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COSTS OF HIV VIRAL LOAD AND EARLY INFANT DIAGNOSIS TESTING IN KENYA

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This publication was produced for review by the United States Agency for International Development.
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COSTS OF HIV VIRAL LOAD AND EARLY INFANT DIAGNOSIS TESTING IN KENYA

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ACRONYMS

Abbot	Abbott *m*2000 RealTi*me*
AIDS	Acquired Immunodeficiency Syndrome
Alere™	Alere™ q HIV 1/2 Detect
ART	Antiretroviral therapy
ARV	Antiretroviral drugs
CDC	Centers for Disease Control and Prevention
CE-IVD	European Conformity – In Vitro Diagnostic
Cepheid	Cepheid GeneXpert IV
CHAI	Clinton Health Access Initiative
DBS	Dried blood spot
EID	Early infant diagnosis
HFG	Health Finance and Governance Project
HIV	Human Immunodeficiency Virus
ICAP	International Center for AIDS Care and Treatment Programs
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Agency
MOH	Ministry of Health
MSF	Médecins Sans Frontières
MTCT	Mother-to-child transmission
NASCOP	National AIDS and STI Control Programme
NSRC	Non-salary recurrent costs
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PLWH	People living with HIV
POC	Point of care
PPS	Probability proportional to size
RNA	Ribonucleic acid
Roche	Roche Cobas AmpliPrep - Cobas TaqMan
UNAIDS	The Joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
VL	Viral load
WHO	World Health Organization
WISN	Workload Indicators of Staffing Need

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EXECUTIVE SUMMARY

Background: Kenya's current HIV care guidelines call for universal coverage of routine viral load (VL) monitoring for people receiving antiretroviral therapy and early infant diagnosis (EID) testing for all children born to women with HIV. Universal coverage, essential to reaching UNAIDS 90-90-90 targets and ending the AIDS epidemic, will incur significant costs given Kenya's large number of people living with HIV (PLWH) of 1.5 million. To support the Kenya Ministry of Health (MOH) and Kenya Medical Research Institute (KEMRI), this USAID-funded Health Finance and Governance project (HFG) study estimates comprehensive and component-specific unit costs of HIV VL and EID testing in Kenya using a centralized laboratory network, and reports on network utilization and outputs. It also estimates HIV VL and EID testing unit costs under a range of scenarios for two point-of-care (POC) diagnostic platforms being considered for deployment by the Ministry and partners.

Methods: HFG conducted activity-based costing of HIV VL and EID testing at the KEMRI Center for Global Health Research in Kisumu County and of a probability sample at 21 health facilities in neighboring Siaya County. The health facilities send blood samples via a network of hub hospitals to the central lab in Kisumu for testing. Unit costs were calculated for VL and EID tests on two platforms used at KEMRI, the Abbott m2000 RealTime and the Roche Cobas AmpliPrep - Cobas TaqMan. Cost inputs include reagents, non-reagent supplies, equipment, human resources, fees, labor, and supplies for quality assurance, training, transportation, and non-salary recurrent costs involved at all stages of the testing network. All costs were estimated in 2016 U.S. dollars.

Data from the central lab costing exercise and secondary sources were also used to estimate unit costs for VL and EID testing on two POC diagnostic platforms, the Alere™ q and Cepheid GeneXpert IV. We then conducted one-way sensitivity analysis of baseline POC unit costs, estimated the impact on cost of using existing health facility staff or deploying dedicated POC technicians with each machine, and projected the unit costs for POC VL and EID testing at the 21 sample facilities based on their demand for testing in 2016.

Results: Average unit costs were similar for VL and EID testing at $24.63 and $25.05 respectively. Reagents accounted for the largest proportion of unit cost for each test, averaging 68 percent of VL costs and 65 percent of EID costs. The costs of reagents and equipment are affected by procurement through reagent rental schemes, in which manufacturers provide testing equipment at no upfront cost in exchange for exclusive reagent purchasing agreements at negotiated rates. Human resource costs are relatively low due to little hands-on time needed in sample collection, preparation, and testing. KEMRI tested an average of 497 samples per day in 2014, compared with a potential 708 sample maximum.

We estimated that POC VL testing would have an average of unit cost of $29.74 and POC EID testing an average unit cost of $28.33 in our baseline scenario, which assumed testing was performed by existing health facility staff and at maximum daily capacity. Reagents comprised on average 74 percent of the unit cost for each test. Accordingly, in one-way sensitivity analysis a 20 percent change in reagent cost had the ability to shift total unit costs by over $4, a 15 percent difference. Deploying a full-time dedicated POC technician to perform sample collection, preparation, and testing for VL and EID would increase human resource costs compared with using existing staff and also result in a sizable amount of idle time for the technician, given POC workflows and capacity constraints. Finally, we used testing demand data from 2016 to assess how much of each POC platforms' output capacity would be used at each facility, and the extent of the inverse relationship between capacity used and unit cost.

Under the dedicated POC technician scenario and compared with 100 percent capacity utilization, the unit cost of testing would double at 22 percent capacity used for the Alere™ q and 15 percent for the Cepheid GeneXpert IV, rising more rapidly thereafter.

Conclusions: Unit costs of central lab-based HIV VL and EID testing in Kenya are relatively low compared with previous estimates in Kenya and sub-Saharan Africa. The budgetary implications for scaling up to reach the VL monitoring and EID targets will be largely influenced by the number of test ordered per patient per year. Monitoring VL at least once a year for 90 percent of PLWH receiving treatment under the test-and-treat strategy would require financing of $33.25 million per year. At least one EID test for 90 percent of children born to HIV-positive mothers would require financing of $1.79 million per year.

Constituting over half the total unit costs of testing, reagents represent the greatest potential for future cost savings. Strategies to reduce reagent unit costs include negotiating volume-based procurement prices, testing samples as near to maximum machine capacity as feasible, and pooling samples for testing. Task shifting for sample collection and testing may lower human resource and training costs over time. Eliminating routine CD4 monitoring could free staff and fiscal resources for redistribution to HIV VL and EID programming.

The addition of POC testing for HIV VL and EID would enable equipped facilities to deliver patients same-day test results, hastening treatment assessments and linkages to care. Our estimates show the costs of such service would vary according to the details of implementation, but on average would be more expensive than central lab-based testing. Decisions on which POC platforms to deploy and where should be guided by evaluations of patient demand for testing, facility staffing, cost-effectiveness comparisons of POC and central lab-based testing, and available financing.

Overall our findings show that Kenya's approach to HIV VL and EID testing handles a high volume of tests at relatively low unit costs. We identified reagents as the main cost driver and discussed strategies for lowering procurement costs. We also estimated costs for potential POC testing options and their fit within the Siaya County testing network. The results of this report provide the Kenya MOH with the data to project financing needs for achievement of the UNAIDS 90-90-90 targets and an AIDS-free generation through continued focus on central lab-based testing or the integration of POC testing.

1. INTRODUCTION

1.1 Background and Context

In 2014(a) UNAIDS unveiled ambitious targets to end the AIDS epidemic by 2030, calling for 90 percent of people living with HIV (PLWH) to know their status, 90 percent of people with diagnosed HIV to be on antiretroviral therapy (ART), and 90 percent of people on ART to have viral suppression, all by 2020. Universal coverage of HIV testing for early infant diagnosis (EID) is essential to achieving the first 90-90-90 target, while coverage of HIV RNA viral load (VL) testing is essential to the last (UNAIDS 2016a). Eliminating delays in testing and treatment and achieving viral suppression are major priorities in Kenya's 2016 HIV care guidelines, evinced in recommendations to initiate ART for **all** PLWH as soon as possible, provide prophylaxis treatment and test all HIV-exposed infants at birth, and monitor ART effectiveness in all patients through routine VL testing (MOH 2016). To support the Kenya Medical Research Institute/Centers for Disease Control and Prevention (KEMRI/CDC) and the Ministry of Health (MOH), the USAID-funded Health Finance and Governance project (HFG) estimated comprehensive and component-specific (reagents, equipment, human resources, etc.) unit costs of VL and EID testing in Kenya's existing central laboratory-based testing network, and also estimated unit costs for point-of-care (POC) testing in Siaya County of Western Kenya. This report presents costs per test from the perspective of the health service provider.

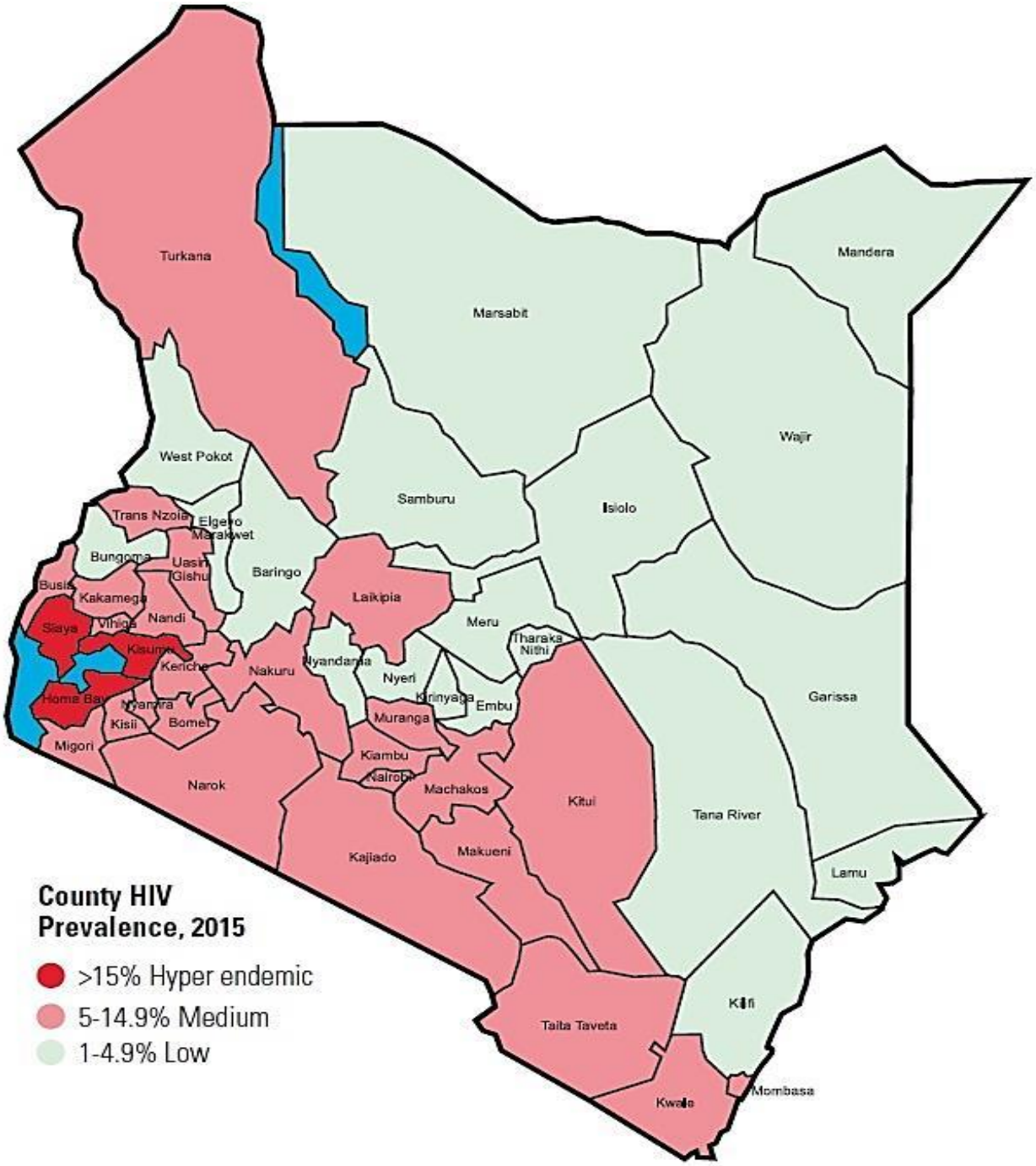
Kenya faces a generalized HIV epidemic, with a national adult prevalence of 5.9 percent and 1.5 million PLWH, including 98,000 children (UNAIDS 2016b). Incidence of new infections declined by 19 percent among adults and 49 percent among children between 2013 and 2015, but nearly 78,000 new cases are still diagnosed each year (NACC 2016). In 2013, an estimated 65 percent of all new infections occurred in nine of Kenya's 47 counties, mainly clustered in the Nyanza region in Western Kenya (NACC and NASCOP 2014). The Nyanza region, with an overall HIV prevalence of 15.1 percent in 2012, includes the three highest prevalence and incidence counties in Kenya: Homa Bay, Siaya, and Kisumu (NASCOP 2014). These three counties are colored red due to their adult HIV prevalence rates of greater than 15 percent in Figure 1, which depicts adult HIV prevalence by county for all of Kenya (NACC 2016). The region is also home to KEMRI/CDC's Center for Global Health Research (hereafter referred to as KEMRI) in Kisumu City, which serves as the central lab for VL, EID, and other tests from over 400 health facilities. HFG collaborated with KEMRI to conduct activity-based costing of VL and EID testing as well as train KEMRI staff in conducting cost-effectiveness studies.

