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The Quality Management System in Medical Laboratories: Seventeen Years of Strengthening Laboratory Management Towards ISO 15189 Accreditation in Tanzania

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Abstract

Background

Recent advances in development and changes in laboratory technology seen in modern medicine have increased the demand on timely, accurate, reliable, and reproducible laboratory results. In public health settings, the laboratory plays a key role in disease surveillance for early detection and confirmation of disease outbreaks. We aimed to describe and document the 15189 accreditation in Tanzania.

Methods

We conducted a cross-sectional study involving databases for medical laboratories in the Ministry of Health and African Society for Laboratory Medicine (ASLM). All laboratories which participated in quality management system in Tanzania were included in the study from national to health centre levels.

Results

Out of 157 laboratories implementing QMS from 2007 to 2024, a total of 81 (51.6%) laboratories were accredited. Secondary laboratory level had high number of enrolments into QMS program 117 (74.5%) followed by tertiary laboratories 26 (16.6%). The proportion of accredited laboratories at tertiary level was (73.1%) *($p < 0.033$)* which was significantly higher compared to other levels. There was significantly higher proportion of laboratories accredited through direct laboratory accreditation process 25/28, (89.3%), compared with SLMTA program 59/129 (44.4%) *($p < 0.001$)*. There was a significant increase of accredited laboratories among SLMTA program from 1/76 (1.3%) in 2017 to 56/157 (35.7%) in 2024, (*$p = 0.027$)* compared to direct laboratory accreditation approach.

Conclusions

Laboratory accreditation is a hallmark of quality management system implementation which can be achieved either through direct laboratory accreditation approach or the SLMTA program. The seventeen years of experience in implementing QMS indicates that the SLMTA program is more efficient, effectiveness and user-friendly than the direct laboratory accreditation approach.

Background

In recent years, there has been an increasing focus on enhancing healthcare services as a whole to ensure high quality, increased accessibility, and better value for money (1). Recent advances in development and changes in laboratory technology seen in modern medicine have increased the demand on timely, accurate, reliable and reproducible laboratory results (2). Given the critical role of the laboratory in healthcare, quality laboratory testing is crucial for confirming clinical diagnoses. In public

health settings, the laboratory plays a key role in disease surveillance for early detection and confirmation of disease outbreaks (3).

The laboratory quality management system (QMS) is a coordinated approach designed to coordinate laboratory operations by ensuring they align with the requirements of the ISO 15189 standard (4). It is a systematic, integrated set of activities and programs to establish and control the work processes from pre-examination, examination and post-examination processes, manage resources, conduct evaluations, and make continual improvements to ensure consistent quality laboratory test results in clinical and public health settings (5). A simplified way of implementing QMS was introduced by World Health Organization (WHO) AFRO in collaboration with United States Centre for Disease Control and Prevention (CDC) and other Development Partners for which “Strengthening Laboratory Management Toward Accreditation” (SLMTA), was launched in July, 2009 in Kigali, Rwanda, after recognizing that laboratory accreditation was beyond reach for majority of sub-Saharan African countries (6).

SLMTA program was launched simultaneously with Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA), which monitors and evaluates laboratory performance with objective verification of established, documented and implemented QMS using WHO AFRO SLIPTA checklist (7). The checklist is designed to assess the quality of laboratory services. It provides a structured framework for laboratories to align with ISO 15189, through a stepwise process. The checklist evaluates various aspects of laboratory operations, including management, infrastructure, and technical processes to ensure continuous quality improvement and readiness for accreditation (8). The goal of SLIPTA is to recognize and raise laboratory performance, and dependability so that they can eventually apply for accreditation by meeting the necessary standard requirements (8).

SLMTA is a mentorship and training programme designed to bring about immediate and measurable improvement in quality of laboratory services using available resources (9). The emergence of COVID-19 and other re-emerging diseases has underscored the importance of quality laboratory testing services for the entire health system to deliver quality results that guide appropriate public health action and clinical management of patients (10). SLMTA and SLIPTA have proved effective tools for empowering laboratory practitioners and improving laboratory quality in developing countries (11).

