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The effectiveness of quality management strategies in health care organizations: an analysis of quality standards implementation and clinical performance improvement

Ефективність стратегій управління якістю в організаціях охорони здоров'я: аналіз впровадження стандартів якості та покращення клінічних показників

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Abstract

Quality management strategies in healthcare institutions require an increasingly refined quality management system. This study aims to analyze the ISO 9001:2015 Standard for the implementation of a quality management system in the field of medical services provided by healthcare facilities, as well as to determine patterns during performance to assess the effectiveness of the quality management strategy. The article discusses key factors for achieving the quality management strategy through the implementation of a quality management system to improve clinical indicators. This system, according to the requirements of the ISO 9001:2015 Standard, ensures quality service provision.

A cyclical sequence of actions is used to analyze quality management system implementation. It is applied to quality service processes in healthcare organizations and reflects some key aspects

Анотація

Стратегії управління якістю в закладах охорони здоров'я вимагають дедалі вдосконаленої системи управління якістю. Це дослідження має на меті проаналізувати стандарт ISO 9001:2015 щодо впровадження системи управління якістю у сфері медичних послуг, що надаються закладами охорони здоров'я, а також визначити закономірності під час виконання для оцінки ефективності стратегії управління якістю. У статті розглядаються ключові фактори досягнення стратегії управління якістю шляхом впровадження системи управління якістю для покращення клінічних показників. Ця система, відповідно до вимог стандарту ISO 9001:2015, забезпечує надання якісних послуг.

Для аналізу впровадження системи управління якістю використовується циклічна послідовність дій. Він застосовується до процесів надання якісних послуг в організаціях

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(planning, execution, activities, and verification of all relevant processes as described in the ISO 9001:2015 Standard). The authors have examined the quality management strategy based on the literature review and the analyzed standard. This strategy includes leadership, adapting quality improvement initiatives, setting the boundaries of managerial and clinical policies. All the above allow the integration of quality improvement initiatives into a sustainable, organized system with continuous enhancement.

Keywords: improvement, ISO 9001, personnel competence, quality management strategy, quality management system.

Introduction

In today's world, many healthcare organizations provide services and care for their patients. Therefore, they are faced with the challenge of ensuring that patients receive high-quality and efficient healthcare services. The first step in achieving this goal is to develop and implement quality management standards and continuously improve clinical performance. It is an essential aspect of the reliability and effectiveness of healthcare services (Donev, 2022). The implementation of such standards helps to ensure the high quality of treatment and nursing during patient care. It also reduces the risk of complications and improves the effectiveness of treatment and prevention (Hibbert et al., 2021).

A quality management strategy's effectiveness in healthcare organizations significantly impacts treatment outcomes and patient satisfaction (Haleem et al., 2022). For this purpose, there is a list of factors that influence the determination of the strategies' effectiveness:

- leadership (successful and trouble-free implementation of a quality management strategy requires strong leadership in organizations, where managers must embrace the concept of quality and actively support its performance) (ISO, 2015);
- employee involvement (effective quality management strategies require the active participation of all organization's employees, which may include staff training, seminars, and participation in decision-making);
- use of evidence-based medicine (effective strategies should be evidence-based, using the latest data and scientific recommendations to ensure that services are

охорони здоров'я та відображає деякі ключові аспекти (планування, виконання, дії та перевірка всіх відповідних процесів, як описано в стандарті ISO 9001:2015). Автори дослідили стратегію управління якістю на основі огляду літератури та проаналізованого стандарту. Ця стратегія включає лідерство, адаптацію ініціатив щодо покращення якості, встановлення меж управлінської та клінічної політики. Все вищесказане дозволяє інтегрувати ініціативи з покращення якості в стійку організовану систему з постійним вдосконаленням.

Ключові слова: вдосконалення, ISO 9001, компетентність персоналу, стратегія управління якістю, система управління якістю.

delivered at the time of service at the best possible time);

- monitoring, surveillance, and assessment (the existence of management systems that provide monitoring, surveillance, and assessment processes that allow the organization to obtain unbiased data on the effectiveness of its strategies, as well as to identify problem situations and make appropriate adjustments to prevent them) (ISO, 2015);
- implementation of innovations (effective strategies of the quality management system are constantly updated and improved, and the use of the latest technologies, modern methods, and approaches can improve treatment outcomes and contribute to the improvement of clinical performances);
- patient-centricity (effective quality management system strategies are focused on meeting the patient's needs, where the key aspect of management is to provide affordable, effective, and empirical healthcare).

