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Research Article

Development of Scenario-based Online Training Flatform For Laboratory Quality Management System

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Abstract

Aim: This study aimed to describe the way to develop and perform a scenario-based online training method and assess its effectiveness to medical staff in laboratories in Vietnam.

Background: A laboratory quality management system (LQMS) is a tool that ensures the service quality of laboratories, and it, therefore, contributes to patient safety. The training is a key factor to improve the perceptions and behavior of laboratory staff to maintain and ameliorate the LQMS.

Design: This study blended self-learning through scenario-based training methods and solving a problem-based meeting online.

Methods: Based on the format of the "3C" (Challenge, Choice, Consequence) model, the question of each 12 Quality System Essential (QSEs) was created on Microsoft forms as an exchanged format between participants and lecturers that sent to participants everyweek. After two weeks, the meeting online was held to discuss the concept of QSEs from previous lessons and any related problems in more detail through Microsoft teams.Consequently, participants scored each QSE lesson according to how interesting it was/they found it using a Likert scale. They also assessed their perception of their progress in understanding how to use LQMS. In addition, selecting the continual improvement of participants was considered a plus indicator of the success of the methods.

Results: The 490 participants scored 4.0/5.0 for the whole course. At the first stage - before entering the course, the perception of participants was 45.95% of level 1, 38.2% of level 2, 14.2% of level 3, 1.35% of level 4, and 0% of level 5. Then, these ratios changed spectacularly to 0% of level 1; 12.4% of level 2; 46.8% of level 3; 40.15% of level 4 and 0.7% of level 5. The priority of continual improvement focused on process control (25.88%), documents and records (23.68%), facility and safety (12.72%). The total time for completing the mandatory component varied from 29 mins to 73 mins. This method enhanced the confidence and knowledge of staff about the QSEs and understandably chose the priority nonconformities to solve after joining the course.

Conclusion: Most of these participants reshaped their knowledge and showed a positive response to the course. This online training fits both to outbreak situation, limitation of sources for the education, and is available for directly applying the lesson in their routine work.

Keywords: Scenario-based; LQMS; Online Training; ISO Standard; Laboratory

Graphical Abstract

Background

Implementation of a laboratory quality management system (LQMS), based on the ISO 15189 or ISO/IEC 17025 or national standard, contributes to patient care and improves the reliability of test reports [1,2]. Many reports showed the errors from the total testing process differed from the preanalytical phase (61.9 - 68.2%), the post- analytical (18.5 - 23.1%), and then followed analytical (13.3 - 15%) [3], the performance of quality program prevented errors and adverse events from 25 - 42.6% [4,5]. However, the utmost important key for the success of application and maintenance of the system is the great commitment of laboratory staff [6]. To operate and maintain the whole system, laboratory staff needs to contribute time, align their performance to the procedure, and effort to comply with the requirements. It was a significant correlation between staff's positive attitude to quality assurance and their commitment to organizational goals [7]. The role of education and training, continual training is a crucial factor contributing to ameliorating their practical skills and knowledge, attitude, and behavior to crosswalk the requirement of the standard.

It cannot be denied the effectiveness of strengthening laboratory management toward accreditation (SLMTA) program which has been deployed in many countries as well as e-Learning course has been created recently [8,9]. Despite this, the program has still taught in-person classroom in some countries, face to face which is quite a challenge in the outbreak time and limit the number of participants for each class because of assurance engagement of the class activities.

With the booming of the internet and online-based training, many training formats been developed and got successful in medical education [10,11]. Some LQMS based online training course has been recently conducted and continued transferring theory to staff through the quality main concept of quality, not focusing on the situation or scenario which meets the laboratory staff's need. Moreover, most of the recent evaluation of the training module has only applied one-way discussion between participants and lecturer, based on the pre and post-test. Recently, quality control has changed from one-size-fits-all to evidence-based, risk-based, outcome-based in the new era [12].

