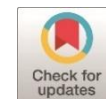



■ PROFESSIONAL PAPER

Quality Management Systems in Healthcare Facilities: Between Rules, Standards, and Business Excellence



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ABSTRACT

Purpose: This paper explores the role of quality management systems (QMS) in Croatian healthcare institutions, emphasizing their regulatory foundations, the implementation of international standards (ISO 9001, EN 15224, ISO 7101), and their potential to enhance safety, performance, and organizational excellence. **Design/Methodology:** A thematic literature review was conducted using sources from PubMed, Web of Science, Scopus, Google Scholar, and Hrčak, covering the period from 2015 to 2025. Inclusion criteria focused on peer-reviewed studies and official regulations related to healthcare QMS, international certification models, and performance monitoring practices. Selected examples of good practice from Croatian hospitals were also analyzed. **Findings:** The implementation of QMS in Croatian healthcare institutions has advanced considerably, driven by legislation and the support of national bodies such as the Ministry of Health and the Croatian Health Insurance Fund. Institutions that adopt ISO standards report improvements in documentation, communication, risk management, and patient satisfaction. Case studies, such as those from the Special Hospital Medico and General Hospital Pula, demonstrate that multi-standard certification fosters a strong safety culture and strategic excellence. Nonetheless, challenges remain, including uneven implementation, limited human and financial resources, and the absence of a unified national accreditation framework. **Practical Implications:** To ensure sustainable quality improvement, healthcare institutions must embed QMS into everyday management, invest in continuous staff education, strengthen leadership engagement, and adopt digital solutions. QMS should not be viewed solely as a regulatory obligation but as a strategic imperative involving all stakeholders. **Originality/Value:** This paper offers a comprehensive overview of QMS development in Croatian healthcare and demonstrates how alignment with international standards can significantly elevate both patient care quality and institutional effectiveness.

Keywords: quality management, healthcare institutions, ISO standards, patient safety, accreditation

JEL codes: I8, L15, M11

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1. Introduction

The healthcare system represents one of the most critical and demanding sectors of public administration, with a direct impact on the lives, health, and overall well-being of the population (Jagrič et al., 2021; Kruk et al., 2018). Due to its complexity, high expectations, and the sensitive nature of its operations, healthcare institutions are required not only to provide professionally and ethically grounded services, but also to establish organizational mechanisms that ensure continuous quality, safety, and accountability to both users and society as a whole (Fukami, 2024).

Quality management in healthcare is no longer a matter of institutional discretion or goodwill; it has become a regulatory and professional obligation. Global trends, World Health Organization (WHO) standards, European Union initiatives, and rising patient expectations are all driving the implementation of quality systems based on clearly defined standards, systematic process and outcome monitoring, performance evaluation, and continuous service improvement (Kruk et al., 2018). Today, healthcare quality is viewed through a multidimensional framework that includes patient safety, effectiveness, accessibility, continuity, communication, user-centeredness, and the professional competence of healthcare staff (Ljungholm et al., 2022).

In the Republic of Croatia, significant progress has been made through the adoption of laws and by-laws regulating the field of healthcare quality and safety (Official Gazette 31/2011; Official Gazette 79/2011; Official Gazette 118/2018). The mandatory establishment of quality management offices, the appointment of quality committees, the definition of quality indicators, and the implementation of internal and external assessment tools have become integral parts of the healthcare system. Special emphasis is placed on the application of international standards such as ISO 9001 and EN 15224, and more recently ISO 7101, which introduce added value through process-based management, clinical risk reduction, and a focus on treatment outcomes (McCaskill et al., 2025).

However, despite the establishment of basic structural elements, numerous challenges persist. These include disparities in the implementation of standards across institutions, limited human and financial resources, varying levels of managerial engagement, and resistance to change at the operational level. Nevertheless, an increasing number of institutions are achieving measurable improvements through systematic and strategically oriented quality management, enhancing both patient and staff satisfaction and strengthening their professional reputations.

The aim of this paper is to examine the legal, institutional, and professional aspects of quality management systems in Croatian healthcare, to analyze current standards and policies, and to highlight, through selected examples of good practice, the potential of quality management to transform healthcare towards greater safety, accountability, and excellence. Special attention is given to the role of leadership, staff education, monitoring of key performance indicators, and the integration of quality systems into the daily operations of healthcare institutions.

