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Evaluation of the Performance of OraQuick® Rapid HIV-1/2 Test among decedents in Kisumu, Kenya

Valarie Opollo[1], **Emmanuel Nyakeriga**[2], **Leonard Kingwara**[4], **Alex Sila**[2], **Macxine Oguta**[1], **Boaz Oyaro**[1], **Dickens Onyango**[5,6,7], **Frankline O. Mboya**[3], **Anthony Waruru**[3], **Paul Musingila**[3], **Mary Mwangome**[2], **Lilly M. Nyagah**[4], **Catherine Ngugi**[4], **Solomon Sava**[4], **Wanjiru Waruiru**[2], **Peter W. Young**[3], **Muthoni Junghae**[3]

[1]Kenya Medical Research Institute, HIV-Research Branch, Kisumu, Kenya

[2]University of California, San Francisco, Nairobi, Kenya

[3]Division of Global HIV and TB, U.S. Centers for Disease Control and Prevention, Kenya

[4]Ministry of Health, Kenya

[5]Kisumu County Department of Health

[6]Utrecht University

[7]Instituite of Tropical Medicine, Antwerp

Abstract

Background: Estimating cause-related mortality among the dead is not common, yet for clinical and public health purposes, a lot can be learnt from the dead. HIV/AIDS accounted for the third most frequent cause of deaths in Kenya; 39.7 deaths per 100,000 population in 2019. OraQuick® has previously been validated on oral fluid and implemented as a screening assay for HIV self-testing in Kenya among living subjects. We assessed the feasibility and diagnostic accuracy of OraQuick® for HIV screening among decedents.

Methods: Trained morticians collected oral fluid from 132 pre- and post-embalmed decedents aged >18 months at Jaramogi Oginga Odinga Teaching and Referral Hospital mortuary in western Kenya and tested for HIV using OraQuick®. Test results were compared with those obtained using the national HIV Testing Services algorithm on matched pre-embalming whole blood specimens as a gold standard (Determine® HIV and First Response® HIV 1–2-O). We calculated positive predictive values (PPV), negative predictive values (NPV), Area Under Curve (AUC), sensitivity and specificity of OraQuick® compared to the national HTS algorithm.

Results: OraQuick® had similar sensitivity of 92.6%, (95.0% confidence interval (CI):75.7–99.1) on pre- and post-embalmed samples compared to the gold standard. Specificity was 97.1%

Corresponding author: Valarie Opollo, Kenya Medical Research Institute, Tel: +254723903176, vopollo@kemricdc.org.

Competing interests
None exist

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(95.0% CI:91.9–99.4) and 95.2%, (95.0% CI:89.2–98.4) pre and post embalming respectively. Pre and post embalming PPV was 89.3% (95.0% CI:71.8–97.7) and 83.3% (95.0% CI:65.3–94.4) respectively. The AUC pre-and post embalming was 94.9% (95% CI: 89.6 – 100) and 93.9% (95% CI, 88.5 – 99.4) respectively.

Conclusions: The study showed a relatively high performance sensitivity and specificity of OraQuick® HIV-1/2 test among decedents, similar to those observed among living subjects. OraQuick® HIV-1/2 presents a convenient and less invasive screening test for surveillance of HIV among decedents within a mortuary setting.

Keywords

OraQuick®; HIV; Rapid Testing; minimally invasive HIV testing; HIV Mortality Surveillance

Introduction

The annual number of global deaths from AIDS-related illnesses among people living with HIV (PLHIV) has declined from a peak of 1.7 [1.3–2.4] million in 2004 to 770,000 [570,000–1,100,000] in 2018[1]. Estimates from the 2018 AIDS survey in Kenya indicate a HIV prevalence of 4.9%[2], in the same year approximately 25,000 people died from AIDS-related illnesses. While this is still high, the death rate has declined steadily from 64,000 in 2010[3]. Studies conducted among descedents in Kisumu and Nairobi, Kenya have shown a HIV prevalence of 28.5% and 20.9% respectively[4, 5]. Population-level all-cause and cause-specific death rates are an important indicator of local disease epidemiology[6, 7] and can be used for monitoring trends in population health status[8, 9]. However such reliable data are scarce, thus limiting efforts for health policy formulation, planning, monitoring and evaluation in documenting the countrys' progress towards the Sustainable Development Goals. Creating simple, routine ascertainment of HIV status among all deaths in a given jurisdiction would allow for more direct monitoring of mortality patterns in the HIV-infected population and mathematical modelling for estimation of HIV incidence.