Of the 1.5 million PLWH in Kenya, approximately 900,000 were on ART in 2015 (MOH 2016). The scale of VL testing has increased substantially over the last three years, from 234,282 tests with valid results in 2014 to 857,530 in 2016 (NASCOP 2017). Kenya conducts routine VL monitoring and EID testing using a network of sample collection facilities, hub hospitals with sample preparation capacity, and central laboratories. The centralized testing model simplifies supply chain, equipment, human resource, quality assurance, and training needs, and minimizes costs through high-volume testing (MSF 2013). However, it can also contribute to extended delays in patients receiving test results due to transportation issues, supply stock-outs, machine failures, and testing backlogs. The incorporation of POC diagnostic platforms at strategic points in the testing network may help alleviate these issues and eliminate delays, with patients and providers able to receive and act on VL or EID results during a single facility visit.

Lost or delayed test results at any point in the process increase the risk of patients remaining on ineffective ART and having an unsuppressed VL, with negative consequences for their health and retention in care, and risk of continued HIV transmission (Meloni et al. 2014; Quinn et al. 2000).

The purpose of this study is to estimate unit costs of adult VL and EID testing in the Nyanza region of Western Kenya. We also estimate unit costs for POC VL and EID testing, and describe the central lab-based testing network structure and utilization.

Figure 1. Adult Prevalence by County in 2015



2. METHODS

Between 2014 and 2016 HFG conducted an activity-based costing study of HIV VL and EID testing in Western Kenya at KEMRI/CDC. Using input, utilization, and cost data from 21 health facilities in Siaya County and the KEMRI/CDC central laboratory in Kisumu County, we calculated the unit cost per sample of VL and EID testing using conventional laboratory methods on two testing platforms, the Abbott *m*2000 RealTi*m*e (Abbott) and the Roche Cobas AmpliPrep - Cobas TaqMan (Roche). Unit cost estimates for VL and EID testing on POC platforms are also made based on available data. Prices were adjusted to 2016 U.S. dollars using the Gross Domestic Product deflator from the International Monetary Fund's Global Economic Outlook Database for October 2016 and currency exchange rates from the World Bank.

2.1 Site Selection

The study target population is all MOH facilities with patients on ART in the Siaya County sub-counties of Alego Usonga, Gem, and Rarieda. Under the MOH facility-level classifications, dispensaries and health centers are level 2/3 facilities, sub-county and district hospitals with sample processing capabilities are level 4, and KEMRI is a central lab. We used probability proportional to size (PPS) sampling to select a representative sample of health facilities in each sub-county, resulting in 21 of 37 eligible health facilities surveyed. The probability of selecting a health facility i is represented by the following equation:

$$i = n\frac{X_i}{X}$$

Where X_i is the number of patients in facility i, X is the total number of patients on ART in that sub-county, and n is the number of health facilities in that sub-county. Based on this probability, some very large health facilities were selected with certainty, and the remainders were selected with PPS. Facility sizes were based on the number of ART patients as of June 2014. The KEMRI lab in Kisumu County was selected with certainty, as it is the reference lab providing VL and EID testing services for the sampled facilities.

2.2 Data Collection and Entry

HFG provided costing training to KEMRI staff and piloted two data collection tools, one for health facilities and one for laboratories. Following piloting and revision of the tools, data were collected by HFG through interviews and registry reviews at KEMRI, and by four of the staff trained at KEMRI at the dispensaries, health centers, and hub hospitals. Input data included supplies, reagents, equipment, and human resource time needed for collecting, preparing, and testing samples. Cost data included input item prices, personnel salaries, quality assurance fees, sample transportation expenses, and facility capital. Utilization data included the numbers of HIV VL, EID, and other samples collected and tested in a calendar year, and the capacities of testing platforms. Data collectors entered information into a Microsoft Excel-based data collection template. Gaps or other issues in the collected data were addressed through a follow-up trip to KEMRI in September 2016, correspondence with facility contacts, and secondary data. HFG stored all data electronically, on password-protected laptops. Data cleaning and unit cost construction was performed in Microsoft Excel.

2.3 Testing Network

Figure 2 illustrates the network used to send samples and receive results for VL and EID tests in the sample of 21 health facilities in Siaya County. Madiany Subdistrict Hospital is the sample hub for five facilities in Rarieda Sub-County, collecting whole blood specimens for VL and dried blood spots (DBS) for EID, centrifuging them to separate plasma samples, and sending the plasma to KEMRI for testing. Siaya County Referral Hospital serves the same role for five facilities in Alego Usonga Sub-County, as does Yala Sub-County Hospital for eight facilities in Gem Sub-County. Samples are transported between collection points, hubs, and KEMRI by motorcycle couriers who visit multiple sites daily. Facilities generally send VL and EID samples twice per week. After testing at KEMRI, test results are sent electronically via National AIDS and STI Control Programme (NASCOP) systems back to the hubs they were received from. Hubs print paper copies of the results, which are then sent via couriers back to their points of origin. Finally, providers at health facilities attempt to call patients to inform them of results needing prompt action (virologic failure or positive EID test), or wait until patients next visit for non-urgent results.

Figure 2. Organizational Map of Sample Testing Network

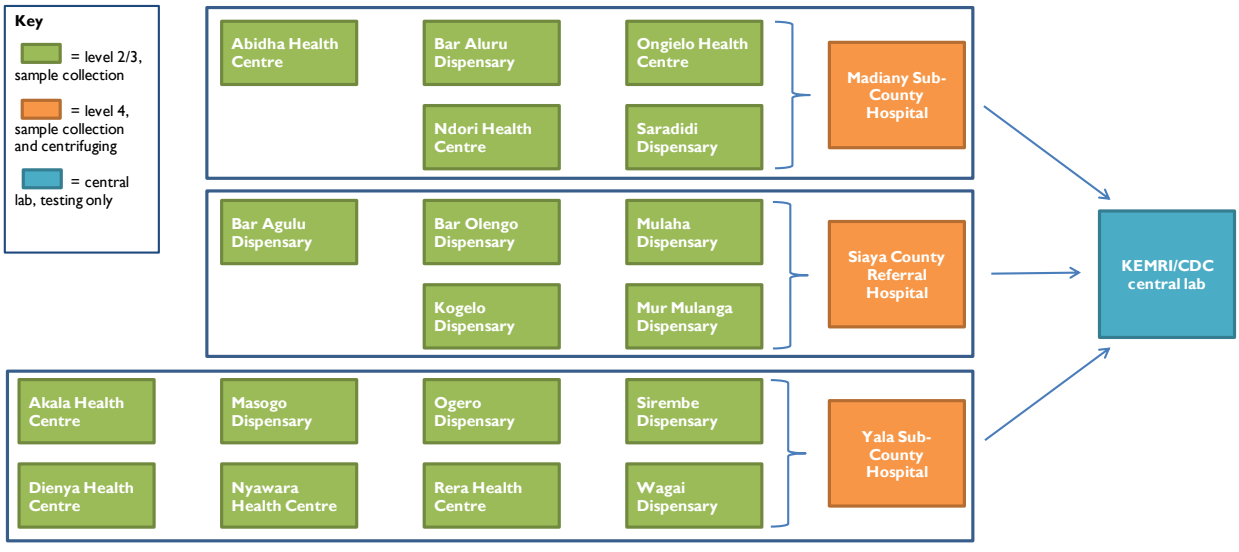


Table 1 shows quantities for VL and EID sample collection at each facility in 2014, along with sub-totals for each hub of the testing network. Siaya County Referral Hospital was the busiest facility, accounting for 33 percent of VL samples and 17 percent of EID samples. Bar Aluru Dispensary did not begin VL testing until 2015, but did offer EID testing in 2014 and was thus retained in our sample. In total, 1,734 VL and 708 EID samples originated in level 2/3 facilities, while 2,643 VL and 375 EID samples originated in level 4 hubs. Out of 1,066 samples tested for EID, 60 (5.6 percent) had positive results.

Table 1. VL and EID Utilization in 2014, by Facility

Facility	VL Samples Collected	EID Samples Collected
Madiany Subdistrict Hospital	825	89
Abidha Health Centre	54	47
Bar Aluru Dispensary†	0	24
Ndori Health Centre	5	49
Ongielo Health Centre	208	55
Saradidi Dispensary	30	8
Madiany Hub sub-total	1122	272
Siaya County Referral Hospital	1446	180
Bar Agulu Dispensary	267	70
Bar Olengo Dispensary	13	52
Kogelo Dispensary	219	40
Mulaha Dispensary	7	53
Mur Malanga Dispensary‡	Missing	15
Siaya Hub sub-total	1952	410
Yala Sub County Hospital	372	106
Akala Health Centre	168	76
Dienya Health Centre	108	53
Masogo Dispensary	38	17
Nyawara Health Centre	141	34
Ogero Dispensary	8	14
Rera Health Centre	177	24
Sirembe Dispensary	105	32
Wagai Dispensary	186	28
Yala Hub sub-total	1303	384
Total	4377	1066

† Bar Aluru Dispensary began VL testing in 2015

‡ Mur Malanga Dispensary records on VL samples were missing

Table 2 displays the number and proportion of VL and EID tests performed on each testing platform at KEMRI in 2014. Several facilities included in our sample reported not receiving results for all requested VL tests, including 59 missing tests at Akala Health Center, 36 at Dienya Health Center, 13 at Kogelo Dispensary, 107 at Ong'ielo Health Center, and 103 at Rera Health Center. No facilities reported missing EID results. Supply stock-outs, samples rejected due to errors or damage, time lost due to equipment failure, and insufficient staff time all contributed to the backlog of incomplete tests at year's end.

Table 2. VL and EID Testing at KEMRI in 2014

Test	Platform	Number Completed	% of Total
VL	Abbott	64251	52%
VL	Roche	32126	26%
EID	Abbott	18635	15%
EID	Roche	9318	7%
Total		124330	100%

VL and EID samples were tested on the same platforms, Abbott and Roche, but samples in a batch cannot be mixed. In 2014, KEMRI had two Abbott machines, which have capacity to run two 93-sample batches in an eight-hour working day, and two Roche machines, which have capacity to run eight 21-sample batches a day. Each batch tested on either platform also includes three control samples for quality assurance purposes. Operating all four machines at maximum capacity, KEMRI has the theoretical capacity to test 708 VL and/or EID samples in a day, and could therefore test 177,000 samples in 250 working days per year. In actuality, KEMRI tested an average of 497.3 VL/EID samples per day in 2014 for a total of 124,330 tests. However, KEMRI reported four instances of machine failure for the Roche platforms and four for the Abbott platforms, resulting in 25 and 7 lost days of testing capabilities, respectively. In total, there were 218 days where maximum testing capacity was possible at KEMRI in 2014. NASCOP covers the costs of service and maintenance warranties for each platform.

2.4 Activity-based Costing

We present unit costs by activity and per component along with overall average unit costs per sample for VL and EID. The two perspectives each offer unique ways for program managers to assess cost-saving opportunities. Sample collection, centrifuging, testing, and transportation are the four sub-activities costed for VL and EID testing in the centralized testing network.

Sample collection includes the costs of supplies for safely drawing blood samples and of equipment for cold storage of whole blood or for drying blood spot samples, facility costs of the needed space and utilities, and the relevant labor and training costs of personnel who collect samples. Sample collection costs can apply at dispensaries, health centers, or hub hospitals.

Centrifuging costs are those incurred only at hub hospitals. They are the cost of supplies for centrifugation; equipment used for sample storage, results reporting, and centrifugation; lab facility use; and training and labor of the lab technicians, assistants, and phlebotomists who centrifuge samples.

Testing costs are incurred at KEMRI. They are the costs of supplies and reagents consumed in testing and doing quality assurance; equipment (excluding the testing platforms) used for sample storage and results reporting; lab facility use; training of lab technicians and assistant research officers; and labor of personnel for testing and quality assurance.

Transportation costs occur between facilities as couriers deliver whole blood or DBS samples to hub hospitals, centrifuged samples to KEMRI, and test result forms back to sample origin facilities.

Each activity comprises various component costs, defined in Table 3 and described in more detail after. The eight components are reagents, supplies, equipment, human resources, quality assurance, training, transportation, and non-salary recurrent costs.

