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Performance and usability of mPIMA™ HIV 1/2 viral load test in point of care settings in Kenya

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ABSTRACT

Background: HIV viral load testing is the standard of care for monitoring antiretroviral therapy. In resource-limited settings such as Kenya, access to HIV viral load monitoring is suboptimal due to reliance on centralized laboratory based in vitro diagnostics. Point of care technologies have the potential to improve access and reduce test to result turnaround time.

Objective: To determine the performance and usability of the mPIMA™ HIV-1/2 Viral Load (VL) test in point of care settings in Kenya.

Method: This was a cross-sectional study conducted amongst 568 HIV positive adults recruited from selected health facilities in Western Kenya between June and November 2018. Five hundred and sixty-six plasma samples (566) were tested successfully on Abbott™ Real*Time* HIV-1 quantitative test (reference assay) and mPIMA™ HIV-1/2 Viral Load test to determine diagnostic accuracy. Usability data was collected through simple structured questionnaires. Statistical analysis was done using Stata/MP Version 14 for Mac OSX. Concordance and misclassification values were calculated at the clinical cut-off of 1000 copies/ml.

Results: The positive, negative and overall agreement of the mPIMA™ HIV-1/2 V L test were 95.45% (95% CI 89.49–98.11%), 95.96% (95% CI 93.66–97.44%) and 95.86% respectively. All users (7/7, 100%) reported that the machine was easy to use and that the results interpretation and workflow were simple. The test to result turnaround time was 69 min. All clinicians (4/4, 100%) felt that a Point of care test would fit easily within their workflow and would facilitate decision-making. There were 44 (7.77%) errors in 566 tests; 38 (6.71%) were user related and four (4, 0.71%) were software related.

Conclusion: The mPIMA™ HIV-1/2 V L test can be used interchangeably with reference assays for HIV viral load monitoring. At the point of care, mPIMA™'s simple workflow, ease of use and short test to result turnaround time have the potential to improve access to HIV viral load monitoring.

1. Background

In Kenya, Highly Active Antiretroviral Therapy (HAART) became routinely available in 2010. Response to HAART was monitored immunologically until September 2015, when HIV virologic monitoring became the standard of care [1].

Up to 1.5 million Kenyans were HIV positive in 2017; up to 75% were on HAART [2] and virologic monitoring coverage was 29.7–84.6% depending on region [3]. Routine HIV virologic monitoring is conducted in ten reference labs located in major cities using automated high-throughput molecular testing technologies such as Roche COBAS AmpliPrep®/COBAS TaqMan® and Abbott™ Real*Time* HIV-1 quantitative assays [4,5]. This approach to VL monitoring is wide spread in HIV high burden African countries.

Challenges to this strategy are similar across countries and include the fact that the technologies are expensive, sophisticated, require dedicated laboratory space and must be operated by trained technicians [6,7]. Delivering samples to the reference laboratories requires an effective courier system for ferrying samples while delivering results requires a well-developed information management system [8,9]. Additionally, HIV viral load testing volumes are constantly growing and challenging the capacity of centralized laboratories to provide timeous results.

The global health community is continually seeking ways to simplify and improve the efficiency of HIV virologic monitoring without diminishing the quality of patient care in resource-limited settings [10]. Point of care technologies may be a potential solution especially if they are affordable, sensitive, specific, user-friendly, robust/rapid,

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equipment-free, and deliverable to those who need the test [11].

In the recent past, several near patient care technologies for quantitative HIV molecular testing have been developed. mPIMA™ HIV 1/2 system (Alere Technologies GmbH Jena, Germany), GeneXpert® System (Cepheid® Sunnyvale, California) and SAMBA platforms (Diagnostics for the Real World, Little Chesterford, United Kingdom) have all been prequalified by the World Health Organization (WHO) and approved for use [11–13]. mPIMA™ HIV 1/2 system is a true point of care device that runs quantitative viral load tests while the GeneXpert® System is not [14]. SAMBA platforms are only semi quantitative [15] and even though they could be useful in infant diagnosis, they would have a limited role in viral load monitoring.

