Original Article

Evaluation of OraQuick HIV 1/2 Self-Test Kit in a Developing Country

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ABSTRACT

Background: For persons who desire to screen themselves for HIV, self-testing for HIV, which involves performing, reading and interpreting their own HIV test, is convenient and confidential. This study aimed to evaluate the performance characteristics of the OraQuick HIV 1/2 self-test and establish the ease of using the HIV self-test kit by persons seeking HIV testing.

Methodology: This evaluation was a cross-sectional field-based performance characteristic study with a sample size of 1008. Specimens were taken from the six geopolitical zones of Nigeria. These specimens were then characterised and utilised to evaluate the test kit at a reference laboratory. The data were analysed using IBM-SPSS version 25.0 (IBM Corp, Armonk, NY). The sensitivity and specificity (with 95% confidence interval) of the test were determined.

Results: The OraQuick HIV 1/2 self-test had a sensitivity of 98.39%, specificity of 98.42% and accuracy of 97.6%. All the participants (100%) said that the test kit was reasonable, liked the packaging and said that it was easy to read. Almost all respondents (99.9%) said that they would recommend it to others, and 99.8% said that the kit was easy to dispose of and easy to learn. Almost all said that the test was easy to perform, while 99.1% said that the device was comfortable.

Conclusion: This evaluation has shown good performance in the testing result, but it has also demonstrated good acceptability of the OraQuick test device by the public members who used the device. This development would also contribute to actualising the sustainable development goal of eradicating HIV by 2030.

Key words: Accuracy, HIV/AIDS, rapid test kits, sensitivity, specificity

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INTRODUCTION

Establishing and providing accurate and reliable diagnoses is critical for HIV/AIDS interventions such as Prevention of mother-to-child-transmission (PMTCT), antiretroviral therapy (ART), HIV Testing Services (HTS), blood safety and HIV surveillance by the Nigerian government and partners to control HIV/AIDS infection.[1,2] Detection of specific antibodies in the blood or other body fluids is the primary testing method for HIV and the standard procedure for diagnosing HIV infection. HIV self-testing (HIVST) is a process in which an individual takes a specimen, administers a test and interprets the results, frequently in a private setting, either alone or with a trusted person. HIV self-testing allows individuals to determine their HIV status anywhere and anytime, without stigmatisation or coercion, particularly those in hard-to-reach areas.[3] HIVST can be performed with or without assistance. HIVST is a unique technique for increasing HTS use, particularly among hard-to-reach and marginalised populations.[4]

HIV Diagnostics started in Nigeria in the 1980s and involved the use of ELISA for screening and Western blot for confirmation.[5,6] The procedure required highly skilled Medical Laboratory Scientists (MLS), and clients had to endure long waiting times for results to be released as testing was restricted to mainly University Teaching Hospitals and the Central Public

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Health Laboratory. Evaluations were done in collaboration with teaching hospitals, and NASCP coordinated the process. Back then, the procedure was simple, and NAFDAC issued approvals for the use of test kits in Nigeria based on recommendations of the evaluation team.[7] The scale-up of HIV testing to enhance access to HIV support services and tailoring a prevention programme to meet country-specific needs made it necessary to develop national guidelines and directions for testing procedures.[1,8-10] In August 2005, the Nigerian government constituted a multi-agency working group to evaluate HIV Rapid test kits (RTKs).[11,12]

A rapid test is one of the assays used in detecting HIV-specific antibodies. RTKs are evaluated in the laboratory and placed in appropriate combinations (Testing Algorithm) for reliable diagnosis of HIV infection.[13] On the one hand, self-tests can reach individuals who would otherwise not seek testing and are at the highest risk of HIV infection; and promote mutual partner testing, thereby avoiding unprotected sex between discordant partners. [14] It has been suggested that using body fluids other than blood as specimens for identifying HIV antibodies could be a viable alternative to blood testing.[15,16]

