russia have an issue of focus for PWID and Thailand has an issue of focus for MSM.

UNAIDS and WHO have had a policy position since the early 2000s stating that HIVST should be considered. A more concerted and focused push is needed. Having multistakeholder consultation on HIVST, such as this meeting, has proven to be useful and the dialogue should be continued considering the areas of non-consensus. UNAIDS and/or WHO can play a key role in supporting:

- people living with HIV (PLHIV) and key populations to understand benefits, risks, limitations of HIVST and provide them with platforms to discuss their priorities and key concerns;
- policymakers, implementers and civil societies to explore different models of community-based service delivery that will ensure linkage to and retention in care following the use of an HIV RDT for self-testing;
- all stakeholders to explore what the anticipated demand of treatment generated will be were HIVST to be scaled-up and rolled-out, and how that demand can be met.

Objectives for day two:

- build on what was learned and discussed to develop a framework for action
- outline policy implications for HIVST
- draft a consensus statement
- set the operational research agenda for HIVST
- plan a special issue on HIVST.

Small working groups were formed to discuss the following key topics:

- *Confirmatory testing, QA, and regulatory guidance*: led by Anita Sands and Roger Peck
- *Priority populations for impact*: led by François Venter and Paul Semugoma
- *Access and affordability*: led by Steve Forsythe and Liz Corbett
- *HIVST and combination prevention*: led by Mannesseh Phiri and Vincent Wong
- *Social and ethical issues for policy and implementation*: led by Lignet Chepuka and Heidi van Rooyen
- *Policy and normative guidance issues*: led by Rachel Baggaley and Katie Curran

Each group discussed opportunities, knowledge gaps and policy implications and formulated key concepts for inclusion in the consensus statement. These concepts are presented together below, rather than group by group. Research questions were then formed by examining and identifying knowledge gaps. Identified gaps can then be utilised by researchers to contribute to the overall HIVST agenda. Finally, a consensus statement was developed after review of feedback from all working groups.

Potential opportunities warranting further investigation

- There is potential for large-scale demand for HIVST.
- RDTs other than oral fluid may be used for HIVST (i.e. fingerstick whole blood).
- Some existing RDTs can likely be adapted for HIVST.
- Many existing national programmes and distribution systems, utilising pre-established expertise, can support HIVST.
- HIVST has the potential to change and expand the role that pharmacists play in HTC.
- There is potential to leverage the demonstrated purchasing power of those who currently buy HIV RDTs over-the-counter for public health purposes (e.g. Nigeria, Namibia and Kenya).
- HIVST can be targeted to groups with limited accessibility to HTC and health services.
- It is anticipated that HIVST will provide an opportunity for increased privacy.
- HIVST is likely to be appropriate for groups that have a high burden of HIV prevalence and incidence, and require frequent re-testing (i.e. MSM, transgender, sex workers, PWID and serodiscordant couples) (19).
- HIVST provides a more accessible option for currently neglected or undeserved groups (e.g. married and older women, youth, middle class, men, HWs and “the worried well”).
- HIVST has the potential for use in outreach settings.
- There is the potential to involve members of key populations in HIVST discussions.
- HIVST has the potential to enhance linkage to ART for those who test positive, especially among individuals who would not otherwise test.

- HIVST has the potential to reduce barriers for accessing PrEP/PEP. Self-testing could be utilised prior to PEP or PrEP initiation, and/or for re-testing following PrEP and PEP initiation.
- HIVST has the potential to reduce barriers to voluntary adult male circumcision (MC). There is also the potential for partner HIVST through test kit distribution at MC services, and possible utilization of verbal report of HIVST result for circumcision.
- HIVST has the potential to increase partner testing through HIVST, especially in antenatal care (ANC) and Prevention of mother-to-child transmission of HIV (PMTCT).
- HIVST has the potential to help with partner notification efforts.
- HIVST has the potential to reach those in multiple concurrent partnerships.
- HIVST has the potential to help expand opportunities for family testing and counselling.
- There are opportunities to learn lessons from other existing RDTs for self-testing (e.g. malaria, pregnancy) and how to work together with existing laboratory services.
- There are opportunities to learn from FDA experiences (e.g. balancing an evaluation of test kit performance against the public health modelling benefits).

