Cost Effectiveness of Adopted Quality Requirements in Hospital Laboratories

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Abstract

Background: The present study was designed in quasi-experiment to assess adoption of the essential clauses of particular clinical laboratory quality management requirements based on international organization for standardization (ISO 15189) in hospital laboratories and to evaluate the cost effectiveness of compliance to ISO 15189.

Methods: The quality management intervention based on ISO 15189 was conceded through three phases; pre – intervention phase, Intervention phase and Post-intervention phase.

Results: In pre- intervention phase the compliance to ISO 15189 was 49% for study group vs. 47% for control group with P value 0.48, while the post intervention results displayed 54% vs. 79% for study group and control group respectively in compliance to ISO 15189 and statistically significant difference (P value 0.00) with effect size (Cohen's d) of (0.00) in pre- intervention phase and (0.99) in post – intervention phase. The annual average cost per-test for the study group and control group was 1.80 ± 0.25 vs. 1.97 ± 0.39, respectively with P value 0.39 whereas the post-intervention results showed that the annual average total costs per-test for study group and control group was 1.57 ± 0.23 vs 2.08 ± 0.38, P value 0.019 respectively, with cost-effectiveness ratio of (0.88) in pre -intervention phase and (0.52) in post-intervention phase.

Conclusion: The planned adoption of quality management requirements (QMS) in clinical laboratories had great effect to increase the compliance percent with quality management system requirement, raise the average total cost effectiveness, and improve the analytical process capability of the testing procedure.

Keywords: Quality management, Cost effectiveness, ISO1518

Introduction

Medical laboratories represent a crucial an area of healthcare, provide medical services to different clients; clinicians, patients, public health and medical legal instance referral laboratories and authoritative bodies (1). The clinical laboratory errors may arise mainly from the lack of awareness and denial of the essential and practical quality management standards (2). Quality Management (TQM) is a comprehensive and structured approach to organizational management that seeks to improve the quality of products and services through ongoing refinements in re-

sponse to continuous feedback (3, 4). However International Organization for Standardization "ISO" 15189 are the first quality management system for the medical laboratories, it involves particular requirements for quality and competence, provides a framework for the design and improvement of process-based quality management systems (5). The total quality management (TQM) has been adopted by many health care organizations (3, 4) but compliance with "ISO" 15189, and international standard for accreditation of medical laboratories is becoming

progressively accepted as optimal approach to assuring quality in medical testing (1). ISO 15189 outlines the controls required to manage risks that may have an impact on the validity of examination results, and tools to help the laboratory to improve its operations and customer satisfaction (4, 6). Two contradictory pressure; high quality and cost reduction require are critical factor affecting the laboratory outcome. The clinical laboratories must provide a high quality service by producing accurate, precise, relevant comprehensive data, which can be applied to medical management of patient with reasonable price (7). However, a new trend to develop quality management systems towards total quality management systems can be observed including additional aspects such as economic and quality interests of society, customers and owners of laboratories (8). In health, cost-effectiveness analysis is the primary tool for comparing the cost of a health intervention with the expected health gains. The central purpose of cost-effectiveness analysis (CEA) is to compare the costs and the values of different health care interventions in creating better health and longer life (9).

Financial management, budget and cost accounting considered as the basic "tools" for identifying the activities and expenses, which were, support the decision-making process, as well, it governed the laboratory operations and services (10). It is essential for the director and manager in clinical laboratory to understand and practice the budget development and cost accounting in order to take proper decision for laboratory quality management operations and justified it in terms of financial benefit (6, 11). The goal of all these activities is to create a network of confidence, which provides some guarantee to the clients, i.e. the physicians and their patients, that they will receive a high-quality medical laboratory service (8).

In this paper, we present strategies designed to aid medical laboratories with the ISO 15189 and to determine the impact of this implementation on annual average cost per test.

Methods

This Quasi-experimental study was carried out at governmental hospital laboratories in Khartoum State (Republic of Sudan) in 2010-2011. Its empirical study design used to estimate the causal impact of an intervention on the study group. Twelve clinical laboratories of similar facilities i.e. similar personnel qualification, equipment, building, supplier, etc. were elected for this study and divided in to study group and control group each of which had 6 laboratories.

