Variations on External Quality Assessment Performance of Public Medical Laboratories: Experience from SLMTA Program in Morogoro and Iringa, Tanzania

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Abstract

Background The International Organization for Standardization has recommended monitoring and evaluation of quality laboratory services to ensure accuracy and reliability of diagnoses. The extent of accuracy and reliability of medical laboratory diagnoses in Tanzania has been scarcely documented. Through strengthening laboratory management towards accreditation (SLMTA) program, the researcher evaluated changes in quality indicator. Objective The evaluation aimed at determining the effect of SLMTA program on external quality assessment participation and performance of public laboratories in Iringa and Morogoro in Tanzania. Methodology A comparative laboratory-based cross-sectional design was conducted in Kilosa and Turiani districts in Morogoro region and Iringa Municipal and Mufindi district in Iringa region. External quality assessment (EQA) level of participation was assessed by observing how frequent the laboratory performs PTs, and the number of laboratory tests that are involved in EQA. A total of 178 EQA proficiency malaria, HIV and Haemoglobin (Hb) test results from the public laboratories were gathered by using a checklist. Eighty test results were from SLMTA laboratories (59 from Turiani and 21 from Mafinga lab) while 98 were from non-SLMTA laboratories (63 from Kilosa and 35 from Ngome laboratory). Data were analyzed using software to prepare contingency tables for test sensitivities, specificities, and predictive values. Statistics such as percentage distributions and cross-tabulations were used to analyze data. Findings SLMTA and non- SLMTA labs are participating regularly in EQA for HIV rapid tests (RTs), however, their participation is not regular for malaria and Hb tests. Proficiency test (PT) performance for HIV RTs in SLMTA laboratory category was 64%, while in non-SLMTA was 85%. PT performance for malaria test in non SLMTA was 44%, while it was zero percent in SLMTA lab category. Test performance for Hb was zero percent in SLMTA labs and no datum for Hb PTs available in non SLMTA laboratories. The sensitivity and specificity for HIV RTs was 100% in both laboratory categories (SLMTA and non-SLMTA).

Background

1.1 Overview of laboratory quality

A medical laboratory plays a vital role in disease prevention and control. Medical laboratories are responsible for providing a correct diagnosis of continuing or past infections, thus Quality in clinical laboratory has a vast impact on disease diagnosis and patient management. Providing accurate and reliable diagnosis rather than empirical diagnosis counteracts resources wasting, worsening patient's health condition and drug resistance. A study indicates that about 6% to 12% of laboratory errors direct the clients (patients) at danger of incongruous care and expose them to adverse effects, and negative impact on different dimensions of patient management been contributed by 26% to 30% of errors (Fausta, 2011).

In consideration of the above-said roles of quality in the laboratory, the gapes of status of public clinical laboratories and the ISO 15189 requirements for quality and competence, Tanzania adopted the SLMTA program for laboratory quality improvement. Its purpose was to strengthen laboratory management for

immediate and measurable laboratory transformation, where the External quality Assessment was among the major indicators to measure the improvement. SLMT program involves three short sessions of training laboratory personnel from selected laboratories in different Cohorts, followed by mentorship session to the site of work (hands-on training) (SLMTA, 2008).

1.2 Approach to laboratory Quality improvement

In the past one decade, health care in Sub-Saharan Africa was paying attention to communicable diseases particularly Tuberculosis (TB), Human immunodeficiency virus (HIV) infections and AIDS, and malaria (Petti *et al.,* 2006). The diagnosis confirmation and treatment and monitoring of these diseases were to depend on Laboratory investigations, nevertheless, the utilization of laboratories tests was undervalued and uncared (Andric & Massambu, 2006). Stakeholders had no trust in the laboratory outputs, but also they fail to recognize that laboratory diagnosis is of paramount to the prevention and treatment of diseases. Hence, the needs for demanded devote in clinical laboratory services in Africa were highlighted (Petti *et al.,* 2006).

Clinical/Medical laboratories are dependable for providing a correct diagnosis of continuing or past infections for proper disease management (WHO, 2008), thus laboratory quality assessment (LQA) in clinical laboratory become the stamina of laboratory performance as quality has the vast impact on disease diagnosis and patient management (Jegede *et al*., 2015). Implementation and /or strengthening of LQA programs give a country to recover the trustworthiness of laboratory services and reproducibility of results (Jegede *et al*., 2015).

The meetings of African laboratory network in Harare (2002) and that in Addis Ababa (2006) followed by Maputo declaration, intended to strengthen clinical laboratory systems for quality health services (The Maputo declaration, 2008). The International Organization for Standardization (ISO, 2012 E) has suggested monitoring and evaluation of quality management system (QMS) in a clinical laboratory as quality advancement attempt for quality laboratory services. Following the WHO Regional Committee for Africa resolutions (WHO-AFR/RC58/R2), several activities for capacity building by the member countries has been implemented (WHO, 2008). In 2010 Tanzania through the Ministry of Health and Social welfare (MoHSW) "by then" adopted SLMTA Program as an option approach to train Laboratory managers and quality officers from 12 laboratories (6 regional, and 6 districts laboratories) in cohort-1 as selected by the Country's Laboratory Task Force and 18 (14 regional, 1 special, 2 faith-based and 1 private) laboratories in Cohort-2 (Andric & Massambu, 2014), on LM and QMS, to generate assessable improvements as per international clinical laboratory standards (SLMTA, 2008).

