

# **How Should HIV Self-Test Kits be Packaged in Kenya?**

Petra Stankard, Population Services International  
Olivier LeTouzé, Population Services International  
Meghann Jones, Ipsos

**Grantee Final Report**  
**Accepted by 3ie: June 2014**



**International Initiative  
for Impact Evaluation**

## **About 3ie**

The International Initiative for Impact Evaluation (3ie) was set up in 2008 to meet growing demand for more and better evidence of what development interventions in low- and middle-income countries work and why. By funding rigorous impact evaluations and systematic reviews and by making evidence accessible and useful to policymakers and practitioners, 3ie is helping to improve the lives of people living in poverty.

## **About the HIV Self-Testing Thematic Window**

Thematic Window 2 on HIV self-testing in Kenya is structured under two phases—phase 1, which funded formative research and phase 2, which will be informed by results from the first phase and will fund pilot interventions and their impact evaluations. 3ie identified key questions related to HIV self-tests by reviewing relevant literature and by meeting with key stakeholders in Kenya. 3ie and Kenya's National AIDS and STI Control Programme selected six of these questions in a request for applications under phase 1. The call was open to organisations implementing HIV and AIDS programmes in Kenya.

## **About this report**

This report has been submitted in partial fulfilment of the requirements of a grant issued under the HIV Oral Self-Testing Thematic Window. 3ie is making this final report available to the public as it was received without any further changes. All content is the sole responsibility of the authors and does not represent the opinions of 3ie, its donors or its board of commissioners. Any errors and omissions are the sole responsibility of the authors. All affiliations of the authors listed in the title page are those that were in effect at the time the report was accepted. Any comments or queries should be directed to the corresponding author, Olivier LeTouzé at oletouze@psi.org.

Suggested citation: Stankard, P, LeTouzé, O, and Jones, M, 2014. *How Should HIV Self-Test Kits be Packaged in Kenya?*, 3ie Grantee Final Report. Washington, DC: International Initiative for Impact Evaluation (3ie).

Funding for this thematic window was provided through the generous support of the Bill & Melinda Gates Foundation.



**Ipsos Public Affairs**

The Social Research and Corporate Reputation Specialists



## **How should HIV Self-Testing kits be packaged in Kenya?**

### **Report for 3ie**

Submitted January 17, 2014

Revised June 15, 2014

Contact: Olivier LeTouzé  
Population Services International  
1220 19<sup>th</sup> St NW, Suite 600  
Washington DC, 20036  
Phone: 202-785-0072  
Email: [oletouze@psi.org](mailto:oletouze@psi.org)

---

## Contents

<b>Executive Summary .....</b>	<b>6</b>
<b>1) Description of study and data .....</b>	<b>8</b>
<b>i) Context / Background.....</b>	<b>8</b>
<b>ii) Aims and Objectives of the study .....</b>	<b>10</b>
<b>iii) Study design .....</b>	<b>11</b>
a) Study process .....	11
b) Number of interviews .....	12
c) Recruitment of interviewees.....	14
d) Data collection .....	15
e) Data analysis .....	16
<b>2) Interpretation of data .....</b>	<b>17</b>
<b>i) Perceptions related to HTC .....</b>	<b>17</b>
<b>ii) Previous experience with self-testing.....</b>	<b>18</b>
<b>iii) Perceptions of HIV self-testing .....</b>	<b>18</b>
<b>iv) Perceived benefits of HIV self-testing .....</b>	<b>19</b>
<b>v) Concerns about HIV self-testing .....</b>	<b>20</b>
<b>vi) Distribution of HIV Self Test Products.....</b>	<b>21</b>
a) Health Centers as Distribution Channel.....	22
b) Pharmacies as Distribution Channel .....	23
c) Alternate Distribution Channels.....	25
<b>vii) Packaging considerations .....</b>	<b>26</b>
a) Tertiary Packaging Considerations.....	26
b) Secondary Packaging Considerations .....	27
c) Primary Packaging Considerations—Instructions for Use and Other Packaging Inserts .....	32
d) Primary Packaging Considerations—Sachet and other Physical Test Components .....	38
<b>viii) Summary findings from Phase II – Reaction to packaging mockups.....</b>	<b>41</b>
<b>3) Conclusions and Recommendations .....</b>	<b>43</b>
<b>i) Summary conclusions .....</b>	<b>43</b>
<b>Annex 1 – List of References .....</b>	<b>51</b>
<b>Annex 2 - Document review – Review of international and national policies that affect HIV self-testing .....</b>	<b>52</b>
<b>Annex 3 - Creative brief .....</b>	<b>64</b>
<b>Annex 4 – Kenyatta Hospital ethics board approval letter .....</b>	<b>71</b>
<b>Annex 5 – PSI Research Ethics Board approval letter .....</b>	<b>73</b>
<b>Annex 6: Packaging mockups tested during Phase II - Avow .....</b>	<b>74</b>

<b>Annex 7: Packaging mockups tested during Phase II - Cogni .....</b>	<b>75</b>
<b>Annex 8: Potential Self-Test Kit Distributors - Discussion Guide.....</b>	<b>76</b>
<b>Annex 9: Pharmacists - Focus group discussion Guide .....</b>	<b>81</b>
<b>Annex 10: Health providers - Triad discussion guide.....</b>	<b>86</b>
<b>Annex 11: Potential HIV self-test kits users - interview discussion Guide for Phase 1 .....</b>	<b>90</b>
<b>Annex 12 – Phase II discussion guide.....</b>	<b>96</b>
<b>Annex 13: Informed Consent: Potential Distributors of HIV Self-Test Kit.....</b>	<b>100</b>
<b>Annex 14: Informed Consent: Potential users of HIV Self-Test Kit .....</b>	<b>102</b>

## Executive Summary

This report presents the findings from a 2013 qualitative research study on how to effectively package and label HIV oral self-test kits for a Kenyan market. In response to 3ie's Thematic Window #2, entitled "HIV Oral Self-Testing", PSI and IPSOS engaged key policy makers, test manufacturers, packaging experts and potential test kit users in a provocative discourse that could shape the future for HIV testing and counseling in Kenya and other African settings. Packaging and labeling of a product, particularly a product that carries enormous clinical and social implications, is crucial to both the product's efficacy and marketability. Packaging and labeling protects the product, communicates important information (such as contents and instructions for use), facilitates easy usage, ensures client safety and markets the product to potential consumers. In order to gain insights on how to package and label the HIV oral self-test kit, which is a new product not yet on the Kenyan market, PSI and IPSOS conducted in-depth interviews and focus group discussions with key stakeholders. These included Kenyan government regulatory officers, HIV oral self-test kit manufacturers, packaging experts, potential distributors and potential users. Potential users included members of the general population and two key populations at high-risk for HIV transmission; men who have sex with men (MSM) and female sex workers (FSW). The variety of participants in the study enabled the researchers to analyze packaging and labeling from various perspectives, including how to approach key decisions that impact distribution, client safety, and product promotion. The study took place in Mombasa (an urban setting) and Siaya, a rural district of Nyanza province in the southwest of Kenya.

Stakeholders were asked to provide insights related to 1) the regulatory environment for HIV oral self-test kits and the implications of those regulations for packaging and labeling; 2) considerations for product stability, both within the supply chain during procurement processes as well as with end-users; 3) how packaging and labeling of the product can ensure accurate use, including the facilitation of pre and post-test counseling services and appropriate disposal of the used test kit; 4) users' preferences for packaging design; and 5) viability and costs of producing new test kits and over-branding or co-branding existing kits.

The study included two phases. During the first phase, potential test-kit users were asked to react to the concept of HIV self-testing and to provide feedback on an existing HIV oral self-test kit called AWARE. AWARE is not currently on the market but has been tested with community health workers in Kenya. Results from the feedback were used to develop two new packaging mock-ups, which were then tested again with potential test-kit users during the second phase of the study. This report presents full findings of phase one, and summary findings of phase two.

Data analysis revealed several benefits and challenges of HIV self-testing that appropriate packaging and labeling may be able to address. Overall, interviewees responded positively to the idea of HIV self-testing, noting increased privacy, confidence, and personal empowerment as possible advantages of the product. However, pharmacists and community health workers did express several concerns pertaining specifically to the shift of responsibility from the health provider (in a traditional HTC setting) to the end-user (in a HIV self-testing setting); mainly that the end-user is responsible for accurately administering the test, interpreting the results and accessing pre and post-test counseling. Concerns were exacerbated during discussions about the potential for a HIV positive test result. Regulatory officers and packaging experts spoke largely to considerations for tertiary packaging, including the size, weight, and durability of the package and implications of these for different distribution channels. Labeling information such as storage temperature, fragility, batch numbers, expiration date, manufacturing dates and shipment dates were also discussed extensively.

These stakeholders also spoke to essential elements of secondary and primary packaging that facilitate accurate and effective use of the product including the way text and illustrations are presented, the ergonomic design of the package, and how information about the product is presented on the outside and inside of the test kit package.

Potential users noted the importance of sturdy materials for secondary and primary packaging, in order to communicate a high quality product. They stressed the importance of using simple language on the packaging, particularly with reference to the purpose and contents of the kit. Emphasis was placed on the instructions for use and how to strike a balance between simplicity and comprehensiveness.

The insights and recommendations collected through this study can be used to develop an oral HIV self test kit for distribution in Kenya. If packaging and labeling is designed optimally, potential consumers will be able to safely, accurately, and privately test themselves for HIV and access additional services to ensure their own health and the health of others.

## 1) Description of study and data

### i) Context / Background

Population Services International (PSI), and its local affiliate organization, PSI/Kenya responded to the request for proposals entitled, “HIV Oral Self-Testing”, under 3ie’s Thematic Window #2, as an opportunity to build evidence towards understanding how to effectively maximize uptake of HIV oral self-test kits in Kenya, as well as in other countries with a similar context. PSI was selected to conduct research to inform Question #2: **How should HIV self-test kits be packaged and labeled?**

The Government of Kenya (GoK) has adopted the Joint United Nations Program on HIV/AIDS (UNAIDS) strategy of Universal Access to HIV Prevention, Treatment, Care and Support as a key objective in the current Kenya National AIDS Strategic Plan 2009–2013 (KNASP III). As part of this strategy, the GoK is eager to achieve knowledge of HIV status among 80% of the population.<sup>1</sup> Knowledge of HIV status is necessary for increasing access to HIV treatment and has been shown to positively influence sexual risk behaviors, especially among persons who test positive for HIV.<sup>2</sup>

To reach an 80% target, the National AIDS and STD Control Program (NASCOP) has introduced new approaches to increase uptake of HIV testing and counseling (HTC), including an increased emphasis on couples testing, national HIV testing campaigns and expanded service delivery models. Currently, both client and provider initiated models of HTC are made available through workplaces, mobile outreach, home-based and health facility-based services. In these models, HTC services are administered by Ministry of Health (MOH)-trained providers using a serial testing algorithm that employs up to three MOH-approved whole blood ultra-rapid HIV tests. These test packages include a screening test using Diagnostic Kit for HIV (1+2) Colloidal Gold, a confirmatory test using First Response HIV 1-2-0 Card Test and a ‘tie breaker’ test using Unigold HIV-1/HIV-2.<sup>3</sup> After testing, individuals are provided post-test counseling and referred to appropriate services based on their HIV status.

Today, there are approximately 6,000 existing HTC sites across the country, and knowledge of testing facilities is high, such that a majority of adults (95%) and youth (88%) report knowing where one can get tested for HIV.<sup>4</sup> Rates of HIV testing have increased steeply in Kenya, with 72% of adult Kenyans reporting that they had ever tested for HIV in 2012 versus 34% in 2007 (in 2012: men: 63%; women: 80%), and 67% that had tested more than once in their lifetime.<sup>5</sup> Despite this sharp increase, innovative HIV testing models are needed to address barriers to testing among individuals who remain unaware of their status.

---

<sup>1</sup> Kenya National AIDS Strategic Plan 2009/10-2012/13 (KNASP III). Accessed 26 February 2013 at: [http://www.nacc.or.ke/index.php?option=com\\_content&view=article&id=112&Itemid=87](http://www.nacc.or.ke/index.php?option=com_content&view=article&id=112&Itemid=87).

<sup>2</sup> Denison JA, O’Reilly KR, Schmid GP, Kennedy CE, Sweat MD. HIV voluntary counseling and testing and behavioral risk reduction in developing countries: a meta-analysis, 1990–2005. *AIDS Behav.* 2008;12(3):363-373.

<sup>3</sup> Ministry of Public Health & Sanitation, Approved HIV Testing Algorithm.

<sup>4</sup> Kenya Demographic Health Survey (DHS). 2009. Accessed online 28 February 2013 at: <http://www.measuredhs.com/publications/publication-FR229-DHS-Final-Reports.cfm>

<sup>5</sup> 2012 Kenya AIDS Indicator Survey (KAIS). Preliminary Report. Available online at: <http://nascop.or.ke/library/3d/Preliminary%20Report%20for%20Kenya%20AIDS%20indicator%20survey%202012.pdf>

Oral HIV self-testing presents an opportunity to increase testing coverage by addressing key barriers to HIV testing uptake: limited access to HIV-testing and HIV-related stigma and discrimination.<sup>6,7</sup> By allowing individuals to access tests where and when they procure other health commodities, self-testing may make HTC more convenient and accessible for individuals who would no longer be required to seek testing services from a facility-based or mobile testing service. Once procured, a self-test may also increase an individual's perception of testing privacy by allowing him/her to choose where and when to administer the test.<sup>8,9</sup> This may remove many of the concerns related to HIV testing, including lack of privacy, inconvenience, stigma and discrimination. Moreover, preliminary research suggests that oral self-testing is a feasible and acceptable response to increasing HIV testing uptake in Kenya and other African settings.<sup>10,11</sup>

Appropriate packaging and labeling is one of many key elements to determine when bringing a new health product to market. The packaging and labeling of health commodities serves several purposes such as protecting the product, arranging specific elements of the product to facilitate easy usage, relaying information about the contents and how to use the product, ensuring safety and marketing the product to potential consumers. **Packaging** typically consists of three layers: primary, secondary and tertiary.

- The primary packaging is the first packaging layer in which the product is contained (e.g. the individually packaged components of an HIV test).
- The secondary packaging is used to group various pre-packaged products together (e.g. a box that contains an HIV test kit, additional information on administering the test and key counseling messages).
- The tertiary packaging is used for bulk handling and shipping (e.g. a large box containing multiple self-test products).

Each of these layers of packaging serves a specific purpose and can be used to communicate different information based on the desired target audience. For example, the primary and secondary packaging for a self-test kit would need to communicate information to consumers about how to use the test and interpret its results while also communicating specific information about what to do given the test result. Tertiary packaging would need to communicate how to store and transport the product to maintain quality.

**Labeling** specifically refers to the text, visuals and any other elements (e.g. bar codes) on packaging and on the package insert to communicate the correct use of a given product, as well as mandatory regulatory information such as test kit name, name of manufacturer, type/s of specimens on which the test can be used, shelf life, expiration date, lot number, country of manufacture, distributor and other information as may be required by the drugs regulatory agency in the country of distribution. For products targeted directly at consumers, labeling must use clear, simple language and visuals.

---

6 Spielberg F, Levine R, Weaver M. (2004). Self-testing for HIV: a new option for HIV prevention? *The Lancet Infectious Diseases*, 4, 640-646.

<sup>8</sup>Kachroo S. (2007). Promoting self-testing for HIV in developing countries: potential benefits and pitfalls. *Bulletin of the World Health Organization*. 84(12): 999-1000.

<sup>9</sup>National Guidelines for HIV Testing and Counseling in Kenya

20 WHO, 2011. HIV self-testing among health workers: a review of the literature. Accessed February 23, 2013 at: <http://www.who.int/hiv/pub/vct/9789241501033/en/index.html>. 20 WHO, 2011.

<sup>10</sup>Population Council. (2007). *Knowing Myself First: Feasibility of self-testing amongst health workers in Kenya*.

<sup>11</sup>Choko AT, Desmond N, Webb EL, Chavula K, Napierala-Mavedzenge S, et al. (2011) 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 Med* 8(10): e1001102. doi:10.1371/journal.pmed.1001102.

Due to its ease of use, the oral HIV self-test (as opposed to tests that require a blood sample through a finger prick) is thought to be the most promising development in the HIV testing sphere. The oral self-test for HIV is conducted by using a mouth swab to collect antibodies located on the upper and lower gums and mixing the sample collected with a liquid reactive. The swab is then submerged into the liquid. The result can be read between 20 and 40 minutes later.

The United States introduced HIV oral self-test kits into the market in 2012. Since then, a handful of developing countries have worked on adapting the test for their own markets, as product designed in the United States for a United States audience cannot simply be placed in a market elsewhere. While no HIV self-testing product is yet available in Kenya, two oral HIV self-test brands, AWARE and Orasure, are viable candidates for introduction into Kenya in the near future. AWARE's packaging has been tested with community health workers in Kenya during a study in 2011, with a positive response.

## ii) Aims and Objectives of the study

The **primary aim** of this study is to understand how HIV oral self-test kits should be packaged and labeled for a Kenyan market. The findings of this study, as well as other formative research on HIV self-testing in the country, will inform the potential introduction of self-testing in Kenya. As per the proposal submitted to 3ie, the questions that the study addressed were:

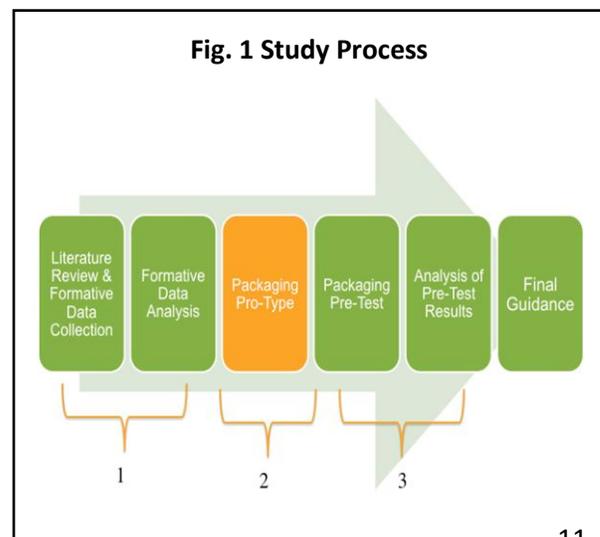
- 1) What are the GoK's existing or planned regulations and considerations regarding the packaging and labeling of medical products that are applicable to the HIV oral self-test? In the global HIV testing community, what are the key considerations regarding a HIV oral self-test kit's labeling and packaging?
  - What information must be included on the packaging, based on GOK regulations and policy, including any local language considerations?
  - What information should be considered for inclusion based on global best practices in HIV testing and counseling, and self-test kit packaging and labeling experience in other countries?
  - What is the regulatory authority's review process, if any, for HIV oral self-test kit packaging and labeling? How long does this process take?
- 2) Do test kit manufacturers have any considerations related to packaging and labeling?
  - What is the manufacturer's position with regard to re-packaging of test kits and to which part of the packaging do any limitations/restrictions apply (i.e. primary, secondary, tertiary packaging)?
  - What is the manufacturer's position with regard to over-branding of test kits?
  - Does the manufacturer require that it approve artwork and packaging prototypes prior to finalization? How long does this process take?
  - What are the cost considerations related to packaging and labeling from a manufacturer's point of view?
- 3) What considerations and related packaging and labeling designs and instructions should be explored to ensure the test kits are:
  - Stable in humid and hot environments, including during shipping and storage;
  - Physically secure so the buffer vial and test kit are not impacted during shipping, handling and storage;

- Packed in quantities that are both low cost and practical at all levels of the distribution system, including pharmacies; and
  - Used within the shelf life (including identification of innovative ideas such as using a label that changes color once expired, e.g. vaccine labels, or a mobile phone text message notification to the customer based on the test lot number)?
- 4) How can packaging and labeling of the product ensure accurate use of the self-test kit by intended users?
- What instructions for use must be included in the packaging to ensure consumers use the test kit accurately (including specimen collection, processing and interpretation of the test results)?
  - What methods and channels (e.g., instructions in the kit, video, helpline) should be used to provide instructions for use regarding accurate test kit use?
  - What aspects of the primary and/or secondary packaging can be used to facilitate adherence to testing instructions?
  - What aspects of the primary and/or secondary packaging can be used to facilitate correct interpretation of the test results?
  - What aspects of the primary or secondary packaging can be used to provide relevant information on linking to onward testing and/or care, based on the test result?
  - What aspects of the packaging can be used to facilitate appropriate disposal of test-related waste?
- 5) What are potential users' and providers' preferences of the packaging design?
- What is the preferred packaging design and features for ease of use?
  - What is the preferred packaging design and features for ensuring privacy for users?
  - What are key elements of packaging and labeling that could increase demand for self-test kits at point of sale? These include shape and size of the package and location of kit display.
  - What are distributors' and users' initial reactions to the labeling and packaging of the OraQuick self-test kit currently marketed in the US?
- 6) What is the estimated cost for producing the existing OraQuick In Home HIV Test kit versus an oral self-test kit prototype that has modified packaging and labeling elements to address key considerations in the Kenyan (and wider African) operating context?

### iii) Study design

#### a) Study process

The study was a multi-stage process conducted by four stakeholders: PSI/Washington, PSI/Kenya, IPSOS/Public affairs USA in Washington, DC and IPSOS/Kenya. The study involved a literature review, qualitative data collection, development of mockups and analysis of data collected through pre-testing of the mockups. The stages can be summarized as follows:



- PSI developed and submitted the study protocols to two ethics review boards: a Kenyan Board (Kenyatta Hospital), and PSI's research ethics board in Washington, DC. Approval was obtained respectively on September 12, 2013 and September 23, 2013. Approval letters are attached (Annex 4 and 5).
- PSI reviewed international and national standards and guidelines on HIV counseling and testing to make sure the self-test kit includes critical information to maximize appropriate, accurate and safe use of the product. Items for review included the Kenyan and World Health Organization (WHO) guidelines on HIV counseling and testing, and the United States Food and Drug Administration regulations on oral HIV self-testing. This review was synthesized in a document included in Annex 2.
- Data collection- Phase 1 – October 2013 (*Step 1 in Figure 1*)
  - All study instruments (discussion guides and consent forms) were developed jointly by PSI/Washington, PSI/Kenya, IPSOS/Kenya and IPSOS/Public Affairs USA. .
  - IPSOS/Kenya conducted key informant interviews with relevant Government of Kenya regulatory officers to understand specific regulations and considerations for self-test kits.
  - PSI/Washington conducted key informant interviews with oral HIV test kit manufacturers, global regulatory bodies, packaging experts and international HIV testing experts to understand restrictions placed on re-packaging and re-labeling of these products, packaging best practices to support accurate use, and key considerations for ensuring product stability.
  - IPSOS/Kenya conducted in-depth interviews (IDIs) with potential users and distributors (pharmacists and healthcare providers) to explore what information and packaging components are necessary to ensure accurate use, including correct interpretation of test results and use of the kit prior to expiration. These interviews also identified consumer preferences for the delivery of usage instructions, including where in the test kit packaging to provide referral information for onward testing and/or care. These in-depth interviews also explored packaging preferences that might increase demand at point of sale. PSI/Kenya supported interviewer briefing for this stage of the study. Additionally, PSI/Washington and IPSOS/Public affairs USA teams traveled to Nairobi for a week in October 2013 to brief and train the team of IPSOS/Kenya interviewers, as well as conduct pilot interviews to test the discussion guide.
- IPSOS/Public Affairs USA coded and analyzed the data with input from PSI/Washington. Based on data collected, PSI/Kenya contracted an advertising agency to develop two additional prototypes of self-test packaging, each with instructions for use that reflect recommendations made by potential test kit consumers that participated in the study. During prototype development, quotes for production of the packaging were sourced from potential packaging/labeling manufactures. (*Step 2 in Figure 1*)
- Data collection - Phase 2 - January 2014 (*Step 3 in Figure 1*)
  - IPSOS/Kenya pre-tested the new mock-ups using in-depth interviews and observation with potential test-kit users and distributors, exploring whether the packaging and labeling facilitates accurate use of the product, with appropriate interpretation of test results.
- PSI/Washington and IPSOS/Public Affairs USA analyzed data and developed a report that documents findings and makes recommendations for packaging and labeling of the HIV oral self-test kit for a Kenyan market. This document, combined with findings from other Phase 1 research questions, will inform final packaging and labeling decisions in phase two of the project.

## **b) Number of interviews**

Qualitative research methods were used to answer the study question because of the method’s ability to generate insights about the product’s chief qualities for packaging and labeling: attractiveness, compliance and comprehension. As for all qualitative studies, the sample size was not determined to be representative of a population, but rather to gather a diversity of perspectives until “data saturation” (e.g. until respondents’ answers converged and the information shared with the researcher becomes repetitive and contains no new ideas) was reached. Experience with similar studies is what helps assess when data saturation is likely to be reached and how many interviews are needed. The numbers we proposed are based on IPSOS’ decades of experience doing packaging research and on PSI’s own experience.

**Table 1: Number of HIV self-test kit potential users interviewed by target population: Phase I**

	FSW	Gen. Pop.	MSM	Total
<b>Mombasa</b>				
F	2	4		6
M		4	5	9
<b>Siaya</b>				
F	3	4		7
M		4		4
<b>Total</b>	<b>5</b>	<b>16</b>	<b>5</b>	<b>26</b>

To achieve this diversity of perspectives, PSI interviewed the following groups:

- *Key policy makers and regulatory officers of the Government of Kenya:* Five in-depth interviews (IDI) were conducted with this population.
- *Oral HIV test kit manufacturers:* Two IDIs were conducted with the manufacturer of Oraquick.
- *Potential product distributors, particularly pharmacists and health care providers:* One focus group discussion (FGD) with 8 pharmacists took place in Mombasa, and one triad with community health workers took place in Siaya. One triad with pharmacists took place in Mombasa during phase 2.
- *Potential self-test kit users:* This included the general population of adults ages 18-49 years and key populations, specifically men who have sex with men (MSM) and female sex workers (FSW). All participants had a negative or unknown HIV status (by self-report). Twenty six IDIs were conducted during the first phase, and twenty during the second phase.
- *Packaging manufacturers and regulatory authorities:* One IDI was conducted with the Indian Institute for Packaging. Two IDIs were conducted with product regulators. One was a representative from the World Health Organization, the second a former regulator of HIV test products at the US Food and Drug Administrator.
- *International HIV Test Experts:* We conducted IDIs with three experts in HIV testing, and self-testing in particular.

**Table 2: Number of HIV self-test kit potential users interviewed by target population – Phase II**

	FSW	Gen. Pop.	MSM	Total
<b>Mombasa</b>				
F	2	3		5
M		3	4	7
<b>Siaya</b>				
F	2	3		5
M		3		3
<b>Total</b>	<b>4</b>	<b>12</b>	<b>4</b>	<b>20</b>

The study was conducted in both an urban setting (Mombasa) and in a rural district of Nyanza province in the southwest of Kenya (Siaya). It was believed that these two settings would yield a diverse array of perspectives that might help determine what packaging and labeling options would be most effective for a wide and varied audience.

### **c) Recruitment of interviewees**

To be included in the study, all participants had to be willing to provide informed consent. Professional audiences (pharmacists, community health workers, manufacturers, policymakers) were sampled purposively. Policymakers and regulatory officers, test kit manufacturers, packaging manufacturers and HIV testing experts were recruited based on their role within international or Kenyan regulatory bodies, their experience with oral HIV test kit packaging or their experience with the packaging of health products, including diagnostics for in-home use. Professional audiences did not meet the definition of human subjects participants, and the only inclusion criteria was that they needed to be 18 years or older.

