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RESEARCH AND EVALUATION REPORT

Evaluation of a point-of-care HIV testing improvement intervention in Kenya

MARCH 2020

This research report was prepared by University Research Co., LLC (URC) for review by the United States Agency for International Development (USAID) and authored by Edward Broughton, Charles Kimani, Maero Lutta, and Mark Mwanja of URC. The Kenya point-of-care HIV testing improvement intervention was funded by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) through the USAID Applying Science to Strengthen and Improve Systems (ASSIST) Project. The USAID ASSIST Project, managed by URC, is made possible by the generous support of the American people through USAID.

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For more information on the work of the USAID ASSIST Project, please visit www.usaidassist.org or write assist-info@urc-chs.com.

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Acronyms

ART	Antiretroviral therapy
ASSIST	USAID Applying Science to Strengthen and Improve Systems Project
CCC	Comprehensive care clinic
CHV	Community health volunteer
CME	Continuing medical education
CT	Control testing site
DBS	Dried blood spot
EQA	External quality assessment
HIV	Human immunodeficiency virus
HTS	HIV testing services
IT	Intervention testing site
MOH	Ministry of Health
NASCOP	National AIDS and Sexually Transmitted Infection Control Program
NHRL	National HIV Reference Laboratory
OPD	Outpatient department
POC	Point of care
QI	Quality improvement
RTQII	Rapid Test Quality Improvement Initiative
SOP	Standard operating procedure
T&C	Testing and counseling
UNAIDS	Joint United Nations Programme on HIV/AIDS
URC	University Research Co., LLC
USAID	United States Agency for International Development
WHO	World Health Organization

EXECUTIVE SUMMARY

Introduction

Obtaining and delivering accurate results from HIV rapid test kits is an important component of addressing the first element of the UNAIDS 90-90-90 strategy. There are several reports of a high proportion of inaccurate results achieved from point-of-care (POC) rapid tests, and many factors have been shown associated with rapid test inaccuracies.

We evaluated the effectiveness and efficiency of an intervention to improve the processes of POC rapid testing in participating facilities in western Kenya. The QI intervention was conducted over six months in five facilities in Busia County.

Methods

This is a prospective pre-/post-intervention, quantitative evaluation using primary data collection from five intervention facilities and five comparable facilities undergoing no improvement intervention. We collected data from direct observations of service delivery on a sample of 455 testing and counseling procedures in intervention sites and 276 testing and counseling procedures in control sites. Twenty-three indicators were analyzed individually and in three groups for counseling, testing procedure, and data management.

Health workers in the five intervention facilities were supported to analyze and iteratively test changes to processes of care for patients undergoing POC rapid testing. The objective was to increase the proportion of patients receiving accurate HIV test results and link those testing HIV-positive and those know positives to the comprehensive care clinic. Monthly data were collected to inform the improvement activities in the five intervention facilities.

Supervisory visits to counsellors/testers at the five health facilities were conducted in which a health ministry supervisor observed service delivery to determine if nationally mandated testing protocols were followed. Counsellors/testers in each facility, supported by County supervisors and staff of the USAID Applying Science to Strengthen and Improve Systems (ASSIST) Project, iteratively tested changes to achieve compliance with national counseling and testing standards.

Cost data for the intervention included personnel costs, transport, consumable costs of providing support to the facilities to improve POC testing, per diems, and accommodation. These were collected from the implementing organization (the USAID ASSIST Project).

Results

Baseline performance in intervention and control sites was high. In the control facilities, counseling performance dropped by 28%, whereas it increased in the intervention facilities by 19%.

When considered together, there was no statistically significant difference in the improvement seen in the quality indicators for testing procedure between the intervention and control groups.

For data management indicators considered together, there was no significant improvement in either the intervention or control facilities.

When the results were considered for individual intervention facilities, for the counseling overall indicator, the two smallest facilities improved the least while for the testing variables, two of the larger facilities improved the least, though it is notable that they started at the highest initial level of compliance among the intervention facilities. The two smallest clinics also improved the least for the data management indicators.

Excluding the external evaluation costs, the total cost of the intervention from the program perspective was $123,000 over the nine months. The total number of people receiving HIV testing over 12 months was 12,828 for a program total per HIV test conducted of $9.58 per person. The cost-effectiveness of this

intervention is US$10 per additional patient provided counseling to full compliance to standards, compared the business-as-usual scenario, assuming the effects lasted two years without attenuation. The intervention was not shown to be cost-effective in improving testing indicators in this evaluation.

Conclusion

The intervention appeared to improve counseling indicators but not testing or data management indicators in this setting. The cost-effectiveness of improving the counseling indicators is comparable to other HIV testing interventions reported from the same setting.

The improvement would likely have been more cost-effective but for the two prolonged health workers strike during the intervention and an abbreviated implementation period. Several indicators starting at already high levels of compliance allowing little or no room for improvement. Also, if baseline indicators had been lower, the intervention may have been more cost-effective.

I. INTRODUCTION

Knowledge of HIV status is essential for achieving universal access to HIV services. As such, HIV testing and counseling (T&C) are fundamental elements of all HIV prevention, care, and treatment programs. The Joint United Nations Programme on HIV/AIDS (UNAIDS) launched the 90-90-90 strategy and targets that aimed at ensuring that 90% of all HIV-positive persons are diagnosed, 90% of all those identified as HIV-positive are put on antiretroviral therapy (ART), and 90% of those on ART are virally suppressed (1).

Obtaining and delivering accurate results from HIV rapid test kits is an important component of addressing the first 90 target of the UNAIDS strategy. Studies of HIV diagnostic algorithms including point-of-care (POC) rapid tests have shown positive predictive values of 93% or lower in low-resource settings (2-4). More recently examined rapid test algorithms showed sensitivities and specificities as high as 100% (5). There are substantive adverse consequences of incorrect diagnoses to the individual, public health, and health financing (6). One example is among pregnant women. False-positive HIV diagnoses disproportionately affect this group because they are routinely screened for HIV as part of prevention of mother-to-child transmission programs. The personal consequences of misdiagnosis to the woman can be devastating, and treatment with ART imposes an unnecessary risk for her and her fetus (7).

There are several reports of a high proportion of inaccurate results achieved from POC rapid tests, and many factors have been shown associated with rapid test inaccuracies (4, 8-10). Some involving the testing process itself were identified in a study of primary health clinics and community health centers in South Africa (11). These included incorrect specimen collection methods, unavailability of consumables required for testing and analysis, short incubation periods before reading test results, inadequate staff training, and generally low-quality practices. This report found overall testing and counseling (T&C) compliance was 3.4%. We know of no other studies conducted in low- and middle-income countries (LMIC) settings that have examined the processes of POC rapid HIV testing.

While no published accounts of applications of quality improvement (QI) methods specifically to POC HIV rapid testing were found, this approach has been used in several settings to increase the accuracy of laboratory diagnostic testing by improving adherence to standard procedures (12). The Rapid Test Quality Improvement Initiative (RTQII) was developed in 2012 (13) but no subsequent reports of its implementation or effectiveness have been found in the published or gray literature. Similarly, we could find no reports on the implementation of the World Health Organization (WHO) “A handbook for improving HIV testing and counseling services” (14).

A. Kenyan National HIV Testing Strategy, Policies, and Guidelines

As of 2016, more than half (53%) of the 1.6 million people living with HIV in Kenya are unaware of their HIV status (15). The national Ministry of Health (MOH) through the National AIDS and Sexually Transmitted Infections Control Program (NASCOP) created three documents guiding HIV prevention and testing services. These are:

- Kenya AIDS Strategic Framework 2014/15 – 2018/19
- Kenya National AIDS Strategic Plan
- Kenya HIV Testing Services guidelines, 2015

In addition to policies and guidelines, the MOH has the National HIV Reference Laboratory (NHRL) whose mandate is to lead and advocate for improved laboratory quality, conduct HIV surveillance testing, and provide quality assurance for HIV testing services (HTS).

B. Selection of Busia County and the Intervention Facilities

Busia County is one of the 34 counties in Kenya that have been prioritized for assistance with funding from the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) for HIV prevention, care, and treatment because of its high HIV burden and infection rate. It is a border county with a high number of

long-distance truck drivers, a high prevalence of commercial sex work, and a large fisher worker population. The USAID ASSIST Project was implementing a quality improvement (QI) project in Busia and seven other counties prior to introduction of this point-of-care improvement project. Busia County was selected as an appropriate setting to test the effectiveness of QI integration into service delivery on HIV testing services.

Busia County has a one comprehensive facility which acts as the county's highest public referral hospital; five secondary care (sub-county) hospitals; 13 basic primary health care facilities (health centers); and 56 dispensaries and outpatient clinics. Ten facilities representing the different levels of the health system were selected by the USAID ASSIST Project in consultation with the County Health Management Team to participate in the POC QI project—five as intervention and five as control facilities.

Among the 10 facilities selected, there was one county referral hospital, three sub county hospitals, four health centers, and two dispensaries (**Table 1**).

Table 1: Characteristics of participating facilities

Facility type	Beds	Cots (children)	average number of clients tested	Facility Workload	Doctors	Clinical officers	Nurses	Lab Technicians	HTC counselors
Dispensaries	2	0	7	157	0	1	4	2	1
Secondary care hospitals	14	0	12	740	1	8	18	4	3
Primary care hospitals	130	0	9	803	3	13	42	7	4
Basic primary health care facility	12	0	8	621	0	6	11	3	3
Dispensaries	0	0	13	331	0	1	2	1	1
Basic primary health care facility	7	0	9	552	0	6	9	3	2
Secondary care hospitals	185	1	12	1831	6	17	38	11	10
Basic primary health care facility	25	1	10	982	2	7	15	3	4
Basic primary health care facility	15	0	6	202	0	1	4	1	1
Basic primary health care facility	24	0	7	232	0	2	5	2	2

C. Evaluation Objectives

We evaluated the effectiveness and efficiency of an intervention to improve the processes of POC rapid testing in participating facilities in western Kenya. The QI intervention was conducted over six months in five facilities in Busia County, with five other similar facilities in Busia County serving as controls. Baseline data, process output data, and end line data were collected in the five intervention facilities and five control facilities. The 10 sites are listed in **Table 2**, which also shows the average monthly HTS case load at each site. It should be noted that the intervention facilities were chosen as the County's highest volume facilities.

