



HIV SELF-TESTING TO HAUS DUR COMMUNITY-LED AND COMMUNITY-BASED HIV TESTING:

Review of evidence from low and middle-income countries and community acceptability
of new HIV testing models to reach key populations in Papua New Guinea



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CONTENTS

ABBREVIATIONS	2
EXECUTIVE SUMMARY	3
1. INTRODUCTION	5
2. METHOD	6
2.1 Review of existing literature	6
2.2. Community consultation on HIV self-testing: Acceptability and program implications	6
3. FINDINGS	7
3.1 Acceptability of HIV self-testing	7
3.2 Type of HIV self-testing: oral vs blood	9
3.3 HIV self-testing delivery approaches	10
3.4 Linkage to further HIV testing, prevention, treatment and care services	13
3.5 Key messages for users and implementers	14
4. RECOMMENDATIONS	16
4.1. Key factors for consideration in a model piloting Haus Dur HIV testing among key populations	16
4.2 Community stakeholder feedback validation	17



ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral therapy
DFAT	Department of Foreign Aid and Trade
HIV	Human Immunodeficiency virus
LMICS	Low- to middle- income countries
MVCT	Mobile voluntary HIV counselling and testing
NACS	National AIDS Council Secretariat
NDoH	SURV National Department of Health Surveillance Forms
PNG	Papua New Guinea
RDTs	Rapid diagnostic tests
SMS	short message service
STI	Sexually transmitted infection
TB	Tuberculosis
UN	United Nations
UNFPA	United Nations Population Fund
UNAIDS	The Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization



EXECUTIVE SUMMARY

Latest World Health Organization (WHO) guidelines on HIV testing services recommend HIV self-testing and support to trained lay providers to deliver HIV testing services. The aim of this report is to review available literature from low and middle-income countries that documents acceptability and learnings relating to HIV self-testing; report on acceptability of HIV self-testing and current models of HIV testing with key populations in Papua New Guinea; and outline considerations for introducing HIV self-testing in Papua New Guinea. Findings in this report draw on a review of 84 peer-reviewed papers that focus on HIV self-testing in LMICs, and community consultation involving 52 representatives from key populations and wider stakeholders.

EVIDENCE FROM THE LITERATURE

HIV self-testing has proven to be highly acceptable among various groups of users in diverse LMICs settings, including key populations. HIV self-testing results in enhanced uptake of HIV testing among first time testers, as well as increased re-testing among at risk populations.

Reasons for acceptability of HIV self-testing included, for example, enhanced privacy and confidentiality; ease and convenience; greater control over the speed, efficiency, and location of testing; and reduced stigma, fear and anxiety associated with testing and waiting in clinics. Concerns about HIV self-testing included a lack of pre- and post-test counselling; accuracy of results, false negative results and associated psychological costs of inaccurate results; absence of health worker; and limited linkage to care.

As compared with trained healthcare workers, self-testers can reliably and accurately do HIV self-tests using rapid diagnostic tests. Oral and blood-based protocols for self-testing are perceived as acceptable, feasible and easy among diverse populations in LMICs.

Whilst there is evidence of directly-assisted and unassisted HIV self-testing in LMICs, recommendations point to the need for: supervised self-testing among people with limited education due to difficulties understanding the instructions and interpreting the results; and high-quality instructions, including clear wording, local translations, pictorial aids, or live demonstration. There is evidence to support community-based and lay distribution of HIV self-testing kits with key populations in LMICs, partner-based lay distribution strategies, and home-based and facility-based self-testing.

There is little evidence of screening and confirmatory testing strategies, and very limited evidence of linkage to care beyond confirmatory testing associated with HIV self-testing strategies.

There is limited research in LMICs about the health promotion dimensions of HIV self-testing to date. Some evidence was available to support the need for appropriate, validated, clear and concise instructions for use, and community education.

EVIDENCE FROM THE COMMUNITY CONSULTATION

Individuals and organisations consulted during this review recognised the need for new initiatives and models for

increasing peer outreach to key populations with the explicit aim of increasing HIV testing rates. Those consulted were open to a variety of HIV testing models to increase testing among these populations. This included, but was not limited to, self-testing as described by WHO.

Reasons for acceptability of HIV self-testing included: greater uptake of HIV testing among those who have not tested before if done at *haus dur* (house door/community); enhanced privacy and safety for testing among people of diverse gender and sexual identities; reduced stigma associated with testing in a clinic; reduced costs associated with testing in clinics.

There were crucial objections to introducing HIV self-testing in Papua New Guinea. These included: the loss of opportunity for HIV counselling and testing; lack of preparation for the consequences of HIV positive test results from HIV self-testing, and a lack of knowledge about available treatment; the inability for people to read and follow self-test instructions; substantial financial and human resources required to launch HIV self-testing; increase potential for stigma if distributing HIV self-test kits in public spaces; reliance on an individual's desire and motivation to test.

There are no HIV self-testing policy or guidelines in Papua New Guinea, and there is no regulatory support for the 15 available HIV self-test kits, of which only one has WHO pre-qualification (as of July 2018). The pre-qualified WHO test is OraQuick® HIV Self-Test, which is a saliva-based HIV RDT.

Findings from the community consultation illustrated strong objection to HIV self-testing using an oral based protocol. Reasons included concern that the ability to identify the virus in saliva would undermine the country's HIV prevention and education efforts that have repeatedly emphasised that the risk of HIV transmission via saliva is low; introducing the idea that HIV could be tested for using saliva would confuse people, and heighten fears associated with sharing food and kissing; and concern about betel nut (*buai*) affecting the performance of the oral based HIV self-test.

No HIV self-testing has been approved in Papua New Guinea and no organisations are implementing HIV self-testing. HIV self-testing was not supported by those consulted during this scoping study, including strategic staff within the PNG

Department of Health. It was recommended that access to HIV self-test kits be restricted, with assurance that these would not be made available in pharmacies, over the internet or other technology-based distribution points, from vending machines or other public and unrestricted access points. The distribution of HIV self-test kits to pregnant women for their husband's use is not being considered by the PNG National HIV Technical Working Group so it was not included in the community consultation.

There is evidence of mobile voluntary counselling and testing (MVCT) strategies, but these are not perceived as suitable for enhancing HIV testing and treatment among key populations. Reasons provided include: limited yield; a lack of privacy, associated with the public nature of MVCT; a lack of confirmatory testing in the community; a lack of involvement of lay or peer counsellors.

This consultation identified a preference for community-based HIV Testing, described locally as a 'Haus Dur' model. This would involve blood-based finger-prick testing, in the company of a trained lay worker or peer to assist with interpretation of the result, provision of counselling, and, ART initiation at time of confirmation. Here was strong support for undertaking screening and confirmation at the same time in community.

This model would use the PNG national HIV testing algorithm. It was felt that any new model of community HIV testing should incorporate the use of other RDTs for infections such as Hepatitis B Virus and Syphilis.