Policy implications

- Issues concerning HIVST need to be addressed and incorporated into national guidance.
- Quality concerns about RDTs sold over-the-counter and used for HIVST need to be addressed from a regulatory and import/export perspective.
- Pre-market QA standards should be observed for HIVST in the private and public sector.
- National test kit performance evaluations should be performed in self-testing settings, if that is the intended use.
- Post-market QA standards should be observed for HIVST.
- QA standards may need to be re-considered/interpreted for HIVST systems.
- The place of HIVST should be considered within the whole system of care, and it should be ensured that if HIVST is supported that it is contributing to closing a gap in services.
- Guidelines on recommended testing approaches and strategies for different populations should be developed for different countries/context. Based on context, frequency of testing should be defined for key populations and higher risk groups.
- Re-testing policy for confirming HIVST results is needed. Re-testing negatives, in addition to positives, in some situations, i.e. for those in the window period.
- Minimum standards should be established for the delivery of HIV RDTs for self-testing, e.g. pre-test information, referral information/directory.
- Legal implications of non-disclosure should be considered.
- A technical update may be more appropriate than normative guidance at this time. Some additional issues to be addressed before normative guidance:

- unregulated/poorly regulated test kits;
- the need for a legal/human rights policy framework;
- the need for a global observatory for documenting adverse consequences and a way for redress;
- how to work with a range of stakeholders including manufactures to catalyse new HIVST product development;
- the process for developing and field testing the necessary packaging and instructions for use in countries/ settings that could support HIVST when available.

Key additional comments/discussion points

Repeat HIVST for negatives should not be encouraged as a complete HIV prevention strategy

In a context with reliable, quality RDTs, it is important that messaging does not inadvertently suggest that users self-test until they receive a positive result and then link to care. Messaging must be communicated carefully. Repeat testing should not be the only message provided to people at high risk of HIV infection. Rather, HIVST should be offered along with a package of prevention messages and opportunities for referral to HIV prevention services. Additionally, HIVST may also be embraced as a tool to affirm that personal prevention strategies are working.

Associated information required

Pre-test information should be provided at the point-of-sale or delivered to the client with a HIVST device, or as part of supervised HIVST and delivered as a minimum standard. A range of approaches to provide information should be explored, e.g. recordings, e-technology, pictures, booklet(s). The need for confirmation of all positive tests and the possibility for referrals, including access to counselling and supported linkage to care and treatment for positives, should be articulated to test kit users, both positives and negatives.

Learn from other self-screening tests

There are lessons to be learned from self-testing or monitoring devices for other medical conditions, e.g. home blood pressure monitoring, home blood sugar monitoring, and pregnancy testing. Such self-management is a growing trend in chronic disease management and is often encouraged. It should be coupled with clinical consultations, and appropriate follow-up care and treatment.

Legal issues around disclosure of HIV test result to others, including sexual partners

Many countries have laws criminalising HIV transmission and exposure, as well as failure to disclose HIV status to sexual partners. These complex issues are not unique to HIVST. Many of the human rights issues and ethical considerations discussed in relation to HIVST are relevant to other HTC approaches. To further discuss these issues, WHO will be convening a meeting in 2014 on issues regarding disclosure and partner notification; these challenges will be discussed particularly in the context of HIVST. However, it is imperative that messaging around HIV testing consider locally relevant legal implications of HIVST and disclosure, keeping in mind that disclosure should not be discouraged where it is safe and beneficial.

How should HIVST fit into existing HIV testing strategies and algorithms?

Discussion took place regarding the position of HIVST results within the nationally validated testing algorithm. The following key question was discussed: Do HIVST devices have the potential to replace the first-line screening test (A1) of the national testing algorithm, bearing in mind the likely lower performance characteristics?

There are inherent problems with the approach regarding the design of first-line screening (A1) tests. More specifically, A1 tests typically have poorer specificity as they are designed to screen, i.e. maximise sensitivity. The intent of the test must be taken into consideration. There was widespread concern about using the results from HIVST to replace A1. Based on these concerns, the meeting consensus was for confirmation of reactive HIVST results; a person should follow the current testing algorithm employed at a testing site.

