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Healthcare Service Quality Improvement Using ISO 9001: 2015 Gap Analysis at PT Hurip Putera Husada

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Abstract
The implementation of the ISO 9001:2015 Quality Management System (QMS) has become an important strategy for improving healthcare service quality through a systematic and continuous management approach. However, evaluating the level of conformity with the standard remains essential to identify implementation gaps that may affect the effectiveness of the quality management system. This study aimed to evaluate the implementation of ISO 9001:2015 at Klinik Utama Pupuk Kujang using a gap analysis approach, identify conformity gaps, and formulate improvement recommendations. A descriptive quantitative approach supported by qualitative data was employed. Data were collected through direct observations, semi-structured interviews, questionnaires based on ISO 9001:2015 clauses, and document reviews. The data were analyzed by calculating the conformity level of each ISO 9001:2015 clause and supported by root cause analysis and the Plan–Do–Check–Act (PDCA) framework to develop improvement strategies. The results revealed an overall conformity level of 77.39%, indicating that the Quality Management System has been implemented at a good level. Clause 8 (Operation) achieved the highest conformity score of 81.71%, while Clause 7 (Support) obtained the lowest score of 72.00%, making it the highest priority for improvement.
Keywords: *iso 9001:2015, quality management system, gap analysis, healthcare services, continuous improvement*

Abstrak
Penerapan *Quality Management System* (QMS) berdasarkan ISO 9001:2015 menjadi salah satu strategi untuk meningkatkan mutu pelayanan kesehatan melalui pendekatan yang sistematis dan berkelanjutan. Namun, tingkat kesesuaian implementasi standar tersebut pada fasilitas pelayanan kesehatan masih perlu dievaluasi untuk mengidentifikasi kesenjangan yang dapat memengaruhi efektivitas sistem manajemen mutu. Penelitian ini bertujuan untuk mengevaluasi tingkat kesesuaian penerapan ISO 9001:2015 di Klinik Utama Pupuk Kujang menggunakan metode gap analysis, mengidentifikasi kesenjangan implementasi, serta menyusun rekomendasi perbaikan. Penelitian menggunakan pendekatan deskriptif kuantitatif yang didukung data kualitatif. Data diperoleh melalui observasi, wawancara, penyebaran kuesioner berbasis klausul ISO 9001:2015, dan studi dokumentasi. Analisis dilakukan dengan menghitung tingkat kesesuaian setiap klausul ISO 9001:2015 dan didukung analisis akar penyebab serta pendekatan Plan–Do–Check–Act (PDCA) untuk menyusun strategi perbaikan. Hasil penelitian menunjukkan tingkat kesesuaian keseluruhan sebesar 77,39%, yang mengindikasikan bahwa sistem manajemen mutu telah diterapkan dengan kategori baik. Klausul 8 (Operation) memperoleh tingkat kesesuaian tertinggi sebesar 81,71%, sedangkan Klausul 7 (Support) memperoleh nilai terendah sebesar 72,00%, sehingga menjadi prioritas utama perbaikan.
Kata Kunci: *iso 9001:2015, sistem manajemen mutu, analisis kesenjangan, pelayanan kesehatan, peningkatan mutu*

1. Introduction

Healthcare service quality has become a strategic priority in many countries due to the increasing public awareness of health and the growing demand for safe, effective, and patient-centered healthcare services [1]. As healthcare organizations face increasing competition and higher expectations from patients, maintaining consistent service quality has become essential for achieving patient satisfaction and organizational sustainability [2]. Unlike manufacturing industries, healthcare services involve complex interactions between healthcare professionals, patients, medical facilities, and administrative processes, making quality management more challenging [3]. Therefore, healthcare organizations are required to implement a systematic quality management approach to ensure that healthcare services are delivered consistently while complying with applicable regulations and professional standards [4]. Previous studies

have highlighted that patient satisfaction is strongly influenced by service quality, effective organizational management, competent human resources, and continuous quality improvement practices [5]. Consequently, healthcare organizations increasingly adopt internationally recognized quality management standards to enhance operational performance and service reliability [6].