Linkage to care and prevention was a major concern raised during the consultation. Community members expressed a preference to be linked to care and treatment in the community with the lay/peer staff member.

RECOMMENDATIONS

Based on these findings, a range of considerations for piloting Haus Dur HIV testing among key populations are outlined.

During a community and stakeholder validation meeting, group consensus was sought on the next steps to take the Haus Dur model forward, with priorities outlined relating to human resources, programming, and policy and research.

Both are presented in detail in this document.



INTRODUCTION

The theme for World AIDS Day 2018 highlighted the importance of HIV testing: Live life positively—know your HIV status. HIV testing is the only way to know if a person is infected with HIV, and therefore opens the door to life saving care and treatment. Without knowing your HIV status, the universal efforts to bring HIV under control, and reduce HIV associated morbidity and mortality, are not possible. Four decades in, we can no longer rely on conventional and historical means of addressing the HIV epidemic. The global response calls each of us to take stock of the successes we have had, and focus on areas where greater progress is needed. In doing so we need to be willing to adapt to new models and approaches. This includes the approaches and models we have relied on for reaching members of key populations, preventing the transmission of HIV among key populations, and supporting people to learn of their HIV status. The introduction of HIV self-testing is the most recent models to be introduced in international settings.

In 2015, the World Health Organization (WHO) released the 'Consolidated guidelines on HIV testing services. 5Cs: consent, confidentiality, counselling, correct results and connection' [1]. These guidelines issued a new recommendation to support trained lay providers to deliver HIV testing services using rapid diagnostic tests (RDTs). The guidelines also considered the potential of HIV self-testing to increase access to and coverage of HIV testing services, especially among key populations. Since the release of the 2015 guidelines, there has been growing recognition of the need to support HIV self-testing in a more regulated way, and to use HIV RDTs for self-testing that are approved by the relevant regulatory authority, or following results of international regulatory review.

In 2016 WHO released the 'Guidelines on HIV self-testing and partner notification: supplement to consolidated guidelines on HIV testing services' [2]. HIV self-testing refers to:

"a process in which a person collects his or her own specimen (oral fluid or blood) and then performs an HIV test and interprets the result, often in a private setting, either alone or with someone he or she trusts. As with all approaches to HIV testing, HIV SELF-TESTING [self-testing] should always be voluntary, not coercive or mandatory. Although reported misuse and social harm are rare, efforts to prevent, monitor and further mitigate related risks are essential" [2].

This supplement issued a new recommendation that HIV self-testing should be offered as an additional approach to HIV testing services, and outlines additional guidance to support the implementation and scale-up of evidence-based approaches to this recommendation.

The aim of this report is three-fold¹:

- 1) To review available HIV self-testing literature from low and middle-income countries (LMIC) to document acceptability and learnings in relation to different aspects of the latest WHO recommendations;
- 2) To report on acceptability of HIV self-testing and current models of HIV testing with key populations and key informants in Papua New Guinea;
- 3) Provide options and issues to consider for introducing HIV self-testing in Papua New Guinea.

¹See Annex 1 for UNFPA/UNAIDS Terms of Reference



METHOD

2.1 REVIEW OF EXISTING LITERATURE

The following databases were searched to identify relevant peer-reviewed papers: Scopus and PubMed. The following search term was used during the search: HIV self-testing. The publication period included all years from 1 January 2013 to present. In the initial search, there were no limits about the study population or location in order to obtain the fullest collection of papers possible. Further searches were made using the reference lists of each paper, at the UNSW Sydney university library, using Google Scholar, and relevant websites (e.g. WHO, www.HIV SELF-TESTING.org), which included papers dating back to 2011.

During the review process, duplicate papers were removed, and papers were excluded if they did not report on primary data, were not published in English, and did not focus on LMIC settings. A total of 439 references were identified from the literature search. After screening for the above characteristics, 84 peer-reviewed papers were retained for review and are included in this report.

2.2. COMMUNITY CONSULTATION ON HIV SELF-TESTING

Community consultation was undertaken over a four-day period in Port Moresby, September 2018, with a focus on understanding the acceptability of HIV self-testing and discussing program implications. In total, 52 individuals representing 11 organisations participated in the consultation, including representatives from government, international non-government organisations, faith-based organisations

and civil society groups representing key populations and people living with HIV. Young people were also included in this consultation.

Participants included: representatives of PNG National Department of Health (1), Igat Hope (4), UNAIDS (2), WHO (1), Hope Worldwide (3), Population Services International (2), FHI 360 (3), Anglicare Stop AIDS (1), and Catholic Health Services (3); female members of Friends Frangipani (17); and sexually and gender diverse people from Kapul Champion (14). Two interviews were arranged with representatives of Word Vision and National AIDS Council Secretariat, but due to other pressing matters, appointments were cancelled by them.



FINDINGS

3.1 ACCEPTABILITY OF HIV SELF-TESTING

WHO [2] reports that HIV self-testing is acceptable to many users across different contexts, and can increase uptake and frequency of HIV testing, particularly among populations at high ongoing risk of HIV (e.g. key populations, serodiscordant couples) who may be less likely to access testing or test less frequently than recommended. It is reported that HIV self-testing would lessen the time and burden of HIV testing on health services and reduce the costs of frequent testing incurred by the individual.

EVIDENCE FROM THE LITERATURE

HIV self-testing has proven to be highly acceptable among various groups of users in diverse low to middle income country (LMIC) settings [3-6], including key populations [3, 7, 8]:

- female sex workers in Cambodia [9], Central African Republic [10], China [11], Kenya [12], Uganda [13, 14] and Zambia [15];
- men who have sex with men in Argentina [16], Brazil [17, 18], Cambodia [9], Central African Republic [10], China [19-23], Nigeria [24], Mexico [25], Myanmar [26], Peru [18, 27] and South Africa [28];
- transgender women in Myanmar [26], Cambodia [9] and Peru [27];
- fisherfolk in Uganda [14, 29];
- truck drivers in Kenya [30, 31];
- serodiscordant couples in Kenya [32] and Malawi [33];
- adolescents and/or young people in the Central African Republic [10], Malawi [34], Mozambique [35], South Africa

[36, 37], Tanzania [38, 39], Zambia [40], and Zimbabwe [41].

Acceptability was also reported as high among:

- health care workers in Ethiopia [42], Kenya [43] and South Africa [44];
- the general population in the Democratic Republic of the Congo [45], Kenya [46-49], Malawi [34, 49], South Africa [49-55], and Zambia [40];
- cohabiting couples in Malawi [33];
- pregnant women India [56];
- pregnant women and their male partners in Kenya [57], Malawi [34, 58], and Uganda [59, 60].

Research on HIV self-testing reports enhanced uptake of HIV testing among first time testers [8, 15, 21, 24, 61], as well as increased re-testing among at risk populations [13].