The aforementioned factors can ensure the effectiveness of the quality management system strategy. These strategies can be implemented in healthcare facilities and organizations while providing patients with high-quality services (Leggat & Balding, 2018).

The implementation of a quality management system (QMS) and the improvement of clinical practice are key tasks in the healthcare field. This process typically involves the development and implementation of standards, protocols, and guidelines that define best practices, procedures, and treatment methods (Hibbert et al., 2021).

One of the key aspects of QMS implementation is to ensure patient safety. The development of protocols and procedures accompanies it to ensure safe medical care and prevent errors and complications. Such protocols and procedures include:

- patient identification checks before performing necessary procedures;
- use of safe medicines;
- implementation of infection control procedures, etc (World Health Organization, 2021).

Furthermore, QMS implementation helps improve clinical outcomes. For instance, implementing treatment protocols for specific diseases can enhance treatment outcomes and reduce mortality (Yabroff et al, 2019). Developing standards and improving clinical characteristics also ensures consistent quality of service provision to patients regardless of their social status or place of residence (Brouwers et al., 2021). QMS implementation, along with improved clinical characteristics, is an ongoing process that involves continuous updates of protocols and procedures, as well as training of medical personnel. It helps develop and enhance healthcare practices to ensure the highest level of service (Darr et al, 2021).

Modern organizations in the healthcare sector are classified based on ownership and management models. They can be either private or public, depending on the provision of public services. Public services involve various measures to serve and meet the needs of citizens (clients, patients) for service provision (Zhang et al., 2019). Healthcare organizations within public entities are obligated to provide effective services aimed at improving health and addressing the population's health dynamics in each country worldwide (Kristiningrum et al., 2021).

Governments worldwide strive to find models for their healthcare systems that ensure patient service quality. Over the past two decades, various external quality control mechanisms have been introduced and tested in many European countries. These mechanisms range from hospital accreditation to compliance with ISO standards, as defined by European research projects on mechanisms of external expert assessment⁸. First, the quality definition models are used to analyze the indicators related to the quality assurance requirements in the hospital. After that, the opportunities for improvement are identified (Moldovan & Bataga, 2022).

The standards are used to improve and enhance the quality management strategy, based on which a quality management system (QMS) can be implemented (Eisner & Patel, 2017). One such quality standard is "Quality Management Systems – Requirements" ISO 9001. This standard enables organizations, regardless of the industry in which they exist, to properly implement a quality management system (Gupta & Rokade, 2016). Over the past ten years, this standard has attracted attention in the healthcare industry for the provision of medical services. It defines a value system that combines a set of criteria for quality management. For example, they include organization management, compliance, procedural management, etc (Petkovska & Gjorgjeska, 2014).

The following factors may be relevant problems in the implementation and enforcement of quality standards in healthcare organizations:

- insufficient knowledge and incompetence of medical staff. healthcare professionals may not have a sufficient understanding of quality standards and their importance, which affects their direct implementation;
- insufficient funding and limited resources. implementation of quality standards requires large expenditures on equipment, staff training, and implementation of new systems. insufficient funding and resources can make this process difficult and, in some cases, impossible;
- insufficient use of technology when old and outdated systems, equipment, and devices may make it impossible to comply with the methodology of performance per quality standards.

The effectiveness of the quality management strategy in healthcare facilities may depend on numerous factors. These factors should be determined by the quality management standard in compliance with the requirements for the implementation of the quality management system. A mismatch or non-compliance with the requirements in each standard's clauses may trigger a chain failure in the quality management system. For example, when engaging maintenance personnel to perform work at the planning stage, problems may arise due to the incompetence of maintenance personnel. This may have a negative impact on the collection, receipt, and processing of data for analysis, affecting the organization's performance. In addition, incompetence can significantly affect continuous improvement and jeopardize the improvement of patient care methods.

The planning, development, and implementation of the QMS may also result in inconsistencies with subsequent developments that may limit the needs for patient care. Therefore, all possible risks and their opportunities should be considered in advance during planning and implementation. Therefore, it reduces the possibility of undesirable consequences and thus prevents damage to the interests of the organization.