Potential self-test kit users, who met the definition of human subjects participants, were sampled using two methods.

For each city, general population participants were sampled by sex (half male, half female), age (18-49 years old), and HIV status (all needed to self-report that their HIV status was negative or unknown). Selecting those with an unknown or negative HIV status was required because these individuals are most representative of potential consumers of HIV self-test kits. To minimize participants' discomfort and to ensure privacy when responding, participants were asked to report their HIV status using flashcards rather than verbalizing their response.

One district in each city was randomly selected. Within each district, a community or ward was randomly selected. Then households and participants within the selected community or ward were purposely selected, stratified by gender and age. Recruitment was conducted door to door. Per established procedures, a randomly selected starting point was designated in the area. Interviewers were instructed to proceed from the starting point in a designated direction (e.g., the address to the right of the starting point). Since the study was not designed to obtain a statistically representative sample of the general population, households with nobody at home were skipped and there were no callbacks. Interviewers had quotas to fill based on respondents' gender and age.

As part of recruitment protocol, interviewers approached the residence and introduced the study to a person opening the door. The interviewer visually assessed whether the person opening the door was over 18. If a child opened the door, the interviewer asked the child to summon an adult member of the household. After the informed consent procedure, the interviewer administered a screener. No other members of the household were required to participate in any aspect of the study. If the individual screened did not qualify for the study, or the screener indicated that the participant belonged to an age quota that was already filled, the interviewer moved onto the next residence. If a particular gender quota was filled, and the person opening the door was identified as over 18 and of the gender corresponding to the filled quota, the interviewer asked to speak to someone in the household of the opposite gender. If no such person was there, the interviewer moved on.

Snowball sampling (in which peers refer peers to the study) was used to recruit MSM and FSW for study participation. Key informants from each target group were asked to refer other potential participants. Snowball sampling is often employed in qualitative research to recruit hard to reach populations. PSI/Kenya supported this component of the study by coordinating with NGOs that manage drop-in centers and programs with key populations. Initial contacts in MSM and FSW groups were given cards with a request to participate and the researchers' contact information. Key informants did not receive

incentives for recruiting peers. For the purpose of this study, FSWs were defined as women, 18 years of age or older, who reported selling sex for money, drugs, or goods to a man at least once in the past 3 months. MSM were defined as men, 18 years of age or older, who reported having anal/oral sex with another man at least once in the past 3 months.

International stakeholders did not receive any compensation for participating in the study, nor did Kenyan policymakers. Potential test kit users received 500 Kenyan shillings (this amount buys a non-street lunch style meal at a food court or a medium ranged restaurant. It is the minimum daily wage of an unskilled worker). Pharmacists and community health workers received a compensation of 2,500 Kenyan shillings, as these audiences typically require higher compensation to participate in research, particularly focus groups, which last much longer and require transportation. Based on IPSOS' experience doing research with these audiences, 2,500 Kenyan shillings is an adequate amount to ensure participation of these target audiences in focus group discussions. All compensation was provided in the form of vouchers, which are gift certificates for large retail outlets like supermarkets. Vouchers do not contain any personally identifiable information.

#### **d) Data collection**

Different data collection methods were used for the different audiences. IDIs were chosen for potential HIV self-test kit users given the sensitivity of the topic and the personal nature of the decision to take an HIV test. IDIs were also chosen for international and Kenyan policy makers and test manufacturers so that their technical expertise and insights could be captured in full detail. Focus groups and triads were used with pharmacists and community health workers to generate discussion and debate.

All interviews, focus groups and triads took place face-to-face, except for interviews with international stakeholders, which were conducted by telephone. Prior to administering the screening questionnaire, interviewers obtained informed consent from participants and assured confidentiality of their responses. Interviewers read the consent form to participants and answered any questions. If the participant consented, he or she was asked to sign the consent form to acknowledge his/her understanding of the purpose of the study, the risks and benefits of participation and their willingness to participate in the study. Those unable to sign were asked to provide a personal mark.

The interviews, focus groups and triads was audio-recorded, with participants' permission during the informed consent process. Interviews, focus groups and triads with professional audiences were all conducted in English, while interviews with potential test-kit users were conducted in whichever language they felt comfortable: English, Luo or Swahili. Audio recorded interviews were transcribed in the language of the interview and where relevant, transcripts in a language other than English were translated into English. No personal identifying information other than participant IDs were included on the recordings. If a respondent inadvertently mentioned potentially personally identifiable information, this information was removed from the transcripts. All study data and material were stored on a secured computer using power-on and login passwords with backup copies of the data stored on secure backup devices only after adequate file encryption. Similarly, any file transfers between locations used secure file transfer (FTP) protocols.

Discussion guides for different target populations and consent forms are attached in Annexes 8 to 14.

## **e) Data analysis**

Anonymous audio-recorded data from the IDI and FGD were transcribed as a Microsoft Word file and transferred into MS Excel for analysis. The data was coded to identify common patterns and salient themes, stratified by target population. IPSOS / Public Affairs USA led the process of qualitative analyses, and PSI supported interpretation of themes. The process included the following steps:

- Two coders reviewed a subset of interviews in parallel, identifying specific themes in response to each interview question
- Coders convened to review major themes, looking for agreements and disagreements in their analyses.
- The IPSOS / Public Affairs USA research team then reviewed the coders suggestions for themes, and provided operational definitions.
- Two coders proceeded to code the transcripts, identifying themes based on the operational definitions
- If specific statements by the respondents did not fit the established definitions of the themes, coders proposed additional themes as necessary.
- The research team reviewed coders' suggestions and either developed definitions for a new theme or clarified the definitions of the existing theme
- At the end of coding, the agreement between coders was assessed

Findings from the analysis were summarized, compiled and used to develop the final report.

## 2) Interpretation of data

Please note that all findings from i) to vii) relate to Phase one, which included general discussions about HIV self-testing, and assessing reactions to a stimulus packaging (AWARE). Summary results from Phase two, which included reactions to new stimuli developed based on the inputs of Phase one, can be found in section viii).

### i) Perceptions related to HTC

#### *Potential Users*

Awareness of HTC centers was universal among all target populations, and getting tested in a hospital or a clinic was described as the **established practice**, because of the perceived quality of counseling and reliability of results. However, all potential HST kit users (including key populations) said that **taking an HIV test remained a difficult thing to do**, particularly for the first time. In addition to the fear of being diagnosed HIV positive, the vast majority of interviewees associate HTC with elements that they consider intimidating: having blood drawn, anxiously waiting for the results, the perception of being judged by others, being recognized by someone at the clinic, and having to receive potential life-changing diagnosis from a stranger (or authority figure, as many people, particularly key populations, do not trust health providers).

*"Before I went to the VCT center to be tested I was very nervous, there was a day I went to a VCT center in Ganjoni and I joined the queue and when I was about to get in I panicked instead of getting inside I went away due to fear, I did that about three times and the fourth time I decided to get inside [...]"*, MSM, Mombasa

*"At the hospital you might think that this person knows me and he is going to expose me."*, Female, General Population, Mombasa

Many respondents explain that taking an HIV test is a somewhat solemn 'moment of truth' **to take responsibility** for their past unsafe sexual activity. Potential users report handling this differently from one another. Most say they **prefer to be in control of that moment**, but some feel reassured to have specialists handle it. Most interviewees saw value in the counseling received in clinics and HTC centers.

*"You know that when you were drunk you did things that were not morally upright like without using protection"*, MSM, Mombasa

*"You are the person who has decided to go for it. You know it always becomes difficult when somebody else tells you"*, Female, General Population, Mombasa

*"Interpretation of the result for someone who is self-testing would be a challenge without a professional trained counselor."*, Male, General Population, Siaya

The participants' comments speak to the need for intentionality when framing the oral HIV self-testing message. The goal is not to replace facility-based HTC with self-testing as a gold standard. Rather, the goal is to reach those people with self-testing who would otherwise not test in a clinic. Furthermore, it is imperative that the self-test kit be packaged and labeled in a way that facilitates access to appropriate post-test counseling, onward confirmatory testing and treatment and care services.

## ii) Previous experience with self-testing

### *Potential Users*

Most potential HIV self-test kits users that participated in the study had already heard of some form of self-testing product. For instance, the large majority of female participants were familiar with pregnancy self-tests. Other types of self-test kits less frequently mentioned included those for malaria, diabetes and blood pressure. Since HIV oral self-test products are new to the market, it was helpful that participants were familiar with other types of self-test kits so that they had some measure of experience and perspective to base their feedback on. Interviewees reported that they liked the low cost practicality and convenience of taking a test at home. Those who had used other types of self-test kits perceived them as a good way to monitor a condition.

*"I had sugar which was very high [...] When I have a headache and I feel like my pressure is high and I am not sure, I have to test and when it is high, it helps me to get medical [attention if needed] before things get worse."*, Female, General Population, Mombasa

*"It was a lot cheaper, convenient and private to use the [pregnancy] self-test"*, Female, General Population, Siaya

*"It is simple when you have been educated about the results; it is easier to check your results and understand"*, Female, General Population, Mombasa

### *Influencers*

Some pharmacists expressed concerns with pregnancy self-test kits, because customers administer and interpret the test results on their own without professional intervention. This also illustrates pharmacists' concerns over their potential liability, or at least moral responsibility, towards their clients.

*"Pregnancy test. When you give them without knowing the patient well, and maybe she will misuse and get wrong results, something there may go wrong."*, Pharmacist, Mombasa

Most of the perceptions that providers had of the costs and benefits of self-testing for other conditions (e.g. pregnancy, diabetes) were also echoed in discussions about the HIV self-test kits. At the crossroads between a user-group that sees enormous benefits to HIV oral self-testing, and a provider group that is more cautious in its enthusiasm, packaging and labeling will play a key role in ensuring the product responds to users' needs while also supporting pharmacists to comfortably provide it.

## iii) Perceptions of HIV self-testing

### *Potential Users and Influencers*

Perceptions varied greatly between potential HIV self-test kit users and professionals (pharmacists and community health workers). While **all potential users were enthusiastic** about the product when the concept was explained, most **professionals expressed reservations** because of the lack of follow-up counseling support to users after receiving results. Several interviewees understood the potential of HST to increase HIV testing rates, and were supportive of it.

*"It [HIV self-testing] will help many people know their HIV status then of course they can live right"*, Female, General Population, Siaya

*"That is wonderful, it is better than getting to be tested at VCT or clinics... Many people will be comfortable because many people fear going to the clinic", Male, General Population, Mombasa*

*"It will be a challenge to recommend to someone who has never done the testing or unless you do it with the person there. I will not recommend that they do it at home.", Community Health Worker, Siaya*

Interviewees thought that HST kits could be used for both first-time and repeat testing. Many perceived that the product could provide a "boost of confidence", which can overcome the nervousness of first time testing, while others reported that HST could make routine repeat testing easier. Interviews indicate that HST is perceived as a first step towards knowing one's HIV status. Several interviewees wanted to have their results confirmed at a HTC center, whatever the outcome of the HIV self-testing process.

*"[HIV self-test kits] offer privacy, and added confidence in subsequent testing. ", MSM, Mombasa*

*"Maybe if I am not satisfied [after using a HST kit], then I can visit the VCT to be more satisfied.", Male, General Population, Mombasa*

#### **iv) Perceived benefits of HIV self-testing**

##### *Potential Users*

Some key benefits sought from potential users emerged from interviews. The key benefit mentioned by all participants is the the **added privacy** that HST kits offer compared to traditional HTC in health centers. This addresses one of the barriers that interviewees mentioned when they talked about HTC: the fear of being judged or recognized. As described earlier, HIV remains a highly sensitive and personal matter, and many perceive that taking an HIV test at home would put them in better conditions to face the results, without any interference from other people.

*"It is good because many people are too shy to go to the VCT due to lack of privacy. Someone might feel that if they walk inside the centers and they look sad, other people at the center will start to assume that they are HIV positive... the self-test kit is better.", MSM, Mombasa*

*"Some of these counselors, some of them are our friends, and some know us, and some make you uncomfortable, so it's better if I test myself", FSW, Mombasa*

*"I would be very happy if I can use the self test kit at home. I will not be stressed of going to sit at the clinics. [...] You will be confident to check the results because no one is watching you", FSW, Mombasa*

HIV self-test kits also offer clear **convenience and ease of use** benefits for the user, at several levels. The mouth swab is perceived as less intrusive and easier to administer than a blood test. The gesture of using the swab is seen as simple and makes HST kits user-friendly and approachable. It can be inferred from interviewees' replies that HST kits are perceived to be moving away from the medical, controlled product category, into the category of mainstream products. Taking an HST kit at home is also perceived as saving time compared to taking the test at a HTC center. This addresses both concerns about the anxious wait for results, and the time spent going to and waiting at the health center.

*"You don't need to pierce any part of your body or squeeze any fluid out of your body. So it is good, you just rub on the gums and dip it in the kits test and you get the result which is very good.", MSM, Mombasa*

*"The self-test will save me time. I am a busy woman and I might not get time to run to the VCT, but with this test kit, I will have adequate time to carry out the test in my house.", Female, General Population, Siaya*

HST kits are also perceived as an **empowering** product. As discussed previously, potential users expressed strong preference towards being able to control the testing process as a way to take control of their lives and demonstrate responsibility.

*"Like I mentioned, I like going out and many things happen when we go out. So, if you are in doubt of your behavior, you have to be responsible and take control of your life", MSM, Mombasa*

*"I monitor my life status so I know my ways", Male, General Population, Mombasa*

*"It will make you comfortable because you have seen the results yourself", Male, General Population, Mombasa*

## **v) Concerns about HIV self-testing**

### *Potential Users and Influencers*

While the perceived benefits of HIV self-test kits addressed many of the perceived shortcomings of HTC, potential users also voiced some concerns. Since the product is very new, many interviewees expressed distrust of the product, and a couple of participants qualified the HST kits as a "gadget". Product credibility is not yet established for most users, and this is clearly a topic that HST kits will have to address. In a market where consumers are worried about counterfeit drugs, this will be essential. Potential users have their own strategies to minimize the uncertainty around buying drugs (checking expiration dates, checking the integrity of the box). Given this, HST kit packaging should make it easy for consumers to be reassured of product quality (visible stamp of approvals, signs of quality and certifications).

*"Some people will start saying that we have been brought for some gadgets that probably have side effects and others [...] will start questioning about the authenticity of this gadget ", MSM, Mombasa*

*"Before I trust the gadget I need to have tried using it like twice.", Male, General Population, Mombasa*

The mode of collection of the specimen also raised questions. Most interviewees understood that the device collected saliva, which is inconsistent with what they know about HIV modes of transmission. This led some interviewees to either question the solidity of their own knowledge, or to doubt whether this method can produce results with a level of accuracy similar to blood tests. Some interviewees were wondering about the sensitivity of the test.

*"if I am wrong you correct me, the virus is only in 4 fluids in the body, which is the blood, vaginal fluids, the semen, and the breast milk.", Female, General Population, Siaya*

*"We have always said that you cannot get HIV from for example kissing so if the kit we introduce is oral based there will be fears people will say if I can diagnose HIV from my mouth, what you have been telling me is a lie", MSM, Mombasa*

*"[...] this self-test kit [is] so sensitive [...], it means that it might be very sensitive to any virus which of course means that if it is positive you cannot be very sure that you are HIV positive or maybe you are positive for another virus [...].", Male, General Population, Siaya*

While most potential users like the idea of performing the test by themselves in the comfort of their home, they expressed concerns about how they would react to the results. The HST packaging provided as stimulus for the study did not include a list of referrals nor contact details for a counseling hotline. The vast majority of interviewees noticed this, since they identified the lack of counseling as a key challenge associated with uptake of HIV self testing. Professional audiences strongly insisted on the need for pre-test counseling. These strong reactions demonstrate that any self-test kit packaging needs to include clear resources for counseling, or need to be linked to counseling services elsewhere.

*"If [the test] is positive, you cannot be completely sure that you are HIV positive. But someone who has no information about counseling or confirmatory test could become depressed and commit suicide.", Male, General Population, Siaya*

*"If it comes out negative, I would really want to confirm, which means I will have to go for other superior tests to confirm, but if it is positive then I think it will be more scary.", Male, General Population, Siaya*

Almost all interviewees perceive the importance of correct usage instructions to obtain accurate results. Interviewees' reactions during the test suggest that there is a lot to do in this area. While most say they feel confident using the test, observations during the interviews suggest otherwise and some users expressed expectations that at least a quarter of individuals would use the product incorrectly. Moderators noted that potential users, when presented with a sample kit, looked at the box, opened it, and inferred how to use the kit by observing its contents. Only when they could not understand how to use the kit did they refer to the instructions within the box. They were quickly frustrated by the detailed and crowded instructions and preferred the simple diagrams.

*"If I am taught how it is done, I can just do it well...It depends on the training.", Male, General Population, Siaya*

*"Once you read the precautions very well and you follow them as you are told I am sure you are going to get the correct results", Female, General Population, Mombasa*

*"75% accuracy, and the other 25% could be due to someone not reading the instructions carefully", Male, General Population, Mombasa*

There are several areas that interviewees identified as potentially problematic, particularly the interpretation of results. Most potential users feel they would not be able to read the results with accuracy, requiring them to take another confirmatory test at a HTC center. Some are afraid that they would not collect the specimen correctly. These reactions need to be taken into consideration when developing primary and secondary packaging.

## **vi) Distribution of HIV Self Test Products**

HIV self-test kit packaging and labeling requirements are, in part, dependent on how the product will be distributed. Distribution models affect tertiary packaging (packaging in which the product is shipped from manufacturers to distributors), as well as primary and secondary packaging (the product inserts and sachet, and the outer box in which the product is sold to consumers). For example, limited supply chain and warehousing capacity of a particular sector may dictate the size of tertiary packaging.

Distribution of an HST product in a counseling and testing center or through community health workers, where counselors can demonstrate appropriate use and provide post-test counseling, may require fewer written instructions and information about linkage to care. In contrast, distribution in a pharmacy would require detailed instructions, as well as information on in-home storage and use of the product. Study participants were therefore asked to comment on their distribution channel recommendations for HST.

## **a) Health Centers as Distribution Channel**

### *Potential Users*

Potential users rarely mentioned health centers or hospitals as a distribution channel. When they were mentioned, it was typically in addition to other channels, particularly pharmacies, suggesting that users expect to see distribution through multiple channels. This may be reflective of their experience accessing the same medical products in both the public and private sectors.

Potential users who did reference these distribution channels also reported concerns that products distributed elsewhere may not have adequate quality.

*"...most of the things used in the hospital like reproductive health things are approved to some standards and that is why they are allowed in the hospital and most of them go through the ethics committees that must approve that they are good.", Male, General Population, Siaya*

The perceived strength of public sector products, versus those in the private sector, suggests that packaging for products distributed in the private sector may need to do more to overcome perceptions of lower quality among potential users.

### *Influencers and Stakeholders*

Influencers and stakeholders by and large recommended distribution through health centers or existing HIV testing centers. The primary driver for this preference was an expectation that counseling services would be available to ensure support to users upon receipt of test results, preventing adverse events and strengthening linkage to care.

*"You **have** to introduce counseling. Maybe where they are buying, for example in the pharmacy there should be someone to counsel that person. If you are buying from the hospital also someone has to counsel them before they test themselves.", Influencer, Pharmacists and Distributors*

While there is a clear legitimate concern about access to counseling, this finding may also be driven by the fact that self testing represents a significant shift from the HTC delivery method familiar to most of these professionals. This shift may alter the professional mandate and role for many of these individuals, leading to a desire to keep self testing within a health facility.

It is important to note that distributors and stakeholders did not necessarily expect that the test would be *used* on-site. Instead, some influencers suggested that distribution through these sites would allow the health system to identify a community health extension worker to provide counseling through

follow-up. This suggests that influencers and stakeholders may be open to other distribution points if follow-up counseling was ensured.

## **b) Pharmacies as Distribution Channel**

### *Potential Users*

Potential users unanimously expected that pharmacies would distribute HIV self-test kits. References to the purchase of other health products in pharmacies, including sexual and reproductive health (SRH) commodities (condoms and pregnancy kits), suggest that this expectation is driven by prior health product purchasing experience. A number of users expected to see HST products alongside other commonly sought health commodities.

*"The pharmacy can place them where they keep the family planning medicals and the sanitary towels.", Female, General Population, Mombasa*

*"They can keep them where they keep their medicines or a place people can see...they can be placed near children's medicines because most of the people go to the chemists because of the children. ", Female, General Population, Mombasa*

The participant's insights suggest that users will expect to see HST kits in pharmacies, due to their prior purchasing experience, and they will expect HST products to be made approachable and accessible by placing them alongside other more routinely used products. It is inferred that such placement would increase a potential user's ability to access the product.

However, such recommendations about product placement were not universal. Some users reflected that they would not "fear" purchasing an HST product, if it was displayed correctly. Yet, correct display was understood differently, by different users. This potential user presents his view that display on an easily accessible shelf will prevent stigma.

*"They should not display it in a manner that it looks fishy, there are some products that when you walk to the chemist they are not on display but if you ask for them they walk to the back to get them and you wonder why it is hidden so it should be somewhere open like the way they display Hedex [paracetamol]..."**It should be clearly seen on the shelf and the more people see it the more comfortable they will get with it so it will not be a big deal when someone goes to buy it but if its hidden ... For instance the other customers come to buy drugs and they are well displayed and easily accessible but when I ask for mine the attendant goes to the back some customers might start wondering what I suffer from and why my drug has to be hidden but if its in the open it becomes easier.**", MSM, Mombasa*

The belief that open display would decrease stigma around the product and increase user purchasing comfort suggests a powerful role for HST in changing norms surrounding HIV testing. However, a few potential users did contradict this view, reporting that placement behind the counter was preferable.

*"If the test was openly displayed, it would make me feel uncomfortable...it should be behind the pharmacist such that when you ask for it he just turns back and brings it.", Male, General Population, Mombasa*

This discomfort appears driven by concerns about quality. Products behind a counter may be perceived as more controlled, and at less risk of tampering. Ultimately, the data suggest that product placement can indeed influence purchasing behavior.

Overall, the perception of quality was a clear motivator, not only of where products were placed, but in the decision to seek HST products at pharmacies in the first place. Some users reported that pharmacy distribution could ensure greater product stability.

*"They will have enough room to store them properly so that they don't get into contact with dust and there is enough movement of customers so that they don't stay long on the shelves. ", MSM, Mombasa*

The user seems to suggest that pharmacy distribution is a means for preventing the sale of expired product and ensuring the integrity of the product is not damaged by poor storage.

Additionally, potential users also perceive that pharmacy distribution will ensure access to trained professionals who can provide instructional support.

*"Because even if I don't find the doctor the pharmacists have knowledge about drugs and they can give instructions and if you don't know how to read they can tell you rather than going to the local shops because they are in business and they might not be willing to assist. ", MSM, Mombasa*

This data underscores the concerns some participants have about their ability to use the product correctly, and suggests that distribution through trusted channels can assuage user concerns by ensuring they have the necessary product support from a trusted source. However, this finding also underscores high risk potential if pharmacists are not trained in proper administration of a HST.

Access and quality, therefore, underlie the divergence in opinions about product placement. High levels of HIV-related stigma lead some users to recommend product placement on an easy to access shelf. Such placement will not only limit need for interaction with pharmacy staff, but it will also further normalize purchasing behaviors. On the other hand, participants note that contact with pharmacists is key to ensuring accurate use and product quality. Decisions about product placement will have to negotiate this tension.

### *Stakeholders and Influencers*

While stakeholders and influencers also suggested distribution through pharmacies, support for distribution through this channel was by no means universal and contrasted sharply with the enthusiasm expressed by potential users. The primary concern from these participants was the lack of counseling services directly available to users of the HST. Influencers in particular emphasized that pharmacy distribution would require that pharmacists be able to provide support to users in cases where users seek assistance with test administration and/or interpretation of results. To support pharmacists in such an expanded role, stakeholders and influencers recommended pharmacist training on product use and the inclusion of counseling information on the external packaging to serve as a job aid.

Kenyan stakeholders cited existing distribution monitoring tools as a starting-point for pharmacy-based distribution.

*"You start with the pharmacies licensed with the board so the board will know exactly who is selling what; we have their data here so I'll recommend the pharmacies.",  
Stakeholder, Pharmacy and Poisons Board*

Collaboration with the Pharmacy and Poisons Board would allow the National AIDS Council to easily track product distribution, particularly during initial roll-out when concerns about adverse events are likely to be highest. Additionally, these systems may help prevent illegal product use. Importantly, data suggest that these systems would not require extensive additional resources to support HST roll-out.

International stakeholders identified the strength of the private sector supply chain as an additional benefit of this distribution channel, specifically its ability to store large amounts of product at wholesaler warehouses. Larger distribution capacity would allow for larger tertiary packaging. In contrast, international stakeholders reported that central medical stores may have limited space to store HST products for distribution in the public sector, restricting the potential size of tertiary packaging and decreasing capacity for bulk procurement.

### **c) Alternate Distribution Channels**

Although the majority of participants referenced either health care facilities or pharmacies as distribution points, a few alternate venues were reported.

Male potential users referenced distribution in non-traditional venues such as supermarkets and bars. These suggestions appear related to their experience purchasing condoms.

*"Like I told you earlier, where condoms there are condom dispensers or sometimes the shop or the chemist or pharmacy, but others we are given free in the hospitals, so I am telling you that where condoms can be accessed, it would be good if we can access the kit like that. Pharmacies is where can access condoms, shops also sell condoms and if there can be a provision of getting them for free, where they put the condom dispensers in bars, or wherever they put there should be gadgets for self tests.", Male, General Population, Siaya*

This ubiquitous reach of condoms was cited as one means by which condom use was destigmatized and a few potential users thought that widespread product access could achieve a similar goal for HIV test products.

In contrast to men, reference to non-health venues was infrequent among women and some female participants explicitly stated that medical products should not be distributed in such venues.

*"There are no medications in the supermarket. Medications are good in the pharmacy.",  
FSW, Mombasa*

This finding may be related to the fact that women are more likely to have contact with the health system and are therefore more comfortable seeking products in a pharmacy or health center. Men, with far less frequent health system contact, would expect distribution at convenient access points. Additionally, they are far more likely to buy condoms and thus to have experience buying HIV-related products from non-traditional venues. This indicates that HST uptake by gender may be affected by distribution method.

In addition to this gender difference, many users reported concerns about the quality of products distributed through non-traditional venues, suggesting that quality concerns may limit the utility of this distribution channel.

*"The others may bring things which are not originals you know we have duplicates so it's better if they are in health centers and chemists so that if you have any problems with it you can go and complain than having it anywhere.", Female, General Population, Mombasa*

Some users, particularly women, reported that they would not want to procure the product outside a health facility or pharmacist and desire some type of sales certification to inform them that the test kit is of high quality and not a counterfeit product. The reference to complaints also reinforces the idea that users desire the ability to contact trusted individuals when using this product.

Domestic and international stakeholders also mentioned the possibility of online sales. Despite the suggestion of this idea, there were concerns about how product sales would be regulated, suggesting concern about ensuring counseling, and adherence to age restrictions. Concerns about the mail system were also cited. If online distribution were considered, stakeholders suggested restrictions on who would be allowed to procure HST products in this manner.

## **vii) Packaging considerations**

### **a) Tertiary Packaging Considerations**

Tertiary packaging refers to the box in which HST products are shipped from a manufacturing facility to a distributor. Users rarely see this packaging and as such did not share insights, nor did influencers. Again, these individuals are often at the end of the supply chain and give less consideration to these factors. However, international and domestic stakeholders often had experience engaging with tertiary packaging at various points in the supply chain. As a result, a few key themes regarding tertiary packaging emerged.