2. Methodology

This paper is based on a thematic review of scientific and professional literature, aiming to identify key standards, models, and institutional practices of quality management in

healthcare institutions. Instead of a chronological approach, a thematic analysis was applied, allowing the grouping of content according to concepts such as international standards (ISO 9001, EN 15224, ISO 7101), accreditation models (e.g., AACI, JCI), clinical indicator measurement, and the implementation of evaluation cycles (e.g., PDCA – Plan–Do–Check–Act).

The literature search was conducted in July and August 2025 using scientific databases including PubMed, Web of Science, Scopus, Google Scholar, and national sources available through the Hrčak portal. The included works were published between 2015 and 2025 in Croatian and English. The following keywords (and/or their combinations) were used: "quality management in healthcare," "accreditation," "ISO 9001," "EN 15224," "ISO 7101," "quality improvement," "healthcare accreditation," "hospital performance," "PDCA," "patient safety," "clinical indicators," and others.

Defined inclusion and exclusion criteria were applied (see [Table 1](#)), ensuring methodological consistency and content relevance. The literature includes peer-reviewed scientific articles, reports by international organizations (WHO, Institute of Medicine), valid laws and bylaws of the Republic of Croatia, as well as examples of best practices from hospital systems across Europe and worldwide.

Table 1

Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Studies addressing quality management systems in healthcare institutions	Studies not related to the healthcare sector
Publications analyzing the application of ISO standards (ISO 9001, EN 15224, ISO 7101)	Studies that do not mention quality standards or management systems
Articles from peer-reviewed scientific journals and relevant professional publications	Online sources without peer review, or without clearly identified authors and sources
Sources in Croatian and English	Sources in other languages
Publications available in full text	Papers without full text availability (e.g., abstracts only)
Studies and reports analyzing the implementation of accreditation, certification, and PDCA cycles	Literature focusing solely on management theory without a healthcare context
Sources published between 2015 and 2025	Publications older than 2015, unless of historical relevance (e.g., Donabedian, 1988)

Note. Inclusion and exclusion criteria were defined by the author based on a systematic review of the literature on quality management systems in healthcare. Source: Author.

The literature selection was independently conducted by the author based on relevance, topicality, and methodological appropriateness. Based on the content analysis of the selected sources, several thematic areas were identified, forming the backbone of the paper's structure and enabling a grounded discussion on the current state and future perspectives of quality management in the Croatian healthcare system.

3. Findings

3.1. The concept of quality in healthcare – definitions and development

Quality of healthcare is generally defined as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes in accordance with the latest professional knowledge (WHO, 2025). This definition, proposed by the World Health Organization, has also been adopted by the Institute of Medicine (IOM), which emphasizes that quality care must be effective, safe, timely, and patient-centered (Institute of Medicine, 1990). In other words, high-quality healthcare is evidence-based, provides patients with what they need in an appropriate manner without unnecessary delay or harm, and respects their needs and rights.

The key dimensions of quality that are globally monitored today include effectiveness, meaning the achievement of desired health outcomes, patient safety, accessibility and timeliness of services, and humaneness or user-centeredness, which involves respecting patient values and including them in decision-making (Kruk et al., 2018). Some institutions also add equity, defined as equal quality for all groups, and efficiency in terms of good use of resources, thus making quality a multidimensional concept.

3.2. Historical Development

Quality management in healthcare has developed through several phases, drawing on insights from industry as well as the specific nature of medical practice. At the beginning of the twentieth century, the focus was on basic safety and hygiene such as the introduction of antiseptic practices inspired by Semmelweis. By the mid-twentieth century, experts like Avedis Donabedian introduced concepts of structured quality assessment based on the structure, process, and outcome of healthcare (Donabedian, 1988).

In the second half of the twentieth century, industrial quality control methods began to be applied in healthcare including standardization of procedures, peer review of physicians' work, and the establishment of the first hospital accreditation systems.

At the end of the twentieth and beginning of the twenty-first century, emphasis shifted from mere process control to continuous improvement and risk management especially following the publication of the report "To Err is Human" which globally raised awareness about the frequency of medical errors (Institute of Medicine, 2000). Quality culture became an integral part of hospital organizational culture with increasing focus on treatment outcomes and patient experience rather than mere procedural compliance (MacGillivray, 2020).

Today the evolution of quality management systems in healthcare reflects a shift from a reactive approach correcting errors to a proactive and preventive approach that emphasizes safety, the prevention of adverse events, and continuous service quality improvement (Waldman & Terzic, 2019).