Numerous reasons for the acceptability of HIV self-testing were reported in the literature:

- enhanced privacy and confidentiality [14, 26, 33, 35, 38, 39, 41, 42, 49, 50, 52, 55, 62, 63];
- enhanced ease and convenience [14, 26, 38, 39, 42, 52, 53, 62, 63], related to no longer having to wait in lines, make appointments, or travel long distances to clinics [33, 49];
- greater control over the speed, efficiency, and location of testing [33, 49];
- feeling empowered due to enhanced autonomy [32, 41, 53, 55], and greater control over individual testing needs [41, 62];
- reduced stigma, fear and anxiety associated with testing and waiting in clinics [26, 32, 42, 49];

- the normalisation of testing in daily life [33];
- the ability to test before sex [14];
- a new way to test with one's partner [33, 64];
- enhanced involvement of male partners in testing, removing the testing burden from women [65];
- financial benefits associated with avoidance of spending money to test in facilities, omission of follow-up fees, affordability relative to private clinics, increased time for earning income and other activities, and indirect savings associated with transport, purchasing meals away from home and long wait lines when accessing testing in services [66].

Concerns about HIV self-testing reported in the literature included:

- lack of pre- and post-test counselling [26, 38, 39, 54], and associated mental health effects from being unable to discuss issues [26, 52];
- the accuracy of results [11, 41, 43], false negative results [54] and associated psychological costs of inaccurate results [66];
- absence of health worker [14, 26];
- limited linkage to care [14, 26];
- pressure and coercion from husbands on their wives' decision to test [33];
- concern about confirmation of infidelity when testing with partner [33];
- price of the kits in pharmacies [27, 66].

EVIDENCE FROM COMMUNITY CONSULTATION

Kauntim i tu, the key population biobehavioural survey undertaken in Port Moresby [67], Lae [68] and Mt. Hagen [69] (2016-2017), showed poor rates of ever having tested for HIV, and, of those with HIV (as confirmed in the study), close to half of female sex workers, men who have sex with men and transgender women in each of the three sites were unaware of their HIV positive status. Subsequently, widespread support for increasing HIV testing among key populations in Papua New Guinea was expressed.

The individuals and organisations consulted for this review understood the need, and desired new initiatives and models for increasing peer outreach to key populations with the explicit aim of increasing HIV testing rates. Informants realised the importance of increased HIV testing in order for Papua New Guinea to reach the first 90 in the ambitious UNAIDS 90-90-90 goals. Those consulted were open to a variety of HIV testing models to increase testing among these populations. This included, but was not limited, to self-testing as described by WHO.

The UNFPA and UNAIDS Terms of Reference clearly identifies the need to ascertain acceptability of self-testing. Therefore, we provide the findings for this model below, but in later sections describe a preferred community-based testing model as identified in the community consultation.

Reasons why people thought that HIV self-testing was acceptable included:

1. If done at haus dur (house door/community) there will be greater uptake of HIV testing among those who have not tested before;
2. People may be more comfortable to test privately due to cultures of shame related to diverse gender and sexual identities in Papua New Guinea, and the illegal nature of the sexual practices of key populations;
3. Waiting at the clinic for an HIV test can result in perceived stigma that a person is HIV positive;
4. It would assist people who are afraid to access clinics, including high profile members of the key populations who would be able to undertake testing without needing to travel overseas or request out of hours appointments with clinics or trusted health care workers;
5. It would reduce the cost of attending a clinic, overcoming barriers associated with transport (which is also described as an 'excuse' for not testing).

The reasons people objected to HIV self-testing included:

1. Counselling is an integral part of the Papua New Guinea approach to HIV counselling and testing, and would be lost in HIV self-testing. Counselling needs to be taken seriously in any future models of HIV testing;
2. Concern that people who self-test may not be well prepared for the consequences of the results, nor know that HIV treatment available and can enable people to live a normal life with HIV;
3. HIV self-testing is reliant on people being able to read or follow instructions correctly;
4. Large financial and human resources would be needed for marketing, preparation, design and distribution of educational material for HIV self testing to occur;
5. Depending on distribution, HIV self-testing could increase stigma or simply not work as a model. For example, if test kits were to be purchased at a pharmacy, the consumer may be reluctant to ask questions to clarify the testing method, the staff in the pharmacy may not know how to instruct the

customer in self-testing, and a person purchasing the test kit may experience stigmatisation or discrimination;

6. Self-testing relies on a person having a real desire to know their HIV status and be motivated to test.

3.2 TYPE OF HIV SELF-TESTING: ORAL VS BLOOD

Rapid diagnostic tests used by self-testers can perform as accurately as when used by a trained tester, provided the HIV self-testing products meet quality, safety and performance standards [2].

There are two types of self-testing: oral fluid/saliva-based testing, where a person swipes a mouth swab across the upper and lower gums in mouth to collect oral fluid, puts swab in test tube and a few minutes later sees the result; or blood from a finger prick, which comes with simple retractable lancet to collect the blood [2].

Any HIV rapid diagnostic test for self-testing, whether oral or blood, which is procured or used for HIV self-testing should be approved by the relevant regulatory authority or the results of an international regulatory review, before use [2]. There are several HIV self-testing kits on the market worldwide. Only the oral OraQuick In-Home HIV Test has been prequalified by the WHO [70, 71]; for pilots, researchers can buy products approved for procurements from the Global Fund to Fight, more information is available on the Global fund cited reference [71].

EVIDENCE FROM THE LITERATURE

As compared with trained healthcare workers, self-testers can reliably and accurately do HIV RDTs [72]. The most common error that affected test performance was incorrect specimen collection (oral swab or finger prick), though errors in performance might be reduced through the improvement of RDTs for self-testing, particularly to make sample collection easier and to simplify instructions for use [72].

Empirical and review-based studies documenting self-testing in LMICs report on the use of oral [24, 27, 28, 35, 41, 44, 46, 49, 55, 60, 73, 74] and blood-based [10, 18, 28, 45, 48, 49, 55, 73] protocols for self-testing. Overall, there is high acceptability of both approaches to testing.

The use of oral HIV self-testing was documented as acceptable, feasible and easy among:

- pregnant women in India [56];
- pregnant women and their partners in Kenya [75];
- adolescents and young people in rural Mozambique [35 and Malawi and Zimbabwe [41];
- men who have sex with men in Nigeria [24] and China [11];

- female sex workers in China [11], and;
- the general population in Kenya [46], South Africa [50, 51] and Malawi [34].

For example, in Nigeria – where the median age of the participants was 25 years, 88.7% were literate and 17.9% were first-time testers – almost all participants reported that the HIV self-testing kit instructions were easy or somewhat easy to understand (99.6%); the most common reasons they liked the test were ease of use (87.3%), confidentiality/privacy (82.1%), convenience (74.1%) and absence of needle pricks (64.9%) [24].

The use of blood-based and oral HIV self-testing was documented as acceptable, feasible and easy among:

- the general population in the Democratic Republic of Congo [45] and Kenya [48];
- young people in the Central African Republic [10] and South Africa [76];
- men who have sex with men and female sex workers in the Central African Republic [10];
- men who have sex with men in Peru and Brazil [18] and in China [77].