Table 2: HTS facility workload

	Average monthly HTS load
Control facilities	**237**
Amaase	262
Lukolis	445
Lupida	150
Madende	155
Nangina	171
Implementation facilities	**804**
Alupe	541
Amukura	597
BusiaCRH	1,653
Nambale	658
Sioport	570
Overall	**523**

The primary objectives of the evaluation of the improvement intervention were to:

1. Determine deficiencies in service delivery performance across the entire POC HIV rapid testing process.
2. Determine the causes of and test solutions to the deficiencies in the POC rapid test procedures from the perspective of the providers delivering the services.
3. Evaluate the effectiveness of using the quality improvement approach to address deficiencies identified in POC rapid testing processes
4. Determine the cost of implementing the quality improvement approach in this setting with technical assistance provided by the USAID ASSIST Project.

Secondary objectives of the evaluation were to:

1. Determine what health facility factors are associated with deficiencies in the testing processes.
2. Estimate the cost-effectiveness of the improvement intervention in terms of expenditure per change in process measures observed and outcomes measures modeled.

It is important to determine the efficiency of the improvement intervention in terms of process and outcome indicators. While it is difficult to judge the true value of the program when the result of the cost-effectiveness analysis is expressed in terms of expenditure per additional process of care completed to compliance, it does allow at least some comparison of the improvement program's worth compared to the costs of the POC tests itself and related activities.

II. Methods

A. Study Design

1. Selection Criteria and Sample

This was a prospective pre-/post-intervention, quantitative evaluation using primary data collection. Baseline data were collected in May 2017, and end line data were collected in December 2017. The intervention was implemented in 10 high-volume public health care facilities located in a border county in Kenya in facilities that provide POC HIV T&C as a routine service and have a HTS patient load of approximately 500 clients per month. The sampled facilities had a total of 12 medical doctors and 56 clinical officers, 137 nursing staff, and 34 clinical laboratory staff working full-time. Ten facilities were

selected because we considered them representative of the county to allow for generalization of the results. Of the 10 facilities, five received the POC QI intervention, and the other five served as controls. Facilities chosen were based on their relatively high volume of HIV care and support services that would improve the chances of reaching the required sample sizes.

For baseline and end-line surveys, a total of 346 clients were selected from the facilities. Allocation of number of clients per facility was based on the average volume of clients per month that would be tested using probability proportional to size sampling. The total sample was based on detecting a difference of 15% in the level of compliance between baseline and end line allowing for a design effect of two to account for clustering by facility.

Table 3 details the number of clients selected per facility for the baseline and end line data collection, grouped by intervention and control facilities.

Table 3: Number of participants sampled and control and intervention facilities

	Sample Size	
	Baseline	**Endline**
Control Facilities	**94**	**182**
Amaase	26	56
Lukolis	25	58
Lupida	15	28
Madende	10	20
Nangina	18	20
Intervention Facilities	**252**	**203**
Alupe	26	44
Amukura	40	26
BCTRH	110	70
Nambale	38	40
Sio Port	38	23
Grand Total	**346**	**385**

B. Intervention

In the five intervention facilities, teams analyzed gaps and iteratively tested changes to processes of care for patients undergoing POC rapid testing in participating health centers. The objective was to increase the proportion of patients receiving accurate HIV test results at the different testing points within each facility and link those testing HIV-positive and those know positives to the comprehensive care clinic.

The timeline of intervention and evaluation activities is shown in **Table 4**. Baseline data collection to determine compliance with guidelines for all elements of the POC testing process in both the intervention and control facilities was carried out from December 2016 to February 2017. QI teams for POC improvement were organized in January 2017, and coaching to support teams in making changes in care processes began in February 2017.

Table 4: Timeline of activities

Activity	Oct 16	Nov 16	Dec 16	Jan 17	Feb 17	Mar 17	Apr 17	May 17	Jun 17	Jul 17	Aug 17	Sep 17	Oct 17	Nov 17	Dec 17	Jan 18	Feb 18
Review Program Concept																	
Draft Work Plan																	
County Inception Meeting																	
Facility Mapping																	
Sub county meeting																	
Adopt/Develop asses. Tools																	
Review tools assess. Tools																	
Orient on baseline assess																	
Baseline assessment& data																	
Form QI teams																	
Select QI coaches																	
Orient coaches																	
QI training for teams																	
Develop routine database																	
Orientation to r. database																	
Monthly coaching																	
QI continuing medical education sessions																	
Coaches review meetings																	
HTS sensitization / training																	
Counsellor supervision																	
Harvest meetings																	
PT corrective action support																	
Concept of partner notification																	
Cross-border direct support																	
Learning session																	
Orientation to end line tools																	
End line assessment & data entry																	
Documentation and reports																	

Throughout the activity, QI teams self-assessed their compliance with nine HTS standards and plotted the results using time series charts. The quarterly average values from self-assessment by QI teams is presented in **Annex 1**. Depending on the gaps identified in meeting HTS standards, different changes were tested. The changes tested at all participating facilities were compiled into a package of changes, included as **Annex 2**. This "change package" included what had worked or not and how it worked under different circumstances. The change package was made available to other sites in Busia to use in improving POC testing. **Table 5** shows an excerpt from the change package of changes tested by the QI team at Nambale Secondary Care Hospital.

Table 5: Example of process changes made in one intervention site

Improving HIV testing uptake at Nambale Secondary Care Hospital by Reducing Missed Opportunities

Root Causes	*Change Idea*
- Distant HTS room	- Lobby for a HTS room in outpatient department (OPD) - Pitch HTS tent near OPD
- Clients' poor attitude towards HIV testing	- Encourage clinicians to talk to clients to know their HIV status - Health talks to incorporate HIV testing services
- Clients not knowing their way to HTS room from the consultation room	- Look for community health volunteer to direct and escort clients - Post signage showing HTS room direction

There were supervisory visits to counsellors/testers at public health facilities in which a supervisor from the MOH observed service delivery to determine if nationally mandated testing protocols were followed. As part of ensuring quality of the HIV test kits and in conformity with the national guidelines, the project supported the NHRL certified evaluators to conduct semi-annual quality assurance tests on the HIV test kits at facility level. This was done using the national testing algorithms and strategy developed by the MOH. Per NASCOP policy, external quality control (using known HIV-positive and -negative samples) should be carried out at the county or facility level for all new kit lots, new kit consignments, and when storage facilities change.

C. Data Collection

1. Baseline and end-line data collection

Baseline and end line data collection was conducted using the same quantitative data collection tools (see **Annex 3**) by a team of HTS mentors and trainers who were trained on the data collection tools by ASSIST staff. ASSIST also developed a digital database for data entry.

2. Monthly routine QI improvement data

Nine process indicators were identified and tracked monthly at the intervention facilities by the facility-based QI teams. This was done as part of the improvement intervention, and the data were used to guide the ongoing implementation of the improvement activity. The ASSIST study team worked with the county and sub-county supervisors to collect data from the control facilities as part of their routine monitoring practice (**Table 6**). A POC QI database was developed to help facility QI teams track the performance on the indicators. The coach and QI team met monthly to review the process data to check on whether the change ideas were resulting in improvement and to change them as needed. These monthly data were not included with the data collected from observations that were used in the program evaluation and cost-effectiveness analysis.

Table 6: Compliance with quality of HIV testing services indicators

		% (Dec 2016-Feb 2017)		% (Apr – Jun 2017)		% (Jul – Sep 2017)		% (Oct – Dec 2017)	
		CT*	IT**	CT	IT	CT	IT	CT	IT
1	% of patients receiving HIV pre-test counseling	78%	64%	79%	84%	80%	65%	80%	94%
2	% of test samples collected according to guideline	96%	100%	84%	90%	87%	94%	98%	100%
3	% of samples processed according to guidelines	99%	100%	100%	100%	100%	100%	100%	100%
4	% of results recorded accurately	74%	86%	79%	81%	73%	88%	76%	82%
5	% of patients receiving result	100%	100%	100%	100%	100%	100%	100%	100%
6	% of patients receiving post-test counseling	91%	86%	84%	81%	73%	94%	85%	88%
7	% of patients with HIV referred for HIV care	100%	100%	100%	92%	100%	100%	92%	92%
8	% of patients referred for HIV care and retested	86%	93%	100%	91%	67%	100%	100%	93%
9	% HIV-positive patients linked to HIV care	86%	100%	100%	90%	100%	100%	100%	100%
	Unweighted average	90%	92%	92%	90%	87%	93%	92%	94%

* CT = Control Testing Sites (2 sites within each of the 5 facilities)
** IT = Intervention Testing Sites (2 sites within each of the 5 facilities)

3. Cost data

The cost of implementing the intervention from the perspective of the implementers were collected from the accounting records of URC. They included personnel costs, transport and consumable costs of designing and conducting their part in the improvement activity, per diems, and accommodation. The cost to the Busia County Health system were not included in the calculations because health workers employed by the county conducted regular meetings for continuing education and general management of the HIV service delivery and testing program. As such, their involvement in this improvement intervention was not significantly more than the normal burden of non-patient hours. Per diem payments, transportation, and accommodations costs for county-employed facility-based health workers were included because these were part of the costs of the intervention borne by the USAID ASSIST Project.