Among the internationally recognized quality management frameworks, the ISO 9001:2015 Quality Management System (QMS) has been widely implemented across various industries, including healthcare institutions [7]. The standard emphasizes a process-based approach, risk-based thinking, leadership commitment, evidence-based decision-making, and continual improvement to improve organizational performance and customer satisfaction [8]. Previous studies have reported that the implementation of ISO 9001:2015 contributes to improving service quality, operational efficiency, documentation control, and organizational performance in healthcare organizations [9]. However, several studies also indicate that healthcare institutions continue to experience difficulties in fully complying with all ISO 9001:2015 requirements, particularly regarding organizational context analysis, risk management, documentation control, employee competence, and continual monitoring of quality performance [10]. Most previous studies primarily focused on evaluating the overall effectiveness of ISO implementation or measuring customer satisfaction, while relatively limited attention has been given to systematically identifying compliance gaps within each clause of ISO 9001:2015 using a structured gap analysis approach. As a result, organizations often lack detailed information regarding which specific clauses require priority improvement to achieve full compliance with the standard.

Klinik Utama Pupuk Kujang, operating under PT Hurip Putera Husada, has implemented a Quality Management System to support the delivery of high-quality healthcare services. Nevertheless, the extent to which the existing practices comply with the requirements of ISO 9001:2015 has not been comprehensively evaluated. Without a systematic assessment, potential discrepancies between current organizational practices and the standard may remain unidentified, limiting opportunities for continuous quality improvement. Accordingly, conducting a comprehensive evaluation based on ISO 9001:2015 is essential to determine the current level of compliance, identify existing implementation gaps, and provide evidence-based recommendations for organizational improvement.

The novelty of this study lies in the application of a clause-by-clause gap analysis to evaluate the implementation of the ISO 9001:2015 Quality Management System within a primary healthcare clinic. Unlike previous studies that generally emphasize the overall impact of ISO certification or service quality outcomes, this research systematically measures the level of conformity for each ISO 9001:2015 clause, identifies priority areas requiring improvement, and proposes practical recommendations to strengthen the effectiveness of quality management implementation. This approach provides a more comprehensive understanding of organizational readiness for continual improvement while supporting evidence-based decision-making for healthcare management.

Therefore, this study aims to evaluate the implementation of the ISO 9001:2015 Quality Management System at Klinik Utama Pupuk Kujang using a gap analysis approach. Specifically, the study seeks to determine the level of compliance with ISO 9001:2015 requirements, identify gaps between existing organizational practices and the standard, and formulate improvement recommendations to enhance healthcare service quality through continual improvement. The findings are expected to contribute both theoretically and practically by enriching the existing literature on quality management implementation in healthcare organizations and by providing management with a systematic framework for improving organizational performance and service quality.

2. Material and Methods

This study employed a descriptive quantitative research design supported by qualitative data to evaluate the implementation of the ISO 9001:2015 Quality Management System (QMS) at Klinik Utama Pupuk Kujang, operating under PT Hurip Putera Husada. A gap analysis approach was adopted to measure the level of conformity between the organization's current quality management practices and the requirements specified in ISO 9001:2015 [11]. The study assumed that the respondents possessed adequate knowledge of the organization's quality management practices and that the documents and operational activities observed accurately reflected the actual implementation of the quality management system. By integrating quantitative and qualitative evidence, the research provided a comprehensive evaluation of organizational compliance and identified opportunities for continuous quality improvement [12].

The research was conducted at Klinik Utama Pupuk Kujang, where the ISO 9001:2015 Quality Management System had been implemented to support healthcare service delivery. Primary data were

collected from employees directly involved in quality management implementation and healthcare service processes. Secondary data consisted of organizational documents, including quality policies, standard operating procedures (SOPs), quality records, internal reports, and other documents relevant to ISO 9001:2015 implementation. These data sources were used to verify organizational practices and support the interpretation of the quantitative findings [13].

Data collection was performed using four complementary techniques. First, direct observations were conducted to examine healthcare service processes, operational workflows, and the practical implementation of ISO 9001:2015 requirements within the organization. Second, semi-structured interviews were carried out with employees responsible for quality management activities to obtain detailed information regarding implementation practices, operational constraints, and employee understanding of the quality management system. Third, a structured questionnaire based on the clauses of ISO 9001:2015 was distributed using a five-point Likert scale to evaluate the degree of compliance with each requirement. Finally, document analysis was conducted by reviewing quality manuals, standard operating procedures, quality records, and other supporting documents to verify the consistency between documented procedures and actual organizational practices. The integration of these four data collection methods enabled data triangulation and improved the credibility of the research findings [14].

The research procedure was conducted systematically in several stages. Initially, a preliminary study was undertaken through field observations and a review of relevant literature concerning ISO 9001:2015 Quality Management Systems and gap analysis in healthcare organizations. Subsequently, research instruments were developed according to the requirements of ISO 9001:2015. Primary and secondary data were then collected through observations, interviews, questionnaires, and document reviews. After data collection was completed, the information was organized according to the relevant clauses of ISO 9001:2015 to facilitate systematic analysis [15].