For example, in the Democratic Republic of Congo, using the prototype self-test Exacto((R)) Test HIV (Biosynex, Strasbourg, France), the majority of participants performed the HIV self-test correctly (98.4%), found that performing the self-test was easy (95.3%), and interpreted the results correctly (90.2%). The main obstacle for HIV self-testing was educational level, with execution and interpretation difficulties occurring among poorly educated people [45]. Similar results were found in the Central African Republic study by the same research team [10]. Using the 'INSTI® HIV-1/HIV-2 Self-Test' in Kenya, of the 350 participants, 98% found instructions for use easy to follow, 94% found the finger prick device easy to use, 87% were confident while performing the test, 98% felt result interpretation was easy, 87% declared results within the recommended five minutes, 98% were willing to use the test again, and 98% would recommend the kit to a sexual partner [48].

In the limited studies that combined both approaches in LMICs, the blood test appeared superior. A study amongst men who have sex with men in South Africa found that the fingerprick was preferred to oral fluid tests by approximately 2:1 [28]. Another study of five prototype HIV self-testing kits in Malawi, South Africa and Kenya found that less than half of participants collected the oral sample correctly and that performance of blood-based HIV self-testing was slightly better [49]. However, a study amongst lay users in South Africa [55] found that there is high acceptability regardless of self-test prototype.

EVIDENCE FROM COMMUNITY CONSULTATION

There are no HIV self-testing policy or guidelines in Papua New Guinea, and there is no regulatory support for the 15 available HIV self-test kits, of which only one has WHO pre-qualification (as of July 2018). The pre-qualified WHO test is OraQuick® HIV Self-Test, which is a saliva-based HIV RDT.

While international data confirms that OraQuick® is acceptable and easy to use, there are some concerns about its performance, as identified above. In Papua New Guinea, worries about betel nut (buai) affecting the performance of the oral based HIV self-test was raised as an issue. This was also noted in the Kautim mi tu study during TB testing of sputum; to reduce the interference of betel nut particles on TB testing using sputum, study participants were asked to rinse their mouth twice with water before providing a sample. The effect of betel nut on the OraQuick® HIV Self-Test is undocumented, but should be taken into consideration in the Papua New Guinean context where the practice is extensive.

The greatest objection to an oral based HIV self-test kit was that stakeholders, including HIV positive people and members of key populations, were concerned that the ability to identify the virus in saliva would undermine the country's HIV prevention and education efforts that have repeatedly emphasised that the risk of HIV transmission via saliva is low. People also believed that, because HIV testing has always focused on blood, introducing the idea that HIV could be tested for using saliva would confuse people, and heighten fears associated with sharing food and kissing. As with Determine HIV-1/2 (Alere, Hannover, Germany) and Stat-Pak HIV-1/2 (Chembio, New York, USA), OraQuick® is an antibody test. Yet people undergoing HIV testing in Papua New Guinea are not routinely told that they are being tested for HIV antibodies, rather than the virus itself. Similarly, general education does not make the distinction between testing for the virus and testing for the antibodies. Some informants felt people could be told that the test is screening for the 'HIV army' but not the virus, but this would require a great deal of effort and risk undermining educational efforts to date. Most were not in favour of this approach.

The PNG National HIV Technical Working Group would need to review all HIV self-test kits for the performance, sensitivity, user friendliness, and other specifications to ensure it meets HIV testing standards in Papua New Guinea. A recommendation, policy and guideline will need to be issued. Depending on which test the PNG government approves, there may be implications for

procuring HIV self-test kits from donors such as Global Fund to Fight AIDS, TB and Malaria in the future.

If HIV self-testing is not adopted in the way that WHO outlines (i.e. as a test to triage), and a Community-based HIV Testing Model is implemented, issues relating to these test kits will be redundant as tests used in the PNG national HIV testing algorithm would be used. Should a community-based testing approach be adopted, guidelines on whether such a model should also act as a triage will need to be decided. The consensus from the community consultation was that testing should provide confirmation at the same time. To date all programs that report community-based HIV testing in PNG are ONLY providing HIV screening. This should not be confused with community-based HIV testing where confirmation is provided.

3.3 HIV SELF-TESTING DELIVERY APPROACHES

WHO [2] specifies that approaches may vary in terms of the level and type of support provided, including directly assisted and unassisted methods:

- Directly assisted HIV self-testing refers to trained providers or peers giving individuals an in-person demonstration of how to perform the test and interpret the test result, before or during a self-test;
- Unassisted HIV self-testing refers to when individuals self-test for HIV and only use an HIV self-testing kit with manufacturer-provided instructions for use.

WHO [2] outlines various public and private sector channels through which HIV RDTs for self-testing could be distributed and used. These include: community-based or lay distribution; couples and partners testing; facility-based distribution; integration of services and outreach, to include community- and facility-based distribution of HIV self-testing kits, as well as integration with other service delivery models across existing public health programs; internet-based outreach to key populations; pharmacy-based distribution; pre-exposure prophylaxis programs; and workplace programs.

EVIDENCE FROM THE LITERATURE

Self-testers can reliably and accurately do HIV rapid diagnostic tests, as compared with trained healthcare workers [72].

Directly assisted HIV self-testing is reported in the Democratic Republic of Congo [45], India [56], Kenya [48], Malawi [34], South Africa [44, 51] and Uganda [29]. The Democratic Republic of Congo study recommends supervised use of HIV self-testing among poorly-educated people, due to frequent difficulties understanding the instructions for use in addition to frequent misinterpretation of test results [45].

Unassisted HIV self-testing is reported in Kenya [43, 46, 49], Malawi [49], South Africa [44, 49, 50] and Uganda [29]. HIV self-testing kits were described as easy to use by health care workers, pregnant women and heterosexual couples in Malawi [33, 56], with participants correctly interpreting negative and positive HIV results from self-testing. However, other studies report that high-quality instructions, such as clear wording, local translations (where necessary), pictorial aids, or live demonstration, were valued and facilitated correct operation of self-test kits [49, 56].

A summary of findings relating to distribution of HIV self-testing approaches is outlined below.

Community-based/lay distribution: Successful implementation of lay distribution is documented with:

- the general population in urban Zambia [34],
- men who have sex with men in South Africa [28], Nigeria [24] and Vietnam [63],
- female sex workers to their partners in Kenya [78].

In the South African study, for example, 127 HIV-negative men who have sex with men were provided with up to 9 test kits of their choice – oral fluid or blood – to use themselves and/or distribute to their networks; 728 of the 1143 tests were distributed to sexual partners (18.5% of kits), friends (51.6%), and family (29.8%) [28]. In Nigeria, a study illustrated that HIV self-testing distributed by 'key informants' – other respected men who have sex with men who were trained as HIV counsellors in a community-based health centre – was feasible; the most acceptable place to obtain self-testing kits being a community-based or non-governmental organisation (96.2%), followed closely by peer educators or key informants (86.2%) [24]. Lay community distribution was preferred by young people aged 16-25 years in Malawi and Zimbabwe due to a lack of trust in health providers [41].

