

Analysis of ISO 9001:2015 Implementation in Hospitals: A Narrative Literature Review

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Abstract – The purpose of writing this article is a narrative literature review of three articles that discuss the analysis of ISO 9001:2015 implementation in hospitals, aiming to identify and summarize previously published articles without any criticism for the articles reviewed. The results of the review indicate that the hospital makes quality and performance improvements and that the application of risk is carried out continuously to maintain the quality of service. The standard indicator of the assessment is the ISO 9001:2015 Quality Management System (QMS) certification. The implementation of integrated quality management in the hospital has been well implemented based on standard service procedures. Factors consisting of customer focus, leadership, HR involvement, process approach, continuous improvement, fact-based decision-making, and relationships with stakeholders have a very good correlation to the ISO 9001:2015 Internal Quality Audit. It is recommended that all parties involved in the hospital's operational processes are expected to be able to improve and prioritize service quality to provide satisfaction to every patient who comes to visit the hospital.

Keywords: Integrated Quality Management, Internal Quality Audit, ISO 9001:2015.

I. INTRODUCTION

According to Yanuariska & Miharti (2017), hospitals are healthcare institutions that organize comprehensive individual health services that provide inpatient, outpatient, and emergency services (Indonesian Law No. 44 of 2009). The public wants safe and quality health services that can answer their needs; therefore, efforts to improve quality, risk management, and patient safety need to be applied in hospital management when providing comprehensive health services to the community. The evaluation of performance assessment is also intended to show appreciation to the hospital for implementing excellent service or meeting the needs of the community. ISO 9001:2015 QMS certification specifies the requirements and recommendations for the design and assessment of a quality management system certification, which aims to ensure that the organization will provide products (goods or services) that meet the requirements set by the world body or ISO body. This can meet the needs of patients, where hospitals can already provide quality services. Based on the results of the preliminary study, information was obtained that RSJD Dr. RM. Soedjarwadi, Central Java Province, has made preparations for the ISO 9001:2015 QMS audit, conducted an ISO 9001:2015 QMS audit, which was held on November 21–22, 2016, and passed the ISO 9001:2015 QMS audit. The purpose of Yanuariska and Miharti's research (2017) is to find out the shortcomings and obstacles in preparation for the audit so that for future preparations, these things can be minimized. In addition, it is expected to be a reference for other hospitals that want to conduct an ISO 9001:2015 QMS audit.

According to Fransisca & Aliya (2018), the implementation of the quality management system in Indonesia has had a positive impact on all types of entities in the country. Audits are very useful for entities to maintain consistency with the efficiency and effectiveness that have been achieved, both in the commercial sector and in the public sector. The implementation of ISO 9001:2015 is allegedly able to minimize risks in the environment of the Kayu Agung Regional General Hospital, Ogan Komering Ilir Regency. The purpose of Fransisca and Aliya's research (2018) is to find out how to analyze the ISO 9001:2015 internal quality audit factors at the Kayu Agung Regional General Hospital, Ogan Komering Ilir Regency, using internal audits.

According to Bakobat et al. (2021), Law No. 36 of 2009 concerning health states that the definition of health is a state of health, both physically, mentally, spiritually, and socially, that allows everyone to live a productive life socially and economically. Budi Mulia Bitung Hospital is the only private hospital located in Kadoodan Village, Madidir District, Bitung City. Budi Mulia Bitung Hospital must be able to improve the quality of service to the community because, in essence, health services are organized to meet the needs and demands of users, which, if successfully met, can lead to a sense of satisfaction with the health service. As for some of the problems that occur at Budi Mulia Bitung Hospital, some patients and families of patient companions are dissatisfied with the services provided by Budi Mulia Hospital. The purpose of the research by Bakobat et al. (2021) was to find out how the implementation of integrated quality management at Budi Mulia Bitung Hospital went.

II. REVIEW OF THE LITERATURE

A. ISO 9001:2015

ISO is a word derived from the Greek word isos, which means 'same' or 'equal'. The prefix "iso-" is also commonly found in the words "isometric", "isomer", "isonomy," and so on. Many people see a mismatch between the full name "International Organization for Standardization" and its abbreviation "ISO," which is commonly abbreviated as 'IOS'. This assumption would be correct if the name was based on an abbreviation. Finally, the ISO designation is no longer an abbreviation but the name of an international class organization, according to Suryatama (2014). ISO 9001 is a quality management system or quality assurance system. ISO 9001 is a standard mechanism that is compiled, agreed upon, and implemented by an organization in carrying out the activities of an entity.