Tanzania started implementing QMS officially in 2007, in collaboration with Clinical Laboratory Standards Institute (CLSI) whereby five (5) medical laboratories (National level = 2; and Zonal level = 3) were enrolled for ISO 15189 accreditation using a direct laboratory accreditation approach (12). Additionally, in 2009, the National Health Laboratory Quality Assurance and Training Centre (NHLQATC) currently known as the National Public Health Laboratory (NPHL), was enrolled as the sixth laboratory (12). In 2010, Tanzania introduced SLMTA approach for medical laboratories by enrolling twelve (12) laboratories; six (6) from regional and six (6) from district hospital laboratories. Thus, the aim of this study is to describe and document the seventeen years’ experience of implementing QMS and ISO 15189 accreditation in Tanzania.

Methods

Study design and setting

We conducted a cross-sectional study involving databases for medical laboratories in the Ministry of Health (MoH) and African Society for Laboratory Medicine (ASLM). All laboratories which participated in QMS in Tanzania were included in the study from national to health centre levels.

Data collection

Data were extracted from the Diagnostic Services Section, MoH database, from 2007 to October 2024. The tertiary laboratory level included laboratory from National, Zonal and Specialized laboratories, Primary level laboratories included Regional and District laboratories and Primary levels included Health centre laboratories.

QMS implementation process

Implementation of QMS and accreditation in Tanzania was done in two arms, the direct approach and the SLMTA program. In direct laboratory accreditation approach, enrolled laboratories did not use or by-passed the stepwise laboratory quality improvement processes toward accreditation as invented by WHO AFRO (SLMTA program), hence laboratories implemented QMS and directly applied for accreditation to conformity assessment bodies.

Direct laboratory accreditation approach

The MoH in collaboration with CLSI and the American Society for Clinical Pathology developed a roadmap towards accreditation by using direct laboratory accreditation approach in 2007. The approach involved conducting gap analysis and providing training and mentorship to the identified gaps. The approach provided mentorships and training into two circles of three months in a year. The roadmap aimed at capacitating all National and Zonal Referral Hospital Laboratories on the accreditation process based on ISO15189. A direct laboratory accreditation approach was a “Pass-fail-process” or “All or nothing” approach which was unable to recognize the stepwise quality improvements towards accreditation (13) especially to laboratories with limited resources. Therefore, SLMTA program was introduced as the key intervention to address this challenge (Fig. 1).

SLMTA program

SLMTA implementation (2010–2017) using the generic approach

Tanzania adopted the program in 2010, following its initial launch in 2009 in Kigali, Rwanda, by WHO AFRO. This program was implemented in three cycles (training, mentorship and supervision) within 12 to 18 months all of which involved working on improvement projects (14) (Fig. 2).

Tanzania opted to implement the three cycles within 12 months, thus enrolling laboratories for SLMTA cohorts each year. SLMTA cohort involved three workshops which were conducted for five-days each, held at three-month intervals, aimed at equipping laboratory managers, quality officers, safety officers and other self-committed personnel, with essential knowledge and skills according to the curriculum package. Trainees received tools like the Laboratory Management Framework, Assessment Checklist, and SLMTA Toolkit, which outlined their responsibilities in line with ISO 15189 standards. From 2010 to 2012, when SLIPTA checklist was not yet adopted, WHO-AFRO accreditation checklist was used as an evaluation tool of the implemented SLMTA program. In 2013, SLIPTA checklist was adopted (15) and was used as an audit tool. Additionally, participants were provided with modules detailing best practices and improvement projects. These modules incorporated lessons learned from previous workshops and addressed common nonconformities identified during baseline audits (16).