Partner-based lay distribution: distribution between pregnant women to their husbands/partners was well documented in Kenya [79], Malawi [33, 58, 80] and Uganda [59, 60]. In Kenya, 79.4% (335/422) of the women in the self-testing study arm (two oral HIV self-test kits and HIV testing information) reported that their partner tested for HIV compared to 28% (114/406) and 37% (142/387) in comparison study arms (standard-of-care and a standard information card vs. an improved card stating the importance of male HIV testing), respectively; over 90% of male partners who used the oral HIV self-test kits reported it was easy to take sample and read the test results [79]. In Malawi, women contrasted the ease with which they could encourage their husbands to self-test with unsuccessful attempts to get their husbands to attend facility-based HIV testing [33]. Women in Malawi also said they were

likely to use HIV self-testing for their next HIV test and stated they would recommend HIV self-testing to family and friends [65]. There was good distribution in Uganda among pregnant women to husbands and other family members, but not to co-wives [59]. In Malawi, men more likely to decline a self-test with their partner due to fear of exposure of infidelity or not being at home due to economic reasons [80].

Home-based testing: There was high acceptability associated with HIV self-testing at home among:

- the general population in Malawi (where uptake was similar for both genders despite historically low testing rates among men) [65, 81] and South Africa [64, 82];
- men who have sex with men in Brazil [83] and China (where tests were sent by mail after online registration) [19];
- men who have sex with men and female sex workers in China [11].

In a South African study [64], for example, based on 20 in-depth interviews documenting opinions about self-administered at-home oral HIV testing, self-testing was seen as enabling confidentiality and privacy, saving time, and facilitating testing together with partners. Concerns were raised about psychological distress when testing at home without a counsellor. Some participants suggested that this concern could be minimised by having experienced clinic-based HIV testing and counselling before getting self-testing kits for home use.

Facility-based distribution: Facility-based distribution of HIV self-testing – either through attendance at a health facility or through community health workers – was reported:

- during antenatal screening for HIV and supervised by auxiliary midwives in rural India (which documented the important role of the community health worker) [56];
- with adult clients at primary health care clinics and Médecins Sans Frontières-run fixed-testing sites in rural KwaZulu Natal in South Africa [51];
- adolescents in rural Mozambique [35] and South Africa [76];
- health care workers in Kenya [43].

In Mozambique, for example, adolescents aged 16-20 years were invited to attend the local hospital's youth friendly service for directly assisted oral HIV self-testing. In total 496 adolescents were included, of which: 299 performed an oral HIV self-test; 70% were first time testers; while 20% thought it would be good to do HIV self-testing at home, 76% preferred to do HIV self-testing at the health centre, for reasons including increased security, privacy, and the presence of a counsellor [35].

Technology-based outreach: Technology-based HIV self-testing interventions have the potential to improve access to HIV testing among gay, bisexual, and other men who have sex with men [70]. Internet-based outreach and online distribution of HIV self-testing has been documented among men who have sex with men in China [19, 22, 84], Vietnam [63] and Brazil [17], and men who have sex with men and Transgender women in Thailand [85]. For example, among men who have sex with men in Brazil, a multipronged approach to increase HIV testing and linkage to care included a webbased platform and associated mobile application designed to provide HIV prevention information, allow for selfassessment of risk, and deliver HIV self-testing oral-fluid test kits to eligible individuals via home delivery by mail or pickup at a governmentsponsored pharmacy [17]. The project had 7,352 HIV selftest requests over 24 months; 31% of men who have sex with men who had never tested before [17].

Pharmacy-based distribution: There is limited research documenting pharmacy-based approaches in LMIC settings. One example documented an oral HIV self-testing approach as feasible in a rapidly urbanising area of coastal Kenya (population c. 100000) [47]. Five pharmacies – typically small to medium-sized businesses, employing two people and serving 60 clients per day – were involved. Pre- and post-test counselling was offered in line with national guidance. Between November 2015 and April 2016, 463 clients were invited to participate; 174 (38%) were enrolled, 161 (35%) bought a test, and uptake was higher among clients seeking HIV testing compared to those seeking other services (84% vs. 11%). All but one tester reported the process was easy (29%) or very easy (70%).

EVIDENCE FROM COMMUNITY CONSULTATION

HIV Self-Testing: No HIV self-testing has been approved in Papua New Guinea and no organisations are implementing HIV self-testing. Within the bounds of this study it was not possible to determine if people are purchasing HIV self-test kits from overseas via the internet or bringing them into the country.

HIV self-testing was not supported by those consulted during this scoping study, who objected to the implementation of HIV self-testing in PNG. It was recommended that access to HIV self-test kits be restricted, with assurance that these would not be made available in pharmacies, over the internet or other technology-based distribution points, from vending machines or other public and unrestricted access points. The distribution of HIV self-test kits to pregnant women for their husband's use is not being considered by the PNG National HIV Technical Working Group so it was not included in the community consultation.

Unassisted HIV self-testing was not supported for implementation in Papua New Guinea. Dr Boas, the Acting Program Director, HIV and STIs, at the PNG National Department of Health stated that, in his position as national advisor on HIV in the government, he would recommend against HIV self-testing and would not support any efforts to introduce this approach. Nevertheless, if HIV self-testing was to go ahead in Papua New Guinea, now or in the future, the National STI and HIV Strategy and the National HIV Testing guidelines would need to be updated to accommodate this change.

Mobile Voluntary Counselling and Testing (MVCT): Three separate organisations (FHI360, Anglicare StopAIDS, Hope Worldwide) have implemented and piloted MVCT clinics in vans. At the time of the community consultation, no MVCT clinics were operating, due to funding shortages and changes in program focus. While these initiatives have also been called community-based testing, they are not. These initiatives only provide HIV screening.

Numerous problems with MVCT were raised by participants in the consultation:

1. Limited yield, suggesting that the MVCT clinics have not proven effective in reaching key populations;
2. A lack of privacy, associated with organisational logos being 'splashed' across vans, large speaker phones announcing the presence of MVCT, and key populations having to wait under large tents;
3. MVCT only screens for HIV, with confirmatory testing still required in clinics;
4. No lay/peer HIV counsellors are engaged in MVCT models;
5. Operating hours were limited to accommodate same day triage for confirmation.

Community-based HIV Testing: Instead of HIV self-testing, this consultation identified a preference for Community Based HIV Testing, described locally as a 'Haus Dur' model. In this approach it would be possible for a person to prick their own finger, but it must be done in the company of a lay person trained in HIV STI testing to assist with interpretation of the result, provision of counselling, and, if acceptable to the PNG National HIV Technical Working Group, ART initiation at time of confirmation. A Haus Dur approach would ensure screening and confirmation simultaneously. This is in contrast to models used by Anglicare StopAIDS, FHI360

and Hope Worldwide. There is growing global evidence about community-based HIV testing and same day pre-ART assessment and initiation in the community by lay personnel showing improved linkages to care and improvements along the HIV cascade [86, 87]. The Government of Papua New Guinea and its stakeholders would be advised to consider a strategy for ART initiation and distribution in the community.

