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Implementation of Laboratory Quality Management System (LQMS) in public hospitals in Cambodia: An evaluation of training program 2011-2020

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ABSTRACT

Introduction

Laboratory Quality Management System (LQMS) training program was implemented in Cambodia in 2011 under the coordination of National Institute of Public Health (NIPH) and the Bureau of Medical Laboratory Services (BMLS), Hospital Department, Ministry of Health. LQMS training program has been contextualized from a program called "Strengthening Laboratory Management Towards Accreditation" (SLMTA) which intended to improve the quality management in clinical laboratories. This study aims to evaluate the effectiveness of the LQMS training program in 24 laboratories in public hospitals in Cambodia between 2011 and 2020.

Methods

Quality of the laboratory was assessed in percentage point using assessment tool which consists of twelve quality principles based on ISO 15189 requirements. The effectiveness of LQMS program was evaluated by comparing the assessment score (percentage point) before and after participating in LQMS program (using paired t-test) and between laboratories with and without LQMS training (using t-test). Linear regression was used to identify factors associated with the quality improvement of the LQMS group.

Results

Considerable quality improvement was observed at the laboratories after completing LQMS program (before LQMS=18.5% vs after LQMS=64.1%, p-value < 0.001). The laboratories with LQMS had significantly higher score than those absence of LQMS implementation, (11.4% vs 63.7%, p-value <0.001). Results showed that the most recent batches of LQMS training program have positive correlation with the laboratory quality improvement while smaller number of onsite mentoring in laboratory can make more improvement in lab quality management. However, being a laboratory of higher level (provincial level), and applying Laboratory Information System (LIS) did not affect quality of lab management system. There were 4 sections of the LQMS components which remained big gaps in the QMS implementation: management reviews, internal audits, non-conformity managements, and incidence managements.

Conclusions

After nearly a decade of LQMS implementation in Cambodia at 24 laboratories, their quality has been improved significantly. Further scale-up is needed to expand the LQMS program to other laboratories in response to the need for quality improvement of health services in Cambodia.

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Introduction

Clinical laboratory test results play an important role in supporting the effective diagnosis and treatment for patients as well as disease surveillance system and research. As a matter of fact, an accurate, reliable, and timely results from laboratory could preliminarily eliminate medical errors that contribute to 60-70% of all diagnoses [1, 2]. Most of the harmful consequences such as unnecessary treatment, treatment complications, failure to provide the proper treatment, delay in correct diagnosis, and additional and unnecessary diagnosis testing could be minimized by good quality laboratory results [2].

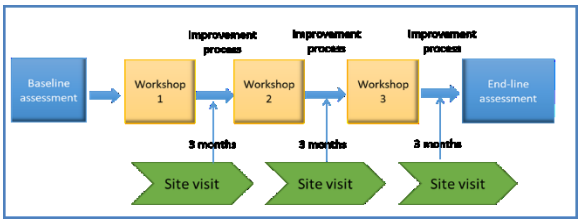
In Cambodia, clinical laboratories are distributed throughout the country, mostly, under management of public hospitals. Between 2013 and 2014, 28 selected public hospital laboratories, across the country, were reported to get 36-60% scores based on the capacity assessment conducted by Cambodia MoH, US-CDC and WHO. The results showed that not only there is an absence of the quality management system in place, but also the capacity of most laboratory was not complied with international health regulation requirements and population health demands. In 2014, a review of data from proficiency testing schemes conducted in 30 public hospitals in Cambodia showed unsatisfying results (< 50% accuracy) in hematology and biochemistry, while the minimum standard for an acceptable result should be at least 80% [3].

One of the main functions of National Institute of Public Health (NIPH) is serving as the National Reference Laboratory (NRL) that provides clinical testing services and training on laboratory quality management system, coordinates external quality assurance (EQA) program, conducts laboratory research and surveillance of infectious diseases. NRL was the first government laboratory receiving international recognition ISO 15189 accreditation from Canadian Institute of Quality Management in Healthcare (IQMH) in early 2019.