Literature Review

The work with standards is an effective method of continuous improvement of production systems using helpful tools for maintaining documentation of the most efficient ways of creating a product or service. Working with standards helps maintain quality, ensures efficient operations, and guarantees proper use of tools and equipment. It also helps train employees to identify and eliminate non-value-added actions. Therefore, such standard work is a diagnostic tool that identifies issues and contributes to continuous improvement (Patkal & Anasane, 2022).

There are numerous concerns about improving the quality and safety of patient care in healthcare facilities. For this reason, Quality Management Systems (QMS) are widely applied to develop effective strategies for enhancing service provision (Gargasas, Samuolaitis & Mūgienė, 2019). One common strategy is a system described in the International Organization for Standardization (ISO) Standard ISO 9001. The ISO 9001 QMS standards family is used by organizations aiming to enhance the quality of their products or services (Betlloch-Mas et al., 2019). This standard represents an international agreement on quality management. It ensures that workers consistently provide products and services that meet customer requirements, continuously improve organizational performance, and increase customer satisfaction (Heydari, Lai & Xiaohu, 2019). However, the research by Kristiningrum (2021) analyzed that inefficient medical centers and organizations still exist today, even with the implementation of ISO 9001 QMS.

A quality system is defined as an organizational structure that manages quality or as a coordinated working structure across the entire company, documented in effective, integrated technical and managerial procedures to guide coordinated actions of workforce, machinery, and information to ensure customer satisfaction with

quality and operational efficiency (Kumar, Maiti & Gunasekaran, 2018).

The components of a quality system to achieve high-quality assistance can be found in separate documents, such as "National Standards for Safety and Quality in Healthcare." This document covers a list of QMS components:

- policy development and review;
- compliance requirements;
- risk management;
- clinical documentation;
- accreditation and scope of practice;
- training and development;
- healthcare rights charter;
- confidentiality.

In the research by Leggat & Balding (2018), a concise overview is provided where the National Health Service (NHS) proposes four QMS components:

- strategy;
- capabilities and culture;
- processes and structures;
- assessment.

The implementation of a surveillance system and policies contributes to overall problem-solving and prevention in over 50% of cases within healthcare organizations. It not only results in cost savings for the organization but also, on a global scale, reduces variation in the delivery of medical services during patient care. In the study by Petkovska & Gjorgjeska (2014), the expected benefits of implementing the system in the Republic of North Macedonia healthcare sector are explored. These benefits are related to the establishment of an essential basis for obtaining all necessary resources, as well as reducing costs by minimizing inadequate personnel in clearly defined departments.

Future accreditation processes can be implemented in a much shorter time frame, especially with established communication and collaboration between departments. Financial savings are evident in healthcare organizations that have implemented an ISO 9001 quality system. This redirection of resources allows for the development and implementation of new treatment technologies that may lead to QMS improvements.

Ultimately, standards are designed to improve outcomes, and the primary logic of the QMS application is to:



- improve organizational performance and create a process-dependent system;
- improving systems and microsystems through process dependency;
- improving the system and microsystem to improve services;
- increasing service resilience and effectiveness (Darr et al., 2021).

Therefore, a thorough analysis of the standard QMS implementation requirements is necessary to assess the risks and potential occurrences during the servicing of healthcare facilities, as well as to analyze methods and measures for their prevention.

The study aims to conduct an analysis of the ISO 9001:2015 Standard for the implementation of a quality management system in the healthcare sector, as well as to identify patterns during the implementation process to assess the effectiveness of the quality management strategy.

The following tasks need to be accomplished to achieve this goal:

- to conduct a literature review on the use of international standards in healthcare organizations and identify factors that influence the adoption of new standards.
- to analyze the ISO 9001:2015 Standard ("Quality management systems – Requirements") to determine the effectiveness of the implementation strategy in the healthcare sector.
- to analyze key indicators and factors contributing to healthcare facilities' quality service provision.

Methodology

International Standard ISO 9001:2015 "Quality management systems – Requirements"

ISO 9001:2015 Standard is used for developing Quality Management Systems (QMS) in healthcare organizations. It can be utilized to enhance processes, organization, and patient satisfaction. This standard aims to improve clinical indicators within healthcare organizations by establishing a QMS focused on processes, organization, and improvement (ISO, 2015). Despite having multiple versions, the author has analyzed the 2015 version.

ISO 9001 Standard imposes requirements on QMS under the following conditions:

1. The organization must demonstrate the ability to consistently provide services and products that meet customer needs and requirements (including legislative and regulatory requirements).
2. The organization is oriented towards increasing customer satisfaction, which is explained by the effectiveness of the system's application, specifically through system improvement processes and ensuring compliance with customer requirements based on legislative and regulated requirements.

