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ARETROSPECTIVE EVALUATION OF PROFICIENCY TESTING, AND RAPID HIV TEST KITS STOCK-OUTS AMONG HTC FACILITIES WITHIN NAIROBI COUNTY

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**A RETROSPECTIVE EVALUATION OF
PROFICIENCY TESTING, AND RAPID HIV TEST KITS
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M. E. IRERI, M. W. MUTUGI, N. L. MUTHAMI, M. KIPTOO and E. M. SONGOK

ABSTRACT

Background: Proficiency testing (PT) has been implemented as a form of External Quality Assurance (EQA) by the National HIV Reference Laboratory in Kenya since 2007 in order to monitor and improve on the quality of HIV testing and counselling HTC services.

Objective: To compare concordance between National HIV Reference laboratory, and HIV testing and counseling (HTC) facilities.

Design: A telephone survey was conducted to access consistencies in PT schemes. An independent EQA assessment questionnaire was developed and pretested on a randomly chosen sample of HTC facilities.

Setting: HTC facilities selected from Client-initiated HTC and Provider-initiated HTC facilities, within Nairobi County.

Subjects: The HTC facilities were randomly selected (n = 45).

Results: Inconsistencies and tremendous increase in non-participation in PT schemes. Gender χ^2 (5, N = 45) = 13.83; $p = .017$, experience using rapid test kits χ^2 (5, N = 45) = 5.417; $p = .020$, and current facility ever participating in any PT scheme χ^2 (5, N = 45) = 15.38, $p = .009$, had significant effects in participation in PT schemes. Some facilities experienced test kits stock-outs most of the time ($2.552 \geq 3.777$), while others sometimes ($1.326 \geq 2.551$), t (43) = 3.105; $p = 0.003$. However, there was no link between non-participation in PT schemes and test kits stock-outs.

Conclusion: The results generated by the study revealed inconsistencies in PT schemes and Test Kits stock-outs from 2012 up to May 2014. These findings will assist in the full adoption of HTC policy guidelines and ensure each and every HTC personnel participate in all PT quarters consistently. Challenges in forecasting, and quantification remains a major barrier to HTC supplies.

INTRODUCTION

HIV testing and counseling (HTC) is the main entry point to prevention, care and treatment (1-3). HTC has experienced very rapid growth in Kenya since it was launched in 2001. It has contributed significantly to the reduction of stigma associated with HIV/AIDS, and the promotion of behaviour change. It has also facilitated access to prevention, care and treatment for people living with HIV/AIDS. Hence the need for quality assurance systems being established at all sites carrying out HIV testing (4). The earliest data available regarding HIV testing in Kenya is from the 1998 Kenya Demographic Health Survey (5). The report (6) outlined district VCT services as core indicators whereas the quality of VCT laboratories that adheres to the WHO testing protocol, and blood safety protocol were prioritised as additional indicators. In

2002, the government of Kenya developed a proposal to seek funds at the Global Trust fund on AIDS, TB, and Malaria with the intention of reduction of HIV prevalence through prevention and advocacy with the broad activities in scaling up existing VCT Services and training of counselors (7).

The report on (3), also lead to the development of quality assurance on HTC in Kenya. The quality assurance includes, proficiency testing at test site. Quality assurance systems were to be established at all sites carrying out HIV testing. The systems were to include validated standard operating procedures, internal and external quality assessment (for example. proficiency testing), testing aligned with national algorithms, and use of HIV assays approved and validated by the national reference laboratory (8). Retesting by random sampling of 5% or 10% of all specimens positives and negatives

