


■ REVIEW ARTICLE

## Total Quality Management in Healthcare: Quality Principles, Implementation and Digitalization



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### Abstract

**Purpose:** This paper reviews and synthesizes the theoretical foundations and practical applications of Total Quality Management (TQM), highlighting current trends, organizational prerequisites, benefits, and common barriers, with emphasis on operationalizing core TQM principles and adapting them to healthcare settings. The quality of healthcare is increasingly recognized as a strategic priority due to its impact on treatment outcomes, system efficiency, and user experience. Within this context, TQM is affirmed as a comprehensive, sustainable model for systematic quality improvement. **Methodology:** A narrative literature review with thematic analysis of recent literature was conducted using Web of Science, Scopus, PubMed and Google Scholar. **Findings:** TQM principles are associated with improvements in safety, efficiency, patient experience, and resource use. Lean, Six Sigma, and Lean Six Sigma report measurable gains, including shorter waiting times, fewer errors, and cost reductions. Successful implementation depends on leadership commitment, open communication, a participatory culture, and staff capability, while common barriers include bureaucratization, fragmentation, limited empowerment and training, and poorly defined processes. Quality 4.0 and Healthcare 4.0 expand opportunities for predictive, data-driven, and personalized quality management. **Practical implications:** Organizations should operationalize TQM with clear accountability, leadership commitment, and a participatory quality culture, leveraging Lean/Six Sigma for measurable improvements while aligning digital initiatives (Quality 4.0/Healthcare 4.0) with core TQM principles and building skills and infrastructure. **Originality/Value:** The paper connects TQM with current healthcare challenges and digital transformation, highlighting how organizational and technological factors jointly shape quality outcomes and system-level improvement.

**Keywords:** total quality management, healthcare quality, continuous quality improvement, lean six sigma, quality 4.0

*JEL codes:* I18, L11, M15

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## 1. Introduction

Total Quality Management (TQM) is a comprehensive management philosophy toward the continuous improvement of all organizational processes, with the ultimate goal of optimizing quality and user satisfaction (Aichouni et al., 2024). The American Society for Quality (ASQ, 2025) defines it as an integrated system based on strategy, data, and effective communication, aiming to embed a culture of quality throughout the organization, its processes, products, services, and management. The professional and scholarly literature also uses related terms such as total quality control, total quality improvement, company-wide quality control, and strategic quality management (Lazibat et al., 2023).

TQM is grounded in principles and approaches shaped by leading authorities in the field of quality, including Philip B. Crosby, W. Edwards Deming, Armand V. Feigenbaum, Kaoru Ishikawa, and Joseph M. Juran (ASQ, 2025). In contemporary contexts, TQM is positioned as a comprehensive managerial philosophy operationalized through international standards such as ISO 9001, business excellence models like the European Foundation for Quality Management (EFQM) model, and quality award programs including the Deming Prize and the Malcolm Baldrige National Quality Award.

Amid intensifying global competition and increasing sustainability pressures, recent research increasingly reinterprets TQM as a managerial philosophy that engages a broader spectrum of stakeholders and integrates objectives of social responsibility, environmental sustainability, and economic efficiency (Silvestri et al., 2024). Accordingly, TQM seeks to meet the needs of all stakeholders, relying on the continuous improvement of organizational quality and interpersonal relations as core mechanisms for achieving competitiveness across social, environmental, and economic dimensions, while supporting the aims of sustainable development (Bolboceanu, 2025).

The advantages offered by TQM have driven its widespread adoption across healthcare organizations worldwide (Aburayya et al., 2020). Research in this domain is predominantly concentrated in the United States and European countries, while Canadian institutions notably lead in international scholarly collaboration (Hu et al., 2024).

Contemporary health systems face multiple pressures, including rising costs, regulatory demands, workforce constraints, growing user expectations, population aging, and challenges related to the introduction and interoperability of new technologies. High-quality health systems are defined as those that, in a given context, optimize care delivery by consistently providing services that improve or maintain health outcomes and adapt to changing population needs (Kruk et al., 2018). In parallel, digital transformation is reshaping the quality paradigm (Ali & Johl, 2022; Sader et al., 2022). Quality 4.0 augments TQM with digital technologies and advanced analytics, enabling a shift toward predictive quality management

(Sader et al., 2022). Healthcare 4.0 is described as a digital health ecosystem integrating physical and cyber systems (Sony et al., 2023).

In this context, practice-relevant evidence on TQM in healthcare is often discussed across partially separated themes, including the operationalization of core TQM principles, measurable process-improvement approaches such as Lean and Six Sigma, and the emerging digital quality agenda. This review therefore focuses primarily on 2019–2025 to capture recent literature that reflects contemporary quality challenges and the growing role of digitalization in healthcare quality management (e.g., Quality 4.0/Healthcare 4.0).

The aim of this paper is to synthesize recent literature on TQM implementation in healthcare (mainly 2019–2025), with an emphasis on operationalizing core TQM principles and adapting them to healthcare contexts, identifying organizational prerequisites, reported benefits, and common implementation barriers, and linking these insights to Lean/Six Sigma and the Quality 4.0/Healthcare 4.0 agenda by outlining practical and system-level implications for policy and practice.