B. Benefits of International Standards

The benefits that entities can feel if they implement International Standards according to Suryatama (2014) are (1) Cost savings, as international standards help optimize the entity's business operations; (2) Increase customer satisfaction, as international standards help improve quality, as well as increase customer satisfaction and increase sales; (3) Access to new market shares, international standards help prevent trade barriers and open global markets; (4) Increased market share, international standards help increase productivity and competitive advantage; (5) Environmental benefits, international standards help reduce negative impacts on the environment.

C. Audit

An audit is an examination that is carried out critically and systematically by an independent party of the financial statements that have been prepared by management, along with accounting records and supporting evidence, to be able to provide an opinion on the fairness of the financial statements (Agoes, 2014).

D. Definition of Integrated Quality Management

Integrated Quality Management is an organizational philosophy and culture that emphasizes efforts to create a management commitment that can motivate all members of the organization to contribute as

much as possible to the organization, which is the shared responsibility of all members of the organization (Gani, 2014).

E. Principles of Quality Management

According to ISO 9001:2015, in its implementation, there are seven basic principles of an integrated quality management system: (1) Customer focus. This principle is the main focus of quality management, where every organization must be able to meet customer requirements; (2) Leadership. The principle of leadership explains that leaders at all levels of the organization must have unity of purpose and direction and create conditions where every employee is involved in achieving organizational quality goals; (3) Engagement of people. This third principle explains that in an organization, every employee is competent, can be empowered, and can be involved in carrying out its business processes, by applying the principle of employee involvement; (4) Process Approach. To achieve organizational goals most effectively and efficiently and understanding the interdependence between the processes of the system, can help the organization in providing a better understanding of the roles and responsibilities to achieve common goals, reduce barriers and cross-functional targeting, and can define more easily how specific activities in a system should operate; (5) Improvement. The principle of improvement in quality management emphasizes the importance of organizations providing training to their employees related to improved methods and tools in the organization, and making product, process, and system improvement objectives for each individual in the organization; (6) Evidence-Based Decision Making. This principle explains that every organization in making decisions must be based on the results of data and information analysis and evaluation; (7) Relational Management. The principle of relational management explains that to achieve sustainable success, organizations must manage relationships with various interested parties. (Rundle, 2015).

F. The Elements of Integrated Quality Management

The elements of Integrated Quality Management according to Tjiptono (2003) have ten characteristics, namely (1) Customer focus; (2) Obsession with quality; (3) Scientific approach; (4) Long-term commitment; (5) Teamwork; (6) Continuous system improvement; (7) Education and training; (8) Freedom and control; (9) Unity of purpose; (10) Employee involvement and empowerment.

G. The Benefits of Integrated Quality Management

The benefits of integrated quality management can be grouped into two categories: improving the competitive position and increasing output free from damage (Nasution, 2005).

H. Implementation of Integrated Quality Management in Hospitals

According to Hardjosoedarmo (1996), to ensure the successful implementation of TQM in the company, it is necessary to follow the following steps: (1) Instill a philosophy of quality; (2) Management must guide and demonstrate quality leadership; (3) Make changes to the system that are more conducive; (4) Educate, train, and empower all employees. Integrated quality management in the health sector must prioritize the fulfillment of quality needs because quality is a major factor in service delivery. Improving quality is done by making continuous improvements to all aspects of the hospital.

I. Barriers to Integrated Quality Management

According to Tjiptono and Diana (2003), there are six inhibiting factors in integrated quality management, including the following: (1) Delegation and poor leadership from senior management; (2) Team mania; (3) Deployment process; (4) Using a limited and dogmatic approach; (5) Excessive and unrealistic expectations; (6) Premature empowerment.

J. Quality Control: Seven Tools

Quality control was first introduced by Kaoru Ishikawa in 1968. The analysis techniques are (1) check sheet; (2) histogram; (3) stratification; (4) Pareto diagram; (5) scatter diagram; (6) control chart; and (7) fishbone diagram.