, presented a considerable burden to the reference laboratory and hence emphasize on-site monitoring was recommended for performing external quality assessment (9). The phrase HIV testing and counseling, is the essence of the strategy to bridge the gap between two distinct HTC approaches in Kenya. Many Kenyans are familiar with *Client-initiated HTC*, which is also known as voluntary counseling and testing (VCT). Health workers are also familiar with *Provider-initiated HTC (also called PITC)*, which was previously known as Diagnostic HIV testing and counseling (DTC). Unlike DTC which targets sick people PITC targets all patients and clients in the health facility. The CDC (10) recommendations acknowledged that Kenya had adopted some of their concepts on testing personnel and training which includes personnel qualification for V.C.T (Grade C+ and above at O level), adopted modern methods of training (In service training and computer literacy) , modes of competence assessment (through pre-course theory , post-course theory, and continuous active participation throughout the course), certificate awards and assessing of performance tasks for HIV testing before, during and after testing (10,11) During the past fifty years, the use of telephones for the collection of survey data has been transformed from a rare and often criticised practice into the dominant mode of data collection in government, academic, and private sector survey research. Researchers in all fields have come to recognise that the advantages of telephone interviewing are numerous, most notably the substantially lower cost (12).The appeal of telephone interviewing (13-15), (15), is multifaceted, because this method has many practical advantages, most notably reduced cost, the possibility of quick turnaround time, and the possibility of closer supervision of interviewers to assure greater standardisation of administration.

A telephone evaluation survey was undertaken to identify gaps in 45 HTC sites in Nairobi County with the view of recommending appropriate interventions and action plan to address the gaps and scale up proficiency testing overtime. In the study, knowledge of PT schemes, current site participation in PT scheme, participation in PT schemes since 2012 up to May 2014, and levels of education were investigated using gender, type of HTC facility, designation of HTC personnel and experience in testing HIV using rapid test kits. This paper provides an overview of the general achievements and gaps for Proficiency Testing in HTC facilities in Nairobi County as at May 2014 with references to (4,16).

MATERIALS AND METHODS

A randomised telephone survey was conducted from May 28th, 2014 to June 6th 2014 excluding 1st June (Sunday) and 2nd June (Public Holiday).

Socio-demographic and explanatory variables were collected using a structured questionnaire. The measurable indicators were designed from the (4) guidelines. We combined the structured questionnaire and semi-structured interview with telephone survey for the first time. In the structured questionnaire, the HTC staff responded to prompts by selecting from predetermined answers (for example Likert scales, multiple choice responses), and these data were typically analysed quantitatively. In the semi-structured interview, we began with a small set of open-ended questions, but spend considerable time (average time ≥ 40 minutes per respondent) probing responses, encouraging them to provide details and clarifications, and the data was analysed qualitatively. The questionnaire had both quantitative and qualitative questions. Data was captured on MS Excel spreadsheet. The data set was cleaned and imported to R script version 3.0.3 (2014-03-06) for coding and analysis. An exploratory data analysis was carried out to check for inconsistencies. The relationships between variables were explored using cross-tabulations. The data from the questionnaire was categorical (both the predictors and the outcomes variables). Univariate analysis, logistic regression, and Chi-square tests were performed. A 5% level of significance was considered significant for all analysis.

RESULTS

Logistic regression was used to predict the categorical dependent variables from a set of predictor categorical variables: The dependent variables were: knowledge of PT, HTC analysts ever participating in any PT schemes in their career, the analysts current HTC facility participation in any PT scheme, Participation in any PT scheme (from 2012,2013, up to May 2014), and the highest level of education of the HTC analyst. The categorical dependent variables were: gender, type of HTC facility, designation of the HTC analyst, years worked at the present HTC facility, and experience in testing HIV using rapid HIV test kits.

Knowledge of Proficiency Testing (PT): Overall a majority of respondents (61.9%) had greater than five years' experience in HIV testing using rapid test kits. Logistic regression analysis was employed to predict the probability that the HIV analysts would have knowledge of PT. The predictor variables were participant's gender, type of the HTC facility, designation at the facility, years spent at present facility, and experience in HIV testing using rapid test kits. The dependent coding used were knowledge of PT=1, Lack of knowledge =0. A test of the full model versus a model with intercept was tested. The omnibus test of model co-efficient effect of experience in testing HIV using rapid test kits fell short of significance, $\chi^2(5, N = 45) = 8.316, p = .140$. The model was able to

correctly classify 100% of those who had knowledge of PT with ≥ 5 years testing experience and .0% of those lacking knowledge on PT with ≥ 5 years testing experience, for an overall success rate of 93.3%.

