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Compliance and Performance Benefits of the ISO 9001:2008 Quality Management System in Cotabato Regional and Medical Center

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Abstract

Quality in healthcare is a relatively novel concept in public health in our country. It is a world trend that government departments, statutory bodies and other public organizations have to undergo transformation in order to become more efficient, effective, and accountable in order to provide consistent and good quality services. This is the reason why some organizations, including the health sectors have gone through the re-engineering and privatization processes and transformed themselves as successful enterprises.

For others, privatization is not an option, but they have nonetheless responded to the pressing demands from the public by adopting the service delivery models and management practices used in the private sector (Brown, et. al., 1998). Hence, the International Standardization for Organizations (ISO) 9001 or the Quality Management System is one best tool to realize this transformation (Chu, et. al., 2015).

Although, there are considerable amounts of ISO 9001 studies, they were mostly focused on manufacturing organizations (Singh & Smith, 2016). ISO 9001:2008 is a modification of the ISO 9001:2000 where its main purpose is to enhance efficiency, competitiveness, and customer satisfaction, an increasing number of companies are developing or adopting a quality management system (QMS) (Magd, 2013). The QMS is a standard used by many companies to assist them in implementing and operating an effective quality policy by enhancing its ability to design, produce, and deliver quality products and services (Wahid, et. al., 2014; Sroufe & Curkovic, 2013). Thus, the standard provides guidelines on procedures, controls, and documentation for a QMS to help a company identify mistakes, streamline its operations, and maintain a consistent level of quality (Kartha, 2014).

In India, the quality system in a healthcare organization facilitates the standardization of the systems and processes (both clinical and administrative). This standardization further ensures improving the performance of the hospital thus acts as a vehicle for healthcare organizations to focus on patient and provider needs and expectations (Sharma, 2012).

In the Philippines, the Department of Health (DOH) announced the first DOH-retained hospital to be ISO 9001:2008-certified for Quality Management System. The Quirino Memorial Medical Center (QMMC) received the certification from AJA Registrars, Inc., which covers all the medical, nursing, ancillary, and administrative support services (gov.ph, 2013). Regionally, the Cotabato Regional and Medical Center in Cotabato City is the only government hospital in the region that was certified by the TUV Rheinland as an ISO 9001:2008 certified. This goes to show that when a hospital is certified as complying with ISO 9001: 2008 standards implies that it is able to provide services that meet patient's requirements and complies with statutory and regulatory requirements applicable to the services and aims to enhance patient satisfaction through effective application of the quality management system and through processes for continual improvement (BSI British Standards, 2013).

It is in this light that the researcher seeks to determine the relationship between the level of implementation of the ISO 9001:2008 Quality Management System (QMS) standard and the performance outcomes it can contribute upon attainment of the certification.

Theoretical Framework

This study based on theory which states that the quality of the outcome is focused on the end results system of auditing clinical care (Codman, 1916). Other theorists with significant influence on clinical quality improvement theory include Donabedian (1966), who outlined a definition of quality which focused on structure, process and outcome, and Berwick (1991), who spearheaded the application of industrial approaches within a clinical environment (Boaden, et. al., 2008).

Similar theory that closely captures the idea of quality management is developed by Shew hart (1931) which he termed as the Plan-Do-Study-Act (PDSA) which was later changed to Plan-Do-Check-Act (PDCA) as proposed by Deming (1986), which is a cycle that generally used in healthcare to small tests of change, used as part of a continuous improvement approach (Dale, 2013).

Another theory that is considered to be applicable in adhering to quality management system is the Theory of Constraints (ToC) proposed by Goldratt in the early 1980s (Goldratt & Cox, 1984). Goldratt believed that ToC represented an overall theory for running an organization (Goldratt, 1988) where constraints are not viewed as negative, but as opportunities to improve" (Rahman, 2010).

All these theories brought about change in giving quality outcomes through establishing Quality Management System (QMS) standards through the formation of the International Organization for Standardization (ISO), which serves not only to establish performance standards but, also, to specify the processes by which the quality management standards may be met, and by which the effectiveness and efficiency of the QMS may be improved (Walker & Johnson, 2009).

