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Impact of Critical Success Factors on International ISO Accreditation for the Botswana Public Health Laboratories

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Abstract

The purpose of this study is to identify critical success factors and their impact on implementation of quality management system at selected Public Health Laboratories in Botswana. The study population was from the targeted seven accredited Public Health Laboratories in Botswana. Data on critical success factors was collected using a questionnaire. The questions were based on the critical success factors for implementation of total quality management identified during the literature review. Ten Critical Success Factors for successful implementation of the quality management system were rated by a group of questions using a five point Likert scale method. The 5-point Likert scale includes the items: strongly agree, agree, neutral, disagree, and strongly disagree. Strongly agree was assigned a score of 5, agree is assigned a score of 4, neutral is assigned a score of 3, disagree is assigned a score of 2 and strongly disagree a score of 1. The mean of the assigned ratings is 3.0. Critical success factors which score mean greater than 3.0 will be classified as agree while those mean less than 3.0 will be classified as disagree. All the ten critical success factors had a mean above of 3.0, with a range of 4.77 to 3.57. All the ten success factors were deemed critical; Employee empowerment Strategic quality planning, Process management, Performance management, Quality culture, Management and leadership, Training, Supplier Management, Customer focus, Information analysis.

Keywords: *Accreditation, Critical Success Factors, Public Health Laboratory, Quality Management System, Questionnaire.*

Introduction

Botswana is a landlocked country in Southern Africa, which shares the border with Namibia, South Africa, Zambia and Zimbabwe. It has an area of 582,000 sq km, with a population of about 2, 2 million people. The country is sparsely populated because up to 70% of the country is covered by the Kalahari Desert [1]. The economy is mainly sustained by mining, tourism and agriculture. The country got independence on the 30TH September 1966 and has a flourishing multiparty constitutional Democracy [2]. It has a total of 54 Public Health Laboratories which are all under the Botswana Ministry of Health.

Botswana in its endeavors to improve the health and safety of its nation, in 2005 it embarked on accreditation for its health care facilities. Hospitals were to be accredited under the Council for Health Service Accreditation of Southern Africa (COHSASA) programme and medical laboratories under the ISO 15189:2010 [3]. Support was provided

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through training and mentorship program. Despite all the efforts, only seven laboratories out of fifty-four (13%) achieved accreditation as of May 2021 [4].

Objective of the Study

The purpose of this study is to identify critical success factors and their impact on the implementation of quality management systems at seven accredited Public Health Laboratories in Botswana. This research project will address the following research questions;

Research Question 1: What were critical success factors which enabled the seven laboratories in Botswana to successfully implement its quality management system and attain international accreditation?

Research Question 2: Which elements of these critical success factors were adequately deployed, resulting in them becoming enablers for successful implementation of Quality Management System (QMS) and attainment of international accreditation? Lessons learned from the seven can inform how accreditation can be expanded to other laboratories targeted for accreditation. The research identified through literature review, ten critical success factors for successful implementation of quality management system [5].

Research Methodology

This is a study which uses both qualitative and quantitative data. The critical success factors were identified from the literature review [6]. The data collection tool was adopted from the literature review [7]. The factors with a mean of 3.0 were classified as critical. So since these factors have been identified and used elsewhere by different researchers, their reliability is confirmed. The tool uses several questions to identify the deployment of the ten critical success factors. The quantitative methodology, which used the ordinal scale of measurement, was chosen to allow the researcher to analyze data using statistical tools that would have been impossible with qualitative methods [8].

Sample Size Determination

The study population was from the targeted seven accredited Public Health Laboratories in Botswana. A study sample of participants was randomly selected to include participants from each category of employees within the organization to complete the questionnaire. The researcher requested contact details of staff in the seven laboratories, and put them into separate boxes then performed stratified sampling by randomly picking eight participants from each box.

Data Collection

Data on critical success factors was collected using a questionnaire. The first part of the survey used a 5-point Likert style to determine the level of agreement or disagreement among survey participants with elements of the critical success factors. The 5-point Likert scale includes the items: *strongly agree, agree, neutral, disagree, and strongly disagree* [9]. Using this type of scale allows participants to choose how strongly they agree or disagree with elements of the ten critical success factors. *Strongly agree* was assigned a score of 5, *agree* was assigned a score of 4, *neutral* was assigned a score of 3, *disagree* is assigned a score of 2 and *strongly disagree* a score of 1. The mean of the assigned ratings is 3.0. Critical success factors which score mean greater than 3.0 will be classified as *agree* while those mean less than 3.0 will be classified as *disagree* [10]. The study did not seek to establish causation but intended to identify practices that are common with Public Health laboratories that have achieved accreditation in Botswana. The questionnaire for the quantitative part of the study was sent to participants/respondents through email or courier services. Participants were assured of the confidentiality of their responses. The completed survey was sent to the researcher

through email or hand delivery. The participants returned the questionnaire within two weeks.