The quality management intervention based on ISO 15189 was adopted by study group while the control group remains without any intervention throughout the course of study. The adoption of ISO 15189 and the impact of implementation on annual average cost per test of medical laboratories were accounted according to the following procedures:

Biochemical tests

Three Biochemical tests namely Glucose (Bio-system), Urea (Bio-system) and Creatinine (Bio-system) were elected to be one of the tools used for judging the compliance and impact of implementation ISO 15189. Reference serum sample with known biochemical concentration was sent monthly to study group and control group to assess the level of Glucose, Urea and Creatinine.

Blood glucose was assessed by enzymatic method, blood Urea was assessed according to Berthelot enzymatic method and Blood Creatinine was determined using Jaffe kinetic methods.

Adoption of ISO 15189 and compliance assessment

The intervention comprised twelve clues involving 154 required derived from ISO 15189, these clues were designed in a check list composing; organization (had 10 requirements), personnel (had 12 requirements), equipment (had 18 requirements), reagents (had 10 requirements), pre- analytical (had 14 requirements), analytical (had 12 requirements) post-analytical (had 8 requirements), documentation (had 10 requirements), Assuring quality (had 14 requirements), environment (had 14 requirements), audit (had 8 requirements) and continual improvement (had 24 requirements) as shown in Table 2. However, the interpretation of the checklist was depends on marks obtained by

laboratories [2] marks means the requirement adopted and documented [1] mark means incomplete adoption or documentation and (zero) mark means the item is neither adopted nor documented. Thus, the total marks obtained from designed checklist were used as an assessment means.
The adoption was conceded through three phases pre –intervention phase, intervention phase and post-intervention phase.
Pre-intervention phases: in this phase, current laboratory quality management was assessed for compliance to ISO 15189 using the prepared checklist.
Intervention phase: in this phase, the selected ISO 15189 coleuses was applied to the study group while the control group continues without intervention. The implementation of TQM was traced by an effective correction and prevention actions in the daily practice and required activities through high effort, continue training and workshop "skill and knowledge" to the employee throughout the course of this phase (two year).
Post-intervention phase: in this phase, the compliance to ISO 15189 was reassessed for both groups (study group and control group) tow year after implementation using the initial prepared checklist.
Calculation of cost effectiveness
Annual average cost per-test
In order to calculate the total annual cost per test, the study was introduced two annual costs [2010 and 2011]. The total annual cost involves all the expensive of reagent, instrument maintenance, personnel, environmental cost and administrative ect. It was considered from the relevant cost data and the annual average cost per-test was calculated and used as a managerial indicator for quality management system effectiveness by the following equation:
Cost per-test = (annual total of cost) / (annual total of tests)   [1]
Cost-effectiveness ratio
The average cost effectiveness (CE) was calculated by the following equation:
CE= Average cost per-test for group /Average QMS compliance % for group   [2]

The cost-efficiency ratio (CER) was obtained according to the following equation:
CER=Study group cost effective/ Control group cost effective   [3]
Effect size: it is a statistical concept measures the strength of the relationship between two variables. In this study, the effect size was calculated to quantifying the difference between the compliance of the two groups. The most commonly used effect size is a measure of the standardized mean difference known as Cohen's d, which was calculated according to the following equation
Cohen's d = (study group mean- control group mean)/ (Pooled standard deviation)   [4]
Interpretation of Cohen's d results was done according to the value in Table 1.

Table 1: Interpretation of Cohen's d results

Cohen's d	Interpretation
0.2	Small
0.5	Medium
0.8	Large

Data analysis: the compliance to quality management requirements was calculated by spread excel program. The SPSS program, namely independent and paired t- test was used to assess the statistical difference between the compliance means. *P*-value (0.05) was used for the justification of significance.

Results

The selected biochemical tests (Glucose, Urea and Creatinine) were represented 55% of total requested investigation in Khartoum state (data not shown). However, glucose and urea were endpoint technique whereas the creatinine was kinetic technique.
The compliance of study group and control group to ISO15189 was 49% for study group vs. 47% for control group with *P* value 0.48 in pre-intervention phase and 79 % for study group vs. 54% for control group with *P* value 0.00 in post intervention phase (Table 2). Simultaneously, the effect size (Cohen's d) of the quality management activities in the pre intervention phase was moderate (0.00) and substantially different in the post-intervention phase which was large (0.99) Table 3.