On site supportive supervision was conducted by trained and experienced team from MoH CLSI and implementing partners to oversee and follow up on implementation progress of improvement projects to enrolled laboratories. During visits, supervisors got opportunities to clarify complex issues, including translating workshop contents to live and practical operations and providing them with appropriate guidance (16). Each participating laboratory underwent an audit at the commencement (baseline) and the end (exit) of the program using a WHO AFRO SLIPTA checklist. The differences in scores between the baseline and exit, along with their star ratings (15), were analysed and compared to assess the program's effectiveness on the laboratories' performance and improved quality (17). The SLIPTA checklist ranked laboratory's quality performance into five (5) stars levels (0–5). The assessment was conducted by ASLM certified auditors, some of whom were based in Tanzania. Laboratories with at least three stars were recommended to proceed with the accreditation process.

Data analysis

Data were cleaned by using Microsoft Excel and analysed using Epi info version 7.2.5.0 software. The frequency and proportion were reported in tables and figures. The chi square test was used to check the relationship between the accreditation status and other variables. The map that shows the distribution of accredited laboratories were drawn by QGIS desktop version 3.24.2 software.

Results

Demographic characteristics of laboratories enrolled in QMS

Out of 157 laboratories implementing QMS from 2007 to 2024, a total of 81 (51.6%) laboratories were accredited. Secondary laboratory level had high number of enrolments into QMS program 117 (74.5%)

followed by tertiary laboratories 26 (16.6%) (Table 1). At least each region had one accredited laboratory in the country with Dar es Salaam having most 18 (11.5%) of accredited laboratories (Fig. 3).

Table 1
Demographic characteristics of laboratories enrolled in QMS from 2007 to September 2024 (N = 157)

Characteristics	Frequency	Proportion
Laboratory level		
Primary	14	8.9
Secondary	117	74.5
Tertiary	26	16.6
QMS implementation		
Direct accreditation approach	28	17.8
SLMTA program approach	129	82.2
Laboratory ownership		
Private	42	26.8
Public	115	73.2
Accredited		
Yes	81	51.6
No	76	48.4

Proportion of accredited laboratories by level, QMS implementation approach and the ownerships

The proportion of accredited laboratories at tertiary level was (73.1%) *($p < 0.033$)* which was significantly higher compared to other levels. There was significantly higher proportion of laboratories accredited through direct laboratory accreditation process 25/28, (89.3%), compared with SLMTA program 59/129 (44.4%) *($p < 0.001$*). Private laboratories had high proportion of accreditation 23/42 (54.8%) compared to public laboratories 50.4% (*$p = 0.719$*) (Table 2).

Table 2
Relationship of accredited laboratories by level, QMS implementation type and ownership from 2007 to September 2024.

Characteristics	Total enrolled	Accredited	Proportion	P-value
Laboratory levels				
Primary	14	5	35.7	
Secondary	117	57	48.7	
Tertiary	26	19	73.1	**< 0.033**
QMS implementation type				
Direct to accreditation	28	25	89.3	
SLMTA process	129	56	44.4	**< 0.001**
Laboratory ownership				
Private	42	23	54.8	
Public	115	58	50.4	0.719

Trend of accreditation in direct laboratory accreditation approach and SLMTA program approach

There was a significant increase of accredited laboratories among SLMTA program from 1/76 (1.3%) in 2017 to 56/157 (35.7%) in 2024, *p = 0.027* compared to direct laboratory accreditation approach. In the year 2014 a total of 4/48 (8.3%) to 25/157 (15.9), *p = 0.379* laboratories under direct accreditation approach were accredited after almost seven years of QMS implementation (Fig. 4).

Discussion

The study aimed at describing and documenting the seventeen-year's journey and experience of implementing QMS and accreditation on ISO 15189 in Tanzania. The implementation of QMS with a direct laboratory accreditation approach produced low output of accredited laboratories. This is because, the direct laboratory accreditation approach is a "pass or fail" process that does not recognize stepwise quality improvement suggesting that, many laboratories are either discouraged to implement QMS or did not afford to apply the direct laboratory accreditation approach. The SLMTA program, significantly increased the number of accredited laboratories from four in 2014 to 81 laboratories in September 2024, indicating that many laboratories not only could they afford to implement QMS through SLMTA approach, additionally the accreditation process was simplified by the use of mentorships and onsite supervision supported by MoH attracting more laboratories to implement QMS. Furthermore the implementation of the QMS using the SLMTA approach, proved to be reliable and effective.