Data Analysis

A study questionnaire developed by the researcher was used in this study. Participants were asked to rate the level of agreement or disagreement with the different statements using a five-point scale Likert method [11]. The data analysis was done using Microsoft Excel 2007 or SPSS. The mean for the responses for each factor will be computed and returns with a mean greater than 3.0 were classified as critical successful factors for Botswana Public Health laboratories. Those factors that score a mean of less than 3.0 were classified as not critical.

Results (Findings)

Responses from participants were analyzed for each critical success factor. For each element, a mean score was computed and returns with a mean greater than 3.0 were classified as critical while those factors that scored a mean of less than 3.0 were classified as not critical. The mean score of each element was used to indicate performance on each element. Mean scores of less than 3.0 meant poor performances (barriers) on a particular element while those greater than 3.0 meant good performance (enablers) (Table 1).

Table1. Average Responses of the Seven Accredited Laboratories in Botswana about the Ten Critical Success Factors, in 2021

Number	Critical Factors	Average Mean	Average Coefficient of Variant (CV)
1.	Employee empowerment	4.77	0.193
2.	Strategic quality planning	4.74	0.151
3.	Process management	4.49	0.130
4.	Performance management	4.23	0.311
5.	Quality culture	4.20	0.120
6.	Management and leadership	3.97	0.245
7.	Training	3.94	0.121
8.	Supplier management	3.83	0.190
9.	Customer focus	3.77	0.163
10.	Information analysis	3.57	0.224

Table 1 summarizes the average mean of the ten critical success factors identified in the literature review section. Critical success factors with average means of above 3.0 and above will be regarded as very critical while those with average means of less than 3.0 are not critical.

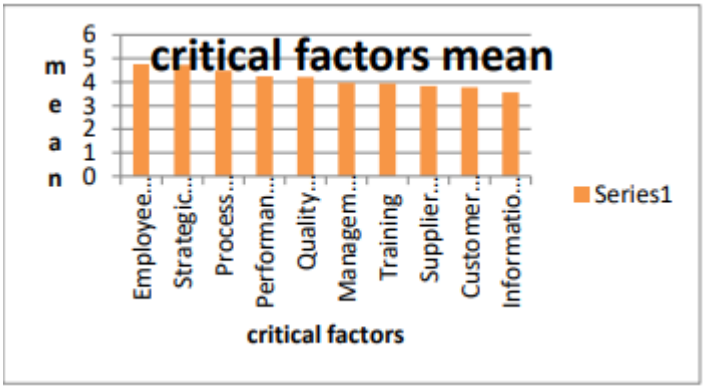

Figure 1. Graphical Average Response of the Seven Accredited Laboratories in Botswana, in Relation to the Ten Critical Success Factors, in 2021

Figure 1 is a graphic representation of Table 1 that represents the average mean of the ten critical success factors that were assessed by the participants. Staff empowerment had the highest mean of 4.77 while information analysis had the lowest mean of 3.77.

Leadership and Management

Respondents generally agree that top management can mobilize employees towards the achievement of laboratory goals and objectives. The mean score of 3.970 and CV = 0.178 suggest there is small variability in this opinion. Respondents were neutral to the statement that there is effective communication between top management and employees. The mean of 3.240 and corresponding CV = 0.264 suggest there is small variability in this opinion amongst the respondents. Individuals agreed that top management is committed to and supports quality management activities. The mean is 3.800 and the corresponding CV is 0.237 reflecting a small level of variability. There is a general agreement that top management provides the resources needed to perform quality management activities [12]. The average for responses was 3.800 corresponding with agreement and the small CV of 0.246 suggests respondent opinions are slightly variable **(Table 2)**.