Table 2: Compliance of the study group and control group to ISO 15189 in pre and post intervention phases

Study phases Laboratories	Pre – intervention (2008)			Post – intervention (2009)		
	Study %	Control %	*P*-value	Study %	Control %	*P*-value
LAB1	53	57		82	60	
LAB2	47	39		82	49	
LAB3	51	47		82	56	
LAB4	47	44		79	56	
LAB5	49	46		79	51	
LAB6	45	48		75	55	
Average compliance %	49	47	0.48*	79	54	0.00

Table 3: Size effect of quality management activities of study group and control group in pre and post intervention phases

Study phases		Pre – intervention (2010)			Post – intervention (2011)		
QMS clauses	Required	Study Adopted requirement	Control Adopted requirement	Cohen's d	Study Adopted requirement	Control Adopted requirement	Cohen's d
Organization	10	4	4		9	5	
Personnel	12	4	4		10	6	
Equipment	18	11	10		16	9	
Reagent	10	5	5		7	5	
Pre-analytical	14	7	6		11	7	
Analytical	12	7	6		10	7	
Post- analytical	8	3	3		6	5	
Assuring quality	14	7	7		12	8	
Environment	14	9	9		13	9	
Documents	10	5	5		7	6	
Audits	8	5	4		6	5	
C. Improvement	24	9	9		18	12	
Mean (± SD)	13± 5	6 ± 2	6 ± 2	0.00	10 ± 4	7 ± 2	0.99

The pre- intervention results showed that the annual average total costs per-test of the study group was 1.8 ± 0.25 Sudanese pound (SDG) it was equal to 0.33 USA dollar and control group was 1.97 ± 0.39 SDG, with insignificant effect (*P*= 0.39) (Table 4), whereas the post-intervention results showed that the annual average total costs per-test for study and control groups was 1.57 ± 0.23 and 2.08 ± 0.38 SDG, respectively with significant effect (*P*= 0.019) Table 4.

The cost effectiveness of the study group was not substantially lower than that of control group (3.71 vs. 4.25 respectively) with efficiency ratio 0.91 and cost-effectiveness ratio 0.88 (Table 5) while in post-intervention results the cost effectiveness of the study group (1.98) was substantially lower than that of control group (3.84) with efficiency ratio (0.75) and cost effectiveness ratio (0.52) Table 6.

Table 4: Annual average cost per-test of pre and post intervention phases

Study phases Laboratories	Pre – intervention (2008)			Post – intervention (2009		
	Study cost/ test	Control cost/ test	*P*-value	Study cost/ test	Control cost/ test	*P*-value
LAB1	1.52	1.87		1.48	1.92	
LAB2	1.61	1.85		1.5	1.98	
LAB3	2.21	1.42		1.49	1.49	
LAB4	1.82	2.03		1.77	2.26	
LAB5	1.7	2.02		1.29	2.2	
LAB6	1.93	2.62		1.92	2.62	
Mean (± SD)	1.80 ± 0.25	1.97± 0.39	0.39*	1.57 ± 0.23	2.08 ± 0.38	0.019

Table 5: Cost efficiency and cost-effectiveness ratios of study and control groups in pre- intervention phase

Study groups	Study group			Control group			Efficiency ratio	Cost effectiveness ratio
Laboratories	QMS Compliance %	cost/ test	Cost effectiveness %	QMS Compliance %	cost/ test	Cost effectiveness %		
LAB1	53	1.52	2.87	57	1.87	3.28		
LAB2	47	1.61	3.43	39	1.85	4.74		
LAB3	51	2.21	4.33	47	1.42	3.02		
LAB4	47	1.83	3.87	44	2.03	4.61		
LAB5	49	1.7	3.47	46	2.02	4.39		
LAB6	45	1.93	4.29	48	2.62	5.46		
Average	49	1.8	3.71	47	1.97	4.25	0.91	0.88

Table 6: Cost efficiency and cost-effectiveness ratios of study and control groups in post- intervention phase