The mPIMA™ HIV-1/2 Viral Load (VL) test detects viral nucleic acids to HIV 1/2 in human whole blood and plasma samples. In Kenya, HIV-1 is most prevalent; HIV 2 has not been reported. The assay is based on a fully automated nucleic acid amplification and detection technology. The range of detection lies between 800–1000000 copies/ml. The portable mPIMA™ analyser enables point of care access to suit molecular assays, bypassing challenges with centralized testing and potentially reducing patient loss to follow up [16–20]. This technology has been approved for use in early infant diagnosis of HIV but its performance and utility for HIV viral load monitoring remains undetermined in Kenya.

We compared the performance of the mPIMA™ HIV-1/2 V L test in field settings with the Abbott™ Real*Time* HIV-1 system at the reference laboratory. We also assessed the usability of the device in professional hands.

2. Materials and methods

2.1. Study design

This was a prospective cross-sectional study conducted between June and November 2018. HIV positive adults were recruited from Alupe, Nambale and Matayos Sub County Hospitals as well as Siaya County Referral Hospital. These facilities were selected due to their proximity to the research institute and their high sample volumes. They were the point of care sites and mPIMA™ analysers were placed in each of them. Only consenting participants were enrolled in the study.

For performance evaluation, a venous blood sample was drawn from each participant. A simple form containing basic socio-demographic and ART data accompanied each sample. Usability data was collected through simple structured questionnaires to document user experience. These were administered by the researcher to the lab technicians using the mPIMA™ machines at the health facilities and to the clinicians expected to use the results generated for patient care. Study personnel in the reference lab were already trained and certified on the use of Abbott™Real*Time* HIV-1 assay for routine viral load monitoring. All study personnel received training on the mPIMA™ assay being evaluated and were certified in their use by qualified Abbott trainers. Training materials for the personnel were developed according to the manufacturer's standards.

2.2. Health facility and reference lab procedures

At the heath facilities, four ml of venous blood was collected from each consenting HIV positive adult into an EDTA tube using a vacutainer needle. On the same day, the tubes were centrifuged at 1100 g for 10 min to separate the plasma. Using the provided teat pipette, 25 µl of the resultant plasma was loaded onto the test cartridge; the cartridge was immediately inserted in the mPIMA™ analyser and the test was left to run until complete. The HIV-1 results were recorded after 69 min in copies/ml. The remnant samples in the EDTA tubes were shipped to the KEMRI HIV Lab in Alupe at 2–8 °C.

In the reference lab, the remnant samples were received and stored at −30 °C until the next day when they were tested on the comparator assay, Abbott™ Real*Time* HIV-1 assay according to manufacturer's instructions as previously described [21].

2.3. Ethical considerations

The evaluation was carried out in line with existing ethical guidelines and was approved by the Institutional Review Board of the Kenya Medical Research Institute (KEMRI/SERU Protocol No. 2657). The study was conducted according to the principles of the Helsinki Declaration.

2.4. Data analysis

Data was transferred manually from the analysers and the questionnaires into a Microsoft Office Excel 2016 database. The analysis was done using Stata/MP Version 14 for Mac OSX. A 2 by 2 table was used to determine clinical misclassification at a cut-off of 1000 copies/ml [22]. Quantitative data were log transformed, and results which were outside the limits of detection were not used for analysis. The coefficient of determination (r^2) was used to describe the linear fit of the paired log transformed values of the two assays. Bland Altman analysis was used to determine the limits of agreement and the mean bias. Usability findings were reported using simple descriptive statistics.

3. Results

3.1. Participant characteristics

A total of 568 participants were recruited for the quantitative study. Three hundred and twenty (320, 56.33%) of the participants were female while 103 (18.13%) were male. Six (6, 1.06%) participants were aged 13–19 years, 266 (46.83%) were aged 20–49 years, 136 (23.94%) were older than 49 years, while 158 (27.82%) did not provide data on their age. Four hundred and five (405, 71.30%) participants visited the health facility for routine viral load monitoring, 18 (3.17%) for confirmation of treatment failure while 145 (25.53%) did not provide a reason for the visit. A total of 301 (54.57%) participants were on TDF + 3TC + EFV or NVP, 40 (7.04%) were on AZT + 3TC + NVP, 22 (3.87%) were on TDF + 3TC + DTG, 42 (7.39%) were on other ART regimens while data was not available for 154 (27.11%). These characteristics are summarized in Table 1.