Table 2. Average Responses of the Seven Accredited Laboratories in Botswana, in Relation to the Six Elements Assessed, Under Management and Leadership, by the Year 2021

Statement	Mean	Standard deviation	Coefficient of variation (CV)	Majority opinion
Top management is able to mobilize employees towards achievement of laboratory goals and objectives.	3.970	0.707	0.178	Agree
There is effective communication between top management and employees.	3.240	0.855	0.264	Neutral
Top management is committed to and supports quality management activities.	3.800	0.901	0.237	Agree
Top management has developed necessary quality	3.860	0.974	0.252	Agree

management system documents.				
Top management coaches and assists employees to improve their performance.	3.63	1.060	0.292	Agree
Top management provides resources needed to perform quality management activities.	3.800	0.933	0.246	Agree

Respondents generally agree that top management is able to mobilize employees towards achievement of laboratory goals and objectives.

Customer Focus

There was a general agreement for all the 6 items that were stated under the customer focus element. Respondents agreed that the laboratory strategic plan is customer driven. The mean score is 3.77 with a CV of 0.233 which indicates that the variability between the responses is small. The respondents also agreed that management and employees are committed to satisfy customer needs with a mean score of 4.34 and CV of 0.136 [13].

Table 3. Average Responses of the Seven Accredited Laboratories in Botswana, in Relation to the Five Assessed Elements Under Customer Focus, in 2021

Statement	**Mean**	**Standard deviation**	**Coefficient of variation (CV)**	**Majority opinion**
The laboratory strategic plan is customer driven.	3.770	0.877	0.233	Agree
Quality at the Laboratories is defined by the customer.	3.710	0.667	0.180	Agree
The laboratory collects and analyses customer feedback.	4.290	0.667	0.155	Agree
Customer feedback is used for continual improvement purposes.	4.490	0.507	0.113	Agree
Management and employees are	4.340	0.591	0.136	Agree

committed to satisfy customer needs.				

There was a general agreement for all the 5 items that were stated under the customer focus element. Respondents agreed that the laboratory strategic plan is customer-driven.

Employee Empowerment

The respondents strongly agreed that as employees, they were involved in developing standard operating procedures. This item has a mean score of 4.77 with a CV of 0.089 which indicates that there is a small variability in the responses. The respondents were neutral to the statement that says employees are recognized or rewarded for their performance, which then makes this element not a good enabler to quality implementation [14]. This had a mean score and CV of 3.000 and 0.370 respectively. There was also a general agreement to the statement that management recognizes employee performance on quality with a mean score of 3.710 and CV of 0.191.

Table 4. Average Responses of the Seven Botswana Accredited Laboratories about the Ten Assessed Elements, Under Employee Empowerment, in 2021

Statement	**Mean**	**Standard deviation**	**Coefficient of variation (CV)**	**Majority opinion**
As employees, we were involved in developing standard operating procedures.	4.770	0.426	0.089	Strongly agree
At the Laboratory, there is democratic/participative management.	3.800	0.759	0.200	Agree
Employees are encouraged to provide suggestions to management.	4.030	0.747	0.185	Agree
Management uses a non-punitive approach to nonconformities	4.460	0.611	0.137	Agree
Employees are recognized or rewarded for their performance.	3.000	1.111	0.370	Neutral
Employees are encouraged to control, manage and improve processes within their area of responsibility.	4.000	0.728	0.182	Agree
Management recognizes teamwork within the laboratory.	3.690	0.758	0.205	Agree

Human resource practice is aligned to the laboratory strategy.	4.090	0.981	0.240	Agree
Employees have well developed roles and responsibilities.	4.060	0.591	0.146	Agree
Management recognizes employee performance on quality	3.710	0.710	0.191	Agree

For the employee empowerment element, the respondents mostly agreed with given statements. However, they strongly agreed that as employees, they were involved in developing standard operating procedures.

Training

Respondents agreed to the statement that employees are given adequate training on the quality management system with a mean score of 3.940 and CV of 0.106 which shows that there is a small variability in the responses of individuals. However, respondents strongly agreed that employees are assessed and certified competent to perform all technical processes in their areas of responsibility [15]. This statement had a mean score and CV of 4.770 and 0.089 respectively.

Table 5. Average Responses of the Seven Accredited Laboratories in Botswana, about the Five Elements Assessed Under Training, in 2021

Statement	**Mean**	**Standard deviation**	**Coefficient of variation (CV)**	**Majority opinion**
Employees are given adequate training on the quality management system.	3.940	0.416	0.106	Agree
Employees are equipped with necessary skills to successfully perform their tasks through training on technical processes and procedures.	4.340	0.482	0.111	Agree
Employees understand their roles and responsibilities in the quality management system.	4.030	0.747	0.185	Agree
Employees are assessed and certified competent	4.770	0.426	0.089	Strongly agree

to perform all technical processes in their areas of responsibility.				
Training is viewed as a continuous process.	4.200	0.473	0.113	Agree

There is a general agreement by the respondents to all the statements that were given under the training element.