Study Groups Laboratories	Study group			Control group			Efficiency ratio	Cost effectiveness ratio
	QMS compliance %	cost/ test	Cost effectiveness	QMS compliance %	cost/ test	Cost effectiveness		
LAB1	82	1.48	1.8	60	1.92	3.2		
LAB2	82	1.5	1.83	49	1.98	4.04		
LAB3	82	1.49	1.82	56	1.49	2.66		
LAB4	79	1.77	2.24	56	2.26	4.04		
LAB5	79	1.29	1.63	51	2.2	4.31		
LAB6	75	1.92	2.56	55	2.62	4.76		
Average	79	1.58	1.98	1	2.08	3.84	0.75	0.52

Discussion

ISO 15189 being an important template for assessing and recognizing the competence of medical laboratories in their technical capacity and the effective quality management of a professional service and its staff (5, 8). Several authors were selected ISO 15189 as reference for the applicable QMS requirement in clinical laboratories. Westgard reported that ISO 15189 is a particular requirement for quality management in medical laboratories, provides guidance for relating performance specifications and encourages standardiza-

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tion of laboratory operations across international borders (12, 13).

The situation of the laboratories under study (in pre intervention phase) revealed that these laboratories were inappropriate size, the majority of instruments were semi-automated and most of the laboratories personnel and the managers lacked basic knowledge and experience in the field of quality management (data not shown). However, similar situation was reported in 90% of clinical laboratories in developing countries (14).

The compliance of the study group and control group to ISO 15189 in pre –intervention phase was almost similar and there was no statistical difference (*P* value 0.48), while the compliance to ISO 15189 in post intervention phase for both groups was statistically significantly difference (*P* value 0.00). The improvement occurred in (50%) of the control group compared to (100%) in study group. These results indicated that the improvement could occur even without planned quality requirements intervention; which might be due to nature of life in developing countries where they tried to catch current technology and knowledge without proper planning. Moreover, the majority of developing counties are using the traditional farm work of quality management which primary involves identification and correction of the defects after they have occurred (3, 4).

However, the significant improvement (100%) occurred in study group confirmed that the planned adoption of quality management requirements had excellent impact and proved that the clinical laboratories of poor centauries had an ability to comply with the suitable international standard without major obstructed. Similarly, Rizk et al., 2009 assessed the quality of work in Clinical Pathology Department, Alexandria Main University Hospital, Egypt; as regards the pre-analytical and analytical phases of testing. This evaluation was performed using inspection sheets. The degree of requirements fulfillment in checklists were develop from 0 - 21.1% at the start of the study to 63.2-85.7%.at the end of the study and they concluded that the presence of standardized protocol for the pre-analytical activities had improved the quality (15).however, this concept of developing applicable QMS requirement was in alignment with the Iranian national quality management standards and Thai model which has been earlier published by WHO (16, 17).

Clinical laboratories have to justify quality assurance efforts in terms of financial benefit (18, 19) . The healthcare organizations use cost accounting to estimate the unit cost of services they provide. Based on the cost information, appropriate adoptions concerning priorities, technique choice, workers policies and investments can be done (20, 21).

The present study revealed that there was statistically insignificance difference between the annual cost per-test of the study group and control group in pre- intervention (*P*=0.39) while, significant improved in average annual cost per-test was observed in post –intervention of study group (*P*=0.019), this result indicating that adoption of ISO 15189 largely affect the cost of test. Similar reduction in the annual cost per-test was reported by Broughton who concluded that the basic requirements for a satisfactory laboratory costing method are the attribution of all items of expenditure (22).

In this study-the cost efficiency ratio and the cost-effectiveness ratio of study group and control group were developed from 0.91and 0.88 in pre-interventions phase to 0.75 and 0.52 in post intervention phase respectively. Interestingly implementation of TQM did not consume addition incur. Therefore, these findings could encourage the developing countries, which suffered from limited resources to adopt the TQM and improved the medical laboratories serves.

Conclusion

The findings of this study showed that the planned adoption of quality management requirements (QMS) in clinical laboratories had great effect to increase the compliance percent with quality management system requirement, raise the average total cost effectiveness, and improve the analytical process capability of the testing procedure. However, the laboratories outcome generally affect by the kind of quality management, which they applied rather than the financial status.

Ethical considerations

Ethical issues (Including plagiarism, Informed Consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc) have been completely observed by the authors.

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