5. Summary

There was consensus on support for HIVST as a complementary strategy to increase knowledge of HIV status and uptake of prevention, care and treatment.

Potential benefits of HIVST

- ↑Access
- ↑Autonomy
- ↑Confidentiality
- ↑Convenience

Key populations for HIVST

HIVST is an evolving approach that has potential to meet the needs of underserved and marginalised populations, the general population and health workers (HWs) in high prevalence areas, individuals in serodiscordant relationships and other priority populations.

HIVST may be suitable for individuals and couples who are re-testing due to on-going exposure, particularly if they have previously received HIV counselling (19).

This includes:

- “window period” repeat testers
- negative individuals, within serodiscordant relationships
- key populations or individuals with on-going risk.

Possible cautions with HIVST³

- **Inadequate regulatory controls**- The use of RDTs for HIVST requires a regulatory

³ Many of the cautions mentioned are also pertinent to other approaches to HIV testing, and not unique to HIVST.

framework ensuring quality diagnostics, which provide accurate results in the hands of intended users. To accommodate HIVST, national testing algorithms must be adapted.

- **Potential for human error**- Inaccuracies in performing tests and interpreting results will likely continue to be an issue for lay users, especially among first-time testers.
- **Imperfect performance**- HIVST can have low sensitivity, especially during seroconversion. All users with a reactive result must seek confirmatory testing in a medical setting. Re-testing should be advised for users with negative test results and recent/on-going risk
- **Linkage to care**- Counselling or referral for first-time testers is not ensured. Additional effort to support the client's linkage to care should be supported.
- **Coercion, social harms**- Current evidence on HIVST does not indicate social harm. However, data are limited; additional research and on-going monitoring is necessary.
- **Potential for adverse outcomes**- Governments and donors should support HIVST strategies that include meaningful community engagement and monitoring of the legal, ethical, gender, human rights and public health consequences of HIVST scale-up.
- **Repeated HIVST should not be seen as a substitute for risk reduction**- The need to support continuing prevention measures for people at on-going HIV risk should be prioritised.

Next steps for WHO

May 2013 – HIVST meeting report distributed to meeting participants

June 2013 – WHO HIVST policy brief

March 2014 – Special *AIDS & Behaviour* issue on HIVST

2014 – WHO meeting on disclosure and partner notification

2014 – HIVST guidelines as part of 'consolidated HTC guidelines' including work with WHO Diagnostics and Laboratory Technology team on regulatory frameworks for HIVST

6. Knowledge gaps and priority research questions

Based on the meeting discussions, it was agreed to consolidate the numerous questions into broad headings that connect to the type of research/methodology. Since there is substantial overlap between methodology and key policy areas, a first step was to group questions by policy area. What is presented here will require further refinement. A narrowed scope on how these questions can be addressed by methodology will be needed.

Policy area	Knowledge gap	Priority operational research questions	Comments
Regulatory, Confirmatory testing Private Sector, and QA	<ol style="list-style-type: none"> 1. What is the target product profile of RDTs used in self-testing? How should desirable operational characteristics for HIV RDTs used in self-testing be defined? 2. Which currently available HIV RDTs are most suited for use in self-testing? 3. What QA needs to be in place for the HIVST RDT to work correctly when operated by lay users? 4. What is needed to get HIVST devices into market in the private versus public sector? 5. How do HIVST RDTs link to the national validated testing algorithm? 6. How can the regulatory capacity and monitoring of quality of RDTs used for HIVST in the public and private sectors be strengthened and become more effective? What are the most effective 	<ol style="list-style-type: none"> 1. How can the use of HIVST devices be systematically assessed, including user feedback and test results to select specifications, as well as the relative import of each test kit specification when used for self-testing to determine true positive proportion (TPP)? What will the use-case scenarios be? 2. What are the findings after comparing and analysing risk of test failure to assess currently available HIV RDTs? Which HIV RDTs are best suited for HIVST in low income settings? 3. What kinds of procedural and design controls are needed within the HIV RDT to ensure the kit is working properly in the hands of a lay user? How does this vary by the specimen type and the type of device? 4. How can a private sector needs assessment to better leverage demonstrated consumer interest for public health impact be developed? 5. Which priority elements inform strategy and algorithms for RDTs used for HIVST? 6. What are the safest and most effective approaches to strengthening of: (a) the 	