Methods for mortality surveillance in limited resource settings include conducting full or verbal autopsies (VA), or testing for HIV from blood drawn from decedents. Verbal autopsy is a tool for retrospectively interviewing families/caregivers of the deceased to understand the circumstances that have led to death[10]. VAs, in particular, have significantly contributed to the understanding of mortality in resource-limited settings but have limitations, especially for diagnosing illnesses with non-specific symptoms including HIV[11]. Testing for HIV involving collection of blood through trans-thoracic needle biopsies or intravenous methods have been used previously and found to be feasible[4, 12]. However, in some populations, blood collection is not well accepted for religious or cultural reasons[13]. Additionally, using blood samples for HIV testing can be logistically challenging due to factors such as safety during collection and handling during transportation to testing point. Samples collected using non-invasive techniques such as oral fluids[14, 15] provide a viable alternative. In the last two decades, oral fluid was introduced as an additional sample type to plasma, dried blood spots (DBS) and serum for HIV antibody-based assays[14, 16], and one that is preferred over blood-based testing[17, 18]. Oral fluid rapid HIV assays have only been validated among living persons.

With the possibility of using this sample type for HIV-related mortality surveillance, we set out to evaluate the performance of OraQuick® rapid HIV-1/2 test kit among descedents. The assay performance was evaluated in both pre and post –embalmed specimens to determine if the embalming process would interfere with the kit functionality. The specificity and sensitivity of the OraQuick® HIV 1/ 2 antibody test on the oral fluids from decedents was compared to the results obtained from matched whole blood specimen using the national HIV testing algorithm[19]. These findings will be used to inform HIV-associated mortality surveillance systems, policy, planning, monitoring and evaluation in the country.

Methods

Study setting, participants and sample size

This sub-study was part of a larger cross-sectional HIV surveillance study carried out between April 16 and July 12, 2019, amongst decedents admitted to the Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH) mortuary[20], Kisumu County, in the Nyanza region of western Kenya. This mortuary has the largest volume of bodies admitted in Kisumu County and is co-located on the same campus as the Kenya Medical Research Institute's (KEMRI) Clinical Research Center (CRC) laboratory where all study samples were tested. Informed consent was waived by the ethical review committees. The decedents admitted in the mortuary were either hospital deaths or brought in dead (BID) i.e. occurring outside of a health facility. Police cases that required a post-mortem for legal reasons were also included. We excluded decedents who at the time of sample collection were dead for more than 48 hours, were already preserved, whose condition was too deteriorated or had blood in the oral cavity. The eligibility criteria is shown in Figure 1.

We set out to validate a simple, minimally invasive procedure for testing HIV status in decedents that could potentially be rolled out widely in settings with a significant burden of HIV in order to determine the rate of HIV among decedents. We evaluated the performance of OraQuick® rapid HIV-1/2 test kit among matched pre-embalmed and post embalmed decedents admitted at the JOORTH mortuary. For this sub-study, sampling relied on the decedents from the larger study and sample size calculation was based on CLSI guidelines[21] for validation of qualitative tests which requires testing of a minimum 120 samples. The sample size was increased by 10% to account for potential losses; specifically, the need to carry out testing on oral fluids within a stipulated time frame of 30 minutes after sample collection. Following convenience sampling and availability of matched pre-embalmed and post embalmed samples, a total of 132 decedents were used.

Sample collection and processing

Non-clotted cardiac blood (approximately 6mL or 2ml/4ml for infants) was collected from unembalmed decedents through percutaneous transthoracic aspiration using a 12 cm needle, into a sterile EDTA blood collection tubes (Becton, Dickinson and Company, Franklin Lakes, New Jersey, USA). Blood samples were stored at 2–8°C after collection and transported in a cooler box with ice packs to KEMRI CRC laboratory within 4 hours of collection.

Upon verification of specimen quality against a predefined acceptance criteria in the laboratory, the blood samples were used to test for HIV 1/ 2 antibodies as described below. Dried blood spot (DBS) samples[20] were prepared from the remaining blood and stored at −20°C in case additional testing was required to resolve inconclusive results.

The OraQuick® HIV test kit was used to collect pre- and post- embalming oral fluid samples from descedants that had a blood specimen collected according to the inclusion criteria. Post-embalming samples were taken within an hour of embalming. Briefly, the swab was placed above the teeth against the outer gum and gently swabbed around the outer gums, both upper and lower, one time around while ensuring that the roof of the mouth or the inside of the cheek or tongue were not swabbed.