SLMTA program has shown to improve coverage of medical laboratories implementing the QMS at different levels from tertiary to secondary levels; and hence preparing more laboratories for accreditation. This is contrary to the direct accreditation approach that involved only tertiary laboratories which could afford the direct approach; and had enough resources for QMS implementation. The SLMTA program allows quality improvement in a stepwise approach, gaining more experience and expertise overtime until highest level of quality performance and accreditation are attained. Similar results have been observed in the Kenyan study where the performance of QMS increased from 32% at baseline to 44% at the exit assessment. In Caribbean Region where the average performance was 35.5% at initial assessment and 60% at exit assessment (18, 19). Although both the direct laboratory accreditation approach and SLMTA program took a minimum of seven years for the first laboratory to achieve accreditation, laboratories in the SLMTA program increased rapidly in numbers thereafter compared to the direct laboratory accreditation approach, demonstrating a more effective and efficient path to accreditation in SLMTA program.

Our study identified a significantly high proportion of accredited laboratories at tertiary level. This could be attributed to the implementation of the quality services influenced by a well-established laboratory systems and design. Moreover, this could be explained by factors such as good leadership, adequate, skilled and experienced laboratory personnel working with these laboratories. Furthermore, financial resources allocated to essential areas such as infrastructures, trainings, procurement of safety and modern diagnostic equipment and the use of robust information systems, have bolstered these higher-level medical laboratories. These factors collectively contribute to the higher accreditation rate observed in this level. In 2021, France reported similar findings, emphasizing notable gaps shaped by various factors, including disparities in national and local infrastructures, available funding and priorities, regulatory frameworks and access to expertise, training and equipment resources (20). A study done at Bugando Medical Centre in year 2018 showed that financial support, motivated skilled staff and good infrastructure were the key factors for the roadmap towards accreditation (21). Disparities between higher and lower-level laboratories in infrastructure and number of skilled laboratory personnel highlight the need to strengthen QMS efforts across all laboratory levels for better patient outcomes.

Our results show that, a higher proportion of laboratories were accredited using the direct approach compared to the SLMTA program. This could be attributed to the relatively smaller total number of higher-level laboratories (national to regional level) than the total number of lower-level laboratories (district to health centres). In addition, QMS implementation in Tanzania started with the higher-level laboratories using the direct accreditation approach (26). However, in overall, trend analysis indicates that the SLMTA program significantly increased the number of accredited laboratories compared to the direct laboratory accreditation approach as evidenced in Fig. 4. The effectiveness and efficiency of SLMTA program are also supported by a study conducted in Lesotho in which SLMTA program demonstrated an immediate, measurable and positive impact on laboratories (22).

Private laboratories showed a higher proportion of accredited laboratories compared to public laboratories. Similar findings were reported in a study by Kinyenje E. et al in 2023 where private health

sector performed better than the public health sector (27). This finding underscores the effectiveness of private health sector investments in QMS and infrastructure improvements. The enhanced focus on quality assurance and better resource allocation in private laboratories has led to higher accreditation rates, reflecting their commitment to maintaining high standards and achieving excellence in laboratory services. The finding also emphasizes the need for the public laboratories to adopt similar quality management system strategies to improve their accreditation outcomes.

Different implementing partners that are working closely with MoH played a crucial role in the success of SLMTA and the accreditation process in Tanzania. They supported training, resources and mentorship by ensuring ongoing support and direction. Their participation greatly enhanced laboratory quality resulting in successful accreditation and improved healthcare services throughout the nation.