Since 2011, NIPH, in collaboration with the Bureau of Medical Laboratory Service (BMLS) of Hospital Department, Cambodia Ministry of Health (MoH), has developed Laboratory Quality Management System (LQMS) training program for improving clinical laboratories of the public hospitals. LQMS training program was contextualized from a program called "Strengthening Laboratory Management Toward Accreditation" (SLMTA) supported by US-CDC to improve the quality of laboratories in many African countries [3–5]. Although implementing LQMS could not guarantee error free in the laboratory, the system could at least minimize errors and preliminary predict consequences or the likelihood of source of errors or risks. The integration of a good training program on laboratory quality management is tremendously crucial for resource limited countries where the health facility and health workforce are under development.

LQMS is a complementary between in-class training and onsite mentoring program which has been implemented for nearly a decade in Cambodia. Usual process, it takes about 16 months from baseline lab assessment, training, onsite mentoring to follow-up assessment or end-line assessment (**Figure 1**). In the past, not many references have been documented or assessed about this program. Although, some changes may have been notified during the practice, proper records were not well documented. Therefore, this paper aims to assess the effectiveness of the LQMS training program implemented in 24 laboratories in Cambodia from 2011 to 2020 and document it.

Figure 1: Summary of LQMS training program



Methods

Assessment tools

Quality management of the laboratory was assessed using assessment tools based on ISO 15189 requirements which include 12 essential components: 1). Document and records, 2). Management reviews, 3). Organization and personnel, 4). Client management and customer services, 5). Equipment, 6). Evaluation and audits, 7). Purchasing and inventory, 8). Process control, 9). Information management, 10). Non-conformity management, 11). Incident management, and 12). Facilities and biosafety.

Criteria for laboratory recruitment

The criteria of recruiting laboratories to join the program were commitments of the management team and laboratory staff for quality improvement, laboratory testing capacity and a priority was given to the provincial laboratory level.

Data collection and management

The data were collected by three trainers and/or mentors. The assessment process consists of asking questions to all lab staff, reviewing document and records and observing the practice of the lab staff's performance. The pre-training data were collected at the beginning of the training program (batch-1 in 2011, batch-2 in 2013, and batch-3 in 2018). Post training data were collected after the end of the program (batch-1 in 2013, batch -2 in 2015, and batch-3 in 2020) (**Table 1**).

Also we used data from a follow up assessment conducted in 2018 as a comparing point between 12 laboratories with LQMS training (batch 1 and 2) and 12 laboratories in batch 3 without receiving LQMS training yet to assess whether the trained laboratories (batch 1 and 2) had better laboratory quality management compared to new batch (batch 3).

The assessment scores were calculated based on the assessment tool checklist consisting of 117 questions. If an answer to any question was Yes, receiving 100% of the total score from the question, Partial, receiving 50% of the total score from the question, and No, receiving no score. The score presented was percentage point (the total assessment scores by total scores). The data from the assessment scores then, were entered, cleaned and stored into computer using excel version 2012. The cleaned data were exported and analyzed with Stata V14. Variables were assessment scores, laboratory level, available Laboratory Information System (LIS) application in the respective laboratory, and number of onsite mentoring offered by the program.

Data analysis

The effectiveness of LQMS implementation was measured by comparing the assessment scores before and after participating in LQMS training program using paired t-test; and between laboratories with (batch 1 & 2) and without LQMS training (batch 3) using t-test. Finally, a simple linear regression was used to identify factors associated with the quality improvement score, the difference of percentage point between pre- and post- training in the laboratories participating in the LQMS training program.

Table 1: Information related to the three batches receiving the LQMS training program

Batch number	Started year	Ended year	Year of follow up assessment	Number of laboratories recruited	Number of Workshop training	Number of onsite mentoring
1	2011	2013	2018	7	3	9
2	2013	2015	2018	5	3	6
3	**2018**	2020	N/A	12	3	3