Modern quality management requires a holistic systemic approach encompassing the entire organization. Quality is no longer the responsibility of individual enthusiasts but an integrated part of institutional strategy (Bisho & Bin Mohd Sam, 2022). It is essential to clearly define a quality policy describing what the institution aims to achieve in quality and safety, a strategic plan with objectives, and to establish measures and performance indicators that are regularly monitored. Healthcare institutions implement monitoring and improvement mechanisms including internal audits, incident reporting systems, risk management procedures, and cyclical improvement processes such as Deming's Plan Do Check Act cycle (Hanskamp-Sebregts et al., 2019; Healthcare Engineering, 2023).

A key prerequisite for success is an organizational culture that fosters responsibility, open communication, and learning from mistakes. In practice, this means employees must be educated and motivated to implement quality policies, patients should be involved through feedback collection and participation in care decisions, and leadership must continuously support these processes (Engle et al., 2021). A systematic approach also includes documentation of processes and results ranging from medical records to reports

on implemented improvements ensuring continuity of monitoring and the ability to analyze the impact of changes ([Čerfalvi, Košec & Benceković, 2016](#)).

3.3. Advantages of Quality Management

The establishment of an effective quality management system brings numerous benefits to healthcare institutions, healthcare staff, and patients. Standardized and documented procedures enable clearly defined treatment protocols and precise allocation of responsibilities, ultimately reducing the likelihood of errors and inconsistent practices ([Aggarwal et al., 2019](#); [Endalamaw et al., 2024](#)). Such systems significantly improve communication and coordination among different departments and professional teams because all participants have insight into the entire care process. This facilitates mutual cooperation and encourages a team approach in patient treatment.

Emphasis on quality also includes regular maintenance of medical equipment, up-to-date medical documentation, and alignment of clinical practice with the latest professional guidelines. Healthcare institutions that implement quality management systems more easily conduct internal self-assessments and analyze key performance indicators ([Sreedharan et al., 2024](#)), enabling timely identification of weaknesses and implementation of corrective and preventive measures.

For patients, a quality-oriented approach means greater safety in healthcare delivery. The likelihood of adverse events and errors decreases, while trust in the institution increases. According to available research, hospitals that apply the international ISO 9001 standard report a lower incidence of errors, higher patient satisfaction levels, and greater public recognition due to their commitment to standardized and safe care ([Khanna et al., 2023](#); [Villa-Gallón et al., 2024](#); [Yousefinezhadi et al., 2015](#)).

Internal benefits also include increased professional motivation of healthcare staff, as their suggestions and improvement ideas are valued and continuous education is provided. Moreover, more rational use of available resources often leads to reduced overall operational costs. Quality management systems enable decision-making based on real data, which is the foundation of modern and responsible management of healthcare institutions.

3.4. Regulation and Quality Standards in Croatian Healthcare

The development of quality management systems in the Republic of Croatia is based on a clearly defined legislative and normative framework that obliges healthcare institutions to establish and maintain quality assurance programs. The foundational document is the Healthcare Quality and Social Care Act ([Official Gazette 124/2011](#)), adopted in 2011, which sets national foundations for systematic quality management. The Act defines key principles and measures for quality improvement, including the accreditation of healthcare institutions and the establishment of the Agency for Quality and Accreditation in Health and Social Care ([Official Gazette 118/2018](#)).

The Act also defines important concepts such as healthcare procedure safety, which includes protecting patients from harmful events, and patient-centeredness, recognizing patients as active participants in decisions regarding their care. It stresses the need to harmonize national quality systems with international standards and to continuously monitor and improve quality based on evidence-based medicine.

To implement the Healthcare Quality and Social Care Act, relevant bylaws were adopted, notably two key regulations from 2011: the Regulation on Quality Standards for Health and Social Care ([Official Gazette 79/2011](#)) and the Regulation on Accreditation Standards for Hospital Healthcare Institutions ([Official Gazette 31/2011](#)). These regulations specify areas such as patient safety, medical record management, hospital infection control, monitoring treatment outcomes, and patient rights protection. They also

define measurable quality indicators that enable the monitoring and comparison of results among healthcare institutions. The patient safety standard obliges institutions to establish systems for reporting, analyzing, and preventing medical errors. The goal is to develop an organizational climate where mistakes are opportunities for learning and improvement rather than concealment.

Accreditation standards set conditions hospitals must meet to obtain accredited status, including outcome evaluation, care oversight, and staff education. The law also requires each institution to establish a Quality Committee chaired by the assistant director for quality. The committee coordinates activities, monitors indicators, and reports to management.