Our study had number of limitations. First, the varying number of laboratories at different levels could lead to discrepancies in the data, making direct comparisons challenging. Second, the study might not fully capture the geographical and laboratory infrastructural disparities within Tanzania, which could affect the generalizability of the findings. Third, the study might have a positive bias by focusing on laboratories that have achieved accreditation, potentially overlooking those that struggled or failed in their attempts. Forth, we were unable to get the information about costs of the different approaches towards accreditation that the laboratory could bear and the information of the accreditation renewal cost over the five year accreditation cycle as were not available. The study had a strength of the seventeen-year timeline provides a robust dataset that allows for thorough analysis of trends and outcomes over a substantial period.

Conclusion

Laboratory accreditation is a hallmark of quality management system implementation which can be achieved either through direct laboratory accreditation approach or the SLMTA program. The seventeen years of experience in implementing QMS indicates that the SLMTA program is more efficient, effectiveness and user-friendly than the direct laboratory accreditation approach.

Abbreviations

QMS	Quality management System
SLMTA	Strengthening Laboratory Management Toward Accreditation
GIS	Geographic Information System
WHO	World health Organisation
SLIPTA	Stepwise Laboratory Improvement Process Towards Accreditation
CLSI	Clinical Laboratory Standards Institute
MoH	Ministry of Health
ISO	International Standard Organisation
NPHL	National Public Health Laboratory
NHLQATC	National Health Laboratory, Quality Assurance and Training Centre
FELTP	Field Epidemiology and Laboratory Training Program
PO-RALG	President's Office, Regional Administration and Local Government
CDC	Centre for Disease Control and Prevention
ASLM	African Society for Laboratory Medicine

Declarations

Ethics approval and consent to participate

Not Applicable

Consent for publication

Permission to publish was granted by the Ministry of Health through letter ref. no. MA.155/174/01/625.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests

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Author Contributions

Conceptualization: PRT, JL, CM and NM, **Data curation**: PRT, JL and RJ, **Formal analysis:** PRT, **Methodology:** PRT, RJ, NM, CM, MEK, MM, AJ, AK and JL, **Resources:** PRT, RJ, NM, CM, and JL, **Supervision:** JL, **Validation:** PRT, RJ, AK, and JL, **Writing-original draft:** PRT, RJ, NM, CM, MEK, MM, AJ, AK and JL, **Writing – review & editing:** PRT, RJ, NM, CM, MEK, MM, AJ, AK and JL.