Policy area	Knowledge gap	Priority operational research questions	Comments
	<p>models? What adverse event reporting systems will be designed and implemented?</p> <p>7. What are best ways to assess the population-level risks and benefits of expanding HIV testing through HIVST?</p>	<p>sustainable regulatory processes and practices for HIV RDTs used for self-testing and their manufacturers; (b) post-market surveillance; and (c) adverse event reporting to one or more appropriate regulatory authorities? How will these strategies differ by national versus regional approaches for harmonisation of emerging regulatory mechanisms?</p> <p>7. How can mathematical models and approaches, which countries adapt to, assess the population-level benefits and risks of expanding HIV testing through HIVST, be developed and validated?</p>	
<p>Priority populations—varies by context</p>	<p>1. What are the preferred models of HIVST and of linkage as defined by the communities and users?</p> <p>2. What is the impact of HIVST on HIV epidemiology within different populations?</p> <p>3. What is the impact of HIVST on early diagnosis in priority populations?</p> <p>4. What is the impact of HIVST on key populations—in relation to risk reduction and repeat testing?</p>	<p>1. What is the feasibility, acceptability, and accuracy of HIVST in priority populations in specific contexts?</p> <p>2. What are the legal and social implications for uptake of HIVST in priority populations?</p> <p>3. Who is underserved by current HTC approaches?</p> <p>4. What effect does HIVST have on vulnerable populations, employees, inmates and children?</p>	<p>Focus is needed initially on individual benefit(s) of HIVST. Eventually, population level benefit(s) should be evaluated.</p>
<p>Access, affordability, logistics and procurement (public and private sector)</p>	<p>1. What is the cost effectiveness of HIVST?</p> <p>2. What are people willing and able to pay for HIVST? How does this vary by socio-economic status and context?</p> <p>3. What research can be conducted</p>	<p>1. How can costs be determined?, i.e. (a) Costs for HIV-positive identified; (b) Cost per late presentation averted (mean CD4 greater than 350); (c) Costs for couples tested; (d) Cost per test provided; (e) Cost per person enrolled in care compared to other HTC broken down by linkage strategy; (f) Cost per first time test; and</p>	<p>It is suggested that studies take place in countries with existing cost data in HTC.</p>

Policy area	Knowledge gap	Priority operational research questions	Comments
	<p>to support social marketing?</p> <ol style="list-style-type: none"> 4. What are the existing channels and prices for HIVST devices? 5. How does user information and packaging affect uptake, accuracy and linkages to care? 6. How can the person at the point-of-sale (e.g. pharmacist) or the distributor of HIVSTs enhance access to devices? 7. How can we leverage supply chain and management systems? And strengthen systems to support HIVST? 8. Why are people buying RDTs in private pharmacies, groceries and other settings? 	<p>(g) Cost per DALY⁴ averted?</p> <ol style="list-style-type: none"> 2. What is the user profile of self-testers? 3. What is the cost of HIVST services to users? 4. What is the cost by service delivery channel e.g. mobile, pharmacy outlets? 5. What is the usability of HIVST in different contexts? 6. What factors influence uptake of OTC HIVST RDTs in the private sector? 7. What are the facilitators of and motivations for client purchase of OTC HIVST RDTs? How can these results be used to inform programming? 	
HIVST as a part of combination prevention	<ol style="list-style-type: none"> 1. What are the prevention and behavioural impacts for reactive and non-reactive self-test results? When testing independently? When testing as a couple? 2. How are we strengthening linkages from self-testing? 3. Where is the demand for HIVST among the “worried well”? 4. What is the test kit utilisation versus loss? 5. What is the impact on the health 	<ol style="list-style-type: none"> 1. How is self-testing different? How can models of self-testing be compared? 2. How do people respond to different HIVST programmes? 3. What are the key elements required for quality HIVST? 	<p>A definition of self-testing needs to be determined as a pre-cursor to answering these research questions (i.e. supervised, semi-supervised, and unsupervised) Various models of HIVST need to be</p>

⁴ DALY stands for the disability-adjusted life year. It is the measure of disease burden expressed as the number of years lost due to ill health, disability or early death.