Sample testing

Oral samples were tested immediately by trained morticians at the mortuary per manufacturer's instructions[22]. Blood samples were tested at KEMRI CRC for HIV antibodies per the Kenya national HIV testing algorithm. Briefly, third generation Determine™ HIV-1/HIV-2 (Abbott Diagnostic Division, Hoofddorp, Netherlands) was used as the screening assay and First Response® (PMC Medical Pty. Ltd) as the confirmatory assay. Serial HIV testing was used, samples that were non-reactive on the screening assay were reported as negative while those that were reactive on the screening assay were retested using the confirmatory assay. If the results were concordant on both tests then the results were reported as positive. Specimen with discrepant results on both tests were retested again, serially, using the screening and confirmatory tests. Samples reactive on both were considered positive. If the results were still discordant they were then considered inconclusive and a qualitative DNA PCR (Abbott RealTime HIV-1 assay) was performed on a DBS sample to confirm HIV status.

Data analysis

Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), false detection rate (FDR), false omission rate (FOR), and their corresponding 95% confidence intervals were calculated to evaluate the performance of OraQuick® HIV 1/ 2 test on pre- and post embalming oral fluid samples. We also performed a receiver operating characteristic (ROC) curve analysis of sensitivity against 1-specificity and the area under the curve (AUC) to measure accuracy of the OraQuick® HIV 1/2 test. The Kenya national algorithm for HIV diagnosis on blood was considered as the gold standard. Data were analyzed in STATA Version 14 (STATA Corporation, College Station, TX).

Ethical considerations

The study was approved by Kenya Medical Research Institute's Science and Ethical Review Unit (KEMRI/RES/7/3/1), JOOTRH ethics committee (ERC.IB/VOL.1/615), CDC Center for Global Health, Associate Director for Science (2018–256) and UCSF IRB (230355).

Results

Demographic characteristics of the decedents

Results on overview of the decedents and HIV status is presented elsewhere[5]. From April 1st 2019 to July 31st 2019, a total of 697 decedents were admitted into JOOTRH, out of which 132 decedents met the inclusion criteria for this sub-study(Figure 1). The participants demographics are shown in Table 1. Of the 132 decedents enrolled, 57 (43%) were female with a median age of 46 years (interquartile range [IQR] 18 months – 105 years) (Table 1).

Performance of the OraQuick® Rapid HIV-1/2 test at pre-embalming

Gold standard results were based on final HIV result on pre-embalmed whole blood samples. Twenty seven of the 132 blood samples 20.5% (95% CI 13.9%, 28.4%) tested using the gold standard were positive. The OraQuick® Rapid HIV-1/2 detected a total of 28 positives (21.2%) using pre-embalmed oral fluid samples of which 25 were true positives and 3 were false positive compared to the gold standard. The sensitivity and PPV was 92.6% (95% CI, 75.7%, 99.1%) and 89.3%, (95% CI, 71.8%, 97.7%) respectively. Compared to the gold standard which detected 105 negative samples, OraQuick® detected 102 HIV-negative samples from pre-embalmed decedents. Two samples were false negatives giving a specificity of 97.1% (95% CI 91.9% - 99.4%) and NPV of 98.1% (95% CI 93.2% - 99.8%) respectively (Table 2). The AUC of the ROC curve for OraQuick® test kit to distinguish between the positive and negative results on an oral fluid sample collected before embalming of the body was 94.9% (95% CI 89.6%, 100%).

Performance of the OraQuick® Rapid HIV-1/2 test at post embalming

Of the 132 post embalmed samples tested, OraQuick® Rapid HIV-1/2 detected 30 positives (22.7%) using post embalmed oral fluid samples of which 25 were true positives and 5 were false positive compared to the gold standard. The sensitivity and PPV were 92.6% (95% CI 75.7%, 99.1%) and 83.3%, (95% CI 65.3%, 94.4%) respectively (Table 2). Compared to the gold standard which detected 105 negative samples, OraQuick® Rapid HIV-1/2 test detected 105 negative samples from the post-embalmed samples. Two samples were false negative giving a specificity of 95.2% (95% CI 89.2%, 98.4%) and NPV of 98.0% (95% CI 93.1%, 99.8%) respectively (Table 2). The AUC of the ROC curve for OraQuick® test kit to distinguish between the positive and negative results on an oral fluid sample post embalming was reported to be 93.9% (95% CI 88.5%, 99.4%).