Table 3. Definitions of Sub-unit Cost Components

Sub-unit Components	Definition
Reagents	Consumable components needed to run a batch of tests on a given test platform.
Supplies	Consumable and durable supplies used in sample collection and preparation for testing through centrifuging.
Equipment	Equipment used for sample collection, storage, centrifuging, testing, and result reporting.
Human resources	Labor for sample collection, centrifuging, and testing.
Quality assurance	Consumable components needed to run tests for quality assurance certification, control samples during testing, additional certification costs, and human resources needed for quality assurance activities.
Training	Human resource time, transportation, accommodations, and food for personnel receiving training, and cost of attending trainings.
Transportation	Couriering samples from level 2/3 to level 4 facilities and from level 4 to KEMRI, electronically sending test results from KEMRI back to level 4, and couriering paper copies of test results back to level 2/3.
Non-salary recurrent costs	Space, electricity, water, and other utilities used in the processes of collecting, preparing, and testing samples at all facilities.

Reagent costs are incurred only at KEMRI, where all VL and EID testing occurred, and thus do not vary by sample origin facility. Costs include the test-specific VL or EID assays and other components needed to run a batch of tests. KEMRI exclusively uses reagents procured from Abbott and Roche (for their respective platforms) in exchange for no upfront cost of the testing equipment, an agreement known as "reagent rental." Accordingly, costs of the testing platforms are blended with long-term costs of the reagents, and not included in the equipment sub-unit cost described later. Reagent sub-unit costs are the sum of price times quantity needed per sample of all reagents used to run VL or EID tests on a given testing platform.

Supply costs are incurred for sample collection at all facilities (except KEMRI) and for sample centrifuging at the three level 4 facilities. Sample collection costs vary according to the supplies (different types of waste disposal, bandages, sanitizing agents) and quantities each facility reported using in routine sample collection, as well as by test type. Supplies for EID sample collection came in the form of a kit, while the supplies used in VL sample collection were procured individually. Supply sub-unit costs are the sum of price times quantity needed per sample for all supplies used to collect and centrifuge samples. While facilities reported procuring various supplies and equipment from the Kenya Medical Supplies Agency (KEMSA), the International Center for AIDS Care and Treatment Programs (ICAP), the MOH, or other facilities, we assume that all like-items are procured for the same prices, given that all are publicly funded MOH facilities. Further, for items where KEMRI was unable to provide a price, we used retail prices.[1]

[1] www.fishersci.com/us/en/catalog/search/products; www.jumia.co.ke/

Equipment costs are incurred at all facilities and account for items expected lifespan, but included equipment varies by facility level. Level 2/3 facility equipment costs include DBS sample drying racks, refrigerators and freezers, and cabinets used for sample storage. Level 4 costs include all of the above plus equipment for centrifuging whole blood or DBS samples into plasma and the processing of test results. KEMRI costs include all lab equipment used to store and process samples and report on test results. As previously stated, the Abbott and Roche platforms were procured "on placement" and thus their costs are not included here. Equipment sub-unit costs are the sum of equipment prices times the percentage of the equipment used for VL or EID testing, divided by the expected equipment lifespan. We assumed a lifespan of five years for all equipment. To illustrate, the equipment sub-unit cost for a sample collected in Abidha Health Center includes equipment used for storing the sample until transport, equipment used for storing, centrifuging, and reporting on the sample at Madiany Subdistrict Hospital, and equipment used for storing, processing, testing, and reporting on the results of the sample at KEMRI.

Human resource costs are incurred at all facilities for time spent collecting, centrifuging, and testing VL and EID samples. Sample collection may occur at level 2/3 or level 4 facilities, while centrifuging occurs only at level 4 and testing occurs only at KEMRI. Clinicians, nurses, phlebotomists, lab technicians, and other cadres may all be involved in these activities to different degrees. Human resource sub-unit costs are the sum of minutes spent on an activity multiplied by salary per minute, weighted for the proportion of the activity performed by a given cadre. Activity times, salaries, and cadre involvement vary by facility and were collected using specific data collection forms.

Quality assurance costs are incurred only at KEMRI, as they relate directly to the sample testing process. Accreditation of VL testing is issued annually by the College of American Pathologists following quality assurance testing, documentation, and fees; the CDC provides EID testing accreditation and covers annual fees. Human resource costs associated with the aforementioned activities are included as quality assurance costs, as are control reagents used in every batch of tested samples. Quality assurance sub-unit costs are the sum of control costs per sample, supply and human resource costs per certification tests, human resource costs for quality assurance monitoring, and annual fees, per VL or EID test performed in a year.

Training costs were calculated using comprehensive training costs for VL and EID-related staff provided by KEMRI. They do not account for specific training on the operation of the testing platforms for VL or EID, the costs of which are covered by the manufacturers as part of the reagent rental agreement. There are a number of different trainings, including but not limited to Strengthening Lab Management towards Accreditation, Good Clinical Practice, and Bioethics. Staff participate in new or refresher trainings yearly. Lab technicians, lab technologists, phlebotomists, and scientists have a total of 10 trainings that they must attend, while clinicians, nurses, counselors, and lab assistants attend three trainings. Staffs attending regional trainings incur an additional cost of travel (flights and taxi), per diem, and incidentals, which are accounted for in total cost of training per person per year. Once the total cost of training per staff person per year was calculated, the cost was divided by the number of samples processed to arrive at the training cost incurred per sample.

Transportation costs are incurred between facilities as blood samples and test results are transported via couriers for a per batch charge, with couriers traveling between multiple facilities daily. While samples originating in level 2/3 facilities incur courier costs three times (to level 4, to KEMRI, to level 2/3), samples collected in level 4 facilities only incur courier costs once (to KEMRI).[2]

[2] The cost of sending test results from KEMRI back to level 4 facilities electronically via NASCOP systems is factored into the equipment sub-unit costs as computers and printers.

The average transportation sub-unit costs account for the proportion of VL and EID samples originating at level 2/3 or level 4, while the facility specific transportation sub-unit costs are disaggregated by origin facility level.

Non-salary recurrent costs are incurred at all facilities and based on annual space, electricity, water, and other utilities use apportioned to VL or EID testing activities. Facilities provided annual utility expenses, while space values are based on estimated property costs per square foot in Nairobi (Oxford Business Group 2016), local property listings, and the assumptions that costs per square foot for publicly owned facilities would be less than the cost of space in the capital and not exceed local private property costs. Data collection included measurement of entire facilities and specific rooms used for VL or EID activities as well as numbers of VL, EID, and all other samples collected, centrifuged, and tested. Space and utility costs are allocated to VL and EID-involved rooms based on their relative size within the facility, and those costs are sub-divided to VL or EID based on their representative proportion of all samples/tests processed in those facilities. Sub-unit non-salary recurrent costs are thus the cost of space, electricity, water, and other utilities needed per sample at each stage of the VL/EID testing life cycle.

2.5 Ethics

This research protocol received ethical review approval through Abt Associates Institutional Review Board, the KEMRI Ethical Review Committee and Scientific Steering Committee, and the CDC Institutional Review Board. No identifiable data from individual patients or records were collected, only aggregated patient status information from facilities. Costing data for the purpose of our study were facility-specific and unrelated to any particular patient.

3. COST OF HIV VL TESTING IN CENTRAL LABORATORIES

3.1 Background

Routine HIV VL testing is the gold standard in monitoring the effectiveness of ART in HIV patients (UNAIDS 2016c). VL tests measure the number of HIV particles in patients' blood, indicating whether treatment is suppressing viral replication or if the virus continues to proliferate, hastening progression toward AIDS. Patients may "fail" ART, indicated in World Health Organization (WHO) criteria by a VL greater than a 1,000 viral copies per milliliter of blood, due to inadequate treatment adherence or genetic resistance of HIV to the medication; in either case intervention is needed to reverse growth of VL and/or drug resistance.[3] Conversely, when ART works as intended and VL is suppressed, patients are healthier and less likely to transmit HIV, including mother-to-child transmission (MTCT) through childbirth or breastfeeding (Attia et al. 2009; Cohen et al. 2011; Garcia et al. 1999). Compared with CD4 testing, VL testing allows for earlier and more accurate detection of treatment failure, preventing delayed or unnecessary switches to second-line ART (Keiser et al. 2011). Routine VL testing also supports facilities capacity to provide VL differentiated ART, distinguishing virally suppressed patients from those who need more intensive or frequent follow-up (MSF 2016). VL differentiated ART, also referred to as different models of care, can help improve patient satisfaction, outcomes, and the efficient use limited resources in facilities.

Under Kenya's current guidelines for ART, all patients on ART are eligible for routine VL monitoring, which begins with a VL test six months after ART initiation (MOH 2016). Patients with a VL under 1,000 copies/mL, Kenya's threshold for treatment failure, are provided with routine adherence counseling, retested at 12 months, and thereafter tested once annually, provided their VL remains below 1,000 copies. Patients with VL results over 1,000 copies are suspected of treatment failure and enrolled in enhanced adherence counseling to detect and address any issues with their adherence to treatment. After three months of enhanced counseling and when clinicians are satisfied with the patient's adherence, they receive another VL test to confirm or rule out failure. Two consecutive results over 1,000 copies indicate virologic failure of treatment, and prompt a switch to second-line ART.

National scale-up of routine VL monitoring began in 2014, increasing the proportion of ART patients tested annually from 8 to 38 percent between 2013 and 2015 (Lecher et al. 2015). During the same period, the proportion of tested patients with viral suppression also increased, from 64 to 84 percent, but the average turnaround time on specimens increased from 18 to 31 days. Self-reported challenges to scale-up include budget constraints, sample transportation, supply and equipment shortages and delays, and a lack of human resources for VL testing (Lecher et al. 2015). Targeted VL testing began at KEMRI in 2009, and scaled up to routine monitoring along with the national policy.

[3] In North America the threshold for suspected VL failure is > 200 copies/mL (Panel on Antiretroviral Guidelines for Adults and Adolescents 2017), while in Europe the threshold is > 50 copies/mL (EACS 2016).

High costs and complexity have been the principle barriers to VL testing in developing countries (UNAIDS 2016c). Contextual factors like testing demand, network design, and particularly manufacturer-country price negotiations are also important cost drivers of VL monitoring. Implementing new VL testing programs involves obtaining testing equipment and supplies, hiring and/or training personnel for sophisticated lab work, integrating VL samples into existing sample referral networks or designing new networks, and ensuring all related activities achieve the necessary standards for quality assurance certification. Costs of high-capacity, lab-based testing platforms from Abbott, Roche, bioMérieux, and Siemens range from $40,000 to over $200,000, while costs per test from the same companies have ranged between $20 and $90, depending on location (Murtagh 2013). Despite the costs, public sector VL testing programs have recently begun or expanded in several sub-Saharan African countries. Médecins Sans Frontières (MSF) reported VL unit costs from national- and district-level public sector programs in 2013: $43.42 in Kenya, $39.03 in Zimbabwe, $35.38 in Malawi, $34.17 in Lesotho, and $24.90 in Swaziland. Reagents and consumables accounted for an average of 62 percent of costs in these programs.

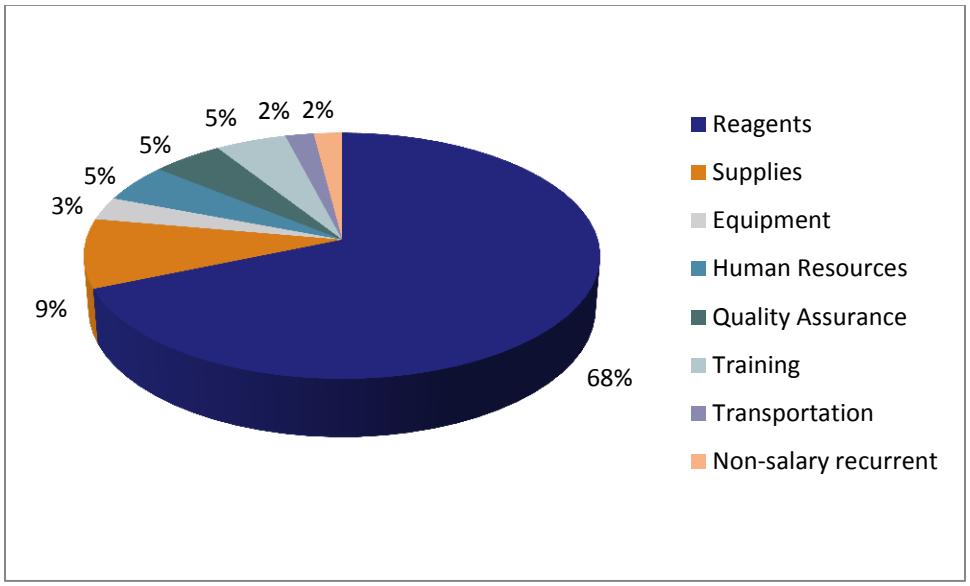
3.2 HIV VL Testing – Unit Costs

Table 4 shows the average unit cost of a VL test within the sampled testing network, as well as the total cost of testing in 2014. Reagents are by far the largest cost component in VL testing, accounting for 68 percent of the total unit cost. As noted in the unit cost definitions, testing platforms are provided to KEMRI at no upfront cost, but are paid for over time through the premiums on reagent costs, contributing to the high reagent costs and low equipment costs. Human resource costs are low, given the short amounts of time needed for all activities in the VL testing lifecycle. Although a batch of samples takes several hours to test, the hands-on time of lab personnel is small and diffused over all samples in a batch. Figure 3 shows the distribution of cost components as a percentage of the total unit cost.