*Labeling:* Domestic stakeholders emphasized the importance of appropriate tertiary packaging labeling to ensure that everyone handling the product is aware of the contents and necessary storage conditions. Key information points for inclusion on the packaging were storage temperature, whether the material within the box is fragile or not, batch numbers, expiration date, manufacturing dates and the date the product was shipped.

*Durability:* International stakeholders, particularly those with experience developing self test kit packaging for a US market, highlighted that tertiary packaging requires close analysis to ensure that it can withstand "rough and tumble" environments during shipping.

*Weight:* Domestic stakeholders highlighted the need to consider the weight of tertiary packaging because of implications in the supply chain, particularly for workers.

*"The bigger box is normally an implication of what is in those smaller boxes and then in the bigger boxes you are again going to talk of quantity, how many of those pieces are in that quantity and then again you are going to talk of the weights because again there is a legal requirement that somebody should only lift so much particularly when arranging or*

*packaging those box into the container, what sort weight, its normally limited to about 50kg.*”, Stakeholder, KEBS

These data suggest that while tertiary packaging could be large depending on demand and supply chain capacity (e.g. warehouse facility size), doing so may risk making each package too heavy and introducing challenges in the supply chain when special staff or resources are necessary to move the shipment.

*Size:* Stakeholder data indicate that tertiary packaging directly impacts the ability of a central warehouse to store the product. Small tertiary packaging for a fast moving product may allow for the product to be stored in warehouses with limited available space, particularly central medical stores in the public sector.

## **b) Secondary Packaging Considerations**

Secondary packaging refers to the box in which the product is placed for sale to consumers. Secondary packaging can achieve a number of goals including assuring test confidentiality, appropriate use, and product quality, both perceived and real. A great deal of feedback about secondary packaging was driven by feedback on the Aware packaging. As a result, much of the data builds off of this product baseline but is generalizable to any oral self-test product.

### **PACKAGING MATERIAL**

Packaging materials can ensure product quality by addressing both real and perceived quality, preventing product damage or tampering prior to receipt by the consumer.

#### *Potential Users*

Potential users reported that the physical strength of the secondary packaging directly affected the perceived quality of the product,

*“The AWARE package is a bit hard to open, but that is good because it is natural that way. It has to be sealed.”, Female, General Population, Siaya*

This emphasis on strong packaging and references to a physical seal suggest that this secondary packaging addresses user concerns about counterfeit or tampered product, as well as product stability. Sturdy materials will address concerns about product damage during shipping or storage, while tight closure and a seal will prevent the product from being altered or re-sold after previous use.

#### *Stakeholders and Influencers*

Stakeholders and influencers also reported that secondary packaging would be critical to ensuring quality. Similar to consumers, they reported that the packaging would need to be strong enough to protect the product as it moved through the supply chain.

Despite the benefit of sturdy materials, international stakeholders in particular referenced potential drawbacks. First, if materials are too robust, users may use “their teeth or razors”, potentially affecting product quality. Second, thicker materials will increase shipping costs due to weight. Thus, while product integrity must be assured, cost-effectiveness considerations should inform whether packaging material goes above and beyond basic requirements to allay consumers’ perceived quality concerns.

## **MANUFACTURING AND STORAGE INFORMATION**

Manufacturing and storage information can ensure product quality by limiting damage during storage and transport, and by supporting easy removal from the market in case of a quality defect. Additionally, this information, which is often considered regulatory in nature, can be crucial to ensure accurate product use.

### *Potential Users*

Potential users referenced the need for clear expiry information to ensure product stability. Users indicated that the expiration date was not easily visible on the AWARE package. Patient education efforts throughout the health system often encourage users to check expiration dates before product use, including other HIV-related products such as condoms. This suggests that while expiry dates are required for regulatory purposes, well-displayed expiry dates can be used to further limit use of expired product and to increase consumer confidence in product quality.

### *Stakeholders and Influencers*

Like potential users, stakeholders and influencers emphasized the importance of a clearly marked expiration date. An international stakeholder emphasized the need for particular attention to how the date is written (e.g. day/month/year) to prevent confusion in user interpretation.

Influencers and stakeholders also emphasized the need to include storage temperature information on the box, due to the impact storage conditions could have on integrity of the product, leading to a greater number of invalid or inaccurate test results. Again international stakeholders emphasized the need for absolute clarity in how storage information is communicated. For example, 3-30 degrees has been interpreted by some users at 3 to -30 degrees, leading them to store a product in the freezer. Finally, regulators require that the manufacturing date and lot number be included on all secondary packaging.

*“Lot number is important because that is used if you were to do a recall, how you will recall without the lot number.”, Stakeholder, Kenya Bureau of Standards*

This finding is expected as this information is standard in the packaging of pharmaceutical products.

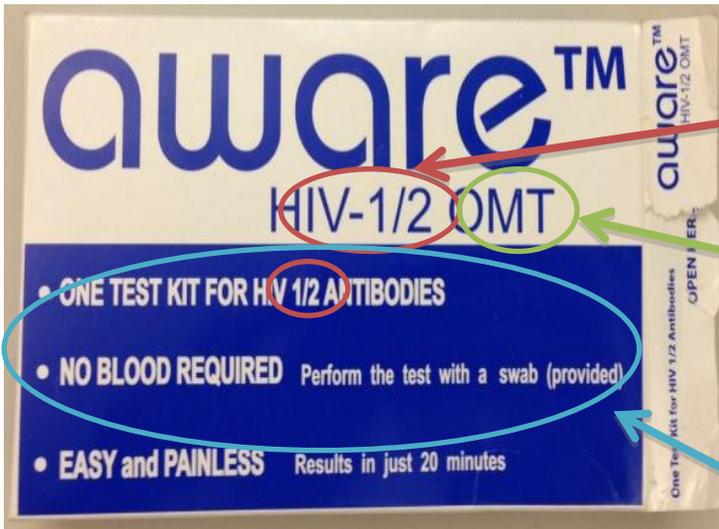
## **PRODUCT LABELING TO ENSURE ACCURATE USE AND PRODUCT QUALITY**

Product labeling on secondary packaging can support accurate use by the proper individuals, and build user comfort during their purchase of an HST product.

### *Potential Users*

By and large, potential users reported that the Aware packaging included information that was considered too complex for ease of comprehension by a lay audience. The use of terms such as “HIV-1/2”, “OMT” and “antibodies” caused particular confusion.

**Figure 2: Certain information on AWARE package was unclear (circled)**



*"[Regarding HIV 1/2] According to me, this 1/2 shows that it is not 100% effective."*

*--Female, Siaya*

*"[Referring to "OMT"] This word, I cannot understand what it means."*

*--Female, Siaya*

*"HIV half antibodies written on this AWARE package, then no blood required, perform the test with a swab, these terms should be simplified."*

*--Male, Siaya*

In a best-case scenario, these data suggest that this labeling causes confusion. But in a worst-case scenario, it can lead the user to question the product's quality. Believing the test to be less than 100% effective, users may not purchase the test or they may question the accuracy of results.

Additionally, these calls for simpler language suggest user discomfort with the language. Given the significant apprehension that surrounds HIV testing, and use of medical diagnostic terminology most people are unfamiliar with, confusion caused by the outer packaging may be enough to deter users from purchasing the product or further increase their anxiety during test administration.

#### *Influencers and Stakeholders*

Influencers urged that secondary packaging labels include reference to the importance of reading and understanding the instructions prior to use.

*"I think a lot of emphasis should be put on the outer package, indicate that the consumers should read the leaflet before using the kit. It is very important for them to read the leaflet and understand before using the kit", Influencer, Pharmacists and Distributors*

Stakeholders also called for the secondary packaging to reference the instructions for use that would be found inside the package. This speaks to the overwhelming concern among stakeholders and influencers that instructions for use will not be read, leading to invalid test results. By placing the recommendation on the secondary packaging, the user is primed to look for and consider the instructions for use. Additionally, by referencing instructions for use, the secondary packaging may assure nervous consumers that they will have the information necessary to administer the test.

International stakeholders also recommended that secondary packaging include an image of the test components. This can allay concerns about quality by allowing consumers to confirm that the product has not been tampered with and that all component parts are included prior to starting the test process. Consumers in the US also preferred such an image when an oral HIV test product was developed for that market.

Finally, stakeholders recommended that the secondary packaging include basic information about the test and its use. In the US product, this included basic information on what the test does, when to use the test (particularly timing in relation to risk events) and a list of individuals who should not use the test (individuals under 17 years of age, individuals on treatment for HIV). Data suggest that similar information should be included on a product for the Kenyan market.

*"I think one of the things we didn't discuss about regulation is who can access these kits, because again you don't want minors accessing the kits... You can't have a ten year old come and say I want to be tested, unless they belong to a category we call mature minors which is somebody who is at risk: you are sexually active, you are pregnant, and you are married at that tender age. So then we need to be sure that as part of regulation we only make sure its eligible persons who access it.", Stakeholder, NASCOP*

The insights speak to the idea that consumers will make important decisions about whether to purchase the test or not at the point of purchase (rather than beforehand only), so having essential information about what they can expect once they open the kit is important for secondary packaging.

#### **PRODUCT LABELING TO ENSURE CONFIDENTIALITY AND TESTING COMFORT**

Just as it can affect product quality and accurate use, secondary packaging and labeling can also ensure that consumers feel their purchase and subsequent test procedures are private. Additionally, labeling can do much to address user discomfort with a new and unfamiliar product.

##### *Potential Users*

Potential users differed widely on their opinions regarding the inclusion of "HIV" on the secondary packaging. Those who supported the inclusion of "HIV" reported that this text could both decrease stigma around HIV testing, and increase clarity regarding the product's purpose.

*"They should write HIV test kit in large fonts. The way it is currently being written is not very clear. Someone might think these are HIV drugs but they would not know that it is a HIV test kit.", Male, General Population, Siaya*

This confusion about product contents is similar to that reported for other aspects of the Aware packaging. However, risk of confusion was not a dominant theme and as the product is increasingly marketed to directly to users, it is unlikely that this type of confusion would remain.

Those who discouraged its inclusion appeared to do so out of concerns regarding client privacy, suggesting an important method by which secondary packaging can ensure confidentiality.

*"This HIV should be in small font and kept in the insert and on the outside you just write Test kit so that the aspect of HIV is in the insert and cannot be seen from outside.", Male, General Population, Siaya*

Inclusion of HIV in the insert would provide greater confidentiality and address concerns that purchasing the test kit would subject users to stigma. It also suggests that if labeling includes "HIV", the size of the text should be considered closely as it may affect product uptake.

Secondary package labeling was also cited as a means to building user comfort around test use. This could be done by including encouraging language on the secondary packaging, emphasizing the benefits of testing.

*"Maybe a writing that tells somebody that...whether you are negative or positive, they should be encouraged to continue living.", Female, General Population, Siaya*  
*"Have safe sex, have a bright future after knowing your HIV status [should be on the package].", FSW, Mombasa*

Users also reported that they liked that the Aware packaging explicitly stated that the test used no blood and was ready in twenty minutes. These types of insights will be crucial to development of branding of the product. The data suggest that the brand and its positioning statement should address these user concerns about pain and anxiety during testing, and consider messages about the potential of the product to improve their future, regardless of the result.

#### *Influencers and Stakeholders*

In contrast to potential users, influencers and stakeholders were clear that the secondary packaging label should specify that the product is for HIV testing.

*"On top, I think the most important thing is that this is a HIV kit.", Stakeholder, NASCOP*

This is likely driven by pharmaceutical labeling regulations. Few, if any, countries would allow a product to be sold without clear labeling regarding its use on secondary packaging. However, international stakeholders with experience in the US market, highlighted a potential solution,

*"If you look at [the FDA-approved Oraquick product], the biggest part as far as font is around the logo and underneath where it says it is an in home HIV test. But at first glance you don't really notice that it is a HIV test... people felt comfortable that you can't really tell that it is an HIV test.", International Stakeholder*

These data suggest that the question of labeling and confidentiality may be less one of exclusion or inclusion, but instead simple graphic design.

Although stakeholders wanted "HIV" included on labeling, influencers suggested including information on the secondary packaging that would further enforce the principle of client confidentiality.

*"It should be written that it's an oral self-testing kit for the consumer to know. It's his and he is supposed to do it alone", Influencer, Health Service Provider*

By supporting confidentiality, such language may also allay some user discomfort with the test. Additionally, some stakeholders recommended expanding on this to explicitly state that the test should not be used in a coercive manner. Doing so may further boost perceptions of and self-efficacy to ensure test confidentiality. Inappropriate use by employers, sexual partners, family members or others may be specifically referenced and overtly discouraged.

Finally, as seen among potential users, stakeholders also recommended that secondary packaging labels include messaging to ease user concerns about test outcomes.

*"For me it will be sort of also a method of social mobilization. So a message sort of like know your status, plan your life - that sort of message. So that when I am buying, I know that I am making a decision that is going to change my life for the better, just that sort of message to tell you it's good to do this thing.", Stakeholders, NASCOP*

These data also suggests that final brand and brand positioning must support overall national HIV testing campaign messages which may emphasize HIV testing as part of a healthy lifestyle choice.

## PACKAGING SIZE

There was overwhelming agreement across study populations that the product packaging should be smaller to increase client confidentiality and limit concerns related to a variety of sources of stigma.

### *Potential Users*

Potential users reported that secondary packaging for self test kits should be discreet, again to address concerns regarding confidentiality and privacy. Specifically, they reported that stigma around HIV and HIV testing may lead some users to fear purchasing the test in public where they may be seen.

*"I will feel like people will be staring at me and saying 'this woman wants to test herself for HIV?' then I will be ashamed.", Female, General Population, Mombasa*

The primary factor that would make a package discreet was its size. A smaller package allows for a more private purchase, particularly when exiting a pharmacy or health facility. A number of users specified the ideal size of the secondary packaging.

*The package should be the size of a phone but not long like a ruler...like the old Nokia 1100.", Female, General Population, Siaya*

Users reported that the size of a mobile phone would allow it to be placed discreetly in a back pocket or under a short sleeve. The Aware kit was perceived to be too large.

### *Influencers and Stakeholders*

Stakeholders within the Kenyan government and internationally echoed the need for smaller packaging to allow for discreet purchasing.

*"If you look at other kits on the market, they are normally very small. If you have very big boxes, they will be stored in the back room and people view 'the back' with stigma.", Stakeholder, Kenya Bureau of Standards*

In contrast to users, stakeholders do not reference HIV-related stigma but instead stigma associated with the back of the pharmacy. This stigma may be related to the fact that products from the back of the pharmacy are perceived as treatment for more severe conditions, or alternatively, that procuring product from behind the counter requires pharmacist interaction about HIV-related needs. The data was inadequate to make this determination. In either case, these findings echo those found among potential users interested in seeing the product placed on accessible shelves within a pharmacy, not behind the counter.

International stakeholders did highlight theft as a potential concern related to smaller packaging. Experience in the US market suggests that pharmacists prefer placement behind a counter to discourage theft. If secondary packaging is made small to ensure discreet purchasing, it may also increase the risk of theft. Depending on distribution channel selection, the desire for discreet packaging when exiting the facility may need to be balanced against the desire for ease of access.

## **c) Primary Packaging Considerations—Instructions for Use and Other Packaging Inserts**

All study populations consider instructions for use and other packaging inserts as critical components in ensuring accurate product use and appropriate linkage to follow-up care or counseling. However, there

are significant challenges surrounding the task of ensuring that users review instructions in-depth, and then follow these instructions. Data suggest a number of means to achieve this goal.

Instructions for Use (IFU) in particular can ensure that tests are administered accurately by providing detailed, clear and concise instructions. However, doing so can be challenging, particularly in populations that may be illiterate and have little familiarity with oral HIV testing, let alone personal administration. As one international stakeholder reported, *“People really don’t read instructions.”*

## **LANGUAGE AND PICTURES**

### *Potential Users*

Potential users were universal in their recommendation that instructions within the kit be presented in both English and Swahili. Similar to the findings regarding unclear text on the Aware packaging, poorly presented instructions could severely limit user confidence in using the kit and may result in invalid or inaccurate results.

*“Let’s say if it was conducted in the coast I would like it in Kiswahili because it is widely spoken in the coast region. In other places like Nairobi it will be printed in English because they do understand that better.”, Female, General Population, Mombasa*

Data also suggest that language translations may be affected by the geographical targeting of the HST product. However, English and Swahili translations appear to be the minimum acceptable translation. Additional languages may need consideration as and when distribution channels and target populations are determined. Users also emphasized the importance of including pictures that can be used to complement written instructions for illiterate populations.

### *Influencers and Stakeholders*

Stakeholders strongly emphasized that users are unlikely to use instructions. As a result, instructions should not be text heavy and there should not be an expectation that a user will read through all of the instructions prior to use. To respond to this reality, IFU should be as simple and uncluttered as possible.

Influencers in particular highlighted the need for pictures within the instructions for use to increase user confidence and maximize the likelihood of accurate use, particularly given the potential for use by low literacy populations.

*“You can put the pictures and words in English or Kiswahili. Africa is not like Europe, we need more of the instructions clearly written in English and illustrated for those who don’t know how to read and write.”, Influencer, Pharmacists and Distributors*

International stakeholders recommended that IFU use drawings rather than photographs. Photographs are open to greater misinterpretation, while the clear lines of drawing are easier to manipulate and can make it easier for users to understand the various test components and their placement during the testing procedure. Any image should use the skin color of intended users.

However, influencers and stakeholders were clear that pictures alone were not adequate and should be accompanied by text. By providing both modalities of instruction, including bilingual translation, there is greater likelihood of comprehension by the variety of target populations likely to be reached by this product.

## EXPLICIT KEY STEPS

### *Potential Users*

Participants' lack of familiarity with the test hindered their ability to provide detailed recommendations for how to present the IFU. Where input was provided, users appeared most concerned about two aspects of testing. First, users were concerned about ensuring appropriate preparation for the test, particularly how long to wait after eating before use and whether the test should be administered with bleeding gums. This reflects how users are likely to take their prior experience with other diagnostic or pharmaceutical products and apply it to this new product. For example, concerns about eating may be related to prior pharmaceutical use or even the use of other diagnostics such as blood sugar monitors.

Second, users voiced concern about appropriate disposal.

*"First as I said, cleanliness, you could have some dirt that may give a different result. So information about cleanliness, information about how to work with it, information on how to dispose it. Then with these, chances are high that results will be well. You know how to dispose it also helps our children who are playing in the compounds because they may find it and want to put it in their mouths and it may harm them. Maybe somebody has just finished working with it and a child has picked it and scratched her mouth it. That is why information about disposing it is very important.", Female, General Population, Siaya*

It is important that IFU or other packaging inserts address administration of the test as well as the time period surrounding administration. Unlike testing in an HIV testing center, HST moves such matters from the domain of the healthcare worker to that of the consumer.

### *Influencers and Stakeholders*

Overall, stakeholders stressed the importance of ensuring that instructions articulate in *extreme* detail each step of the testing process – from what items should be in the kit when the product is opened, to how to interpret results.

*"The instructions should walk you through taking out the vial and placing the vial into the test stand in the box. The next steps show you how to open the package, where to touch the device, how to swab, how to time the test.", Stakeholder, FDA*

The various loose components of a HST product are considered primary threats to accurate product use. Hence IFU must be explicit on the use of each component. No consumer familiarity can be assumed.

The call for explicit instructions should not be interpreted as a call for detailed and lengthy instructions. Indeed, stakeholders warned against the inclusion of too much information. As one international stakeholder reported, labels should guide the users. *"Now you have read your test result and now you do this."*

- **Swab:** The use of the oral swab was flagged as a potential area of confusion. Pictorial instructions need to be explicit about the space between the lips and the gum. Confusion is possible, with samples erroneously gathered from the roof of the mouth or the tongue. Additionally, users often want information about how hard to press the swab against their gums and which end of the swab to hold in their hands.
- **Buffer Solution:** Stakeholders reported previous issues regarding the use of the buffer solution, including some individuals who have consumed the buffer solution. The existence of liquid inside the buffer vial for all test steps needs to be made clear in all instructions, including

pictures. Additionally, if stability of the test is compromised during transit, the buffer solution may evaporate prior to package opening. Alternatively, users may spill the buffer solution during opening of the vial. If users attempt to use an empty or partially full vial, the test will be inaccurate. Clear instructions need to detail what to do in the event of spilled or evaporated buffer solution.

- Dessicant Pack: Stakeholders report that when included, dessicant packs often cause confusion. Users do not understand their utility and may use them inappropriately. While product innovations may address this hurdle, clear instructions on not opening or using the dessicant pack are needed.
- Laboratory Language: Stakeholders reported that HST instructions are often replications of instructions intended for laboratory staff. Lab specific language (such as instructions not to wear jewelry or cosmetics) needs to be removed and, based on stakeholder experience, improved instructions for a few key steps in the testing process should be considered.

Similar to potential users, stakeholders also highlighted the need for clear instructions about when to use the test, particularly as it relates to eating and drinking. Data for influencers suggest that without instruction, these individuals may actually increase the risk of inaccurate results due to incorrect information.

*“He should clean the mouth first or the food particles might interfere with the result. Like when someone has taken alcohol, alcohol will interfere with the results.”, Influencer, Health Service Providers*

The Oraquick product cannot be used within 30 minutes of any oral care product. Recommendations from healthcare providers that the mouth be clear may lead to direct contradictions with test instructions, underscoring the importance of training any distributor of this product—including health service providers who, while familiar with blood-based HIV tests, may not be familiar with instructions around oral fluid collection.

In addition, stakeholders emphasize the importance of addressing waste management in IFU. While oral tests carry fewer biohazard concerns, users will need explicit disposal instructions. As one stakeholder asked, “burn it, bury it, or put it in a bin?” In addition to safety, clear disposal instructions will ensure the confidentiality of test results.

*“You also want to do it in such a way that it should be destroyed because of the secrecy and sensitivity of the kit. It should be something that can be easily destroyed or easily disposed, which again is a packaging issue. Disposal information is essential, how do we dispose of it because if it’s something that you are going to test and then throw away, somebody can easily follow you to the garbage where you are going to throw it and open it up.”, Stakeholder, Kenya Bureau of Standards*

This data suggests that concerns about confidentiality do not focus merely upon confidentiality during test use, but instead from the moment of purchase (e.g. with smaller packaging that is easily accessible) to the moment of disposal. This comprehensive view of confidentiality will be important in considering packaging decisions.

Given the large universe of challenges users may face when administering the test, international stakeholders have recommended inclusion of a “frequently asked questions” insert to highlight key problem areas. This may help ensure that critical points are emphasized in a third format (written instructions, pictorial instructions, FAQ) for users who do not fully read instructions. Recommended

points for this FAQ document included: what to do if the buffer spills; what to do if the test is expired; what to do if the test is non-reactive; who absolutely cannot use this test.

## **RESULT INTERPRETATION**

Interpretation is a stage in the HST experience that received increased attention by users, influencers and stakeholders. There was clear agreement that IFU could, and should, support accurate and reliable test result interpretation.

### *Potential Users*

Users had limited specific feedback regarding the interpretation of results. However, they did report that the AWARE interpretation information (on the secondary packaging) was unclear. Not only was interpretation unclear, users were even uncertain about the purpose of the text.

While using the secondary packaging to support interpretation is an innovative use of space, and can decrease overall packaging bulk, instructions to guide such interpretation will need to be far more robust for widespread use.

### *Influencers and Stakeholders*

Influencers and stakeholders emphasized the need for all interpretation guidance to highlight three potential test results—positive, negative and invalid. The invalid result was frequently cited as a test outcome that is under-explained in most packaging. Additionally, the control and test lines may need particular attention because stakeholders highlighted this as a frequent area of confusion. It should be noted that physical limitations, such as far sightedness, may impact user capacity to read and interpret tests.

## **COUNSELING INFORMATION TO SUPPORT LINKAGE TO CARE**

### *Potential Users*

Users voiced a great deal of concern about ensuring access to follow-up counseling based on the test results; lack of this counseling was the primary hesitation associated with HIV self testing. When prompted, users reported that if they were to seek follow-up counseling, they would do so by either attending a health center or calling a phone number included in the test packaging.

*“You can display a number on the kit [inside] where if you need more information you can call that number to be given more information or you can go to a health center. So a person will choose which one to use.”, Female, General Population, Mombasa*

Phone-based counseling was also highlighted for its potential to provide anonymity, again addressing the continuum of concerns related to testing and confidentiality.

Follow-up counseling was underscored as most important for individuals with a positive test result. However, there was some discussion of counseling for individuals testing HIV-negative.

*“Include information on how you can keep your negative status. You will always ask yourself the precautions you should take so that you don’t acquire the disease, the virus.”, Female, General Population, Mombasa*

References to counseling for negative and positive individuals suggest some recognition among potential users that follow-up care is important for all HST product users. This would suggest potential significant increases in demand for counseling services.

#### *Influencers and Stakeholders*

Influencers and stakeholders also reported on the capacity of packaging inserts to ensure linkage to care and access to counseling.

*“In the instructions, you need to state clearly the expected results and what to do next after each result so this person can go for further discussion – either a phone number or an address. Something very specific for the client is needed so that they know where they need to go or the number to call.”, Stakeholder, NASCOP*

Indeed, these study populations were much more explicit about the need for clear instructions not just about follow-up, but about follow-up specific to the result of the test. For positive results, stakeholders by and large recommended clear guidance on attending a health facility for confirmatory testing.

*“You need to put the right information on the insert: if positive go for confirmatory test and then you say that for confirmatory test visit any established health facility. This way, people will go to the health facility and ask to confirm their status. This instruction is going to be a very important tool within the insert.”, Stakeholder, NASCOP*

Although stakeholders did recommend that a list of confirmatory testing sites be referenced, one stakeholder made clear that the responsibility to include this information in the product packaging could not be placed on the manufacturer. For a global company, making such local modifications would not be feasible. As a result, references to follow-up testing may need to be an additional packaging insert made once the product is in country. This may complicate efforts to use a seal to address consumer quality perceptions, unless the seal is placed on the packaging after importation.

Stakeholders also emphasized the need for clear guidance on follow-up for negative results.

*“If negative, we need to make sure people don’t use it as a basis for making a decision about high risk behavior”, Stakeholder, FDA*

This concern is not new to HIV counseling and testing. However, post-test counseling has been designed to mitigate this risk. Carrying these principles into the development of counseling inserts will be necessary. Influencers and stakeholders were also concerned about including re-testing messages for HIV-negative individuals. This included the need for clear information about the window period.

As mentioned above, stakeholders also noted that action steps for an invalid result are often left out of instructions. Users need to be instructed to repeat the test using a new test, or to seek test administration support at a local health facility.

Using primary packaging to mimic the existing counseling system was again proposed when stakeholders referenced inclusion of an insert with basic information about HIV, including transmission routes, how HIV affects the body and how HIV is treated. This is similar to the content in pre-testing counseling/education sessions.

*"I think we need to have pretest and general information just like the same thing that happens when you are having a physical session, information that gives basic facts about HIV in general and then basics about HIV testing. That needs to be very clear.", Stakeholders, NASCOP*

Inclusion of this information would move the HST product closer to approximating an actual HIV testing session, and allay ongoing concerns about counseling as a component of HST. Additionally, some such text may be used to address the anxiety that potential users expected to experience while the test ran, because it would give them an explicit activity to reorient their attention during that time.

As with potential users, influencers and stakeholders also referenced the possible role of telephone counseling services.