The set of requirements of this standard are common. They are intended to be applied in any field of activity, regardless of key parameters (type, size, etc.).

The following factors need to be considered to implement QMS standards:

- to define the object (enterprise, company) and the service area (pharmaceutical and medical sectors, metallurgical and engineering sectors, etc.) for QMS implementation.
- to define the organization's environment and analyze needs (identify priorities and areas).
- to familiarize oneself with the requirements of international standards (e.g., ISO 15189:2022).
- to adapt standards according to the organization's interests.
- to conduct planning and involve personnel in team collaboration, etc.
- to collect and analyze data for result compilation.
- to determine more suitable monitoring and observation systems to integrate into QMS.
- to conduct internal audits and certification.
- to implement a continuous improvement process.

Results and Discussion

An interdependent cycle of sequential actions applied to the processes in the field of service quality in healthcare organizations is used to analyze the QMS standards implementation. This cycle reflects key aspects of QMS and demonstrates the Plan-Do-Check-Act circle (PDCA) of all relevant processes described in the ISO 9001:2015 Standard. Figure 1 depicts the PDCA cycle, which is explained as follows:

- plan (defining the system's objectives involving its processes and necessary resources to achieve planned outcomes



- during service provision, as well as identifying risks and opportunities of their occurrence).
- do (implementing the planned, defined objectives and developing minimization of risk occurrences and their avoidance).
- check (conducting monitoring and observation systems with process measurements to obtain service performance and adequate service provision, followed by reporting).

- act (taking safety measures based on corrective actions to improve effectiveness).

The PDCA cycle describes internal organizational factors (planning, improvement, QMS maintenance, and effectiveness evaluation) according to the organization's needs and its position in the environment, stakeholder requirements, and their needs. However, stakeholder satisfaction and the provision of services with resulting products significantly impact QMS, affecting performance and efficiency.

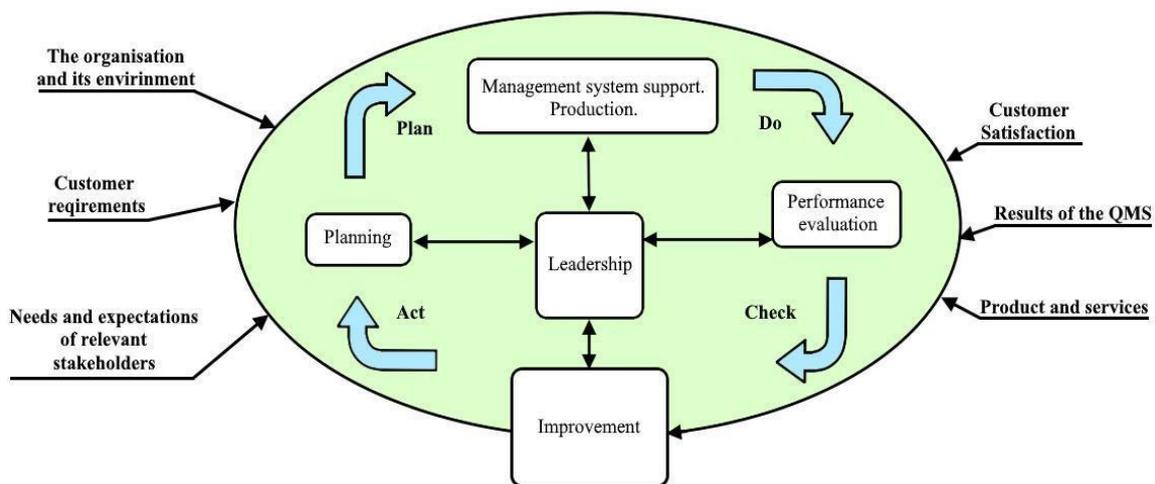


Figure 1. Plan - Do - Check - Act cycle for QMS implementation.
 Source: ISO 9001:2015 "Quality management systems – Requirements".

Now, we will take a closer look at the QMS. It is considered for a healthcare organization, and the requirements for its implementation as described by the ISO 9001:2015 Standard. The improvement, development, and implementation

of QMS standards are considered in the Table 1. The table describes the operations of the standard for a more detailed study and analysis. The table contains the main operations.

Table 1.
 Requirements of the ISO 9001:2015 clauses for analyzing the implementation of standards in a healthcare organization.