D. Ethics Plan

This study protocol and survey instruments were submitted to the University Research Co., LLC Institutional Review Board in the United States and the African Medical Research Foundation board in Kenya, now Health Africa.

All health workers involved in HIV POC T&C and all patients selected as part of the sample were asked to sign the informed consent form. Those who chose to participate were informed that they could leave the study at any time with no negative consequences for their medical care or employment. No individual identifying information was collected in this study.

E. Data Analysis

Descriptive statistics were used to compare the pre- and post-intervention groups to determine differences in characteristics that may be confounders. Linear regression models were used to determine if there is a difference between baseline and end line measure of the quality of the processes of HIV testing. These were done for the groups of indicators (counseling, testing, and data management) and for the individual indicators that comprised these three groups.

Decision trees were used to determine the incremental cost-effectiveness ratios of the intervention versus business-as-usual (control group), controlling for secular trends in the control group from baseline to end line. Total costs of the intervention were divided by the number of patients expected to benefit from the intervention in 12 and 24 months. The probabilities of achieving the quality standards for the two measures of counseling and testing protocol compliance were taken from the regression equations. Estimated values for the probabilities with their distributions of compliance with counseling and testing were entered in the model to give 95% confidence intervals. Given that the same intervention achieves several goals simultaneously, results were also stated as expenditure to achieve the outcomes.

III. RESULTS

A total of 23 indicators, within three counseling and testing thematic areas were assessed. The three thematic areas covered were the “Skills and Knowledge” area that had nine indicators, “HIV Testing” component which had ten indicators and “Data Management” with four indicators.

In the analysis, one indicator (*Did a condom discussion and demonstration*) in the general Counseling area was dropped because during the study implementation and data collection, there was a general condom shortage in some parts of the country, including Busia County. Reasons for the shortage were varied, but they were documented and shared with the relevant authorities for action. **Annex 4** presents the baseline and end line value for each indicator comparing control and intervention facilities.

A. Counseling Indicators

In the control facilities, counseling performance dropped by 28 percentage points, whereas it increased in the intervention facilities by 19 percentage points (**Table 7**), a difference that was highly significant (p<.001).

Table 7: Change in performance on nine counseling indicators combined

	Control (%)	Intervention (%)	Difference in differences (percentage points)	p value
Baseline	81.5	62.3		
End line	53.4	81.3		
Difference	-28.1	19	47.2	p<0.001

Considering the individual components of counseling, the three areas in which there was greatest divergence between the intervention and control sites were discussing condom use, disclosure of HIV status, and referral options, with the intervention sites showing improvements while the control sites decreased performance on these counseling tasks (**Table 8**).

Table 8: Change in performance on individual counseling indicators

Indicator	Control (%)		Intervention (%)		Difference in differences (percentage points)	p value
	Baseline	End line	Baseline	End line		
Counselling	98.3	96	96.3	100	6	p=0.014
Explained to client what to expect during the session	98	91	95	97	9	p=0.001
Used appropriate counselling skills	98.1	94.9	97	98.7	4.9	p=0.031
Gave correct and up-to-date information regarding HIV/AIDS	98.6	94.2	98.1	98.1	4.4	p=0.070
Performed risk assessment	91.9	93.8	92.4	98	3.7	p=0.335
Did a condom discussion and demonstration	66.2	50.4	54.8	76.4	37.4	p<0.001
Helped client attain risk-reduction plan	93.6	81.3	87.3	93.1	18.1	p<0.001
Discussed disclosure of test results	86.7	70.4	76.4	89	28.9	p<0.001
Discussed referral options with client	87.4	62.2	78.8	89.7	36.1	p<0.001

B. Testing Indicators

When considered together, there was no statistically significant difference in the improvement seen in the testing quality indicators between the intervention and control groups (**Table 9**). When considered

separately, appropriate collection of dried blood spots (DBS) for external quality assurance (EQA) and participating and adhered to the National Health Reference Laboratory Proficiency Testing Procedures improved in the intervention facilities but decreased in performance in the control facilities (**Table 10**).

Table 9: Change in performance in 10 HIV testing indicators combined

	Control (%)	Intervention (%)	Difference in differences (percentage points)	p value
Baseline	95.1	88.5		
End line	97.1	93.6		
Difference	2	5.1	3.1	p=0.457

Table 10: Change in performance on individual HIV testing indicators

Indicator	Control (%)		Intervention (%)		Difference in differences (percentage points)	p value
	Baseline	End line	Baseline	End line		
Preparation of testing area complete with required testing commodities	99.1	98.6	96.4	96.6	0.7	p=0.767
Performed adequate finger-pricking	99.7	99.7	99.8	98.7	-1.1	p=0.203
Adequately collected client's blood sample	99.9	99.9	99.5	99.9	0.4	p=0.521
Adhered to HIV testing procedures	99	97.4	97.1	96.5	1	p=0.666
Adhered to HIV testing procedures	99	97.4	97.1	96.5	1	p=0.666
Adhered to HIV testing algorithms	98.4	99.5	96.8	99.4	1.5	p=0.340
Adhered to testing standard operating procedures (SOPs)	95.6	97.4	91.3	94.7	1.6	p=0.579
Disaggregated and disposed waste appropriately	100	100	96.9	100	3.1	p=0.081
Appropriately collected samples on DBS for EQA	81.2	44.2	76.7	92.6	52.9	p<0.001
Participated and adhered to the NHRL Proficiency Testing Procedures	81.2	44.2	76.7	92.6	52.9	p<0.001

C. Data Management

For data management indicators considered together, there was no significant improvement in the results for the intervention and control facilities (**Table 11**). When considered separately, the indicator for submission of timely, accurate, and complete data reports to the sub-county by the fifth day of the month as mandated improved substantively in the control group but remained mostly unchanged in the intervention group (**Table 12**).

Table 11: Change in performance on the four data management indicators combined

	Control (%)	Intervention (%)	Difference in differences (percentage points)	p value
Baseline	99.6	99.3		
End line	99.1	99.6		
Difference	-0.5	0.3	0.8	p = 0.302

Table 12: Change in performance on the individual data management indicators

Indicator	Control (%)		Intervention (%)		Difference in differences (percentage points)	p value
	Baseline	End line	Baseline	End line		
Timely, accurate and complete entry of client data using national data collection tools	97.5	98.1	99.3	99.7	-0.2	p=0.885
Summarized data accurately, timely and completely using national data reporting tools	95.8	98.1	97.2	98.6	-0.9	p=0.668
Submitted timely, accurate and complete data reports to sub county by 5th monthly	82.9	96.3	96.8	97.1	-13.1	p<0.001
Utilized generated data for continuous quality improvement of HIV T&C services	90	96.9	89	97.8	1.9	p=0.564

D. Individual Intervention Facilities Results

Further analysis was done on the intervention sites to examine individual facility differences. For the combined indicator for counseling, the two smallest facilities (Amukura and Sio Port) improved the least (**Table 13**). For the testing variables, two of the larger facilities improved the least but they started at the highest initial level of compliance among the intervention facilities (**Table 14**). Individual facility improvement was not statistically significant for the counseling and testing indicators. For the data management indicators, the two smallest facilities improved the least (**Table 15**). Improvements seen in the two larger facilities for data management were statistically significant.

When considering a combination of all of the quality indicators from the three domains, the two smallest facilities decreased their overall performance (number of clients seen to full compliance), but they also started at a higher baseline than the two largest facilities that started at zero (**Table 16**). When all indicators were combined, pre- to post-intervention changes were statistically significant for each facility, although in the case of the two smaller facilities, performance declined.

Table 13: Change in performance on the combined counseling indicators by intervention facility

Facility	Pre-intervention (%)	Post-intervention (%)	Difference (percentage points)	p value
County Teaching and Referral Hospital	67	96	28	p<0.001
Amukura	40	46	6	p=0.628
Nambale	61	100	39	p<0.001
Sio Port	87	65	-22	p=0.047
Alupe	81	93	12	p=0.118

Table 14: Change in performance on the combined testing indicators by intervention facility

Facility	Pre-intervention (%)	Post-intervention (%)	Difference (percentage points)	p value
Busia County Teaching and Referral Hospital	97	100	3	p=0.165
Amukura	48	80	32	p=0.621
Nambale	100	100	0	p=1.000
Sio Port	95	100	5	p=0.271
Alupe	85	95	10	p=0.121

Table 15: Change in performance on the combined data management indicators by intervention facility

Facility	Pre-intervention (%)	Post-intervention (%)	Difference (percentage points)	p value
Busia County Teaching and Referral Hospital	0	93	0.93	p<0.001
Amukura	100	0	-100	p<0.001
Nambale	100	100	0	p<0.001
Sio Port	100	83	-17	p=0.007
Alupe	0	98	98	p<0.001

Table 16: Change in performance in all 23 indicators combined by intervention facility

Facility	Pre-intervention (%)	Post-intervention (%)	Difference (percentage points)	p value
Busia County Teaching and Referral Hospital	0	89	89	p<0.001
Amukura	28	0	-28	p<0.001
Nambale	61	100	39	p<0.001
Sio Port	79	48	-31	p=0.0116
Alupe	0	86	86	p<0.001

E. Cost Analysis

The total cost of the intervention from the program perspective was US$123,000 over the nine months (**Table 17**). This included the implementation costs in the county and the Kenya-based team that implemented the improvement. It did not include the time, travel and overhead expenses for the international consultant who led the evaluation. The total number of people receiving HIV testing over 12 months was 12,838 for a program total per HIV test conducted of $9.58 per person. Considering the effectiveness of the program, this equates to an additional 1065 (95% CI: 760 – 1367) people tested that were given HIV pre- and post-test counseling that met or exceeded standards and an additional 70 people (95% CI: -12 – 254) who were tested to standards that met or exceeded the national protocol for HIV POC testing. If we assumed that this intervention had the same impact in improving quality of POC testing for an additional year following the intervention, the effect would have been twice the magnitude for the same expenditure. These gave the incremental cost-effectiveness ratios listed in **Table 18**. An example of the interpretation, taking the upper left data point is: the cost-effectiveness of this intervention is US$115 per additional patient provided counseling to full compliance to standards, compared the business-as-usual scenario. Amounts are given in 2017 US dollars, using the prevailing exchange rate with Kenyan shillings.