Data analysis was performed using a gap analysis approach by comparing the organization's existing practices with the requirements specified in ISO 9001:2015. Questionnaire responses were analyzed descriptively by calculating the percentage of conformity for each assessment item and subsequently averaging the scores within each ISO clause to determine the overall level of compliance. The conformity percentage was calculated by dividing the total score obtained by the maximum possible score and multiplying the result by 100%. The resulting percentages were then classified into predetermined conformity categories to identify areas that required improvement. Qualitative data obtained from interviews, observations, and document analysis were analyzed descriptively to explain the causes of identified gaps and to strengthen the interpretation of the quantitative results [16].

Descriptive statistical analysis was employed because the primary objective of this study was to measure the level of conformity with ISO 9001:2015 requirements rather than to test causal relationships between variables. Consequently, inferential statistical tests were not applied. Instead, descriptive statistics, including frequency distributions, average scores, and conformity percentages, were used to summarize the implementation status of each ISO 9001:2015 clause. The integration of quantitative measurements with qualitative findings enabled a comprehensive evaluation of the organization's Quality Management System and supported the formulation of evidence-based recommendations for continual quality improvement.

3. Results and Discussion

Overview of ISO 9001:2015 Quality Management System Implementation

The implementation of the ISO 9001:2015 Quality Management System (QMS) at Klinik Utama Pupuk Kujang was evaluated through a combination of semi-structured interviews, direct observations, document reviews, and questionnaire-based assessments. These complementary data collection techniques provided comprehensive evidence regarding the conformity of the existing quality management practices with the requirements of ISO 9001:2015.

Interviews with the Head of Risk Management and employees involved in quality management revealed that ISO 9001:2015 has become an integral part of the clinic's operational management. The quality management system has been implemented to ensure standardized healthcare services, improve service consistency, minimize operational errors, and increase patient satisfaction. The implementation covers almost all organizational activities, including patient registration, medical treatment, pharmaceutical services, document management, internal evaluation, and corrective actions. Furthermore, management demonstrated a strong commitment to maintaining service quality by establishing quality objectives, implementing Standard Operating Procedures (SOPs), and conducting periodic internal evaluations.

Direct observations confirmed that healthcare service processes generally followed documented operational procedures. Patient services were performed systematically from registration to medical

examination and treatment, indicating that operational activities had been standardized. Nevertheless, several weaknesses were identified during field observations. Documentation related to organizational context, stakeholder analysis, and risk management had not yet been fully developed. Likewise, several quality records were inconsistently maintained, reducing the effectiveness of document control and limiting the organization's ability to demonstrate conformity during quality audits.

Document analysis further supported these findings. Although the clinic possessed documented quality policies, SOPs, and operational records, some documented information required by ISO 9001:2015 was either incomplete or had not been updated regularly. Internal audit reports and corrective action records also indicated that continual improvement activities had been implemented; however, the documentation process remained inconsistent across departments. Consequently, while the Quality Management System has been operationally implemented, further improvements are required to strengthen documentation management, risk-based thinking, and evidence-based decision-making.

Overall, the qualitative findings indicate that Klinik Utama Pupuk Kujang has successfully established the fundamental elements of an ISO 9001:2015 Quality Management System. However, the maturity of the system varies among different ISO clauses, suggesting that continuous improvement efforts remain necessary to achieve full compliance with international quality management standards.

Gap Analysis Results

A quantitative gap analysis was conducted to measure the level of conformity between the existing Quality Management System and the requirements of ISO 9001:2015. The assessment covered Clauses 4 to 10, which represent the operational components of the standard. Each assessment item was evaluated using a five-point Likert scale, and the obtained scores were converted into conformity percentages.

The conformity levels were classified into three categories. Scores below 50% indicate that significant improvements are required because the existing quality management practices differ substantially from ISO 9001:2015 requirements. Scores ranging from 50% to 74% indicate partial conformity, suggesting that further improvements are necessary before the organization can fully comply with the standard. Meanwhile, scores between 75% and 100% indicate that the organization has achieved an acceptable level of implementation and is ready to maintain the system through periodic evaluation and continual improvement.

The assessment results demonstrated that the average conformity level of the clinic reached 77.39%, indicating that the organization generally complies with the requirements of ISO 9001:2015 and has entered the continual improvement stage. Nevertheless, the results also revealed several clauses requiring greater managerial attention.