Venous whole blood samples were successfully drawn from 567 participants. Twelve [12] samples were excluded from the quantitative data analysis: one sample was only tested on Abbott™ Real*Time* HIV-1

Table 1
Participant characteristics.

Participant characteristics	Frequency n = 568	Percentage (%)
Gender		
Female	320	56.33
Male	103	18.13
No data	145	25.53
Age (years)		
13-19	6	1.06
20-49	266	46.83
≥49	136	23.94
No data	158	27.82
Reason for Viral load test request by participants		
Routine viral load monitoring	405	71.30
Confirmation of treatment failure	18	3.17
No data	145	25.53
Current ART regimen taken by participants		
TDF + 3TC + EFV/NVP	310	54.57
AZT + 3TC + NVP	40	7.04
TDF + 3TC + DTG	22	3.87
Other regimens	42	7.39
No data	154	27.11

test platform, four tests failed on the mPIMA™analyser due to user errors [2], software errors [1] and equipment failure [1]. Seven tests failed on the Abbott™ Real*Time* HIV-1 test platform due to insufficient sample volume.

A total of 555 samples were successfully tested on both platforms and the viral loads were evenly distributed across the dynamic ranges of the assays. A total of 267 samples had no detectable viral load on the Abbott™ Real*Time* HIV-1 test, 118 samples had viral loads that were detectable but below 40 copies/ml, 60 had viral load counts between 40 copies/ml and 1000 copies/ml, 49 had between 1000 copies/ml and 10,000 copies/ml, 41 had 10,000 copies/ml to 100000 copies/ml while 20 had between 100000 copies/ml and 1,000,000 copies/ml. A total of 126 samples which had a detectable viral load on Abbott™ Real*Time* HIV-1 test did not have a detectable viral load on mPIMA™HIV-1/2 V L test. Conversely, 21 samples which had detectable viral load on mPIMA™HIV-1 test did not have a detectable viral load on Abbott™ Real*Time* HIV-1.

3.2. Agreement between the mPIMA™ HIV-1/2 assay and Abbott™ RealTime HIV-1 assays

From the 555 successfully paired comparisons that were made between mPIMA™ HIV-1/2 V L and the Abbott™ Real*Time* HIV-1 quantitative assays, the overall agreement was 95.86% at the clinical cut-off of 1000 copies/ml. The positive agreement was 95.45% (95% CI 89.49–98.11%) while the negative agreement was 95.96% (95% CI 93.66–97.44%) as shown in Table 2. At the quantification threshold of the mPIMA™assay (800 copies/ml), the overall agreement was 97.77%. The positive agreement was 94.83% (95% CI 89.70–97.80%) while the negative agreement was 94.76% (95% CI 93.40–95.50%) as shown in Table 2. At the detection limit for each device, the overall agreement was 72.61%. The positive agreement was 56.25% (95% CI 52.90–58.90%) while the negative agreement was 90.26% (95% CI 86.70–93.20%) as shown in Table 2.

Simple linear regression was used to predict Abbott™ Real*Time* HIV-1 viral load results based on mPIMA™ HIV-1/2 V L assay results. A total of 433 samples were excluded from regression analysis because results returned by either one or both assays were not quantifiable. Altogether, a total of 122 samples had quantifiable numeric values and were used for regression analysis. A significant regression was found (F (1, 120) = 700.81, $p < 0.05$), with an r^2 of 0.8538 (n = 122). The predicted (log10) Abbott™ Real*Time* HIV-1 viral load result was equal to -0.33 + 1.04 ((log10) mPIMA™ HIV-1 VL test) (Fig. 1).

Table 2
Positive, negative and overall agreement between the mPIMA™ HIV-1/2 V L test and the Abbott™ Real*Time* HIV-1 quantitative assays at the 1000 copies/ml thresholds.