The OraQuick® HIV Self-Test is an *in vitro* diagnostic medical device that detects HIV-1 and HIV-2 antibodies in oral fluid. This test is intended to aid in the detection of HIV-1 and HIV-2 antibodies in infected persons.[17] The kit is designed to enable an individual to take the HIV test anonymously and privately by collecting an oral fluid sample using the test device to swab the upper and lower gums.[18]

Several rapid test kits have been evaluated between 2006 and to date, and algorithms were developed based on laboratory performance characteristics and other specified parameters, including specificity, sensitivity and ease of use. The WHO announced global guidelines in December 2016 advocating supported partner notification services and HIVST) as new tactics for HIV testing among high-risk and hard-to-reach populations.[4] Amethyst's oral quick HIV 1 and 2 test kit was evaluated in 2016 and launched in Nigeria in 2017.[19] However, studies that evaluate OraQuick HIV 1/2 self-test to make information available for researchers and recommend for people in rural or hard-to-reach areas are very scanty. Therefore, this study aimed to evaluate the performance characteristics of the OraQuick HIV 1/2 self-test and determine its field sensitivity, specificity and accuracy. In addition, this study seeks to establish the ease of use of the HIV self-test kit by persons seeking HIV testing at ANC clinics, heart-to-heart centres and blood donation centres. The masses in developing countries will benefit from the availability of a test device that can be used confidentially and privately.

METHODOLOGY

Ethical considerations

Consent was obtained from participants voluntarily after adequately informing them on all aspects of this study. Prospective participants were told that they did not have to participate in the research and could decline at any study point. Consent was obtained in writing in the presence of a witness. The Protocol for the study was reviewed by the National Health Research Ethics Committee (NHREC) that issued ethical clearance number NHREC/01/01/2007–9/03/2018.

Study design

This study was a cross-sectional field-based evaluation of performance characteristics of the OraQuick HIV 1/2 self-test. Samples were collected from six teaching hospitals across all the geopolitical zones of Nigeria. These samples were then characterised and utilised to evaluate the test kit at a reference laboratory.

Study population

The participants for this study were individuals accessing HIV services on knowledge of their HIV status from antenatal care clinics, heart-to-heart centres and blood donation centres, whose consent was sought and obtained. Participants were between the ages of 18 and 65 years.

Sample size

The sample size was determined using the Cochran's formula:

$$(n) = z^2 p\,(1-p)/d^2$$

Where n = minimum sample size, Z = the standardised normal deviation corresponding with a specified confidence level, P = is the level of sensitivity and specificity expected from the test kit and d is the required precision.

The minimum sample size for the study is to provide 95% confidence intervals (CLs) with a precision of ± 2% for an estimated sensitivity and a specificity of 95%, respectively. With the above specifications, the required sample size was 912, made up of 456 positives and 456 negatives. Considering the possibility of non-response, the sample size was adjusted upwards by 5% to a final size of 479. Hence, for positives and negatives, the combined sample size was made 958. The sample size was further adjusted to one thousand and eight (1008) to make additional room for loss of specimen quality during storage or transfer to the reference testing laboratory.

Selection of subjects

Consenting individuals that participated in the evaluation were recruited consecutively during sample collection until the required sample size was attained.

Source of specimen

A total of 168 specimens were collected from each of the 6 sites indicated below. The sample was collected from six geopolitical zones, including southeast (Imo Specialist Hospital, Owerri, Imo state), South West (General Hospital, Lagos state), South-South (Rivers State University Teaching Hospital, Port Harcourt, River state), North West (Sokoto Specialist Hospital, Sokoto state), North East (Federal Medical Center, Jalingo, Taraba state) and North Central (Bishop Murray Comprehensive Centre Makurdi, Benue state).

Field test

Trained MLSs ensured that all consenting participants were able to use the kit independently. The MLS closely monitored the participants while conducting the self-test. MLSs were trained on the proper specimen collection, storage and transportation of blood samples collected from the participants who consented. The health facility used in the evaluation involved quality management systems and mandatory proficiency testing. Internal quality controls (positive and negative) were run alongside specimens each day.