Table 17: Costs of intervention to project

Cost element	2017 US$
ASSIST staff salaries and travel costs	**95,245**
Participant travel, per diems, and accommodation	**8,312**
Administration, conference facilities, and materials	**19,085**
Total	**122,643**

Table 18: Incremental cost-effectiveness ratios for quality indicators

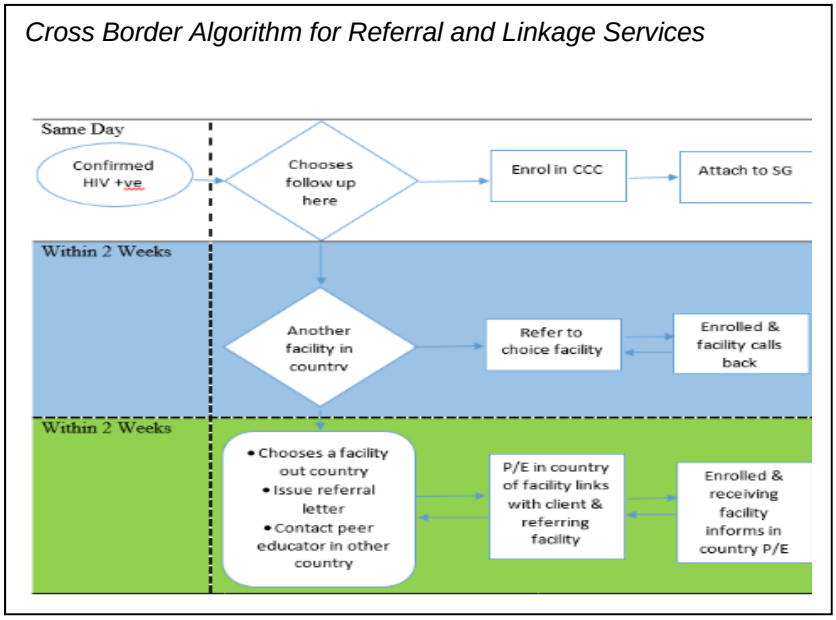
Assuming effects for 12 months	Estimate	95% confidence internal	
Counseling to compliance	20	17	28
Testing to compliance	477	191	990
Assuming effects for 24 months			
Counseling to compliance	10	8	14
Testing to compliance	239	-96	477

IV. DISCUSSION

This study was conducted over the whole of 2017. The first three months were spent finalizing the study protocol and identifying the facilities in consultation with county health officials, conducting the baseline evaluation, identifying QI coaches, organizing QI teams, and training coaches and QI team members. It was only after this set-up that the actual implementation of improvement got underway with change ideas being tested in the facilities. This initial process took some of the intervention time, and it is possible that the activities were not implemented for a long enough time to have achieved as much improvement as would have been possible with a longer period of implementation. It is also possible that the strikes that took place with health care providers over the intervention period may have reduced the overall

performance of the intervention. Nevertheless, there was substantive improvement in the counseling performance indicators in the intervention sites whereas there was a decrease in the performance of those indicators in the control sites.

Figure 1: Cross-border linkages algorithm



In Sio Port Sub County Hospital, the facility faced several challenges, including the linkage and referral and follow-up of HIV-positive patients. This was attributed by the health workers in that facility to the high proportion of their clients coming from neighboring Uganda. The reason reported for this was the fear among patients of disclosure and stigmatization among their home country community. Facility providers identified this as a major challenge and formed a cross-border HTS team with their Ugandan counterparts to address the issues.

The project supported several cross-border meetings which culminated in development of a "*Cross Border Algorithm for Referral and Linkage Services*" (**Figure 1**). It sought to advance the cross-border referrals and linkages of services between facilities in the two countries (Sio Port and Majanji). The cross-border algorithm for linkage is a guiding tool used at POC testing sites to guide with the decision options for referral of clients testing HIV-positive and ultimately their linkage. It fits with the national guidelines of both Kenya and Uganda and has been tested by teams from both countries (Sio Port and Majanji, respectively). Data and qualitative feedback from the teams in both facilities have been positive, indicating that it has played an important role in strengthening linkages and improving patient services.

A. HIV Counseling and Testing

Comparison of results between intervention and control facilities showed that whereas there were marked differences between the two in terms of improvement in performance in HIV counseling, there was no or very little difference in actual HIV testing and data management. Non-improvement in some of the indicators may be associated with the following:

- Some indicators such as "Adherence to HIV testing procedures", at 99% in control and 97.1% in intervention facilities at baseline, started at very high levels. It may not have been feasible for teams to improve performance from this very high level with the given time and resources. It is known that improvements from such high levels are subject to diminishing marginal returns (16).
- Some indicators require a longer period for the effects of the intervention to be seen. An example is the utilization of generated data for continuous quality improvement of HTS services. It is possible that, given more time, this may have improved to a greater degree.

In HIV counseling indicators, when considered separately, seven out of the nine indicators improved significantly in the intervention facilities from baseline to end line period compared to the control facilities. After the QI intervention, participating facilities improved adherence to counseling guidelines to 100%. Similar results were observed in explanations to clients about what to expect and appropriate counseling

and condom demonstration. Improvement was not seen in control facilities, which saw a slight drop in most counseling indicators. Two indicators whose improvement was not significantly different between the intervention and control were “Performed risk assessment” and “Gave correct and up-to-date information regarding HIV/AIDS”. For the “Gave correct and up-to-date information regarding HIV/AIDS” indicator, the baseline values for the intervention facilities were already very high at 98.1%, and even after the intervention, there was no change. However, in the risk assessment indicator, there was no significant difference between control and intervention facilities.

Analysis of the individual HIV testing indicators showed that seven out of nine in the intervention facilities did not improve more than in the control facilities from the baseline to end line periods.

This could be attributed to baseline values being significantly higher. Before the intervention, control facilities were performing at 95.1% whereas implementation facilities were at 88.5%. “Preparation of testing area complete with required testing commodities” started at a baseline value of 99.1% in control and 96.4% in intervention facilities. This left little room for facilities to improve. Similar trends were observed in “Performed adequate finger-pricking”, “Adequately collected client’s blood sample”, “Adhered to HIV testing procedures”, “Adhered to HIV testing algorithms”, “Adhered to testing standard operating procedures (SOPs)” and “Disaggregated and disposed waste appropriately”.

“Appropriately collected samples on DBS for EQA” and “Participated and adhered to the NHRL Proficiency Testing Procedures” did show marked improvements. However, DBS were longer being collected according to the current QA guidelines mandated by the Ministry of Health, which may explain the low uptake at baseline and also at end line for control facilities. For the NHRL proficiency testing procedures, there was reported to be inadequate support from the national NHRL team. Teams in the facilities were blinded to the results of the exercise. The POC teams had to wait until July or August 2017, well into the implementation. Improvement that took place may have been more due to these results rather than the QI interventions.

B. Data Management

Three of the four data management indicators did not improve significantly in the intervention facilities as compared to the control facilities. Only one indicator showed a significant drop in performance in the intervention facilities as compared to the control facilities. USAID and the MOH through the work of implementing partners and facilities have been on a drive to improve data management and especially reporting over the last decade. Systems for documentation, collection, collation, and reporting had been developed and rolled out to the lowest level of health service delivery. The implementing partner, APHIA Plus-Western, ensured that data were reported accurately and on time. Therefore, the data management thematic area was already performing very well in both the intervention facilities and the control facilities, with no opportunity for substantive improvement.

C. Cost-effectiveness

The incremental cost-effectiveness of the improvement intervention was less than $9 per person receiving testing services from the participating facilities. It is comparable to the cost-effectiveness reported for other HIV testing interventions in Kenya. One study of the Home-based Partner Education testing initiative in Nyanza, Kenya reported an incremental cost of $31–37 per woman in antenatal care for testing and $14–17 per couple (17). Another study of multi-disease testing in Kenya and Uganda reported a cost of $20.50 per additional HIV test, including an additional $16 per HIV-positive patient identified and given a POC CD4 count test (18). Two other studies on the cost-effectiveness or HIV testing and linking to treatment for young women were underway in 2017 but results are unavailable as of March 2018 (19, 20). Implementation of the intervention in this current study to improve the testing and counseling quality in the antenatal testing and the multi-disease testing would add about 50% to their implementation costs. Therefore, this quality improvement intervention would be a significant additional investment.

It is possible that this intervention would be more cost-effective if it had been conducted at a time when facility operations had not been adversely affected by the health workers' strikes or if the intervention could have lasted longer to achieve greater effectiveness. However, without supporting data, this is speculation.

D. Contribution of this Study

This study is important because it examined 23 indicators of quality of HTS in a setting in which we know of no other similar evaluation. In examining all 23 indicators, it is possible for those implementing improvement interventions in this setting to concentrate their activities in the areas where they see the greatest deficits compared to standards of care.

With the cost component, it provides information on the resources required to replicate this intervention in other settings.