Nº	Requirements of standard clauses	Explanation
1.	Analysis of needs	The beginning of the analysis of the healthcare organization's needs. Identification of priorities and areas for improvement.
2.	Familiarization with international standards	Research of international ISO standards, such as ISO 9001:2015, ISO 15189:2012, and other standards related to QMS and medical laboratories, equipment, etc.
3.	Adapting the standards to the organization's needs	Consideration of specific organizational features and adaptation of standards to the needs of the medical institution.
4.	Implementation planning	Development of a detailed plan for the implementation of healthcare quality standards, which should define roles and responsibilities, performers, and deadlines.
5.	Personnel involvement	Designation of responsible persons for each aspect of the implementation and staff training on the new procedures as required.

6.	Data analysis based on the collected documentation	Collection of internal data on processes and work performance to assess the current state and identify existing problems in the quality system.
7.	Implementation and monitoring	Implementation of new quality control procedures and mechanisms, as well as monitoring their effectiveness and making the necessary changes if problems are identified.
8.	Audit and certification	The planning of internal audits to verify compliance with standards, as well as external audit certification, if necessary.
9.	Continuous improvement	Implementation of a continuous improvement process based on the results of audits and feedback from staff and patients.

Source: compiled by the authors.

Analysis and understanding of stakeholders' needs and expectations

The organization's task is to identify external and internal factors relevant to its purpose and strategic direction with the impact and ability to achieve the intended result. Therefore, a company should monitor and analyze information from external and internal factors.

Any organization in a particular service sector with the provision of services should identify the stakeholders that can be involved in the QMS from a reasonable point of view, as well as regulate the requirements of the stakeholders involved in the QMS.

Adaptation of standards to a company's needs

The healthcare organization adapts the QMS standards by establishing the service area based on ownership and considering internal and external factors, stakeholder requirements, and the products and services. To meet the ISO 9001 quality control standard, the organization must ensure all requirements are met without fail. In addition, this service considers the applicable limits in its defined service area. It is essential to properly regulate and validate all information regarding the scope of application and service. It should be noted that within the application area, all types of covered products and services must be described with relevant documentation and justification, following the standard's requirements.

Furthermore, the organization must consistently maintain and improve the documented information required for process functioning. Keeping records ensures confidence in executing planned processes during servicing.

Implementation planning

Planning involves actions related to risks and opportunities identified and considered by the Quality Management System (QMS) to achieve the intended outcome. These actions also aim to

prevent undesirable (sudden) aspects and reduce their occurrences. In addition, they are aimed at increasing desirable effects that can lead to QMS improvement. The task of a healthcare organization is to plan activities regarding risks and opportunities based on the integration and implementation of preventive actions according to QMS requirements.

The primary goal of healthcare organizations during planning is to define quality objectives and plan actions for their effective achievement. An institution establishes quality goals involving relevant departments for the execution of medical operations and processes directly considered by QMS. Quality goals should be aligned with policies, applied requirements, updated, applicable to service conformity for patient satisfaction, and covered by monitoring and safety systems.

An institution aims to identify the necessary resources and responsible people, as well as set deadlines for completion with an assessment of the results to ensure quality and effective planning to achieve the service quality goals. In the case of planning with changes, the organization addresses the need for changes to QMS if modifications need to be executed as planned. During these changes, there are considered consequences of designated shifts, QMS integrity, delegation of authority, and responsibilities.

Personnel involvement

The medical institution's personnel in the healthcare organization should possess proficiency and expertise. These efforts evaluate the QMS's effectiveness. Achieving this requires the organization to ascertain a person's competency before assigning tasks. This involves assessing their qualifications, conducting exams, reviewing prior work experience, and providing orientation training, among other measures. The competence and knowledge of medical professionals involve their ability to apply knowledge for the professional

execution of their duties in delivering quality services. Knowledge in the quality field of the organization is driven by management policies, objectives, personal contributions to improve system performance, and enhancements to performance indicators while also considering consequences for non-compliance with QMS requirements.

Competency can encompass various aspects of medical practice, such as:

- medical personnel should possess sufficient knowledge in their acquired specialty, including anatomy, physiology, pathology, and the treatment of various diseases.
- they should also possess the necessary skills to perform various procedures and manipulations, such as conducting examinations, administering drugs and medications intravenously, and providing emergency assistance.