Policy area	Knowledge gap	Priority operational research questions	Comments
	system with increased demand for care? 6. What is the required messaging for HIVST?		tested.
Social and ethical issues for policy and implementation	<ol style="list-style-type: none"> 1. How will ethical issues play out during HIVST scale-up of programmes versus a research trial? 2. What form should counselling take? When and how should it take place? 3. What type of community support is needed? 4. How do other HTC models compare to HIVST in relation to couples and other priority populations? 5. Will HIVST increase rates of GBV against background violence? What experiences can be drawn from? 6. What is meant by consent and coercion in the HIVST context? 7. What are the responsibilities of disclosure in the context of a screening test versus a confirmed diagnosis? 	<ol style="list-style-type: none"> 1. What are the alternative models of “counselling”? What are the minimum sets of information? 2. What are the social benefits of HIVST? How will HIVST impact trust, bonding and linkage to care? 3. How will studies demonstrate and achieve community support? 4. How will the community be meaningfully engaged? What are the perceived needs, fears and ideas from communities regarding HIVST? 	Qualitative studies should be utilised to answer these questions.

7. Consensus statement from the meeting on the legal, ethical, gender, human rights, and public health implications of HIVST scale-up

This meeting encourages countries to actively explore HIV self-testing as a complementary strategy to increase knowledge of HIV status and uptake of prevention, care and treatment.

HIV RDTs are already being used as self-tests in various settings. As an evolving approach, HIVST has the potential to increase access to testing and meet the needs of underserved populations. It is likely that HIVST will be of value for general populations and HWs in high prevalence areas, for individuals in serodiscordant relationships and other priority populations in all settings. It may also be suitable for individuals and couples who are re-testing due to on-going exposure, particularly if they have previously received counselling.

The current evidence on HIVST does not indicate social harm, but data are limited and additional research and on-going monitoring is necessary.

The use of rapid tests for HIVST requires a regulatory framework that ensures quality diagnostics that give accurate results in the hands of the intended user(s). National testing algorithms will need to be adapted to accommodate HIV self-testing, especially to ensure that persons who screen HIV-positive receive confirmatory testing.

Governments and donors should support HIVST strategies with meaningful community engagement, as well as with monitoring the legal, ethical, gender, human rights and public health consequences of HIV self-testing scale-up.

HIVST special issue plan

As a follow-up to the meeting, a special issue on HIVST is planned to be ready for March 2014 and launched at the 2014 Conference on Retroviruses and Opportunistic Infections (CROI). All agreed that there should be an open call for papers after concept notes are solicited from meeting participants and reviewed to ensure that all perspectives are considered.

12 people were chosen to form the core editorial group:

Elizabeth Marum	Liz Corbett
Sue Mavedzenge	Vincent Wong
Charlene Brown	Rachel Baggaley
Annette Brown	Krishna Jafa

Ed Ngoksin
Heidi van Rooyen

Miriam Taegtmeier
Roger Peck

Everyone listed is willing to be a peer reviewer and each participant has been asked to name two additional peer reviewers.

The following timeline was proposed:

Milestone	Date
Symposium – core group agreed, peer reviewers volunteer and nominate others as well	8–9 April 2013
Completed meeting report – pulls out key themes from the meeting, starts to group these and forms basis of the editorial piece	16 May 2013
Abstracts to core group for review/selection for inclusion	7 June 2013
Editorial drafted and submitted with completed application to Brocher for funds for printing	14 June 2013
Full papers submitted	31 October 2013
Reviews completed	15 December 2013
Authors responses back	21 January 2014
Second review	5 February 2014
Special issue comes out	March 2014

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We are also grateful to the Brocher Foundation for providing a beautiful venue and supporting the meeting in every way possible.

The Brocher foundation mission is to encourage research on the ethical, legal and social implications of new medical technologies. Its main activities are to host visiting researchers and to organise symposia, workshops and summer academies. More information on the Brocher Foundation programme is available at www.brocher.ch.