Table 4. Unit and Total Costs of HIV VL Testing at KEMRI (2016 US$)

	Unit Costs	Total Cost of Testing in 2014	%
Reagents	$16.82	$1,621,523	68%
Supplies	$2.17	$209,229	9%
Equipment	$0.71	$68,098	3%
Human resources	$1.34	$129,288	5%
Quality assurance	$1.20	$115,471	5%
Training	$1.29	$124,353	5%
Transportation	$0.55	$53,294	2%
Non-salary recurrent	$0.54	$52,307	2%
Total unit cost	$24.63	$2,373,562	100%

Figure 3. Distribution of Costs for HIV VL Test



Different costs are incurred at each activity of the VL/EID testing process, which can involve two to three different facilities. Table 5 breaks down the average unit costs of central lab VL testing into four processes: sample collection, centrifugation, testing, and transportation. Costs incurred during testing at KEMRI account for nearly 79 percent of the total unit cost for VL, driven mainly by reagent and quality assurance costs.

Table 5. Average Unit Costs of Central Lab HIV VL Testing, by Activity (2016 US$)

	Sample Collection	Centrifugation	Testing	Transportation	Total
HIV VL	$2.55	$2.24	$19.41	$0.55	$24.63

Activity-based costing at KEMRI and 21 health facilities for VL testing are comparable to costs reported elsewhere in sub-Saharan African central laboratories. Our VL unit cost for the Abbott, $23.92, is within a $5 range of Abbott costs reported for Burundi, Democratic Republic of Congo, Malawi, Morocco, and South Africa (MSF 2014a; MSF 2014b). VL unit costs for Roche at $26.05 per sample are below Roche unit costs reported in Mauritania, Niger, and South Africa (MSF 2014a; MSF 2014b). For more VL unit cost breakdowns, see Annex A: Table A1.

4. COST OF HIV EARLY INFANT DIAGNOSIS IN CENTRAL LABORATORIES

4.1 Background

Globally, an estimated 90 percent of children living with HIV were infected by MTCT, despite known methods of prevention (UNAIDS and WHO 2013). Without any intervention, 20 to 45 percent of mothers will transmit HIV to their child during pregnancy, birth, or breastfeeding (NASCOP 2014). Although HIV testing of pregnant women in Kenya is rising, one in 10 women receiving antenatal care goes untested. Among those with HIV, only 71 percent received prophylaxis during pregnancy and 67 percent during childbirth in 2012. Meanwhile, prophylaxis coverage for infants at birth was 73 percent, and coverage during breastfeeding was 72 percent (NASCOP 2014). Estimates of EID coverage in Kenya range from 40 to 87 percent, with first tests generally occurring later than recommended (Goggin et al. 2016). A recent study of Kenyan mother-infant pairs found that being informed by a health worker about EID during pregnancy, having a primary or secondary education, and having less feelings of stigma about HIV were significantly associated with receiving on-time EID testing at or before six weeks of age (Goggin et al. 2016). Location was also a significant predictor of on-time or late testing. In all, these conditions leave roughly 20,000 pregnant women and their children without adequate prevention of mother-to-child transmission and EID coverage (NACC 2016).

EID testing at KEMRI began in 2006, under protocols recommending first testing at six weeks of age (Finocchario-Kessler et al. 2016; Imbaya et al. 2015). The six weeks guideline remains the WHO standard for EID due to cost-effectiveness, ability to detect intrauterine, intrapartum, and postpartum infections, and synchronization with health facility visits for routine immunization schedules, but at-birth testing is also supported when feasible (WHO 2016a). Mortality among infants infected before or during birth can reach 10 percent by two months of age and as high as 40 percent by three months (Marinda et al. 2007; Bourne et al. 2009; Marston et al. 2011; Becquet et al. 2012; Kim et al. 2012). Accordingly, postponing first EID testing until six weeks, even with quick results turnaround, leaves little time for optimal intervention in HIV infected infants (Mofenson 2016). In Kenya, despite the theoretical availability of EID services, even six week testing may be delayed for weeks or months, result turnaround times can be equally long, and only a third of infants diagnosed with HIV are initiated on ART (Finocchario-Kessler et al. 2016). Still, 300,000 infants in Kenya were tested for HIV between 2006 and 2014 (Imbaya et al. 2015), a key step in preventing MTCT or initiating needed ART.

Kenya's 2016 guidelines have opted for at-birth testing or as soon thereafter within two weeks, a follow-up test at six weeks, and subsequent tests every six months during breastfeeding. HIV-exposed infants receive prophylaxis until breastfeeding ends, while HIV-positive infants are immediately initiated on ART. In a South African trial comparing at-birth and six-week testing, 29 of 38 infants (76 percent) eventually found HIV-positive were detected through at-birth testing (Lilian et al. 2013). Infants with detectable HIV at birth were infected through intrauterine transmission, which is associated with elevated mortality risk beginning at three weeks of age (Marinda et al. 2007; Bourne et al. 2009), and thus before six-week testing would begin. While MTCT in all forms has declined significantly due to developments in ART, the proportion of MTCT from intrauterine infections has increased (Lilian et al. 2012; Magder et al. 2005; Tornatore et al. 2010), prompting examination of whether first testing at six weeks is still the most cost-effective strategy. Francke et al. (2016) modeled South African cohorts to compare the outcomes and

cost-effectiveness of several EID testing strategies. In terms of one-year survival and life expectancy, two tests (at birth then at six weeks) was superior to single testing, while testing only at six weeks was superior to testing only at birth. The two tests and six weeks only options were also cost effective, at costs of $2,900 and $1,250 per life years saved, respectively (2013 US$). Testing only at birth produced slightly inferior outcomes at a higher cost, and was considered "weakly dominated" by the other strategies.

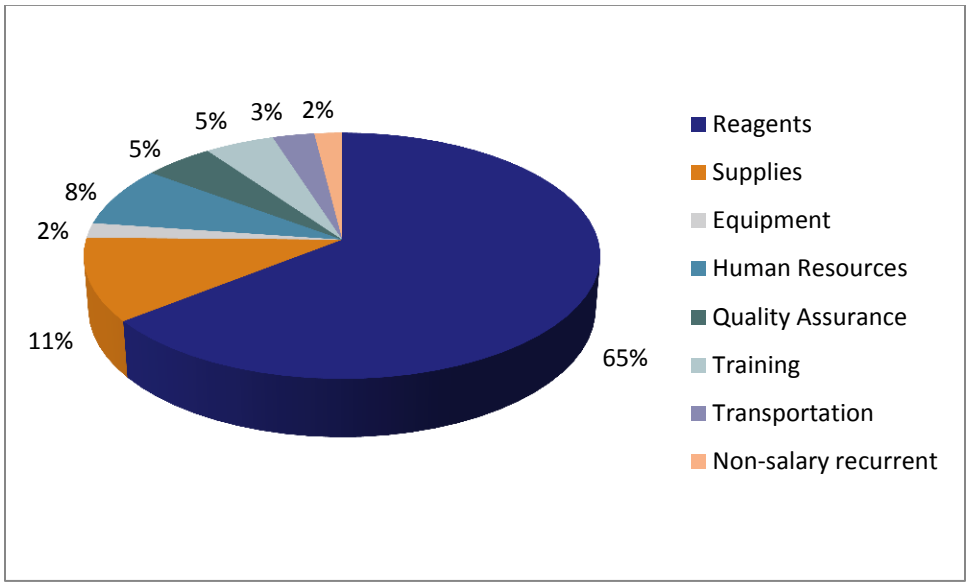
4.2 HIV EID Testing – Unit Costs

Table 6 shows the average unit cost of an EID test within the sampled testing network, and the total cost of testing in 2014. The breakdown of cost components closely resembles that of VL testing: reagent costs are the highest, followed by supply costs, and most costs are similar, leading to nearly identical unit costs. Sample collection and centrifuging supply costs are higher for EID than for VL testing, as more supplies, many of which come in an EID sample kit, are needed. Equipment costs are lower than for VL as the DBS samples for EID do not need immediate cold storage. Average transport costs were higher for EID samples than for VL ones, due to a higher proportion of EID samples originating in level 2/3 facilities than in level 4, and thus requiring three rounds of transport instead of two. Figure 4 shows the distribution of cost components as a percentage of the total unit cost.

Table 6. Unit and Total Costs of HIV EID Testing at KEMRI (2016 US$)

	Average	Total Cost of Testing in 2014	%
Reagents	$16.21	$453,128.61	65%
Supplies	$2.83	$79,004.10	11%
Equipment	$0.59	$16,602.31	2%
Human resources	$1.88	$52,669.40	8%
Quality assurance	$1.14	$31,773.39	5%
Training	$1.29	$36,067.09	5%
Transportation	$0.72	$20,037.27	3%
Non-salary recurrent	$0.39	$10,877.38	2%
Total unit cost	$25.05	$700,159.56	100%

Figure 4. Distribution of Costs for HIV EID Test



Costs incurred at each activity of the EID testing process can involve two to three different facilities. Table 7 breaks down the average unit costs of central lab VL and EID testing into four processes: sample collection, centrifugation, testing, and transportation. Driven by the cost of reagents, the testing process accounts for 75 percent of the total unit cost.

Table 7. Average Unit Costs of Central Lab HIV EID Testing, by Activity (2016 US$)

	Sample Collection	Centrifugation	Testing	Transportation	Total
HIV EID	$3.23	$2.24	$18.89	$0.72	$25.05

Unit costs for EID testing on Abbott and Roche platforms were nearly the same, at $25.04 and $25.06 per test, respectively. Analytic costing estimates for EID testing are limited, with most studies excluding cost components such as training, quality assurance, transportation, or capital (Ciaranello et al. 2011). Studies in sub-Saharan Africa that did include most of these components found EID unit costs of $21.50 in Kenya (Khamadi et al. 2008), $23.90 to $24.01 in Uganda (Menzies et al. 2009), and $19.60 in Botswana (Creek et al. 2008), all with costs in 2007 US$. Breakdowns of these and other EID unit costs found in the literature are located in Annex A: Table A2. Our comprehensive EID unit costs suggests there has been relatively little change in EID pricing over the last decade, despite the critical importance of early detection and timely initiation of treatment.

5. COSTS OF HIV VL AND EID TESTING USING POC

POC technologies have been proposed as innovative solutions for last-mile coverage issues in HIV VL and EID testing and enabling more timely treatment decisions (Cogswell et al. 2016). Newer POC platforms and assays are closely comparable to central lab-based tests in terms of the detection thresholds, sensitivity, and specificity needed for detecting HIV in newborns or virologic failure. The Alere™ q (Alere™)and Cepheid GeneXpert IV (Cepheid) both have WHO prequalified assays for EID (WHO 2016b; WHO 2016c), and the Cepheid is also CE-IVD certified for quantitative VL testing (UNITAID 2015). Alere™ assays with requisite quantitative testing capabilities for VL are still in development, but a field evaluation in Mozambique found 96.83 percent sensitivity and 47.8 percent specificity for VL failure at the 1,000 copies/mL threshold (Jani et al. 2016). While these technologies have promised to simplify the workflow of VL and EID testing, relatively little information on their costs is available.

5.1 HIV POC Cost Estimation Methods

Our costing methodology was based on activity-based costing; first, we described and identified all the activities required to conduct a POC HIV VL test using two different commercial platforms. Activities included sample collection, preparation, and testing. Second, we assigned a cost to each activity using monetary units. These inputs included labor, equipment, laboratory space, and consumables according to actual consumption. Third, we applied cost drivers to attach activity costs to outputs.

In addition we conducted one-way sensitivity analysis and explored alternate testing scenarios to identify how variation of cost drivers affects the cost per test. A POC platform working at full capacity will show optimal operation and therefore lower costs; however, productivity and output can be affected by demand for service. Deploying POC platforms to clinics with low catchment population or low HIV prevalence would reduce utilization and result in some platforms working at less than full capacity. We estimated unit cost per test in relation to testing capacity utilization and finally applied these costs to the expected VL and EID demand at each clinic in Siaya County to estimate total budgetary impacts of POC implementation.

Estimated unit costs for POC testing are based on applicable data from the sampled health facilities in Kenya and from secondary sources. Costs are based on the POC platforms under consideration in Kenya, the Alere™ and the Cepheid, both of which can perform VL and EID testing. VL and EID testing on the Alere™ involve two activities, sample collection and testing. EID testing on the Cepheid also only involves sample collection and testing, but centrifuging is also required for Cepheid VL testing.