*"I think it's good to provide a number in there. If maybe the patient is not satisfied to go and tell the clinician in the nearby facility, he could call the number.", Influencer, Health Service Providers*

These data suggest that influencers and stakeholders often view a telephone hotline as a "redundant system", designed to act as a resource only if individuals are unwilling to seek support by the local health system. Established counselors appear to be seen as the primary means by which follow-up care and counseling will be provided. However, stakeholders familiar with the HST product in the US market report that the hotline is often used for basic HIV information and clarification about proper test administration. As a result, it is possible to mandate that a hotline exist in order to ensure users have access to information before, during and after taking the test.

#### **d) Primary Packaging Considerations—Sachet and other Physical Test Components**

Similar to secondary packaging, primary packaging can allay users concerns about product quality and ensure the stability of the product. Importantly, primary packaging elements may also support the actual physical administration of the test to ensure accurate use.

##### **SACHET**

###### *Potential Users*

Reaction to the AWARE packaging sachet was largely positive. Specifically, users referred to the sealed sachet. By breaking the sachet themselves, users felt they could be sure the product had not been used before or tampered with.

It is clear that concerns about the quality of the test need to be addressed by all components of product packaging and product placement. Distribution in a pharmacy or health center communicates quality; secondary packaging material and physical seal communicate quality; and the inner sachet seal conveys

quality. This repeated effort to assure users of quality is likely to be critical during early introduction of this product.

**Figure 4: All audiences liked that inner AWARE package was sealed and waterproof**



*"I told you it is air tight, so I don't think it can be contaminated in any way"*

*--Female, Mombasa*

*"It is safe and it is sealed so no one can tamper with it. If it was just packaged in a box without the inner, sealed sleeve, then someone could open and tamper with it"*

*--Male, Mombasa*

### Stakeholders

While users appreciated the seal on the sachet, international stakeholders underlined the importance of ensuring that any cassette pouch must rip open easily. This will protect the product integrity and prevent users from using knives or scissors that may damage the test components.

Aside from this, potential users provided little additional feedback about how aspects of the physical packaging could support them in using the test. Their unfamiliarity with this product and with oral HIV testing in general likely drove this lack of data.

### COLOR CODED AND ORDERLY TEST COMPONENTS

#### Stakeholders

The number of test components emerged as a key driver of inaccurate testing. Efforts to ensure orderly use of the components with IFU alone has proven challenging. Multiple stakeholders recommended color-coding each test component. This color-coding would make pictorial drawings easier to follow and make obvious which test component a given piece of text referred to. Given user discomfort with text on the Aware label, color coding that negates the need to use terms like "sachet" and "buffer vial"

should be considered. Additionally, stakeholders report that components should be packaged in the order of their use to further facilitate use.

## **BUFFER VIAL**

### *Stakeholders*

International stakeholders underlined the importance of ensuring proper use of the buffer vial. The buffer vial should be a snap lid, not a threaded screw lid, to facilitate opening. However, users often expect a screwable lid, leading to product spillage. Information in instructions and, where possible, on the vial itself should emphasize the importance of opening the vial carefully because of the presence of liquid.

Additionally, the buffer vial must stay upright and at a particular angle when the cassette is placed inside. Packaging must include a means for ensuring the vial stays upright during testing, especially in settings where smooth flat surfaces may be limited. Stakeholders acknowledged that while a stand could help address this, including too large a stand could affect packaging dimensions and decrease the extent to which the product fulfills users' desires for discreet packaging.

## **EXPIRY DATE**

### *Stakeholders*

In addition to tertiary and secondary packaging, stakeholders emphasized again that all components of product packaging must be marked with an expiry date.

## **TIME KEEPING**

### *Potential Users*

Users were also asked to consider how they might keep time during the testing process and how packaging might support them in doing so. Users reported comfort with timing the test and referenced use of a clock or their mobile phone to do so. However, the inclusion of a small stop watch to support time keeping was a persistent theme.

*"If the test kit came with a timer I think that would be the best because yes I might have my watch but the batteries might decide to fail me or anything like that or a phone call comes so I think it would be best to have a timer.", Female, General Population, Siaya*

On a few occasions, users recommended including a space for writing down when the test started and when it should be read, similar to what is seen in the current Oraquick packaging in the US market. These suggestions indicate that some users recognize risks inherent in using a wall clock or phone. However, others did not acknowledge this risk, despite reporting that they would do chores or other activities while waiting, suggesting high risk of distraction and reading of test results outside the recommended time frame.

### *Stakeholders*

Echoing potential users, stakeholders also underscored the potential for primary packaging to support time-keeping. One stakeholder highlighted the approach used in the US market.

*"We use the traffic light colors – green is when they should read, yellow is when they shouldn't read it, and red is past its expiration because it has to be read within 40 minutes.", Stakeholder, FDA*

This comment references an insert that asks the user to write down the time the test was started, the 20 minute mark at which time the test can be read (shaded green), and the 40 minute mark at which time the test should no longer be read (shaded red). This low-cost approach prompts the users to think through the implications of the 20-40 minute window, and presumably improves adherence to instructions.

### viii) Summary findings from Phase II – Reaction to packaging mockups

Phase II fieldwork took place the week of January 13, 2014. The objective of this final phase of the study was to test potential users' and pharmacists' reactions to packaging mockups designed by a Kenyan advertising agency based on the inputs from Phase I. The advertising agency was briefed (see briefing document in Annex 3) to produce two packaging options that were sufficiently different from one another to facilitate exploration of potential users' reactions to different designs options and to identify which design or instruction manual choices seemed to be most promising. (Annex 6 and 7 include detailed pictures of packaging mock-ups.) Key findings include:

Figure 5: Packaging mockups developed for Phase 2



- The mention “Oral HIV test kit” helped interviewees identify immediately what the product was. Some recommended making the font smaller to avoid any potential embarrassment / stigma when buying the product at point of sale.
- Participants thought that the packaging design conveyed the idea of a product meant for home use, rather than for hospital / professional use.
- Packaging size was still considered too large. This was especially important for men who do not carry bags and would want to buy a product that can easily be carried in their pocket.
- Interviewees noted that information on key product benefits, such as the use of saliva rather than blood, needed to be on the packaging.
- These packaging options were perceived to be relatively high end: (*“It looks like it will be an expensive product”*)
- There is a need for clear counseling information on the outer packing, which would cover (at a minimum) benefits of using the product, importance of HIV testing, etc. This was compared to the kind of information included on packs of condoms.
- Interviewees noted that neither packaging option included stamps / branded seals of quality. GoK’s stamp of approval and country of origin would be important information to include in order to reassure potential users of the legitimacy of the product.
- Pictures in the inner packaging were considered appealing and clear, but the English language used in the instructions manuals was perceived as too complicated.

### Instructions

- There was progress compared to Phase I instructions, as respondents were better able to understand how to read their test results.
- However, there were areas in which the instructions remain unclear. It was difficult to explain a number of steps:

- Instructions for collecting the sample were considered confusing. Some respondents could not explain the step whether they should put the swab first in their mouth or in the test vial.
- For some, it was not clear that the swab should be used on both the upper and lower gum.
- Respondents also wanted to understand why they needed to open the tube carefully. They suggested indicating within the instructions that the tube contains liquid that could pour out if not opened prudently.
- It was also not clear whether the strip should be left **in** the test tube while you wait for the 20 minutes, or if it should be **removed** and placed on a surface while you wait for the results.
- The instructions mentioned the importance of hygiene, but without specifying how it should be applied to the HIV self-testing process. Potential users wondered whether they needed to put on gloves (which they felt should be included in the packaging if it were the case) or to wash their hands before administering the test.

### **3) Conclusions and Recommendations**

#### **i) Summary conclusions**

HIV self-test kits, just like other self-test health kits, represent a new way for people to manage their health proactively, and take charge of it in a more active and engaged way than traditional health systems have made possible thus far. HST kits represent a new step in HIV prevention, but also a somewhat frightening leap into the unknown. While potential users perceived undisputable value in facility-based HTC, which they thought remained the best solution to obtain accurate results and professional counseling, they were also excited by the prospects that this new intervention offers. They saw it as potentially addressing the pitfalls they perceived in facility-based HTC. For the vast majority of interviewees, HST kits were seen as an empowering new product, approachable and easy to use, and which put user in control of the environment and the time when the test is administered. Professional audiences however, perceive important risks with this new product, which they think is prone to error and does not provide adequate counseling support.

The vast majority of users also perceived some clear shortcomings with HST kits. They wondered how this new product worked, as collecting samples from the mouth seemed to contradict what they knew about HIV transmission. This translated into doubts about the accuracy of test results and the legitimacy of this new product, in a context where consumers are wary of counterfeit drugs, and where products must display visible signs of quality to be credible. Potential users perceived usage instructions to be essential, but struggled to demonstrate correct product use with the materials provided for the study. Overall, consumers said they were willing to buy this product, particularly if they could do it discreetly.

Given that distribution channels will influence packaging and labeling consideration, it is important to note that potential users overwhelmingly prefer pharmacy distribution. However, this channel would require greater investments in product packaging in order to communicate the quality of the product and to ensure its proper use, particularly regarding linkage to care, counseling, test administration, and consumer confidentiality. It is likely that distribution through health centers and existing HIV testing sites would require less rigorous packaging design, because of the presence of a trained counselor to demonstrate test administration and provide follow-up counseling. However, given that users see drawbacks in existing HTC models, the use of pharmacies as a distribution channel may increase overall product access, particularly among males. Negotiating this tension between access (increased through pharmacy sales) and quality (increased by the presence of a counselor) will be a key consideration in selection of a distribution channel. Additionally, placement within a given distribution channel will need careful consideration. Placement of the product behind a counter was perceived to decrease product accessibility, but pharmacists are likely to place the product here due to theft concerns.

The study found that packaging and labeling can do a great deal to convey perceived benefits of HIV self-test kits and to address concerns from different audiences, playing a key role in the success of an HIV self-testing program. Specifically, data revealed that HIV self test packaging labeling can: increase user comfort, increase the likelihood of accurate use, ensure accurate and reliable interpretation of test results, support linkages to care, build the level of testing privacy and confidentiality and protect the product as it moves through the supply chain. In Table 2 we outline the manner in which packaging can achieve these goals.

**Table 3: How Packaging and Labeling Can Support and HIV Self-Testing Program**

<b>Confidence</b>	Build user self-efficacy to conduct the test with clear and explicit step-by-step instructions and address concerns about the quality of the test with robust and sealed secondary packaging.
<b>Accurate Use</b>	Use primary packaging to support users through the entire testing process (from preparation to waste disposal). Ensure clarity through pictures and text, decrease clutter and directly acknowledge and address frequent errors. Use packaging components, such as a time guide or buffer vial stand, to further support use.
<b>Interpretation of Results</b>	Ensure that all potential test outcomes, including invalid results, are directly addressed. Use photographs within the primary packaging (or printed on the secondary packaging) to show what each result looks like.
<b>Privacy and Confidentiality</b>	The secondary packaging should be kept small to ensure privacy through a discreet purchasing experience. Size should not become so small that theft concerns require placement behind a counter. Include language on all packaging to emphasize that the test is only for use by the individuals purchasing the kit.
<b>Product Stability</b>	Use tertiary and secondary packaging to protect the product during shipment and adhere to regulatory requirements. Use unambiguous symbols or language on the packaging to ensure product stability once taken home.

*Tertiary Packaging*

The analysis of drivers of packaging preferences demonstrated that the size of tertiary packaging (shipping cartons) will be influenced by the selection of a distribution channel and the concomitant supply chain considerations. The potential for larger tertiary packaging may allow greater bulk procurement to achieve cost savings. However, some aspects of tertiary packaging are unlikely to change (e.g. labeling requirements) and advances in this packaging can be made immediately. Product manufacturers are likely to have many of the tertiary packaging considerations already finalized based on their experience in other markets. Recommendations for tertiary packaging based on study findings are detailed in Table 4.

**Table 4. Key Recommendations for HIV Self-Test Tertiary Packaging**

*Include proper labeling:* Tertiary should include information on contents, storage temperature, fragility of the contents, batch numbers, manufacturing dates, expiration dates, and shipping dates.

*Keep packed weight below 50kg:* Tertiary packaging should ensure that when packed, boxes are less than 50kg given Kenyan legal requirements about lifting weight above this number.

*Select tertiary packaging size in consideration of the supply chain:* Larger tertiary packaging may be challenging for sectors with limited warehousing capacity or sectors in which an HIV self-test product moves more slowly. Distribution channel selection will impact tertiary packaging.

### *Secondary Packaging*

Secondary packaging plays the most crucial role in ensuring perceptions of quality, privacy and confidentiality, and consumer confidence in the product. To both ensure and convey product quality, secondary packaging needs to demonstrate that product integrity has been maintained. Physical strength of the box material and presence of a seal can achieve this. Clearly located expiration dates as well as storage temperature information are also important to ensure product stability and because consumers will look for this information to ensure quality. The Aware packaging (which was used as stimulus to elicit feedback during this study) was perceived as having too complex information and language on secondary packaging, which confused interviewees, threatening their confidence and interpretation of test results. Language must not be technical and at an appropriate grade level. Secondary packaging can also help testing privacy and confidentiality. While influencers and stakeholders reported that “HIV” should be clearly mentioned on the pack, users had divided opinions about it. Some saw it as a potential deterrent to product purchase due to stigma, while others saw it as an opportunity to normalize HIV self-testing. Some suggested that encouraging language easing concern about HIV testing and its potential outcomes should be included on secondary packaging to increase uptake. All users expressed preference for a small packaging to facilitate discretion. Recommendations for secondary packaging based on study findings are detailed in Table 5.

**Table 5: Key Recommendations for HIV Self-Test Secondary Packaing**

*Secondary packaging should be made of a durable material and be sealed:* This material will ensure product stability as it moves through the supply chain, and bolster user confidence in the product due to an increased perception of quality. The addition of a physical seal will also be helpful in addressing concerns about counterfeit and tampered product. Packaging materials should not be so strong that it requires the use of knives or scissors to open the product, nor so heavy that it drives up the cost of product shipping.

*Secondary packaging should be small to allow discreet purchasing:* Users desire a product the size of a cell phone or cigarette pack that can ensure privacy. Distributors should also be consulted when selecting the final product size to address any concerns they may have about product size increasing the risk of theft.

*Place an image of the product components on the secondary packaging:* This can build user confidence by indicating what to expect inside the packaging. It may also allay user concerns about potential tampering, allowing them to cross-check the actual contents with those depicted on the secondary packaging. Finally, the image may increase accurate use by allowing distributors to use this as a point-of-sale job aid when educating users about test administration.

*Ensure that relevant regulatory information is present and easy to read:* Secondary packaging must include the expiration date, storage requirements, manufacturing date and lot number. All of this information ensures product stability, supports recall of compromised product and ensures accurate use once the test kit is taken home by the consumer. Expiration dates should be easy to read, in larger font than expirations stamps on current product. Text and images used to convey information about storage condition (e.g. drawings of thermometers) should be pre-tested with the final target population.

*Avoid Technical Language:* Current HST products include a variety of technical words that are confusing to users and may increase anxiety about the test product or worse, cause questions about the product quality. Terms such as “OMT” “HIV ½” and “antibodies” are particularly problematic. Text specifying that the product is an “HIV test” should be present, but smaller than the brand logo.

*Include information about who should use the test:* To guide purchasing decisions, a text box should highlight which populations should not use the test. This is particularly important for supporting confidentiality goals by stating that the test should only be used in private by the consumer and should not be used in a coercive manner on any individual.

*Reference instructions for use:* Study populations had little faith that users would read the instructions before product use. The secondary packaging should be used to highlight the presence of IFU and the need for their review.

*Link language to broader HIV testing campaign language:* Users wish to see language framing HIV testing as a positive step for their future. This suggests that messaging on packaging should be designed to increase testing uptake even at the point of purchase.

*Co-branding or over-branding may be feasible:* Current discussions with oral test kit manufacturers suggests this may be feasible. In addition to over-branding or co-branding, a branded seal or stamp of quality may also be used to allay user concerns about potential counterfeit product.

*Primary Packaging* Primary packaging consists of the actual product, any sachet that holds it, as well as instruction manuals and inserts. Users’ reactions to the Aware sachet were largely positive, as it conveyed quality and was reassuring to users: they had to break a seal to access the contents. However, primary packaging needs significant improvement. While users had little to say about the actual components of the kit, influencers and stakeholders had many suggestions about primary packaging considerations. Many of these considerations will require support from manufacturers because they involve modifications to components manufactured in their facilities. They mentioned color coding test components (buffer vial, swab, buffer stand) and packing them in the order of use to increase understanding and accurate use. They suggested avoiding a screw-like system for the vial, because of the high risk of spillage. They proposed to either use a color-coding system to facilitate time keeping during the test, or having users write the time when the test is started and when the test was ready for interpretation. Based on these findings, primary packaging recommendations which may require advocacy with manufacturers are detailed in Table 6.

**Table 6: Key Recommendations for HIV Self-Test Primary Packaging that May Require Advocacy with Manufacturers**

*Include a stand or other mechanism to ensure the buffer vial stays upright:* There is a high risk that during test administration, the buffer vial will spill. Packaging should include a mechanism to keep the buffer vial upright—either by using the secondary packaging (e.g. Aware) or including a separate buffer vial stand. If a stand is advocated, we recommend limiting its size in consideration of potential increased shipping costs associated with bulkier and heavier packaging.

*Color-code the product components to support user comprehension of instructions:* The multiple test components introduce significant threats to accurate use. Color-coding each component of the test would allow instructions to reference each component by color, rather than complex technical names.

*Include a simple stop watch to ensure time keeping:* While most users can employ a wall clock or telephone to ensure results are read within the appropriate window, inclusion of a time keeping device would further support accurate test interpretation.

*Ensure sachet seal does not make the product too difficult to open:* This does not appear to be a problem for current oral HIV tests. However, should new products enter the market, it will be important to advocate with manufacturers that such tests be sealed to protect the product, but remain easy to open. This will ensure product stability during transport and prevent damage to the product if knives or scissors were used to open the sachet.

It came across very clearly in the research that users are unlikely to read detailed instructions and great attention should be paid to design drawings (rather than photographs) that explain HIV self-testing steps in extreme detail. It is important that the language on the instruction manual be simple, every day language rather than language meant for laboratory staff. Additionally, there are a number of known common errors and challenges (e.g. buffer spilling or invalid test result) that should be directly addressed through the inclusion of an “FAQ” text box.

In contrast to many existing test kit instructions, HST instructions must start with preparations before the components are opened and end with disposal instructions. These instruction components may not be included in directions for laboratory technicians who have the support of the broader health system, but they are crucial for an in-home test. In the same vein, users felt that the Aware packaging did not

offer adequate support in the interpretation of results, which was a key concern about HST. Instructions for interpretations and the clear visual aids are crucial.

The other essential element that users were expecting to find in the pack was information on counseling and linkages to care. Most users said they would seek follow-up through health centers, but most requested a hotline to be established to assist HST users, counsel them, and refer them to convenient resources. A hotline was perceived as a means to maintain confidentiality, one of the key benefits sought in using HST kits. In all instances, a hotline was seen as a support, not a replacement, for in-person counseling provided by the existing health system. Product inserts must include clear guidance on attending a facility for confirmatory testing, including local contact information. This responsibility cannot be borne by HST manufacturers, who produce products for global markets. An additional insert may need to be produced locally and added to the product. It could also include basic messages about HIV, and messages about the window period to encourage re-testing. Recommendations for secondary packaging based on study findings are detailed in Table 7.

#### *Additional Regulatory Considerations*

Finally, study findings indicate that a self-test kit product in Kenya would require both pre-qualification by the World Health Organization, as well as evaluation by the Medical Technicians Board in Kenya. An approved product would require registration with the Pharmacy and Poisons Board. This board conducts its own product evaluation. A certificate of registration is issued upon successful completion of this evaluation.

Kenyan regulations require that tertiary packaging be clearly labeled to indicate the product that is being handled, as well as its weight and whether it is fragile. Standard labeling information for secondary packaging—batch numbers, storage temperature, expiration date, manufacturing date and shipping date—should also be included to adhere with Kenyan regulatory requirements.

The price of a self-test product could be regulated by The Kenyan Bureau of Standards to prevent the product from being sold at high profit margins, potentially placing it out of reach of low-income populations.

**Table 7: Key Recommendations for HIV Self-Test Primary Packaging**

*Instructions for use should be presented in multiple languages:* Study participants all recommend the inclusion of both Swahili and English instructions to support accurate use among a diverse potential target population.

*Instruction text should be limited:* Study participants underscored the likelihood that users will not fully read instructions for use. To increase instruction use, text should be kept to a minimum.

*Use pictures alongside text for instructions:* Given the potential for use by low literacy populations, as well as the limited time any consumer takes to read instructions, text should be accompanied by pictorial instructions for each step of the testing process. Data suggest drawings should be used instead of photographs because of their greater visual clarity and easier manipulation. Pictures should include individuals of the skin color of the target population and the use of gloves should not be depicted.

*Instructions should be explicit:* Lack of familiarity with in-home diagnostic products requires detailed step-by-step instructions. No level of prior experience or understanding should be assumed.

*Ensure that all aspects of the testing process are included in instructions:* Instructions often begin with opening of the test package. Self-test products will require instructions to begin prior to this point, highlighting information about when the product can be used. Similarly, explicit disposal instructions also need to be included, specifying whether the test should be burned, buried or placed in a bin.

*Special attention to key test components:* Study participants reported that buffer solution, oral swabs, and desiccant packs are frequent sources of user error. Instructions need to pre-empt these common errors by directly addressing them.

*Include a “frequently asked questions” sidebar:* Because of the likelihood that individuals will not fully read instructions, we recommend the inclusion of a “FAQ” to address key areas that are likely to be problematic for users, threatening accurate use and interpretation. This should include: what to do if the buffer spills; what to do if the test is expired; what to do if the test is non-reactive; and who cannot use this test.

*Interpretation instructions must include all potential testing outcomes:* In addition to the interpretation of HIV positive and HIV negative test results, packaging inserts should also include details on an invalid test result. Photographs of each result should be included to support interpretation.

*Counseling information should mimic the existing HIV testing process:* Participants desired the packaging to support a standard counseling session. This included the provision of basic HIV education and information about risk reduction and linkage to care based on each testing outcome.

*Linkage to care information will need local customization:* If possible, information about where to seek care after a test result should be context specific. A packaging insert with referral information in **a local language**, and if necessary referencing referral points by name, may need to be printed and inserted once the product arrives in country.

*All components of the primary packaging must include an expiration date:* This ensures that secondary expiration date and lot number do not contradict with contents, indicating a tampered product.

*Primary packaging should include a time-keeping job aid:* Users are most likely to use wall clocks or a mobile phone to keep time during the test process. However, packaging should support the user to read the result within the allocated time period.

It is important to note that findings from other 3IE studies may further contextualize these findings, and impact the final adoption and adaptation of these findings. These include:

- *Accuracy and Reliability:* Direct observation of individuals using the Orasure product were conducted under Thematic Window #2 Question 1. Analysis of the data from these observations is ongoing but will likely reveal common errors among users. These errors may need to be considered in primary packaging development.
- *Target Population:* Data analysis is ongoing for Thematic Window#2 Question 3. These results will have important effects on the inclusion of the “HIV test” language on secondary packaging, as well as messaging to increase test uptake. Most importantly, the packaging and labeling considerations reported here did not explore marketing considerations for HST, such as branding and key messages for inclusion on the secondary packaging. This adaptation of packaging will be crucial once the product target population is determined.
- *Distribution Channel:* Results from Thematic Window #2 Question 4 could have far reaching packaging decisions. If products are distributed in HIV testing facilities with a counselors available to demonstrate use of the test and provide immediate follow-up counseling, the primary packaging detail may be significantly reduced (less counseling material, fewer detailed instructions). Distribution in health facilities for in-home use or distribution through pharmacies would require the robust primary packaging recommendations outlined here. Additionally, distribution channels are likely to affect the size of the secondary packaging. Specifically, pharmacy distributors may be concerned about theft if this packaging is too small, moving the product behind the counter and reducing access.
- *Linkages to Care:* Final recommendations about how self-tests can ensure linkage to care, under Thematic Window #2 Question 5, will also affect packaging and labeling. Examining or developing counseling inserts was beyond the scope of this study, but primary packaging is likely to need adaptation to ensure inclusion of this information to adequately prompt follow-up care and prevent adverse consequences.

It is clear that packaging and labeling will be an integral part of the development and roll-out of HIV self-testing in Kenya. By ensuring accurate use, building consumer confidence, guaranteeing product stability, providing privacy and confidentiality, and supporting interpretation of results and linkage to care, packaging and labeling will make a measurable contribution toward achieving the Government of Kenya’s HIV testing goals.

## Annex 1 – List of References

1. Kenya National AIDS Strategic Plan 2009/10-2012/13 (KNASP III). Accessed 26 February 2013 at: [http://www.nacc.or.ke/index.php?option=com\\_content&view=article&id=112&Itemid=87](http://www.nacc.or.ke/index.php?option=com_content&view=article&id=112&Itemid=87).
2. Denison JA, O'Reilly KR, Schmid GP, Kennedy CE, Sweat MD. HIV voluntary counseling and testing and behavioral risk reduction in developing countries: a meta-analysis, 1990--2005. *AIDS Behav.* 2008;12(3):363-373.
3. Ministry of Public Health & Sanitation, Approved HIV Testing Algorithm.
4. Kenya Demographic Health Survey (DHS). 2009. Accessed online 28 February 2013 at: <http://www.measuredhs.com/publications/publication-FR229-DHS-Final-Reports.cfm>
5. UNAIDS, 2012. The Kenya AIDS Epidemic Update 2011. Accessed 29 September 2012 at: [http://www.unaids.org/en/dataanalysis/knowyourresponse/countryprogressreports/2012countries/ce\\_KE\\_Narrative\\_Report.pdf](http://www.unaids.org/en/dataanalysis/knowyourresponse/countryprogressreports/2012countries/ce_KE_Narrative_Report.pdf).
6. 2007 Kenya AIDS Indicator Survey (KAIS). Preliminary Report. Available online at: [http://www.who.int/hiv/pub/progress\\_report2011/en/index.html](http://www.who.int/hiv/pub/progress_report2011/en/index.html), National AIDS and STI
7. Spielberg F, Levine R, Weaver M. (2004). Self-testing for HIV: a new option for HIV prevention? *The Lancet Infectious Diseases*,4, 640-646.
8. Kachroo S. (2007). Promoting self-testing for HIV in developing countries: potential benefits and pitfalls. *Bulletin of the World Health Organization.* 84(12): 999-1000.
9. National Guidelines for HIV Testing and Counseling in Kenya
10. WHO, 2011. HIV self-testing among health workers: a review of the literature. Accessed February 23, 2013 at: <http://www.who.int/hiv/pub/vct/9789241501033/en/index.html>. WHO, 2011.
11. Population Council. (2007). *Knowing Myself First: Feasibility of self-testing amongst health workers in Kenya.*
12. Choko AT, Desmond N, Webb EL, Chavula K, Napierala-Mavedzenge S, et al. (2011) 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 Med* 8(10):e1001102.doi:10.1371/journal.pmed.1001102.
13. CIA World Factbook. Available online at: <https://www.cia.gov/library/publications/the-world-factbook/geos/ke.html>.
14. Sanders EJ, Graham SM, Okuku HS, van der Elst EM, Muhaari A, et al. (2007). HIV-1 infection in high risk men who have sex with men in Mombasa, Kenya. *AIDS.* 2007;21(18):2513-2520.
15. Luchters SM, Vanden Broeck D, Chersich MF, Nel A, Delva W, et al. Association of HIV infection with distribution and viral load of HPV types in Kenya: a survey with 820 SW. *BMC Infect Dis.* 2010;10:18. doi: 10.1186/1471-2334-10-18.