Quality Culture

Respondents generally agreed that employees are aware of the goals of implementation of the quality management system with a mean and CV score of 4.200 and 0.097. Respondents also agreed that employees treat quality as an integral part of the business processes, and this had a mean of 4.170 with a CV score of 0.109, Table 6 So the results agree with the results obtained from other studies [8].

Table 6. Average Responses of the Seven Accredited Laboratories in Botswana in Relation to the Five Elements Assessed Under Quality Culture, in 2021

Statement	**Mean**	**Standard deviation**	**Coefficient of variation (CV)**	**Majority opinion**
Employees are aware of the goals of implementation of the quality management system.	4.200	0.406	0.097	Agree
Leadership of the laboratory has embedded a coherent quality culture within the laboratory.	4.110	0.583	0.142	Agree
All staff members believe that the quality management system helps the laboratory to achieve its goals.	4.060	0.539	0.133	Agree
All employees participate in quality management system activities.	4.140	0.494	0.119	Agree
Employees treat quality as an integral part of the business processes.	4.170	0.453	0.109	Agree

Respondents agreed to all the statements that were given under the quality culture element.

Supplier Management

Respondents were neutral to the statement that the laboratory staff members participate in the evaluation of suppliers with a mean and CV score of 3.260 and 0.097 respectively. The respondents agreed that the laboratory provides technical assistance to the procurement unit on issues related to the laboratory with a mean value of 3.770 and a CV score of 0.214. All CV values were relatively small which indicated that there was a small variability in the responses of the individuals. Table7.0. Respondents were neutral on the element of participation in the selection of suppliers; the mean was 3.2, so it is not a good enabler [16].

Table 7. Average Responses of the Seven Accredited Laboratories in Botswana Regarding the Six Elements Assessed Under Supplier Management, in 2021

Statement	Mean	Standard deviation	Coefficient of variation (CV)	Majority opinion
The Laboratory staff members participate in the evaluation of suppliers.	3.260	1.010	0.310	Neutral
There are good working relations between the Laboratory and the procurement unit.	3.510	0.781	0.223	Agree
The Laboratory provides specifications for all critical items of supplies.	4.060	0.539	0.133	Agree
All incoming critical items are inspected and tested prior to use.	4.170	0.453	0.109	Agree
There are effective inventory management procedures.	4.200	0.632	0.150	Agree
The Laboratory provides technical assistance to the procurement unit on issues related to the Laboratory	3.770	0.808	0.214	Agree

For the supplier management element, the respondents generally agreed with most of the items that were stated.

Strategic Quality Planning

The respondents strongly agreed that there is a quality policy for the laboratory and there are appropriate vision/mission statements [17]. They strongly agreed that there is a quality policy for the laboratory with a mean and CV score of 4.740 and 0.093 respectively. The respondents also agreed that the goals and objectives of the quality management system are clearly defined with a mean of 4.430 and CV score of 0.126.

Table 8. Average Responses of the Seven Accredited Laboratories in Botswana Regarding the Six Elements Assessed Under Strategic Quality Planning, in 2021

Statement	Mean	Standard deviation	Coefficient of variation (CV)	Majority opinion
Quality is an integral part of the laboratory strategy.	4.340	0.873	0.201	Agree
There is a quality policy for the laboratory.	4.74	0.443	0.093	Strongly agree
There are appropriate vision/mission statements.	4.740	0.443	0.093	Strongly agree
The laboratory strategy is effectively implemented.	3.940	0.802	0.204	Agree
There are key performance indicators for monitoring implementation of the strategy.	4.490	0.742	0.165	Agree
Goals and objectives of the quality management system are clearly defined.	4.430	0.558	0.126	Agree

For the strategic quality planning element, respondents agreed to most of the stated items and also strongly agreed to others.

Process Management

The researcher used four questions to investigate the deployment of process management. The respondents agreed that process that impact quality have been identified and developed with a mean and CV score of 4.490 and 0.113 respectively. The

respondents strongly agreed that the processes are reviewed periodically to ensure continual improvement, and this had a mean value of 4.740 and a CV score of 0.093 [18].