Table 2 shows the logistic regression co-efficient, Wald test, and odds ratio for each of the predictors. Employing a .05 criterion of statistical significance, experience in testing HIV using rapid test kits had significant effect on knowledge of Proficiency Testing. Inverted odds ratio for experience in HIV testing using rapid test kits indicate that the odds of knowledge on PT schemes were 30.3 times less for the analysts with <5 years testing experience than for those with ≥ 5 years testing experience. Univariate analysis indicated that HTC analysts with ≥ 5 years testing experience were significantly likely to have knowledge of PT (97.4% against 2.2%) than those with <5 years testing experience (66.7% against 33.3%) in HIV testing using rapid test kits, and $\chi^2(1) = 7.912$, $p = .005$. Likewise 2.2% of analysts with ≥ 5 years testing experience against 33.3% with <5 years testing experience didn't have even the slightest knowledge of the meaning of Proficiency Testing.

Overall, 84.4% with ≥ 5 years testing experience against 8.9% with <5 years testing experience, had knowledge on Proficiency Testing. Results on gender, type of HTC facility, designation of the analyst at the facility, and years worked at their present HTC facility were insignificant. This finding strongly indicates the evidence that participation in PT schemes is influenced by prior knowledge of PT schemes (figure 1). Our findings on participation in PT schemes versus the experience in testing HIV using rapid kits revealed the experience bracket 5-10 years had the highest participation in PT schemes. Therefore HTC analysts with ≥ 5 years testing experience are more likely to be aware of PT schemes and ever participating in any of PT schemes (89.7% against 10.3%) than those with <5 years testing experience (66.7% against 33.3%) in HIV testing using rapid test kits, $\chi^2(1) = 11.32$, $p = .001$ (figure 1).

The analysts' current HTC facility participation in any PT scheme: Overall a majority of respondents (71.4%) with greater than 5 working years at their present facility acknowledged that their present facility had participated at least once in a PT scheme. Logistic regression analysis was employed to predict the probability that the current HTC facilities had participated in PT schemes. The predictor variables were participant's gender, type of the HTC facility, designation at the facility, years spent at present facility, and experience in HIV testing using rapid test kits. The dependent coding used were current facility participation=1, Lack of knowledge=0. A test of the full model versus a model with intercept was tested. The omnibus test of model coefficient effect of years worked at the current facility was significant,

$\chi^2(5, N = 45) = 15.38$, $p = .009$. The model was able to correctly classify 91.4% of those with ≥ 5 years testing experience at current facilities and 50% of those with ≥ 5 years testing experience but had not participated in PT at their current HTC facilities, for an overall success rate of 82.2%. Table 2 shows the logistic regression coefficient, Wald test, and odds ratio for each of the predictors. Employing a .05 criterion of statistical significance, years spent at the current HTC facility had significant effect on acknowledging that the current HTC facility had participated in any PT scheme. Inverted odds ratio for years spent at the facility indicate that the odds of acknowledging participation PT schemes at current facilities were 26.32 times less for the analysts with greater than five years working experience at present facility than for those with ≥ 5 years working experience at present facility. Univariate analysis indicated that HTC personnel with less than five years were significantly unlikely to have acknowledged their current HTC participation in PT (28.6%) than those with ≥ 5 years' experience (71.4%), and $\chi^2(1) = 8.571$, $p = .003$. Also (80%) with <5 years working experience couldn't recall their facility participating in any PT scheme against (20%) with ≥ 5 years working experience. Overall, 77.8% against 22.2% recalled PT schemes being conducted at their facilities. Results on gender, type of HTC facility, designation of the analyst at the facility, and experience in HIV testing using rapid test kits were insignificant.

Participation in any PT scheme (from 2012, 2013, up to May 2014): The logistic regression co-efficient, Wald test, and odds ratio for each of the predictors for participating in PT schemes in 2013 up to May 2014 were insignificant. However, the results for 2012 were significant employing a .05 criterion of statistical significance.