At the national level, the Agency for Quality and Accreditation in Health (AKAZ), established under the Healthcare Quality and Social Care Act, is responsible for developing standards, certifying and accrediting healthcare institutions, conducting education, and overseeing the quality system ([Official Gazette 118/2018](#)). Croatia's participation in the WHO PATH program has enabled additional quality monitoring in six dimensions, including clinical effectiveness, safety, and patient orientation ([Kadoić et al., 2021](#)).

In 2010, the Ministry of Health adopted the Plan and Program of Measures for Quality Assurance and Monitoring, which defines institutional obligations including semi-annual reporting and submission of clinical indicators ([Official Gazette 114/2010](#)). This has enabled national monitoring and benchmarking.

Despite clear legal frameworks, practical implementation is uneven. While some institutions have developed mature quality systems, others have met only basic requirements. Challenges include a shortage of trained personnel, resistance to change, and poor integration with other management functions. Nevertheless, the trend is positive as quality in Croatian healthcare gradually improves, albeit with regional differences. Croatia ranks mid-level in the European scale, with strong normative foundations and a growing number of initiatives for further improvement.

3.5. International Quality Standards in Healthcare (ISO 9001, EN 15224)

3.5.1. ISO 9001 in Healthcare Institutions

ISO 9001 is one of the most recognized international standards for quality management, applicable to all types of organizations. Although originally developed for industry, since the early 2000s it has been increasingly used in the healthcare sector, particularly for organizing processes and documentation in hospitals ([Avruscio et al., 2022](#)). The ISO 9001:2015 version is based on principles such as customer focus, leadership, process approach, data-driven decision-making, and continuous improvement. Its implementation contributes to clarity in work organization, increased transparency, and effective management of all phases of healthcare delivery.

Hospitals across Europe have adopted this standard as proof of commitment to quality and safety. Benefits of certification include reduced errors, clearly defined responsibilities, better resource utilization, and higher levels of patient and staff satisfaction. Although it does not replace clinical guidelines, ISO 9001 provides an organizational framework that supports their implementation ([Kyriakeli et al., 2025](#)). Interest in certification has significantly increased in Croatia since 2007, especially among specialized hospitals and clinical hospital centers.

3.5.2. EN 15224: Sector-Specific Standard for Healthcare

The EN 15224 standard is based on ISO 9001 but is specifically adapted for the healthcare sector. It focuses on clinical processes, risk management, and patient experience. It defines eleven key quality characteristics of healthcare services, including safety, accessibility, continuity, effectiveness, timeliness, and compliance with evidence-based medicine

(Kyriakeli et al., 2025). Certification according to EN 15224 is possible independently of possessing ISO 9001 certification (Shaw, Groene & Berger, 2019). Numerous healthcare institutions in Croatia have adopted it, often as an enhancement to existing quality management systems. Examples include General Hospital Pula and Special Hospital Medico in Rijeka.

3.5.3. ISO 7101: New Global Standard for Healthcare

ISO 7101:2023 is the first international standard specifically designed for healthcare organizations. It encompasses requirements for systematic quality management, placing the patient at the center of the system and emphasizing the importance of a human-centered culture, staff safety, risk management, and continuous improvement (McCaskill et al., 2025). The standard consolidates principles from previous norms but adapts them to the contemporary challenges faced by healthcare systems. Croatia is among the first countries to begin implementing this standard. General Hospital Pula was certified according to ISO 7101 in 2023, becoming the first such institution in the country.

3.6. Case Example: Multiple Certification and Accreditation at Special Hospital Medico

Special Hospital Medico in Rijeka stands out as one of the most convincing examples of successful integration of multiple quality management systems and accreditation frameworks in the Republic of Croatia. It is the first private hospital in the country to obtain the international American Accreditation Commission International - AACI accreditation for clinical excellence. Additionally, the hospital holds certificates according to ISO 9001:2015 and EN 15224:2016 standards, thereby meeting the highest international quality and safety requirements.

In practice, Medico has developed a comprehensive quality management system fully aligned with the requirements of these standards. The hospital's Quality Committee actively meets regularly to coordinate all activities related to quality improvement. Planned internal audits of all departments are conducted, clinical outcome indicators are systematically monitored, and all identified nonconformities are addressed through corrective and preventive actions.

Special attention is paid to patients' rights and privacy protection in accordance with legal and ethical obligations. The institution clearly states its consistent application of all provisions of the Patients' Rights Act, including the right to informed consent, access to medical records, and the possibility of filing complaints.