Table 1. Gap Analysis Results

ISO 9001:2015 Clause	Conformity (%)	Category
Clause 4 – Context of the Organization	74.86	Needs Improvement
Clause 5 – Leadership	77.14	Good
Clause 6 – Planning	79.43	Good
Clause 7 – Support	72	Needs Improvement
Clause 8 – Operation	81.71	Good
Clause 9 – Performance Evaluation	77.71	Good
Clause 10 – Improvement	78.86	Good
Overall Average	**77.39**	**Good**

The results indicate that Clause 8 (Operation) achieved the highest conformity score (81.71%), while Clause 7 (Support) recorded the lowest score (72.00%). These findings suggest that operational processes have been effectively standardized, whereas supporting activities such as document control, competency development, communication, and resource management require further improvement.

Figure 1 illustrates the conformity level for each ISO 9001:2015 clause. Clause 8 (Operation) achieved the highest conformity score (81.71%), while Clause 7 (Support) obtained the lowest score (72.00%). These findings indicate that operational activities have been effectively standardized, whereas supporting processes still require significant improvement.

To facilitate the interpretation of the conformity level across all ISO 9001:2015 clauses, the assessment results are further presented in the form of a heatmap, which provides a visual representation of organizational strengths and improvement priorities.

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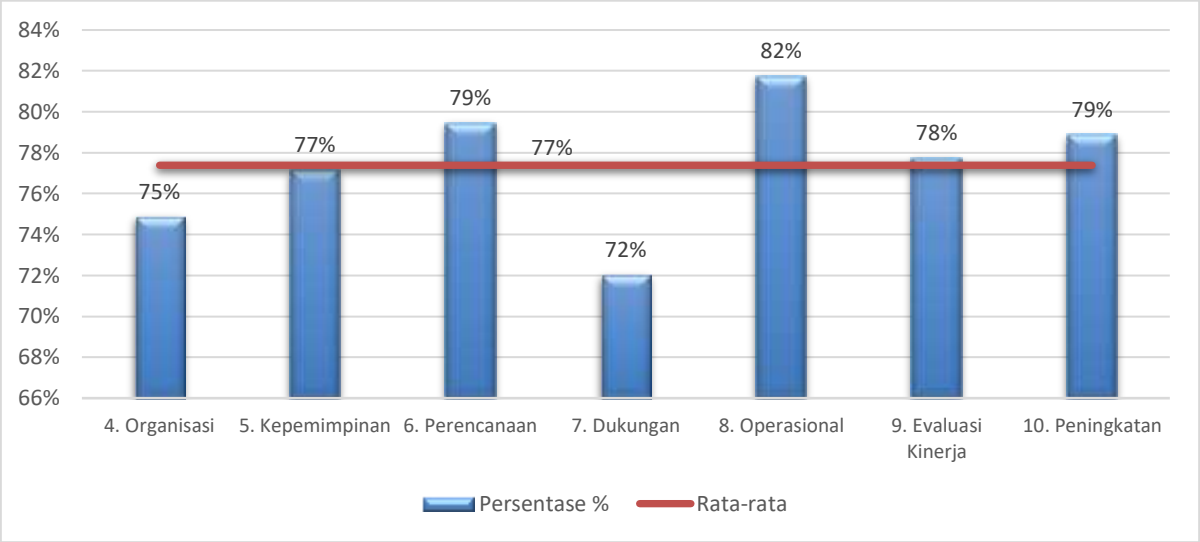