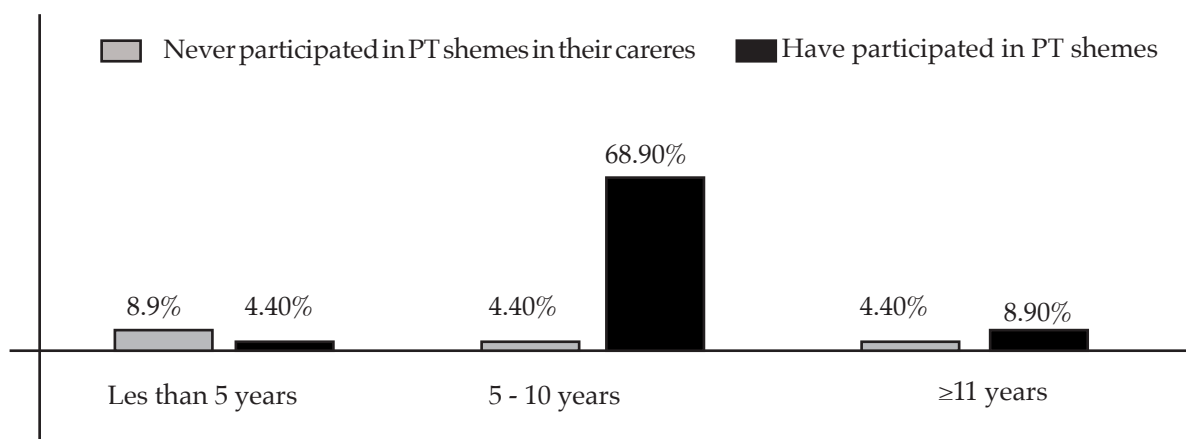
Overall a majority of females (88.9%) had not participated in a PT scheme in 2012 while (55.6%) had participated. The males' statistics indicated (11.1%) had not participated in a PT scheme in 2012 while (44.4%) had participated. The results also indicated that majority (96.7%) of HTC analysts with greater than 5 years' experience in HIV testing using rapid test kits participated in proficiency testing in 2012 while 72.2% didn't. Also 27.8% of those with less than 5 years of testing experience didn't participate in PT in 2012 while only 3.7% participated. Logistic regression analysis was employed to predict the probability of participating in any PT quarter in 2012. The predictor variables were participant's gender, type of the HTC facility, designation at the facility, years spent at present facility, and experience in HIV testing using rapid test kits. A test of the full model versus a model with intercept was tested. The omnibus test of model coefficient effect for gender was significant, $\chi^2(5, N = 45) = 13.83$, $p = .017$. The model was able to classify

correctly 85.2% of HTC analysts had participated in any PT quarter and 38.9% of them had not participated in any PT quarter, for an overall success rate of 66.7%. The success rate of the model improved from 60% to 62.2% for gender, and 60% to 68.9% for experience in HIV testing using rapid test kits. Table 2 shows the logistic regression co-efficient, Wald test, and odds ratio for each of the predictors. Employing a .05 criterion of statistical significance, gender had significant effect on participation in any PT quarter in 2012. Inverted odds ratio for gender indicates that the odds of participation in any PT quarter in 2012 were 11.36 times less for the female HTC analysts than their male counterparts. The table also shows the odds ratio for the predictor experience in HIV testing using rapid test kits having a significant effect on participation in any PT quarter in 2012. Inverted odds ratio for experience indicates that the odds of participation in any PT quarter in 2012 were 22.22 times less for the HTC analysts with less than 5 years testing experience than those with greater than 5 years testing experience. Univariate analysis indicated that the female HTC analysts were significantly likely not to participate in PT in 2012 (88.9%) than males (11.1%), and $\chi^2(1) = 5.599$, $p = .018$. The analysis on experience indicated that HTC analysts with greater than 5 years were significantly likely to participate in PT schemes in 2012 (96.3%) than those with less than 5 years (3.7%), and $\chi^2(1) = 5.417$, $p = .020$. Results on type of HTC facility, designation of the analyst at the facility, and years spent at current facility were insignificant.

The highest level of education of the HTC analyst: The logistic regression coefficient, Wald test, and odds ratio for the predictor designation was significant employing a .05 criterion of statistical significance. Overall a majority of HTC counselors (95.8%) had secondary education with counseling courses while (38.1%) had tertiary education. Majority of the medical personnel (61.9%) had tertiary education while (4.2%) had secondary education with counseling courses. Logistic regression analysis was employed to predict the probability of having the highest level of education and offering HTC services. The predictor variables were participant's gender, type of the HTC facility, designation at the facility, years spent at present facility, and experience in HIV testing using rapid test kits. A test of the full model versus a model with intercept was tested. The omnibus test of model coefficient effect for the highest level of education attained by the analyst was significant, $\chi^2(5, N = 45) = 22.70$, $p < .001$. The model was able to classify correctly 95.8% of HTC analysts had secondary education with counseling courses and 61.9% of them had