Given the high level of compliance of most testing indicators measured in this study before the intervention began, it also shows the importance of identifying the specific areas of weakness in service provision and concentrating improvement efforts in those areas.

E. Limitations

During implementation in the intervention facilities, several complicating events beyond the control of the project team took place. These events may have affected the continuous improvement work in the intervention facilities and skills transfer to the control facilities. These may have increased or lessened the effect of the improvement activities on the outcomes of interest. The events include:

1. **The health workers strike**: Between June and November, all government-employed nurses went on strike. The testing services in the antenatal clinic were halted, and those in the outpatient clinic continued but at a lower scale. The reason services continued in the OPD was because testing services were done by HTS counselors supported by USAID implementing partners.
2. **County governments' mentorship and improvement needs**: The project team engaged the county health managers to be coaches at the implementing facilities. However, the same health managers mentored all health facilities in the jurisdiction. Some coaches mentoring the control facilities in other health areas disseminated change ideas being rolled out in the intervention facilities.
3. **Reassignment of health workers from HTS sites to other departments**: Nursing in-charges in intervention facilities sometimes reassigned their nursing staff to different sections of the facility as a routine part of human resource management. This may have been detrimental to the interventions because new staff required training and coaching on QI methods. Some staff were transferred by the county health department to other facilities, also disrupting the intervention. Some HTS nurses in the intervention facilities were transferred to control facilities, possibly transferring their QI skills to the control facilities. At least two providers were transferred between control and implementation facilities. All intervention sites received new hires who were either recent graduates or clinicians with little or no experience in HTS.
4. **Implementing partners' intervention and reporting needs**: The USAID implementing partners in the facilities had targets in health service delivery measures to meet beyond the HTS targets. To meet these targets, QI teams were formed in almost all the facilities in the county supporting HIV and malaria services. These QI teams developed change ideas that may have changed the performance, positively or negatively, of HTS services. This contamination may have led to changes in the control facilities or in the intervention sites not specifically attributable to this intervention.

5. **Shortage of condoms for condom demonstration and sharing with clients**: Kenya experienced a nationwide shortage of government-issued condoms from November to December 2017. This in turn led to shortage of condoms for demonstration and sharing with clients in some of the facilities.
6. **No random assignment of facilities**: We were not able to randomize the sites into intervention and control sites because we needed to respect the wishes of the county health authorities to implement the intervention in the sites of their choosing. We were still able to achieve adequate representation for larger and medium facilities throughout the county and also achieved good matching on facility characteristics between intervention and control groups. However, having true randomization would have improved the rigor of the study.
7. **No balancing measures**: We did not collect data on balancing measures to determine if there was spill-over from this intervention to other part of service delivery at the participating facilities. For example, we did not investigate changes in compliance with maternal and child health indicators from the same facilities to determine if there was a change over the same period. There may have been positive or negative spill-over effects in other clinical areas.
8. **Equal weighting of elements of HTS**: We did not weight the individual elements of the counseling, testing, and data management domains of HTS service delivery. It could be argued that some tasks in HTS services are more closely linked to outcomes than others, and weighting of the latter may have affected the results.

One positive aspect of the study not captured in measurement of the indicators of quality metrics was the work the intervention team did improving the follow-up and referral of patients who crossed the nearby border with Uganda. The flow of patients seeking care was in both directions and so coordination of both Kenyan and Ugandan health workers was important to ensure patients testing HIV positive were enrolled in and remained in care. As these aspects of care were not captured in the measures of quality used in this evaluation, the benefits of the intervention remained unaccounted.

V. CONCLUSION

This improvement intervention succeeded in addressing deficits in counseling. If it could be implemented at lower cost, which may be possible in the absence of the protracted health workers' strike, then it may be appropriate in similar settings. We found compliance with most HIV testing indicators high before the improvement intervention, indicating that such an intervention should be targeted to only the components of the activity in which deficits are measured.

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ANNEXES

Annex 1: Average Quarterly Performance on HTS Indicators as Self-assessed and Reported by QI Teams

		% (Jan – Mar 2017)		% (Apr – Jun 2017)		% (Jul – Sep 2017)		% (Oct – Dec 2017)	
		Control Testing Sites (10)	Intervention Testing Sites (10)	Control Testing Sites (10)	Intervention Testing Sites (10)	Control Testing Sites (10)	Intervention Testing Sites (10)	Control Testing Sites (10)	Intervention Testing Sites (10)
1	% patients receiving HIV pre-test counseling	78%	64%	79%	84%	80%	65%	80%	94%
2	% test samples collected according to guideline	96%	100%	84%	90%	87%	94%	98%	100%
3	% samples processed according to guidelines	99%	100%	100%	100%	100%	100%	100%	100%
4	% results recorded accurately	74%	86%	79%	81%	73%	88%	76%	82%
5	% patients receiving result	100%	100%	100%	100%	100%	100%	100%	100%
6	% patients receiving post-test counseling	91%	86%	84%	81%	73%	94%	85%	88%
7	% patients with HIV referred for HIV care	100%	100%	100%	92%	100%	100%	92%	92%
8	% referred for HIV care and retested	86%	93%	100%	91%	67%	100%	100%	93%
9	% HIV+ patients linked to HIV care	86%	100%	100%	90%	100%	100%	100%	100%

Annex 2: Change Concepts for Improving the Quality of Point-of-Care HTS

1. Change Concepts to Improve Documentation of HTS at POC

Change Ideas	How to guide	Notes on level of evidence from rating
Regular point-of-care team meetings to review HTS documentation using a simple checklist.	Documentation of HTS (testing, referrals, linkages and RTKs used) was done weekly at start of improvement projects, and later monthly as teams reported sustained improvement of at least six consecutive occasions, and in members of the department were tasked and a review done in subsequent meeting.	**Scored 25 / 25** No checklist existed and despite the teams trying to change their process map, and holding monthly improvement team meetings, they still stagnated. However, with the introduction of the checklist, and more frequent meetings they got better.
Continuing medical education (CME) sessions for health care providers on HTS using a QI perspective.	Continuous medical education integrated with the questioning techniques and concepts of root causes analysis, development of countermeasures, and development of simple actionable and time bound work plans were conducted to improve understanding of the team members, and staff in implementation facilities.	**Scored 25 / 25** No facility was conducting CMEs integrated with QI concepts and the teams were highly receptive of the quarterly CME sessions that were conducted.
Regular spot checks and reviews on documentation	Facilitative and supportive supervision done at random times of the day but preferably weekly and when the provider is not serving a client. Coach or unit lead reviews the critical elements in the registers and tools to confirm that they complete, accurate and timely done.	**Scored 21 / 25** Coaches considered this approach an objective way of firming up implementation and progress of each member to achieving improvements.
Daily self-reflection and assessment of documentations done to improvement documentation of services.	Team members in the department were required to reflect and review on their documentation daily and this was reported to the departmental lead, and / or asked about during work improvement team / QI team meetings.	**Scored 20 / 25** A new concept to improvement team members who reported increased remembrance of the tools and registers to use and complete encouraging them to complete documentation at the time they are serving clients.

2. Change Concepts for Improving Counselling and Testing Sessions

Change Ideas	How to guide	Notes on level of evidence from rating
Regular supportive observation sessions during HIV counselling and testing	Experienced HIV counsellor observes another HIV counsellor counsel and testing a client.	**Scored 25 / 25** No observed practice was happening when the project was rolled out. Hence, random

for HTS providers at their points-of-care.		fortnight point-of-care supportive observations were supported and those providers visited said they were strongly enriched by the hands-on experience and guidance from a more experienced colleague.
Provide and use SOPs and job aids for HTS counselling and testing.	Develop and / or adapt SOPs and job aids from the national or WHO HTS guidelines, print and distribute in all points-of-care.	**Scored 24 / 25** There were SOPs and job aids available in all points-of-care and facilities except that on HIV pre-test counselling.
Integrate counsellor supervision sessions with observed practice for routine HTS.	Have an experienced senior counsellor supervisor support the tester in their concerns, worries (offer avenue for ventilation), and share and learn; such sessions can be at the point-of-care or elsewhere within the facility.	**Scored 23 / 25** No counsellor supervision meeting had taken place in the county for more than a year citing lack of resources; therefore, providers considering its importance sought that it is integrated with observed practice / supportive supervision sessions.
Regularize CMEs for HTS providers.	Conduct CMEs on HIV counselling and testing based on needs assessment.	**Scored 20 / 25** Teams reported infrequent CME sessions focused on HTS; the more conversant the testers were with the knowledge in HTS the more likely they would offer better services.

3. Change Concepts for Improving Referral and Linkage of HIV-Positive Clients

Change Ideas	How to guide	Notes on level of evidence from rating
Engage community health volunteers (CHVs) and / or peer educators as linkage navigators for HIV positive clients at all POCs.	Engage volunteer peer educators / CHVs to escort the client to the comprehensive care clinic (CCC), ensure that they are enrolled, and to provide feedback to the testers, and update the Master Facility Linkage register.	**Scored 25 / 25** All facilities had peer educators / CHVs linking clients testing positive to the CCC but most were not updating the master facility linkage register, and / or were failing to relay feedback on successful linkage to sending facility or point-of-care.
Use a referral and linkage algorithm at all POCs daily.	Adapt referral and linkage algorithm as provided for in the latest national ART guideline; print and disseminate as a job aid to all POCs.	**Scored 25 / 25** Defaulter tracing algorithm were available at all points-of-care unlike an algorithm for referring and linking clients testing HIV positive. Participating facilities suggested that unlike the defaulter tracing algorithm, they would proactively use the linkage tool, especially in cross border populations to strengthen their referrals and linkages.
Regularize cross-border meetings.	Work with MOH departments and facilities from neighboring facilities through monthly or at least quarterly meetings to highlight and address sticking service delivery challenges and forge common	**Scored 20 / 25** Cross border meetings had stopped taking place at both Sio Port and Alupe hospitals since they required regular logistical support unavailable from the county

	resolutions to these; Having patient representatives in the meetings such as peer educators or CHVs will make them client oriented.	department of health and good will from all parties involved and supporting partners.
Continuously educate key populations on their rights.	Encourage health providers to make it routine informing clients of their rights, and informing them of what to expect during HIV testing sessions, and available alternatives.	**Scored 17 / 25** Key populations in the county preferred drop-in centres put up by rights and advocacy groups in the county; therefore, most providers were less familiar with the special needs of these clients in their routine practice with only three facilities reporting have occasional visits by these clients.