To improve laboratory services, a constant monitoring and assessments of the LQMS are vital. Jegede in Nigeria also described the key measures for improving laboratory services should sight on the total testing process, the use of quality indicators to site improvement opportunities and estimate efficacy of specific interventions thus to meet the LQMS main objectives- accurate and precise results in a timely manner and meeting patient's needs and client satisfaction (Jegede et al. 2015). "The clinical laboratory

is the epicentre of the health care sector" (Chawla et al., 2010, par. 1). Empirical diagnosis is a carry out that waste resource and contributes to drug resistance as well (World Health Organization, 2008).

1.3 Laboratory tests involved

Focusing on three (HIV rapid tests, Haemoglobin level estimation, and blood smear for malaria parasites (B/S)) among many laboratory tests that are performed in the laboratory facilities, the researcher tried to consider the popularized and commonly performed laboratory investigations as per infrastructures settings in most areas of Tanzania. A consequential effect of misdiagnoses of any one of the three has a threatening implication.

There are many transmittable diseases imitate malaria, leads to elevated rates of over-diagnosis and overtreatment of malaria disease. Microscopy, considered to be the gold standard for the diagnosis of malaria, is usually available at district hospitals. However, it has only 70–75% accuracy (Amexo et al., 20014). The technique depends on well-maintained equipment, good quality reagents, well-trained laboratory personnel, and good quality assessment and supervisory systems.

1.4 Consequences of misdiagnosis

The consequences of misdiagnosis of malaria are felt at individual, household, and national levels. Non malarial cases are treating as malaria, thus masks fundamental potential deadly conditions. Individuals incorrectly diagnosed with malaria are exposed to unnecessary side effects of drugs, while the factual cause will not be identified or treated. This situation is likely to lead to extended and worsening illness with loss of income or productivity and repeated visits to health facilities (Amexo et al., 20014).

HIV misdiagnosis occurs as an HIV-uninfected person is inaccurately diagnosed as infected with HIV by the laboratory test used or vice versa. There are numerous factors that can lead or contribute to HIV misdiagnosis. Deviation from standardized testing guidelines or algorithms, users errors like improperly performing test procedures, incorrectly interpreting laboratory test results, non-compliance to SOPs as well as clerical errors (Kufa et al., 2017). False-positive (FP) rates as high as 10.3% upon retesting have been found in a number of settings (Kufa et al., 2017). The penalties for HIV misdiagnosis are serious.

An FP HIV test result leads to unnecessary treatment of HIV-uninfected person and also exposure to stigmatization and as well as exposure to psychological trauma that is associated with HIV infection and the loss of credibility of laboratory facility and HIV testing programs. On the other hand, FN HIV test results signify missed opportunities for enrolled in HIV care and treatment and of course, the risk of unintentionally HIV transmitting to uninfected partners (Kufa et al., 2017). To lessen the risk of HIV misdiagnoses, Tanzania use approved testing algorithms as well as the execution of HIV rapid test quality assessment (QA) programs (NHLQTC). Key facets of these programs comprise training, retraining

and mentoring of testing staff, conducting external and internal quality controls, proficiency testing (PT) and external quality assessments (EQAs) (Kufa et al., 2017).

1.5 Review on Quality performance

If considering the pilot laboratories in the study that was done by Nevalainen to represent American current situation of laboratory quality performance during the year 2000, then it demonstrates that for about ten years of quality assurance programs in America yet, there had been no significant improvement in laboratory quality performance among public laboratories (Nevalainen et al., 2000). Nevalainen statement was trying to justify that addition of quality assurance components is not direct proportional to quality improvement when it comes to practical point of view. His statement was as a response to what Hilborne stated 12 years before, when explained the expansion of quality assurance components of clinical laboratory necessitated the passage of clinical laboratory improvement Act of 1967, in which participation in proficiency testing became mandatory. However, Hilborne pointed out that the assessment to ensure conformity with established guideline and standard Operational procedures (SOPs) is one of the major quality assurance activities (Hilborne et al., 1988). Even in Tanzania settings the issue of frequent auditing programme to assess lab services delivery is important.

Agarwal *et al* (2012) in Nigeria conducted a study in diagnostic laboratories that received more than 42000 samples for different lab tests. They found that, following sensitization of laboratory staff on quality performance; most significant quality improvement was in pre-and post-analytical phase, however, did not significantly have much impact on the analytical phase (Agarwal et al., 2012). This is the point why the researcher thought of including the main quality indicators (IQCs, EQA & TAT) found in the analytical phase, where the laboratory personnel are directly involved in their daily professional practices.