tertiary education, for an overall success rate of 80%. The success rate of the model improved from 53.3% to 80%. Employing a .05 criterion of statistical significance, the levels of education had significant effect on the designation of the analyst at the HTC facilities. Inverted odds ratio for education indicates that the odds of having tertiary education were 37.04 times less for the HTC counselor than the medical personnel offering HTC services. Univariate analysis indicated that the medical personnel offering HTC services were significantly likely to have tertiary education (28.9%) than HTC counselors (17.8%), and $\chi^2(1) = 17.421$, $p < .001$. Likewise 51.1% of HTC counselors had secondary education coupled with a counseling course compared to 2.2% of the medical personnel (Table 2).

Comparison of test variables: participation in PT quarters in 2012, 2013, up to May 2014 : A composite score was designed to measure the predictor variables, and the number of quarters participated in proficiency testing from 2012, 2013, up to May 2014. The composite score for participation in Proficiency Testing in 2012 had mean scores of 0= none, 0.1 \geq 1.09= 1PT Quarter, 1.1 \geq 2.09= 2 PT Quarters, 2.1 \geq 3.09= \geq 3 PT Quarters. The maximum score was 3 and the minimum score was 0. Table 10 shows the independent sample t-test results for the statistically significant predictor variables and participation in PT scheme in 2012. An independent-samples t-test was conducted to compare participation in PT schemes in 2012 for male analysts and female analysts. Overall, the mean score on PT participation in 2012 was (M=1.33, SD=1.28). This result reveals that in 2012, a majority of HTC facilities only participated in two PT Quarters. The composite score for participation in Proficiency Testing in 2013 had mean scores of 0= none, 0.1 \geq 1.09= 1PT Quarter, 1.1 \geq 2.09= 2 PT Quarters, 2.1 \geq 3.09= \geq 3 PT Quarters, \geq 3= 4 PT Quarters. The maximum score was 4 and the minimum score was 0. A composite score was also designed to measure the stock-out experiences of rapid test kits at the HTC facilities and the spent at the present HTC facility. The composite score had mean scores of 0= none, 0.1 \geq 1.325= Rarely, 1.326 \geq 2.551= Sometimes, 2.552 \geq 3.777= Most times, and 3.778 \geq 5.000= All times. The maximum score was 5 and the minimum score was 0. There was no statistically significant differences between participation in PT schemes in 2012 and facility type, designation, years worked at the facility and level of education.

Figure 1*Participation in PT schemes versus the experience in testing using rapid HIV test kits***Table 1***Summarizes the significant binary logistics regressions*

Predictors	B	Wald χ^2	p	Odds Ratio
Logistic Regression Predicting Decision on Knowledge of Proficiency Testing (PT).				
Experience	-3.42	4.012	0.045	0.033
Constant	23.398	0	0.998	1.45E+10
Logistic Regression Predicting Decision on the analysts' current HTC facility participation in any PT scheme.				
Years spent at Facility	-3.269	7.276	0.007	0.038
Constant	2.214	1.289	0.256	9.151
Logistic Regression Predicting Decision on Participation in any PT scheme 2012.				
Gender	-2.436	4.535	0.033	0.088
Experience	-3.1	4.443	0.035	0.045
Constant	2.071	1.852	0.174	7.932
Logistic Regression Predicting Decision on Designation and PT participation.				
PT 2014	1.769	4.229	0.04	5.867
Constant	-20.785	0	0.999	0

DISCUSSION

"Lack of structured training on quality management in HIV and AIDS programmes, weak and sometimes lack of support in quality systems, inadequate and selected supervision, inadequate external quality assessment system as examples, impact negatively on quality of HIV testing and counselling services. Quality system strengthening through training, supervision, quality assessment provision of relevant tools and engagement of laboratory within the settings are the missing links required to provide impetus for good quality management in HTC programme" (12). This paper provides an overview of the general achievements and gaps for proficiency testing in HTC sites in Nairobi County as at May 2014 with (4, 16) as references.