Fig. 1: Conformity Level of ISO 9001:2015 Clauses at Klinik Utama Pupuk Kujang

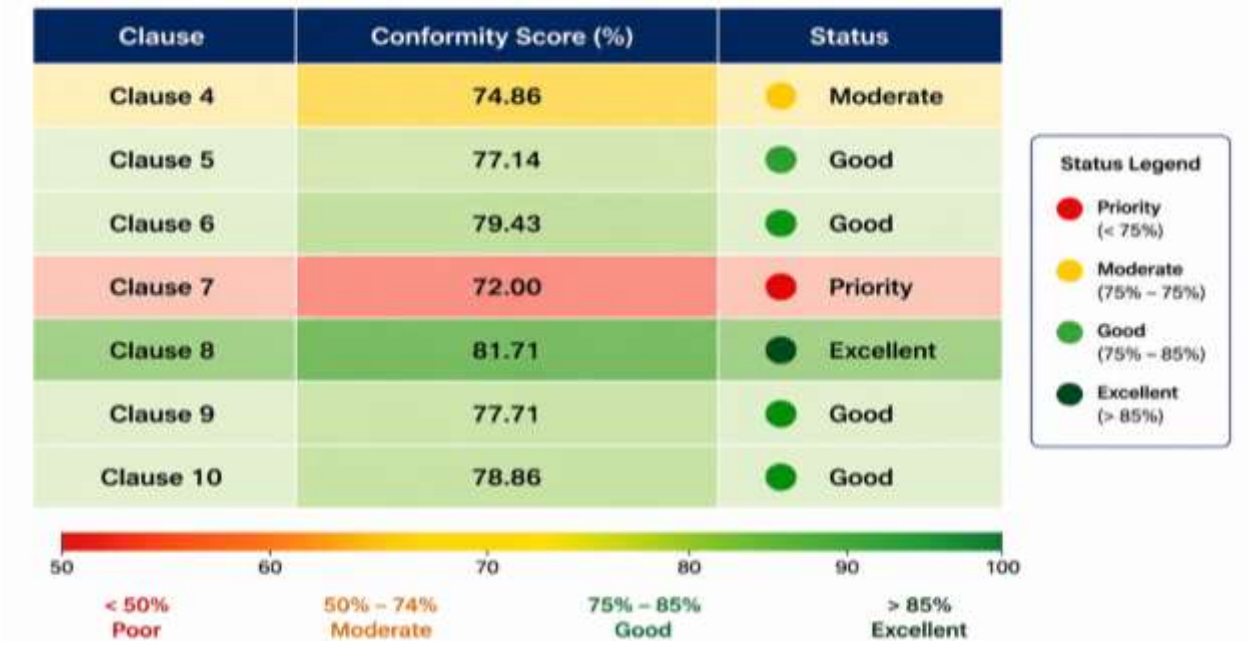

Fig. 2: Heatmap of ISO 9001:2015 Clause Conformity Levels

Figure 2 provides a visual representation of the conformity level for each ISO 9001:2015 clause. The color intensity reflects the implementation status of the Quality Management System, enabling easier identification of organizational strengths and weaknesses compared with numerical values alone. Green indicates clauses with satisfactory implementation, yellow represents clauses approaching the required conformity threshold, and red highlights priority areas requiring immediate improvement.

Based on the heatmap, Clause 8 (Operation) demonstrated the highest conformity level (81.71%), indicating that the clinic has successfully standardized its core healthcare service processes in accordance with ISO 9001:2015 requirements. Similarly, Clauses 5 (Leadership), 6 (Planning), 9 (Performance Evaluation), and 10 (Improvement) were categorized as Good, suggesting that these management components have been implemented effectively and provide a solid foundation for continual quality improvement.

In contrast, Clause 7 (Support) was identified as the primary improvement priority because it obtained the lowest conformity score (72.00%). This finding indicates that supporting elements, including document control, competency management, communication, and resource management, have not yet fully met the requirements of ISO 9001:2015. Furthermore, Clause 4 (Context of the Organization), with a conformity level of 74.86%, was classified as Moderate, suggesting that the organization is approaching

satisfactory compliance but still requires improvements in documenting organizational context, stakeholder needs, and risk-based planning.

Compared with the numerical table, the heatmap provides a more intuitive overview of organizational performance by clearly distinguishing between well-implemented clauses and those requiring corrective actions. Therefore, this visualization serves not only as a presentation tool but also as a practical decision-support instrument for management in prioritizing improvement initiatives and allocating organizational resources more effectively.

Discussion of Individual ISO Clauses

a. Clause 4 – Context of the Organization

Clause 4 obtained a conformity score of 74.86%, placing it slightly below the satisfactory threshold established in this study. Although the clinic has identified its organizational objectives and implemented quality management activities, documentation regarding internal and external organizational issues remains limited. Similarly, stakeholder identification and analysis have not been systematically documented. The absence of comprehensive organizational context documentation may reduce the effectiveness of strategic planning because organizational risks and opportunities cannot be adequately identified. ISO 9001:2015 emphasizes that organizations should understand both internal and external issues that influence the achievement of quality objectives. Therefore, strengthening organizational context analysis would improve strategic decision-making and facilitate continual improvement. Another important issue concerns the implementation of risk-based thinking. Although several operational risks have been recognized during daily activities, formal risk registers and documented mitigation plans have not been consistently developed. Consequently, risk management remains reactive rather than preventive.