Results

Laboratory Quality Improvement after participating in LQMS training program

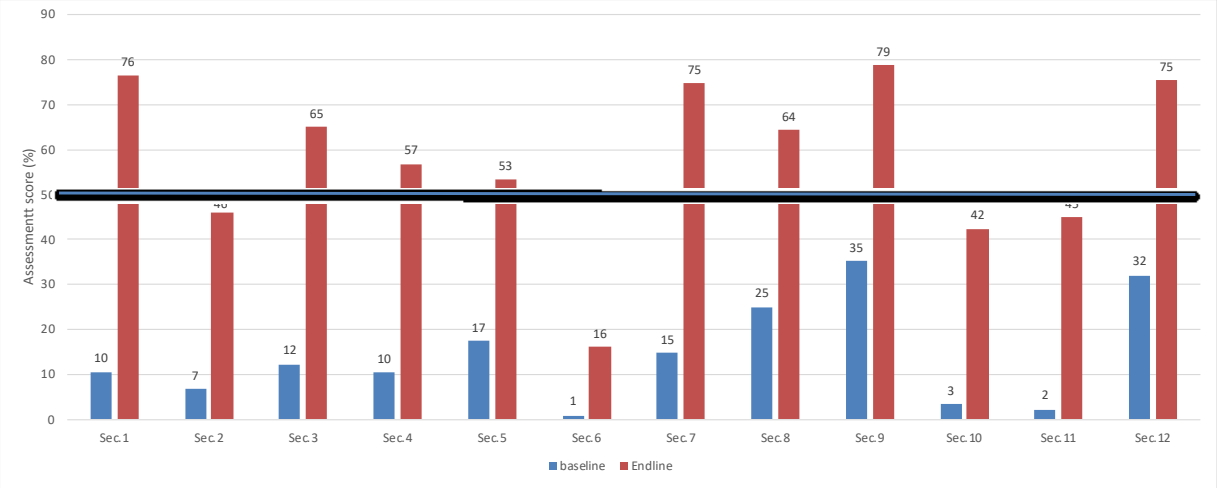
As shown in **Table 2**, the quality improvement score was statistically significant difference observed at the laboratories after completing the LQMS program (before LQMS=18.5%, after LQMS=64.1%, p-value < 0.001. The mean difference of improvement score was **45.6%** (95% CI: 41.5%-49.7%). The scores of quality management at non-implemented LQMS in 12 laboratories were significantly lower than those with implemented LQMS laboratories (11.4% Vs 63.7%, p-value < 0.001; the mean difference of improvement score was **52.5%** (95% CI: 42.9%- 62.0%)

Table 2: Difference of mean scores in percentage point of participant laboratories before and after the LQMS training program

Paired t-test	**Mean**	**N**	**95% CI**
Assessment score before LQMS	18.5%	24	14.1% - 22.9%
Assessment score after LQMS	64.1%	24	60.0% - 68.3%
Difference of mean score (before and after LQMS)	45.6%	24	**41.6% - 49.7%***
Unpaired t-test	**Mean**	**N**	**95% CI**
Assessment score of non-LQMS group (batch 3)	11.4%	12	7.9% – 14.8%
Assessment score of LQMS group (batch 1&2)	63.7%	12	54.3% - 73.4%
Difference of mean score (non-LQMS and LQMS)	52.5%	24	**42.9% - 62.0%***

* *Highly significant difference at p-value < 0.001*

Figure 2: Average different scores of 12 essential quality components before and after participating in LQMS training program (n = 24 labs)



Note: 1- Document and records, 2- Management reviews, 3- Organization & personnel, 4- Client management & customer, 5- Equipment, 6- Evaluation and audits, 7- Purchasing & inventory, 8- Process control, 9- Information management, 10- Non conformity management, 11- Incidence management, 12- Facility & biosafety

Furthermore, the 12 sections of the assessment tool were presented separately as shown **Figure 2.** The average score of section 1 (Document & records), 7 (Purchasing & inventory), 9 (Information management), and 12 (Facility & biosafety) were noticeably higher than 70% in the final assessment. However, other sections including section 2 (Management reviews), section 6 (Internal audit), section 10 (Non-conformity management), and section 11 (Incident management) **remained below 50%**

Factors associated with quality improvement

The study indicated that latest batch (Batch 3) of LQMS training program was significantly improved in LQMS compared to early batches. When looking at a number of onsite mentoring in laboratory, a negative significantly linear relationship with quality improvement score was observed. However, being provincial or district level laboratories and using Lab Information System (LIS) application were not statistically significant linear relationship with better improvement of lab quality management (**Table 3**).