Testing with the OraQuick device at the field

When opened, each OraQuick HIV 1 and 2 self-test kit was labelled with a unique identification number for the participant by the medical laboratory scientist. The test was then performed according to the manufacturer's instruction after the MLSs adequately explained the instruction to the participant before testing and monitored the testing by the participants to ensure that it was correctly done. The participant equally interpreted the result of the test independently. The MLSs also analysed the results of the participant and documented them.

Collection of blood sample

Venipuncture 10 ml of whole blood was collected in Ethylenediaminetetraacetic acid Vacutainer tubes through venipuncture from all participants that performed the OraQuick test. These samples were labelled with the participant's ID number, centrifuged and plasma harvested into cryovials in three aliquots of 2 ml each. Two vials of the aliquots were transported to the reference laboratory, and one was left at the facility. All aliquots were stored immediately after plasma harvesting at the facility and the reference testing laboratory at −2°C. The cold chain was maintained from the facility during transportation to the reference testing laboratory. No personal information of participants was transmitted or transported to the reference testing laboratory. Designated MLSs in the facilities were responsible for collecting, processing, storing and transporting all specimens to the reference laboratory. Supervisors were selected from officers in NASCP. The study team who saw the proper implementation ensured the MLSs adhered to the quality of sample collection, storage and transportation as directed. They were also responsible for all logistics and strict adherence to the protocol without any breach that ensured good clinical practice was maintained.

Testing at the reference laboratory

All corresponding blood specimens of OraQuick self-tested subjects were tested in the laboratory using the first two test kits in the National Algorithm. All samples that tested concordantly positive and negative were used as standards. These standards were used to evaluate participants' test results with the OraQuick test device from the field.

Data management

Data analysis

Numerous critical parameters for this assay were evaluated, including sensitivity, specificity, positive and negative predictive values compared to the standard. The assay's sensitivity and specificity are calculated as follows:

$$\text{Sensitivity} = \frac{\text{Number of true positives reported by the participant}}{\text{Total no. of true positives}} \times 100$$

$$\text{Sensitivity} = \frac{\text{Number of true negatives reported by the participant}}{\text{Total no. of true negatives}} \times 100$$

$$\text{Positive predictive value} = \frac{\text{Number of true positives reported by the participant}}{\text{All positives reported by the participants}} \times 100$$

$$\text{Negative predictive value} = \frac{\text{Number of true negative reported by the participant}}{\text{All negatives reported by the participants}} \times 100$$

The data were entered, edited and analysed using IBM-SPSS version 25.0 (IBM Corp., Armonk, NY). The sensitivity and specificity (with 95% confidence interval [CI]) of the test were determined.

RESULTS

A total of 1008 samples were received in the reference laboratory for characterization and subsequently used for the evaluation. Seven of them did not qualify to be used as standard because they had discordant results when tested with Determine and Unigold. As shown in Table I, One thousand and one (1001) samples characterized tested positive or negative concordantly with Determine and Unigold. These were used as the standard for the evaluation of the Oraquick self-test kit. Out of the 1001 samples, 498 tested positive while 503 tested negative in concordant with Determine and Unigold. Out of the 498 positive and 503 negative samples by the standard, 490 tested positive and 495 tested negative using Oraquick rapid test yielding an accuracy of 98.4% and 96.8%, respectively.

As shown in Table II, OraQuick recorded 98.4% true positive and only 1.6% false positive in the HIV-positive outcome. The true negative value was 98.45% and 1.6% false negative ($P < 0.001$).