b. Clause 5 – Leadership

Clause 5 achieved a conformity level of 77.14%, indicating satisfactory implementation. Management demonstrated commitment to quality improvement by establishing quality policies, communicating organizational objectives, and supporting healthcare service delivery through standardized procedures. Interview findings indicated that leadership plays an important role in maintaining service quality by coordinating quality meetings, supporting internal audits, and encouraging employee participation in continual improvement programs. This commitment has contributed to consistent implementation of operational procedures throughout the organization. Nevertheless, greater involvement of top management in monitoring quality indicators and evaluating corrective actions would further strengthen leadership effectiveness. Continuous communication regarding quality objectives should also be enhanced to ensure that every employee understands organizational priorities.

c. Clause 6 – Planning

The planning clause obtained a conformity score of 79.43%, indicating that planning activities have generally complied with ISO 9001:2015 requirements. Quality objectives have been established, operational planning has been documented, and improvement programs have been implemented periodically. Despite these positive results, planning activities remain primarily focused on operational performance rather than strategic risk management. Risk identification is still conducted informally and has not yet been integrated into annual organizational planning. Consequently, opportunities for preventive action may not be fully optimized. To strengthen compliance with Clause 6, the clinic should integrate structured risk assessment into strategic planning, establish measurable quality indicators for each department, and periodically review organizational objectives according to changes in internal and external conditions.

d. Clause 7 – Support

Clause 7 recorded the lowest conformity score (72.00%) among all evaluated clauses. This finding indicates that supporting processes represent the primary weakness of the current Quality Management System. Field observations revealed several issues related to document control, employee competency records, training documentation, communication procedures, and infrastructure management. Although supporting activities have been implemented operationally, documentation practices remain inconsistent. Some quality records are incomplete, while document revisions are not always performed systematically. In addition, employee competency evaluations are conducted periodically but are not comprehensively documented. Training programs also require better planning to ensure that competency development aligns with organizational quality objectives. Since documentation serves as objective evidence of conformity

within ISO 9001:2015, strengthening document management should become a priority for organizational improvement. Implementing digital document management systems, standardized document coding, scheduled document reviews, and competency-based training programs would substantially improve compliance with Clause 7.

e. Clause 8 – Operation

Clause 8 obtained the highest conformity score of 81.71%, indicating that operational processes represent the strongest aspect of the Quality Management System implemented at Klinik Utama Pupuk Kujang. This finding demonstrates that the clinic has successfully standardized its core healthcare service processes in accordance with ISO 9001:2015 requirements. The observation results showed that patient registration, medical examinations, pharmaceutical services, laboratory support, and patient discharge procedures followed established Standard Operating Procedures (SOPs). Employees demonstrated a good understanding of their respective responsibilities, allowing healthcare services to be delivered consistently and efficiently. The implementation of standardized operational procedures has also reduced service variability and minimized the possibility of operational errors. These findings suggest that the organization has successfully translated quality management principles into daily healthcare operations. Standardized operational activities contribute not only to service consistency but also to patient safety, operational efficiency, and organizational reliability. Nevertheless, continuous monitoring remains necessary to ensure that operational procedures remain aligned with changing healthcare regulations and patient expectations. Despite achieving the highest conformity score, opportunities for improvement remain available. The clinic should periodically review and update its SOPs, strengthen process monitoring through measurable performance indicators, and integrate operational risk assessments into routine healthcare activities. These initiatives will further enhance service effectiveness and support continual quality improvement.

f. Clause 9 – Performance Evaluation

The conformity score for Clause 9 reached 77.71%, indicating that performance evaluation activities have been implemented satisfactorily. Internal evaluations, patient complaint management, management review meetings, and periodic monitoring have become integral components of the organization's quality management practices. Interview results revealed that management regularly reviews operational performance and discusses improvement opportunities during evaluation meetings. Patient feedback is also collected and considered during decision-making processes. These practices demonstrate management's commitment to maintaining healthcare quality through systematic performance evaluation. However, document reviews identified several limitations regarding the documentation of monitoring activities. Performance indicators have not yet been standardized across all organizational units, making longitudinal performance comparisons relatively difficult. Furthermore, documentation of corrective action effectiveness following internal audits remains inconsistent. To strengthen compliance with Clause 9, the clinic should establish standardized Key Performance Indicators (KPIs) for each department, implement digital monitoring dashboards, and improve documentation of management review outcomes. Such improvements would enhance evidence-based decision-making and facilitate continual organizational learning.

g. Clause 10 – Improvement

Clause 10 achieved a conformity score of 78.86%, indicating that continual improvement activities have been incorporated into the clinic's management system. Corrective actions are generally implemented following internal findings, patient complaints, and operational evaluations. The organization has demonstrated awareness of the importance of continual improvement by encouraging employees to report operational problems and participate in quality improvement initiatives. Corrective actions have been performed whenever service deficiencies were identified, contributing to progressive improvements in healthcare service quality. Nevertheless, the improvement process remains predominantly corrective rather than preventive. Preventive actions based on systematic risk identification and trend analysis have not yet been fully integrated into organizational management. Consequently, improvement initiatives tend to respond to existing problems instead of anticipating future risks. Developing a structured continual improvement program supported by quality indicators, trend analysis, and periodic risk assessments would enable the organization to adopt a more proactive quality management approach. Such initiatives are fully aligned with the continual improvement philosophy promoted by ISO 9001:2015.