ANNEX 1: MEETING AGENDA

THE LEGAL, ETHICAL, GENDER, HUMAN RIGHTS AND PUBLIC HEALTH IMPLICATIONS

OF HIV SELF-TESTING SCALE-UP

BROCHER FOUNDATION, GENEVA

8 – 9 APRIL 2013

DAY ONE: 8 April 2013

08:30-09:00	Registration	
09:00-09:05	Dr Miriam Taegtmeier Senior Lecturer, LSTM	Welcoming remarks
09:05-09:15	Dr Rachel Baggaley HIV/AIDS Department WHO, Geneva	Introduction and overview: why debate HIV self-testing?
Session One: Accuracy and Efficacy Session Chair: Dr Miriam Taegtmeier		
09:15-09:35	Dr Elliot Cowan Regulatory Expert, USA	Approval process for the first over-the-counter home-use rapid HIV test in the USA
09:35-09:55	Ms Anita Sands Diagnostics and Laboratory Technology, WHO, Geneva	WHO prequalification and evaluation of oral testing
09:55-10:15	Prof Liz Corbett LSHTM, UK/Malawi	Accuracy of self-testing and linkage to care and treatment
10:15-10:35	COFFEE BREAK	
Session Two: Public Health and Health Systems Session Chair: Ms Annrita Ikahu		
10:35-10:55	Dr Nicola Desmond and Mr Moses Kumwenda Malawi Liverpool Wellcome Trust, Malawi	Social impacts of HIV self-testing
10:55-11:15	Prof François Venter University of the Witwatersrand, South Africa	Potential models for self-testing in clinical settings
11:15-11:35	Dr Sam Kalibala Population Council, USA	Targeting health care workers
11:35-12:00	DISCUSSION	
12:00-13:30	LUNCH	
Session Three: Ethics, Gender and Human Rights Session Chair: Mr Jason Sigurdson		
13:30-13:50	Prof Anne Scott Dublin City University, Dublin	Autonomous choices and relational responsibilities
13:50- 14:10	Dr Mark Heywood (via Skype) SECTION27, South Africa	Self-testing and human rights
14:10-14:45	DISCUSSION	

14:45-15:00	COFFEE BREAK
15:00-17:00	Discussion on HIVST experiences from the field Panel: Dr Paul Semugoma, Dr Peter Cherutich and Dr Sally Theobald Opportunity for participants to share field experience
17:00-17:30	SUMMARY, CLOSING REMARKS
19:30	DINNER IN GENEVA PROVIDED BY BROCHER FOUNDATION

DAY TWO: 9 April 2013

09:00-09:10	Dr Rachel Baggaley HIV/AIDS Department, WHO Geneva	Overview of day one
	Michael Bartos UNAIDS, Geneva	Update from UNAIDS
	Annette Brown 3ie, USA	Update from 3ie's HIVST work
09:10-09:20	Dr Miriam Taegtmeier Senior Lecturer, LSTM	Objectives for day two
09:20-9:40	COFFEE BREAK	
9:40-12:30	Session One: Action and policy to scale up self-testing- Small working groups Session Facilitator: Dr Elizabeth Marum	
	<ul style="list-style-type: none"> Confirmatory testing and quality assurance Priority populations for impact Access, affordability, logistics and procurement Self-testing as part of combination prevention Social and ethical issues for policy and implementation Policy and normative guidance issues 	
12:30-14:00	LUNCH	
14:00-16:00	Session Two: Setting the operational research agenda Session Facilitators: Prof Liz Corbett and Dr Christine Rousseau	
	<ul style="list-style-type: none"> Research gaps in low-income settings and priorities for future research Process and development of papers for a special issue 	
16:00-16:30	Session Three: Development of a consensus statement on HIV self-testing Session Facilitator: Dr Miriam Taegtmeier	
16:30-16:50	COFFEE BREAK	
16:50-17:30	Session Four: Closing Session Plan for a special issue in AIDS and Behaviour Acknowledgements	