According to ISO 9001:2008 standard (ISO 9001:2008, 2008), the main concern of the Quality Management System are to conform with the standards on 1) processes, documentation and control, 2) quality policy and objectives, 3) customer-focused and feedback, and 4) continuous improvement. These standards are specifically determined not only by the management experts themselves but also by many academics and experts worldwide (Heras, et. al., 2013; Gotzamani, et. al., 2012).

Conceptual Framework

This study utilizes the independent and dependent framework of determining the relationship between two variables. The main variables of the study which the first box as the independent variable discusses the indicators of the Quality Management System (ISO 9001:2008) based on the quality management principles such as: process, documentation and control, quality policy and objectives, customer focus and feedbacking, and continuous improvement (Heras, et. al., 2013;Gotzamani, et. al., 2012).

The dependent variable measures the performance benefits as a an essential management tool in correlating with the QMS, because the only way to improve something is to measure it. The indicators include operational benefits, employee-related and customer-related benefits (Salaheldin, 2009).

Objectives of the Study

The purpose of the study is to determine the significant relationship between the level of compliance and the level of performance benefits of the ISO 9001:2008 Quality Management System (QMS) standards Cotabato Regional and Medical Center in terms of Process, Documentation and Control, Quality Policy and Objectives, Customer Focused and Feedback; and Continuous Improvement. It also determine the level of performance benefits in terms of operational benefits, employee-related benefits and customer-related benefits.

Materials and Methods

This study utilized the descriptive-survey method as part of quantitative research. Survey method is where participants answer questions administered through questionnaires. After participants answer the questions, researchers describe the responses given. In order for the survey to be both reliable and valid, it is important that the questions are constructed properly (Jackson 2014). A total of 100 respondents from selected respondent from Cotabato Regional and Medical Center namely, Medical Services, Nursing Services, Hospital Operations and Support Services, and Finance Services. Each Service Unit has its respective departments, were chosen to answer the survey questionnaire, For valid reliable interpretation of data, statistical treatment using mean was used to measure the level of implementation and the level of performance benefits of the ISO 9001:2008 Quality Management System (QMS) standards.

Definition Of Terms

To provide a clear understanding of the study, the flowing terms below were defined conceptually and operationally.

ISO 9001:2008

A Quality Management System (QMS) standard ensuring compliance with customer and regulatory requirements.

In this study: Focused on four standards-Process, Documentation and Control; Quality Policy and objectives; Customer Focus and Feedback; Continuous Improvement.

Process, Documentation and Control

Involves clear process flow, effective documentation, and proper control of records to meet quality requirements.

Quality Policy and Objectives

Set goals and policies aimed at establishing a compliant and effective quality system.

Involves systems for collecting customer feedback and ensuring proper corrective actions for service improvement.

Continuous Improvement

Uses the PDCA (Plan-Do-Check -Act) cycle to regularly assess and enhance processes.

Performance Benefits

Overall impact of ISO certification on operations, employees, and customer service.

Operational Benefits

Improved decision-making, documentation, strategy, and problem management

Employee-related Benefits

Better human resource planning, job satisfaction, motivation, and quality awareness.

Customer-Related Benefits

Enhanced understanding of customer needs, increased satisfaction, loyalty, and improved complaint response.

Results and Discussion

This section presents the data gathered, analyzed and interpreted based on the statistical result to measure the level of compliance and the level of performance benefits of the ISO 9001:2008 Quality Management System (QMS) standards Cotabato Regional and Medical Center.

For the level of compliance

Range of Measure	Description	Interpretation
4 3.50 - 4.00	Always	Highly Complied
3 2.50 - 3.49	Occasionally	Slightly Complied
2 1.50 - 2.49	Sometimes	Less Complied
1 1.00 - 1.49	Never	Not Complied

For the level of performance benefits

Range of Measure	Description	Interpretation
4 3.50 - 4.00	Very High	Highly Complied
3 2.50 - 3.49	High	Slightly Complied
2 1.50 - 2.49	Low	Less Complied
1 1.00 - 1.49	Very Low	Not Complied

Table 1: Extent 0f Compliance of the ISO 9001:2008 Quality Management System Standards (N=100)