Comparative Discussion with Previous Studies

The findings of this study indicate that the overall conformity level of ISO 9001:2015 implementation at Klinik Utama Pupuk Kujang reached 77.39%, suggesting that the organization has established a functional Quality Management System but still requires continuous improvement to achieve full compliance. This result is consistent with previous studies reporting that healthcare organizations generally demonstrate stronger implementation in operational processes than in supporting management processes such as documentation, competency management, and risk-based planning.

The highest conformity score obtained in Clause 8 confirms that healthcare organizations usually prioritize operational standardization because clinical service delivery directly influences patient safety and satisfaction. Standardized operational procedures enable healthcare providers to reduce process variability while ensuring service consistency. Similar findings have been reported in previous healthcare quality management studies, where operational control consistently achieved higher implementation levels than strategic management clauses.

Conversely, Clause 7 produced the lowest conformity score, indicating that documentation management, competency development, communication, and resource management remain common challenges during ISO 9001:2015 implementation. These findings reinforce previous research demonstrating that supporting processes frequently become barriers to achieving complete ISO compliance because they require strong administrative discipline, continuous employee training, and effective document control systems.

Another important finding concerns organizational context and risk-based thinking. Although the clinic has implemented quality management practices effectively, documentation regarding organizational context and strategic risk management remains incomplete. This condition reflects a common implementation challenge among healthcare organizations transitioning from conventional quality assurance toward fully integrated quality management systems. Consequently, strengthening organizational context analysis and formalizing risk management documentation should become strategic priorities for future quality improvement initiatives.

Overall, the present findings support the argument that successful ISO 9001:2015 implementation requires balanced development across all organizational dimensions. Operational excellence alone is insufficient without strong leadership, systematic documentation, effective competency management, structured performance evaluation, and proactive continual improvement.

Root Cause Analysis

To identify the underlying causes of the implementation gaps, a qualitative root cause analysis was performed based on interview findings, field observations, and document reviews. The analysis indicated that the principal weaknesses originated from organizational management rather than technical healthcare activities.

Several contributing factors were identified. First, documentation practices were not consistently standardized across departments, resulting in incomplete quality records and irregular document revisions. Second, employee competency development had not yet been supported by a structured training management system, limiting the organization's ability to demonstrate competence objectively. Third, risk identification was performed informally without comprehensive risk registers, reducing the effectiveness of preventive actions. Finally, performance monitoring relied primarily on periodic evaluations rather than continuous measurement using standardized quality indicators.

These root causes explain why Clauses 4 and 7 obtained lower conformity scores than the remaining ISO clauses. Addressing these fundamental issues is expected to improve overall organizational compliance while strengthening the sustainability of the Quality Management System. The causes contributing to the implementation gaps identified in Clauses 4 and 7 are summarized in Figure 2.

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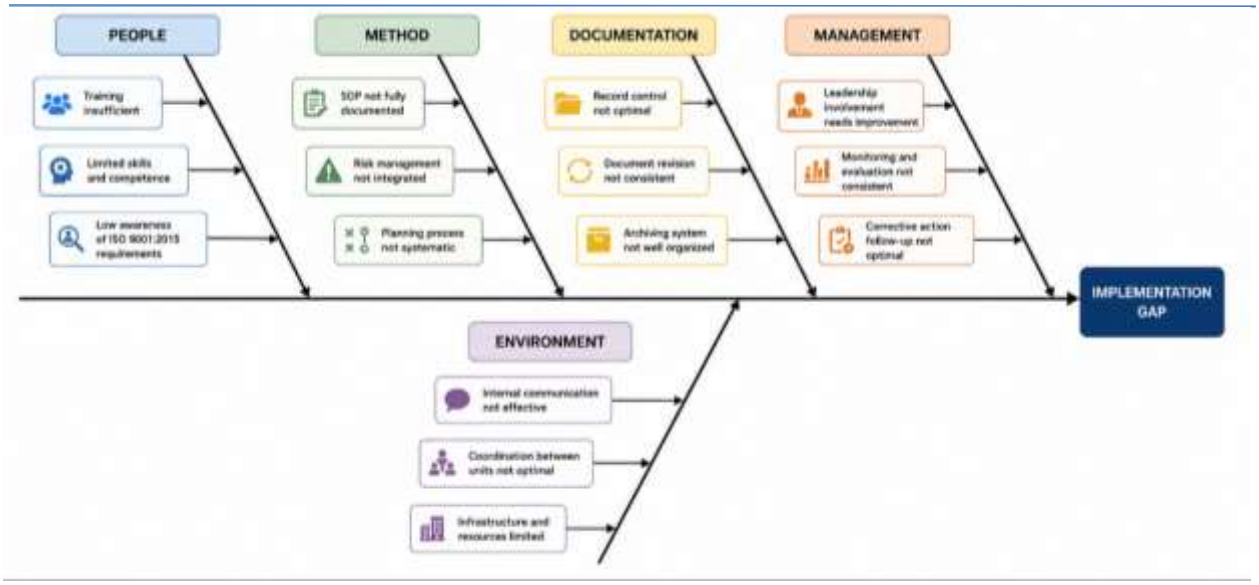