## **Annex 2 - Document review – Review of international and national policies that affect HIV self-testing**

### **Document Review: Insights into Packaging and Labeling for HIV Oral Self-Test Kits in Kenya**

*International Initiative for Impact Evaluation Thematic Window 2: HIV Oral Self-Testing*

---

#### **Objective**

Appropriate packaging and labeling is one of many key elements to determine when bringing a new health product to market. The packaging and labeling of health commodities serves several purposes, such as protecting the product, arranging specific elements of the product to facilitate easy usage, relaying information about the contents and how to use the product, ensuring safety, and marketing the product to potential consumers.

PSI will review national and international standards and guidelines on HIV counseling and testing (HTC) to make sure the self-test kit includes critical information to maximize appropriate, accurate and safe use of the product. Items for review include the Kenyan and World Health Organization (WHO) guidelines on HIV counseling and testing, and the United States Food and Drug Administration (FDA) regulations on oral HIV self-testing.

#### **Kenyan Policies and Guidelines on Self-testing**

The Kenyan *National Reproductive Health and HIV and AIDS Integration Strategy* discusses that the National AIDS Control Council (NACC), as per the legal notice No. 170 of 1999, remains the lead government agency in coordinating HIV and AIDS-related programs. Its key role is to spearhead HIV activities with a focus on creating a supportive policy and regulatory framework.

According to the *National Quality Management Guidance Framework for HIV Testing and Counseling in Kenya 2010*, all HIV test kits in Kenya must be evaluated, approved, and registered at the national level by the National Blood Safety Committee (NASCO 2010a). Only HIV test kits that are provided for in the national algorithm by the Ministry of Public Health and Sanitation can be used for HIV testing in Kenya.

Rapid scale up of HTC in Kenya created a need for a national quality assurance policy (NASCO 2010a). The National Quality Assurance Team, a subcommittee of the National VCT Taskforce was created. A National HTC curriculum, a three week curriculum of HIV/AIDS information counseling theories and a testing component. All HTC service providers must receive training as stipulated in the national HTC curriculum. Qualified TOTs across the country were identified and trained and only they were allowed to train VCT counselors. To ensure quality trainings, a limited number of institutions outside the GoK were accredited to train counselors and all certificates issued post training were signed by the Head of NASCO. In 2001, NASCO initiated a registration scheme that would enable it to have an up-to-date register of all VCT sites in the country.

Registration mandatory process through which all new standalone and integrated VCT sites are evaluated and certified, using a standard tool with the specific objective of assessing whether they meet

certain minimum set criteria to provide HTC services. This registration should be done by the DASCO and forwarded to NASCOP. The registration is done by name and physical address. Only registered sites will have access to HTC commodities such as rapid HIV test kits, HTC laboratory registers, as well as condoms. Additionally, HTC service provision facilities/sites/models shall make every effort to ensure privacy of HTC service provision.

Additionally, the minimum commodities required for HTC in Kenya are (NASCOP, 2011):

- Test kits and their accessories
- Consumables—gloves, cotton wool, spirit, disinfectant, lancets
- Data recording tools
- Waste disposal container
- Quality assurance package—filter papers, zip lock bags, glycerin bags, serviettes, humidity indicators, desiccants, filter paper drying racks, cotton wool, alcohol swabs, detergents.
- Male and female condoms
- HTC service delivery protocols

The primary document discussing Kenya’s guidelines on self-testing is the “National Guidelines for HIV Testing and Counseling in Kenya.” Kenya was the first country in Africa to develop policy guidelines on access to self-testing kits for the general public over the counter. The following is an excerpt from the 2009 national guideline document:

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

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

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

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

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

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

At the first international symposium on self-testing it was discussed that although the HIV self-test kits was first approved for use in Kenya in 2006, it has not been widely implemented or used in Kenya because (WHO 2013):

- lack of clarity about whether HIV self testing 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;
- HIV self testing has been included in the national guidelines, but there is no clear implementation plan on how it can be best utilized in programs;
- task shifting to lay counselors to provide HTC has been a successful policy shift in Kenya, but “task shifting to the individual” has yet to be appreciated and realized.

#### ***Key findings from review of Kenyan Policies:***

- Self-test kits users must be informed ON THE PACKAGING that the results are not confirmed until a second, confirmatory test is conducted.
- The instruction leaflet should mention that vendors can provide the client with step-by-step instructions for: How to conduct the test; How to correctly interpret the test results; and Where to access follow-up and support services in the surrounding area.
- All HTC sites need to be registered with the NASCOP; Pharmacists and other suppliers of self-test materials should undergo HTC training and be certified by the Ministry of Health.
- Confidentiality needs to be ensured at the point of sale; pharmacist should provide a private room for clients who may need further information, counseling and social support.
- All HIV test kits in Kenya must be evaluated, approved, and registered at the national level by the National Blood Safety Committee

#### **International Policies and Guidelines on Self-testing**

The document “HIV Self-testing among Health Workers” discusses the shift in HTC policies. Over time policies have become more public-health oriented emphasizing the need for convenience, better integration into routine health services, and prioritizing wide coverage through sustainable strategies rather than in-depth pre-and post-test counseling. While guidelines for self-testing have not been addressed in UNAIDS/WHO documents on HTC, the shift in policies has expanded feasibility of other HTC models, including self-testing. A summarization of key points from UN and WHO documents are below:

- The UN General Assembly adopted the Declaration of Commitment on HIV/AIDS in 2001, which stated that prevention of HIV infection must be the mainstay of the response to the epidemic and this should include commitment to expanded access to HTC. This was reaffirmed in the Political Declaration on HIV/AIDS in 2006.
- In 2004, UNAIDS and WHO issued a revised Policy Statement on HIV testing, which emphasized

that HIV testing is the gateway to expanded prevention, treatment and care. Current WHO policy supports this public health approach, recognizing the importance of knowing one's HIV status and promoting expanded access to HIV testing through, for example, routine facility-based provider-initiated testing and counseling.

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

The first international symposium on self-testing for HIV was held April 8<sup>th</sup> and 9<sup>th</sup> in 2013 (WHO, 2013). There was consensus that the instructions on HIV self-test kits must be clear, uncluttered, and less complex than the instructions found on products for professional use. Suggestions included using more illustrations and fewer words in the instructions-for-use. Additionally to promote correct product use, it was suggested that innovative training approaches be used, such as supervised self-testing, demonstrations at point-of-sale/distribution, and YouTube videos.

A presentation at this symposium shared findings from a feasibility and acceptability study of HIV self-testing among health workers in Kenya. 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. Self-testing was highly acceptable in the study (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. Participants reported that they found self-testing to be more confidential than HTC and that the oral fluid rapid diagnostic test (RDT) was easier to conduct than whole blood-based RDT. Importantly, 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. Limitations were that the telephone hotline was only used by a few people to clarify test procedure and was not used to seek post-test counseling. No adverse events were reported.

Lessons learned from this study:

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

The WHO document *Planning, implementing and monitoring home-based HIV testing and counseling: A practical handbook for Sub-Saharan Africa*, states that the “greatest concerns with home-based self-testing are: the potential absence of pre- and post-test counseling and follow-up mechanisms, the potential for adverse consequences particularly following a positive result, and the lack of quality assurance systems to ensure tests are not misused, that results are accurate, and that appropriate linkage to care takes place. Self-testing should follow the Five Cs of HTC as outlined by WHO: consent, confidentiality, counseling, correct results and linkage to care (WHO 2013).

The following are general HTC guidelines that may influence packaging and labeling decisions for an over the counter HIV self-test kit.

### **Quality Assurance Guidelines**

General guidelines to ensure quality assurance for HIV rapid testing may apply to self-testing. Some guidelines include (WHO 2005):

- Ensuring national system of quality assurance that randomly tests kits
- Clear storage instructions for vendors and consumers
- Purchased kits must have an expiration date far enough into the future to allow for efficient use and to prevent waste. A policy of “first expired, first out” will also help to assure minimum waste.
- There is a need to develop standard operating procedures for transport, storage, and distribution of HIV test kits.

### **Re-testing Guidelines**

Likely, guidelines for re-testing will need to be developed for self-test kits. Generally, those who have tested positive should be immediately referred to a health facility where their HIV status will be verified by testing performed on a second specimen (WHO 2010). Re-testing is also recommended for those whose initial test results were indeterminate, those who tested negative but are at ongoing risk for acquiring HIV, and those who may be in the early stages of infection, but have not yet developed a sufficient level of antibodies that can be detected by serological testing (WHO 2010).

### **Other Considerations**

Other HTC aspects that may extend to self-test packaging and labeling include:

- Packaging guidelines on age restrictions and age specific testing results (WHO 2012). Issues around children include coercive testing and misunderstandings around the source of HIV transmission. Additionally WHO has set out guidelines for testing procedure for different age groups under the age of five.
- Packaging information that discusses modes of transmission to avoid confusion, especially if testing is performed on children/adolescents (WHO 2012); there is risk that perinatal transmission could be misunderstood as sexual transmission leading to negative actions against the child/adolescent if modes of transmission are not explained adequately
- Guidelines for confidentiality and safety at the point of sale (WHO 2013)

- Post-test counseling should describe follow up services that are available in the community, highlighting treatment (WHO 2007)
- Post-test counseling should provide information on how to prevent transmission of HIV, including provision of male and female condoms (WHO 2007)
- Post-test counseling should discuss possible disclosure of results, when and how this might happen, and to whom (WHO 2013).
- Post-test counseling should encourage referral for testing and counseling of partners and children (WHO 2007)

### ***Key findings from International Policies and Guidelines on Self-testing***

- Instructions on HIV self-test kits should be clear, uncluttered, and less complex than the instructions found on products for professional use. Illustrations and fewer words should be used in the instructions-for-use.
- Innovative training approaches should be used, such as supervised self-testing, demonstrations at point-of-sale/distribution, and YouTube videos.
- Instructions should highlight the potential for adverse consequences particularly following a positive result
- Instructions should discuss proper use of self-test kits, including obtaining proper consent prior to testing
- Confidentiality at point of sale needs to be highlighted among distributors
- Instructions should provide resources for linkages to care; if hotline number is provided on instructions, the hotline for post-test counseling should ensure anonymity, and therefore should not be linked to a local facility.
- Re-testing guidelines should be clearly stated in instructions
- Tertiary packaging should have clear storage instructions for distributors and vendors and product labeling should have clear storage instructions for consumers
- Expiration dates should clearly be stated on packaging
- Packaging should state the ages of appropriate use

### **OraQuick® In-Home HIV Test Packaging and FDA Approval Process**

#### ***FDA Approval Process***

On May 15, 2012, the Blood Products Advisory Committee (BPAC) at the FDA met as a device panel to assess the safety and effectiveness of the OraQuick® In-Home HIV Test (FDA 2012). On the topic of risk mitigation strategies that should be considered in addition to the current proposed labeling, emphasized the importance of stressing three messages:

- A positive result with this test does not mean that you are definitely infected with HIV, but rather that additional testing should be done in a medical setting
- A negative result with this test does not mean that you are definitely not infected with HIV, particularly when exposure may have been within the previous three months
- Re-testing is recommended if you test negative and continue to engage in behavior that puts you at risk for HIV infection.

The FDA's Summary of Safety and Effectiveness discusses a list of warnings, precautions, and limitations for the OraQuick® In-Home HIV Test (FDA 2012):

1. The testing directions must be followed carefully. Not doing so may produce inaccurate test results.
2. Using this test earlier than 3 months since a risk event may not produce an accurate result. This test should not be used by individuals who are anxious about using the test.
3. Reading test results earlier than 20 minutes or later than 40 minutes may yield erroneous results.
4. This test is approved by FDA for use with oral fluid specimens only. Use of other types of specimens may not yield accurate results.
5. Any positive result needs to be followed up with either a confirmatory test performed by a clinical laboratory or consultation with a medical professional to arrange a confirmatory test.
6. Individuals who test negative but engage in behavior that puts them at risk for HIV infection should test or be tested on a regular basis.
7. Persons with increased risk for HIV infection should not interpret a negative test to indicate that engaging in high-risk behavior is safe.
8. This test is not to be used by individuals under the age of 17.
9. Adequate lighting is required to read a test result.
10. This test is not for use by individuals who know they are HIV-positive or who are undergoing treatment for HIV infection.
11. This test should not be used after the expiration date.
12. If the tamper-evident seal has been broken or if any of the package contents are missing, broken, or have been opened, do not use this test.
13. The user should not open any of the packets until ready to begin the test.
14. Do not eat, drink or use oral care products (such as mouthwash, toothpaste or whitening strips) 30 minutes before starting the test.
15. Remove dental products such as dentures or clear braces that cover your gums prior to the oral collection.
16. Do not use the test if it has been exposed to household cleaning products.
17. A positive result may indicate the presence of antibodies to HIV-1 or HIV-2. A person who has antibodies to HIV-1 or HIV-2 is presumed to be infected with the virus, except that a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV.

Pre-market approval was granted by The Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA), with some conditions of approval (

- Expiration dating for this device was established and approved at 30 months.
- Continued approval of this PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA.
- Complete a PMA Post-Approval Study Report on comprehension of the labeling in English and Spanish
- Conduct surveillance of the Consumer Support Center usage to collect information on the number of individuals reporting positive, negative, or unknown results, as well as demographic information.
- Report of adverse events is required for this device

## The OraQuick® In-Home HIV Test Kit

The OraQuick® In-Home HIV Test Kit consists of the following items (Figure 1):

- Outer carton containing plastic molded laptop box
- Instruction Booklet (flipchart design) attached to the plastic molded laptop box
- 1 Test Device
- 1 Developer Vial
- 1 Pre-Test Informational Booklet (HIV, Testing & Me)
- 1 Post Test Informational Booklet (What Your Results Mean to You!)
- 1 Pencil for writing down the read times (not shown) · 1 Disposal Bag (allows for discrete disposal - not shown)
- Accessibility to the OraQuick® Answer Center

Figure 1



The following list is a summary of the changes that were made to the professional product, OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test, to transition it to the OraQuick® In- Home HIV Test.

### Filled Developer Vial:

The Developer Vial cap was modified to add thumb indentations to make it easier and more intuitive for the consumer to open the vial without spilling the developer solution. The cap is made of the same material as the cap of the approved professional product.

The Developer Vial Label artwork has been revised to reflect consumer labeling. The Developer Vial is called the Test Tube for the over-the-counter product. The solution contained in the Test Tube is the same Developer Solution as in the professional product.

#### Device Label:

The artwork present on the Device Label was modified to reflect the branding for the OraQuick® In-Home HIV Test. Construct of the label is the same as the current device label.

#### Pouched Device and Developer:

The test device and developer vial are pouched in a divided pouch with separate compartments for the device and developer vial. Its artwork has been designed to reflect consumer use in an OTC setting. The artwork was developed to show a pictorial of the device and test tube to allow the consumer to follow the step-by-step instructions. The material used to make the divided pouch is the same as that of the foil laminate pouch of the professional product. The two sides of the divided pouch are separated

#### Test Stand:

The test stand into which the device is placed for the test to run and the result to be interpreted was developed to physically incorporate it into the laptop box design. The angle that the laptop opens to is consistent with the angle of the test stand used with the professional product.

#### Instructions for Use:

The instructions for use are provided to the consumer in easy to follow step-by-step instructions. Graphics are used for emphasis and to assist with understanding. The step for removing the cap from the test tube was revised for clarification to target the operational error of spilling the Developer Solution. The step for collecting the Oral Fluid sample was revised to add emphasis that both the top gums and the bottom gums needs to be swabbed to target the operation error of not swabbing the gums. A statement was added to the page that provides the consumer with the directions for interpreting their test results. The Instructions for Use make frequent reference to the toll free number of the Consumer Support Center throughout. This included a detailed list of the types of questions the call center could answer so the consumer understands that there is someone they can call to get clarification.

#### Pre-Test Informational Booklet:

The OraQuick® In-Home HIV Test provides a pre-test informational booklet called “HIV, Testing, & Me”. This booklet is found in the drawer containing all of the components needed for testing. The instructions for use reference the booklet in the introduction page and again at the point in the instructions where the user is waiting for their test results.

#### Post-Test Informational Booklet:

The OraQuick® In-Home HIV Test provides a post-test informational booklet called “What Your Results Mean to You”. This booklet is found in the drawer containing all of the components needed for testing. The instructions for use direct the user to read this booklet once they have interpreted their test results.

#### Packaging:

The OraQuick® In-Home HIV Test contains components to perform a single HIV test. All of the contents are contained within the plastic laptop like box that also serves as the test stand into which the developer vial and test device are placed in order for the test to run. The instructions for use are attached to the box and situated so that the pictures that help an individual to conduct the test and interpret their results are immediately adjacent to the consumer’s test device. The

section explaining the “window period” was revised to include an explanation of a risk event to further help the consumer self-select. The labeling references the toll free number to the Consumer Support Center throughout.

The OraQuick In-Home HIV test should be stored at a temperature of 36 degrees to 80 degrees Fahrenheit (<http://www.oraquick.com/FAQs>). If the test was stored for any extended period of time (3 hours or more) in an excessively hot (80 degrees Fahrenheit and above) or cold (36 degrees Fahrenheit or below) environment, the OraQuick In-Home HIV test should not be used.

***Key Findings from OraQuick® In-Home HIV Test Packaging and FDA Approval Process***

- 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.
- Instructions should discuss that a positive result with this test does not mean that you are definitely infected with HIV, but rather that additional testing should be done in a medical setting
- Instructions should discuss that a negative result with this test does not mean that you are definitely not infected with HIV, particularly when exposure may have been within the previous three months
- Instructions should emphasize re-testing is recommended if you test negative and continue to engage in behavior that puts you at risk for HIV infection
- Packaging should clearly explain the “window period” and explain what a risk event is to help the consumer self-select.

## **Bibliography (\*Cited Literature)**

\*(FDA) U.S. Food and Drug Administration. *OraQuick® In-Home HIV Test Summary of Safety and Effectiveness*. Washington D.C.: FDA, July 3 2012.

<<http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/UCM312534.pdf>>

\*FDA. *OraQuick® In-Home HIV Test Approval Letter*. Washington D.C.: FDA, July 3, 2012.

<<http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm310592.htm>>

\*Mavedzenge, SN et al. *HIV self-testing among health workers: a review of the literature and discussion of current practices, issues and options for increasing access to HIV testing in Sub-Saharan Africa*. Geneva: WHO, 2011.

\*(NAS COP) National AIDS and STI Control Programme, Ministry of Public Health and Sanitation, Kenya. *Operational Manual for Community-based HIV Testing and Counselling*. Nairobi: NAS COP, 2011.

\*(NAS COP 2010a) National AIDS and STI Control Programme, Ministry of Public Health and Sanitation. *National Quality Management Guidance Framework for HIV Testing and Counseling in Kenya*. Nairobi: NAS COP, 2010.

(NAS COP 2010b) National AIDS and STI Control Programme. Ministry of Public Health and Sanitation and Ministry of Medical Services Kenya. *Operational Manual for Implementing Provider-Initiated HIV Testing and Counselling in Clinical Settings 2010*. Nairobi: NAS COP, 2010.

\*(NAS COP) National AIDS and STI Control Programme, Ministry of Public Health and Sanitation, Kenya. *National Guidelines for HIV Testing and Counselling in Kenya*. Nairobi: NAS COP, 2009.

Lekorere, Merina S. *Operational Manual for HTC Community Based Services*. Nairobi: NAS COP, Presentation, November 2009.

\*OraSure Technologies. *Final Advisory Committee Briefing Materials: Available for Public Release: OraQuick® In-Home HIV Test*. OraSure Technologies, Blood Products Advisory Committee Briefing Document, Meeting Report, 15 May 2012.

Pharmacy and Poisons Board, Ministry of Health Kenya. *Code of Promotional Practices for Pharmaceutical Representatives in Kenya*. Nairobi: Pharmacy and Poisons Board, 2006.

Republic of Kenya. *National Reproductive Health and HIV and AIDS Integration Strategy*. Nairobi: Republic of Kenya, 2009.

\*WHO. *Report on the first international symposium on self-testing for HIV: The legal, ethical, gender, human rights and public health implications of self-testing scale-up*. Geneva: WHO, Meeting Report, 8-9 April 2013.

WHO et al. *Planning, implementing and monitoring home-based HIV testing and counseling*. Geneva: WHO, 2012.

**WHO. *Guidance on couples HIV testing and counselling - including antiretroviral therapy for treatment and prevention in serodiscordant couples: Recommendations for a public health approach.* Geneva: WHO, 2012.**

**WHO. *Guide for monitoring and evaluating national HIV testing and counselling (HTC) programmes: Field-test version.* Geneva: WHO, 2011.**

**WHO. *HIV self-testing among health workers: A review of the literature: A review of the literature and discussion of current practices, issues and options for increasing access to HIV testing in sub-Saharan Africa.* Geneva: WHO, 2011.**

**\*WHO. *Delivering HIV Test Results and Messages for Re-testing and Counseling in Adults.* Geneva: WHO, 2010.**

**WHO. *A Handbook for Improving HIV Testing and Counselling Services: Field-test version,* Geneva: WHO, 2010.**

**\*WHO. *Guidance on Provider-Initiated HIV Testing and Counseling in Health Facilities.* Geneva: WHO, 2007.**

**\*WHO. *Guidelines for Assuring the Accuracy and Reliability of HIV Rapid Testing: Applying a Quality System Approach.* Geneva: WHO, 2005.**

## Annex 3 - Creative brief

PSI/Kenya - PSI/Washington

### **Creative brief for 3ie project: How to package HIV oral self-test kits Designing two HIV oral self-test kit packaging options for a qualitative study**

December 1, 2013

=====

#### **1- Background:**

One of the objectives of the Kenyan Government's strategic plan to fight HIV is for 80% of the population to know its HIV status.<sup>12</sup> This is necessary for increasing access to HIV treatment and has been shown to positively influence sexual risk behaviors, especially among persons who test positive for HIV.<sup>13</sup> Despite the high number of HIV Testing and Counseling (HTC) sites across the country (over 6,000), only 36% of adult Kenyans report having ever tested for HIV and received their results<sup>14</sup>. HIV oral self-test kits are expected to be one of the key interventions in increasing that number.

The United States introduced HIV self-test kits into the market in 2012. Since then, a handful of developing countries have worked on adapting the test for their own emerging markets. Due to its ease of use, the oral HIV self-test (as opposed to a finger prick) has been shown to be most promising. The oral test is conducted by using a mouth swab to collect antibodies located on the upper and lower gums, and mixing the sample collected with a liquid reactive. A testing strip, similar to that found in pregnancy test kits, is then plunged into the liquid. The result can be read after 20 to 40 minutes. The HIV oral self-test is proven to be reliable and can be bought discretely and used privately, which removes many of the concerns related to HIV testing, including lack of privacy, inconvenience, and stigma. Preliminary research suggests that oral self-testing is a feasible and acceptable response to increasing HIV testing uptake in Kenya and other African nations.<sup>15,16</sup>

As part of the efforts to understand how to create a market for HIV oral self-test kits in Kenya, PSI/Kenya is implementing a study funded by 3ie to understand how to best package and label the product. Packaging and labeling are important not only for effectively marketing the product, but also for ensuring the product's stability, safety, and accuracy. A product designed in the United States for a United States audience cannot simply be placed in Kenya. Significant adaptation is needed. While no HIV

---

<sup>12</sup> Kenya National AIDS Strategic Plan 2009/10-2012/13 (KNASP III). Accessed 26 February 2013 at: [http://www.nacc.or.ke/index.php?option=com\\_content&view=article&id=112&Itemid=87](http://www.nacc.or.ke/index.php?option=com_content&view=article&id=112&Itemid=87).

<sup>13</sup> Denison JA, O'Reilly KR, Schmid GP, Kennedy CE, Sweat MD. HIV voluntary counseling and testing and behavioral risk reduction in developing countries: a meta-analysis, 1990-2005. *AIDS Behav.* 2008;12(3):363-373.

<sup>14</sup> UNAIDS, 2012. The Kenya AIDS Epidemic Update 2011. Accessed 29 September 2012 at: [http://www.unaids.org/en/dataanalysis/knowyourresponse/countryprogressreports/2012countries/ce\\_KE\\_Narrative\\_Report.pdf](http://www.unaids.org/en/dataanalysis/knowyourresponse/countryprogressreports/2012countries/ce_KE_Narrative_Report.pdf).

<sup>15</sup> Population Council. (2007). *Knowing Myself First: Feasibility of self-testing amongst health workers in Kenya.*

<sup>16</sup> Choko AT, Desmond N, Webb EL, Chavula K, Napierala-Mavedzenge S, et al. (2011) 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 Med* 8(10): e1001102. doi:10.1371/journal.pmed.1001102.

self-testing product is yet available in the country, two HIV oral self-tests brands, Aware and Orasure, are viable candidates for introduction into Kenya in the not-so-distant future. Unlike Orasure's, Aware's packaging has been tested with community health workers in Kenya during a study in 2011, with a positive response. Due to the uncertainty as to when the Kenyan Government will grant approval for these products to be sold, it is possible for other manufacturers to appear with test kits over the coming years. As there is still room for innovation in this nascent market, the purpose of this study is to both test reactions to existing Aware and Orasure packaging, as well as to explore how an optimal packaging should be designed.

PSI/Kenya has commissioned IPSOS to carry out the study, which includes two waves of data collection.

- The first wave of interviews with government stakeholders, international stakeholders, manufacturers, distributors, pharmacists, healthcare professionals and potential users/consumers took place in October 2013. The objective was to understand the different considerations that need to be made when designing HIV self-test kit packaging. PSI also carried out a literature review of local and international regulations and policies.
- The second phase will take place in December 2013 and aims to test consumer preferences and reactions to two new packaging designs. The designs, developed by the agency and with insights from the first wave of interviews, will be tested alongside the Orasure and Aware kits. The results will inform policymakers, manufacturers and decision-makers of how to design HIV self-test kits so that they are safe, accurate, and preferable to consumers.

## **2- Objective**

The objective is to develop two new designs for HIV oral self-test kit packaging and labeling. Rather than develop a brand, the focus is on the packaging itself and how packaging can support correct product use and increase product uptake.

## **3- Expected outputs**

The agency will design two different packaging/labeling options, one for each oral self-test product (e.g. Aware and Orasure). These should be sufficiently different from one another (for example, not just two different color schemes) to represent different concepts/routes/ideas.

Materials developed should include:

- Tertiary packaging (cartons shipped to pharmacists/distributors)
- Secondary packaging (outer packaging of the product as it is sold to the consumer)
- Primary packaging (inner packaging containing the different elements of the kit, if any)
- Instruction leaflet (adapted from existing instruction leaflets)

To further define the scope of the output, it may be useful to understand the key test components of each potential product. PSI will provide the agency with samples of the Aware and Orasure products.

The actual test components cannot be altered and if currently packaged separately, they must remain so in order to ensure stability of the test. For example, the buffer and specimen collection device are packaged separately; the new packaging cannot propose they be placed in a single sachet. Please note that the above does not request development of anything regarding pre or post-test counseling. Instead, the key focus is on instructions for proper use and interpretation of the test. Counseling materials will be developed separately and are not considered to be part of this output.

Mockups developed should be as finalized as possible, and should not be of lower visible quality than Aware and Orasure to avoid any bias in responses during the second phase of the study. Four mockups of each packaging route should be developed.