ANNEX 2: LIST OF PARTICIPANTS

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ANNEX 3: REFERENCES

1. *Testing yourself for HIV*. Washington D.C., U.S. Food and Drug Administration, 2012 August 30. <http://www.fda.gov/biologicsbloodvaccines/safetyavailability/hivhometestkits/ucm126460.htm>
2. Napierala Mavedzenge S, Baggaley R, Corbett EL. A review of self-testing for HIV: research and policy priorities in a new era of HIV prevention. *Clinical Infectious Diseases*, 2013, 57 (1): 126-138.
3. Pai NP et al. Supervised and unsupervised self-testing for HIV in high-and low-risk populations: a systematic review. *PLoS Medicine*, 2013, 10(4):e1001414.
4. Kalibila S et al. '*Knowing myself first*': feasibility of self-testing among health workers in Kenya. Nairobi, Population Council, 2011. http://www.popcouncil.org/pdfs/2011HIV_KenyaHWSelfTesting.pdf
5. Choko A, Desmond N, Corbett E, et al. The uptake and accuracy of oral kits for HIV self-testing in high HIV prevalence setting: a cross-sectional feasibility study in Blantyre, Malawi. *PLoS Medicine*, 2011, 8(10):e1001102.
6. *Service delivery approaches to HIV testing and counselling (HTC): A strategic policy framework*. Geneva, World Health Organization, 2012. http://www.who.int/hiv/pub/vct/htc_framework/en/index.html
7. MacPherson P et al. Home assessment and initiation of ART following HIV self-testing: a cluster randomised trial to improve linkage to ART in Blantyre, Malawi. Oral Abstract LB95, 20th Conference of Retroviruses and Opportunistic Infections (CROI), Atlanta, USA, March 2013.
8. Corbett, EL. Accuracy of self-testing and linkage to care and treatment. First International Symposium on Self-Testing for HIV, Brocher Foundation, Geneva, 8-9 April 2013.
9. *OraQuick® In-Home HIV Test Summary of Safety and Effectiveness*. Washington D.C., U.S. Food and Drug Administration. 2012 July 3. <http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/UCM312534.pdf>
10. Jafa K et al. Investigation of False Positive Results with an Oral Fluid Rapid HIV-1/2 Antibody Test. *Plos One*, 2007, 2(1): e185.
11. *Clinical research programme HIT TB study*. Liverpool, UK, Malawi-Liverpool-Wellcome Trust. http://www.mlw.medcol.mw/Hitting_TB_Hard.html, 2010.
12. Obermeyer CM et al. HIV testing and care in Burkina Faso, Kenya, Malawi and Uganda: ethics on the ground. *BMC International Health and Human Rights*, 2013, 13(1): 6-19.
13. Carballo-Diéguez A et al. Use of a Rapid HIV Home Test Prevents HIV Exposure in a High Risk Sample of Men Who Have Sex With Men. *AIDS & Behaviour*, 2012, 16(7):1753-1760.
14. Steen TW, et al. Two and a half years of routine HIV testing in Botswana. *Journal of Acquired Immune Deficiency Syndrome*. 2007, 44:484-88.

15. Cockcroft A et al. Community views about routine HIV testing and antiretroviral treatment in Botswana: signs of progress from a cross sectional study. *BMC Public Health Human Rights*, 2007, 7:5.
16. Manzi M et al. High acceptability of voluntary counselling and HIV-testing but unacceptable loss to follow up in a prevention of mother-to-child HIV transmission programme in rural Malawi: scaling-up requires a different way of acting. *Tropical Medicine and International Health*, 2005, 10: 1242-50.
17. Chandisarewa W et al. Routine offer of antenatal HIV testing (“opt-out” approach) to prevent mother-to-child transmission of HIV in urban Zimbabwe. *Bulletin of the World Health Organization*, 2007, 85:843-50.
18. *Prevention and treatment of HIV and other sexually transmitted infections among men who have sex with men and transgendered people: recommendations for a public health approach*. Geneva, World Health Organization, 2011. http://www.who.int/publications/2011/9789241501750_eng.pdf
19. *Delivering HIV test results and messages for re-testing and counselling in adults*. Geneva, World Health Organization, 2010. http://www.who.int/publications/2010/9789241599115_eng.pdf

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