Process, Documentation and Control	Mean	Descriptive Interpretation
Interconnection, interrelation and sequence of processes are established.	3.83	Highly complied
Standard Operating Procedures (SOP) and process flow sheets are available.	3.83	Highly complied
Coordination among management, operations, maintenance, and the medical and other non-medical services, and staff are properly informed with the flow of the system.	3.91	Highly complied
Documentation practices, preventive maintenance program, procedure for validating, verifying, monitoring, testing and inspecting of products, and other services are available.	3.86	Highly complied
Documentation practices for recording and analyzing the activities of both the medical and non-medical personnel are observed.	3.83	Highly complied
Over-all Mean	**3.85**	**Highly complied**

Legend

3.50-4.00 Highly Complied
2.50-3.49 Slightly Complied
1.50-2.49 Less Complied
1.00-1.49 Not Complied

Table 2: Extent of Compliance of the ISO 9001:2008 Quality Management System Standard N=100

Quality Policy and Objectives	Mean	Descriptive Interpretation
Quality policy of the organization and its objectives are observed.	3.91	Highly complied
Quality Policy and Objectives (QPOs) are defined by the top management	3.90	Highly complied
Quality Policy and Objectives (QPOs) set by each unit/department is specific, well defined and measurable and time bounded.	3.89	Highly complied
Quality Policy and Objectives (QPOs) are posted or Displayed in every unit/ department.	3.90	Highly complied
Employees are involved, familiar and aware of the Quality Policy and Objectives (QPOs).	3.84	Highly complied
Over-all Mean	**3.89**	**Highly complied**

Legend

3.50-4.00 Highly Complied
2.50-3.49 Slightly Complied
1.50-2.49 Less Complied
1.00-1.49 Not Complied

Table 3: Extent of Compliance of the ISO 9001:2008Quality Management System Standard N=100

Customer-Focused and Feedback	Mean	Descriptive Interpretation
Feedback reporting system are taken into consideration.	3.87	Highly complied
Audit results and suggestions are implemented	3.88	Highly complied
The non-conformity and deviation from standards are recorded	3.87	Highly complied
Customer feedback are included in the revision of the quality manual.	3.82	Highly complied
All corrective actions are reviewed.	3.87	Highly complied
Over-all Mean	**3.86**	**Highly complied**

Legend
3.50-4.00 Highly Complied
2.50-3.49 Slightly Complied
1.50-2.49 Less Complied
1.00-1.49 Not Complied

This implies that customer feedback as a means of improving quality healthcare service requires a thorough audit trail. This audit trail serves as a mechanism to ensure that corrective actions as bases for the improvement of plans should be complied. This is why, noticeably, each unit/department in the hospital puts a suggestion box as a feedback.

Table 4: Extent of Compliance of the ISO 9001:2008 Quality Management System Standards

Continuous Improvement	Mean	Descriptive Interpretation
Feedback/suggestion box is placed in every department.	3.89	Highly Complied
The use of Plan-Do-Check-Act (PDCA) cycle is observed.	3.86	Highly complied
Top management conducts root cause analysis (RCA).	3.89	Highly complied
Top management applies the records Complied retention guide (RRG) and the 5S (sorting, straightening, shining, standardizing, and sustaining).	3.89	Highly complied
Internal Quality Auditors and/or quality circle teams/ quality management council are properly organized.	3.88	Highly complied
Over-all Mean	**3.88**	**Highly complied**

Legend
3.50-4.00 Highly Complied
2.50-3.49 Slightly Complied
1.50-2.49 Less Complied
1.00-1.49 Not Complied

Table 5: Level of Performance Benefits as a Result of the ISO 9001:2008 Quality Management System Standards.