The quality culture is also evident in continuous investments in modernizing medical equipment, staff education, and fostering a partnership relationship with employees. This creates a positive working environment and encourages professional development; all aimed at delivering top-quality healthcare. This example confirms that even institutions outside the public sector, if strategically investing in quality, can reach levels comparable to the best European practices.

The integration of multiple quality management systems and independent accreditation is not only objective evidence of excellence but also a means to achieve sustainable competitive advantage in the healthcare services market.

3.7. Quality Monitoring, Quality Offices, and Continuous Improvement

According to legal requirements, every large healthcare institution is obliged to establish an appropriate quality body. In practice, this is usually implemented through the Quality Office and Quality Committee, which together form the foundation of the institutional quality management system. The Quality Office is typically headed by an assistant director

for quality, who coordinates the implementation of the quality policy across the entire institution ([Official Gazette 118/2018](#)).

The responsibilities of the Quality Office are manifold and include drafting quality plans and programs, organizing staff training, conducting internal audits, communicating with external institutions such as the Ministry of Health and the Agency for Quality, managing patient complaints and compliments, and preparing reports on quality indicators. This organizational unit must be sufficiently staffed and organized to act strategically rather than merely administratively. In other words, the Quality Office should be involved in all major decisions, including those related to finance and medical operations. Some Croatian hospitals have already recognized this. For example, at the University Hospital Centre Sisters of Charity in Zagreb, the Quality Office is managed by a healthcare graduate, while quality coordinators systematically monitor indicators (e.g., hospital mortality rates for specific diagnoses) and initiate targeted improvements within clinics.

The Quality Office collects data, prepares analyses, and proposes corrective measures. For example, in the case of increased hospital infections, it initiates the activity of the infection control team to analyze practices and revise clinical protocols. For effective operation, the Quality Office must ensure a sufficient number of trained staff. Quality is a multidisciplinary field ideally involving experts in medicine, management, statistics, and informatics. Besides personnel capacity, IT support is crucial, as modern quality management systems require digital tools for collecting and processing large amounts of data. Investments in these resources directly affect the institution's ability to identify weaknesses, predict risks, and continuously improve its processes.

Quality monitoring in Croatian healthcare operates at multiple levels. Internal monitoring is conducted by healthcare institutions themselves through the collection and analysis of indicators such as infection rates, waiting times, clinical outcomes, and the number of patient complaints. This is supplemented by internal audits and compliance control with prescribed standards. This practice is also confirmed in research on quality management systems in Croatian public health institutes, highlighting the importance of regular indicator monitoring and documented evaluation at the institutional level ([Vrtodušić Hrgović & Škarica, 2015](#)).

Evaluation results are discussed at meetings of quality committees and hospital management. When deviations are identified, corrective and preventive measures are implemented, such as additional staff training, procedure revisions, equipment procurement, or workflow reorganization. All changes are documented, establishing a so-called closed improvement loop.

External quality system supervision is conducted by the Ministry of Health and related bodies, primarily through periodic reports that healthcare institutions are required to submit. These data enable national comparison of results and identification of systemic weaknesses. If a hospital significantly deviates from the national average for a specific indicator, inspection supervision, consultation, or targeted measures may be ordered. In the past, the Agency for Quality has also conducted accreditation procedures, including on-site visits and granting accreditation status to institutions that meet prescribed standards. Although accreditation is not yet legally mandatory for public hospitals, some have participated in pilot projects, while certain private institutions have obtained international accreditations (e.g., AACI, JCI).

The Croatian Health Insurance Fund (HZZO) also shows interest in quality by introducing qualitative criteria in contracting healthcare. Institutions meeting additional quality and efficiency requirements may receive financial incentives. This creates extra motivation to maintain high standards not only for compliance but also for concrete reward of results.

3.8. Continuous Improvement and the Role of Management

The culture of quality and business excellence in healthcare institutions begins at the top, and the role of management is crucial. Hospital leadership, led by the director, must be actively involved in the development and implementation of quality management systems (Bhati et al., 2023). This includes strategic planning, ensuring the necessary resources (human, financial, and technological), and setting a personal example of commitment to quality and safety standards.

Management is responsible for defining specific quality objectives (Bugdol, 2024). These objectives may include reducing the incidence of hospital-acquired infections, increasing patient satisfaction based on survey results, shortening waiting times for diagnostic tests, or improving compliance with applicable professional guidelines. Achievement of these goals is monitored through key quality indicators, and their analysis enables informed decision-making about further actions.