Sample collection includes the costs of supplies for safely drawing blood samples, equipment for cold storage of whole blood samples (unless only enough blood is drawn for immediately performing a test), facility costs of the needed space and utilities, and the labor and training costs of personnel who collect samples. Sample collection costs can apply at dispensaries, health centers, or hub hospitals.

Centrifuging costs only occur for VL testing on the Cepheid. Costs include supplies for centrifugation, equipment for sample storage and centrifugation, lab facility costs, and labor and training costs for the lab technicians, assistants, and phlebotomists who centrifuge samples. The need for centrifuging limits where Cepheid platforms can be placed and used as true POC technologies, as most dispensaries and health centers lack personnel and equipment for centrifuging.

Testing costs include reagents consumed for testing and quality assurance, the POC platforms, facility costs, and the labor, training, and quality assurance costs of personnel who perform the testing.

Each activity comprises several components, and their costs have many similarities to but also some important differences from the non-POC component cost definitions presented in Table 3. Sub-unit components for POC testing are defined in Table 8, and described in more detail after.

Table 8. Definitions of POC Sub-unit Cost Components

Sub-unit Component	Definition
Reagents	Consumable components needed to run a test on a given platform. All Alere™ reagents come in a self-contained cartridge. Cepheid reagents also come in a self-contained cartridge, but one additional component must be added for EID testing.
Supplies	Consumable and durable supplies used in sample collection and preparation for testing through centrifuging.*
Equipment	Equipment used for sample collection, storage, centrifuging,* and testing. The Alere™ and Cepheid platforms must be purchased and are not currently available through reagent rental agreements.
Human resources	Labor for sample collection, centrifuging,* and testing.
Quality assurance	Periodic confirmatory testing at KEMRI of samples collected at facilities with POC. Since the methodology of quality assurance for POC is not currently decided, we assume the cost will match the proportionate cost of quality assurance testing at KEMRI, 5 percent of the total unit cost.
Training	Human resource time, transportation, accommodations, and food for personnel receiving training, and cost of attending trainings.
Non-salary recurrent costs	Space, electricity, water, and other utilities used in the processes of collecting, preparing, and testing samples at all facilities.

* Centrifugation is only required for VL testing on the Cepheid GeneXpert IV

Reagent costs for Alere™ and Cepheid are based on baseline prices and do not consider price breaks or committed volume pricing (EGPAF and UNITAID 2016; The Global Fund 2016). Neither manufacturer currently offers reagent rental schemes for the POC platforms of interest, so there is no premium added to the reagent costs accounting for placement, equipment, or service.

Supply costs are based on materials needed for sample collection, centrifuging (for Cepheid VL only), and testing. These costs are adapted from the data collected at health facilities and KEMRI for the central lab costing exercise.

Equipment costs consider sample storage, centrifuging costs for Cepheid VL, maintenance contracts, and costs of the testing platforms per sample, assuming a five-year machine lifespan (EGPAF and UNITAID 2016).

Human resource costs are based on the cadres performing sample collection at each facility (and centrifuging at hub hospitals for Cepheid VL), whom we assume would also perform POC testing, and the hands-on time for testing reported by WHO prequalification documentation (2016b, 2016c) and early field use of Cepheid for POC VL (MSF 2016).

Quality assurance costs differ from their non-POC equivalents, as no external controls are used in POC testing and we assume the large quality assurance certification fees required for KEMRI would not be levied on individual health facilities. Instead, we assume KEMRI would implement a system for routinely collecting and retesting POC samples at the central lab to verify their accuracy. Quality assurance costs for POC are estimated to be 5 percent of the total unit cost, as they were for central lab testing of both VL and EID.

Training costs are based on data from KEMRI about the cost of centrally located half-day training for the new POC testing, per manufacturer recommendations (UNITAID 2015). The total cost of trainings is divided by the number of samples collected in potential POC sites to reach the unit cost of training.

Non-salary recurrent costs are based on the space and utilities costs for HIV VL- and EID-involved rooms at all facilities divided by the sum of samples collected in those rooms. These costs are adapted from the data collected at health facilities and KEMRI for the central lab activity-based costing exercise.

5.2 POC HIV Testing Platforms and Costs by Activity

The Alere™ and Cepheid platforms enable HIV VL and EID testing through relatively simple workflows, directly at the point of care. Testing a single sample on the Alere™ takes 52 minutes, allowing for a total output of eight samples to be tested at full capacity in a standard work day, while the Cepheid can test up to four samples in a 90-minute span, allowing for an output of 20 tests per day. Assuming working at full capacity during the 250 working days of a year, a maximum output of roughly 2,000 VL or EID samples can be tested in a year on one Alere™ platform, and 5,000 on one Cepheid.

Table 9 shows the estimated average unit costs by activity of HIV VL and EID testing with the POC platforms. While there are three activities included for VL, the centrifugation activity only applies for the Cepheid platform. No centrifuging of samples is required for EID testing on either the Alere™ or Cepheid. The majority of costs, around 90 percent for VL and EID, comes during the testing activity, driven by the cost of reagents used.

Table 9. Average Unit Costs of POC HIV Testing, by Activity (2016 US$)

	Sample Collection	Testing	Centrifugation	Total
HIV VL	$2.18	$26.73	$0.83*	$29.74
HIV EID	$2.28	$26.05	n/a	$28.33

*Centrifugation is only required for VL testing on the Cepheid GeneXpert IV

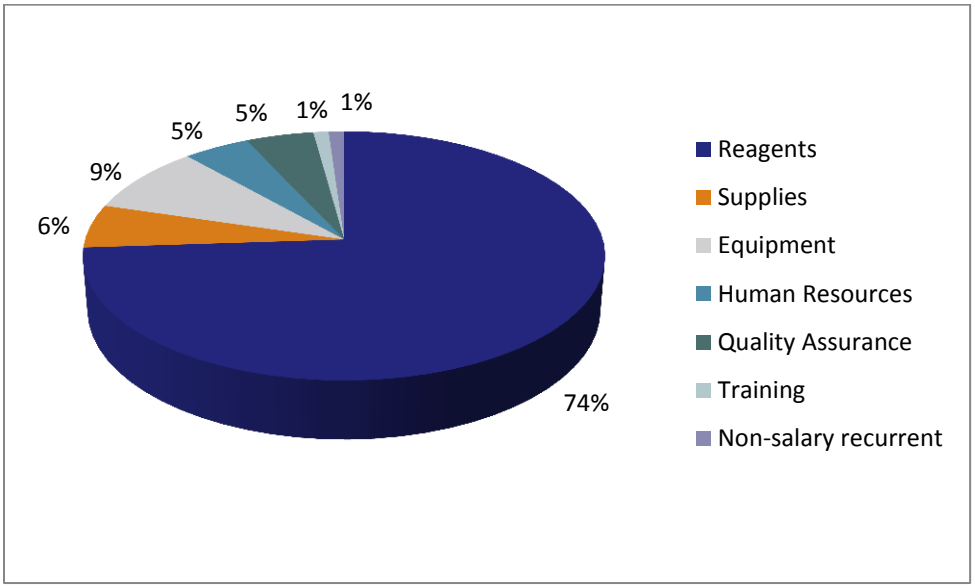
5.3 POC HIV VL Testing – Unit Cost Estimation

Table 10 shows the estimated unit costs of HIV VL testing on the Alere™ and Cepheid POC platforms. As with central lab-based testing, reagents are the largest cost driver for POC testing. The reagent prices shown are based on standard launch pricing, but price breaks may be available at higher committed volumes. Centrifuging, required for Cepheid VL samples but not Alere™, drive the higher supply, human resource, and training costs estimated for Cepheid VL. High equipment costs stem from the need to purchase the new POC platforms and maintenance contracts, either through upfront purchasing or payments over time; reagent rental agreements for Alere™ and Cepheid are not currently offered (The Global Fund 2016). The four-module Cepheid costs approximately $17,000 while the Alere™ costs $25,000, each with additional costs for placement and annual service contracts (EGPAF and UNITAID 2016). Transportation costs are $0 on the assumption of each platform is placed in an appropriate facility, which for Cepheid would include the capacity to produce plasma samples via centrifugation. Figure 5 shows the distribution of cost components as a percentage of the total unit cost.

Table 10. POC HIV VL Test Unit Cost Estimation by Test Platform (2016 US$)

	Alere™	Cepheid	Average	%
Reagents	$25.00	$19.00	$22.00	74%
Supplies	$1.19	$2.17	$1.68	6%
Equipment	$3.73	$1.51	$2.62	9%
Human resources	$1.21	$1.56	$1.38	5%
Quality assurance	$1.59	$1.25	$1.42	5%
Training	$0.29	$0.35	$0.32	1%
Non-salary recurrent	$0.32	$0.32	$0.32	1%
Total unit cost	$33.33	$26.16	$29.74	100%

Figure 5. POC – Distribution of Costs for HIV VL Test



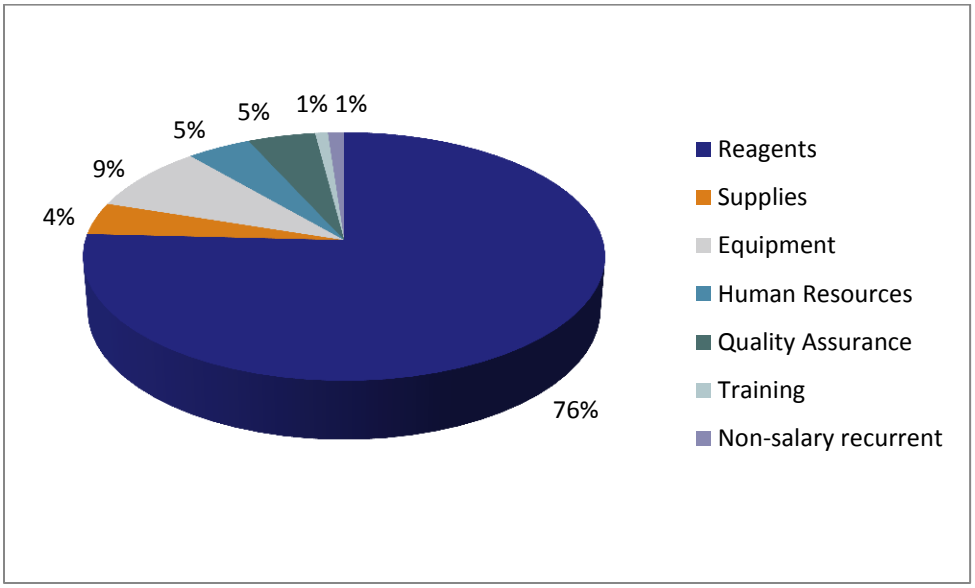
5.4 POC HIV EID Testing – Unit Cost Estimation

Table 11 shows the estimated unit costs of HIV EID testing on the Alere™ and Cepheid POC platforms. Reagent costs are based on standard launch pricing, but price breaks may be available at higher committed volumes. Supply, human resource, and training costs are all relatively low due to simple workflows for EID on each platform. Reasons for high equipment costs and the price gap between platforms are described above for POC VL testing. Figure 6 shows the distribution of cost components as a percentage of the total unit cost.

Table 11. POC HIV EID Test Unit Cost Estimation by Test Platform (2016 US$)

	Alere™	Cepheid	Average	%
Reagents	$25.00	$19.00	$22.00	74%
Supplies	$1.19	$2.17	$1.68	6%
Equipment	$3.73	$1.51	$2.62	9%
Human resources	$1.21	$1.56	$1.38	5%
Quality assurance	$1.59	$1.25	$1.42	5%
Training	$0.29	$0.35	$0.32	1%
Non-salary recurrent	$0.32	$0.32	$0.32	1%
Total unit cost	$33.37	$23.29	$28.33	100%

Figure 6. POC – Distribution of Costs for HIV EID Test



5.5 Sensitivity Analysis of HIV POC Costs

The costs presented thus far represent the unit costs of HIV VL and EID testing on Alere™ and Cepheid under optimal circumstances – i.e., no supplies or time wasted and tests run at maximum daily capacity by existing staff. Variations in input costs and operational procedures would impact unit costs; therefore, we conducted one-way sensitivity analysis for 20 percent variations to input averages. Figures 7 and 8 show the results of the one-way sensitivity analyses.