Therefore, the training methods are also revised to follow the trends of the new requirement. In the 1960s, scenario methods, an effective tool to support decision- making, have widely used in the

military with many different applications. Although their potential and effectiveness have been found in some training applications for mental health, dementia, cancer, biotechnology, and significant influence on the knowledge and behaviors of nurses, invokes more interest in the medical student [13-16], this method hasn't widely varied in the context of health or health care training. In the quality management system, evidence-based decision-making becomes quite crucial. Incredibly, the scenario-based training method hasn't commonly presented as apromising training method. As such, our study aims to create a scenario-based online training of LQMS for laboratory staff, then assess the effectiveness of this method through their score to each designed lesson and measure their amelioration of knowledge - before and after. In addition, selecting the continual improvement of participants was the echo activities to an explanation for their understandable knowledge.

Methods

Course design and concept of LQMS

This course was designed online for 1 month and a half, composed of 4 modules including Management Responsibility, Resource Management, Process control, Evaluation, and Continual improvement - all sections of the QSEs. In each section, there was a total of 10 to 15 questions, based on its notion. Each week, the link of self-study components of two sections is sent to participants through their email. The deadline to complete lessons was one week - 5 days. They could do it anytime during the week, no matter what morning, afternoon, or evening. The only need was a device which is connected to the internet: cell phone, laptop, computer. Meanwhile, they get a suitable answer for each question after finishing each section. The detailed explanation answer for components will send the next week with new links.

Every two weeks, lectures organized meeting online to discuss, explain to participants about the difficulties concept and mentor more instruction for anything related to the previous sections through Microsoft teams. To achieve the certificate, participants need to join the whole course. If not, they must re-join and complete as a new participant to achieve their purpose (Figure 1).

Figure 1: The format of scenario-based training course.

Through the Microsoft forms, the template of each section was three mains' parts: all referent documents and related in the top, then the second was a short scenario or situation followed by what happened, where, when, and who related to the question and what need to do, the sharing current related problem in the last part. Based on the 3Cs model (Challenge, Choice, Consequence), all main concepts were developed to concise 10 to 15 questions for each section. In the selective answer, there was no wrong answer, just not able to fulfill the requirement. This is also another new point of our course to estimate how much understandable the knowledge through their choice. Many types of questions were designed such as multiple-choice, match, fill in the gap, and make in order, to give more information.

Study design

This study blended self-learning through scenario-based training methods and solving a problem-based meeting online. All participants have their own time to learn and practice the concept during one week for two sections. Consequently, during the online meeting, they asked more questions and shared the real facing problem at their organization, and the lecturer mentored to solve that. The total mark participants got after answering the question reflected their changing attitude and knowledge about LQMS. The results of pre and post of self - score evaluations of participants and their score for each section according to how interesting it was/ they found it using a Likert scale with the range of 5 show how effective the method was and their progress amelioration.

Question and validity

Based on the ISO clause and WHO handbook of laboratory Quality Management System, national standard, we created a scenario that followed 12 Quality System Essential, including 10 - 15 questions of each situation as below. Each question has fours choices and gives extra information. All open - questions in our lesson helped the participants to think and find the details in the scenario to answer the question. Most of the questions often used in our lessons are as below:

- Please analyze the information from the following Records to find out the possible cause of the above problem.
- What should you do to determine the cause of the problem?
- What should you/manager of the laboratory need to do when an occurring problem is related to X……
- What should you/ the quality manager do to limit the service interruption?
- Which procedures/Documents, records do you/laboratory manager need to well control laboratories activities
- Who will take responsibility for the X activities?
- What should you do next?

Then, all questions were double-checked carefully and sent to 50 staff who is working in the medical laboratory to perform as pre-test and send feedback to us. All collective feedback from them helped to improve the quality of questions. After revising the questions, these became the training document for our course. The example of the question was below, (Tab 1) and the format of other questions was in supportive data (Figure 5). Scenario: Laboratory X tasked by the hospital Top management (Director of the hospital) to achieve at least level 4 according to the criteria 2429 (standard of Ministry of Health - MoH of Vietnam to assess the quality of medical laboratories) or get accredited with ISO 15189: 2012 or ISO/IEC 17025 : 2017 by the end of year Y Notes:

The right answer was bold

Question

To collect information for planning to accomplish the above task, what should the laboratory do? (Multiple choice).