Ricos and colleagues suggested that 11% is a tolerable proportion of lab result that may go beyond the agreed TAT Ricos et al (2004). Chawla and colleagues in their study that was done in New Delhi, India observed the factors that contribute to prolonged TAT includes delay in analytical phase, lost test request forms, specimens, and reports. Timely reporting may enhance patient management and clients' satisfaction like what Valenstein et al said in their study (Chawla et al., 2010: Valenstein et al., 2003). Using quality indicators to monitor the laboratory quality system improvement is very valuable means in systematic and transparency controlling the total laboratory testing process.

Manickam and Ankanagari (2015), evaluated quality system implementation in large and small sized laboratories which did or did not have knowledge of quality system operation for accreditation, they did as per WHO checklist per the standards requirements for accreditation (ISO 15189:2012) and the general score was 43% for process quality controls/external quality assurance (PT). They concluded that the score was due to lack of simultaneous training to improve performance, negligence in evaluating personnel performance, etc (Manickam & Ankanagari, 2015). However, this low scores result could also be contributed by lack of consistence documentation of records by the lab personnel thus the auditors could not see evidence of the practice, reluctance of laboratory staff and poor managerial skills of

administrators. But again, the WHO checklist that was used, to some of the laboratories was naïve, in contrast to the customized SLIPTA checklist that were used in this study is familiar to the study participants for about eight years.

Andric and Massambu (2014) in their article titled “One laboratory’s progress toward accreditation in Tanzania.” Said about the improvement of quality implementation in Tanzania, the 81% score (three-star rate) from a 36% (zero-star level) was said to be a remarkable achievement by the Amana Hospital Laboratory among the 12 laboratories involved in the SLMTA program in the first cohort. This achievement by the Amana laboratory could be due to less reluctance of the lab personnel that may be caused by the short interval auditing practice conducted during the program. And this fact evidenced by the findings by Andric in the same study in which they observed that seven month post the completion of the SLMTA program, the laboratory declined to 62% score (one star-level) (Andric & Massambu, 2014).

Regardless of ten years of implementing QLMS, quality performance crossways the entirety laboratory testing process is not adequately better in Tanzania. The findings from the current study add to the body of knowledge for what SLMTA program has contributed in improving quality performance of medical laboratories, especially for HIV rapid tests, Hemoglobin level estimation and Blood smears for malaria diagnosis.

We hypothesized that the public medical laboratories which are under SLMTA program have better EQA performance, as compared to those which are not in the program. Hence we aimed to determine performance and participation of SLMTA and non-SLMTA public laboratories in external quality assessment in Morogoro and Iringa region in Tanzania.

Research Methodology

2.1 Study area

This study was conducted in Kilosa and Turiani districts in Morogoro region and Mufindi and Iringa Municipal in Iringa region. Turiani and Kilosa are two districts among the seven districts in Morogoro region. Mafinga and Iringa municipal are among the Iringa Regional districts. These districts have their district hospitals, in which clinical laboratories at the level of District operates. At this level in the hierarchy, all these laboratories are providing a range of laboratory tests including Cluster of Differentiation type four (CD4) cells count, Fully Blood count/picture, microbiological tests, Serologic tests, Chemistry analysis, and Haemoglobin estimation and others. Turiani and Mafinga district laboratories each estimated to provide services to a coverage population of approximately two hundred thousand and servicing about fifty thousand clients per annum. The staffing is above 13 laboratory professionals. The laboratories have several essential equipment; Hematological analyzer, chemistry analyzer and CD4 count machine (low volume). Turiani and Mafinga laboratories were enrolled in the SLMTA program. The enrollment into SLMTA is the only aspect that differentiates Turiani and Mafinga laboratory with Kilosa and Ngome laboratory. The latter laboratories are not enrolled in SLMTA program

but, they have similar other characteristics as found in the former laboratories. Ngome Hospital in Iringa municipal was a health center but is regarded and used as a district hospital since there were no any other hospital of the advanced level apart from the Ngome hospital. However, the hospital had all the necessary required features which were consider for this research.

2.2 Study design

The study involved a comparative laboratory based cross sectional design that employed both primary and secondary data approach on the laboratories those were participating and those which were not participating in the SLMTA program, in two regions of Republic of Tanzania. Secondary data was obtained through document reviewing; EQA results documents, laboratory Quality manual and records for the tests involved in EQA as per the checklist. And primary data to clarify any unclear records was capture using the same checklist (Abay Sisay, 2015).

The current study focused on assessing the effects of SLMTA program on laboratory quality improvement indicators, specifically the EQA performance in terms of proficiency test scores (%), test sensitivity and specificity and EQA level of participation in terms of number of tests involved and frequency of conduction the EQA among the public clinical laboratories which are under SLMTA program and those which are non SLMTA.

2.3 Population and sampling

All public diagnostic laboratories in Tanzania were the target population in which SLMTA and Non-SLMTA public laboratories from Morogoro and Iringa region were chosen. The samples were collected from Turiani, Mafinga, Kilosa and Ngome district laboratories. Primarily, Morogoro and Iringa regions were selected, from which Turiani, Kilosa, and Mafinga and Ngome District hospital laboratories as the secondary sampling units were selected.