K. Previous Research

Kondo (2017), with the research title Analysis of the Application of Total Quality Management and Performance Appraisal System at PT SULUTGO. This study aims to determine the application of total quality management and performance appraisal systems at PT Bank SulutGo. The method of analysis is descriptive-qualitative. The results showed that the application of TQM at PT Bank SulutGo has fulfilled the main elements of total quality management, and the application of the performance appraisal system is by the requirements of an assessment system, namely relevance, acceptability, reliability, and sensitivity.

III. RESEARCH METHOD

This article aims to identify and summarize articles that discuss the analysis of ISO 9001 Implementation: 2015 in Hospitals. The method used in this article is a narrative literature review, which is one of the most common types of literature reviews used in research. This type of review aims to provide a comprehensive summary of previously conducted research on the same topic and generate a better understanding of the topic.

Table 1. Journal articles reviewed

Author	Title	Source	Method	Sample	Engineering
Yanuariska & Miharti (2017)	Preparation of Quality Management System (QMS) Audit ISO 9001:2015 RSJD Dr. RM. Soedjarwadi, Central Java Province, at the Medical Record Installation	Scholar	Qualitative descriptive.	Reporting officer, coding, filing, and head of the medical record installation room.	Interview, observation, and documentation study
Fransisca & Aliya (2018)	Factor analysis of ISO 9001:2015 internal quality audit.	Scholar	Quantitative descriptive.	Interested parties at Kayu Agung Hospital, Ogan Komering Ilir Regency.	Interview and questionnaire
Bakobat et al (2021)	Analysis of the implementation of integrated quality management at Budi Mulia Bitung Hospital.	Scholar	Descriptive and Statistical Processing Control.	2 Directors, 2 Doctors, 2 Nurses, 2 Staff, and 2 Patients.	Observation, Interview, Documentation, Literature study.

IV. RESULTS AND DISCUSSION

The results of research from Yanuariska & Miharti (2017) show that:

1. The ISO 9001:2015 Quality Management System (QMS) audit preparation can be divided into two parts: technical and document preparation.

a) Technical Preparations

1. Internal auditor training and awareness

Internal auditor training was conducted to train several staff members who will later become a team of internal auditors. Awareness and workshops were conducted to introduce staff to the clauses of the ISO 9001:2015 Quality Management System (QMS).

2. Medical records installation meeting

The medical records installation does not conduct special preparatory meetings; coordination is done verbally, and tasks are assigned by the head of the room.

3. Tidying up and reorganizing the room and filing, including making a plan of the filing shelves and putting numbers on the shelves.

This activity also fulfills clause 7.5.3 related to the control of documented information, namely that the medical record installation keeps the room and filing neat to minimize lost or tucked files (RSJD Dr. RM. Soedjarwadi, Central Java Province, 2015).

4. Checking facilities

The activity of checking facilities aims to ensure that the facilities in the medical record installation are still functioning properly and adequately.

b) Preparation of Documents

1. Specially prepared documents

2. Documents that are not specially prepared

The internal audit was conducted on November 9, 2016, on a cross-over basis. Some of the internal audit findings include: (a) some SOP/IK does not exist; (b) some have not been revised; (c) risk of losing medical records; (d) inappropriate equipment needs; (e) insufficient resources and lack of competence. Although it has passed the ISO 9001:2015 Quality Management System (QMS) certification, it still has to make continuous improvements by making improvements to the internal audit findings that have been skipped, considering these findings will affect the service.

2. The problems experienced by the medical records installation are time constraints and a lack of socialization and communication. Related to the time constraints because the preparation took only a few months, resulting in a lot of preparation done by the head of the medical record installation room with the help of three staff, some SOP were added and revised by the consultant and secretariat. With the limited time available, it should be able to optimize the officer's time by dividing tasks to make preparations with careful coordination, meaning that there is no need for an official meeting for clause explanation, division of tasks, and monitoring, which can be done while chatting during free time at work. Awareness or socialization is done only with some people who are included in the ISO team, namely representatives of four people from each installation so that officers who do not participate in the socialization do not know about the ISO 9001:2015 Quality Management System (QMS) and its latest clauses. It is better to do socialization within the scope of the installation so that officers who are not part of the ISO team can also know.