Table III shows the sensitivity of and specificity of OraQuick. Sensitivity was 98.39% and specificity was 98.41%. The positive predictive value was 98.36% and 98.44% for negative

Table I: Comparison of OraQuick test results with the determine and unigold

Instrument	Total	Positive	Negative
Determine	1001	498	503
Unigold	1001	498	503
OraQuick	1001	490	495
Percentage accuracy of OraQuick		98.4	96.8

Table II: Predictive value of OraQuick screening test for HIV

HIV outcomes	Positive (%)	Negative (%)	Total (%)	χ^2 (*P*)
Positive	490 (98.4) (true positive)	8 (1.6) (false positive)	498 (49.3)	938.021 (<0.001**)
Negative	8 (1.6) (false negative)	495 (98.4) (true negative)	503 (50.7)	
Total	498 (49.3)	503 (50.7)	1001 (100.0)	

**Significant at *P*<0.05 level

Table III: Sensitivity and specificity of OraQuick

Statistics (OraQuick)	Value (%)	95% CI
Sensitivity	98.39	96.86-99.30
Specificity	98.41	96.89-99.31
PPV	98.36	96.80-99.17
NPV	98.44	96.94-99.21
Accuracy	98.40	97.42-99.08

CI: Confidence interval, PPV: Positive predictive value, NPV: Negative predictive value

predictive value, with an accuracy of 98.40%. The OraQuick sensitivity had a 95% CI of 96.86% to 99.30% and specificity of 96.89% to 99.31%. Furthermore, the positive predictive value of CI was 96.80%–99.17% and the negative predictive value 96.94% to 99.21% with an accuracy of 97.42%–99.08%.

The participant's perception of the test kits is shown in Figure 1. All the participants (100%) said that the test kit was reasonable, liked the packaging, and was easy to read. While almost all respondents (99.9%) said that they would recommend it to others. In addition, 99.8% of the respondents said that the kit was easy to dispose of and easy to learn. Almost all the respondents stated that the test is easy to perform, while 99.1% said that the device was comfortable.

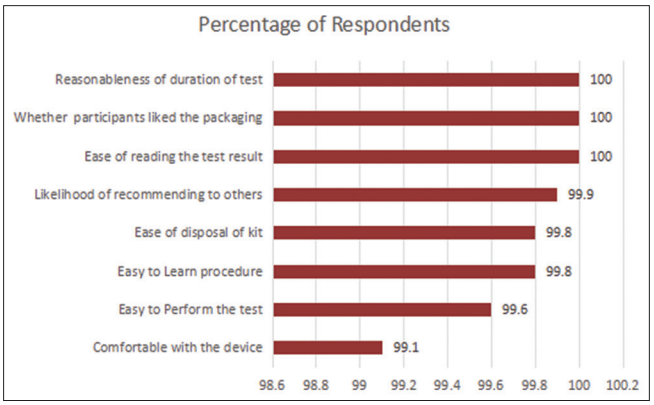

Figure 1: Participants' rating of the test kit validity of the tests

DISCUSSION

HIVST was incorporated into the revised National HIV and AIDS strategic framework 2019–2021 as a priority policy and programmatic approach to HIV response in Nigeria.[20] Nigeria has recently produced guidelines on HIV self-testing. This evaluation complements the government's effort to endure access to HIV testing in developing countries. For persons who desire to screen themselves for HIV, self-testing for HIV, which involves performing, reading and interpreting their own HIV test, is a convenient and confidential choice.[21] HIVST is accepted, enhances coverage and frequency of HIV testing and reaches first-time testers, men, women and adolescents.[21]

The evaluation from this study showed that the OraQuick HIV Rapid self-test Kit was able to detect antibodies to HIV with a high sensitivity of 98.39% and specificity of 98.41%. This result is in correlation with a study conducted by Semá Baltazar *et al*.,[22] who evaluated the performance and acceptability of two rapid oral fluid tests for HIV detection in Mozambique using the National algorithm as the gold standard. Our findings also agree with another UNAIDS' report that HIV rapid diagnostic tests for self-testing using oral fluid are considerably accurate, with a sensitivity of at least 98.7% and specificity of at least 97.95.[23]