(a)

	Abbott™ m2000 platform		
mPIMA™ platform	≥1000 copies/ml	< 1000 copies/ml	Total
≥1000 copies/ ml	105 (95.45%)	18 (4.04%)	123 (22.16%)
< 1000 copies/ ml	5 (4.55%)	427 (95.96%)	432 (77.84%)
Total	110 (100.00%)	445 (100.00%)	555 (100.00%)

(b)

	Abbott™ m2000 platform		
mPIMA™ platform	≥800 copies/ml	< 800 copies/ml	Total
≥ 800 copies/ml	110 (94.83%)	23 (5.24%)	133 (100%)
< 800 copies/ml	6 (5.17%)	416 (94.76%)	422 (100%)
Total	116 (100%)	439 (100%)	555 (100%)

(c)

	Abbott™ m2000 platform		
mPIMA™ platform	Detected	Not detected	Total
Detected	162 (56.25%)	26 (9.74%)	188(100.00%)
Not Detected	126 (43.75%)	241(90.26%)	367 (100.00%)
Total	288 (100.00%)	267 (100.00%)	555 (100.00%)

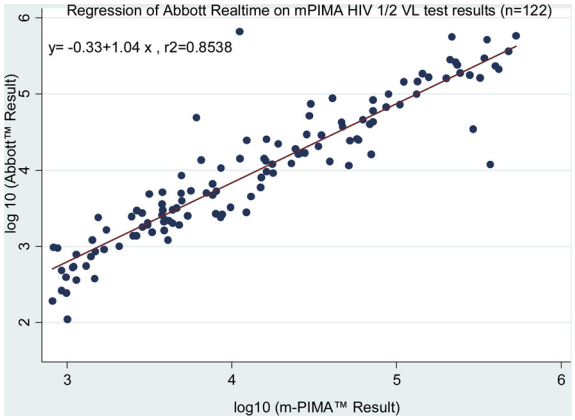

Fig. 1. Linear regression of log transformed viral loads of Abbott™ Real*Time* on mPIMA™ HIV 1/2 V L test.

The 122 samples that had quantifiable numeric values were also used for Bland-Altman analysis. The mean difference was 0.161 log copies/ml (95% LOA -0.514 - 0.835 log copies/ml). No systematic trend in bias was observed (Fig. 2).

3.3. Usability

Of the 566 quantitative tests conducted on the mPIMA™ platform, 522 (92.23%) were successful at the first attempt while 44 (7.77%) returned errors and had to be repeated. Four (4, 9.09%) errors were software related while forty (40, 90.91%) were user related. These user related errors included: Cartridge not fully inserted into the device (17 of all errors, 38.64%); analysis aborted by the operator (3, 6.82%); insufficient valid spots on the micro array caused by poor sample handling (5, 11.36%); internal standard failure due to mPIMA™ cartridge exposure to light (4, 9.09%); insufficient sample volume (2, 4.55%); abrupt switching off of the mPIMA™ device (5, 11.36%) and improperly closed cartridge (4, 9.09%).. All the seven (7, 100%) lab technologists who used the devices reported that they were easy to use, the results were easy to interpret and workflow was simple. The duration per quantitative test was 69 min.

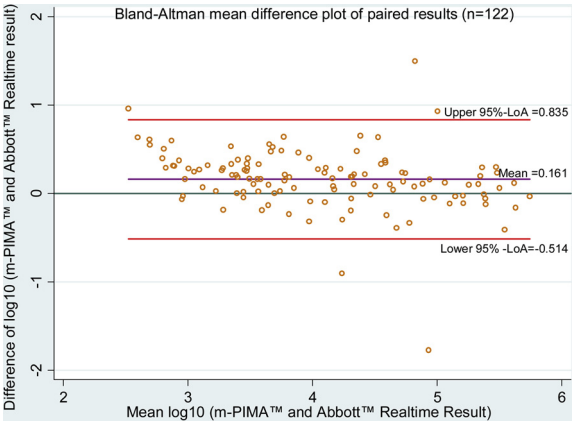

Fig. 2. Bland-Altman analysis of log10 transformed viral loads of mPIMA™ and Abbott™ Real*Time* HIV-1 VL tests.