#### **4- Considerations that should guide packaging design**

The literature review, consumer interviews, potential distributors focus groups (distributors, health service providers, community health workers) and professional stakeholder interviews suggest that a number of issues can be addressed by packaging and/or labeling of the self-test product. These are outlined below. This guidance should inform the overall approach to development of product packaging/labeling.

##### ***Packaging/labeling can ensure that users are comfortable taking the HIV oral self-test***

Building trust is a major issue; since this is a new product in the market, it's important that the users feel they can trust the product and the manufacturers. Suggestions for building that trust include:

- Having a photograph of the test kit on the secondary packaging so that the consumer knows what it looks like and what contents are inside
- Ensuring that the product looks professional and that all of the components come in sealed containers/wrapping so that users know the product has not been used or tampered with.
- Reminding consumers that these are the same tests used by professionals in clinical settings.
- Ensuring the labeling conveys that the tests have been regulated and validated by the appropriate bodies.
- Not using overly technical language or language that is unnecessary for the consumer. For instance, the Aware test says HIV 1/2 OMT, and “antibodies” on the packaging, all of which are unfamiliar words / terms and are not necessary for the user; the language has to be simple, lay-person language

##### ***Packaging/labeling can ensure HIV self-tests are used by appropriate individuals***

Packaging/labeling of the test must convey the following information about *who* should use the product, why they should use it, what the advantages are and what the product contains. Given that this information will affect the decision to procure an HIV self-test, this information should be reflected on the secondary packaging of the product, as well as the instructions within the kit.

- The test is not for use by individuals who know they are HIV-positive or who are undergoing treatment for HIV infection.
- The HIV self-test kit is only for personal use. HIV self-testing should not be used in a coercive or mandatory way.
- The test should not be used by individuals who are anxious about using the test.
- The test will not have accurate results if used before 3 months have passed since a risk event. (Using this test earlier than 3 months since a risk event may not produce an accurate result.)
- The Orasure packaging uses a red box to convey who should not use the test.

##### ***Packaging/labeling can ensure HIV self-tests are administered accurately***

Clear instructions (inside the secondary packaging and inside the kit) support accurate HIV self-test use.

- HIV self-test vendors should be able to provide the consumer with step-by-step instructions for how to conduct the test, how to correctly interpret the test results, and where to access follow-up and support services in the surrounding area. The secondary packaging needs to be able to convey how the test works.
- Instructions on HIV self-test kits must be clear, uncluttered, and adapted for audiences with low levels of literacy. Suggestions included using more illustrations and fewer words.
- Packaging and instructions should be bilingual (English, Swahili)
- Cartoons/line drawings thought to be better than photographs because they can be manipulated easily in order to instruct the user.
- Graphics should convey people that “look like” the potential users i.e. skin-tone
- Colors should be used to help users identify test components and follow instructions. So, any color used in the instructions should match the color on the product (e.g. if the vial has a blue cap, make sure the drawing of the vial in the instructions also has a blue cap)
- The following information must be provided in the instructions for use:

1. The testing directions must be followed carefully. (Not doing so may produce inaccurate test results)
2. Only oral fluid specimens can be used in this test.
3. This test should not be used after the expiration date.
4. If the tamper-evident seal has been broken or if any of the package contents are missing, broken, or have been opened, do not use this test.
5. The user should not open any of the packets until ready to begin the test and should be shown how to line all of the components up correctly before beginning.
6. Do not eat, drink, or use oral care products (such as mouthwash, toothpaste or whitening strips) 30 minutes before starting the test.
7. Remove dental products such as dentures or clear braces that cover your gums prior to the oral collection.
8. Do not use the test if it has been exposed to household cleaning products.
9. Reading test results earlier than 20 minutes or later than 40 minutes may yield erroneous results.

- **Instructions for use should be read in a stepwise fashion. Packaging therefore needs to help facilitate the reading of each instruction, in order to ensure that the user follows every step.**
- Some recommended the use of a trouble-shooting guide to address key challenges likely to be encountered by a user. These include:
  1. What to do if there is no buffer? (The product should be returned as defective.)
  2. What to do if the buffer spills? (A new product should be procured)
  3. What to do if there is no expiration date listed on the product? (Do NOT use the product)
  4. What to do if the expiration date listed has passed? (Do NOT use the product)
  5. Is it okay to use the product if the gums are bleeding?

Other important considerations on accuracy of use:

- Some studies have shown that people do not open the test kit correctly; they open it on the wrong side. It is suggested that packaging can play a key role in facilitating correct opening.
- There is concern that users will grab the wrong side of the swab and use it incorrectly.
- Some studies have shown that people do not know how hard to press when they swab.

- There is concern that if the vial with buffer fluid is opened incorrectly (trying to twist instead of pushing the lid off) the buffer will spill and the product will be un-usable.
- The buffer vial and test cassette must remain upright during testing. There is a risk of the vial falling over when the test cassette is inserted. It needs to be placed in a stand or some other mechanism for keeping it upright. Packaging may be able to play this role. Ideally, the package could be opened and the vial is already in place.
- The packaging can help ensure that the test is read in the correct window of time, and can include an element that help users keep track of time (between 20 and 45 minutes), such as a blank box on the outer pack where start and finish time can be noted.
- Aspects of packaging may be utilized to ensure the product is not used beyond its expiration date. (E.g. Prompts to check the expiration date printed on the packaging)

***Packaging/labeling can ensure HIV self-tests are interpreted accurately***

The packaging itself should help with interpretation of the results.

- Ensure that the user reads the result with the packaging in hand so that the interpretation information is readily available
- Information that must be included in the interpretation of results:

1. Reading test results earlier than 20 min or later than 40 min may yield erroneous results.
2. If a test is non-reactive (no control line shows up), it should be thrown away. No one should attempt to interpret a result from a non-reactive test.
3. Adequate lighting is required to read a test result.
4. Retesting is recommended whether the test result is positive or negative:
  - a. A positive result does not mean that you are definitely infected with HIV; additional testing should be done in a medical setting.
    - i. Any positive result needs to be followed up with either a confirmatory test performed by a clinical laboratory or consultation with a medical professional.
  - b. A negative result does not mean that you are definitely not infected with HIV, particularly when exposure may have been within the previous three months.
    - i. Re-testing is recommended if you test negative and continue to engage in behavior that puts you at risk for HIV infection.

***Packaging/labeling can ensure that HIV self-tests remain stable***

There are concerns that in-home use of HIV self-test kits may result in poor storage of the product, or use beyond the expiration date. Packaging/labeling should be used to prevent this from occurring.

- Tertiary packaging should have clear storage instructions for distributors and vendors. This should include a lot number, an expiration date and temperature for storage.
- Tertiary packaging needs to be able to withstand a “rough and tumble” environment where there could be temperature changes, rains, and/or distribution processes that entail dividing up components of the test kit and then putting it back together.
- Secondary packaging should include temperature storage instructions for consumers. Attention should be paid to reports of misinterpretation of the temperature range. For example, the dash in “3-30 degrees Celsius” is interpreted as a negative sign that indicates proper storage between 3 and *negative* 30 degrees Celsius, rather than 3 and 30 degree Celsius. Additionally,

temperature should be communicated in more than one way given potential use by low literacy populations.

- Expiration date information must be clear and should be **printed** on each component of the packaging (tertiary, secondary and primary (e.g. the pouch holding the test)). Stickers should not be used to convey the expiration date as these can be manipulated by manufacturers.
- As stated above, the instructions for use must be clear that:
  - This test should not be used after the expiration date.
  - If the tamper-evident seal has been broken or if any of the package contents are missing, broken, or have been opened, do not use this test.
  - The user should not open any of the packets until ready to begin the test.
- Instructions for use should include information about how to dispose of the self-test product.

### ***Packaging/labeling can help user maintain confidentiality.***

Stakeholders discussed the ways in which HIV-related stigma must be taken into account when designing the package and the label. Suggestions included:

- Ensuring the package fits inside a small bag or a pocket so that it can be carried discreetly (some users suggested cellphone size).
- Make the logo much bigger than the word HIV so that its clear its an HIV test but its not what draws the eye
- Users fear to be judged by pharmacists and clients of the pharmacy alike, not to mention their partner if they are seen using the test at home. The packaging should be engaging and support potential users through a positive, empathic tone.

### ***Packaging/labeling can ensure that users know where to seek additional care***

Stakeholders did not provide extensive feedback on this issue because the best mode of providing counseling support is unknown and currently under investigation. However, there is widespread agreement that the packaging should include information about accessing care by contacting a hotline number. Any proto-type should include suggested areas where such information could be included.

- Ensuring the hotline/call center information is with the step on interpreting results and not only in an instruction leaflet because many people do not read through all of the instructions.

### ***Specific reactions to the Aware packaging***

Reactions to Aware were overwhelmingly positive among all target groups: it was perceived to be a reliable, quality product. Elements that stand out are:

- Brand name: Refers clearly to what the product is, and avoids at the same time any negative / stigmatizing connotations
- Packaging size: Good size, although potential users would like it to be smaller (some referred cellphone / smartphone as the adequate size). The important thing is that product can be carried around discreetly.
- Colors: simple blue color perceived as a little dull by some, but conveys seriousness and do not send any alarming message about the product
- Quality of secondary packaging carton (glossy, rigid) is very well received
- Primary packaging: sealed pouch reassures about the integrity of the product, and transparent plastic material allows seeing what is included in the self-test kit.

Negative reactions include:

- Instructions regarding reading the test results are unclear. Potential users did not understand that the packaging was supposed to support them in reading test results, and the instructions regarding how to read test results are unclear for all target groups. This is a major area of improvement.
- No clear information regarding pre or post-test counseling on the pack or on the instruction manual. This is a major weakness.
- Technical text: HIV 1/2 (consumers do not know about the difference), antibodies. This technical language is confusing for potential users.
- The contents of the pack should be clearly indicated on the secondary packaging to allow users to check whether the product is complete or not.
- Some mysterious signs / symbols on the side of the packaging: consumers wonder what they mean.
- Unclear location of the expiry date does not reassure potential users, who look for this information in priority.

For all target groups, the user instruction manual is not adapted: too many steps, discouraging to read, consumers are unable to explain to a friend how to take the test after having been exposed to a quick reading of the instructions manual. This is a major area for improvement.

#### ***Look for ideas in other self-testing products***

The agency should explore ideas coming from other self-test kits such as pregnancy, blood pressure or diabetes self-test kits.

#### **5- Timeline**

Mockups should be delivered to PSI/Kenya by December 9, 2013 to allow time to react to the proposed options.

For more questions around the study, please contact Olivier LeTouze, [oletouze@psi.org](mailto:oletouze@psi.org)

For questions relating to the HIV self-testing project, please contact Lucy Maikweki, [lmaikweki@psikenya.org](mailto:lmaikweki@psikenya.org)

## Annex 4 – Kenyatta Hospital ethics board approval letter



UNIVERSITY OF NAIROBI  
COLLEGE OF HEALTH SCIENCES  
P O BOX 19676 Code 00202  
Telegrams: varsity  
(254-020) 2726300 Ext 44355

Ref: KNH-ERC/A/289

Dr. Alec Ulasevic  
PSI/ Kenya  
P O Box 22591-00400  
NAIROBI

Dear Dr. Alec

### RESEARCH PROPOSAL: INSIGHTS INTO PACKAGING AND LABELING FOR HIV ORAL SELF-TEST KITS IN KENYA (P436/08/2013)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 12<sup>th</sup> September, 2013 to 11<sup>th</sup> September 2014.

This approval is subject to compliance with the following requirements:

- a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
- c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
- d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
- e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
- f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
- g) Submission of an *executive summary* report within 90 days upon completion of the study  
This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website [www.uonbi.ac.ke/activities/KNHUoN](http://www.uonbi.ac.ke/activities/KNHUoN).



KENYATTA NATIONAL HOSPITAL  
P O BOX 20723 Code 00202  
Tel: 726300-9  
Fax: 725272  
Telegrams: MEDSUP, Nairobi

12<sup>th</sup> September, 2013

Link: [www.uonbi.ac.ke/activities/KNHUoN](http://www.uonbi.ac.ke/activities/KNHUoN)

Yours sincerely



**PROF. M. L. CHINDIA**  
**SECRETARY, KNH/UON-ERC**

c.c. Prof. A.N. Guantai, Chairperson, KNH/UoN-ERC  
The Deputy Director CS, KNH  
The Principal, College of Health Sciences, UoN  
AD/Health Information, KNH  
Co-investigators: Rhoune Ochako, Olivier LeTouze, Petra Standkard

## Annex 5 – PSI Research Ethics Board approval letter



1120 19th Street, NW, Suite 600  
Washington, DC 20036  
psi.org

### MEMORANDUM

**DATE:** September 23, 2013

**TO:** Alec Ulasevich , Rhoune Ochako

**FROM:** PSI Research Ethics Board

**RE:** 38.2013

**TITLE:** Insights into Packaging and Labeling for HIV Oral Self-Test Kits in Kenya Study Design

The PSI Research Ethics Board (PSI REB) has reviewed and approved the above referenced study via its expedited review process on September 20, 2013 for a period of 12 months. This approval will expire on September 19, 2014.

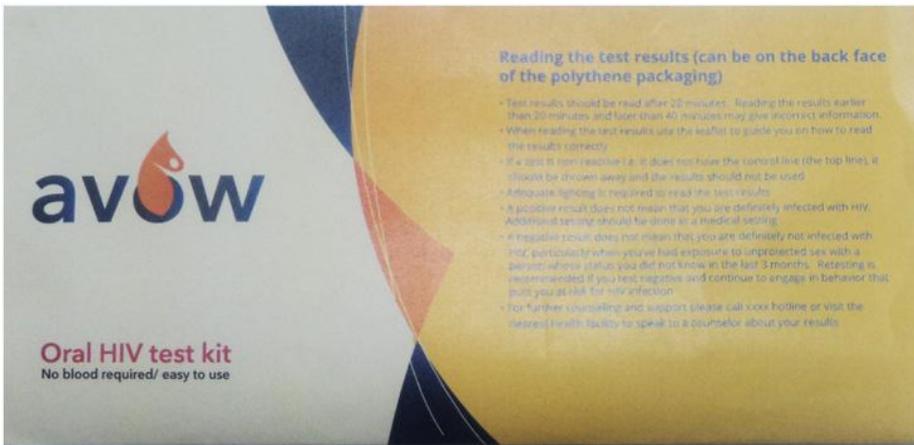
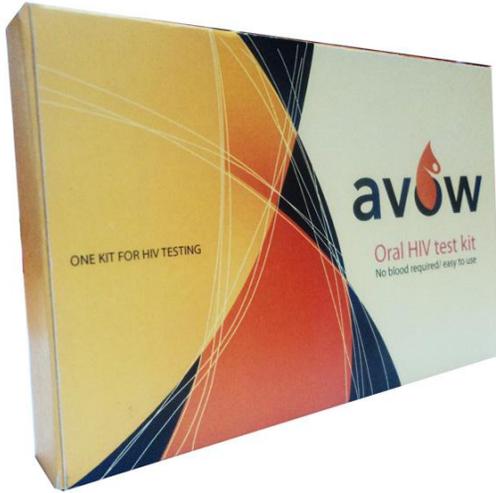
The IRB determined that study meets the criteria for expedited review under category, 45, CFR 46.110 Category 7 (*Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies*).

The PI is required to inform the REB immediately of unanticipated problems or new information which could change the risk/benefit ratio. Modifications to study design, data collection tools, study forms, or PI staffing must be approved by the PSI REB prior to implementation. For more information concerning modification request or reporting unanticipated problems, please refer to the PSI/REB website (<http://www.psi.org/resources/research-ethics-board>) or contact Kelly O'Keefe ([kokeefe@psi.org](mailto:kokeefe@psi.org)).

Sincerely,

Kelly O'Keefe  
Research Ethics Program Manager

Annex 6: Packaging mockups tested during Phase II - Avow





## Annex 8: Potential Self-Test Kit Distributors - Discussion Guide

### Discussion Guide Potential Self-Test Kit Distributors

**Introduction:** thank you for taking the time to participate in this interview. I am going to ask you a number of questions in relation to HIV testing products. There is no right or wrong answers as these are your opinions. Please note that responses provided in this survey will be aggregated with those of other respondents such as yourself. No individual responses will be shared

#### Description of HIV Self-Test Kit

The HIV Self-Test Kit allows you to take a HIV test in the comfort of your home. It involves a person taking a sample, in this case, saliva from the lower and upper gum and using it as a sample. This test produces results in about 20 minutes

#### Awareness of HIV Self-Test Kits

1. Have you heard about HIV Self-Test kits?  
*Ushawahi sikia kuhusu kifaa cha kibinafsi cha kupima HIV?*
2. How do you think it works?  
*Je, unatazamia kinatumika vipi?*

#### Distribution of sensitive products

3. What products would the self-test kits be distributed alongside?
  - What types of in-home diagnostics are distributed in the pharmacy or other facility?  
*Ni bidhaa zipi za kiuchunguzi wa nyumbani zinasambazwa kwa maduka ya dawa au kwingineko?*
  - Why would you put it there?  
*Mbona viwepo hapo?*
  - Do you consider this to be a sensitive product? Why or why not?  
*Je unaweza pendekeza hii kama bidhaa nyeti.Kwa nini/au kwa nini sio?*
4. What is your experience of distributing or selling similar products in the past? That is, products that people might be sensitive about, like oral contraceptives or condoms.  
*Una uzoefu upi wa kusambaza au kuuza bidhaa kama hizo katika miaka ya nyuma? Yaani, kwa bidhaa ambazo watu wanaweza kupenda kutumia kwa siri, kama dawa za kupanga uzazi au kondomu*

#### Probes/Dadisi:

- How has the sensitive nature of products affect consumer behavior?  
*Ni vipi bidhaa za siri zimeweza kutalaamu tabia za wanunuzi?*
  - What aspects of the product packaging and labeling have prevented consumers from purchasing the product? Why?/  
*Ni kanuni zipi za ufungaji wa bidhaa na uwekaji zimewazuia wanunuzi kununua hii bidhaa? kwa nini?*
5. Have you found that there are certain places in your pharmacy or health facility that are best to place these types of sensitive items, so that customers are more likely to buy them?

Je umepata kwamba kuna sehemu nzuri kwa duka lako la kuuzia dawa au kituo cha afya ambapo unaweza weka bidhaa hizi nyeti ili wanunuzi waweze kuzinunua?

**Probes:** What would be the best shelf-positioning for the self-test kits within your pharmacy or health facility? Why do you say that?

*Ni jia ipi mwafaka ya kupanga kwenye rafu bidhaa za kibinafsi za kujipima ukimwi unaweza tumia hapa kwenye duka la dawa lako au kituo cha afya? Mbona unasema hivyo?*

6. What is your experience of distributing or selling in-home screening products in the past? That is, products like pregnancy tests.

*Ni nini uzoefu wako wa kusambaza au kuuza bidhaa uchunguzi katika nyumbani katika siku za nyuma, yaani, bidhaa kama vipimo vya ujauzito*

**Probes:**

- What are common questions that clients ask about such in-home screening products? *Ni maswali yepi ya kawaida ambayo wateja huuliza kuhusu bidhaa za kujipima nyumbani?*
- What aspects of the product packaging or labeling help you to answer some of these questions?

*Ni masuala yepi ya ufungaji au uwekaji hokusaidia wewe kujibu baadhi ya maswali hayo?*

7. What are the differences between how you sell something like a pregnancy test, and how you sell another in-home screening product that is less sensitive?

*Kuna tofauti gani ya wewe kuuza bidhaa kama ile ya kupima mimba na jinsi ya kuuza bidhaa isio ya kisiri sana ya kinyumbani?*

### **Tertiary packaging/storage**

8. Please describe your supply chain for other HIV products or in-home screening tests.

Tafadhali nieleze usambazaji wa bidhaa zingine za kupima ukimwi au zile za kinyumbani.

**Probes:**

- How often do you order product?  
*Ni kwa mara ngapi wewe huitisha bidhaa?*
- How do you manage your stock?  
*Ni jinsi gani wewe husimamia hisa yako?*
- What are the logistical challenges of supplying these products in your store?  
*Ni changamoto zipi za vifaa vya kusambaza wewe hupitia kwa hifadi yako?*

9. Please describe the shipping cartons for other in-home screening tests.

*Tafadhali nieleze jinsi ya kubeba madebe ya vifaa vya kujipima vya nyumbani.*

**Probes:**

- What information is included on the shipping carton?  
*Ni ujumbe upi hupatikana kwenye madebe ya kubebea?*
- How does the packaging communicate the required storage conditions, such as temperature?  
*Ni jinsi ipi mifuko huzungumzia hifadi inayotakikana kama joto?*
- How could this packaging be improved to make it easier to supply this product in your store?  
*Ni vipi hii hifadi ingeweza boreshwa ili iwe rahisi kusabazwa kwenye hifadi yako?*

### **Expectation around packaging**

10. What do you think the inner packaging of the self-test kit itself looks like?

## Ni vipi unafikiria ndani ya hifadi ya kifaa cha kibinafsi cha kujipima hufanana?

### Probes:

- What aspects of the primary packaging can help a consumer use the product accurately?  
*Ni Nyanja zipi za hifadi zinweza saidia wateja kutumia vizuri?*
- What aspects of the primary packaging can help a consumer maintain confidentiality? *Ni Nyanja zipi za hifadi zinaweza saidia wateja kuwa na ujasiri?*

11. What do you think the outer packaging should look like?

*Ni vipi unafikiria kufungaji wan je unafaa kufanana?*

### Probes:

- What aspects of the outer packaging can help a consumer use the product accurately?  
*Ni mambo ngani ya ufunganji was nje unaweza kusaidia wateja kutumia bidhaa inavyo faa kutumiwa?*
- What aspects of the outer packaging can help a consumer maintain confidentiality?  
*Ni mamba gani ya ufunganji wa nje unaweza kusaidia wateja kuiamini?*
- What items, other than the test kit, should be included in the outer packaging?  
*Ni vitu gani, ila kifaa cha kujipima, kinapaswa kuwa pamoja na katika ufungaji wa nje?*
- What aspects of the outer packaging can ensure that the product is not used beyond its expiration date?  
*Ni mambo gani katika ufungaji wa nje zinaweza hakikisha kwamba bidhaa haitumiki zaidi ya siku za matumizi?*

12. What information would you want to see on the label of the product packaging?

*Ni ujumbe upi ungependa kuona kwa lebo ya ufungaji wa bidhaa?*

### Probes:

- How could this information help you to distribute or sell the kits?  
*Ni vipi maelezo haya yanaweza kukusaidia wewe kuuza bidhaa hizi?*
- What pieces of information could be placed on the label to help you to counsel clients on the use of this product?  
*Ni maelezo yepi yangewekwa kwa lebo ili yakusaidia wewe kushauri wateja jinsi ya kutumia bidhaa hizi?*
- Among the information you mention, which is the most important and why?  
*Kati ya maelezo ambayo umetaja, ni yepi yenya umuhimu zaidi na kwanini?*

13. What information do you think should be on the packaging insert?

*Ni maelezo yepi ambayo unaonelea ungewekwa kwenye kijikaratasi kilicho ndani ya ufungaji?*

### Probe:

- Why do you think this information is important to have on the insert?  
*Mbona unafikiri kuwa ujumbe huu ni wa maana kukuwa kwa kijikaratasi hicho?*
- How should this information be communicated? Please consider the fact that many populations who may purchase the product are illiterate.  
*Ni vipi ujumbe huu unaweza wasiliswa? Tafadhali chukulia uwezekano kwamba watu wengi wanaweza nunua bidhaa hii na wawe hawajasoma*
- Among the information you mention, which is the most important and why?  
*Baadhi ya maelezo ambayo umetaja, ni yapi yenya umuhimu zaidi na ni kwa nini?*

14. What information do you think should be on the outer packaging?

*Ni ujumbe upi unadhani unaweza kuwa kwenye ufungaji wa nje?*

**Probe:**

- Why do you think this information is important to have on the outer packaging?  
*Mbona unafikiria maelezo haya ni ya umuhimu kuwekwa kwa ufungaji wa nje?*
- How should this information be communicated? Please consider the fact that many populations who may purchase the product are illiterate.  
*Ni vipi maelezo haya yanaweza kuwasilishwa? Tafadhali zingatia kwamba baadhi ya wateja hawawezi kusoma?*
- Among the information you mention, which is the most important and why  
*Baadhi ya maelezo ambayo umetaja, ni yapi yenye umuhimu zaidi na ni kwa nini?*

15. What aspects of packaging and labeling could help increase demand of the product? Why? *Ni mambo gani ya ufungaji na uchoraji unaweza ongeza ununuzi wa bidhaa hii? Mbona?*

16. What are common client complaints about the use of other in-home diagnostics?

*Ni malalamishi yapi ya kawaida ambayo imewasilishwa na wateja wa bidhaa za kujipima za nyumbani?*

- How might packaging and labeling be used to address these complaints?  
*Ni vipi ufungaji na lebo ya bidhaa inaweza kutumiwa kushughulikia malalamishi haya?*

**Detailed reactions to 'Aware' packaging**

**I'm going to show you packaging from a self-test kit product called Aware. Please examine this product. When you are ready, I will ask you a series of questions about this product.**

**Naenda kukuonyesha ufungaji wa kipimo cha kibinafsi kinachoitwa 'Aware'. Tafadhali chunguza kwa kina hii bidhaa kisha ukiwa tayari nitakuuliza maswali kuhusu.**

17. What did you like about the outer packaging of this product? Why?

*Ni nini kimekupendeza kuhusu ufungaji wa nje wa hii bidhaa? Kwanini?*

What did you dislike? Why?

*Ni nini hukupendezwa nayo? Mbona?*

**Probes:**

- What did you think about the size of the packaging?  
*Ni nini ulifikiri kuhusu ukubwa au udogo wa hifadhi hii?*
- What did you think about the shape of the packaging?  
*Ni nini ulifikiria kuhusu sura ya hifadhi hii?*
- What did you think about other features of the packaging?  
*Ni nini ulifikiria kuhusu sifa ya hifadhi hii?*
- What modifications would you recommend if you were to introduce this product for sale in your pharmacy?  
*Ni mabadiliko yapi ungependekeza kama ungeanzisha kuuza bidhaa hii kwa duka la dawa lako?*

18. What did you like about the inner packaging of this product? Why? What did you dislike? Why?

*Ni nini ulipenda kuhusu hifadhi ya ndani ya bidhaa hii? Mbona? Ni nini hakupendeza ? mbona?*

**Probes:**

- What did you think about the sachets that hold the test kit?  
*Ni nini unafikiria kuhusu mifuko ambayo inashikilia studio hizi?*
- Was there anything missing from these sachets that would make the test easier to use?  
*Je kulikuwa na kitu chochote kilichokosekana katika mifuko ambacho kingefanya udadisi uwe rahisi?*
- What modifications would you recommend if you were to introduce this product for sale in your pharmacy?  
*Ni mabadiliko yapi ungependekeza kama ungetaka kuaza kuuza studio hii kwa duka lako la dawa?*

19. What did you like about the instructions included as part of this product?

*Ni nini ulipendelea kuhusu maelezo yaliopewa kama sehemu ya bidhaa hii?*

**Probes:**

- What about the instructions make them clear?  
*Ni nini kuhusu maelezo ilikuwa bayana?*
- What about the instructions was unclear?  
*Je maelezo hayakuwa bayana?*
- What modifications would you recommend if you were to introduce this product for sale in your pharmacy?  
*Ni mapendekezo yapi ungependekeza kama ungeanza kuuza bidhaa hii kwa duka lako la dawa?*

**Comprehension of usage instructions**

Now I'm going to show you some instructions that have been used to guide consumers through the use of an HIV self-test. Please examine these instructions. I will then ask you questions about these instructions.