Communication in healthcare is essential for maintaining effective telecommunication with patients. Healthcare professionals must provide clear explanations regarding procedures and potential consequences, as well as instructions on medication acquisition.

In critical cases, the organization should consider retraining medical personnel to guarantee their knowledge and practical skills align with theoretical methodologies and practical implementation. Some measures aim to conduct training under the supervision of mentors, transfer personnel to other positions, and involve competent people in contract negotiation.

Data analysis based on the collected documentation

The QMS of a healthcare organization covers a set of recorded and regulated data prescribed by the 9001:2015 Standard. For this purpose, an up-to-date map of recorded information is created. An institution ensures that the documentation is described correctly and identified with its name, date, and expiration date, initials, number, seal with signature, and depending on the format and media. Documented information is usually controlled to ensure its availability and expiration date, its confidentiality, proper use or loss of integrity, etc.

The organization distributes, accesses, and searches the data that have been previously recorded while maintaining the documentation and monitors for changes as required by the

standard to ensure proper data control. In addition, the recorded data of external origin is thoroughly checked and identified in a correct way.

Implementation and monitoring

Surveillance and monitoring management systems are essential components of any healthcare organization to ensure patient safety. These systems should include measuring instruments and equipment that assist in analysis and assessment during service provision. The organization employs various monitoring methods, including remote monitoring, when patients are outside the service-providing organization's premises. Conducting monitoring ensures the evaluation of the effectiveness and performance of the quality management system while preserving relevant information in the documented form with confirmation of the provided results.

In a healthcare organization, monitoring is carried out to reflect the patient's clinical condition and gauge patient satisfaction with their own needs. The organization's task in implementing a monitoring system is to determine methods for obtaining and observing data by providing key features and data analysis during service delivery. Analyzing and evaluating data during monitoring and measurement allows the establishment of:

- adherence to the execution and quality provision of services by staff.
- the level of patient satisfaction.
- expected planning effectiveness.
- the need for corrective actions to enhance the Quality Management System (QMS), as well as the effectiveness of measures to prevent and mitigate risks and opportunities.

Audit and certification

The organization carries out internal audits as per planned schedules to gather information on how well the Quality Management System (QMS) satisfies the needs and demands of the company according to ISO 9001:2015 Standards. To achieve this, the organization plans, executes, and develops audit programs that cover and comprise the audit frequency, methods, planning needs, and duties. The audit program evaluates potential effects on processes that impact the organization and defines each audit's criteria and scope while reporting the results to the management.

The main stages of an internal QMS audit in a healthcare organization include:

1. **Audit Planning.** This stage involves identifying areas subject to audit, creating an audit plan, and selecting the audit team.
2. **Audit Execution.** Auditors assess QMS compliance with defined requirements and procedures. They include reviewing documentation, observing processes, and conducting interviews with staff.
3. **Results Analysis.** After the audit, auditors analyze collected data to determine QMS compliance. They identify discrepancies and provide recommendations for addressing them.
4. **Implementation of Changes.** Based on audit results, the organization develops and implements a plan to make necessary changes to the QMS. These changes might involve updating procedures, enhancing staff qualifications, or adopting new technologies.
5. **Effectiveness Review.** After implementing changes, the organization verifies its effectiveness by conducting subsequent audits. This evaluation assesses the results of changes and identifies any new discrepancies or non-conformities.

Internal QMS audits in a healthcare organization are conducted to identify potential issues, pinpoint areas for improvement, and enhance the quality of medical services provided. Conducting these audits regularly and systematically ensures continuous improvement of quality management.

Continuous improvement

The healthcare organization should consider searching for and addressing opportunities that can improve and perform various actions as necessary to meet the needs of patients and gradually increase the level of satisfaction during the service. The following measures are taken into account:

- improving the types of services aimed at meeting the requirements and needs of patients both in real-time and in the future.
- making amendments (adjustments) to avoid and reduce the impact of negative factors and factors.

- corrective actions, innovations, and reorganization that affect the effectiveness of the quality management system.

In some cases, corrective actions are considered if there is a discrepancy in the quality management system. It is accompanied by complaints from patients and their level of dissatisfaction. In order to resolve the non-conformity, it is necessary to respond and take preventive actions aimed at identifying the causes of the non-conformity and analyzing them to make adjustments and make decisions in advance about the consequences of individual incidents with ongoing monitoring. Based on the identification and analysis of non-compliance, it is possible to conduct a needs assessment to avoid repeated occurrences of undesirable incidents, as well as to anticipate the potential for their occurrence in advance. In some cases, if necessary, risks and opportunities are updated during planning and implementation with changes to the quality management system. It allows for minimizing non-compliance on the part of the healthcare organization during the provision of services and maintenance.