Answer	Why - Consequence
Find out the requirements of the criterion of 2429 or ISO standard (ISO15189:2012 or ISO/IEC 17025:2017)	Determine the requirements of the standard. This is the first step to understanding what should be performed. In addition, if the laboratory wants to achieve ISO approval, it's essential to read more about supplementary documents of accreditation organizations. Eg: ARL 04 (BoA in Vietnam for ISO 15189: 2012) or GR - 02 (AOSC for ISO/IEC 17025: 2017) Training for all the staff on the laboratory quality management system.
Determine the current situation of the quality management system in place	This activity assesses the current capacity of the laboratory system to tailor to the requirements of the standard or not. Then, it determined the position where the laboratory was to achieve the target.

Define goals to be achieved	It's essential to determine the goals to make implementation plans. For example: with the target, at least level 4 - 2429 criteria, the laboratory needs to achieve 85 - < 95% of the score and meet at the 1*, 3* criteria of the MoH.
Ask the information with the laboratories that have implemented criteria 2429 of achievement of ISO 15189: 2012 or ISO/IEC 17025:2017	It's good to exchange information with other laboratories which achieved the standard to learn experiences. Such informative references may not be suitable for actual activities at the laboratory. Therefore, the order of which implemented task must be based on the objectives and actual capacity of the laboratory.

Table 1: Example of scenario used in training course

Recruitment of participants

All laboratory staff working at the hospital, health center, university, research center, and Centre for control disease (CDC) knew about the program through a leaflet sent to their organization and wanted to join in our course. After registering, all informative courses gave out to participants.

Data collection and privacy

All the results of the participant were automatically recorded on the internet cloud. Then, these were downloaded and exported to an excel file for further analysis. Email is only the way to identify participants, so, there was not any personal data collected in this study. Furthermore, informed consent wasn't required for this study, therefore, the results of participants were considered consent to participate, and they could withdraw from the course at any time without any reason.

Data analysis

STATA software 15.0 (Copyright 1985-2017 StataCorp LLC) was applied to draw the chart and calculate statistics.

Results

During the time of the study, a total of 545 responses of participants had randomly recruited from Hospital, Centres for Disease Control, Health Centres, and others that classified into two untrained (41.65%, n = 227) and trained groups (58.35%, n= 318) with different training time from 1 year to over three years. Table 2 showed that males accounted for 31.38% (n= 171), females were 68.62% (n = 374), and the number of participants distinguished to ages groups and organization (table 2). However, 10% of participants were excluded because they didn't join enough full courses and had some personal reason to leave the course.

Gender	Ages	Organization	Previous training LQMS (N = Number)				
			N/A	1 year	2 years	3 years	> 3 years
Male	20 - 25	Hosiptal	8	7	0	0	0
		CDC	1	1	0	0	0
		Health center and others	1	1	0	0	0
	26 - 35	Hosiptal	26	14	6	6	5
		CDC	3	2	2	1	1
		Health center and others	3	2	0	0	0
	36 - 45	Hosiptal	11	6	3	5	26
		CDC	2	0	0	0	3
		Health center and others	1	0	1	2	4
	>45	Hosiptal	2	1	1	4	7
		CDC	0	0	0	0	2
		Health center and others	0	0	0	0	0

Female	20 - 25	Hosiptal	29	11	5	1	0
		CDC	3	2	0	0	5
		Health center and others	3	3	0	1	6
	26 - 35	Hosiptal	84	28	23	15	19
		CDC	5	3	1	2	1
		Health center and others	9	4	2	0	1
	36 - 45	Hosiptal	28	7	9	12	14
		CDC	4	2	1	1	0
		Health center and others	1	2	3	2	3
	>45	Hosiptal	3	0	0	6	1
		CDC	0	2	0	1	4
		Health center and others	0	0	0	1	1
Total number			227	98	57	60	103

Table 2: Distribution of participants to age, sex, organization, and the years of training, untraining group.