A *Haus Dur* model would be best implemented by a mixture of lay workers or peers with training in HIV testing and counselling, and health care workers sensitive to the social practices of communities of key populations. It is expected that this approach would have the highest yield in cities in the National Capital District, and Morobe and Western Highlands Provinces, with possible expansion to other high epidemic areas including Enga Province.

The *Haus Dur* testing approach recommended in this report, and supported by communities, will require endorsement from HIV National Technical Working Group, in line with the current national technical testing algorithm.

3.4 LINKAGE TO FURTHER HIV TESTING, PREVENTION, TREATMENT AND CARE SERVICES

There are a number of elements to the HIV self-testing process which illustrate the importance of linkage to care. As outlined by WHO [2], HIV self-testing is considered to be a test for triage, which requires individuals with a reactive test result to receive further testing from a trained tester using a validated national testing strategy.

Linkage to care is also important after a non-reactive test. Interpretation of a non-reactive (negative) self-test result will depend on the ongoing risk of HIV exposure. Individuals at high ongoing risk, or who test within 6 to 12 weeks of possible HIV exposure, should be encouraged to retest. HIV self-testing is not recommended for users with a known HIV status who are taking antiretroviral drugs, as this may lead to an incorrect self-test result (false non-reactive). There are also limitations around HIV RDTs for self-testing in relation to the window period between HIV infection and the detection of HIV-1/2 antibodies. In most cases, higher-risk users who have a non-reactive self-test and disclose their result to a provider should be referred and, if necessary, linked to additional testing as well as HIV prevention services (such as condoms and lubricants, voluntary male medical circumcision, harm reduction and post-exposure prophylaxis. Referral for further testing and receipt of a confirmed

HIV-negative status by a trained tester will be required before initiation of pre-exposure prophylaxis.

Furthermore, integrating HIV self-testing into comprehensive sexual health service programmes is critical in settings where there is a rising incidence of sexually transmitted infections (STIs). Although HIV self-testing is an innovative way of encouraging greater uptake of HIV testing among clients who might otherwise not know their HIV status, enabling individuals to test without having to attend a sexual health clinic can mean some users may access other health services, such as STI testing, less frequently. Even if high-risk clients have a non-reactive HIV self-test result, they should be provided with information on further HIV testing and treatment, as well as on other STIs and viral hepatitis, and be encouraged to access comprehensive sexual health services.

Associated with these issues, there are a number of related health promotion messages around HIV self-testing that are important to share with clients (these are detailed in a section below).

The WHO [2] outlines a number of linkage strategies following HIV self-testing:

- Community-based follow-up by peer and/or outreach workers, in-person or via telephone/text message/social messaging platforms;
- Home-based treatment assessment and initiation, with support and active follow-up through community-based networks;
- Brochures and flyers distributed together with HIV self testing kits, containing information on HIV testing services, HIV prevention, treatment and care, and other diseases (e.g. TB, STIs);
- Telephone hotlines that users call before or after self-testing to obtain psychosocial and/or technical support, referrals to HIV testing services and other HIV services, and other non-medical services (e.g. legal support, violence support);
- Mobile phone text messaging services that can provide information, reminders, videos and messages that encourage linkage following HIV self-testing;
- Internet- and computer-based programmes and applications;
- Vouchers, coupons or rebates to facilitate linkage, particularly among populations facing structural barriers to accessing services, such as long distance and costly transportation;
- Appointment cards and referral slips.

EVIDENCE FROM THE LITERATURE

There is evidence of confirmatory testing to corroborate the results of the self-test in some studies [18, 19, 24, 34, 44, 88]. At the same time, however, only 55% of men who have sex with men and transgender people would seek a confirmatory test in a

study in Peru [27], and there was very low care-seeking behaviour amongst urban men who have sex with men in a Chinese study [20].

Studies are only starting to examine linkage to care beyond confirmatory testing more recently. For follow up counselling, 44.6% of 242 seronegative participants received follow up counselling by mobile phone in South Africa [44], whilst 75% of 219 subjects reported their results to a local trained counsellor in Malawi [34]. For linkage to ART initiation services, in the first year of a two year study in urban Malawi, of 1,257 HIV-positive participants, 26% were already on antiretroviral therapy, whilst 56.3% newly accessed care (with a median CD4 count of 250 cells/ μ l) [34]; In Vietnam, 90% of 1655 HIV cases among men who have sex with men accessed ART [63].

Little research documents the effectiveness of different strategies designed to try to enhance linkage to HIV prevention and care testing services beyond confirmatory testing. More research is needed in this area [61]. Limited findings report:

- preference to receive a fixed financial incentive of approximately USD\$2 to increase linkage among pregnant women and their husbands in Malawi [58];
- preference for phone call reminders to SMS reminders among pregnant women and their husbands in Malawi [58], as well as a preference of home visits or phone calls to facilitate linkage rather than SMS reminders among general population in Zambia [89];
- mixed support for telephone-based 'hotline' counselling, with only 40% of students wanting this in one South African study [37], compared to this being favourable among general population in a study in Johannesburg, South Africa [52].

EVIDENCE FROM COMMUNITY CONSULTATION

Linkage to care and prevention was a major concern raised during the consultation. The current model used by non-governmental organisations links people to the HIV/ART site on the same day as screening HIV positive, or as soon after as possible. In most cases a vehicle is on standby near the MVCT van to drive people with a peer for confirmation and possible ART initiation. Community members expressed a preference to be linked to care and treatment in the community with the lay/peer staff member.

Participants from civil society organisations representing key populations suggested that more awareness on HIV testing could be made available using Facebook™, as well as dating and sex-related apps such as Grinder. An HIV specific hotline could be linked to the already available counselling hotline for domestic and family violence.

3.5 KEY MESSAGES FOR USERS AND IMPLEMENTERS

WHO [2] recommends a number of key messages for users and implementers which should be part of the health promotion and communication surrounding the implementation of HIV self-testing programs. These include:

- appropriate, validated, clear and concise instructions for the use of HIV self-testing kits to minimise errors and maximise the performance of HIV RDTs used for self-testing;
- educating the community – including networks of people with HIV, such as key and affected populations, trained testers and health workers – about HIV self-testing to increase uptake of self-testing and minimise the risks of misuse.