Table 9. Average Responses of the Seven Accredited Laboratories in Botswana Regarding the Four Elements Assessed Under Process Management, in 2021

Statement	Mean	Standard deviation	Coefficient of variation (CV)	Majority opinion
Process that impact quality have been identified and developed.	4.490	0.507	0.113	Agree
Technical processes are validated to make sure they work as expected.	4.690	0.583	0.124	Strongly agree
Processes are reviewed periodically to ensure continual improvement.	4.740	0.443	0.093	Strongly agree
The laboratory uses process approach to manage its operations	4.090	0.781	0.191	Agree

Respondents agreed to half of the items that were stated under the process management element and they strongly agreed to the other half of statements.

respectively [19]. The respondents also agreed that statistical tools are used to analyze data, and this had a mean value of 3.600 and CV score of 0.204.

Information Analysis

The respondents agreed that the information is used to effectively measure quality with a mean and CV score of 3.570 and 0.282

Table 10. Average Responses of the Seven Accredited Laboratories in Botswana Regarding the Five Elements Assessed Under Information, in 2021

Statement	Mean	Standard deviation	Coefficient of variation (CV)	Majority opinion
Information is used to effectively measure quality.	3.570	1.008	0.282	Agree
Information and data are used to maintain customer focus.	3.830	0.891	0.232	Agree
Decisions are made	3.940	0.891	0.226	Agree

based on facts.				
Information and data are used to drive quality excellence.	3.800	0.677	0.178	Agree
Statistical tools are used to analyse data.	3.600	0.736	0.204	Agree

For the information analysis element, the respondents agreed to all the statements that were given.

Performance Management

The respondents agreed that there is a performance management program in place with a mean of 4.230 and a CV score of 0.191 [19]. The respondents disagreed that staff compensation is linked to achieving quality goals with a mean and CV score of 2.310 and 0.507 respectively. They also agreed that causes of good performance are identified and enhanced with a mean of 3.540 and a CV score of 0.331.

Table 11. Average Responses of the Seven Accredited Laboratories in Botswana Regarding the Five Elements Assessed Under Performance Management, in 2021

Statement	**Mean**	**Standard deviation**	**Coefficient of variation (CV)**	**Majority opinion**
There is a performance management program in place.	4.230	0.808	0.191	Agree
Staff compensation is linked to achieving quality goals.	2.340	1.187	0.507	Disagree
Performance is evaluated against set targets.	3.860	0.810	0.210	Agree
Root causes of poor performance are identified and eliminated.	3.800	1.208	0.318	Agree
Causes of good performance are identified and enhanced.	3.540	1.172	0.331	Agree

Discussion

All the critical success factors had a mean above of 3.0 and the critical success factors with the highest means were; employee empowerment (4.77), strategic quality planning (4.74), process management (4.49), performance management (4.23), Quality culture (4.20), and Management and leadership (3.97). Employee empowerment

was found to be the most important enabler in the implementation of Quality Management System. Empowered employees are motivated to go the extra mile in delivering quality and reliable patient' results [13].

In addition to employee empowerment, strategic quality planning, process management, performance management, Quality culture, customer focus and Management and leadership were also identified as the most important critical success factors which form the foundation on which the rest critical success factors are built [18].

The respondents under performance management disagreed that staff compensation is linked to achieving quality goals. The element of linking employee compensation to achieving quality goals was not deployed, making it not a good enabler to the implementation of the Quality Management System in the Public Health Laboratories [20].

For the strategic quality planning element, respondents strongly agreed with most of the stated items. The element of the participation of the selection of suppliers was identified as not a good enabler to the implementation of the Quality Management System [15], meaning it was not deployed. The participants believe they should take part in the procurement of their reagents, equipment, supplies and consumables. When the employees participate in the selection of suppliers, they have a sense of ownership and utilize the resources appropriately.

Employee rewards and compensations are not directly linked to performance and achievement of quality goals. So management needs to review the reward system and the compensation policies of the country, deserving employees should be rewarded and compensated [16]. The management should uphold to the values of integrity, fairness, impartiality and neutrality. Employees do not participate in the selection of suppliers [17]. Organizations that do not evaluate the ability of suppliers to meet specified requirements most likely, but not always experience quality problems with some of the supplied materials. Satisfied employees are directly linked to satisfied customers.

The first question and **the second question** were all fulfilled because from the results analyzed all the ten success factors were regarded as critical and most elements were deployed resulting in them being enablers.

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