Knowledge of Proficiency Testing (PT): Proficiency testing has always been implemented as a form of

EQA by the National HIV Reference Laboratory (NHRL) in Kenya. The NHRL creates blood or serum samples of pre-known HIV status, sends a panel of different samples to regional laboratories and HTC sites for testing, which then send the results back to the NHRL for analysis. The purpose of this method of EQA is to compare concordance between national and regional laboratories and HTC facilities. Feedback is sent to the HTC facility on whether their results are concordant with the NHRL, and adjustments are made as necessary to improve testing quality. Our study had anticipated that the greater the experience in HIV testing using rapid test kits, the higher the percentage score in terms of PT participation. This was not the real picture (figure 1). The results showed that still there are HTC analysts with over 5 years' experience who cannot tell what the words HIV proficiency testing mean. This is not acceptable under all standards. Lack of Knowledge on PT will continue to be among the factors that will

continue posing major challenge in participation in PT schemes. If an HTC analyst in Nairobi County, a cosmopolitan city does not know the meaning of PT, at what percentage confidence level can we be in stating that the HTC analysts who are based in rural facilities in limited resource settings knows about PT schemes or even have ever participated in this schemes ?. Knowledge and awareness of PT schemes can only be improved through regular HTC refresher courses and other continuous development programmes. A similar study (17) clearly states that experience in rapid HIV testing and proficiency are not necessarily equivalent. Proficiency depends on experience. Experience and training are important before proficiency can be assured.

The analysts' current HTC facility participation in any PT scheme: The study indicated that HTC analysts with ≥ 5 years working experience at present facility are at a better position to recall participation patterns in PT schemes since 2012. The reality on the ground is that the longer the number of years spent at a testing facility, the more likely a HTC personnel is able to recall past events at the facility. This information backs the data that were collected as the real situation in the field. However, other factors needs to be factored in for those with <5 years working experience. Some HTC analysts were part-time volunteers, sessional counsellors, newcomers at their facilities, women on maternity leave, lack of proper documentation on PT programs at HTC facilities, others joined the facilities in 2012 when inconsistencies in PT schemes and test kits stock-outs started. Thus, they were unlikely to participate in any PT scheme and hence their recall to the current facility participating in any PT scheme is highly compromised. Local laboratories and technical staffing within health facilities can be utilised to ensure every HTC personnel participates in PT schemes. We concur with the recommendation (16), that management of some aspects of 'external' quality assessment (out of laboratory but within facility) by a local laboratory needs to be adopted. This will enhance frequency – of participating in PT schemes- and ensure majority of HIV testing provider's access proficiency testing unlike its current situation.

Participation in any PT scheme (from 2012, 2013, up to May 2014): PT schemes are very expensive to conduct right from preparation of panels, transportation and storage of the panels, no forgetting the challenging logistics in terms of location of some HTC facilities. Most facilities have adopted a random rotational method to at least allow each and every member in their HTC facility to participate in PT schemes. The PT scheme were first implemented in Kenya in 2007 and no justification warrants why seven years down the line some HTC staff have never participated in PT schemes even once. To be able to scale up PT schemes, each and every HTC service provider should

be enrolled into the programme irrespective of the setting of their facility. All the analysis on proficiency testing proves that there is a gap in participation in PT programs in Nairobi County and also there are no consistencies in participation. However, the results reveals that almost all the HTC staff interviewed were willing to continue participating in the PT schemes. Qualitative analyses (Figure 3) were done to capture the main reasons for not participating in PT schemes since 2012. Training health care providers as VCT counselors and establishing VCT in health facilities was made challenging by creating additional counseling duties for already sparse staff whose primary priorities were curative, often to the detriment of VCT services. Health worker attitudes and stigma, and the view that HTC was an additional and not a core responsibility were barriers (18). The Provider-Initiated HTC staff had 20% of their staff who had never participated in any PT scheme. The main reason was because of too clouded assignments of duty at their health facility, multitasking and frequent change of working station (staff rotations) common in health facilities (12). Some respondents also missed opportunities to participate in PT schemes due to maternity leave. We run some cross tabulations on gender to see whether we could associate missing PT schemes with maternity leave. The results revealed that the female HTC staff had the highest number of staff who had never participated in PT schemes 6(13.3%) while their male counterparts had the least two (4.4%). Provider-Initiated HTC facilities mostly have integrated HTC services and different staff handling the services. Other commitments had the highest responses at 31.58%. Those affected most in the category are mostly volunteers and sessional counselors who at times are making money elsewhere and only offer their services during their free time and hence priority to participate in PT schemes are given to the full time staff at the facilities. A study in Tanzania (19) clearly indicates some challenges that HTC facilities facing as a result of task-shifting. Kenya is not an exception to task-shifting challenges. The odds ratio on designation of the HTC personnel indicates that the odds of participating in any PT quarter in 2014 were 5.87 times higher for the HTC counselors than the medical personnel. This finding indicates that more medical personnel are finding it difficult to balance between participating in PT schemes and the numerous assignments at their health facilities. We would recommend that the government provides enough budgetary allocation to employ permanent HTC staff dedicated to HIV testing and counseling only. We strongly believe that task-shifting in its true state can hinder an HTC analyst from participating in PT schemes continuously.