4. Change Concepts for Improving Quality Assurance and Control in HTS

Change Ideas	How to guide	Notes on level of evidence from rating
Provide and use SOPs and job aids for HTS.	Develop and / or adapt SOPs and job aids from the national or WHO HTS guidelines, print and distribute in all points-of-care.	**Scored 25 / 25** The Deputy County Laboratory Coordinator adopted one from the HTS operational guideline by WHO 2016, and it was immediately taken up by all facilities without any revisions.
Sub county lab coordinators to regularly check with the facilities on RTK validation.	Integrate RTK validation into regular (monthly / quarterly) supportive supervisions of lab leads.	**Scored 23 / 25** No sub county laboratory leads were reminding or checking with the facility to find out if HIV RTK validations have been carried out; but with coaching, the practices started.
Routinely support peripheral facilities in accessing negative sample panels through networking.	In order for the facilities to run validations, they need both a positive and negative sample; For negative samples, obtaining it from a blood bank is the ideal, and for this to happen most primary care facilities will require to organize means of transporting this sample to their facility at least once a month, otherwise and in most cases will require external help with logistics.	**Scored 20 / 25** Since no facility had access to the negative panels, and we did not have readily available means of transport, we collaborated with APHIA Plus Western through their motorbike riders (serving as sample transporters) and these samples were delivered to facilities that could not organize their own delivery on a monthly basis.
Regularly conduct capacity assessments for proficiency testing to identify providers who require to be enrolled in the proficiency scheme.	Conduct capacity and needs assessments semi-annually; Liaise with county and sub county medical laboratory officers and utilize the national HIV reference laboratory enrolment formats to collect and pass details of the new providers to	**Scored 25 / 25** Needs assessments conducted at the start of the project indicated that 56 eligible providers had not been enrolled in the scheme, and this was done in liaison with the lab leads and the reference laboratory.

	the team which will send an email to the reference lab.	
Conduct corrective actions for those who fail proficiency tests within a month of receiving results.	On site and preferably POC corrective action should be done with the laboratory leads for the sub county and hospital in liaison with the county lab head; Corrective action should address the cause of failure, though in most cases participants fail because of they did not follow instructions on the test form, poorly documented and / or failed to follow the testing algorithm.	**Scored 25 / 25** The reference laboratory took long to release results of the proficiency testing exercise that was done when the project was just starting, moreover, the county and sub county heads did not follow up the participants requiring corrective actions immediately.

Annex 3: Baseline and End Line Data Collection Tools

HTS QM Data Tools

HTS, Documentation and Reporting

County: …… Sub County: ……..
Facility Name: ……..
Point of Care: ……..
Name of Mentee: ……
Designation: Date: ……
Name of Mentor: ……..
Grading

Not done or done incorrectly	Acceptable	Good (done beyond expectation
0	1	2

Skills / Knowledge	Score
Counselling	
Explained to client what to expect during the session	
Used appropriate counselling skills	
Gave correct and up-to-date information regarding HIV / AIDS	
Performed risk assessment	
Did a condom discussion and demonstration	
Helped client attain risk-reduction plan	
Discussed disclosure of test results	
Discussed referral options with client	
Testing	
Preparation of testing area complete with required testing commodities	
Performed adequate finger-pricking	
Adequately collected client's blood sample	
Adhered to HIV testing procedures	
Adhered to HIV testing algorithms	
Adhered to testing standard operating procedures (SOPs)	
Disaggregated and disposed waste appropriately	
Appropriately collected samples on DBS for EQA	
Participated and adhered to the NHRL Proficiency Testing Procedures	
Data Management	

Timely, accurate and complete entry of client data using national data collection tools	
Summarized data accurately, timely and completely using national data reporting tools	
Submitted timely, accurate and complete data reports to sub county by 5th monthly	
Utilized generated data for continuous quality improvement of HTC services	
Logistics	
Timely submission of reports to the different HTC managers (facility, sub – county)	
Total Score	

Comments:
……
……

Mentor's signature: ……. Date
……/……/……
Mentee's signature: …….. Date
……/……/……

HTS Direct Observation Form

Observation date: ……/……/……..

Facility: …….

Point of Care: ……..

Name of HTS Provider: …….

Observer: ……

Instructions

Score as follows: 0 = not done, 1 = attempted with little success, 2 = achieved fairly, 3 = achieved successfully, N/A = not applicable

Aspects of HTC service being assessed	**Score**	**Comments**
Explained to the client what to expect?		
Appropriate skills applied?		
Gave client adequate room to talk?		
Assessed HIV risks?		
Helped client develop a risk-reduction plan?		
Explained and demonstrated correct condom use?		
Discussed other reproductive health methods and options		
Discussed disclosure of test results and, available social support		
Obtained adequate finger-prick?		
Obtained consent (verbal/written) from client prior to testing?		
Correct use of device (pipette/capillary/dropper) to harvest adequate blood sample?		
Explained clearly meaning of rest result to the client?		
Read the results at the correct timing after processing?		
Gave correct results to the right client?		
Helped client handle his / her emotional reaction?		
Gave core conditions to the client throughout the session?		
Gave adequate time to the client?		
Discussed referral options and referred client appropriately?		
Conducted client-centred session		

Session: Start time _____:_____ Stop time _____:_____

Official Stamp

Observer's Signature

National Accreditation (CITC) Tool

Accreditation is voluntary for sites providing HTC services. The accreditation assessment focuses on adequacy of existing structures (human resources, guidelines, infrastructure, safety, and information systems), key processes and results in the delivery of HTC services.

This tool is for accreditation assessment of stand-alone and integrated HTC sites.

Facility Name:	Date:
County:	Time started:
Sub County:	Time finished:
Facility Type: ☐ Stand-alone ☐ Integrated	Managing Agency:
Assessors: 1. 2. 3.	
Staff Interviewed: 1. 2. 3.	

Purpose:

To ensure continuous quality improvement systems are in place for assuring compliance with national HTC standards and guidelines.

Objectives:

1. Assess availability of staffing levels
2. Assess adherence to protocols
3. Assess availability of health education materials and condoms
4. Assess availability and use of record keeping formats
5. Assess availability of test kits and medical consumables
6. Assess adherence to staff roles and responsibilities
7. Assess general aspects of site operations

A) Staff Site Profile

Please complete table for each member of staff working in the facility

Name	Qualification Designation e.g. M.O., EC Nurse, KRCHN, BSN, CO, BScCO, MLT, Pharm tech, receptionist etc	Full Time (FT) Part Time (PT) on HTC services	Employment Status (permanent, contract, paid volunteer, unpaid volunteer, etc)

B) Site Opening Hours

Days of the Week	Opening Hours
Monday – Friday	
Saturday	
Sunday	
Public Holidays	

C) Scoring System

Instructions

Yes: Minimum standards met No: Minimum standards not met

Aim: Critical criteria questions must score 100% (15/15) and all other questions ≥ 75%

1.	At least one HTS provider available?		
2.	Trained lab technician or HTS provider able to do rapid tests available?		
3.	Secure lockable cupboard / cabinet for storing client records available (HTS provider access only)?		
4.	Kits within expiry date?		
5.	Kits stored at an appropriate temperature (fridge required if above 30 °C)		
6.	Protective clothing available and used for testing (gown and gloves)?		
7.	Sharps containers used for disposal of lancets and needles		
8.	Separate, lined bin in testing room for disposal of contaminated waste (gloves, cotton, wool, etc.)?		
9.	Safe site storage of contaminated waste until disposal?		
10.	Pit, incinerator or contractual arrangement in place for disposal of contaminated waste?		
11.	HTC register available and maintained daily?		
12.	For discrepant results, tiebreaker test performed or referred to laboratory?		
13.	Approved testing algorithm used?		
14.	Running water available?		
I.	**Structure**		
1.	*Leadership and supervision*	*Yes*	*No*
1.1.	Regular site meetings taking place?	☐	☐
1.2.	Regular QA site meetings taking place?	☐	☐
1.3.	Named sub County HTS coordinator / CASCO making monthly supervisory visits?	☐	☐
1.4.	Trained HTS supervisor supervising counsellors?	☐	☐