WHO also stress that accessible and available pre-test information and post-test counselling messages should raise awareness of several issues:

- what to do after a reactive self-test result, including the need for a confirmatory test, where to go to access stigma-free HIV testing services, HIV prevention, treatment and care and other support services, as well as information on tuberculosis, STIs and viral hepatitis;
- that a non-reactive test result does not always indicate an HIV-negative status, along with re-testing or facility-based testing for individuals with known or possible HIV exposure in the 6 to 12 weeks prior to testing;
- that HIV self-testing is not recommended for people with a known HIV status who are taking antiretroviral drugs for treatment or prevention;
- that HIV self-test results should not be used to serosort or to justify engagement in HIV risk behaviours. As a negative self test result does not always indicate that a person is HIV negative, users should be encouraged to utilise existing HIV prevention options, such as condoms and pre-exposure prophylaxis, regardless of their self-test result;
- the importance of disclosure in order to mitigate the risk of social harm and help couples and families to cope with a reactive self-test result or discordant self-test results.

EVIDENCE FROM THE LITERATURE

There is limited research in LMICs about the health promotion dimensions of HIV self-testing to date. Some evidence was available in the following areas:

Appropriate, validated, clear and concise instructions for use: Enhanced instructions for use is particularly important for rural settings or where literacy and formal education levels are low. This is documented in Malawi [34], China [88], Uganda

[29], South Africa [51, 90], the Democratic Republic of Congo [45, 91] and the Central African Republic [10, 91]. For example, recommendations from research about the practicability of HIV self-testing using blood-based testing (the Exacto® Test HIV (Biosynex, Strasbourg, France) self-test) in the Democratic Republic of Congo [45] and the Central African Republic [10] focused on the need to adapt the instructions for use to the general public, including adding educational pictograms as well as instructions for use in the local vernacular language(s). This was due to frequent difficulties understanding the instructions for use in addition to frequent misinterpretation of test results. With these efforts in place, there was generally good usability of the HIV self-test.

Community education: This was documented in one study. Announcing the availability of HIV self-testing by text message (three text messages) with female sex workers who were irregular HIV testers in Kenya increased HIV testing (compared with those who received three text messages about general HIV testing) among this high risk group [12].

EVIDENCE FROM COMMUNITY CONSULTATION

HIV self-testing in the sense outlined by WHO is not currently supported for piloting in Papua New Guinea;

Counselling remains a critical aspect to HIV testing in Papua New Guinea and cannot be overlooked;

Cannot undermine efforts to provide accurate HIV information by using an oral based test;

Lay personnel and peers should be trained to provide HIV counselling and testing in the community and initiate ART and

Any new model of community HIV testing should incorporate the use of other RDTs for infections such as Hepatitis B Virus and Syphilis. This is particularly relevant given the development of PNG National Hepatitis B Virus treatment guidelines, and the current validation of the HIV and Syphilis dual test for the country's new three test HIV testing algorithm.





RECOMMENDATIONS

4.1. KEY CONSIDERATIONS FOR PILOTING HAUS DUR HIV TESTING AMONG KEY POPULATIONS

HUMAN RESOURCES

1. Lay peer counsellors cannot be limited to one geographical area, group of clinics or particular time of day to when working in this community-based testing model;
2. The safety of lay counsellors working after hours and on weekends needs to be acknowledged alongside the need for flexibility of delivery of this new model of HIV testing and treatment to increase yield. Tingim Laip 2 (a former DFAT-funded HIV prevention program) implemented evening HIV testing with a MVCT unit along the Highlands Highway and employed a security firm to ensure the safety of the staff and volunteers. An urban Catholic Health facility also opened later at night for professionals and high-profile people. Such lessons are important for community-based testing and treatment support.
3. Consideration for how the lay/peer HIV testing and counselling staff/volunteers will be remunerated will be important (i.e. pay per test, hours worked etc). There is potential for people to fake the number of tests conducted, or report hours worked without success in getting people tested or escorted to clinic.

PROGRAMMING (INCLUDING TESTING SITES, TEST KITS, CONFIRMATION AND ART INITIATION)

1. Confirmation should occur at time of testing, not back at the clinic. Same day escorts risks increasing stigma in the

community by observing who is being escorted. Delays in time between screening and confirmation may cause increased, undue emotional stress;

2. The role (if any) of the Chembio Dual HIV and syphilis test now or in the future should be considered;
3. Issues relating to where and how to register new diagnosis in NDoH SURV forms will need to be explored with the government and service providers, as will ART registration if ART initiation is commenced in the community using a same day test and treat model;
4. ART initiation in the community is recommended unless there are clear signs of HIV co-morbidities;
5. Testing needs to be more discrete, in a home, under a tree away from others, in a car, hotel room etc.;
6. Any new model should involve community distribution of ART along with HIV testing (screening and confirmation). This could assist with follow up, limit the number of times some people need to come to the clinic, and improve retention on treatment. A similar model of community distribution of ART has been long used by the Catholic Health facility in Southern Highlands Province where priests distribute treatment to people who live in their diocese;
7. MVCT units have little value for key populations.

POLICY AND RESEARCH ISSUES

1. Changes to a three test National HIV Testing Algorithm in 2019 will need to be accommodated in any Haus Dur model;

2. HIV counselling guidelines will need to be updated and take account of advances in counselling and testing needs;
3. Operational research should accompany any new HIV testing and treatment model to determine its operational feasibility, acceptability and effectiveness in increasing outreach, yield and retention in care.

4.2 COMMUNITY STAKEHOLDER FEEDBACK VALIDATION

A community stakeholder feedback meeting was held on 18th February 2019, with 26 attendees from key populations and wider stakeholder groups (including NACS, Hope Worldwide, Anglicare, World Vision, Igat Hope and UN partners).

Findings from the literature review and community consultation were presented. Consensus with the recommendations for adopting a Haus dur community-based testing approach, rather than self-testing, was reached. Detailed discussion was undertaken regarding how the findings from this review would build upon, strengthen and develop current models being used to reach key populations for HIV testing, such as the case finders currently being piloted by Anglicare and Hope Worldwide. Based on extensive discussions about HIV drug resistance and significant rates of loss to follow up, Haus dur HIV community-based testing along with case management was viewed favourably to address these pertinent issues in Papua New Guinea's current HIV environment. It was also agreed that the final model designed and piloted must stay as close as possible to the ideas, thoughts and opinions of the key populations as represented in this report.

Group consensus on the next steps and issues to review to take this model forward was reached, and are detailed below:

HUMAN RESOURCES

1. Financing and employment, contacting, payment and professionalisation of lay personnel;
2. Lay staff employed in this model need to be trained in counselling and case management skills related to HIV testing, adherence and other social issues (e.g. domestic violence, HIV disclosure) and be viewed and respected as part of the clinical team;
3. Change Management Plan, and associated training and coaching for key organisations and sectors on how they work with key populations and across geographical areas;
4. Ensure staff employed in this model are supported with relevant and adequate security.