20. In your opinion, what aspects of the instructions were clear and easy to follow?

*Kwa maoni yako, ni nyanja zipi za maelezo zilikuwa bayana na rahisi kufwata?*

**Probes:** What modifications could be used to make the unclear aspects of the instructions more clear?

*Ni mabadiliko yapi yangetumika kufanya nyanja ambazo hazieleweki kuwa bayana?*

21. What aspects of the instruction were unclear and confusing?

*Ni nyanja zipi za maelezo hazikuwa bayana na zinakanganya?*

**Probe:** What made certain aspects of the instructions clear and easy to follow?

*Ni nini ilifanya nyanja Fulani kuwa bayana na rahisi kufwata?*

## Annex 9: Pharmacists - Focus group discussion Guide

### Discussion Guide Potential Self-Test Kit Pharmacists Focus Group Discussion

**Introduction:** thank you for taking the time to participate in this focus group discussion. I am going to ask you a number of questions in relation to HIV testing products. There is no right or wrong answers as these are your opinions. Please note that responses provided in this survey will be aggregated with those of other respondents such as yourself. No individual responses will be shared.

#### Description of HIV Self-Test Kit

The HIV Self-Test Kit allows you to take a HIV test in the comfort of your home. You can take a sample yourself, in this case, saliva from the lower and upper gum and perform the test yourself. This test produces results in about 20 minutes

#### Awareness of HIV Self-Test Kits

**22.** Have you heard about such a HIV Self-Test kit?

*Ushawahi sikia kuhusu kifaa kama kile cha kibinafsi cha kupima HIV?*

**23.** How do you think it works? Please describe.

*Je, unatazamia kinatumika vipi? Tafadhali fafaua*

#### Distribution of sensitive products

**24.** What products would the self-test kits be distributed alongside?

- What types of in-home diagnostics are distributed in the pharmacy?

*Ni bidhaa zipi za kiuchunguzi wa nyumbani zinasambazwa kwa maduka ya dawa au kwingineko?*

- Why would you put it there?

*Mbona viwepo hapo?*

- Do you consider this to be a sensitive product? Why or why not?

*Je unaweza pendekeza hii kama bidhaa nyeti. Kwa nini/au kwa nini sio?*

**25.** What is your experience of distributing or selling similar products in the past? That is, products that people might be sensitive about, like oral contraceptives or condoms.

*Una uzoefu upi wa kusambaza au kuuza bidhaa kama hizo katika miaka ya nyuma? Yaani, kwa bidhaa ambazo watu wanaweza kupenda kutumia kwa siri, kama dawa za kupanga uzazi au kondomu*

#### Probes/Dadisi:

- How has the sensitive nature of products affect consumer behavior?

*Ni vipi bidhaa za siri zimeweza kutalaamu tabia za wanunuzi?*

- What aspects of the product packaging and labeling have prevented consumers from purchasing the product?

*Ni kanuni zipi za ufungaji wa bidhaa na uwekaji zimewazuia wanunuzi kununua hii bidhaa? kwa nini?*

- What they are doing to help consumers overcome the embarrassment of buying a sensitive product.  
Wewe huwa unafanya nini ili kuwasaidi wateja wasiwe nafedheha wanaponunua bidhaa hizi nyeti?

26. Have you found that there are certain places in your pharmacy or health facility that are best to place these types of sensitive items, so that customers are more likely to buy them?  
Je umepata kwamba kuna sehemu nzuri kwa duka lako la kuuzia dawa au kituo cha afya ambapo unaweza weka bidhaa hizi nyeti ili wanunuzi waweze kuzinunua?

**Probes:** What would be the best shelf-positioning for the self-test kits within your pharmacy or health facility? Why do you say that?

*Ni jia ipi mwafaka ya kupanga kwenye rafu bidhaa za kibinafsi za kujipima ukimwi unaweza tumia hapa kwenye duka la dawa lako au kituo cha afya? Mbona unasema hivyo?*

27. What is your experience of distributing or selling in-home screening products in the past? That is, products like pregnancy tests.

*Ni nini uzoefu wako wa kusambaza au kuuza bidhaa uchunguzi katika nyumbani katika siku za nyuma, yaani, bidhaa kama vipimo vya ujauzito*

**Probes:**

- What are common questions that clients ask about such in-home screening products? *Ni maswali yepi ya kawaida ambayo wateja huuliza kuhusu bidhaa za kujipima nyumbani?*
- What aspects of the product packaging or labeling help you to answer some of these questions?  
*Ni masuala yepi ya ufungaji au uwekaji hokusaidia wewe kujibu baadhi ya maswali hayo?*

### **Tertiary packaging/storage**

28. Please describe your supply chain for other HIV products or in-home screening tests.  
Tafadhali nieleze usambazaji wa bidhaa zingine za kupima ukimwi au zile za kinyumbani.

**Probes:**

- How often do you order product?  
*Ni kwa mara ngapi wewe huitisha bidhaa?*
- How do you manage your stock?  
*Ni jinsi gani wewe husimamia hisa yako?*
- What are the logistical challenges of supplying these products in your store?  
*Ni changamoto zipi za vifaa vya kusambaza wewe hupitia kwa hifadi yako?*

29. Please describe the shipping cartons for other in-home screening tests.  
Tafadhali nieleze jinsi ya kubeba madebe ya vifaa vya kujipima vya nyumbani.

**Probes:**

- What information is included on the shipping carton?  
*Ni ujumbe upi hupatikana kwenye madebe ya kubebea?*
- How does the packaging communicate the required storage conditions, such as temperature?  
*Ni jinsi ipi mifuko huzungumzia hifadi inayotakikana kama joto?*
- How could this packaging be improved to make it easier to supply this product in your store?  
*Ni vipi hii hifadi ingeweza boreshwa ili iwe rahisi kusabazwa kwenye hifadi yako?*

- What should the shipping carton to be like for HIV self-test kits? What information should be on it?

Katon ya kusafirishia **kifaa cha kibinafsi cha kujipima ukimwi inafaa ifanane aje? Ni maelezo gani yanafaa yawe juu yake?**

#### **Expectation around packaging**

30. What do you think the inner packaging of the self-test kit itself looks like? By inner packaging we are referring to the packaging that hold the individual products

**Ni vipi ufungaji wa ndani ya kifaa cha kibinafsi cha kujipima hufanana? Ufungaji wa ndani tunaashiria ufungaji unaoshikilia bidhaa zenyewe**

#### **Probes:**

- What aspects of the inner packaging can help a consumer use the product accurately?  
*Ni Nyanja zipi za hifadi zinweza saidia wateja kutumia vizuri?*
- What aspects of the inner packaging can help a consumer maintain confidentiality? *Ni Nyanja zipi za hifadi zinaweza saidia wateja kuwa na ujasiri?*

31. What do you think the outer packaging should look like?

*Ni vipi unafikiria kufungaji wan je unafaa kufanana?*

#### **Probes:**

- What aspects of the outer packaging can help a consumer use the product accurately?  
*Ni mambo ngani ya ufunganji was nje unaweza kusaidia wateja kutumia bidhaa inavyo faa kutumiwa?*
- What aspects of the outer packaging can help a consumer maintain confidentiality?  
*Ni mamba gani ya ufunganji wa nje unaweza kusaidia wateja kuiamini?*
- What items, other than the test kit, should be included in the outer packaging?  
*Ni vitu gani, ila kifaa cha kujipima, kinapaswa kuwa pamoja na katika ufungaji wa nje?*
- What aspects of the outer packaging can ensure that the product is not used beyond its expiration date?  
*Ni mambo gani katika ufungaji wa nje zinaweza hakikisha kwamba bidhaa haitumiki zaidi ya siku za matumizi?*

32. What information would you want to see on the label of the product packaging?

*Ni ujumbe upi ungependa kuona kwa lebo ya ufungaji wa bidhaa?*

#### **Probes:**

- How could this information help you to distribute or sell the kits?  
*Ni vipi maelezo haya yanaweza kukusaidia wewe kuuza bidhaa hizi?*
- What pieces of information could be placed on the label to help you to counsel clients on the use of this product?  
*Ni maelezo yepi yangewekwa kwa lebo ili yakusaidia wewe kushauri wateja jinsi ya kutumia bidhaa hizi?*
- Among the information you mention, which is the most important and why?  
*Kati ya maelezo ambayo umetaja, ni yepi yenya umuhimu zaidi na kwanini?*

33. What information do you think should be on the packaging insert?

*Ni maelezo yepi ambayo unaonelea ungewekwa kwenye kijikaratasi kilicho ndani ya ufungaji?*

#### **Probe:**

- Why do you think this information is important to have on the insert?

*Mbona unafikiri kuwa ujumbe huu ni wa maana kukuwa kwa kijikaratasi hicho?*

- How should this information be communicated? Please consider the fact that many populations who may purchase the product are illiterate.

*Ni vipi ujumbe huu unaweza wasiliswa? Tafadhali chukulia uwezekano kwamba watu wengi wanaweza nunua bidhaa hii na wawe hawajasoma*

- Among the information you mention, which is the most important and why?  
*Baadhi ya maelezo ambayo umetaja, ni yapi yenye umuhimu zaidi na ni kwa nini?*

34. What information do you think should be on the outer packaging?

*Ni ujumbe upi unadhani unaweza kuwa kwenye ufungaji wa nje?*

**Probe:**

- What information would help you sell the product better??

*Mbona unafikiria maelezo haya ni ya umuhimu kuwekwa kwa ufungaji wa nje?*

- How should this information be communicated? Please consider the fact that many populations who may purchase the product are illiterate.

*Ni vipi maelezo haya yanaweza kuwasilishwa? Tafadhali zingatia kwamba baadhi ya wateja hawawezi kusoma?*

- Among the information you mention, which is the most important and why?  
*Baadhi ya maelezo ambayo umetaja, ni yapi yenye umuhimu zaidi na ni kwa nini?*

35. What aspects of packaging and labeling could help increase demand of the product? Why? *Ni mambo gani ya ufungaji na uchoraji unaweza ongeza ununuzi wa bidhaa hii? Mbona?*

36. What are common client complaints about the use of other in-home diagnostics?

*Ni malalamishi yapi ya kawaida ambayo imewasiliswa na wateja wa bidhaa za kujipima za nyumbani?*

- How might packaging and labeling be used to address these complaints?  
*Ni vipi ufungaji na lebo ya bidhaa inaweza kutumiwa kushughulikia malalamishi haya?*

### **Detailed reactions to 'Aware' packaging**

**I'm going to show you packaging from a self-test kit product called Aware. Please examine this product. When you are ready, I will ask you a series of questions about this product.**

**Naenda kukuonyesha ufungaji wa kipimo cha kibinafsi kinachoitwa 'Aware'. Tafadhali chunguza kwa kina hii bidhaa kisha ukiwa tayari nitakuuliza maswali kuhusu.**

37. What did you like about the outer packaging of this product? Why?

*Ni nini kimekupendeza kuhusu ufungaji wa nje wa hii bidhaa? Kwanini?*

What did you dislike? Why?

*Ni nini hukupendezwa nayo? Mbona?*

**Probes:**

- What did you think about the size of the packaging?  
*Ni nini ulifikiri kuhusu ukubwa au udogo wa hifadhi hii?*
- What did you think about the shape of the packaging?  
*Ni nini ulifikiria kuhusu sura ya hifadhi hii?*
- What did you think about other features of the packaging?

*Ni nini ulifikiria kuhusu sifa ya hifadhi hii?*

- What modifications would you recommend if you were to introduce this product for sale in your pharmacy?

*Ni mabadiliko yapi ungependekeza kama ungeanzisha kuuza bidhaa hii kwa duka la dawa lako?*

38. What did you like about the inner packaging of this product? Why? What did you dislike? Why?

*Ni nini ulipenda kuhusu hifadhi ya ndani ya bidhaa hii? Mbona? Ni nini hakikupendeza ? mbona?*

**Probes:**

- What did you think about the sachets that hold the test kit?  
*Ni nini unafikiria kuhusu mifuko ambayo inashikilia studio hizi?*
- Was there anything missing from these sachets that would make the test easier to use?  
*Je kulikuwa na kitu chochote kilichokosekana katika mifuko ambacho kingefanya udadisi uwe rahisi?*
- What modifications would you recommend if you were to introduce this product for sale in your pharmacy?  
*Ni mabadiliko yapi ungependekeza kama ungetaka kuaza kuuza studio hii kwa duka lako la dawa?*

39. What did you like about the instructions included as part of this product?

*Ni nini ulipendelea kuhusu maelezo yaliopewa kama sehemu ya bidhaa hii?*

**Probes:**

- What about the instructions make them clear?  
*Ni nini kuhusu maelezo ilikuwa bayana?*
- What about the instructions was unclear?  
*Je maelezo hayakuwa bayana?*
- What modifications would you recommend if you were to introduce this product for sale in your pharmacy?  
*Ni mapendekezo yapi ungependekeza kama ungeanza kuuza bidhaa hii kwa duka lako la dawa?*

**Comprehension of usage instructions**

**Now I'm going to show you some instructions that have been used to guide consumers through the use of an HIV self-test. Please examine these instructions. I will then ask you questions about these instructions.**

40. In your opinion, what aspects of the instructions were clear and easy to follow?

*Kwa maoni yako, ni nyanja zipi za maelezo zilikuwa bayana na rahisi kufwata?*

**Probes:** What modifications could be used to make the unclear aspects of the instructions more clear?

*Ni mabadiliko yapi yangetumika kufanya nyanja ambazo hazieleweki kuwa bayana?*

41. What aspects of the instruction were unclear and confusing?

*Ni nyanja zipi za maelezo hazikuwa bayana na zinakanganya?*

**Probe:** What made certain aspects of the instructions clear and easy to follow?

*Ni nini ilifanya nyanja Fulani kuwa bayana na rahisi kufwata?*

## Annex 10: Health providers - Triad discussion guide

### Discussion Guide HIV Self-Test Kit – Health providers Triad Group Discussion

**Introduction:** thank you for taking the time to participate in this discussion. I am going to ask you a number of questions in relation to HIV testing products. There is no right or wrong answers as these are your opinions. Please note that responses provided in this study will be aggregated with those of other respondents such as yourself. No individual responses will be shared.

*Asante kwa kuchukua muda wako kushiriki katika mjadala huu. Nitakuuliza maswali kadhaa kuhusu vifaa vya kujipima virusi vya Ukimwi. Hakuna majibu sahihi au yasiyo sahihi kwani haya ni maoni yako. Tafadhali fahamu yakuwa maoni yatakayotolewa katika utafiti huu yatajumlishwa na wahojiwa wengine kama wewe. Hakuna majibu ya kibinafsi yatakayotolewa*

#### Description of HIV Self-Test Kit

The HIV Self-Test Kit allows you to take a HIV test in the comfort of your home. You can take a sample yourself, in this case, saliva from the lower and upper gum and perform the test yourself. This test produces results in about 20 minutes

*Kifaa cha kujipima ukimwi kinakuruhusu kujipima ukimwi nyumbani mwako. Unaweza kuchukua sampuli mwenyewe. Kwa minajili hii kwa kuchukua mate kutoka ufisi wa chini na wa juu unaweza kujipima mwenyewe. Kujipima huku kunatoa majibu baada kya kama dakika ishirini hivi*

#### Awareness of HIV Self-Test Kits

**42.** Have you heard about such a HIV Self-Test kit?

*Je, umewahi kusikia kuhusu kifaa kama hicho cha kujipima ukimwi?*

**43.** How do you think it works? Please describe.

*Je, unafikiria hiki kifaa kinafanya kazi vipi? Tafadhali elezea*

#### Use of HIV self-test kits and health provider counseling

**44.** As a health provider, how would you imagine using / recommending this product?

*Kama mtoa wa afya kwa jamii, ni vipi ungejifikiria kutumia /kupendekeza utumizi wa kifaa hiki?*

##### Probes:

- Who would you recommend this for (probe: people who've never tested, for re-testing)?  
Why?  
*Je, ni nani ungependekeza hiki kifaa (watu ambao hawajawahi kupima, wanaotaka kupima tena) Kwa nini?*
- How would this product help your counseling work?  
*Jinsi gani bidhaa hii itasaidia ushauri kwa wateja wako?*

**45.** What type of support do you think would be required from health providers to use this product?

*Je, ni usaidizi kama upi unafikiria ungetakikana kwa watoa wa afya ya jamii ili kusambaza kifaa hiki*

**Probes:** Training, specific packaging/ mafunzo, ufungaji wa bidhaa

46. What type of support do you think people would need to use this product at home? How would you be able to help?

*Je, ni usaidizi wa aina gani unafikiria watu wangehitaji ili kutumia kifaa hiki nyumbani? Je, ni vipi ungeweza kusaidia?*

### **Expectations around packaging**

47. What do you think the inner packaging of the self-test kit itself looks like? By inner packaging we are referring to the packaging that hold the individual products?

*Je, unafikiria pakiti ya ndani ya kifaa hiki cha kujipima unakaa vipi? Kwa pakiti ya ndani tunamaanisha upakiaji unaositiri vifaa binafsi?*

#### **Probes:**

- What aspects of the inner packaging can help a consumer use the product accurately?  
*Je, ni mambile gani ya pakiti ya ndani yanaweza kusaidia mtumizi akitumie kifaa hiki ipasavyo?*
- What aspects of the inner packaging can help a consumer maintain confidentiality?  
*Je, ni maumbile gani ya pakiti ya ndani ya inaweza kusaidia mtumizi ahifadhi usiri?*

48. What do you think the outer packaging should look like?/Je unafikiria pakiti ya nje utakuwa vipi?

#### **Probes:**

- What aspects of the outer packaging can help a consumer use the product accurately?  
*Je, ni maumbile gani ya pakiti ya nje yanaweza kusaidia mtumizi akitumie kifaa hiki ipasavyo?*
- What aspects of the outer packaging can help a consumer maintain confidentiality?  
*Je, ni maumbile gani ya pakiti ya nje yanaweza kusaidia mtumizi ahifadhi usiri?*
- What items, other than the test kit, should be included in the outer packaging?  
*Je, ni vifaa gani vingine kato na kifaa cha kujipima vinafaa kujumulishwa katika pakiti ya nje?*
- What aspects of the outer packaging can ensure that the product is not used beyond its expiration date?  
*Je, ni maumbile gani ya pakiti ya nje yanaweza kuhakikisha kuwa kifaa hakitumiwi baada ya muda wake wa matumizi kuisha?*

49. What information would you want to see on the label of the product packaging?

*Je, ni ujumbe gani ungetaka kuona kwenye nembo ya pakiti ya kifaa hiki?*

#### **Probes:**

- What pieces of information could be placed on the label to help you to counsel clients on the use of this product?  
*Je, ni ujumbe gani ingewekwa kwenye nembo kukusidia kushauri wateja kuhusu utumizi wa kifaa hiki?*
- Among the information you mention, which is the most important and why?/Miongoni mwa ujumbe uliotaja, ni gani muhimu zaidi na kwa nini?

50. What information do you think should be on the packaging insert?

*Je, ni habari gani unafikiria unafaa kuwa kwenye pakiti ya ndani?*

#### **Probe:**

- Why do you think this information is important to have on the insert?  
*Kwa nini unafikiria ujumbe huu ni muhimu kuwa kwenye pakiti ya ndani?*
- How should this information be communicated? Please consider the fact that many populations who may purchase the product are illiterate.  
*Je, ni vipi ujumbe huu unafaa kuwasilishwa? Tafadhali zingatia ya kuwa wengi watakaonunua kifaa hiki hawajasoma.*
- Among the information you mention, which is the most important and why?

*Miongoni mwa ujumbe uliotaja, ni gani muhimu zaidi na kwa nini?*

51. What information do you think should be on the outer packaging?

*Je, ni ujumbe mgani unafikiria unafaa kuwa katika pakiti ya nje?*

**Probe:**

- How should this information be communicated? Please consider the fact that many populations who may purchase the product are illiterate?  
*Je, ni vipi ujumbe huu unafaa kuwasilishwa? Tafadhali zingatia ya kuwa wengi watakaonunua kifaa hiki hawajasoma.*
- Among the information you mention, which is the most important and why?  
*Miongoni mwa ujumbe uliotaja, ni gani muhimu zaidi na kwa nini?*

What aspects of packaging and labeling could help increase demand of the product? Why?

*Je, ni mambo gani ya upakiaji na nembo yangesaidia kuongeza kutakikana kwa kifaa hiki?*

**Detailed reactions to 'Aware' packaging**

**I'm going to show you packaging from a self-test kit product. Please examine this product. When you are ready, I will ask you a series of questions about this product. Nitakuonyesha pakiti ya kifaa hiki cha kujipima..Tafadhali kitazame kifaa hiki.Ukiwa tayari, nitakuuliza maswali kuhusu kifaa hiki.**

52. What did you like about the outer packaging of this product? Why?

*Je, ni nini umependelea kuhusu pakiti ya nje ya kifaa hiki? Kwa nini?*

What did you dislike? Why?

*Je, ni nini haukupendelea? Kwa nini?*

**Probes:**

- What did you think about the size of the packaging?  
*Je, ni nini unafikiria kuhusu saizi ya pakiti?*
  - What did you think about the shape of the packaging?  
*Je, ni nini unafikiria kuhusu umbo la pakiti?*  
What did you think about other features of the packaging?  
*Je, ni nini unafikiria kuhusu sifa zingine za pakiti?*
  - What modifications would you recommend if you were to recommend this product?  
*Je, ni ukarabati upi mwingine ungependekeza ikiwa ungependekeza kifaa hiki?*
53. What did you like about the inner packaging of this product? Why? What did you dislike? Why?  
*Je, ni nini umependelea kuhusu pakiti ya ndani ya kifaa hiki?Kwa nini? Je, ni nini haukupendelea? Kwa nini?*

**Probes:**

- What did you think about the sachets that hold the test kit?  
*Je, ni vipi unafikiria kuhusu sacheti zinazositiri kifaa hiki cha kujipima?*
  - Was there anything missing from these sachets that would make the test easier to use?  
*Je, kuna kitu chochote kinakosa kutoka kwa sachet hizi amabacho kingefanya kujipima kuwe rahisi kutumia?*
  - What modifications would you recommend if you were to introduce this product for sale in your pharmacy?  
*Je, ni ukarabati upi ungependekeza ikiwa ungeleta kifaa hiki katika duka lako la dawa?*
54. What did you like about the instructions included as part of this product?

*Je, ni nini ulipendelea kuhusu maagizo yalioumulishwa kama kipande cha kifaa hiki?*

**Probes:**

- What about the instructions make them clear?  
*Je, ni nini kuhusu maagizo yanayafanya kueleweka kwa urahisi?*
- What about the instructions was unclear?  
*Je, ni nini kuhusu maagizo yanayafanya kutoeleweka kwa urahisi?*
- What modifications would you recommend if you were to advise your patients to use it?  
*Je, ni ukarabati upi ungependekeza ikiwa ungeshauri wagonjwa wako kukitumia?*

**Comprehension of usage instructions**

**Now I'm going to show you some instructions that have been used to guide consumers through the use of an HIV self-test. Please examine these instructions. I will then ask you questions about these instructions.**

***Sasa nitakuonyesha maagizo kadhaa ambayo yametumiwa kuwasaidia watumizi kuhusu kukitumia kifaa cha kujipima ukimwi. Tafadhali chunguza maagizo haya. Baadaye nitakuuliza maswali kuhusu maagizo haya.***

55. In your opinion, what aspects of the instructions were clear and easy to follow?

*Kwa maoni yako, ni mambo gani ya maagizo yalikuwa wazi na rahisi kufuata?*

**Probes:** What modifications could be used to make the unclear aspects of the instructions more clear?

*Je, ni ukarabati upi ungetumiwa kuyafanya mambo yasiyo wazi kuhusu maagizo yawe wazi?*

56. What aspects of the instruction were unclear and confusing?

*Je, ni mambo gani ya maagizo yalikuwa sio wazi na kuchanganya?*

**Probe:** What made certain aspects of the instructions clear and easy to follow?

*Je, ni nini kilichofanya mambo fulani kuhusumaagizo kuwa wazi na rahisi kufuata?*

**Now, could you please put the packaging and the leaflet away?**

***Sasa tafadhali, weka kando pakiti na karatasi ya maelezo kando***

57. Please explain how you would describe product use to one of your patients?

*Tafadhali elezea vile ungelezea utumizi wa kifaa kwa mmoja wa wagonjwa wako.*

## Annex 11: Potential HIV self-test kits users - interview discussion Guide for Phase 1

### Discussion Guide Potential HIV Self-Test Kit Users (Phase 1) In-depth Interviews

**Introduction:** thank you for taking the time to participate in this focus group discussion. I am going to ask you a number of questions in relation to HIV testing products. There is no right or wrong answers as these are your opinions. Please note that responses provided in this survey will be aggregated with those of other respondents such as yourself. No individual responses will be shared.

#### Description of HIV Self-Test Kit

The HIV Self-Test Kit allows you to take a HIV test in the comfort of your home. You can take a sample yourself, in this case, saliva from the lower and upper gum and perform the test yourself. This test produces results in about 20 minutes

#### Awareness of Self-Test Kits

1. Have you heard about any self-test kits?  
Ushawahi sikia kuhusu kifaa chochote cha kibinafsi cha kupima?
2. Have you ever used any or know anyone who has used it?  
Je, umewahi kutumia hivi vifaa ama kusikia mtu ambaye amevitumia?
3. Can you tell me what you think about a possibility of testing for HIV at home using a self-test kit?/ Unaweza nialeza unacho fikiria kuhusu uwezekano wa kujipima HIV ukiwa nyumbani ukitumia jaribio la kibinafsi?

#### Probes/dadisi

- Would using the kit make someone more comfortable or less comfortable taking an HIV test?/Je kutumia jaribio la kibinafsi inafanya mtu awe huru au sio huru kabisa wakati wa kujipima?
  - Do you believe that you will be able to this yourself correctly?/Je unaamini kuwa unaweza jifanyia hivi mwenyewe?
  - Do you think the test results would be accurate?/Je unafikiri jaribio litakuwa sahihi?
  - Fear of finding out/ una hofu ya kujua matokeo?
  - What may be some other concerns you may have/Je una wasiwasi yoyote?
4. Have you ever heard of HIV self-test kits?/ Je, umewahi kusikia kuhusu vifaa vya kupima virusi vya ukimwi kibinafsi?

#### Probe: /Dadisi

If yes/kama ndio

- What have you heard about the kits?Ni nini umesikia kuhusu jaribio la kibinafsi?
- Where did you hear about it/ Je ulisikia wapi kuihusu?
- Have you heard mostly positive things or negative things?/Je mara kwa mara umesikia mambo mazuri au mabaya kuihusu?

- If no:/Kama la: Where would you normally hear about this type of products?/ Ni wapi wewe husikia kuhusu bidhaa hii?

Describe Self-Test Kit: Home Self-Test HIV kits are now available in some countries. They use a mouth swab and give you results in about 20 minutes.

5. How do you feel about the idea of buying an HIV self-test kit to test yourself?/ Je unahisi aje kuhusu kununua jaribio la kibinafsi wewe mwenyewe?

**Probe:/Dadisi:**Think about going into a pharmacy or health facility./Ukifikiri kuhusu kwenda kwa duka la kuuza dawa au kituo cha afya?