A purposive sampling was employed to select the district hospital laboratories which fulfill the inclusion criteria. The researcher purposefully selected the two public laboratories which were under SLMTA, and another two control laboratories which were not under the program. This purposeful way of selecting was done to suit the convenience of the researcher in terms of budget and the existing working relationship between the researcher and the respective laboratory managers, thus enhance smooth permission process. Of course the sampling technique that used is prone to bias, but in this case the selection of two non-SLMTA laboratories with similar characteristics minimizes the effect of bias. We reviewed all records of PTs for HIV RTs, malaria and haemoglonin which were done at base years (2013), mid-year (2015) and current year (2017) that was available. The population size was 240, as each public laboratory expected to have conducted at least a total of 20 PTs for the mentioned tests per year (EQA Policy). The minimum sample size expected was 94 as recommended by WHO size for facility Quality Improvement studies (WHO, n.d). However, a total of 178 (75%) EQA proficiency test results from the studied public laboratories

were collected. The studied sample size exceeded the minimum size 94 (38 – 47%) for population size of 200-249 for quality improvement assessment (WHO, n.d). Eighty test results were from SLMTA laboratories (59 samples from Turiani and 21 samples from Mafinga hospital lab), while 98 test results were from non-SLMTA laboratories (63 samples from Kilosa and 35 samples from Ngome laboratory).

Laboratory Managers were purposively chosen as well, to give information about laboratory profile.

2.4 Development of collection tools

The checklist was customized from the WHO-AFRO (Region Office for Africa) Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) tool. The elements of the checklist were based on ISO standard 15189: 2012. The customized checklist was piloted at Morogoro regional hospital for its validity before being used for the study. The checklist consists of three parts; laboratory profile that contain demographic variables, Laboratory process audit that determine if EQA is well managed-reviewing laboratory documents, laboratory records, observation made and confirmation of PT results and correction action taken, and last part is the summary of opinions that involves noted commendation, noted challenges and recommendations.

2.5 Data collection Procedures

Data were gathered by using checklist (non-self administered checklist), to record laboratory profile information provided by the LMs, to record the facility EQA results, reference EQA results and corrective actions that conducted by facility laboratories. This way of data collection was appropriate approach to validate the put forth objectives of this study.

The data collector for the current study was a Medical Laboratory Scientist (bachelor degree holder); having worked in medical laboratory for more than seven years thus had enough experience on Laboratory Quality Management System of Tanzania. With this strong experience, he had skills on how laboratory process and procedures should be carried out and how the laboratory data are to be documented and stored as per the laboratory quality manual (policy) and this provided strength to the information that were collected.

Following permission from the local councils through their respective authorities (DMOs, MOI and LMs), the data was collected in the laboratory. EQA documents and records, laboratory manuals, SOPs for EQA were reviewed and observations were recorded in the check list. Addition clarifications from lab staff were also put down on the data collection tool. On completion of the process, within a day the filled checklist was verified by the collector and his colleague for its completeness and clarity before the data were entered in the software to create data set. In any case of non-conformities like lost of the filed checklist the data collection was to be repeated at that sampling unit. However, there was no the case.

2.6 Data management and analysis

After collection, data were computed (transferred from the hard copy to soft copy), coded (codebook), and analyzed using contingency table (two by two tables) for test sensitivities, specificities, and predictive values for PTs performances. The following formulae were used for calculation of the named values. Sensitivity = TP/(TP+FN)*100, specificity = TN/(TN+FP)*100, PPV=TP/(TP+FP)*100 and NPV=TN/(TN+FN)*100 (University, 2018). Descriptive Statistics such as frequencies, percentage distributions and cross-tabulation according to the research questions and hypothesis of the study were used to analyse the data.

The quantitative data, analyzed using software where descriptive statistics were employed to analyse variables. These data were summarized using percentage, and frequency. Cross tabulation was applied to describe EQA performance and participation with SLMTA intervention and each of the variables.

EQA participation was determined through assessing the frequency in regularity of the laboratory participating in the exercise, and determining number of laboratory investigations involved in the EQA. EQA performance, this is evidenced by assessing the PT scores in percentage above 80% in the PT challenges (acceptable mark QI indicators), sensitivity and specificity of the laboratory tests, submission of the PT result on timely manner (within 15 days of panel receipt), reviewing the PT results (feedback). Taking corrective actions required were also determined to measure the EQA performance and test procedures compliance.

2.6.1: Data cleaning

Within a day of data collection at each laboratory, the recorded data were verified by the evaluator together with one of medical laboratory staff at the each laboratory facility to see completeness and clarity of the gathered information. This ensured the cleanliness before data entry. Data entry was done after completion of the collection at all the four facilities. After creating the data set in the, data were proofread by second person (fellow researcher) to spot and cross check for validation. In case where there was nonconformity, the researcher made a call to the laboratory Staff from a respective laboratory for clarification.