1.5.	Trained laboratory supervisor / sub county MLT supervising testing systems?	☐	☐
2.	*Human Resource Management*	*Yes*	*No*
2.1.	List of HTC staff available including registration, qualifications etc?	☐	☐
2.2.	Job descriptions of HTS staff available?	☐	☐
2.3.	Site / facility manager on in-charge available?	☐	☐
3.	*Policy Standards and Guidelines*	*Yes*	*No*
3.1.	National HTC guidelines available and easily accessible to providers?	☐	☐
3.2.	HTC counselling protocols available and on display?	☐	☐
3.3.	HTC testing protocols available and on display?	☐	☐
3.4.	Safety guidelines available and on display?	☐	☐
4.	*Infrastructure*	*Yes*	*No*
4.1.	Facility registered to provide HTC services?	☐	☐
4.2.	Adequate counselling room/s available (well lit, spacious, ventilated, private)?	☐	☐
4.3.	Room/s adequately equipped with 3 chairs, 1 table and separate testing area?	☐	☐
4.4.	Penile model available and on display?	☐	☐
4.5.	Room/s and waiting area well maintained and clean?	☐	☐
4.6.	Adequate waiting area (chairs and space)?	☐	☐
4.7.	Accessible clean toilets with hand washing facilities?	☐	☐
5.	*Supplies and Storage*	*Yes*	*No*
5.1.	Uninterrupted and adequate supply of non-pharmaceuticals (gloves, lancets, condoms, spirit, cotton wool, chlorine, detergent, disposable syringes)?	☐	☐
5.2.	Uninterrupted and adequate supply of rapid test kits in stock?	☐	☐
6.	*Safety*	*Yes*	*No*
6.1.	All HTS staff received Hepatitis B Immunization?	☐	☐
7.	*Referral system*	*Yes*	*No*
7.1.	Referral system in place and functioning?	☐	☐
7.2.	Referral directory / list available?	☐	☐
7.3.	Designated referral site for care and support?	☐	☐
7.4.	Post-test support available (PTC, PLHIV etc)?	☐	☐
8.	*Records and Information System*	*Yes*	*No*
8.1.	Availability of HTC register?	☐	☐

8.2.	System for confidential client information records in place and functioning?	☐	☐
8.3.	Easily retrievable copies of quarterly reports sent to s-CHMT available?	☐	☐
8.4.	Stock register available and up to date?	☐	☐
8.5.	Accident / incident book available and used?	☐	☐
8.6.	DBS and PT from NHRL easily accessible?	☐	☐
9.	*IEC Materials*	*Yes*	*No*
9.1.	Signboards, signs, labels and directions for HTS room/s?	☐	☐
9.2.	Opening hours prominently displayed?	☐	☐
9.3.	Door tags used for privacy (please enter / counselling in progress)	☐	☐
9.4.	Uninterrupted and adequate supply of HTS leaflets or posters?	☐	☐
9.5.	Information leaflets on display and available for clients?	☐	☐
9.6.	HTS posters prominently displayed>	☐	☐
9.7.	Adequate supply of condoms freely available and on display?	☐	☐
10.	Financial Management	Yes	No
10.1.	Fee charges prominently displayed and ≤ 100 KShs? (If FREE skip 10.2 & 10.3 & indicate N/A)	☐	☐
10.2.	Records of accounts available?	☐	☐
10.3.	Clear policy and measures in place for clients unable to pay?	☐	☐
II.	**Process**		
11.	*Adherence to Guidelines / Client – Provider Interaction*	*Yes*	*No*
11.1.	HTC services available on advertised days?	☐	☐
11.2.	Informed consent (signature) obtained before testing the client for HIV?	☐	☐
11.3.	Condoms supplied where appropriate?	☐	☐
11.4.	Same day blood testing conducted on site?	☐	☐
11.5.	HTC Register checked for missing items at the end of each day?	☐	☐
11.6.	Community mobilization activities being conducted?	☐	☐
11.7.	HTS Providers accessing regular supervision?	☐	☐
11.8.	HTC providers working scheduled hours (not assigned to other non-HTC services)?	☐	☐
12.	*Continuous Quality Improvement*	*Yes*	*No*
12.1.	Regular monitoring and analysis of HTS data conducted (summary sheets, graphs)?	☐	☐

12.2.	QA tools used for systematically monitoring quality of service provision (client exit interviews, counsellor self-assessment or other alternatives)?	☐	☐
12.3.	QA meetings identify areas for improvement and plan accordingly?	☐	☐
12.4.	5% of blood samples sent for quality control to a certified laboratory?	☐	☐
12.5.	All discrepant results and filter papers sent to a certified laboratory?	☐	☐
III.	**Results**		
13.	*Performance (are the following indicators calculated on a quarterly basis?)*	*Yes*	*No*
13.1.	Breakdown of clients by age, sex and test result	☐	☐
13.2.	% clients given condoms		
13.3.	% clients counselled who took an HIV test		
13.4.	% HIV +ve clients referred for care and treatment		
13.5.	% test results given same day		
13.6.	% test results indeterminate		
13.7.	Levels of concordance with reference laboratory		
13.8.	Timely submission of monthly / quarterly reports		
14.	*Client*	*Yes*	*No*
14.1.	Mechanisms for client feedback in place (exit interviews, suggestion box, complaints procedures, community meetings etc)?	☐	☐
14.2.	Client satisfaction improved over time>	☐	☐
15.	Provider	Yes	No
15.1.	HTC provider's attitude, motivation, job satisfaction and professional improvement is assessed and monitored over time (annual appraisal)?	☐	☐

Overall Remarks

Please comment specifically on each item that has scored a 'No'

No.	**Remark(s)**

Overall Results

Critical Criteria (Must score 100%)	Total Yes		Total No		Score: Y / (Y+N) * 100	%	

All other questions (Must score ≥ 75%)	Total Yes		Total No		Score: Y / (Y+N) * 100	%	
Recommended for Annual License	PASS	RE-ASSESS WITHIN MONTH/S					TEMPORARY CLOSURE

ASSESSORS

Name: Signature:	Name: Signature:	Name: Signature:

STEPWISE PROCESS FOR IMPROVING THE QUALITY OF HIV RAPID TESTING (SPI-RT) CHECKLIST

PART A: CHARACTERISTICS OF THE FACILITY OR TESTING POINT ASSESSED

Before completing the checklist, it is important to characterize the testing point to be assessed. Please provide relevant information in the summary table below.

Date of Assessment (dd/mm/yyyy)**:**	**Assessment Round No:**
Assessment Start Time:	**Assessment End Time:**
Testing Facility Name:	**Testing Facility ID:** (if applicable)
Type of Testing Point (Circle One) **VCT Inpatient PITC Outpatient PITC PMTCT TB clinic FP clinic Laboratory CCC VMMC Other** (Specify)	
Location/Address:	
Level (Circle One and specify name) **National** **County referral** **Sub-County** **Health center** **Dispensary** **Health Post:** **Other** (Please specify to reflect country context):	**Affiliation** (Circle One) **Government** **Private** **Faith-based Organization** **Non-governmental organization** **Other**(Please specify to reflect country context):
Number of HTS providers:	**Average tested per month:**
Name of the Staff Assessed:	**Name of the Assessor 1:** **Name of the Assessor 2** (if applicable)**:**

PART B. SPI- RT Checklist

For each of the sections listed below, please check **Yes, Partial or No**, where applicable. Indicate "**Yes**" only when all elements are satisfactorily present. Provide comments for each "**Partial**" or "**No**" response. State N/A in the comments section if "not applicable" where appropriate (*).

	SECTION	YES	Partial	NO	Comments	Score
1.0	**PERSONNEL TRAINING AND CERTIFICATION**					**10**
1.1	Have all testers received a comprehensive training on HIV rapid testing using the nationally approved curriculum?					

1.2	Are the HTS providers trained on the use of standardized HIV testing registers?					
1.3	Are the HTS providers trained on external quality assessment (EQA) or proficiency testing (PT) process?					
1.4	Are the HTS providers trained on quality control (QC) process?					
1.5	Are the HTS providers trained on safety and waste management procedures and practices?					
1.6	Have all HTS providers received refresher training within the last one years?					
1.7	Are there records indicating all HTS providers have demonstrated competency in HIV rapid testing prior to client testing?					
1.8	Have all HTS providers been certified through a national certification program?					
1.9	Are only certified HTS providers allowed to perform HIV testing?					
1.10	Are all HTS providers required to be re-certified periodically (e.g., every two years)?					
1.0 PERSONNEL TRAINING AND CERTIFICATION SCORE						
2.0 PHYSICAL FACILITY						**5**
2.1	Is there a designated area for HIV testing?					
2.2	Is the testing area clean and organized for HIV rapid testing?					
2.3	Is sufficient lighting available in the designated testing area?					
2.4	Are the test kits kept in a temperature controlled environment based on the manufacturers' instructions?					

2.5	Is there sufficient and secure storage space for test kits and other consumables?					
2.0 PHYSICAL FACILITY SCORE						
3.0 SAFETY						**11**
3.1	Are there SOPs and/or job aids in place to implement safety practices?					
3.2	Are there SOPs and/or job aids in place on how to dispose of infectious and non-infectious waste?					
3.3	Are there SOPs and/or job aids in place to manage spills of blood and other body fluids?					
3.4	Are there SOPs and/or job aids in place to address accidental exposure to potentially infectious body fluids through a needle stick injury, splash or other sharps injury?					
3.5	Is personal protective equipment (PPE) always available to HTS providers?					
3.6	Is PPE consistently used by all HTS providers?					
3.7	Is PPE properly used by all HTS providers through the testing process?					
3.8	Is there running clean water and soap available for hand washing?					
3.9	Is there an appropriate disinfectant to clean the work area available?					
3.10	Are sharps, infectious, and non-infectious waste handled properly?					
3.11	Are infectious and non-infectious waste containers emptied regularly per the SOP and/or job aids?					