Comparison of test variables for participation in PT quarters in 2012, 2013, up to May 2014: These results suggest that gender has an effect on participation in

a PT scheme. Specifically, our results suggest that males are more likely to participate consistently in more PT quarters in a year than females. The results were supported by the fact that maternity leave contributed to 26.32% as the main reasons for not participating in PT schemes. Experience had an effect on participation in a PT scheme. Specifically, our results suggest that analysts with ≥ 5 years' experience and are males are more likely to participate consistently in more PT quarters in a year than those with <5 years' experience. Knowledge of PT schemes influences directly the participation of an HTC analyst in PT scheme. Specifically, our results suggest that analysts with knowledge on PT are more likely to participate consistently in more PT quarters in a year than those who lack knowledge on PT schemes. Acknowledging current facility participation in PT had been influenced by participation in 2012 PT scheme. However, 2013 had the least number of HTC analysts who missed the PT scheme. Specifically, our results suggest that the longer the number of years spent at a facility, the more likely a HTC analysts increases their chance of participating consistently in more PT quarters in a year than those who spent less time in a facility. The differences between their means were likely due to chance and not likely due to participation in PT scheme in 2012. Nevertheless, the study indicated inconsistencies and tremendous increase in non-participation in PT schemes. The mean score percentage for participating in all PT schemes quarters from January 2012 to May 2014 was 15.34%. This representative sample from our study can only mean that Kenya as a country is yet to achieve a quarter (25%) in scaling up PT schemes. The results clearly prove that scaling-up PT schemes in Kenya is a real problem if not a challenge. Kenya is not the only country facing these challenges. A similar study in Nigeria (20) stated that PT was a means of verifying the reliability of laboratory results, but such programmes were not readily available to laboratories in developing countries.

Stock outs and participation in PT schemes: Overall a majority of HTC counselors (91.1%) acknowledged experiencing test kits stock-outs at their HTC facilities while (8.9%) had never experienced any test kits stock-outs. Analysts with ≥ 5 years working experience responded by acknowledging that they had sometimes experienced stock outs. Those with < 5 years working experience acknowledged experiencing stock outs most of the times. On further enquiries, it was observed that the most experienced analysts had proper records to monitor their stocks and most of them usually place their orders on time, and in excess of their requirements. However, there were no statistically significant associations and relationships between test kits stock outs and participation in PT schemes from 2012 up to May