2.7 Ethical issues

Ethical clearance was sought from the Mzumbe University Ref. No. MU/DPGS/INT/38/VOL.IV/90. Data collection practice was carried out in the laboratory with permission from the respective authorities (DED, DMO, MOI, and LM). Laboratory facilities ware assigned specific identification L1, L2, L3 and L4 to maintaining confidentiality. The names of the studied laboratories are not mentioned in the research findings to comply the research ethics. The author and the Mzumbe University is the owner of this research.

Research Findings

4.1 Findings description

SLMTA labs observed to review their EQA documents and sign the feedbacks from the EQA agents, while non-SLMTA labs were not. All the studied laboratories were managed to submit the PT results within the TAT. Variation in number of laboratory tests involved in the EQA was observed, the tests that were enrolled at mid-year some were not done in the current year, the type of investigations among all the public laboratories are similar

4.1.1Total scores for proficiency tests

For HIV proficiency test total scores that account for 100% (90% score for a correct test result of the rapid test, and 10% score that covers proper documentation and eligibility of records), only 64% of HIV test in SLMTA labs attained 100% (total score), see table 1.

In general, aggregated scores of PT of the studied public laboratories observed to draw back the individual laboratory performance to 36% and averaged to 75% for malaria tests and HIV rapid tests respectively. However, records for Hb data were not available in non-SLMT labs.

4.1.2 Individual laboratory tests performances

Malaria test sensitivity for non-SLMTA labs were 94% while that of SLMTA labs were 100%. Specificity and positive predictive value for the same test were 75% and 90% in SLMTA laboratories however, in non-SLMTA labs negative predictive value was 91% (table 2).

4.1.3Combined PT Performances

Figure 4.1: Aggregated proficiency tests sensitivity & specificity in SLMTA & non-SLMTA laboratories (Morogoro & Iringa)

On aggregation of the two non-SLMTA laboratories, the proficiency tests for malaria was 94%, this has brought about an effect on the negative predictive value (91%). However, the records for haemoglobin were not available. In the other hand, the two SLMTA laboratories on aggregate performance, proficiency test specificity for malaria was 75%, with effect to the probability for the laboratory facility to identify the patents that are really having the malarial infection (positive predictive value of 90%).

4.1.4 Trend of participation in EQA program

Figure 4.2: Trend of Public Laboratories (SLMTA & non-SLMTA) participation in EQA exercise

The figure 4.2 above tells about the inconsistency on participation; some of the tests those were enrolled at baseline year are currently not performed (e.g. Hb). In addition, there is an unequal distribution of laboratory tests for EQA among all the laboratories. However, the types of laboratory tests enrolled for the EQA among all the studied laboratories are the same.

Discussion Of Findings

5.1 Evaluation findings

With an experience of a number of quality indicators, poor documentation of laboratory processes, non-conformances and occurrences is a challenge as the laboratory personnel consider documenting as needless paperwork and extra burden as it was reported in Nigeria (Jegede, 2014). Laboratory performance (as defined as review and documentation of corrective actions as per standards/SOPs) is very often insufficient and is a prevalent problem in low-resource settings (Rowe, 2005). In the current study, the overall performance for proficiency test total scores (that involved test results and documentation) was 75% and 36% of HIV rapid tests and Malaria test respectively. The laboratories were able to attain the HIV RT total score (100%) by 75% and attained the malaria test total score (80%) by 36%. However, it was observed that there was a difference in PT performance between the SLMTA and non SLMTA laboratories. In SLMTA labs, about 36% HIV RTs did not reach score of 100%, while in non-SLMTA, only 15% HIV RTs did not attain the 100% score . But again there was a difference among the two lab categories on PT for malaria tests; in SLMTA labs, all the scores for malaria tests did not reach the 80% total score, contrary to the non-SLMTA labs in which at least 44% of the malaria tests attained the total sore (80%). Principally, as per quality standards, once the lab test is performed and documented by laboratory staff, it should be verified by the second person to counter check the correctness of the result and the records which are documented on the laboratory result form for the particular test (ISO 15189 E). However, in the current study found that, same lab personnel observed regularly performing PTs of which indicates that, they give special attention to the EQA samples thus, special personnel responsible for doing testing, or maybe the fear of assessment thus no one is willing to perform the EQA PTs. Although the current study did not look into the effect of staffing and their training, the observed malpractice concedes the truth to a level of clinical laboratory training may not suffice, but somewhat it has to be amplified with extra quality management systems as previous reported (Taremwa et al., 2017). In the situation where by only same person does the EQA test throughout then it would explain the differences in scores between the two lab categories (SLIMTA and non-SLMTA).