Furthermore, the sensitivity and specificity of the OraQuick rapid HIV 1/2 test result found in this study were similar to the manufacturer's data reported to the U. S. Food and Drug Administration (FDA) sensitivity, 99.3%;(95% CI: 98.4%–99.7%) and specificity, 99.8% (95% CI: 99.6%–99.9%).[24] Furthermore, Kurth *et al*. evaluated the accuracy and acceptability of oral fluid HIV self-testing in a general adult population in Kenya. The HIV self-testing kit gave a sensitivity of 89.7% and a specificity of 98%. This study finding also agrees with studies conducted in Zimbabwe with a sensitivity of 100%; (95% CI: 98.0%–100.0%) and specificity of 99.7%; (95% CI: 98.4%–99.9%) [25] and in Botswana (sensitivity, 98.4%; 95% CI: 96.5–99.4; specificity, 98.3%; 95% CI: 91.9–99.9).[26] A similar result was discovered from a supervised oral self-testing in Malawi, which found an overall sensitivity of 97.9% (95% CI: 87.9%–100.0%) and specificity of 100% (95% CI: 97.8%–100.0%).[27] Our findings with different studies have proven that the Oralqucik HIV self-test is very efficient in detecting HIV to antibodies.

Moreover, the findings from this study showed that the positive predictive value was reasonable at 98.36%, while negative predictive value was 98.44%, with the ease of disposal and easy-to-learn procedure being rated as 99.8% each. The evaluation of the OraQuick has shown good performance in the testing result, but it has also demonstrated good acceptability of the OraQuick test device by lay members of the public who used the device. A study conducted in Kenya by Kurth *et al*. [28] reported that the positive predictive value of OraQuick was 96% though the negative predictive value was slightly lower at 94.1%. The high acceptability of HIVST found in this study is similar to what was reported in studies conducted in Malawi, Singapore and the US.[27-30] These results further prove that

there will be a great deal of interest and acceptance of HIV self-testing among the general population, thereby contributing to expanding awareness about the OraQuick self-test kit and subsequently improving HIV testing in developing countries. This development would also contribute to actualising the sustainable development goal of eradicating HIV in the year 2030. Self-test is a unique testing method targeted at those who would likely not get tested and who are at the highest risk of HIV infection. It promotes mutual partner testing and also helps avoid having sex with partners who are at different stages of infection (Centers for Disease Control and Prevention, 2021a). The potential benefits of HIVST include ease of use and accessibility among others.[31] The study participants attest those errors during a testing performance with the kit are and will be minimal. This attribute makes the kit suitable for private use by the general public, an eligible self-test device. However, it is essential to note that diagnosis of HIV 1 and 2 through an oral fluid is subject to confirmation through the use of Rapid Test Kits in the National algorithm.

CONCLUSION

The findings from this study show evidence that the OraQuick HIV 1 and 2 self-test has excellent diagnostic accuracy in field settings as individual tests compared with a serial algorithm comprising the Determine and Unigold tests. OraQuick HIV 1 and 2 self-testing could be an alternative as an HIV screening test because it is a less-invasive procedure. We, therefore, recommend that additional feasibility and cost-effectiveness assessments be conducted in more remote and limited resource areas as a next step in considering the rollout of testing in low-resource countries such as Nigeria. In addition, approval should be given by the Federal Ministry of Health to use OraQuick for HIV 1 and 2 self-testing. This testing kit will open more channels for the avoidance of stigmatisation and accessibility to diagnosis, which is the way forward for the control of HIV infection in developing countries. Also, any deployment of HIVST should be supported by education about proper usage to eliminate invalid results and promote confirmatory testing and referral to HIV care as needed. Intervention programmes should also be conducted with key stakeholders, including relevant ministries, donors and key non-governmental organisations, regarding the importance of OraQuick self-testing.

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Conflicts of interest

There are no conflicts of interest.

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