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Figures

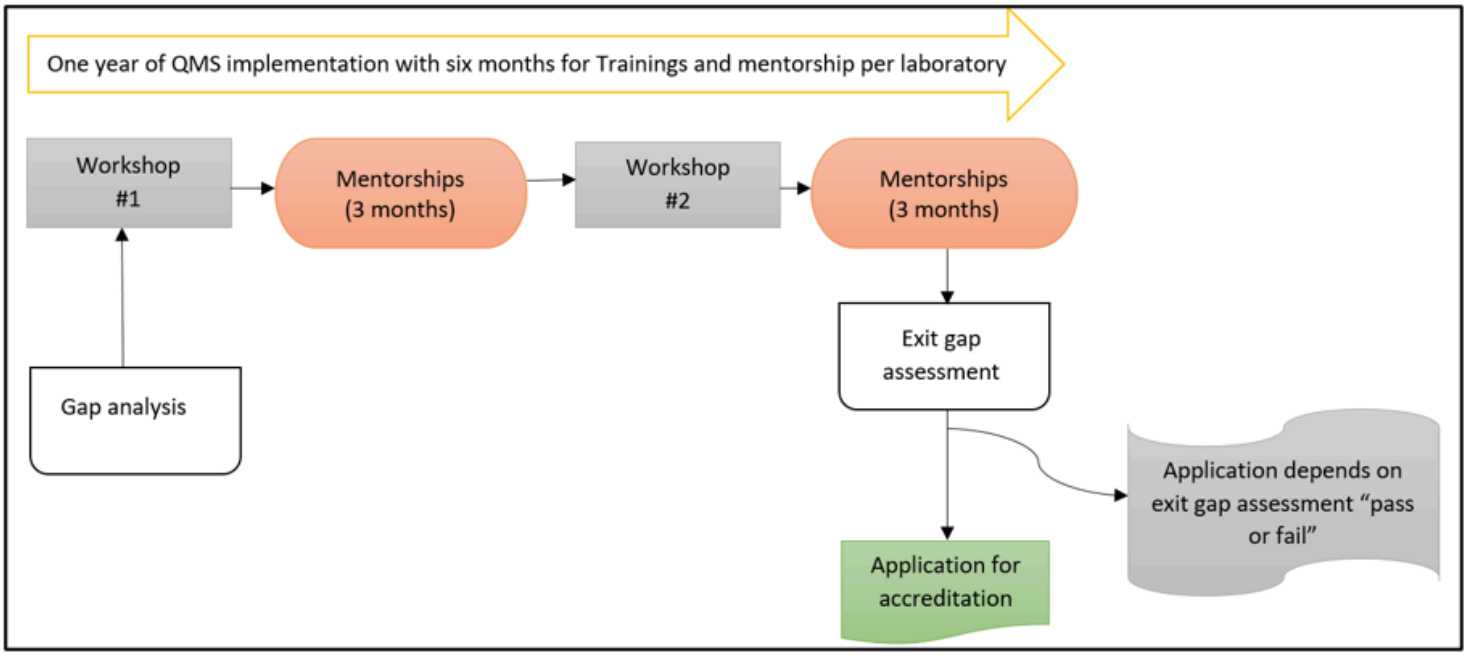


Figure 1

Flow diagram for direct accreditation approach

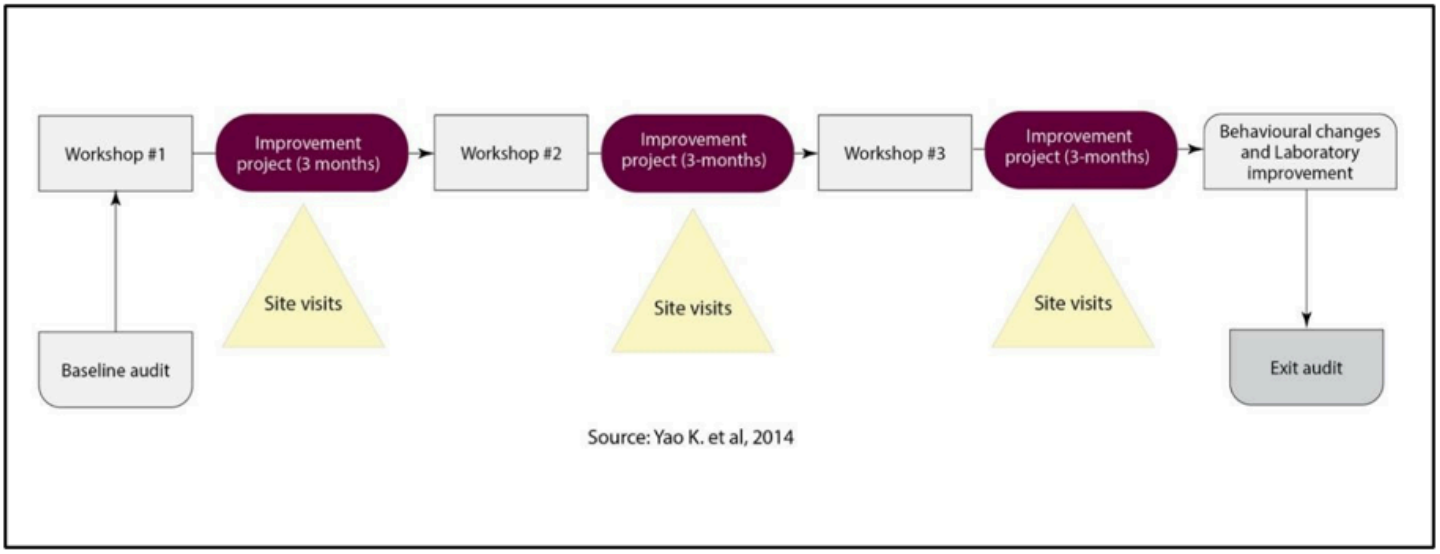


Figure 2

The generic SLMTA program implementation