In general, as Hawkins explained the TAT target for specific laboratory investigation normally set on basis of test type, priorities, a number of clients served to meet client satisfaction and efficiency (Hawkins, 2007). In the current study, a TAT of 15 days set target (set by the agents of EQA) was considered acceptable, as the focus is on EQA Proficiency tests. This study registered a perfect performance, 100% of all the PTs done in both laboratory categories were sent within the acceptable TAT. The particular performance is comparable to the findings involved 118 hospital laboratories that were done in the USA

where the performance was 98.8% (Hawkins, 2007), and it is even above the suggested 11% tolerable proportion of lab results that may go beyond the agreed TAT Ricos *et al* (2004).

The present study registered 100% sensitivity of HIV RTs in both SLMTA and non-SLMTA labs. This implies that the EQA of HIV PTs which was really positive (by reference laboratory) was correctly identified as HIV positive. However, a difference in sensitivity of malaria test between the two lab categories observed whereby; in SLMTA labs the sensitivity was 100% while in non-SLMTA labs the sensitivity was 94%. This tells that, the likelihood of not identifying malaria in the malaria positive samples is about high among the non-SLMTA. In addition, it tells that the accurate cause of the disease will not be identified. When the cause of the disease is not identified, then it is likely to lead to extended and worsening illness with loss of income or productivity, repeated visits to health facilities and probably deaths .Haemoglobin level estimation sensitivity was found to be 87% in SLMTA labs, implies the high possibility of the Hb results to reveal abnormal lower or higher levels with the consequence of delayed accurate patient management. However, no Hb information obtained from the non-SLMTA labs.

There was no difference in specificity of HIV RTs between the SLMT and non SLMT labs. However, a difference in malaria test specificity was noted whereby, in non SLMTA lab it was 100% while in SLMTA labs was 75%. Here the data tells that, the studied public clinical laboratories which are under SLMTA program were not able to accurately exclude the non-malarial samples as malaria negative results. It suggests that about 15% non-malarial cases are treated as malaria cases, this is contrary to what was reported by Celine in the study done in Korogwe, where the specificity was 100% (Mahende et al., 2016). This less specificity in the particular labs can mask fundamental potential deadly conditions. Individuals incorrectly diagnosed with malaria are exposed to unnecessary side effects of drugs. These consequences can be felt at an individual, household, and national level.

The research registered inconsistence on participation; Hb level estimation tests were enrolled at baseline year in both lab categories but are currently not performed in non SLMTA labs, despite that is being done in SLMTA labs but again there is no feedback from the EQA agent thus it's impossible to assess the EQA performance and full participation on the particular test. In addition, unequal distribution of laboratory tests for EQA in all the laboratories was noted. In non-SLMTA labs, HIV RTs were distributed twice a year, while in SLMTA labs were thrice yearly contrary to what is said in the laboratory quality policy-thrice a year (ISO 15189 E). Interestingly, what was the case for HIV RTs distribution in non-SLMTA labs was not the case for malaria tests distribution; PT for malaria tests was distributed (in non SLMTA) thrice a year and twice in SLMTA labs. However, the types of laboratory tests enrolled for the EQA among all the studied laboratories are the same (HIV RTs, Malaria (B/s) tests, Hb level estimation, and CD4 cells count).

The findings tell that SLMTA program has brought about no significant effect on EQA performance and participation among the studied public laboratories. The current study only assessed one quality indicator (EQA) in a narrow scope, thus, most of the components were not touched.

With this narrow scope of the current study, there is a possibility of not seeing other components in which SLMTA might have significantly contributed amid the public laboratories. A comprehensive evaluation

study on SLMTA program is needed to assess the program's value.

5.2 Limitations of the study

Due to time limit, a small number of laboratories were studied, hence, the study findings cannot be generalized. The study was unable to see more components which SLMTA program has significantly contributed. Finally, with regards to the sampling technique used, the finding should be interpreted with care; findings simply represent EQA performance and participation of the studied public laboratories.

Conclusions

EQA participation for HIV RTs, sensitivity and specificity of HIV RTs is improved in both SLMTA and non-SLMTA labs. Malaria specificity is lower in SLMTA labs, while in non-SLMTA labs it is the sensitivity that is lower. Proficiency test score performance for HIV RT and malaria test is high in non-SLMTA labs than it is in SLMTA labs. There is no significant contribution on EQA performance and participation that SLMTA has brought about among the public labs. The study highlights the need to continuously assess LQIs and calls for an improved attempt on reviewing EQA and use of proficiency testing records in all public laboratories. A comprehensive study that can assess more components of laboratory quality improvement to evaluate SLMTA program is need.

Recommendations

A comprehensive evaluation study on SLMTA program to assess the program's value is needed.

There is a need to continuously assess laboratory quality indicators and calls for an improved attempt on reviewing EQA and use of proficiency testing records in all public laboratories.

Much more is needed to assess performance of the public medical laboratories for quality improvement using more facilities.

The EQA agent for malaria and haemoglobin tests should send the EQA results feedbacks to the facilities.