3.0 SAFETY SCORE						
4.0 PRE-TESTING PHASE						**12**
4.1	Are there national testing guidelines specific to the program (e.g. HTS, PMTCT, TB, etc.) available at the testing point?					
4.2	Is the national HIV testing algorithm being used?					
4.3	Is there a process in place for redistribution of test kits in case of expired or shortage of test kit(s)?					
4.4	Are there SOPs and/or job aids in place for each HIV rapid test used in the testing algorithm?					
4.5	Are only nationally approved HIV rapid kits available for use currently?					
4.6	Are all the test kits currently in use within the expiration date?					
4.7	Are test kits labeled with date received and initials?					
4.8	Is there a process in place for stock management?					
4.9	Are job aids on client sample collection available and posted at the testing point?					
4.10	Are there sufficient supplies available for client sample collection?					
4.11	Are there national guidelines describing how client identification should be recorded in the HIV testing register?					
4.12	Are client identifiers (name) recorded in the HIV testing register per national guidelines and on test devices?					
4.0 PRE-TESTING PHASE SCORE						
5.0 TESTING PHASE						9

5.1	Are SOPs and/or job aids on HIV testing procedures available and posted at the testing point?					
5.2	Are timers available and used routinely for HIV rapid testing?					
5.3	Are sample collection devices (e.g., capillary tube, loop, disposable pipettes, etc.) used accurately?					
5.4	Are testing procedures adequately followed?					
5.5	Are positive and negative quality control (QC) specimens routinely used (e.g., monthly) according to country guidelines?					
5.6	Are QC results properly recorded?					
5.7	Are incorrect/invalid QC results properly recorded?					
5.8	Are appropriate steps taken and documented when QC results are incorrect and/or invalid?					
5.9	Are QC records reviewed by the person in charge routinely?					
5.0 TESTING PHASE SCORE						
6.0	**POST TESTING PHASE - DOCUMENTS AND RECORDS**					**9**
6.1	Is there a national standardized HIV rapid testing register available and in use?					
6.2	Does the HIV testing register include all of the key quality elements?					
6.3	Are all the elements in the register recorded/captured correctly? (e.g., client demographics, kit names, lot numbers, expiration dates, HTS provider name, individual and final HIV results, etc.)?					
6.4	Is the total summary at the end of each page of the register complied accurately?					

6.5	Are invalid test results recorded in the register?					
6.6	Are invalid tests repeated and results properly recorded in the register?					
6.7	Are all client documents and records securely kept throughout all phases of the testing process?					
6.8	Are all registers and other documents kept in a secure location when not in use?					
6.9	Are registers properly labeled and archived when full?					
6.0 POST TESTING PHASE - DOCUMENTS AND RECORDS SCORE						
7.0 EXTERNAL QUALITY ASSESSMENT (PT, SUPERVISION AND RETESTING)						**8/14**
7.1	Are the HTS provider enrolled in an EQA/PT program?					
7.2	Do all HTS providers at the testing point test the EQA/PT samples?					
7.3	Does the person in charge at the testing point review the /PT results before submission to NHRL or designee?					
7.4	Is an EQA/PT report received from NHRL and reviewed by HTS providers and/or the person in charge at the testing point?					
7.5	Does the testing point implement corrective action in case of unsatisfactory results?					
7.6	Does the testing point receive periodic supervisory visits?					
7.7	Is feedback provided during supervisory visit and documented?					
7.8	If HTS providers need to be retrained, are they being retrained during the supervisory visit?					
If the country external quality assessment program includes retesting of serum or DBS, proceed with questions 7.9 – 7.14.						

Otherwise, STOP here.						
7.9*	Does the site collect samples for retesting according to country guidelines (e.g., collection of every 20th client serum or DBS sample)?					
7.10*	Are the serum or DBS samples collected for retesting properly documented?					
7.11*	Are serum or DBS samples collected properly (e.g., at least 3 complete circles or correct volume and correct tubes, etc.)?					
7.12*	Are serum or DBS samples stored properly (e.g., away from sunlight, separated by glassine paper, desiccant, or at 4oC or 20oC, etc.)?					
7.13*	Are the identifiers of serum or DBS samples sent for retesting properly recorded?					
7.14*	Are the serum or DBS results received from the referral lab properly documented and recorded in the HIV testing register/logbook?					
7.0 EXTERNAL QUALITY ASSESSMENT (PT, SUPERVISION AND RETESTING) SCORE						

- *Those marked with an asterisk are only applicable to sites where sample retesting is performed.

PART C: SCORING CRITERIA

Each element marked will be assigned a point value:

- Items marked “Yes” receive 1 point each.
- Items marked “Partial” receive 0.5 point each.
- Items marked “No” receive 0 point each.

Total points scored for each section should be tallied and recorded at the end of the section.

The overall total points obtained by each HIV testing point Assessed will be weighed to correspond to a specific performance level.

Levels	% Score	Description of results
Level 0	Less than 40%	Needs improvement in all areas and immediate remediation
Level 1	40% - 59%	Needs improvement in specific areas
Level 2	60%-79%	Partially eligible

Level 3	80%-89%	Close to national site certification
Level 4	90% or higher	Eligible to national site certification

Part D. Assessor's Summation Report for SPI-RT Assessment

Site Name: _____ Site Type: _____ Staff Assessed_____	No. of HTS providers: _ Duration of Assessment : ___	Total Scored (exclude) N/A= a Total Score Expected = b % Score = (a/b) x 100 Performance Level: 0 1 2 3 4 (<40%) (40-59%) (60-79%) (89-90%) (>90%)

Section No.	Deficiency/ Issue observed	Correction Actions		Assessor's Comments	Recommendations	
		Immediate	Follow-up		Actions	Timeline / Person responsible

Staff Assessed Signature:_____
_____

Person in Charge Name and Signature:
_____

Assessor Name and Signature:
_____
___

Date (dd/mm/yyyy):
_____
_____

Annex 4: Detailed Baseline and End Line Evaluation Results

Indicator		Control (%)	Intervention (%)	Difference in differences (percentage points)	p value
All counseling	Baseline	81.5	62.3		
	End line	53.4	81.3		
	Difference	-28.1	19	47.2	p<0.000
All testing	Baseline	95.1	88.5		
	End line	97.1	93.6		
	Difference	2	5.1	3.1	p<0.457
Timely submission of reports	Baseline	99.6	99.3		
	End line	99.1	99.6		
	Difference	-0.5	0.3	0.8	p<0.302
Counseling	Baseline	98.3	96.3		
	End line	96	100		
	Difference	-2.3	3.7	6	p<0.014
Explained to client what to expect during the session	Baseline	98	95		
	End line	91	97		
	Difference	-7	2	9	p<0.001
Used appropriate counselling skills	Baseline	98.1	97		
	End line	94.9	98.7		
	Difference	-3.2	1.7	4.9	p<0.031
Gave correct and up-to-date information regarding HIV / AIDS	Baseline	98.6	98.1		
	End line	94.2	98.1		
	Difference	-4.4	0	4.4	p<0.070
Performed risk assessment	Baseline	91.9	92.4		
	End line	93.8	98		
	Difference	1.9	5.6	3.7	p<0.335
Did a condom discussion and demonstration	Baseline	66.2	54.8		
	End line	50.4	76.4		
	Difference	-15.8	21.6	37.4	p<0.000
	Baseline	93.6	87.3		

Helped client attain risk-reduction plan	End line	81.3	93.1		
	Difference	-12.3	5.8	18.1	p<0.000
Discussed disclosure of test results	Baseline	86.7	76.4		
	End line	70.4	89		
	Difference	-16.3	12.6	28.9	p<0.000
Discussed referral options with client	Baseline	87.4	78.8		
	End line	62.2	89.7		
		-25.2	10.9	36.1	p<0.000
Preparation of testing area complete with required testing commodities	Baseline	99.1	96.4		
	End line	98.6	96.6		
	Difference	-0.5	0.2	0.7	p<0.767
Performed adequate finger-pricking	Baseline	99.7	99.8		
	End line	99.7	98.7		
	Difference	0	-1.1	-1.1	p<0.203
Adequately collected client's blood sample	Baseline	99.9	99.5		
	End line	99.9	99.9		
	Difference	0	0.4	0.4	p<0.521
Adhered to HIV testing procedures	Baseline	99	97.1		
	End line	97.4	96.5		
	Difference	-1.6	-0.6	1	p<0.666
Adhered to HIV testing procedures	Baseline	99	97.1		
	End line	97.4	96.5		
	Difference	-1.6	-0.6	1	p<0.666
Adhered to HIV testing algorithms	Baseline	98.4	96.8		
	End line	99.5	99.4		
	Difference	1.1	2.6	1.5	p<0.340
Adhered to testing standard operating procedures (SOPs)	Baseline	95.6	91.3		
	End line	97.4	94.7		
	Difference	1.8	3.4	1.6	p<0.579
Disaggregated and disposed waste appropriately	Baseline	100	96.9		
	End line	100	100		
	Difference	0	3.1	3.1	p<0.081
	Baseline	81.2	76.7		

Appropriately collected samples on DBS for EQA	End line	44.2	92.6		
	Difference	-37	15.9	52.9	p<0.000
Participated and adhered to the NHRL Proficiency Testing Procedures	Baseline	81.2	76.7		
	End line	44.2	92.6		
	Difference	-37	15.9	52.9	p<0.000
Timely, accurate and complete entry of client data using national data collection tools	Baseline	97.5	99.3		
	End line	98.1	99.7		
	Difference	0.6	0.4	-0.2	p<0.885
Summarized data accurately, timely and completely using national data reporting tools	Baseline	95.8	97.2		
	End line	98.1	98.6		
	Difference	2.3	1.4	-0.9	p<0.668
Submitted timely, accurate and complete data reports to sub county by 5th monthly	Baseline	82.9	96.8		
	End line	96.3	97.1		
	Difference	13.4	0.3	-13.1	p<0.000
Utilized generated data for continuous quality improvement of HTC services	Baseline	90	89		
	End line	96.9	97.8		
	Difference	6.9	8.8	1.9	p<0.564

USAID APPLYING SCIENCE TO STRENGTHEN AND IMPROVE SYSTEMS PROJECT

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