An institution must continuously work to improve its quality management system's suitability, adequacy, and effective performance to improve clinical practices and outcomes. The improvement involves the use of available analysis and evaluation results from baseline data to identify the need for improvement of the quality management system.

Development of an effective quality management strategy

The quality management strategy contains a list of requirements of the 9001:2015 Standard that have been reviewed and used to build the quality management scheme shown in Figure 2.

As can be seen from Figure 2, the effectiveness of solutions requires creating conditions (obligations and responsibilities) where leadership includes teamwork with a competent team (staff). After that, it is necessary to adapt quality improvement initiatives and bring them to the organizational context. For strategy development, it is required to create and implement quality management improvement initiatives that are in the organization's interest with practical value and impact on the main helpful contributions to clinical performance.

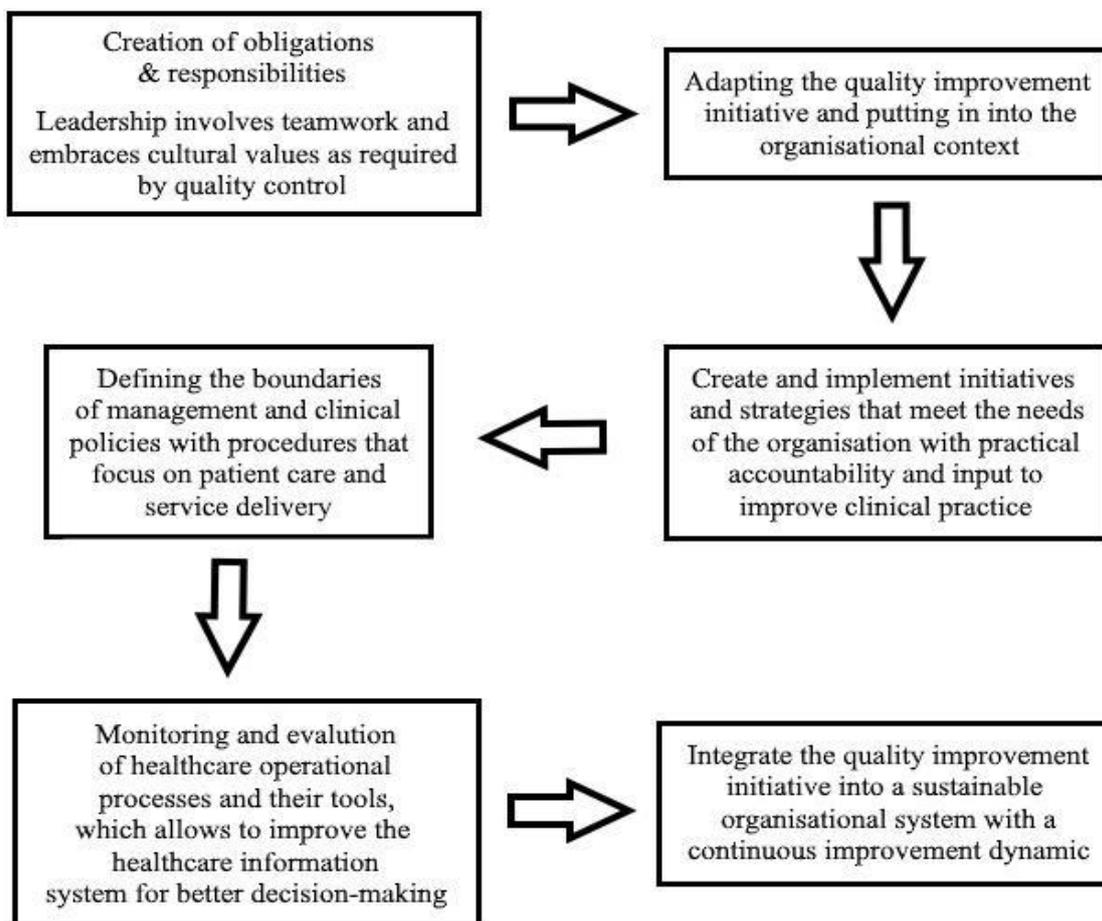


Figure 2. Flowchart of sequential operations for implementing a QMS strategy.