Figure 7. Sensitivity Analysis of POC HIV VL Costs

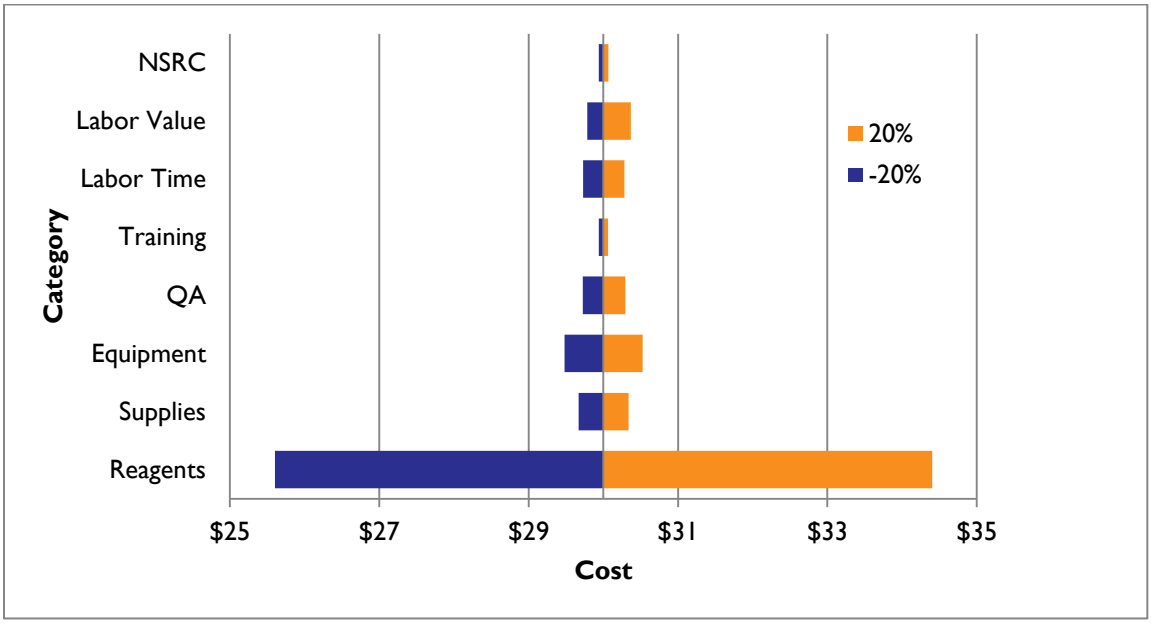
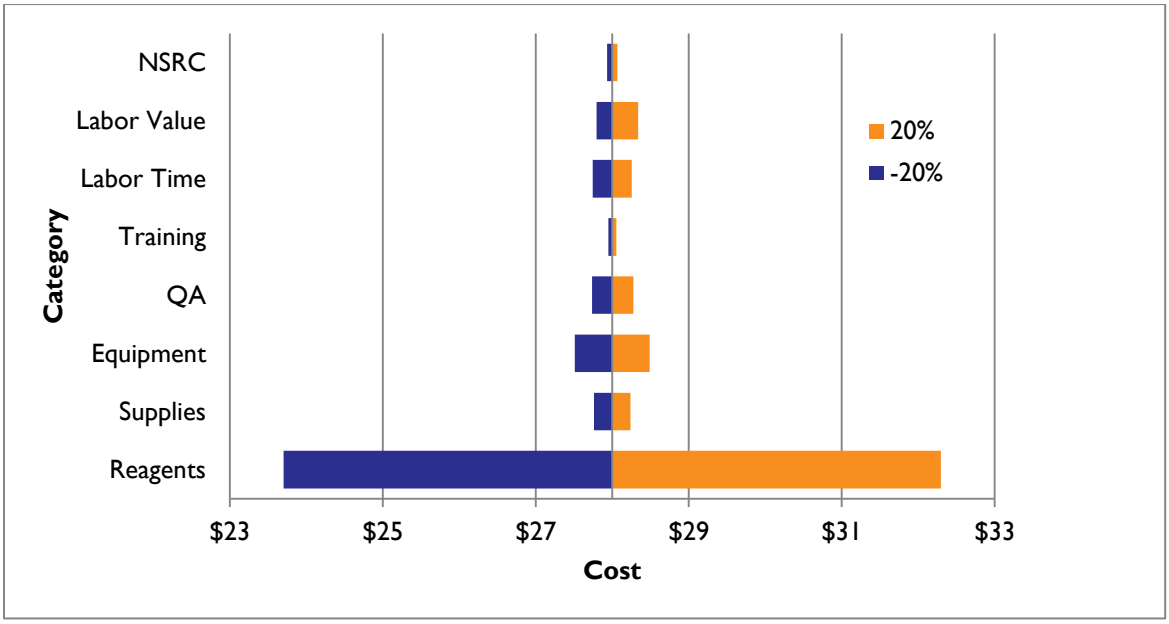


Figure 8. Sensitivity Analysis of POC HIV EID Costs



The tornado graphs for POC HIV VL and EID costs display the impact of 20 percent variations in inputs on the unit costs of testing. Variations to most inputs have relatively minor impacts on the total unit cost. However, 20 percent variations to reagent costs can result in up to 15 percent differences in total unit costs for VL and EID, approximately $4 difference. Accordingly, negotiating for lower reagent costs represents the greatest procurement opportunity to optimize cost-effectiveness of POC testing, promote uptake and utilization, and ensure sustainable use of health financing resources.

Table 12. POC HIV VL Testing Scenario Costs

Scenario	Alere™		Cepheid	
	Existing Facility Staff	Full-time POC Lab Technician	Existing Facility Staff	Full-time POC Lab Technician
Reagents	$25.00	$25.00	$19.00	$19.00
Supplies	$1.19	$1.19	$2.17	$2.17
Equipment	$3.73	$3.73	$1.51	$1.51
Human resources	$1.21	$6.47	$1.56	$2.59
Quality assurance	$1.59	$1.59	$1.25	$1.25
Training	$0.29	$0.81	$0.35	$0.56
Non-salary recurrent	$0.32	$0.32	$0.32	$0.32
Total unit cost	$33.33	$39.11	$26.16	$27.40

Note: All scenarios assume tests are run at maximum daily capacity.

Table 13. POC HIV EID Testing Scenario Costs

Scenario	Alere™		Cepheid	
	Existing Facility Staff	Full-time POC Lab Technician	Existing Facility Staff	Full-time POC Lab Technician
Reagents	$25.00	$25.00	$17.95	$17.95
Supplies	$1.19	$1.19	$1.19	$1.19
Equipment	$3.73	$3.73	$1.18	$1.18
Human resources	$1.28	$6.47	$1.28	$2.59
Quality assurance	$1.59	$1.59	$1.11	$1.11
Training	$0.25	$0.78	$0.25	$0.46
Non-salary recurrent	$0.32	$0.32	$0.32	$0.32
Total unit cost	$33.37	$39.07	$23.29	$24.80

Note: All scenarios assume tests are run at maximum daily capacity.

Under the Existing Facility Staff scenarios in Tables 12 and13, POC VL and EID tests are run only by existing facility staff at maximum daily capacity, 8 tests on Alere™ or 20 on Cepheid, and all staff involved in testing are trained for POC use. This scenario is also the baseline from which the costs in Tables 10 and 11 are derived. The second scenario also assumes testing at full capacity, and introduces a trained dedicated POC lab technician to conduct all sample collection, centrifuging (when necessary), and testing for POC VL and EID; existing staff are also trained so that testing opportunities are not lost if the lab technician is absent. The dedicated POC lab technician increases human resource costs five times for Alere™ and two times for Cepheid, but due to workflow and capacity constraints of the POC platforms only uses on average 55 percent (29 for Alere™ and 83 for Cepheid) of the technicians available time.

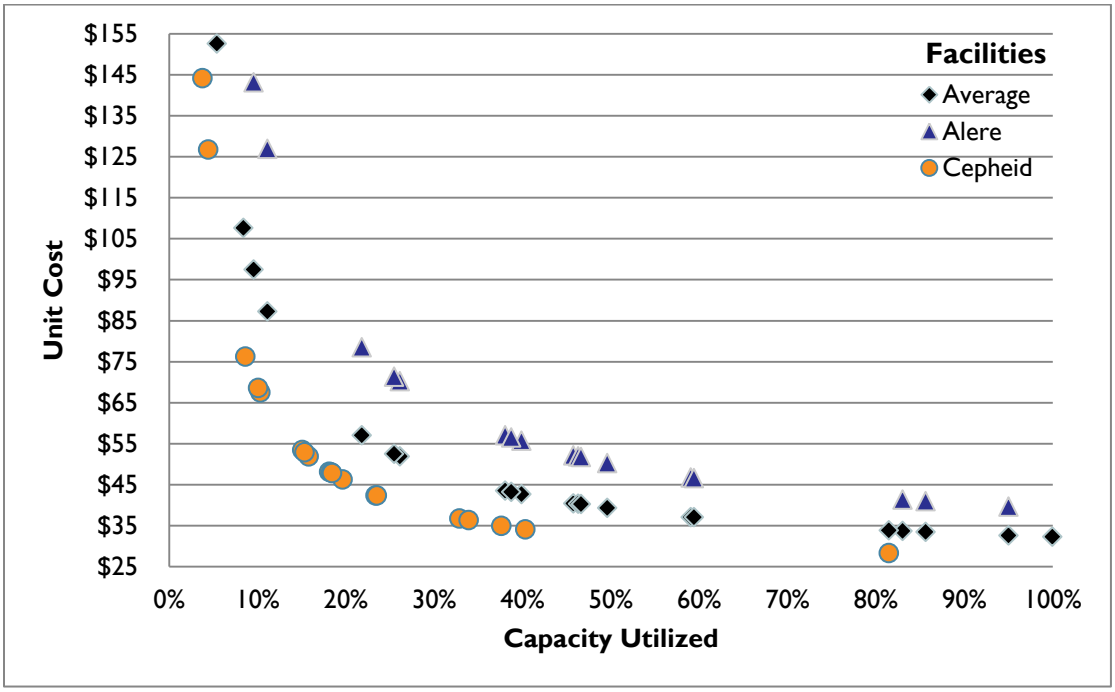
Due to machine failures, supply stock-outs, lack of patient demand, or other circumstances, testing at full capacity is not a guarantee in any given health facility. Sub-unit costs for equipment, human resources, and training will vary in response to the percentage of a platform's maximum capacity used. In light of the impact of capacity utilization on total unit costs, Table 14 explores the demand for VL and EID tests at Siaya County facilities in 2016 (NASCOP 2017). Given a maximum weekly testing capacity of 38 tests for Alere™ and 96 tests for Cepheid, three-fifths of facilities do not demand enough combined VL and EID tests to use an Alere™ at over 50 percent weekly capacity, and only Siaya County Referral Hospital would exceed 50 percent capacity for Cepheid.

Table 14. Testing Demand and Utilization of POC Capacity in Siaya County, 2016

Facility	HIV VL Samples Tested	Tests per Week	HIV EID Samples Tested	Tests per Week	Combined Tests per Week	Utilization of Alere™ Capacity	Utilization of Cepheid Capacity
Madiany Subdistrict Hospital	1806	34.7	72	1.4	36.1	95%	38%
Abidha Health Centre	938	18.0	42	0.8	18.8	50%	20%
Bar Aluru Dispensary	168	3.2	21	0.4	3.6	10%	4%
Ndori Health Centre	841	16.2	63	1.2	17.4	46%	18%
Ongielo Health Centre	1573	30.3	68	1.3	31.6	83%	33%
Saradidi Dispensary	406	7.8	25	0.5	8.3	22%	9%
Siaya County Referral Hospital	3925	75.5	142	2.7	78.2	206%	81%
Bar Agulu Dispensary	1097	21.1	70	1.3	22.4	59%	23%
Bar Olengo Dispensary	894	17.2	21	0.4	17.6	46%	18%
Kogelo Dispensary	1133	21.8	41	0.8	22.6	59%	24%
Mulaha Dispensary	737	14.2	51	1.0	15.2	40%	16%
Mur Malanga Dispensary	153	2.9	13	0.3	3.2	8%	3%
Yala Sub County Hospital	1920	36.9	93	1.8	38.7	102%	40%
Akala Health Centre	1623	31.2	69	1.3	32.5	86%	34%
Dienya Health Centre	494	9.5	22	0.4	9.9	26%	10%
Masogo Dispensary	90	1.7	17	0.3	2.1	5%	2%
Nyawara Health Centre	892	17.2	29	0.6	17.7	47%	18%
Ogero Dispensary	190	3.7	30	0.6	4.2	11%	4%
Rera Health Centre	479	9.2	24	0.5	9.7	25%	10%
Sirembe Dispensary	725	13.9	27	0.5	14.5	38%	15%
Wagai Dispensary	731	14.1	34	0.7	14.7	39%	15%
Total (Average)	20815 (991.2)	400.3 (19.1)	974 (46.4)	18.7 (0.9)	419.0 (20.0)	(53%)	(21%)

Figure 9 projects the average and POC platform-specific unit costs of HIV VL and EID (combined) testing at each facility given their testing demand and the percentage of testing capacity used as shown in Table 13. This projection assumes tests are performed by a dedicated POC lab technician as described earlier. The inverse relationship between unit cost and utilized testing capacity underscores the need to carefully consider demand for testing and/or willingness to pay a higher price per test to achieve same-day results coverage. Unit costs for Alere™ rise rapidly below 60 percent capacity utilization; costs for Cepheid rise rapidly below 30 percent. At approximately 22 percent capacity utilized, the cost of testing on Alere™ is doubled compared to baseline, while the cost for Cepheid is doubled at 15 percent.