The appropriate problems were collected and selected from the laboratory where we were as a mentor. These are materials to build up our lesson in each section, however, all informative laboratories where collected situations or problems didn't mention in our training document. Starting with the problems, the participants needed to identify then choose the proper actions to solve them. Most importantly, how to do that and which documents related to each step were instructions in the final flowchart of the lesson. After finishing the section, the participants will improve their analytic skills and know-how to deal with the same or other problems based on our designed course (Table 3).

Construct of each training section		
Which article in requirements and Referent documents		
Description the scenario to provide the context of section of essential LQMS. Briefing: A short, relevant situation in the laboratory		
What happened?		
Who involve? Or attend?		
Where/When did happen?		
How to solve or which should be done?		
Phases	Knowledges	Skills
Pre – examination ABCD Others	Basic required information in each component Which related document/records/ decisions/rules/circular/criteria…	Identify and determine of problem, analysis the situation
Examination ABCD Others		
Post – examination ABCD Others		

What needs to do	Understand the requirements Determine the starting and end point of activities,responsibility, key process, and measurement	Problem – solving
Share the current problem at participants' lab	Determine the problem	Analysis the problem

Table 3: The template to build up the scenario based questions.

Our template allowed us to transfer LQMS from theory to practical skills under the specific scenario. In the last part of each lesson, the participants found the flowchart show the process to accomplish the requirement of the standard which they applied.

This flowchart showed the activities that need to do, who will be in charge, which document should be included, and some examples of non-conformities that will be occurred if missing or unperformed these activities (Table 3). Interestingly, the participants can share the current problems of their laboratory at the end of each scenario. This sharing helped to present their connection between lesson and currently working, then know how to deal and improve it. This aim was a double-checked what they learn during identification and solve the problem in the scenario.

Each question has an extra explanation or image, supportive information to help the participants understand the situation. The scenario or situation could be presented as a video recording, a specific situation embedded into each related link (Figure 2).

After submitting the answer, participants were able to check the answer. However, this hasn't explained why the answer should be like this yet. Until next week, the full explanation of the situation was sent to the participants.

In such a scenario, the participant understood the problem, determined it, and learned how to solve it step by step. When completing the full course, all documents delivered to participants helped them to fundamental thinking and evidence to solve their problem and continual improvement their LQMS.

Figure 2: Supportive information for each scenario and question.
(A): Video record, (B): Data survey, (C): Calibration results, (D): Hierarchy of documentation, (E): Fishbone diagram, (F): Laboratory plan.

It didn't take much time to answer and learn this way. The Information management accounted for 73.57 mins - the longest time to get through the scenario. Then the Organization, Documents and record, and Purchasing and Inventory followed by 72.25 mins, and 27.17 mins, respectively (Table 4).

12 Quality System Essential (QSEs)	Time (mins)	Score (.../5)
Organization	72.25	4.01
Documents and Records (DRs)	72.25	4.01
Facilities and Safety (FS)	32.04	4.10
Purchasing and Inventory (PI)	27.17	4.19
Personnel	29.6	3.93
Equipment	38.12	4.10
Process control (PC)	35.78	4.05
Information management (IM)	73.57	3.93
Occurrence management (OM)	36.28	3.97
Assessment	66.51	3.96
Continual Improvement (CI)	28.77	3.83
Customer service (CS)	46.35	3.88

Table 4: Time and score for each chapter was assessed by participants.

Notably, most of the lesson was evaluated with a high score from participants, nearly to get the full score for this design. The continual Improvement, however, scored 3.83, but still a high mark. Most of the score was over average (Table 4). There was no significant difference between the trained and untrained groups about their score in each section. The total satisfied evaluation of participants for the whole 12 QESs of our course was no report for scores 1, less than 3% of score 2, 8% of score 3 and 48% of score 4, 41% of score 5 marked by participants for our course.