Abbreviations

AFRO Regional Office for Africa

ASCP American Society for Clinical Pathology

ASLM Africa Society of Laboratory Medicine

B/s Blood smear

CDC Center for Diseases Control and Prevention

EQA External Quality Assurance

Hb Haemoglobin

IQCs Internal Quality Controls

ISO International Organization for Standardization

LM Laboratory Management

MoHCDGEC Ministry of Health community development, Gender, Elderly and Children

NPV Negative predictive value

PPA Positive predictive value

PT Proficiency Test

QIs Quality Indicators

QMS Quality Management System

SLIPTA Stepwise Laboratory Improvement Program Towards Accreditation

SLMTA Strengthening Laboratory Management Towards Accreditation

SOPs Standard Operational Procedures

TAT Tarn around Time

WHO World Health Organization

Declarations

Competing interest

The authors declare that they have no competing interest.

Author's contribution

WMK-contributed on conception, design, data collection, cleaned data, analyzed the data, referencing and wrote the first draft and compiled figures and tables and submitted it. DFM – contributed in editing first draft. BMW- contributed in interpreting data and edited this manuscript from the first to the final version.

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Tables

Table 4.1: Proficiency test total scores for public medical laboratories (Iringa & Morogoro)

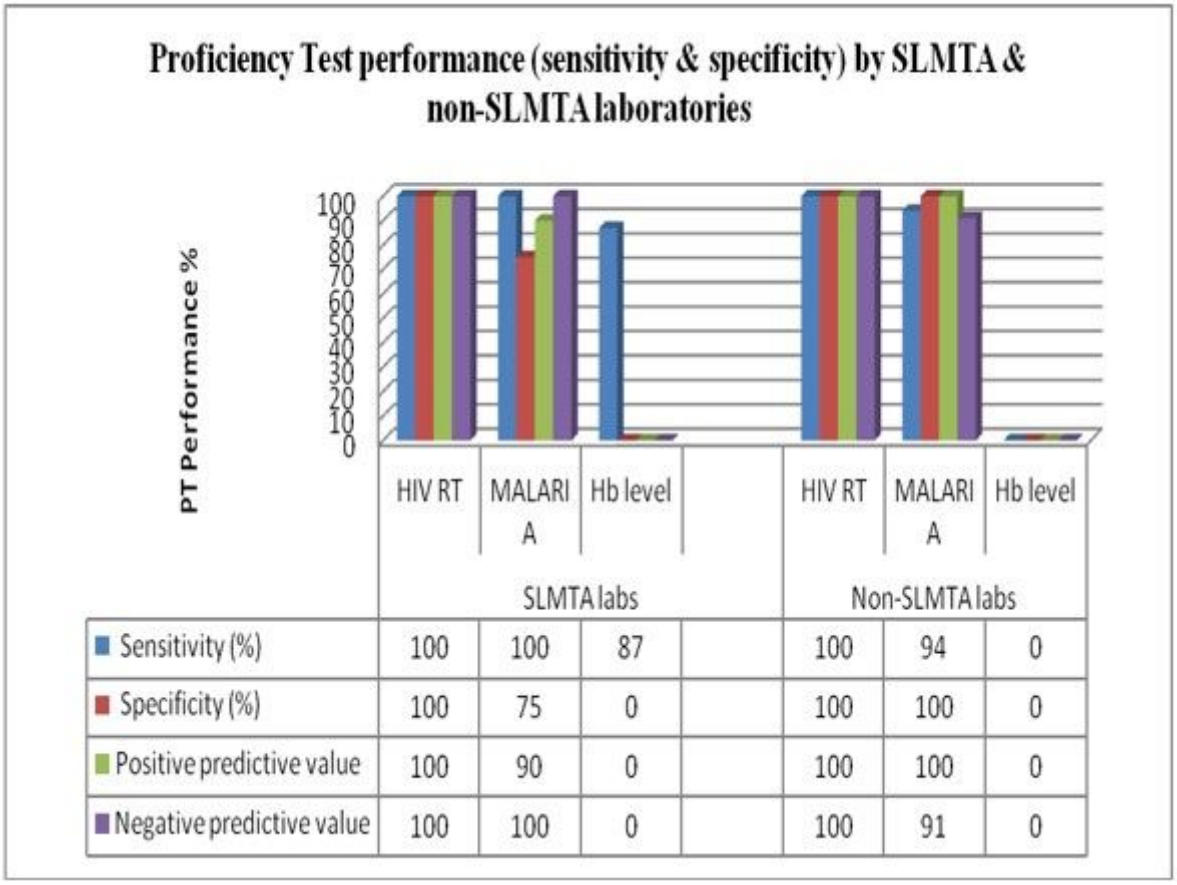
Laboratory category	100% HIV RT , >80% Malaria &Hb score	# of tests involved in EQA (n=46)
SLMTA laboratory		
HIV RT	64 (7)	11
MALARIA B/s	0 (0)	5
Hb Estimation	0 (0)	8
Non-SLMTA laboratory		
HIV RT	85 (11)	13
MALARIA B/s	44 (4)	9
Hb Estimation	-	-
SLMTA + Non SLMTA labs		
HIV RT	75 (18)	24
MALARIA B/s	36 (4)	14
Hb Estimation	0 (0)	8