Figure 9. Projected Distribution of POC Unit Costs



Four unit costs above $155 not shown (Alere™ $159 and $231, Cepheid $161 and $236); one Alere™ unit cost not shown (100% capacity exceeded)

Using the same scenario and projections as Figure 8 (dedicated POC lab technician and 2016 demand for testing), Table 15 shows the facility-specific unit costs for HIV VL and EID testing on Alere™ and Cepheid and the total budgetary impact of testing. Two and five facilities had sufficient demand for testing in 2016 to achieve unit costs below $40 on the Alere™ and Cepheid, respectively. By contrast, unit costs at four low-demand facilities would exceed $120 on either platform, somewhat contradicting the conventional wisdom that POC technology is best suited to low-demand settings. In all, the decision of whether or not to introduce a dedicated POC technician or share testing responsibilities among existing staff must be weighed against demand for testing, available staff time, and willingness to pay potentially higher unit costs to achieve same-day results coverage.

Table 15. Testing Demand and Projected POC Unit Costs and Budgetary Impact in Siaya County, 2016

Facility	HIV VL and EID Samples Tested	Combined Tests per Week	Alere™ Cost per Test	Cepheid Cost per Test	Alere™ Total Budget	Cepheid Total Budget
Madiany Subdistrict Hospital	1878	36.1	$39.68	$34.99	$74,520	$65,715
Abidha Health Centre	980	18.8	$50.29	$46.27	$49,285	$45,344
Bar Aluru Dispensary	189	3.6	$143.13	$144.20	$27,052	$27,254
Ndori Health Centre	904	17.4	$52.15	$48.13	$47,147	$43,513
Ongielo Health Centre	1641	31.6	$41.35	$36.76	$67,860	$60,326
Saradidi Dispensary	431	8.3	$78.55	$76.24	$33,856	$32,861
Siaya County Referral Hospital	4067	78.2	$33.45*	$28.37	$136,034	$115,362
Bar Agulu Dispensary	1167	22.4	$46.73	$42.42	$54,539	$49,501
Bar Olengo Dispensary	915	17.6	$51.87	$48.04	$47,460	$43,953
Kogelo Dispensary	1174	22.6	$46.62	$42.40	$54,737	$49,776
Mulaha Dispensary	788	15.2	$55.70	$51.92	$43,888	$40,911
Mur Malanga Dispensary	166	3.2	$159.09	$161.55	$26,408	$26,817
Yala Sub County Hospital	2013	38.7	$38.90	$34.14	$78,313	$68,723
Akala Health Centre	1692	32.5	$40.95	$36.34	$69,293	$61,485
Dienya Health Centre	516	9.9	$70.24	$67.51	$36,246	$34,834
Masogo Dispensary	107	2.1	$231.26	$236.42	$24,745	$25,297
Nyawara Health Centre	921	17.7	$51.71	$47.83	$47,628	$44,054
Ogero Dispensary	220	4.2	$126.92	$126.76	$27,922	$27,886
Rera Health Centre	503	9.7	$71.33	$68.63	$35,880	$34,523
Sirembe Dispensary	752	14.5	$57.02	$53.46	$42,878	$40,205
Wagai Dispensary	765	14.7	$56.53	$52.90	$43,243	$40,468
Total (Average)	21789 (1037.6)	419.0 (20.0)	($49.06)	($44.92)	$1,068,933 ($50,902)	$978,806 ($46,610)

*Capacity of Alere™ Q exceeded by 106 percent

Literature on POC unit costs for VL and EID are sparse, but our estimated costs for Alere™ and Cepheid fit with previous findings. Based on our findings and assumptions, POC VL testing using existing staff would cost approximately $33.33 per test on Alere™ and $26.16 per test on Cepheid. The Global Fund estimated a unit cost of nearly $20 for tests on the Cepheid, but only considered costs for reagents, equipment, and logistics (2016). No previous estimates for VL on the Alere™ were found. Our estimates for POC EID were similar at $33.37 per test on Alere™ and $23.29 per test on Cepheid. These costs aligned closely with both Global Fund (2016) and EGPAF and UNITAID (2016) estimates of approximately $32 for Alere™ and $22 for Cepheid. High reagent costs, the need to purchase new equipment, low testing throughputs, and facility variations in testing demand are all important drivers of POC unit costs. Increased competition in the POC testing market and negotiations for Global Access prices, like those now available for some central lab testing platforms, are the forces most likely to drive down the costs of POC testing (EGPAF and UNITAID 2016; MSF 2013). New data on costs and outcomes from countries as they implement or scale up POC testing will help inform price negotiations, volume forecasts, and provide evidence on the suitability of POC testing in various settings.

6. DISCUSSION AND CONCLUSIONS

Activity-based costing results at KEMRI for VL and EID testing are comparable to other reports form sub-Saharan African central laboratories. Variations in VL unit costs seen across platforms, countries, and regions indicate that contextual factors like testing demand, network design, and particularly manufacturer-country price negotiations are important determinants of cost.

KEMRI has increased its testing capacity since 2014, and now operates three Abbott and three Roche testing platforms. Assuming adequate lab personnel, and no supply stock-outs or machine failures, the additional machines will help KEMRI meet the growing demand for VL and EID testing brought on by the latest MOH guidelines. Siaya County alone requested nearly 79,000 VL and 4,400 EID tests in 2016, large increases from 2015 requests (NASCOP 2016). The national average turnaround time for EID testing declined from 24 to 19 to 17 days between 2014 and 2016, but rising demand for VL and EID testing will make continued reductions more difficult. The creation of a hybrid testing network, predominantly central lab-based but with strategically positioned POC testing capabilities, is needed to achieve same day results for some and shorter average turnaround times for many (Cogswell et al. 2016). Additionally, while facilities reasonably prioritize delivering results to patients with failing outcomes, qualitative research from Swaziland suggests that informing patients of positive outcomes can improve patients happiness and boost confidence in treatment (Horter et al. 2015).

Ideally, hybridizing the VL/EID testing network would improve outcomes without substantially raising costs. Improving outcomes is straightforward: adding POC capabilities will increase the proportion of patients receiving test results (to 100 percent) and decrease turnaround times (to within one visit) at POC facilities, while non-POC facilities would also see improvements due to decreased testing demand at KEMRI or other central labs. Striking the right balance between single-facility demand and default (centralized testing) average turnaround time is the key to efficiently placing POC platforms. POC will have the greatest impact in facilities with high enough demand to run VL or EID tests at the maximum daily capacity and long default average turnaround times. Additionally, while POC testing will enable at-birth EID testing, health care providers must stress the importance of at-birth testing as an addition to the standard six weeks testing, not a replacement, in order to maximize retention in care and clinical outcomes (Francke et al. 2016).

While achieving same day results through POC testing should be straightforward, maintaining or lowering costs compared with central testing could prove more challenging. Our costing approach found POC testing to be more expensive than centralized testing, mostly due to reagent and equipment costs. Competition may drive these prices downward as more platforms enter the market, but near-future purchasing of platforms such as the Alere™ or Cepheid will demand significant country or donor investment. POC testing may also shift human resource time from dedicated lab workers to general clinic staff or lay workers. On paper, this shift should save costs, but careful human resource planning through tools like the WHO's Workload Indicators of Staffing Need (WISN) would help ensure savings. WISN considers the number of staff trained for an activity, time needed for the activity, available staff time, and activity frequency to identify staff or skill imbalances and opportunities for task shifting or sharing (WHO 2016d). Using WISN, the MOH could identify facilities best suited to implement POC testing, as well as monitor the impacts of POC integration at hub hospitals and KEMRI. Alternatively, our analysis found that deploying dedicated POC technicians would result in higher human resource costs, particularly where demand for testing is low.

Regardless of placement or what staff are operating them, the Alere™ and Cepheid workflows are designed for quick and simple operation that cuts costs associated with centralized testing. Each requires less than a day of training for use and uses single use cartridges, minimizing opportunities for operator error or sample contamination (UNITAID 2015). When used as true POC technologies, transportation costs are also eliminated.

Although POC technology may help Kenya solve some coverage issues, the need for high-volume testing will keep centralized testing and transportation networks the standard, particularly in the Nyanza region. MSF recommends sample transport systems be nationally coordinated and funded, regardless of whether the transportation itself is carried out by MOH personnel, NGOs, or independent couriers (MSF 2016). Trainings on biosafety, cold-chain integrity, and proper sample packing can help ensure no samples are lost due to damage or contamination, which results in wasted resources and delays for patients. Sample transport systems should also be integrated for all sample types, not just VL or EID, to improve cost efficiency and, if demand is sufficient, increase sample delivery to more than twice per week. Additionally, a fully integrated system for all sample types would be less impacted by the introduction of POC technology at some facilities than a system dependent only on VL and EID samples.

Investment in mHealth strategies is another option for reducing and shortening result turnaround times. Internet connectivity constraints prevent KEMRI from sending test results directly back to origin facilities via online NASCOP systems, but cell phones, owned by 82 percent of Kenyans, may be able to fill the gap (Pew Research Center 2015). Modeling programs used in Nigeria (WHO 2013) and Zambia (Seidenberg et al. 2012), KEMRI, or hub hospitals could send VL or EID results via SMS (text) messages to designated staff at health facilities, who in turn would contact patients via SMS or call with their results and/or instructions to return to the facility. The Nigerian approach, SMS Printers to Accelerate Return of Test Results for Early Infant Diagnosis of HIV/AIDS (SMART), was a collaboration between the Clinton Health Access Initiative (CHAI) and two local companies (WHO 2013). EID test results were sent via SMS from the central lab to health facilities, printed on SMS printers, and delivered to patients on their next visit. This approach was previously used on a limited scale in Kenya, where it reduced average EID turnaround times to one week in participating facilities (IATT 2012). The SMS-results system in Zambia operated similarly (sans printers), sending EID results from the central lab to health facility staff, who then contacted the child's caregivers to return for their results and counseling (Seidenberg et al. 2012). Turnaround times fell from 44.2 to 26.7 days after SMS system implementation and the program was slated for scale-up to all facilities providing EID testing by 2014. Implementing an SMS result delivery system will incur costs for software, equipment, and trainings, including measures to ensure patient confidentiality, which should be measured against potential improvements to turnaround times and associated outcomes.

In 2016 Diallo et al. advanced a framework for evaluating POC EID testing platforms and implementing them into an existing testing network. The framework, which is also applicable for POC VL testing, begins with lab-based evaluation of proposed platforms to test performance against manufacturer claims and provide data for WHO prequalification. As Cepheid and Alere™ assays (except Alere™ for VL) are already prequalified, the MOH could proceed to field-based evaluation, wherein platforms are placed at a small number of sites intended for inclusion during full implementation. Field-based evaluation generates in-country data on needs for human resources and task sharing, training, quality assurance, and utilization. The final stage is implementation evaluation, where the outcomes of expanded POC placement are assessed against expected impacts on coverage, costs, turnaround times, and more, compared with the standard testing network. Results from the evaluation phases should guide final decisions on if and how to proceed with POC integration to testing networks, including where to place platforms (Diallo et al. 2016). As discussed earlier, POC testing will be most effective where demand for testing matches maximum daily capacity and where turnaround times are relatively long.

Even in light of global initiatives undertaken before and since 2014, reagents are likely to remain the most expensive component of VL and EID testing in low- and middle-income countries (UNAIDS 2014b, UNITAID 2015). This is partly due to reagent rental strategies, where reagent prices are negotiated to account for countries not purchasing the testing platforms. Reagent rental enables countries to avoid large start-up costs of procuring equipment, encourages prompt equipment maintenance by manufacturers, and affords flexibility within a growing field of diagnostic technologies (WHO 2014). MSF reports that Kenya, through CHAI, had negotiated prices for VL test reagents at $10.50 per test plus $2.50 per test for proprietary controls, calibrators, and other testing consumables (MSF 2013). We found higher VL reagent costs per test, $16.38 on Abbott and $16.54 on Roche in 2014, although our calculations also included additional non-reagent consumables required for running VL or EID tests on both platforms.

Strategies to reduce reagent costs include negotiating volume-based procurement prices, promoting competition among suppliers, testing samples at or near maximum machine capacity, and pooling samples for testing. Countries and diagnostics manufacturers negotiate a set price for reagents when establishing a reagent rental scheme. Countries and their implementing partners can levy increased bargaining power in these negotiations through high-volume procurement agreements. The South Africa National Health Laboratory, purchaser of over half of all VL tests in low- or middle-income countries, used this approach in collaboration with CHAI, PEPFAR, and the Global Fund to seek tenders for a low "global access price" for all PEPFAR- and Global Fund-supported countries (CHAI 2015). Ultimately, Roche submitted the lowest tender and the process culminated in a Global Access Program price of $9.40 per test, including training and reagents (CHAI 2015). Roche and partners also committed to the same global access price for EID testing in 2015 (UNAIDS 2015). Kenya, Global Access Program-eligible and aiming to provide routine VL monitoring of at least one test per year for over 1.5 million people, is positioned favorably to renegotiate for these or lower reagent prices for KEMSA, ICAP, and other implementing partners. Regional procurement agreements may further lower reagent prices for Kenya and its neighbors, although accurate volume forecasting becomes more difficult at this scale (WHO 2014).