Continuous improvement is most commonly implemented using the Deming Plan–Do–Check–Act (PDCA) cycle, which involves planning a change, piloting its limited introduction, analyzing the results, and if successful, implementing it throughout the institution (Naughton et al., 2024). This approach allows controlled and gradual introduction of changes with minimal operational risk.

For example, if data indicate that waiting times in the emergency department are too long, management can initiate an improvement cycle. The planning phase involves analyzing the cause of the problem (insufficient staff, inefficient triage process), followed by testing a new measure during the implementation phase (e.g., shift reorganization or digital triage). Results are then measured, and if positive, the new practice is permanently implemented and extended to other departments.

Beyond the strategic dimension, management plays a vital role in creating a motivating environment for staff. Physicians, nurses, and other frontline personnel often best recognize bottlenecks and potential safety risks in daily work. Encouraging them to propose improvements through meetings, internal suggestions, or digital tools enables the institution to respond quickly, prevent errors, and foster innovation.

Furthermore, the so-called bottom-up approach, where improvement initiatives originate from healthcare workers at the operational level, complements the formal top-down strategies shaped by hospital leadership in line with strategic goals. In this way, all participants in healthcare institutions, from management to operational staff, become active contributors to maintaining and improving quality. This integration of all system levels forms the foundation of organizational excellence and is one of the main goals of modern healthcare.

4. Practical Implications

To ensure sustainable quality improvement, healthcare institutions must integrate quality management systems into everyday operational and strategic management. This requires continuous investment in staff education and training, strengthening leadership engagement at all organizational levels, and the adoption of advanced digital tools for efficient data collection, analysis, and decision making. Rather than being seen as merely a regulatory requirement, quality management systems should be embraced as a core strategic priority that actively involves all stakeholders including management, healthcare professionals, and patients to foster a culture of safety, accountability, and continuous improvement.

The paper offers a comprehensive and up-to-date overview of the development and implementation of quality management systems in Croatian healthcare institutions. It highlights the alignment of national practices with international standards such as ISO

9001, EN 15224, and ISO 7101, demonstrating how such harmonization can substantially improve patient safety, organizational performance, and overall healthcare excellence. The inclusion of Croatian case studies provides practical insights into the challenges and successes of quality management system adoption, making this work valuable for healthcare policymakers, administrators, and practitioners seeking to advance quality initiatives within similar healthcare contexts.

5. Conclusion

Quality management systems have become an integral part of the strategic and operational functioning of healthcare institutions in Croatia. In recent years, a legal framework has been introduced requiring institutions to implement quality and safety standards, while an increasing number of hospitals have obtained certification and improved their processes. International standards such as ISO 9001 and EN 15224 have supported the standardization of organizational procedures and the development of a culture of safety. Many institutions regularly monitor quality indicators, report to competent authorities, and implement corrective measures, making quality a measurable aspect of everyday practice.

Nevertheless, the implementation of quality systems still faces challenges, including limited human resources, insufficient integration of quality into management structures, and resistance to change. The absence of a unified national accreditation program also contributes to variability among institutions. Further progress is possible through stronger institutional support, continuous staff education, digital modernization of processes, and enhanced cooperation among healthcare institutions. Greater involvement of patients in improvement processes and the introduction of incentive systems would further strengthen quality management.

Quality in healthcare should not be viewed merely as a regulatory obligation but as a fundamental element of daily practice based on the shared responsibility of all stakeholders. Such an approach is essential for healthcare institutions in the Republic of Croatia to achieve long-term excellence comparable to the best European practices.

The article is relevant to UN Sustainable Development Goals:



References

- Aggarwal, A., Aeran, H., & Rathee, M. (2019). Quality management in healthcare: The pivotal desideratum. *Journal of Oral Biology and Craniofacial Research*, 9(2), 180–182. <https://doi.org/10.1016/j.jobcr.2018.06.006>
- Avruscio, G., Ragazzo, S., & Ceccato, D. (2022). Implementation of a quality management system according to ISO 9001:2015 standards in an Angiology Unit: An Italian experience. *ANNALI DI IGIENE MEDICINA PREVENTIVA E DI COMUNITÀ*, 34(6), 627–634. <https://doi.org/10.7416/ai.2022.2501>
- Bhati, D., Deogade, M. S., & Kanyal, D. (2023). Improving Patient Outcomes Through Effective Hospital Administration: A Comprehensive Review. *Cureus*, 15(10), e47731. <https://doi.org/10.7759/cureus.47731>
- Bisho, A. I. H., & Bin Mohd Sam, M. F. (2022). Total quality management integrated strategy: Its implication to organizational success. *Proceedings on Engineering Sciences*, 4(3), 371–378. <https://doi.org/10.24874/PES04.03.014>
- Bugdol, M. (2024). Quality Objectives in Standardized Quality Management Systems. *Quality Management in Health Care*, 33(3), 200–205. <https://doi.org/10.1097/QMH.0000000000000426>