Fig. 3: Fishbone Diagram of ISO 9001:2015 Implementation Gaps

Managerial Implications

The results of this study provide several practical implications for healthcare management.

a. First, management should strengthen document control by implementing standardized documentation procedures, periodic document reviews, and electronic document management systems to improve information accessibility and traceability.
b. Second, competency management should become a strategic priority through structured training programs, competency assessments, and regular performance evaluations. Continuous professional development will enhance employee capability while supporting consistent healthcare service delivery.
c. Third, organizational risk management should be integrated into strategic planning through formal risk identification, assessment, mitigation planning, and periodic monitoring. The adoption of risk-based thinking would improve organizational resilience and support proactive decision-making.
d. Finally, management should establish measurable Key Performance Indicators (KPIs) across all departments to facilitate objective performance evaluation and continual quality improvement. Integrating performance monitoring with management review meetings would enable evidence-based strategic decision-making and improve organizational effectiveness.

PDCA-Based Improvement Strategy

Based on the identified implementation gaps, a continual improvement strategy following the Plan–Do–Check–Act (PDCA) cycle is proposed.

a. Plan: Identify internal and external organizational issues, establish a comprehensive risk register, define measurable quality objectives, and revise quality documentation in accordance with ISO 9001:2015 requirements.
b. Do: Conduct employee competency development programs, implement standardized document control procedures, strengthen internal communication, and apply revised Standard Operating Procedures consistently across organizational units.
c. Check: Perform scheduled internal audits, evaluate departmental Key Performance Indicators, monitor patient satisfaction, and periodically review organizational risk management practices.
d. Act: Standardize successful improvement initiatives, update quality documentation based on audit findings, revise organizational policies when necessary, and promote continual improvement through management commitment and employee participation.

The implementation of the PDCA framework is expected to improve conformity with ISO 9001:2015, particularly for Clauses 4 and 7, while strengthening organizational readiness for future certification maintenance and continual quality improvement.

A quantitative gap analysis was conducted to measure the level of conformity between the existing Quality Management.

4. Conclusion

This study evaluated the implementation of the ISO 9001:2015 Quality Management System (QMS) at Klinik Utama Pupuk Kujang using a gap analysis approach. The results indicated an overall conformity level of 77.39%, demonstrating that the clinic has generally implemented the requirements of ISO 9001:2015 and established a functional quality management system. Among the evaluated clauses, Clause 8 (Operation) achieved the highest conformity score (81.71%), reflecting effective standardization of healthcare service processes, whereas Clause 7 (Support) (72.00%) and Clause 4 (Context of the Organization) (74.86%) showed the greatest implementation gaps. These findings indicate that improvements should prioritize document control, competency management, organizational context analysis, and the integration of risk-based thinking to strengthen the effectiveness and sustainability of the Quality Management System.

The findings provide practical guidance for healthcare organizations in prioritizing quality improvement initiatives through systematic gap analysis and a PDCA-based continual improvement approach. The proposed recommendations can support management in enhancing documentation practices, employee competency, performance monitoring, and organizational decision-making to achieve higher conformity with ISO 9001:2015. Future research is recommended to involve multiple healthcare organizations and incorporate additional decision-support methods, such as Failure Mode and Effects Analysis (FMEA) or Analytic Hierarchy Process (AHP), to prioritize improvement strategies and further validate the effectiveness of Quality Management System implementation in healthcare settings.

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