Table 3: Factors associated with quality improvement score in laboratories participated in LQMS training program, simple linear regression analysis

Variable	N	Coeff.	95% CI	P-value	R-squared
Lab. level	23	-0.99	[-6.29-4.30]	0.700	0.007
Use of LIS*	24	-0.18	[-9.36-8.99]	0.967	0.001
No. of onsite mentoring	24	-2.40	[-4.03--0.77]	**0.006**	0.298
Different batches	24	5.75	[1.65-9.85]	**0.008**	0.278

**LIS: Laboratory information system*

Discussion

The improvement score (45.6%) shown in this study is consistently aligned with a systematic review of Luman et al. that reported average improvement of 25% points after the implementation of SLMTA program [6]. The results were confirmed by another study reported an improvement of 18% point from 53% (baseline) to 71% (final audit) of the 3 laboratories enrolled in 9-month SLMTA program [7].

A detailed analysis of the score in each section of the assessment tools revealed a relatively lower scores (under 50%) in four critically important components of the assessment tools namely management review, internal audits, non-conformity management and incident managements. The improvement of these four components requires high commitment and ongoing proactiveness from laboratory team, and could take time, efforts and resources to improve in a long run. Luman et al. also reported similar lower scores related to SLAMTA assessment tool including section 2

(Management reviews) and section 6 (Evaluation and audits) [6]. In quality management system, management reviews are one of the key elements that approach laboratory managers and personnel to review all inputs and outputs of the laboratory management system before moving to next step [8]. For instance, the low score in management reviews and internal audit reflected the low score in section 10 (non-conformity management) and section 11 (Incident managements). This positive correlation is highlighted in the clauses 4.14 and 4.15 of ISO 15189 (2012) requirements which mentioned that most of non-conformities and incidents in laboratory are identified and followed up during management reviews and internal audits. In consequence, while improving the proper and routine reviews and inspection, it will result in improving non-conformity and occurrence management as well. In addition, team work and staff motivation seem to be a mechanism to boost these activities.

The positive association between the improvements in quality management and being the most recent batch and receiving a fewer onsite mentoring found in this study could be due to the accumulated experience of trainers and mentors in the program that makes the program implementation more efficient in the recent batches without regards to level of different setting or availability of electronic information management. As the matter of fact, we can't see the difference of quality improvement among laboratories that have larger or smaller service packages. However, the correlation would have been more clearly observed in a larger sample size. Therefore, further study with larger sample size should be conducted to confirm the findings.

Conclusions

After a decade of LQMS implementation in Cambodia, overall, the laboratory quality has been improved significantly. The connection between each of the 12 quality essentials in the assessment tools are the components that build up the quality management system; hence, it requires good collaboration between laboratory technicians and managers to build up the system. However, key components such as management reviews and internal audits and other necessary components needed to be further improved overtime through curriculum of training program and monitoring process conducted by LQMS team before expanding the LQMS program. A regular review of laboratory quality via meeting and internal audits are necessary to ensure the sustainability of the system. Further investigation is needed to explore the possibility of scaling the program to other laboratories in response to the need for quality improvement of health service in Cambodia.

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References

[1] Agarwal R. Quality-improvement measures as effective ways of preventing laboratory errors. Lab Med. 2014;45:e80–8.
[2] WHO. Quality Management System Handbook. 2011.
[3] Perrone LA, Voeurng V, Sek S, Song S, Vong N, Tous C, et al. Implementation research: A mentoring programme to improve laboratory quality in Cambodia. Bull World Health Organ. 2016;94:743–51.
[4] Yao K, Luman ET. Evidence from 617 laboratories in 47 countries for SLMTA-driven improvement in quality management systems. Afr J Lab Med. 2014;3:1–11.
[5] Yao K, Maruta T, Luman ET, Nkengasong JN. The SLMTA programme: Transforming the laboratory landscape in developing countries. Afr J Lab Med. 2014;3:1–8.
[6] Luman ET, Yao K, Nkengasong JN. A comprehensive review of the SLMTA literature part 2: Measuring success. Afr J Lab Med. 2014;3:1–8.
[7] Mokobela KO, Moatshe MT, Modukanele M. Accelerating the spread of laboratory quality improvement efforts in Botswana. Afr J Lab Med. 2014;3:1–6.
[8] Theodorou D, Giannelos P. Medical laboratory quality systems-A management review. Int J Health Care Qual Assur. 2015;28:267–73.