- Čerfalvi, V., Košec, V., & Benceković, Ž. (2016). Upravljanje sigurnošću pacijenata na primjeru smrtnosti od akutnog miokardnog infarkta tijekom hospitalizacije. *Poslovna izvrsnost – Business Excellence*, 10(2), 137–143. <https://hrcak.srce.hr/170746>. (n.d.).
- Donabedian, A. (1988). The Quality of Care: How Can It Be Assessed? *JAMA*, 260(12), 1743. <https://doi.org/10.1001/jama.1988.03410120089033>
- Endalamaw, A., Khatri, R. B., Mengistu, T. S., Erku, D., Wolka, E., Zewdie, A., & Assefa, Y. (2024). A scoping review of continuous quality improvement in healthcare system: Conceptualization, models and tools, barriers and facilitators, and impact. *BMC Health Services Research*, 24(1), 487. <https://doi.org/10.1186/s12913-024-10828-0>
- Engle, R. L., Mohr, D. C., Holmes, S. K., Seibert, M. N., Afable, M., Leyson, J., & Meterko, M. (2021). Evidence-based practice and patient-centered care: Doing both well. *Health Care Management Review*, 46(3), 174–184. <https://doi.org/10.1097/HMR.0000000000000254>
- Fukami, T. (2024). Enhancing Healthcare Accountability for Administrators: Fostering Transparency for Patient Safety and Quality Enhancement. *Cureus*, 16(8): e66007. <https://doi.org/10.7759/cureus.66007>
- Hanskamp-Sebregts, M., Zegers, M., Boeijen, W., Wollersheim, H., van Gurp, P. J., & Westert, G. P. (2019). Process evaluation of the effects of patient safety auditing in hospital care (part 2). *International Journal for Quality in Health Care: Journal of the International Society for Quality in Health Care*, 31(6), 433–441. <https://doi.org/10.1093/intqhc/mzy173>
- Healthcare Engineering, J. O. (2023). Retracted: Evaluation of the Effect of PDCA in Hospital Health Management. *Journal of Healthcare Engineering*, 2023, 9812870. <https://doi.org/10.1155/2023/9812870>
- Institute of Medicine (1990). *Medicare: A strategy for quality assurance*. The National Academy Press. <https://doi.org/10.17226/1547>
- Institute of Medicine (2000). *To Err Is Human: Building a Safer Health System*. The National Academies Press. <https://doi.org/10.17226/9728>
- Jagrič, T., Brown, C., Boyce, T., & Jagrič, V. (2021). The impact of the health-care sector on national economies in selected European countries. *Health Policy*, 125(1), 90–97. <https://doi.org/10.1016/j.healthpol.2020.10.009>
- Kadoić, N., Šimić, D., Mesarić, J., & Begičević Redep, N. (2021). Measuring Quality of Public Hospitals in Croatia Using a Multi-Criteria Approach. *International Journal of Environmental Research and Public Health*, 18(19), 9984. <https://doi.org/10.3390/ijerph18199984>
- Khanna, P., Haritha, D., Das, A., Sarkar, S., & Roy, A. (2023). Utility of high-flow nasal oxygen in comparison to conventional oxygen therapy during upper gastrointestinal endoscopic procedures under sedation: A systematic review and meta-analyses. *Indian Journal of Gastroenterology*, 42(1), 53–63. <https://doi.org/10.1007/s12664-022-01308-6>
- Kruk, M. E., Gage, A. D., Arsenault, C., Jordan, K., Leslie, H. H., Roder-DeWan, S., Adeyi, O., Barker, P., Daelmans, B., Doubova, S. V., English, M., García-Elorrio, E., Guanais, F., Gureje, O., Hirschhorn, L. R., Jiang, L., Kelley, E., Lemango, E. T., Liljestrand, J., ... Pate, M. (2018). High-quality health systems in the Sustainable Development Goals era: Time for a revolution. *The Lancet. Global Health*, 6(11), e1196–e1252. [https://doi.org/10.1016/S2214-109X\(18\)30386-3](https://doi.org/10.1016/S2214-109X(18)30386-3)
- Kyriakeli, G., Georgiadou, A., Lithoxopoulou, M., Tsimtsiou, Z., & Kotsis, V. (2025). The Impact of ISO Certification Procedures on Patient Safety Culture in Public Hospital Departments. *Healthcare*, 13(6), 661. <https://doi.org/10.3390/healthcare13060661>
- Ljungholm, L., Edin-Liljegren, A., Ekstedt, M., & Klinga, C. (2022). What is needed for continuity of care and how can we achieve it? – Perceptions among multiprofessionals