The study also successfully collected information from users on the pros and cons of the technology. Five (5, 71.42%) lab technologists felt that the results were provided in a timely manner and one (1, 14.29%) liked the minimum sample volume needed. The waste generated was reported by all seven (7, 100%) users as little and included the used test cartridges, teat pipettes and gloves. Three (3, 42.86%) technologists pointed out that the errors they experienced were a distinct disadvantage. They opined that the assay should abort the test immediately an error was experienced without having to wait until the 69th minute to do so. One (1, 14.29%) technologist pointed out that the in-cartridge quality control sometimes failed, while two (2, 28.57%) indicated that the sample throughput was insufficient. One (1, 14.29%) user opined that sample incubation ought to be separate from the machine to enable a higher throughput. Two (2, 28.57%) felt the test was time consuming.

All four (4, 100%) clinicians involved in the study observed that in common practise, it often took longer than two weeks from sample collection to viral load result receipt. When asked about what difference same day results would make, all indicated that they would be empowered to provide timeous clinical interventions such as drug substitutions. All four (4, 100%) clinicians indicated that a point of care test for viral load would fit very well within their clinical workflow, helping reduce turnaround time and hastening interventions. In addition, all four (4, 100%) pointed out that point of care testing would improve clinical workflow, increase certainty of information provided to patients and help improve services to patients.

4. Discussion

In 2016, new WHO guidelines recommended that new point-of-care viral load testing technologies be used to expand access to routine viral load testing [22]. These guidelines were partly informed by the fact that patients visiting many health facilities in HIV high burden countries still had no access to viral load diagnostic services. For instance, by 2017, only 2146 (27.53%) of the 7795 health facilities in Kenya were actively engaged in viral load monitoring in 2017 [23,24]. Courier services are unavailable for a significant proportion of the remaining 72.47% due to remoteness. If implemented for service delivery, point of care testing could make HAART more available even for remote sites [25,26].

The point of care pipeline for viral load testing has not expanded in tandem with this demand, and only recently have promising assays become available. The m-PIMA™ HIV-1/2 V L assay, one of only two assays currently WHO approved for point of care viral load testing, was launched in early 2018. Our study is the first report of the feasibility of using the assay to conduct viral load testing in the Kenyan context.

As with all testing platforms, the accuracy of a point of care technology is a vital consideration before implementation. In this study, concordance was assessed at the clinical cut-off of 1000 copies/ml in line the 2015 WHO consolidated ART guidelines. We observed an overall agreement of 95.86% between mPIMA™ HIV 1/2 V L and the Abbott™ Real*Time* HIV-1 quantitative assays. This excellent concordance corroborates the WHO prequalification report [27] and competes favourably with other point of care assays whose overall agreements range between 96.91%–98.10% [14,27,28]. At the 800 copies /ml threshold, the overall agreement is similarly high at 97.77% suggesting that the device is highly accurate even at that threshold. However, at the detection limit of each assay, the overall agreement dropped to 72.61%. These findings suggest that whereas the device is useful for virologic monitoring of treatment, it would have limited utility in detecting recent infection for instance amongst those taking pre exposure prophylaxis.

The Pearson correlation of log transformed viral loads between the two test platforms showed a significant positive correlation with an $r^2 = 0.8538$. Our findings are corroborated by those from a similar WHO prequalification report which recorded a high correlation of $r^2 = 0.933$ [27]. One study that reported much lower correlation used venous and capillary blood for point of care testing and not plasma [18]. Additionally, the mean difference between Abbott™ Real*Time* HIV-1 and mPIMA™ HIV-1/2 V L test results was 0.161 logs, well within the clinically acceptable limits of ± 0.5 logs [29]. The upper and lower limits of agreement were 0.835 to -0.514 logs. Similar findings were recorded by WHO prequalification report (27).

These performance characteristics suggest that the mPIMA™ HIV 1/2 V L can be used interchangeably with Abbott™ Real*Time* HIV-1 without anticipation of clinical bias.