Discussion

To our knowledge, this is the first study to present findings on HIV testing using OraQuick® Rapid HIV 1/2 test on pre-embalmed and post-embalmed decedents. OraQuick® HIV-1/2 test using oral swabs showed a sensitivity (92.6%) among decedents, similar to those observed among living subjects that found an average sensitivity of 93% among living subjects[13, 23]. The specificity was higher when the sample was collected pre-embalming (97.1%) compared to post embalming (95.2%). There were more false positives detected in the post-embalmed samples, however the difference was not statistically significant. It is unclear why this is the case, though *in vitro* studies have shown that cell fixatives, including

formaldehyde, a compound of embalming fluids, can reveal antigenic sites that had been formerly masked[24]. Additionally, the fixation process can also lead to non-specific binding of antibodies[25]. The post embalming samples were collected soon after the embalming was complete. This study did not evaluate the effect of time on embalming on the assay performance. Moreover, based on the high AUC values in our study and other studies, the OraQuick® test kit is able to discriminate the true state of subjects pre and post embalming with reasonable accuracy[26, 27].

Our findings show that oral fluid may be a suitable sample for HIV testing in decedents for mortality surveillance. Testing for HIV in decedents using blood is complex: a) it is an invasive procedure b) requires training of the mortuary staff on sample collection c) multiple attempts may be required for successful blood draw d) sharps waste originating from blood collection requires additional safety disposal procedures e) sample transport to the testing laboratory may be required and f) there are concerns related to consent, culture and religion[28]. In comparison, HIV testing using oral specimen samples is minimally invasive, requires minimal training, sample collection and testing are performed using the same device and testing can be done in a mortuary setting with minimal training. Additionally, findings from several studies have shown that oral fluids have a lower HIV transmission risk compared to blood [14, 16–18, 29]. Considering all factors above, including the costs attached to each factor, implementing oral testing may be a preferred option compared to blood-based testing in mortuary settings for surveillance purposes.

OraQuick® Rapid HIV-1/2 is a one-test assay compared to the national Kenya HIV testing algorithm which is a two-test blood-sample assay requiring confirmation of the initial result. This makes it simple for implementation in a mortuary setting as long as training is done and the manufacturer's instructions are followed. However, based on evidence from previous studies that false negative and positive test results occur with oral rapid tests[30–34], there is need for continuous and thorough quality assurance measures during implementation of oral fluids HIV rapid testing. In a mortuary setting, the test results may be used for prevalence estimation and not individual diagnosis.

Having demonstrated the feasibility of using OraQuick® Rapid HIV-1/2 test for HIV prevalence estimation among decedents, it may be considered for implementation in future HIV-associated mortality surveillance activities in the country. With these findings, a guidance document on mortuary and hospital-based surveillance of HIV-associated mortality in countries with high prevalence of HIV infection, including Kenya, may be developed.

This study had a few limitations. First, the study was conducted in the western part of Kenya in Kisumu which has a higher HIV prevalence rate (17.5%) than most of other regions in Kenya[35]. Additionally, this study showed a high HIV prevalence among the samples tested, four times higher than the national prevalence of 4.9% and almost similar to the HIV prevalence in Kisumu County; a similar study also showed a high HIV prevalence rate among the same population[4]. The positive and negative predictive values of diagnostic tests are affected by the prevalence of the disease and therefore as prevalence increases, PPV increases and NPV decreases. Thus while the performance of OraQuick® (sensitivity and specificity) in this study are presumably generalizable, the NPV and PPV may not be

generalizable. Secondly, testing of oral fluids using OraQuick® was conducted in a mortuary setting after fulfilling study specific requirements. Mortuary settings outside of a study protocol may not offer the same stringent measures to ensure accuracy of test results. Proper training and adherence to the manufacturers instruction on testing procedures may resolve this if the test is conducted in a setting outside the laboratory. With the use of oral fluid, unlike whole blood, serum or plasma specimen for rapid HIV antibody testing, there is no stored sample that is available in case of need for repeat or confirmatory testing. Finally, the confidence intervals in our study are wide due to the limited sample size therefore any conclusions drawn from our findings need to be interpreted with caution.

Although widespread access to ART has reduced HIV-related mortality in high-income countries[36, 37], decedents showed a high HIV prevalence in this study. Availability of HIV mortality data can be used in the evaluation of ART impact and related programs in strengthening the health care systems and HIV care. This study showed that it is feasible to collect oral swabs from decedents and test for HIV antibodies using OraQuick® Rapid HIV-1/2 with resulting relative high sensitivity and specificity. For mortuary-based HIV surveillance in particular, OraQuick® rapid HIV-1/2 can be employed for HIV-associated mortality surveillance systems. Additional studies evaluating the performance of the OraQuick® Rapid HIV-1/2 Test among decedents in differing HIV transmission settings would help to inform on the application of this technique to the wider decedents population.