2014. The Kenya Medical Supplies Agency (KEMSA) was formed on 11 February 2000 by a legal notice issued under CAP 466 of the Laws of Kenya to replace medical stores. It is a specialised medical logistics provider for MoH and is responsible for procuring key commodities such as test kits. However, the first HIV test kits stock-outs to be documented in Kenya was associated with the introduction of mobile VCT in 2003 which exhausted the test kits and even emergency procurement could not remedy the situation. The stock-outs was further complicated by the pull system in which the KEMSA warehouse arbitrarily determined quantities that were issued to districts, regardless of whether they were needed (18), resulting in test kit and supplies distribution that was not aligned to the need by regions, facilities and sites. In 2009 PEPFAR established a supply chain management system in parallel with KEMSA, which is responsible for HIV testing supplies, with an aim of addressing the challenges of stock-outs. However, questions of sustainability need to be critically thought through and how the systems can be assimilated and strengthened to deliver (18). HTC campaigns in 2007 and 2008 reported persisting shortages and stock-outs of essential commodities such as test kits. The years 2009 and 2010 recorded improvements in commodity supply with more accurate forecasting, consistent and predictable supply and minimal shortage of test kits (18). In June 2010 (22nd-25th) NASCOP organised a forecasting and quantification workshop to strengthen its monitoring and oversight role in commodity security. However, this national planning has not cascaded to districts as envisioned (18). Our study was able to reveal that despite the stock-outs intervention measures, test kits stock-outs have been persistent and on the rise in HTC facilities in Kenya (figure 4). If the forecasting and quantification measures (FY 2010/11 & FY2011/12) were correct, then there is a serious gap in HTC commodities supplies. Our study reported stock-outs from 2011 to May 2014. We conclude that challenges in poor forecasting still remains a major barrier to test kits supplies.

The highest level of education of the HTC analyst: The results for the medical personnel having a secondary level education was because the personnel was over 51 years and was employed when form two school leavers were being employed in the 70's, hence we can only conclude that the O level education was not completed but had some secondary education. Results on gender, type of HTC facility, and years spent at current facility, and experience were insignificant. HTC services are implemented by HTC providers who include health workers, professional or lay counselors. Some of the cadres of health workers who provide HTC include doctors, clinical officers, nurses and laboratory staff. However, majority of these

health workers provide HTC as part of their regular duties, but counselors are mostly full-time (3). For one to be trained as an HTC provider, one needs to have the minimum qualification of a certificate level training in social sciences, health services or other related area. It is however desirable that in the near future this standard will be raised to a diploma level (3). Some of the HTC analysts in the two categories had attained their undergraduate degrees and others were pursuing post graduate studies but not in the fields related to HIV testing. These findings clearly indicate that the HTC analysts have achieved a milestone in ensuring that they attain higher levels of education surpassing the minimum requirement of only having an O level education in order to offer HTC services. These results on the levels of education confirm that the government has been able to adhere to its guidelines on the qualifications of HTC staff "For one to be trained as a HTC provider, one needs to have the minimum qualification of a certificate level training in social sciences, health services or other related area" (4).

In conclusion, our study was designed to investigate the implementation achievements of (4) funded by NASCOP and (16) funded by NACC (National AIDS Control Council) with regard to Proficiency Testing and Supply of test kits. The outcomes of this assessment revealed gaps in procurement and supply chain management test kits by KEMSA, and Inconsistencies PT schemes. We recommend the implementation of effective support systems to improve on the supply and procurement mechanisms of test kits. Regular PT schemes should be made accessible and mandatory to all HTC personnel as a form of Continuous Professional Development in HIV and AIDS. The first response buffer kits were reported to have holes on them, and the pipettes for the new testing kits were reported to be cumbersome as the blood flow in them weren't good compared to those for prior kits. Studies should be conducted on the best repackaging alternatives for the buffer. We recommend for the allocation of more funds for PT schemes by both the central and the county governments. Studies (2,17) have been done on the feasibility of using HIV photogrammetric as complementary tools for HIV proficiency testing in limited resource settings. We strongly recommend the adoption of the technique by developing countries that are experiencing challenges in the full implementation of their PT schemes. The technique will assist in identify HTC analysts with difficulties in results interpretation. In so doing, those with difficulties in interpretation of the results can now be enrolled into the actual PT schemes. The technique happens to be cost-effective as it can operate on different ICT platforms. The only major challenge to the technique is that not every HTC analyst is technologically savvy. Possession of

a Smartphone does not directly translate to one being a computer literate. Therefore, we suggest that once countries decide to adopt photogrammetric, then they should also provide free computers lessons to the HTC analysts. Having the National Policy guidelines and HTC Quality management handbooks that are not implemented to the full are as good as not having them. As Kenya ushers in the use of the new testing algorithms and the decentralisation of HTC services from central government to county governments (Sub-Counties), it's vital to scale-up Proficiency Testing, and increase trainings on the new testing algorithms. Inadequate external quality assessment systems in HIV and AIDS programmes, stock-outs of test kits, lack and non-participation in PT schemes impact negatively on quality of HIV testing and counseling services.

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