No doubly, the knowledge of the participant ameliorated after completing the course. If before joining the course, most of participant scored level 1 (46%), level 2 (38.2%), level 3 (14.2%), level 4 (1.35%) and level 5 (0%). After taking the course, the shift of score moved to higher. There was no existence of level 1 (0), reduced level 2 to 12.4%, increased level 3 to 46.8%, then, level 4 (40.15%) and 0.7% of level 5 (Figure 3). It was true that most of the problem that existed at participants' organization was Process control, Documents, and records, Organization was the highest choice to do continual improvement. The Personnel, Facilities and safety, Equipment, Purchasing, and inventory, Continual

improvement, then, followed their priority to make improvement plan. Among the 12 QSEs of LMQS, Information management was less concerned to upgrade (Figure 4).

Figure 3: The results of self-scoring participants.

Figure 4: The results of choosing Continual improvement plan from participants after joining in the course.

Figure 5: Supportive data used to support the scenario, questions.

Discussion

The effectiveness of scenario-based training has been described in another course, but not for laboratory quality management. The application, therefore, of this method to LQMS is an alternative approach. These training methods have been applied in some courses: improve student's perceptions, socio-cultural perception, and the trainer experiences [17-19]. In our study, this scenario-based training method was a very effective, interactive way to

exchange information between learner and lecturer. Furthermore, in our opinion, this is the first-time scenario-based training method applied to LQMS in Vietnam.

Despite self-learning methods, whether ungiven learning material or just based on the referent document link, participants were also approached to the accuracy concept of each section and link section to section because all essential sections haven't been isolated, they are firmly connected. A large of participants joined our course for the first time, accounted for 41.65%, and haven't trained in LQMS before. All of them were satisfied with this training approach, even a little difficulty at the first time.

The answer without wrong answer reflected the level of understanding of participants for each point in the lesson. Through this, the lecturer could give more advice and support the accurate solution to the participants. After finishing the course, participants received training documents such as explanations with more details for each lesson, diagrams. These documents helped participants re-read in-person and apply their knowledge to solve another problem in their laboratory.

Scenario-based online training contributes to solving the limitation of the number of participants as the in-person classroom did. In addition, this transferred not only theory but improve practical skills. The participants directly applied the new knowledge to their current jobs and improved it. Through the online meeting, participants have a chance to have more discussions and learn more stories, situations from other participants. Some situations which they met or faced in the past; some was new. More importantly, the online meeting was the second time to dip in the problem, analysis, and solve with the knowledge of LQMS. Only did not participants solve the problem by themself, through their friends - other participants, and lecturers. In addition, scenario- based online training contributes significant benefits for low investment, easy to deploy under pandemic conditions [20,21].

We blended video recording to the scenario to provide some exciting experiences to participants. Video helped participants not only easily understand, identify the problem but also connect section to section. The story of quality didn't happen individually, but they are relevant and connected. Therefore, video is a crucial tool in scenario-based training methods. Using the same video is a well-connected story between lesson to lesson and helps participants determine the majority concept of quality management. On the other hand, some research found that video was also an important tool and motivated the participants' concerns [10,19].

Limitation of Study

In this study, the time for the meeting wasn't suitable for all participants. Therefore, some of them sent emails or questions to ask for more explanation instead of joining. In addition, some concepts have still not been easy to transfer through the scenario.

Conclusions

The application of scenario-based online training to LQMS for medical staff to ameliorate their knowledge and attitude to quality management in the laboratory was an alternative approach. Our method is flexible time for learning, saving cost for investment, open - discussing and more interaction between trainer and trainee as well as trainee and trainee. Importantly, our training format fitted all international standards such as ISO 15189 or ISO/IEC 17025 and national requirements. Meanwhile, there was a limitation of meeting time, our course was effective to any employee and fitted for any laboratory to help achievement of their goal on the quality road.

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