The results of Fransisca & Aliya's research (2018) show that the factors that make ISO 9001:2015 include customer focus, leadership, HR involvement, process approach, continuous improvement, fact-based decision-making, and relationships with stakeholders. All factors that make up the variable correlate to 0.870. This means that the factors that make up the ISO Internal Quality Audit variable are very good. The Scree Plot line is almost perfectly horizontal, which means that the customer-focused factors, leadership, people involvement, process approach, continuous improvement, fact-based

decision-making, and stakeholder relationships developed in many internal quality audits are indeed appropriate to represent the quality management of an entity.

The results of Bakobat et al.'s research (2021) show that the implementation of integrated quality management at Budi Mulia Bitung Hospital is based on the principles of total quality management. (1) Focus on patients explains that patient satisfaction can be fulfilled by Budi Mulia Bitung Hospital by means of hospital management always conducting work evaluations, communicating with problem parties, and adding manpower; (2) Leadership at Budi Mulia Bitung Hospital is based on internal regulations (Hospital Bylaws), which, in the implementation of integrated quality, give authority to the heads of sections to manage and organize each section according to the established SPO; (3) Involvement of all employees at Budi Mulia Bitung Hospital has been implemented by involving employees in hospital accreditation and coordination meetings; (4) The process approach at Budi Mulia Bitung Hospital is carried out from the patient's arrival to discharge according to the standard procedure for patient handling flow; (5) Evidence-based decision making at Budi Mulia Bitung Hospital is based on the results of the hospital PMKP committee survey and the BPJS health survey, which are then used as data and information for decision making. The implementation of integrated quality management at Budi Mulia Bitung Hospital has been well implemented based on standard service procedures as an accredited hospital quality document. However, there are still things that need to be improved, such as improving the infrastructure of the patient waiting room, adding new employees, especially in the pharmacy section, reviewing the schedule of specialist doctors, and training new employees.

V. CLOSING

A. Conclusion

Yanuariska & Miharti (2017) concluded that (1) the preparation of the ISO 9001:2015 Quality Management System (QMS) audit carried out is divided into two parts, namely technical and document preparation; and (2) the obstacles experienced in the preparation of the ISO 9001:2015 Quality Management System (QMS) audit in the medical record installation at Dr. RM Hospital, Soedjarwadi, Central Java Province, namely time constraints and lack of socialization and communication. Fransisca & Aliya (2018) concluded that factors such as customer focus, leadership, HR involvement, process approach, continuous improvement, fact-based decision-making, and relationships with stakeholders are very appropriate factors to represent the ISO 9001:2015 Internal Quality Audit. The correlation of the test results shows very adequate results. Bakobat et al. (2021) concluded that (1) the focus on patients at Budi Mulia Bitung Hospital is that there are still obstacles in adjusting SPOs for new employees and that there are still specialist doctors who are often not on time with the specified service schedule; (2) Leadership at Budi Mulia Bitung Hospital, based on internal regulations (Hospital Bylaws), is led by a Director assisted by 4 (four) Deputy Directors, and each Deputy Director oversees and is responsible for 2 fields, and each field oversees several sub-fields; (3) Involvement of all people and employees at Budi Mulia Bitung Hospital: employees are involved in hospital accreditation and coordination meetings; (4) Process quality at Budi Mulia Bitung Hospital is measured through an approach that is carried out from the patient's admission to the patient's discharge; (5) Evidence-based Decision Making at Budi Mulia Hospital is based on evidence found in the field through interviews conducted by the PMKP (Quality Improvement and Patient Safety) committee and surveys from the BPJS called Walk Through Audit (WTA).

B. Suggestion

The suggestion conveyed through the research of Yanuariska & Miharti (2017), namely that medical record installation officers should not take for granted additional or revised SOPs that are not appropriate, hospitals should continue to make continuous improvements to the findings of internal audits that have been skipped, optimize their officers by dividing tasks to make preparations with careful

coordination, and socialization should be carried out within the scope of the installation so that officers who are not part of the ISO team can also find out about ISO clauses, The suggestion conveyed through the research of Bakobat et al. (2021), namely: conducting a review of the specialist doctor's service schedule at the polyclinic that is not in accordance with what has been scheduled; evaluating employee performance at least once a month; conducting socialization to new employees, especially regarding Standard Operating Procedures (SPO) in their respective sections; recruiting new employees, especially in the pharmacy section, so that drug delivery services do not take a long time; and increasing the expansion of the waiting room area for outpatients so that patients can wait safely and comfortably.

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