Source: El-Zein, G. *Impacts of Quality Improvement Strategies on the Performance of Primary Healthcare Organisations* (El-Zein, 2021).

Once sustainability initiatives are established and implemented, it is necessary to define management and clinical policy boundaries with procedures that focus on patient care and service delivery. When defining the boundaries of management and clinical policy, monitoring should be involved to determine the assessment of operational processes that focus on patient safety. Also, it should include available tools that improve the health information system for better decision-making. Based on the developed strategy, the quality improvement initiative is integrated. It creates a sustainable organizational system with a dynamic of continuous improvement.

Continuous improvement of quality in the healthcare system is a challenge for many countries worldwide. It is incredibly challenging for those in complex stages of transitioning from outdated and inefficient quality systems, where medical approaches and services vary significantly due to the lack of consideration and implementation of more modern Quality

Management Systems (QMS). For instance, in recent years, Kosovo, on the path to European integration, has started implementing new quality management systems per EN ISO 9001 requirements, incorporating continuous monitoring systems in healthcare, and establishing benchmarks for best practices (Lleshi, 2020).

The assessment of medical service quality should be based on quality indicators and criteria, with continuous monitoring and evaluation at all stages of healthcare provision being the most crucial. Achieving high-quality medical services requires constant refinement and adaptation to patient needs, involving measures to satisfy patient needs and enhance their experience (Nothacker et al., 2021). Nadziakiewicz & Mikolajczyk (2019) suggested that organizations should shift from numerous disconnected initiatives to integrated strategies capable of improving outcomes and delivering value for money spent. Studying new quality tools and assessment methods can provide healthcare

organizations and patients with fair and sustainable solutions.

Lately, new and innovative sustainable development systems are being introduced and proposed in healthcare organizations. These systems are compatible with hospital accreditation standards and differ from others by focusing on medical institutions with continuous improvement of management systems by establishing performance indicators to achieve sustainability (Burgers, van der Weijden & Grol, 2020). Moldovan & Bataga (2022) proposed a self-assessment based on a framework system that supports medical institutions in determining performance levels in all defined areas. It aids in identifying improvement opportunities and making decisions regarding priority actions.

The implementation of an ISO 15189-based QMS in laboratory work provides a strong foundation for laboratory quality to ensure patient safety and prevent patient safety issues (Allen, 2013). In the case of such issues, effective processes exist for investigation and preventive measures. However, addressing patient safety issues in laboratories largely depends on the presence of an effective quality management system.

Conclusions

In this study, the authors have analyzed the quality management strategy in the healthcare sector. The research examined key factors in the development and implementation of a quality management system standard. These factors include: analysis of organizational needs; adaptation of standards to administrative requirements; planning and implementation; staff involvement; data collection and analysis; monitoring; conducting internal audits to achieve continuous improvement.

Based on the ISO 9001:2015 Standard "Quality Management Systems – Requirements", the authors analyzed each factor's impact on enhancing or compromising the quality management system at each implementation stage. Special attention is given to planning, staff involvement, and conducting internal audits, as these can lead to adjustments during the initial planning stages if expected results are not achieved or if discrepancies arise according to standard requirements.

The primary goal of healthcare organizations during planning is to define quality objectives and plan actions for effective achievement. It

involves setting quality objectives that involve relevant departments in executing medical operations and processes directly linked to the Quality Management System (QMS).

The healthcare institution's medical personnel must be competent and knowledgeable, capable of applying their expertise for proficient service delivery. The competence depends on knowledge, skills, and communication. All these can impact both improvements and deteriorations in patient service quality. Thus, planning may need adjustments based on this personnel competence.

To adequately control documented information, the organization must manage the distribution, access, search, and preservation of documentation, as well as monitor changes as required by the standard. Additionally, recorded external data used for QMS planning should be thoroughly reviewed and properly identified.

Internal auditing of the QMS in healthcare organizations helps identify potential problems, pinpoint areas for improvement, and enhance the quality of medical services. This process should be conducted regularly and systematically to improve ongoing quality management.

Healthcare organizations should actively seek and address opportunities for improvement to meet patient needs and progressively enhance satisfaction levels during service. The organization must consistently improve its quality management system's suitability, adequacy, and effectiveness to enhance clinical practices and indicators. Improvement considers the results of analysis and assessment based on initial data. It aims to identify the needs for improving the quality management system.

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