Figure 3

Distribution of accredited laboratories in the country by October 2024

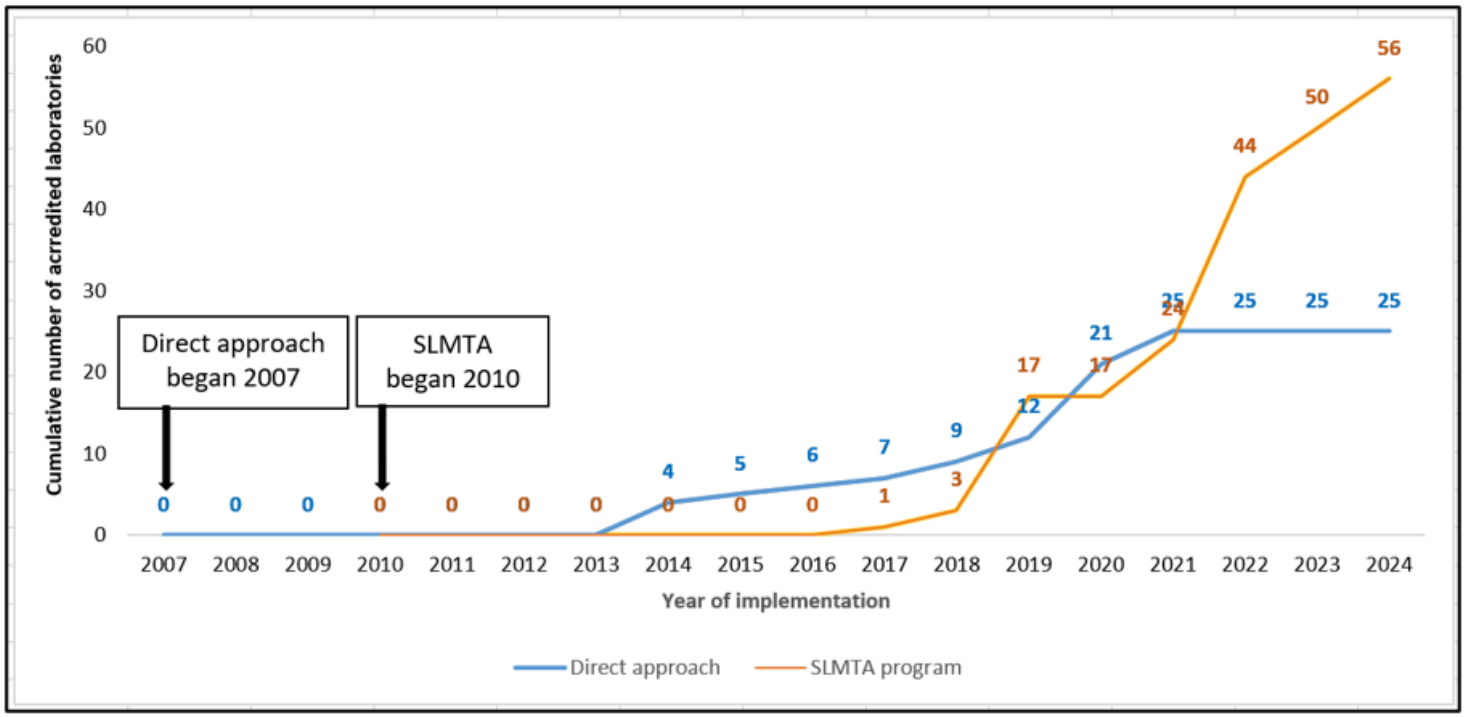


Figure 4

Trend of accredited laboratory by direct laboratory accreditation approach and SLMTA approach