- How would it feel to go and find the self-test kit on the shelf?/Ungehisi aje kwenda na upate jaribio la kibinafsi kwenye rafu?  
Moderator: If any discomfort / barrier, ask,/ Kama kunahisi za kuzuia/kutatanisha, uliza:
  - Is there anything that would make you more comfortable? What would it be? Kuna jambo lolote ambalo linaweza fanywa ili uwe mtulivu? Ni jambo gani hilo?
- How would it feel to ask a store manager about where to find a kit?/Ungehisi vipi kuuliza msimamizi wa hifadhi pahali pa kupata jaribio la kibinafsi?  
Moderator: If any discomfort / barrier, ask,/ Kama kunahisi za kuzuia/kutatanisha, uliza:
  - Is there anything that would make you more comfortable? What would it be? Kuna jambo lolote ambalo linaweza fanywa ili uwe mtulivu? Ni jambo gani hilo?
- What would it be like to pay for the kit at the cashier? Why do you feel this way?/Je ingekuwa vipi kulipia jaribio hilo la kibinafsi kwa keshia?  
Moderator: If any discomfort / barrier, ask,/ Kama kunahisi za kuzuia/kutatanisha, uliza:
  - Is there anything that would make you more comfortable? What would it be? Kuna jambo lolote ambalo linaweza fanywa ili uwe mtulivu? Ni jambo gani hilo?

6. What would make you decide to buy a self-test kit? / Ni nini ingefanya kuamua kununua jaribio la kibinafsi?

**Probe:/ Dadisi**

- If you have ever tested for HIV in the past, think about what made you decide to do that./ kama ushawahi pimwa hapo awali,fikiria ni nini kilikufanya uamue kupimwa?
- If you have ever taken another kind of self-test, like a pregnancy or blood monitor test, what made you decide to do that? / Kama umeshawahi fanya jaribio la kibinafsi lingine kama vile kupima mimba ama damu, nini ilikufanya ufanye uamuzi.?
- If this does not apply to you, imagine one of your close friends. What would you tell him / her make him or her decide to buy a self-test kit? Why do you think that?/Kama hii haitumiki kwako fikiria nani kati ya marafiki wako wa karibu.Ni nini ingemfanya yeye aamue kununua jaribio la kibinafsi?

7. What would prevent you from buying a self-test kit? /ni nini kingekuzuia wewe kununua kifaa cha jaribio la kibinafsi?

**Probe:/Dadisi**

- What are some reasons that you would not buy a self-test kit, even if you wanted one?/Ni sababu zipi zingefanya usinunue jaribio hizi za kibinafsi ingawaje ungetaka?

- If this does not apply to you, think about a friend of yours. kama haitumiki kwako fikiria kuhusu marafiki wako?
  - If he or she wanted to test for HIV, what might prevent him or her from buying the self-test kit? Why do you think this is?/kama yeye angetaka kufanya jaribio la HIV, ni nini ingemzuia yeye kununua jaribio la kibinafsi? mbona unafikiria hivyo?
  - Do you think there is stigma shame associated with buying this product,/Je unafikiri kunaweza kuwa na unyanyapaa ukinunua kifaa hiki?
  - How can it be overcome? Is it something that the distributor / provide can do? What is it? Is it something that you can do?  
Hii inaweza suluhishwa aje? Kuna jambo ambalo wauzaji wanaweza fanya? Ni nini hilo?  
Ni jambo wewe unaweza fanya?
8. Where would you expect to find self-test kits? What type of store or facility? Where in the store/facility do you want the kits to be displayed?/Ni wapi unatarajia kupata kifaa hiki? Aina gani ya hifadhi au kituo /wapi kwenye duka au hifadhi ungependa kifaa hiki kiwekwe?
9. How would you expect to find self-test kits? Would you ask someone who worked at the store?/ Ni wapi ungetarajia kupata vifaa vya kupima virusi vya ukimwi vya kibinafsi? Je, ungeuliza mhudumu wa duka?  
Probe: dadisi
- Would it make you more comfortable or less comfortable to have someone in the store help you locate a self-test kit? Ungekuwa huru au huru kiasi kama mhudumu wa hifadhi angekusaidia kupata kifaa hiki cha jaribio la kibinafsi?
  - If you couldn't find the package on the shelf, what would you do?/kama haungeweza pata pakiti kwa rafu ungefanya nini?
  - Would you leave the store? Would you ask someone who worked at the store? /ungetoka kwenye hifadhi? ungeumulizi mhudumu wa hifadhi?
10. What should the outer packaging of a self-test kit look like?/ Je ni aina gani ya ufungaji ungetarajia vifaa vya kupima virusi vya ukimwi kibinafsi kufanana?  
**Probe:** What size should the packaging be (e.g. large, small, etc.)? What material should the packaging be made out of (e.g. a box, a case, a bag)? /ni aina gani ya ufungaji wa vifaa vya jaribio la kibinafsi ngependa vitengenezwe?
11. What information would you want to see included with the HIV self-test package Ni ujumbe gani ungependa uwekwe kwenye pakiti la jaribio la kibinafsi?  
Probes:/Dadisi
- Should this information be on the outer package?/ujumbe huu ungekuwa nje ya pakiti?
  - Should it be included on insert or brochure insides? ama ingejumuiswa kwenye kipeperushi?
12. How would you like to information to about interpreting administering and interpreting results of the HIV test presented to you? Je ni vipi ungependa kupata ujumbe kuhusu tafsiri ya matokeo ya HIV kuwasiliswa kwako?  
**Probe: dadisi**
- What are the best ways that you follow instructions? Ni njia ipi mwafaka ya kufwata maelezo?

- Do you like to have everything printed in text or do you like to have pictures as well? / Je ungependa kila kitu aindikwe au pia picha iwemo?
- Do you prefer illustrations or photographs?Je unapenda maelezo au picha?
- Think about other times that you have had to follow strict instructions to do something. What was helpful about those instructions?/Fikiria wakiti wewe hufwata maelezo kwa makini. Ni nini ilikuwa ya maana kwa maelezo hayo?
- What made those instructions difficult to follow?/Ni nini ilifanya maelezo hayo kuwa magumu kufwata?

13. Once you have taken the test, what further information would you like to receive about the results?/Baada ya kufanya jaribio ni maelezo yapi ungependa kupata kuhusu matokeo?

**Probe:Dadisi**

- Imagine that the test tells you that you may have HIV and that you have to go to the clinic to have another confirmatory test./Fikiria kama jaribio linaonyesha kwamba una virusi na inahitajika uende kwenye kituo cha afya upate majbu sahihi.
  - What other information would you like to have?/ Ni maelezo yapi ungependa kupata?
  - Would you like to have information about what that positive result means?/ je ungependa kupata maelezo kuhusu majibu kuwa una virusi?
  - How should this information be presented? For instance, would you like to have a phone number that you can call right away to talk to someone about your result?/Ni vipi maelezo haya yangewasilishwa? Je ungependa kupata nambari ya simu ambayo ungeongea na muhudumu mara moja kuhusu matokeo yako?
  - Would you like to have a list of clinics in your area that you can visit?/ungependa kuwa na orodha ya vituo katika eneo unaloishi?
- Now imagine that your result comes back HIV negative. What information would you like to have?/ sasa fikiria kama matokeo yataonyesha hauna virusi. Ni maelezo yapi ambayo ungependa kupata?
  - Would you want information about how to stay HIV negative?/Je ungependa kupata maelezo jinsi ungeishi bila virusi?
  - What questions do you think you might have after you receive your result?/ Ni maswali yapi unayofikiria ungekuwa nayo baada ya matokeo?
- Who would you like to receive this information from./ Ni nani ungependa akupe matokeo haya?
- Where in the packaging would you expect to find information about what to do once you have your test result?/ni wapi kwa pakiti ungependa kupata ujumbe wa kufanya baada ya kupata matokeo?

14. If the test required you to keep time, how would you do so?/ kama jaribio linahitaji kuweka mda ni vipi ungefanya?

**Probe: /Dadisi**

- How do you normally keep track of the time?/ ni vipi wewe huweka mda ?
- For instance, do you use a watch, clock or mobile phone?/ kwa mfano wewe hutumia saa ya mkono ukuta au simu?
- Or do you not necessarily have these things available?/ au wewe hauna hivi vitu mara kwa mara?

- What could be included in the packaging to help you keep time? Ni nini kingeongezwa kwa pakiti kukusaidia wewe kuweka mda?

15. Have you used other types of in-home diagnostic tests before? Such as a pregnancy test or a blood monitor test? What did you like about the packaging? What didn't you like about the packaging?/ Je ushawahi tumia vifaa vingine vya kujipima vya nyumbani?kama vile vya kupima mimba,au kupima damu?

**Now, I'm going to show you packaging from a self-test kit products called Aware. Please examine this product. When you are ready, I will ask you a series of questions about this product.**

Moderator please note: please remove the testing strip out of the pack and show it to the respondent. Please do NOT take the test

16. What did you like about the outer packaging of this product? Why? What did you dislike? Why?/Ni nini ulipendezwa katika ufungaji wa nje wa pakiti la bidhaa?kwa nini?ni nini haukupendezwa nayo?

**Probes:**

- What did you think about the size of the packaging?Ni nini ulifikiri kuhusu ukubwa au udogo wa pakiti?
- What did you think about the shape of the packaging?/ Ni nini ulifikiri kuhusu umbo la pakiti?
- What did you think about other features of the packaging? **Ni nini ulifikiria kuhusu makala ya pakiti ?**
- What would you change about this packaging if you could?Ni nini ungebadilisha kwa hifadhi la pakiti hili kama ungeweza?
- What about this packaging would make you want to purchase this product?/Ni nini kuhusu uhifadhi ungekufanya ununue bidhaa hii?

17. What did you like about the information included on the outer packaging of this product? Why? What did you dislike about the outer packaging? Why?/ Ni ujumbe upi ulikupendeza kwa sehemu ya nje ya bidhaa hii?kwa nini?na ni nini ilikuchukiza katika sehemu ya nje? Na ni kwa nini?

**Probes:Dadisi:** What information was confusing?/ ni ujumbe ulikuwa wa kukanganya?

- What could be done to make the information less confusing?Ni nini ingefanya ujumbe usikanganye sana?
- What was good about the way the information was presented? What was not good?/Ni nini ilikuwa nzuri jinsi ujumbe uliwasilishwa?Ni nini ilikuwa mbaya ?

18. What did you like about the inner packaging of this product? Why? What did you dislike? Why?/ Ni nini ulipendezwa na uhifadhi wa ndani wa bidhaa hii?kwa nini?ni nini ulichukizwa nayo? Kwa nini?

**Probes:**

What did you think about the sachets that hold the test kit? / ni nini ulifikiria kuhusu mifuko ya kubebea jaribio hizi?

Was there anything missing from these sachets that would make the test easier to use? What would you change about this inner packaging if you could?Je kulikuwa na chochote kilichokosekana kwenye mifuko ambacho kingefanya jaribio kuwa rahisi? Ni nini ungebadili katika hifadhi ya ndani ya pakiti kama ungeweza?

What about the inner packaging might make it difficult to use the test kits?/ Ni nini katika sehemu ya ndani ya pakiti ingefanya utumizi kuwa mgumu?

**Now I'm going to show you some instructions that have been used to guide consumers through the use of an HIV self-test. Please examine these instructions. I will then ask you questions about these instructions.**

19. In your opinion, what aspects of the instructions were clear and easy to follow? Kwa maoni yako ni mambo yapi ya maelezo yalifanya jaribio kuwa rahisi kutumia?

**Probes:** What made certain aspects of the instructions clear and easy to follow? Ni nini ilifanya mambo ya maelezo kuwa rahisi kutumia?

20. What aspects of the instruction were unclear and confusing? Ni mambo yapi ya maelezo yalikuwa ya kukanganya?

**Probe:** What modifications could be used to make the unclear aspects of the instructions more clear? Ni mabadiliko yapi yangefanya mambo magumu ya maelezo kuwa wazi

21. Let's imagine that you want to explain how to use the product to a friend back home. Based on what you remember from reading these instructions and seeing the product, what would you tell him / her?

Tuseme kwamba unataka kumuelezea rafiki nyumbani jinsi ya kutumia hiki kifaa. Kulingana na ale ambayo umesoma kwa maelezo ya kukutumia na vile umeona hii kifaa ungemwambiaje?

## Annex 12 – Phase II discussion guide

INTRODUCTION AND CODE OF CONDUCT	Time: 5 minutes
<p data-bbox="237 401 500 432"><b>Introduction to Study</b></p> <p data-bbox="237 470 1094 501">Hello, I am [NAME OF MODERATOR] from IPSOS, the research company.</p> <p data-bbox="237 539 1235 571">We are conducting a study to gain insights into HIV Oral Self-Test Kits in [COUNTRY].</p> <p data-bbox="237 609 1380 678">As [RECRUITER] explained when they made the appointment with you, I'd like to ask you some questions for about 1 hour.</p> <p data-bbox="237 716 1380 821">Everything you say and do will be completely confidential and we will not share your personal details, or any information about your profession, with anyone from another organization. We will destroy your contact details following our study.</p> <p data-bbox="237 858 1380 928">[GAINING CONSENT] Would you like to continue with the interview? Do you have any questions or concerns about the research?</p> <p data-bbox="237 966 1380 1071">We would also like to record this interview so that we can refer back to the recording to write our report later. The recording will not be shared with anyone from another organization and will be destroyed after we write our report. Is this ok with you?</p> <p data-bbox="237 1108 1019 1140">Do you have any questions for me before we begin the interview?</p>	

General information about participant	Time: 3 minutes
<p data-bbox="201 1390 667 1421">To begin, tell me a little about yourself.</p> <p data-bbox="250 1459 748 1491"><i>...PROBE ON... age, education, occupation</i></p>	

## Section 1: Reaction to self-test kit

Time: 15 minutes

Hand participant the external packaging for the first test kit. Please rotate packs.

Please **OBSERVE** participant's behaviour when the kit is first given to them. i.e. where on the package did the participant look before opening the self-test kit?

- What comes to mind when you see this packaging.
- **What kind of product is it? What do you imagine is in the pack?**
- What are some things that stood out to you about the kit we gave you? **PROBE ON...why is that the case?**
- Who do you think would buy this product? What would they be looking for when buying this product? What would be important to them?

## Section 2: Opinions on packaging

Time: 15 minutes

I would like to ask some more specific questions about the packaging of this kit

### EXTERNAL PACKAGING

- What do you think of the outer packaging? **PROBE ON...material, perceived quality, size, color, label, text size, information, ergonomics (stability, easy to hold)**
  - How do you feel about the colors used in the packaging?
  - How do you feel about the quality of this HIV self test kit? What about the packaging makes you feel that way?
  - How do you feel about the size of the packaging? Why do you feel that way?
  - Do you find the text size too big, too small or just right?
  - How does the package feel in your hand? Is it comfortable to hold? Does it feel stable?
  - What information would you like to see added to this external packaging? What information would you like to see removed from this external packaging? What information is unclear/confusing?
  - This packaging includes pictures of the test kit components that are inside. What do you think about these pictures? Are they clear? Please explain to me what you think each picture is of. (For new mock-ups only.)

### INNER PACKAGING

- What do you think of the inner packaging? **PROBE ON...contents, perceived quality, size, material, text**
- The inner packaging includes (actual photographs/drawings) to demonstrate how to use the test. What do you think of these images?
- The inner packaging includes information about how to read the test results. Is this information

clear?

- What information here should be removed?
- What information should be added?
- What information needs to be clarified?

#### OVERALL REACTION

- Overall, how do you feel about this packaging? **PROBE ON**...what did you like / dislike about it, what would make the package more appealing to you, what would you change to make the packaging more appealing? Is this a high-end, medium end or low end product? What makes you say that on the pack?
- What price would you expect to pay for this product?
- How would you compare this packaging with other self-test kits you know of? *i.e. pregnancy, diabetes, blood pressure, other HIV test kits*

### Section 3: Instructions

Time: 15 minutes

Now, I would like to ask some questions about the instructions included in this kit

- After reading these instructions, how would you explain the use of the self-test kits? *Have participant walk you through the instructions, explain no right or wrong answer, we just want to understand their perception*
- After reading these instructions, what other questions do you have, if any, about how to use the self-test?
- *This inner packaging includes information about opening the buffer vial. (Point to the instructions.) Can you show me you would open this vial based on these instructions?*
- *The inner packaging includes information about how to interpret test results. Based on these instructions, could you please interpret the following results? (Show image of various test results). What do the instructions tell you to do for each of the results?*
- How easy would it be to follow these instructions? **PROBE ON**...ways to make instructions easier? *If you were in your home, what might make it difficult to follow these instructions?*
- How clear are the instructions? **PROBE ON**...what is unclear vs. clear, why?
- What do you like about the way instructions are displayed? What do you like / dislike about it?
- Did you notice the counselling messages? Can you locate them for me on the pack? **PROBE ON**... *how useful were the counselling messages? what can make them easier? After reading this pack, how confident are you that you would be able to get the support you need after reading your results? How would you like the information to be presented?*
- How well does this packaging communicate that your results are confidential (not to be seen or known by anybody but you)?
  - What about the packaging makes you feel that your results are private?
  - What about the packaging could be changed to make you feel better about the privacy of the results?

<b>Distributor only: Instructions</b>	<b>Time: 5 minutes</b>
<ul style="list-style-type: none"> <li>• What aspects of packaging and labelling could help increase demand of this product? <b>PROBE ON...why? What could be added?</b></li> <li>• To what extent would this packaging help you explain how to use the product? What would you need to have on the packaging to help you promote it to your customers, or to help you explain how the kit works?</li> </ul>	

<b>Section 3: General Information included</b>	<b>Time: 10 minutes</b>
<ul style="list-style-type: none"> <li>• What other information do you think needs to be included here? <b>PROBE ON...why?</b></li> <li>• How easy would it be to access information about care or support for using this test?</li> </ul>	

<b>Distributor only: General information included</b>	<b>Time: 5 minutes</b>
<ul style="list-style-type: none"> <li>• For you to sell this product, what is needed on the labelling? <b>PROBE ON...why? Where on package is it needed?</b></li> <li>• What information is needed on this product for it to be transported properly? <b>PROBE ON...storage conditions (i.e. temperature)? How could it be improved?</b></li> <li>• <i>What would you need to see on this packaging to help you comply with storage and distribution regulations?</i></li> </ul>	

<b>Section 4: Using the self-test kit</b>	<b>Time: 5 minutes</b>
<ul style="list-style-type: none"> <li>• Would you buy this HIV self-test kit? <b>PROBE ON...why or why not?</b></li> <li>• Would you use this HIV self-test kit? Where?</li> <li>• Would you recommend this HIV self-test kit to other people?</li> </ul>	

<b>Distributor only: Selling self-test kits</b>	<b>Time: 10 minutes</b>
<ul style="list-style-type: none"> <li>• If you were to sell this kit, where would you place the product? Why? <b>PROBE ON...shelf positioning, is it behind counter and why/why not, what products it would be near?</b></li> <li>• Please describe what your supply chain would be like for this product.</li> <li>• How often would you order this product?</li> <li>• How would you manage your stock?</li> </ul>	

THANK AND CLOSE.

## Annex 13: Informed Consent: Potential Distributors of HIV Self-Test Kit

### Informed Consent/ Potential Distributors of HIV Self-Test Kit Insights into Packaging and Labeling for HIV Oral Self-Test Kits in Kenya

Hello. Thank you for taking the time to talk to me today. My name is \_\_\_\_\_. I am working with the Population Services International, Kenya, an international non-profit organization, and the Ministry of Health to understand the issues around the provision of HIV testing services in Kenya. After providing information, if you agree, we would like to include you in this study.

**What is the purpose of the study?** The purpose of the study is to learn about how HIV oral self-test should be packaged and labeled for distribution in Kenya. The information will be used by the Ministry of Health to increase access to HIV testing among Kenyans and to facilitate linkages to care and treatment among people who are living with HIV.

**Why have I been invited to take part?** You have been selected to participate in the study because you are above 18 and currently distribute either HIV prevention products or other in-home screening tools. You may therefore have interesting experiences to share that can inform the provision of HIV testing services in your area.

**What will happen if I take part?** At today's visit we will ask you questions about your business, including things like where it operates and what products you sell. We will also ask for your opinions about how an HIV self-test should be packaged and what information you would want to see included with the test. We will also ask questions about how you think a product like this should be displayed and how you might attempt to sell this product.

**How long will the interview last?** The interview with you will last about 45-60 minutes.

**What are the risks of participating?** An inconvenience may be the time and effort you take to be a participant. You may find one or more questions that we ask to be sensitive. You do not have to respond to any question that makes you uncomfortable. Another risk may be a breach of confidentiality (something you say is accidentally provided to others, or something you say during a focus group is shared with others outside the group, or your contact information is seen by others) but we will take great efforts to make sure that this does not happen.

**What are the benefits of participating?** You will be helping researchers learn more about the provision of HIV testing services in Kenya so that this information can be used by health care providers and government to improve health.

**Will my participation in the study be kept confidential?**

- Because we are asking for your input as part of a focus group discussion, other participants will know what you say during the focus group discussion. However, we will ask participants to keep information shared during the focus group confidential.
- Your answers to interview questions will be recorded and will be kept in locked areas in the Population Services International Kenya office. Your name will not be recorded as part of the study. Transcriptions of the audio recording will remove all personal identifiers and will be stored on a computer that is password protected.

- Information gathered in this study may be used in reports, published papers, or presented in public, but your name or other personal identifier will never be used.

**Your rights:** Your participation in this study is completely voluntary. If you agree to participate in this study, you may end your participation at any time without penalty or loss of existing benefits to which you are entitled. If you decide to take part, you are free to skip any questions. You are free to withdraw at any time without affecting your relationship with the community, providers or study team.

**Who has reviewed the study for ethical issues?** This study has been reviewed by the Population Services International Institutional Review Ethics Board, and locally by the Ethics Review Committee of Kenyatta National Hospital/University of Nairobi.

**What if I need more information?** If you have a concern about any aspect of the study, you may call Ms. Rhouné Ochako of Population Services International, P. O. Box 22591 - 00400 Nairobi; Tel: +254 20 271 4346 / 2714354 / 271 4355.

**What if there is a problem?** Any complaint about the way you have been treated during the study or any possible harm you might suffer will be addressed. Please contact Prof M. L. Chindia, Secretary, Kenyatta National Hospital/University of Nairobi Ethics Review Committee, P.O. Box 20723-00202, Nairobi, Kenya at Tel: 254-02-2726300 Ext 44355. E-mail: [uonknh\\_erc@uonbi.ac.ke](mailto:uonknh_erc@uonbi.ac.ke).

**Do you consent to participate in the study?**

Yes       No (Not eligible to continue)

**Participant's statement**

Study participation has been explained to me. I have been given a chance to ask any questions I may have. I am content with the answers to all of my questions.

---

**Name of Participant: Print**

---

**Date**

---

**Signature: Respondent**

---

**\* (Mark)**

\*In case the respondent is not able to sign this form, this attests that the consent form has been read and explained accurately by a member of the research staff, and that the respondent has marked the spaced with an 'X.'

**Interviewer's statement**

I, the undersigned, have defined and explained to the participant in a language that s/he understands the procedures to be followed, the risks and benefits involved, and the obligations of the interviewer.

---

**Name of Interviewer: Print**

---

**Date**

---

**Signature: Interviewer**

## Annex 14: Informed Consent: Potential users of HIV Self-Test Kit

### Informed Consent/ Potential User of HIV Self-Test Kits Insights into Packaging and Labeling for HIV Oral Self-Test Kits in Kenya

Hello. Thank you for taking the time to talk to me today. My name is \_\_\_\_\_. I am working with the Population Services International, Kenya, an international non-profit organization, and the Ministry of Health to understand the issues around the provision of HIV testing services in Kenya. After providing information, if you agree, we would like to include you in this study.

**What is the purpose of the study?** The purpose of the study is to learn about how HIV oral self-test should be packaged and labeled for distribution in Kenya. The information will be used by the Ministry of Health to increase access to HIV testing among Kenyans and to facilitate linkages to care and treatment among people who are living with HIV.

**Why have I been invited to take part?** You have been selected to participate in the study because you are aged between 18 and 49 years and you may be likely to seek HIV testing services. You may therefore have interesting experiences to share that can inform the provision of HIV testing services in your area. We will interview 20 people in this phase of the study.

**What will happen if I take part?** Before we begin, we will ask several questions about yourself, including your HIV status. If you qualify for the study, we will ask you to look at the proto-type of an HIV self-test kit and then we will ask questions that will explore what you liked and did not like about the test kit, as well as what may have been confusing or unclear. The interview will be audiotaped to help us analyze the data. You can refuse to have the interview taped, but you can still participate in the study.

**How long will the interview last?** The interview with you will last about 45-60 minutes.

**What are the risks of participating?** During this study, you will find out your HIV status. This may cause psychological distress. We will not record your HIV test result or link your name to your responses to the questions. An inconvenience may be the time and effort you take to be a participant. You may find one or more questions that we ask to be sensitive. You do not have to respond to any question that makes you uncomfortable. Another risk may be a breach of confidentiality (something you say is accidentally provided to others, or something you say during a focus group is shared with others outside the group, or your contact information is seen by others) but we will take great efforts to make sure that this does not happen.

**What are the benefits of participating?** . You will be helping researchers learn more about the provision of HIV testing services in Kenya so that this information can be used by health care providers and government to improve health. Your opinion will help us to further refine the design of packaging for self-test kits that will help other people to use it correctly.

Compensation: **You will receive a voucher worth 500KES** for speaking with us today

**Will my participation in the study be kept confidential?**

- Your interviews will be in private.
- Your answers to interview questions will be recorded and will be kept in locked areas in the Population Services International Kenya office. Your name will not be recorded as part of the

study. Transcriptions of the audio recording will remove all personal identifiers, including any names mentioned, and will be stored on a computer that is password protected.

- Information gathered in this study may be used in reports, published papers, or presented in public, but your name or other personal identifier will never be used.

**Your rights:** Your participation in this study is completely voluntary. If you agree to participate in this study, you may end your participation at any time without penalty or loss of existing benefits to which you are entitled. If you decide to take part, you are free to skip any questions. You are free to withdraw at any time without affecting your relationship with the community, providers or study team.

**Who has reviewed the study for ethical issues?** This study has been reviewed by the Population Services International Institutional Review Ethics Board, and locally by the Ethics Review Committee of Kenyatta National Hospital/University of Nairobi.

**What if I need more information?** If you have a concern about any aspect of the study, you may call Ms. Rhouné Ochako of Population Services International, P. O. Box 22591 - 00400 Nairobi; Tel: +254 20 271 4346 / 2714354 / 271 4355.

**What if there is a problem?** Any complaint about the way you have been treated during the study or any possible harm you might suffer will be addressed. Please contact Prof. M. L. Chindia, Secretary, Kenyatta National Hospital/University of Nairobi Ethics Review Committee, P.O. Box 20723-00202, Nairobi, Kenya at Tel: 254-02-2726300 Ext 44355. E-mail: [uonknh\\_erc@uonbi.ac.ke](mailto:uonknh_erc@uonbi.ac.ke).

**Do you consent to participate in the study?**

Yes  No (Not eligible to continue)

**Do you consent to have the interview audio taped?**

Yes  No

**Participant's statement**

Study participation has been explained to me. I have been given a chance to ask any questions I may have. I am content with the answers to all of my questions.

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Signature: Respondent**

\_\_\_\_\_  
**\* (Mark)**

\*In case the respondent is not able to sign this form, this attests that the consent form has been read and explained accurately by a member of the research staff, and that the respondent has marked the spaced with an 'X.'

**Interviewer's statement**

I, the undersigned, have defined and explained to the participant in a language that s/he understands the procedures to be followed, the risks and benefits involved, and the obligations of the interviewer.

\_\_\_\_\_  
**Name of Interviewer: Print**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Signature: Interviewer**