Table 4.2: Proficiency tests sensitivity & specificity per individual laboratory SLMTA & non-SLMTA laboratories (Morogoro & Iringa)

Laboratory category	Test sensitivity (%)	Test specificity (%)	Positive predictive value	Negative predictive value	# of Proficiency tests (n=178)
SLMTA Labs					
Lab 1					
HIV RT	100	100	100	100	15
Malaria	100	100	100	100	4
Hb level	100	-	-	-	2
Lab 2					
HIV	100	100	100	100	44
Malaria	100	67	86	100	9
Hb level	83	-	-	-	6
Non-SLMTA Lab					
Lab 3					
HIV RT	100	100	100	100	35
Malaria	-	-	-	-	-
Hb level	-	-	-	-	-
Lab 4					
HIV RT	100	100	100	100	36
Malaria	94	100	100	91	27
Hb level	-	-	-	-	-

The table above shows that, among the SLMTA labs, specificity and positive predictive values for malaria were less than 100%. While in non-SLMTA laboratories the sensitivity and negative predictive values for the same test ware low (94% & 91% respectively). However, no records for malaria and hemoglobin proficiency test available to almost all the studied laboratories.

Figures



	SLMTA labs				Non-SLMTA labs		
	HIV RT	MALARIA	Hb level		HIV RT	MALARIA	Hb level
Sensitivity (%)	100	100	87		100	94	0
Specificity (%)	100	75	0		100	100	0
Positive predictive value	100	90	0		100	100	0
Negative predictive value	100	100	0		100	91	0

Figure 1

Aggregated proficiency tests sensitivity & specificity in SLMTA & non-SLMTA laboratories (Morogoro & Iringa)

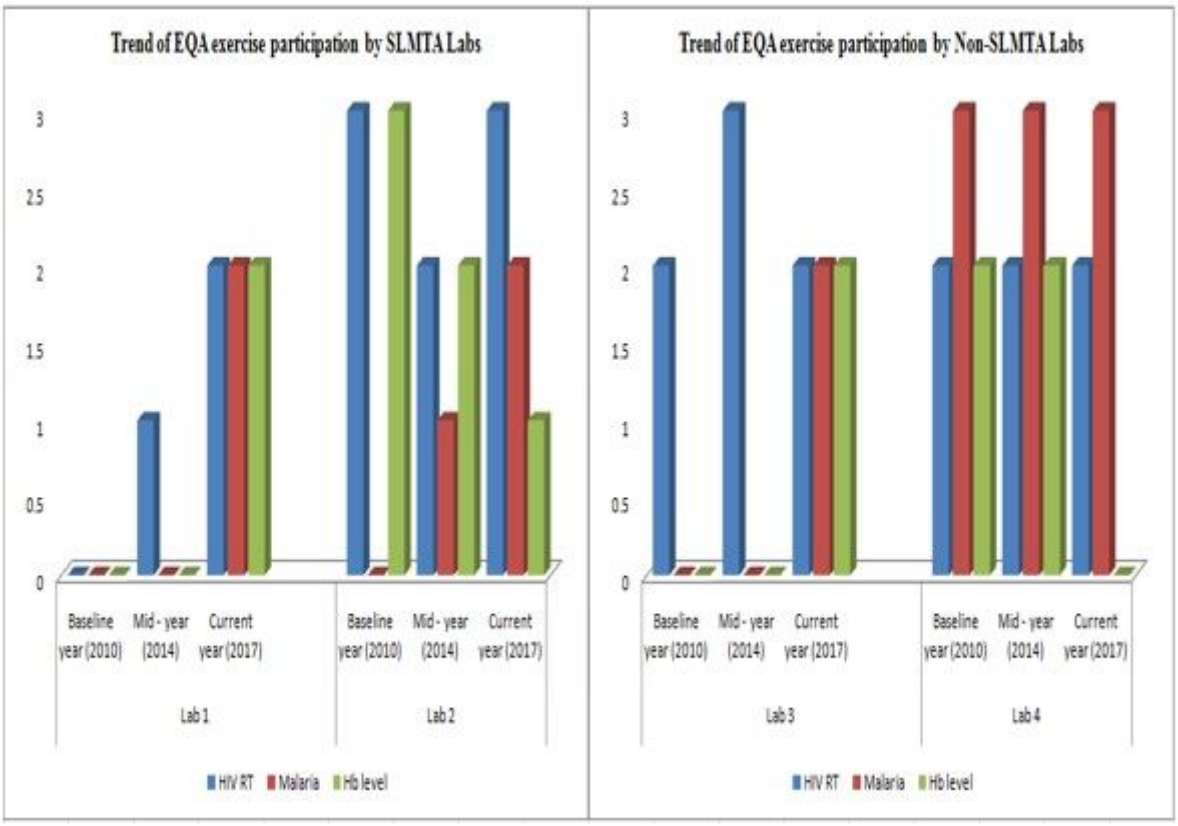


Figure 2

Trend of Public Laboratories (SLMTA & non-SLMTA) participation in EQA exercise