All users (7/7, 100%) of the mPIMA™analyser reported that it was easy to use, the assay results were easy to interpret and the workflow was simple. Additionally, the mean duration per quantitative test was 69 min. All clinicians (4/4, 100%) suggested a point of care test would fit easily within their clinical workflow, helping reduce test to result turnaround time and quickening intervention. These desirable characteristics of the mPIMA™analyser and test assay show that this technology has met the WHO recommendations of being user friendly, rapid, robust and deliverable to end-users ([31]). Other point of care/near patient care viral load monitoring technologies have exhibited similar usability characteristics [30].

In the current workflow, the patient is first seen by the clinician who may also find that previous viral load results are available. The clinician then makes a decision using the previous viral load results and sends the patient to the pharmacy and the lab. At the lab, a viral load sample is taken and shipped to the reference lab for testing. With mPIMA™ available, the clinician sees the patient and either conducts the test himself or sends the patient to the lab. Either way, he/she makes a clinical decision using fresh lab results.

This excellent performance of the mPIMA™ HIV-1/2 V L test is important for policy makers who must make the final decision as to whether to introduce point of care viral load testing countrywide.

The most disagreeable feature of the technology we observed was the error rate of 7.77%. This is slightly higher than the generally accepted error rate of 5% and can affect the costs associated with using the platform. The WHO prequalification report recorded an error rate of 9.2% ([27]). We also noted that 6.71% of the errors were mostly user related. Proper training and experience with the technology can reduce these errors. The study team was uncertain about how best to dispose of used test cartridges. Some point of care technologies use cartridges that have Guanidium Thiocyanate [31], but mPIMA™does not. Nonetheless, a waste disposal policy needs to be adopted for specialized waste that will emanate from point of care assays [31].

An ideal point of care technology should also be affordable [32]. Findings from an observational study reported that the cost per point of care test was US$27.24 while that of a conventional test was US$131.02 (30). It should be noted that mPIMA™ HIV-1/2 V L assays are designed to use plasma. This poses a significant challenge because it requires investment in centrifuges or in plasma separation tubes at an additional cost. However, on balance, the use of point of care technologies such as mPIMA™ HIV-1/2 V L test is likely to be a cost-effective strategy in resource limited settings.

4.1. Study limitations

In this study we did not evaluate the devices in the hands of the clinicians who offer services at the point of care in the specific health facilities, even though we expect that clinicians will eventually be expected to generate viral load results without relying on a technologists. The purpose of usability testing was to see whether the technology could be used without difficulty by health workers with minimal training and this study showed that it can.

We evaluated neither the cost mPIMA™ HIV-1/2 V L test nor its cost effectiveness in our setting and yet these are important characteristics to consider when implementing point of care technologies. Furthermore, the test kit was not evaluated for use in differing

environmental conditions such as humidity and extreme temperatures. Finally, we did not evaluate its utility in the delivery of viral load-informed differentiated care for ART patients.

5. Conclusion

We conclude that the mPIMA™ HIV-1/2 Viral Load test can be used interchangeably with the reference assays for viral load monitoring. At the point of care, the mPIMA™'s simple workflow, ease of use and short test turnaround time have the potential to improve access to HIV molecular testing.

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Ethical approval

The evaluation was carried out in line with existing ethical guidelines and was approved by the Institutional Review Board of the Kenya Medical Research Institute (KEMRI/SERU Protocol No. 2657).

CRediT authorship contribution statement

Priska Bwana: Data curation, Formal analysis, Investigation, Methodology, Project administration, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing. **Joshua Ageng'o:** Investigation, Methodology, Writing - original draft, Writing - review & editing. **Jeff Danda:** Investigation, Methodology, Writing - original draft, Writing - review & editing. **Joseph Mbugua:** Investigation, Methodology, Writing - original draft, Writing - review & editing. **Allan Handa:** Investigation, Methodology, Writing - original draft, Writing - review & editing. **Matilu Mwau:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing.

Declaration of Competing Interest

Neither UNITAID nor CHAI had no role in the planning, execution of the study and development of the manuscript. The authors declare no conflict of interest.

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