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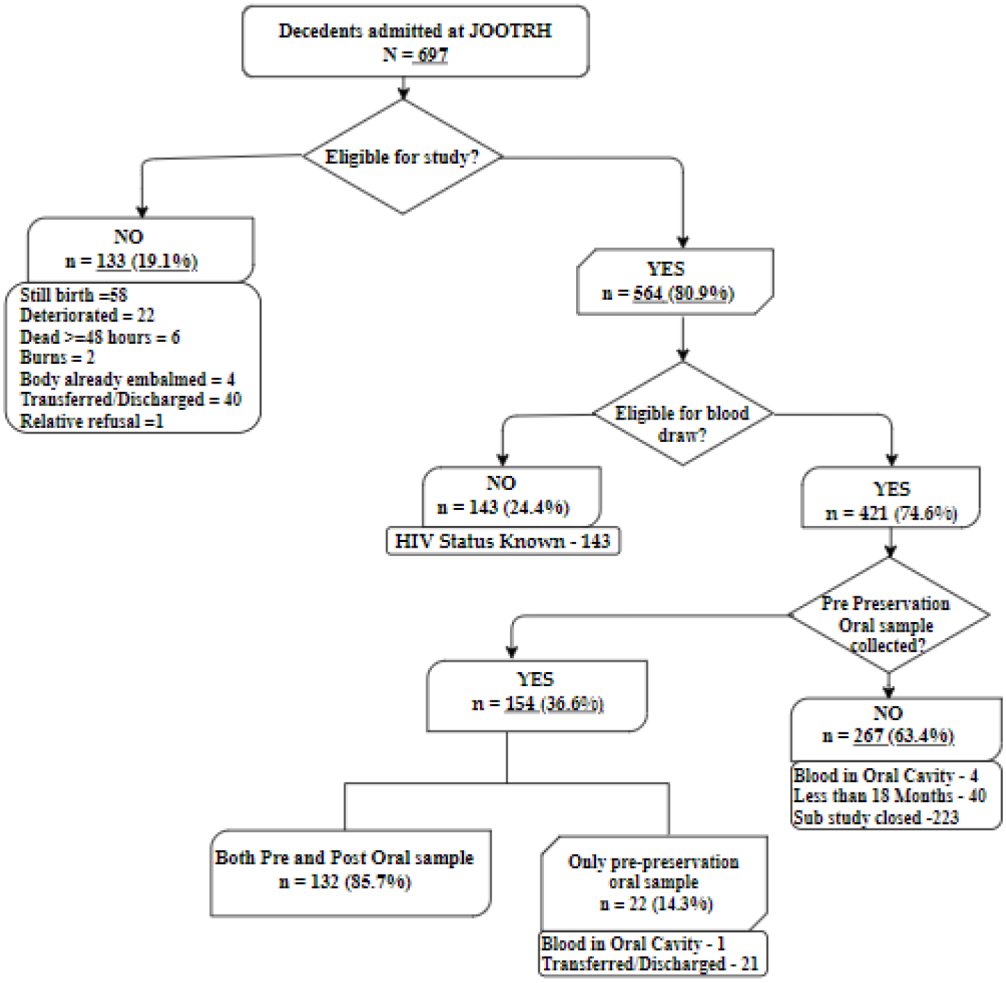

Figure 1:
Flow chart of enrolment to OraQuick® sub-study

Table 1:

Demographic characteristics of the enrolled decedents with matched pre- and post embalming oral sample

	Sex		
	Female	**Male**	**Total**
Age Category (Years):			
18 Months-9 Years	6	5	11 (8%)
10 – 14	0	4	4 (3%)
15 – 24	2	6	8 (6%)
25 – 34	8	14	22 (17%)
35 – 44	5	14	19 (14%)
45 – 54	4	10	14 (11%)
55 – 64	10	3	13 (10%)
65 –74	9	10	19 (14%)
75+	13	9	22 (17%)
Descedent Class:			
Hospital Deaths	38	33	71 (54%)
Brought in dead	19	42	61 (46%)
Total	**57 (43%)**	**75 (57%)**	**132 (100%)**

Table 2:

Performance of OraQuick® Rapid HIV-1/2 against the gold standard on pre and post embalmed samples

	True Positive	True Negative	False Negative	False Positive	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	AUC (95% CI)
Pre-embalming OraQuick® results	25	102	2	3	92.6% 75.7– 99.1	97.1% 91.9 – 99.4	89.3% 71.8– 97.7%	98.1% 93.2– 99.8%	94.9% (89.6%– 100%)
Post-embalming OraQuick® results	25	100	2	5	92.6% (75.7 – 99.1)	95.2% (89.3 – 98.4)	83.3% (65.3 – 94.4)	98.0% (93.1 – 99.8)	93.9% (88.5%-99.4%)