Competition between suppliers can lead to lower prices or better service packages for VL and EID testing, just as in procuring antiretroviral drugs (ARVs) for HIV treatment (WHO 2015). South Africa and Swaziland promoted competition among ARV suppliers by setting price benchmarks and soliciting open tenders (UNAIDS 2013). The winning tenders in South Africa resulted in a halving of ARV prices, while those in Swaziland saved 27 percent compared with the previous agreements. South Africa and Kenya applied this approach to VL pricing, with each country splitting contracts between Roche and another diagnostics manufacturer – bioMérieux in South Africa and Abbott in Kenya – after open tender competitions (MSF 2013). A drawback of this approach is the lack of standardization that comes with operating two or more platforms for testing, but a systematic review comparing several current lab-based platforms found all are sufficiently accurate for VL testing at the 1,000 copies/mL threshold (Sollis et al. 2014).

Pooled sample testing for VL can also lower reagent unit costs while increasing outputs. In a sample pooling strategy, 100 microliters (µL) from five different patient samples are combined and tested as one sample against the VL test threshold, 1,000 copies/mL (MSF 2013). If the pooled sample tests below the threshold, no further testing is needed as no included patients were failing treatment. However, if the pooled sample tests above the threshold, samples for each patient included in the pool are retested individually. This method of testing is therefore only efficient under specific conditions: large enough samples must be collected to allow for both pooled and individual testing, the expected number of failing patients must be low enough that most pooled samples will not prompt individual retesting, the total volume of samples must be high enough that pooling samples does not lead to low-capacity testing or delays, and adequate staff time and supplies must be available to enable pooling samples and avoiding

cross-contamination. Finally, whether using pooled or individual samples, low-capacity testing should be avoided as it can result in reagent unit costs up to twice as high as maximum-capacity testing (MSF 2013). This means 93 sample batches for Abbott and continuous loading of 21 sample batches for Roche, both of which are standard procedure at KEMRI.

Human resources also provide cost saving opportunities through shifting or sharing various tasks. Clinicians, nurses, lab technicians, HIV testing counselors, and phlebotomists all contributed to VL and EID sample collection across the 21 facilities, bringing different skill levels, specialties, and salaries to the task. Clinicians and lab technicians collect the majority of VL samples in labs or phlebotomy rooms while clinicians and nurses collect the majority of EID samples, all in Maternal and Child Health units. High levels of lab technician involvement in sample collection may be an inefficient use of their time, training, and salary. Kenya should consider promoting task sharing so that nurses or lay staff collect the bulk of samples, under clinician supervision as needed. WHO guidelines do not specify who should collect samples but do allow for trained and supervised lay staff to collect fingerstick blood samples (WHO 2016). Evidence from Malawi indicates lower-level health care workers can be trained to effectively conduct DBS sample collection under supervision (Pannus et al. 2014). Though DBS is primarily used for EID and not VL in Kenya, these findings reaffirm DBS sampling as a viable and potentially cost saving option when skilled human resources or cold chain access is limited.

Integrating POC technologies to the VL and EID testing network will also impact human resource costs. Whereas centralized testing requires trained lab technicians, assistants, and phlebotomists for centrifuging, sample preparation, and testing at the hub hospitals and KEMRI, simpler POC technology workflows allow for a modestly trained individual to move more directly from sample collection to testing (UNITAID 2015). Using the Alere™ for VL or EID testing, a worker can use 25µL of fingerstick, heelprick, or venous whole blood to fill the sample cartridge, insert the cartridge into the machine, enter the sample ID, and initiate testing in three to five minutes (UNITAID 2015). Since sample cartridges come fully prepared with all needed reagents and are thus simple to use, it is plausible that even low-level health care workers could use the Alere™ for POC testing in facilities facing human resource constraints. This possibility should be explored and, if found appropriate, codified in Kenya's next HIV care guidelines.

On the other hand, the Cepheid platform requires more labor and may be considered a near-POC machine. The Cepheid can use whole blood or DBS for EID, but requires plasma, and thus centrifugation, for VL testing. For EID on the Cepheid a worker collects whole blood in an EDTA tube, adds 750 µL of sample reagent and 100 µL of whole blood to the sample cartridge, scans the cartridge, and loads it into the machine (UNITAID 2015). VL testing on the Cepheid requires that collected whole blood be centrifuged for 20 minutes to produce plasma, which is then added to a sample cartridge for testing. Thus, VL testing on the Cepheid requires a phlebotomist, which we found were only present in the three hub hospitals. Hospital phlebotomists (and other lab staff) are responsible for sample collection, centrifuging all VL and EID samples bound for KEMRI, and performing other tests, a large workload to which adding VL or EID testing may not be feasible. Use of the Cepheid (or any other platform) for POC EID at facilities without the capacity for VL is not recommended, as it would not use the full testing capacities of the machine, thereby increasing unit costs (MSF 2013). Conversely, the Cepheid can also be used for other tests including tuberculosis, HPV, and hepatitis, including any mix of these tests in a single 90-minute run, improving its potential utility at hub hospitals with large patient volumes and diverse needs (MSF 2015).

Kenya's 2016 HIV guidelines eliminate routine CD4 monitoring for patients with suppressed VL and access to routine VL monitoring, as recommended in the 2016 WHO guidelines on HIV care. CD4 testing is still performed at treatment initiation to determine immunological status and in the event of treatment failure as screening for opportunistic infections. South Africa eliminated CD4 testing for virally suppressed patients in 2013, a move that is expected to reduce testing costs by 51 percent, $68 million, between 2013 and 2017 (Stevens and Ford 2014). Resources saved in Kenya through reduced CD4 testing can in turn be used to scale up VL and EID testing capacities through POC or near-POC technologies.

In conclusion, comprehensive unit costs of VL and EID testing at KEMRI were similar across two high-capacity, high-quality testing platforms. The average unit cost of VL testing, $24.63 in central laboratories, falls along the lower end of a range of previously estimated costs in Kenya and other parts of sub-Saharan Africa (MSF 2014a). The average unit cost of EID testing, $25.05, is also closely comparable to previous estimates in central labs. In addition to relatively low testing prices, we observed that result turnaround times have declined substantially in recent years to an average of 18 days for VL and 12 days for EID. Faster turnaround times facilitate crucial and time-sensitive care decisions that save lives and costs through all patients being on appropriate ARTs or prophylaxis. Monitoring VL at least once a year for 90 percent of PLWH receiving treatment under the test-and-treat strategy would require financing of $33.25 million per year. At least one EID test for 90 percent of children born to HIV-positive mothers would require financing of $1.79 million per year.

The addition of POC testing to Kenya's testing networks will enable some patients, ideally those currently experiencing longer than average turnaround times, to receive their test results within the span of a single health facility visit. We estimated POC VL testing costs at $33.33 per test on Alere™ and $26.16 per test on Cepheid under optimal circumstances. Also, we arrived at similar estimates for POC EID at $33.37 per test on Alere™ and $23.29 on Cepheid. We anticipate that POC testing will come at marginally higher costs than current centralized testing, and cost-effectiveness comparisons of the two approaches will help find the ideal testing network balance. Ultimately, the figures provided by this report should help the Kenya MOH identify opportunities for cost savings in the provision of VL and EID testing, project resource needs as testing coverage expands, make informed decisions on the placement of POC technologies, and help achieve the 90-90-90 targets and an AIDS-free generation.

ANNEX A: COST COMPARISON TABLES

In addition to displaying the broad range of HIV VL and EID unit costs across time and countries, Tables A1 and A2 demonstrate the lack of uniformity in how costs are reported. Blank boxes indicate components not reported by a study, although the same or similar costs may be included under different labels. Costs are sometimes presented by components, other times by activities, and transparency about how either is constructed is not always readily available. Further, the components and activities included vary by author and organization. Greater consistency in how VL and EID unit costs are calculated and presented would benefit country efforts to compare costs and improve leverage in negotiating national or regional agreements for testing equipment and reagents.

Table A1. Comparison of HIV VL Unit Costs and Reported Components

Country (Reference)	Study and Currency Year(s)	Cost Components Reported												
		Reagents/ Consumables	Test*	Lab Overhead	Reagents	Sample Preparation	Freight and Insurance	Handling	Supplies/ Disposables‡	Labor	Transport	Facilities and Equipment	Other Costs	Total Cost
Kenya (1)	2013	$24.79											$18.63	$43.42
Thailand (1)	2013	$36.38											$7.69	$44.07
Lesotho (1)	2013	$20.23											$13.94	$34.17
Malawi (1)	2013	$23.13											$12.25	$35.38
Swaziland (1)	2013	$18.62											$6.28	$24.90
Zimbabwe (1)	2013	$22.86											$16.17	$39.03
India (2)	2014		$29.00	$6.00										$35.00
Malawi (2)	2014		$15.00	$7.00										$22.00
South Africa (2)	2014		$10.00	$19.00										$29.00
Zimbabwe (2)	2014		$23.00	$12.00										$35.00
Burkina Faso (3)	2011- 2014				$27.97	$5.16	$1.56	$2.82						$37.50
Burundi (3)	2011- 2014				$15.92	$5.16	$1.75	$1.48						$24.30
DR-Congo (3)	2011- 2014				$13.13	$5.16	$0.77	$1.47						$20.53
Guinea (3)	2011- 2014				$23.85	$5.16	$8.18	$2.29						$39.48
Mali (3)	2011- 2014				$27.97	$4.90	$5.80	$2.79						$41.46
Morocco (3)	2011- 2014				$19.79	$4.35†	embedded	embedded						$24.14
Ukraine (3)	2011- 2014				$24.55	$5.40†	$0.00	$0.00						$29.95
Burkina Faso (3)	2011- 2014				$29.77	$6.55†	$1.40	$2.53						$40.25
Djibouti (3)	2011- 2014				$30.06	$6.61†	$9.61	$2.55						$48.83

Country (Reference)	Study and Currency Year(s)	Cost Components Reported												
		Reagents/ Consumables	Test*	Lab Overhead	Reagents	Sample Preparation	Freight and Insurance	Handling	Supplies/ Disposables‡	Labor	Transport	Facilities and Equipment	Other Costs	Total Cost
Guina-Bissau (3)	2011-2014				$20.09	$4.42†	$2.56	$1.41						$28.49
Guatemala (3)	2011-2014				$33.90	$7.46†	$0.05	$2.88						$44.29
Mauritania (3)	2011-2014				$22.22	$4.89†	embedded	$2.89						$30.00
Niger (3)	2011-2014				$21.00	$4.62†	$3.46	$1.21						$30.29
Ukraine (3)	2011-2014				$43.34	$9.54†	$0.00	$0.00						$52.88
Burkina Faso (3)	2011-2014				$9.87	$2.17†	$0.46	$0.84						$13.34
Myanmar (3)	2011-2014				$22.00	$0.00	$0.74	$0.00						$22.74
Nicaragua (4)	2008				$79.55				$3.37	$5.68	$4.02	$5.62		$98.24

*Test: source only presented costs in terms of "test" and "cost with labor overheads" (total cost)

† Costs were imputed using Abbott ratio of total costs to amplification and detection costs

‡ Supplies/Disposables: combination of clinic supplies ($0.82) and lab disposables ($2.54)

* Labor: combination of clinic labor ($4.49) and lab labor ($1.19)

(1) MSF (2013)

(2) MSF (2014a)

(3) MSF (2014b)

(4) Gerlach et al. (2010)

Table A2. Comparison of HIV EID Unit Costs and Reported Components

Country	Study and Currency Year(s)	Components Included							Total Cost	Reference
		Reagents	Supplies	Labor	Taxes/Fees	Transportation	Equipment	Other Costs		
Botswana	2005 (2007)	$8.00						$11.60	$19.60	Creek et al. 2008
Kenya	2006-2007 (2007)	$10.00	$6.00	$1.00	$4.00	$0.50			$21.50	Khamadi et al. 2008
Uganda	2005-2006 (2007)	$13.20	$8.63	$1.51			$0.67		$24.01	Menzies et al. 2009
Namibia	2009								$60.92	Touré et al. 2013
Rwanda	2009								$10.91	Touré et al. 2013
Thailand									$20-42	Ngo-Giang-Huong et al. 2008
Thailand	model (2011)								$57.14	Collins et al. 2014

ANNEX B: REFERENCES

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