- on the chronic care trajectory. *BMC Health Services Research*, 22(1), 686.
<https://doi.org/10.1186/s12913-022-08023-0>
- MacGillivray, T. E. (2020). Advancing the Culture of Patient Safety and Quality Improvement. *Methodist DeBakey Cardiovascular Journal*, 16(3), 192–198.
<https://doi.org/10.14797/mdcj-16-3-192>
- McCaskill, A., Gasch-Gallen, A., & Montero-Marco, J. (2025). Results of the process of implementation of ISO 7101 subclause 8.10.5 Health literacy in specialty consultations. *Journal of Healthcare Quality Research*, 40(2), 116–125.
<https://doi.org/10.1016/j.jhqr.2024.11.003>
- Naughton, E., Moran, R., Kharub, M., Sa, J. C., & McDermott, O. (2024). A structured model for continuous improvement methodology deployment and sustainment: A case study. *Heliyon*, 10(21), e40034. <https://doi.org/10.1016/j.heliyon.2024.e40034>
- Plan i program mjera za osiguranje i praćenje kvalitete zdravstvene zaštite (Official Gazette 114/2010).
- Pravilnik o akreditacijskim standardima za bolničke zdravstvene ustanove (Official Gazette 31/2011).
- Pravilnik o standardima kvalitete zdravstvene zaštite i načinu njihove primjene (Official Gazette 79/2011).
- Shaw, C., Groene, O., & Berger, E. (2019). External institutional strategies: Accreditation, certification, supervision. In R. Busse, N. Klazinga, D. Panteli, et al. (Eds.), *Improving healthcare quality in Europe: Characteristics, effectiveness and implementation of different strategies* (Health Policy Series, No. 53). *European Observatory on Health Systems and Policies*.
- Sreedharan, J., Subbarayalu, A. V., Kamalasanan, A., Albalawi, I., Krishna, G. G., Alahmari, A. D., Alsalamah, J. A., Alkhathami, M. G., Alenezi, M., Alqahtani, A. S., Alahmari, M., Phillips, M. R., & MacDonald, J. (2024). Key Performance Indicators: A Framework for Allied Healthcare Educational Institutions. *ClinicoEconomics and Outcomes Research: CEOR*, 16, 173–185. <https://doi.org/10.2147/CEOR.S446614>
- Villa-Gallón, J. E., Valencia-Bernal, J. A., & Garcés-Gómez, Y. A. (2024). ISO Standards in Healthcare Organizations: Research Evolution and Trends from a Bibliometric Analysis. *Publications*, 12(3), 27. <https://doi.org/10.3390/publications12030027>
- Vrtodušić Hrgović, A.-M., & Škarica, I. (2015). Quality management systems in Croatian institutes of public health. In Gomezelj Omerzel, D., & Laporšek, S (Eds.), *International management conference*, 2015, University of Primorska, Faculty of Management, Portorož, 327-338.
- Waldman, S. A., & Terzic, A. (2019). Health Care Evolves From Reactive to Proactive. *Clinical Pharmacology and Therapeutics*, 105(1), 10–13.
<https://doi.org/10.1002/cpt.1295>
- World Health Organization - WHO. (2025). Quality health services [Fact sheet]. Geneva: WHO. Retrieved August 2, 2025, from <https://www.who.int/news-room/fact-sheets/detail/quality-health-services>
- Yousefinezhadi, T., Mohamadi, E., Safari Palangi, H., & Akbari Sari, A. (2015). The Effect of ISO 9001 and the EFQM Model on Improving Hospital Performance: A Systematic Review. *Iranian Red Crescent Medical Journal*, 17(12), e23010.
<https://doi.org/10.5812/ircmj.23010>
- Zakon o kvaliteti zdravstvene zaštite (Official Gazette 118/2018).
- Zakon o kvaliteti zdravstvene zaštite i socijalne skrbi (Official Gazette 124/2011).