PROGRAMMING (INCLUDING TESTING SITES, TEST KITS, CONFIRMATION AND ART INITIATION)

1. Draw on skill sets, training materials and models of existing partners, including Igat Hope, FHI 360 and Catholic Health Service for case management;
2. Donor coordination meeting to talk about options budgets, as it relates to testing three diseases;
3. Fast-track the model being piloted with Anglicare and Hope Worldwide to take on 'Haus dur' community-based HIV testing;
4. Review and update of HIV Testing and Counselling training modules;
5. Strategic Information Technical Working Group needs to be a part of the entire discussion about how to link data and planning;
6. Funding from the Global Fund to fight AIDS, TB and Malaria is available and could be reprogrammed to support training of lay personnel in efforts to implement Haus dur community-based HIV testing;
7. Examine with donors and program designers how to initiate testing for three diseases (HIV, HBV, syphilis) and screening for TB;
8. Quality assurance of HIV testing.

POLICY AND RESEARCH ISSUES

1. Send report to HIV Technical Working Group for endorsement;
2. Define operational research requirements, secure funding and, where available, draw on existing opportunities for data sets;
3. Conduct policy audit of testing and treatment guidelines, particularly as it relates to ART prescribing, differentiated care, and other issues pertaining to ART initiation;
4. Incorporate changes to the national HIV testing algorithm as they are approved;
5. Review and update HIV testing and counselling guidelines as necessary;
6. With support of Strategic Information Technical Working Group, identify reporting mechanisms on HIV testing, ART distribution and retention in care;
7. Clarify need for the second confirmatory test to initiate ART.

TERMS OF REFERENCE

1. Desk review of HIV self-testing in Low Middle Income Countries
2. Scoping of current models of HIV testing in Papua New Guinea including mobile and self-testing
3. Undertake community consultation to ascertain the acceptability of HIV self-testing
4. Provide options and issues to consider for introducing HIV self-testing in Papua New Guinea
5. Undertake community stakeholder validation of findings and recommendations
6. Produce a situational analysis report on HIV self-testing for Papua New Guinea

ANNEX 2

HIV self-test kits prequalified by WHO, approved by a regulatory authority in one of founding-member countries of the International Medical Device Regulators Forum of eligible for procurement on recommendation of United/Global Fund Expert Review Panel for Diagnostics.

Test name (manufacturer/supplier)	Test generation ^a	Specimen	Sensitivity	Specificity	Approval status	Markets	Price in US\$
atomo HIV Self Test (Atomo Diagnostics Australia)	3rd	Whole blood	99.7%	99.7%	CE mark, ERPD (Category-3) ^b	Kenya, South Africa	Public sector: \$3 (depends on volume)
autotest VIH® (three packaging formats) (AAZ Labs, France) ^c	2nd	Whole blood	100.0%	99.8%	CE mark	Registered and available in 15 European countries ^d	HIC retail: \$20-28 Distributors/NGOs: \$8-15 (depends on packaging format)
BioSURE HIV Self Test (hard case & soft case) (BioSURE, United Kingdom Ltd) ^e	2nd	Whole blood	99.7%	99.9%	CE mark, ERPD (Category-3) ^{b,e}	South Africa, United Kingdom	HIC retail: \$42-48 HIC public sector: \$7.50-15 LMIC retail: \$11.75
Exacto® Test HIV (Biosynex, France)	3rd	Whole blood	99.99%	99.90%	CE mark	Europe ^d	Not available
INSTI® HIV Self Test (box & pouch) (bioLytical Lab., Canada) ^c	2nd	Whole blood	Box: 100.0% Pouch: 99.8%	Box: 99.8% Pouch: 99.5%	CE mark, ERPD ^c (Category-3) ^b	Several countries in Europe, Nigeria	Price: \$3-12 MSRP: \$7-36 (Prices depend on packaging format, volumes and market region)
OraQuick® In-Home HIV Test (OraSure Technologies, USA)	2nd	Whole blood	FDA: 91.7%g CE: 100.0%	FDA: 99.98% CE: 99.8%	FDA, CE mark	USA	HIC retail: \$40 Public sector prices vary. Not yet marketed in Europe
OraQuick® HIV Self Test (OraSure Technologies, USA)	Not available ^f	Whole blood	99.4%	99.0%	WHO PQ ^h	Burundi, Kenya, South Africa, Uganda, Zambia, Zimbabwe	LMIC ex-works: \$2 for 50 countries ^j
SURE CHECK® HIV Self Test (Chembio Diagnostic Systems Inc., USA)	2nd	Whole blood	Not available	Not available	ERPD (Category-3) ^b	Not available	Not available

CE: Conformité Européenne; **ERPD:** Expert Review Panel for Diagnostics; **FDA:** United States Food and Drug Administration; **HIC:** high-income country; **LMIC:** Low- and middle-income country; **MSRP:** manufacturer's suggested retail price; **NGO:** nongovernmental organization; **PQ:** prequalification; **USA:** United States of America; **WHO:** World Health Organization.

Note: Product details based on information provided by the manufacturers at the time of report preparation.

^a Test generation is based on product design and formulation of reagents (2nd generation: Protein A-conjugate; 3rd generation: recombinant antigenconjugate) in accordance with WHO prequalification criteria.

^b Additional information is available at: https://www.theglobalfund.org/media/5878/psm_products-hiv-who_list_en.pdf.

^c Different packaging formats are considered different products for regulatory purposes but have been considered a single product for the purpose of this report.

^d Name of countries not available.

^e ERPD approval expired February 19 2018; currently under reassessment.

^f Pending outcome of WHO prequalification review of change notification.

^g United States FD approval required unobserved use testing relying on individuals to correctly report their test results without a trained professional confirming the self-reported result. Additional information is available at: <https://www.fda.gov/biologicsbloodvaccine/bloodbloodproducts/approvedproducts/premarketapprovals/pmas/ucm310436.htm>

^h Additional information is available at: http://www.who.int/diagnostics_laboratory/evaluations/pq-list/170720_nal_amended_pqdx_0159_055_01_oraquickhiv_self_test_v2.pdf?ua=1.

ⁱ Ex-works prices are determined at the manufacturer's factory and do not include any delivery, distribution, taxes or commission charges.

^j A list of countries is available at <http://www.oraquick.com/products-infectious/products-infectious-oraquick-self-test.asp>.

Taken from [71].

ANNEX 3

HIV self-test kits under development..

Test name (manufacturer/supplier)	Specimen	Plan for regulatory approval
Asanté™ HIV Self Test (Sedia Biosciences Corporation, USA)	Oral Fluid (also, a version is under development that can test either an oral fluid or whole blood specimen in a single device)	Not available
Aware™ HIV-1/2 OMT Oral HIV Self Test (Calypte Biomedical, USA)	Oral fluid	Plan to apply for WHO PQ and CE mark
First Response HIV 1-2.0 Card Test (Self Test) (Premier Medical Corporation, India)	Whole blood	Plan to apply for WHO PQ
To be named (Abbott Laboratories, USA)	Whole blood	Not available
To be named (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd., China)	Urine	National regulatory approval in China pending
To be named (Trinity Biotech, Ireland)	Whole blood	Not available

CE: Conformité Européenne; PQ: prequalification; WHO: World Health Organization.

Taken from [71].

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