Operational Benefits	Mean	Descriptive Interpretation
Procedure for documentation, recording as well as visitation of patients has improved.	3.83	Highly Benefited
Continuous quality improvements (CQI's) in all aspects of the services are properly monitored	3.87	Highly Benefited
Quality services provided to patients, clients, customers and the community materials received have improved.	3.89	Highly Benefited
Quality of materials and supplies received has improved.	3.89	Highly Benefited
Working instructions and procedures, effective control of process capability; and process flow has improved and properly controlled.	3.84	Highly Benefited
Over-all Mean	**3.86**	**Highly Benefited**

Legend
3.50-4.00 Highly Complied
2.50-3.49 Slightly Complied
1.50-2.49 Less Complied
1.00-1.49 Not Complied

Table 6: Level of Performance Benefits as a Result of the ISO 9001:2008 Quality Management System Standards

Employee – Related Benefits	**Mean**	**Descriptive Interpretation**
Human resource planning and job responsibility has improved.	3.83	Highly Benefited
Employee's knowledge of processes and services has improved.	3.84	Highly Benefited
Employee's and staff are satisfied and motivated.	3.87	Highly Benefited
Employee's and staff have improved.	3.87	Highly Benefited
Communication among employees and management has improved.	3.83	Highly Benefited
Over-all Mean	**3.85**	**Highly Benefited**

Legend
3.50-4.00 Highly Complied
2.50-3.49 Slightly Complied
1.50-2.49 Less Complied
1.00-1.49 Not Complied

Table 7: Level of Performance Benefits as a Result of the ISO 9001:2008 Quality Management System Standards

Employee – Related Benefits	**Mean**	**Descriptive Interpretation**
Customer requirement like processing of documents and records has improved and increased	3.83	Highly Benefited
Customer/clients complaints, feedbacks and other concerns have lessened and addressed properly.	3.84	Highly Benefited
Customer/clients are satisfied, loyal and have increased referral to other customers/clients.	3.88	Highly Benefited
Customer/clients have better communication with personal, employees and service providers.	3.77	Highly Benefited
Request for medicines, supply, materials and others are promptly responded.	3.85	Highly Benefited
Over-all Mean	**3.83**	**Highly Benefited**

Legend
3.50-4.00 Highly Complied
2.50-3.49 Slightly Complied
1.50-2.49 Less Complied
1.00-1.49 Not Complied

Table 8: Correlation Measures Between the ISO 9001:2008 Quality Management System Standards and Its Performance Benefits

Performance Benefits		ISO 9001 : 2008 Quality Management System Standards			
		Process, Documentation and Control	Quality Policy and Objectives	Customer Focused and Feedback	Continuous Improvement
Operational Benefits	Pearson Correlation	.514**	157**	943**	779**
	Sig. (2-tailed)	.006	120	.000	.000
	N	100	100	100	100
Employee – Related Benefits	Pearson Correlation	.143**	.226**	.715**	.948**
	Sig. (2-tailed)	.104	.024	.000	.000
	N	100	100	100	100
Customer – Related Benefits	Pearson Correlation	.237**	.925**	.428**	.137**
	Sig. (2-tailed)	.119	.000	.080	.176
	N	100	100	100	100

**. Correlation is significant at the 0.01 level (2-tailed)
*. Correlation is significant at the 0.05 level (2-tailed)

Summary

The hospital's compliance with ISO 9001:2008 QMS standards was consistently high, with all four indicators, particularly quality policy and objectives, achieving strong scores. This commitment to quality translated into tangible benefits, as 100% of respondents reported improvements in areas like employee relations, customer satisfaction, and overall efficiency.

While universally acknowledged benefits like increased recognition and cost reductions were evident, some areas, such as potential cost savings for clients, improving operating systems, and increasing quality awareness, were recognized by a large majority but not all respondents.

From a performance perspective, operational benefits stood out, contributing significantly to the overall positive impact of ISO certification. Notably, there's a direct link between the hospital's quality policy and objectives and the resulting employee-related benefits.

Conclusion

The hospital's strong adherence to ISO 9001:2008 QMS standards, particularly in its quality policy and objectives, confirms that employees not only understood but actively met the required performance benchmarks. This commitment was notably influenced by existing commercialties. ISO certification delivered tangible benefits to all stakeholders, fostering stronger employee relationships, leading to greater customer satisfaction, and earning nationwide recognition. These benefits collectively improved overall work satisfaction, solidified customer loyalty, and enhanced the organization's financial stability. Specifically, the Cotabato Regional and Medical Center (CRMC) saw considerable performance gains, with operational benefits emerging as the clearest indicator of the ISO 9001:2008 QMS's positive impact. Finally, the significant correlation identified in the study allows for the rejection of the null hypothesis.

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