## 2. Methodology

A narrative literature review with thematic analysis was conducted to provide a comprehensive, critical synthesis of recent evidence on TQM in healthcare. Narrative literature reviews offer a non-systematic synthesis of published literature to describe the current state of knowledge on a topic (Ferrari, 2015). Web of Science, Scopus, PubMed, and Google Scholar were searched, focusing primarily on 2019–2025 to reflect contemporary quality challenges and the growing role of digital transformation (e.g., Quality 4.0/Healthcare 4.0). Search strings were tailored to each database and combined keywords across four concept blocks: (1) TQM and related terms ("TQM," "Total Quality Management," "Continuous Quality Improvement," "CQI"); (2) healthcare context ("healthcare quality," "healthcare," "hospital"); (3) improvement approaches ("Lean," "Six Sigma," "Lean Six Sigma"); and (4) digital and excellence/decision-making perspectives ("Quality 4.0," "Healthcare 4.0," "Industry 4.0," "EFQM," "evidence-based decision making"). Peer-reviewed articles in English and Croatian addressing the application of TQM in healthcare organizations were included. Comments, editorials, and non-peer-reviewed works were excluded.

## 3. Results

### 3.1. Quality Within the TQM Philosophy

Quality within TQM is commonly understood as the extent to which services meet requirements and user needs, and also implies the absence of defects (ASQ, 2025; International Organization for Standardization, 2015). In healthcare, this concept extends beyond technical conformance to include the relationship between patients' expectations and their perceptions of the service received, as well as emphasizing efficiency and the sustainable use of resources (Chletsos & Saiti, 2019; Lillrank, 2015).

### 3.2. Adapting TQM to Healthcare Organizations

Unlike industrial systems, healthcare organizations face greater complexity and variability, as they are directly accountable for outcomes that immediately affect human lives. According to the European standard EN 15224:2016 (Quality management systems – EN ISO 9001:2015 for healthcare), healthcare is characterized by complex, interwoven relationships among patients, healthcare professionals, external service providers, insurers, industry, and regulatory bodies. The quality of clinical processes depends substantially on the effectiveness of managerial and resource support processes, with systematic identification, management, evaluation, and improvement aimed at meeting quality requirements for

patients as primary service users. The outcomes of these processes are most commonly expressed in services resulting from the direct interaction between patients and healthcare professionals (European Committee for Standardization, 2016).

A fundamental aim of healthcare is patient satisfaction, grounded in patients' needs and expectations. Since patients often lack the capacity to assess all aspects of treatment outcomes independently and comprehensively – including clinical, functional, and subjective dimensions – healthcare organizations are responsible for balancing these expectations with professional judgments regarding necessary interventions. This systemic complexity further underscores the need for careful and systematic adoption of TQM principles aimed at the continuous improvement of quality and efficiency.

In healthcare organizations, TQM is defined as a comprehensive, structured, and measurable management approach focused on delivering high-quality healthcare services while enhancing the efficiency, effectiveness, and flexibility of organizational processes (Hu et al., 2024). This managerial philosophy spans all levels of the system, from strategic decision-making to operational activities, and emphasizes patient satisfaction, timely problem identification, and participatory decision-making. In this context, every employee's role is crucial: each person is responsible for the quality of their own work and actively contributes to the organization's overall performance (Hidayah et al., 2022). This confirms that quality is both a strategic imperative and an operational obligation for all organizational members.

Contemporary research increasingly focuses on quality management models in hospital settings, particularly the EFQM model and the development of performance indicator systems (Hu et al., 2024). Supporting the effectiveness of this approach, a longitudinal study by van Schoten et al. (2016) found that applying the EFQM model in hospitals is associated with improvements in organizational performance over time, establishes a feedback loop in which results inform further process enhancements, and yields stronger gains when all elements of the model are implemented together. Fonseca et al. (2021) present EFQM 2020 as an updated excellence framework that incorporates sustainability and relates to Industry 4.0 transformation, while noting that EFQM 2020 and Industry 4.0 share performance improvement aims but are based on different conceptual and practical foundations. These findings reinforce the importance of an integrated approach to quality management and highlight the need to develop increasingly sophisticated, data-driven models that enable the systematic improvement of healthcare delivery.

### 3.3. Dimensions and Meaning of Quality in Healthcare

Quality in healthcare remains a strategic priority because health systems continue to face variations in care standards, inconsistent outcomes, and pressure to improve services under both resource-stable and resource-constrained conditions (World Health Organization [WHO], 2006). Although no single definition of healthcare quality is universally accepted, the WHO defines it as the degree to which health services increase the likelihood of desired health outcomes and are consistent with evidence-based professional practice (WHO, 2006). In practice, healthcare quality includes both technical and interpersonal dimensions, combining clinical effectiveness with patient experience (Tabish, 2024).

Healthcare quality is commonly described through interrelated dimensions such as effectiveness, safety, patient-centeredness, timeliness, equity, integration, and efficiency in resource use (WHO, 2025). These dimensions broadly correspond to core TQM principles, particularly customer focus, process management, and continuous quality improvement. The WHO Regional Office for Europe (2024) similarly emphasizes effectiveness, efficiency, patient-centeredness, safety, equity, and accessibility, while noting that some dimensions, such as timeliness and integration, are not always measured separately because of conceptual overlap and limited international comparability.

### 3.4. Challenges of European Health Systems and the Importance of High-Quality Care

Contemporary health systems face rising costs, regulatory pressures, workforce shortages, population aging, increasing patient expectations, and challenges related to adopting and integrating new technologies. In this context, high-quality health systems are defined as those that consistently improve or maintain health outcomes, command public trust, and adapt to changing population needs (Kruk et al., 2018). According to the same authors, their sustainability depends on strong governance, appropriate financing, effective regulation, and accountability, making quality a strategic priority rather than merely an operational concern.

Given these challenges, TQM is increasingly recognized as a framework for improving organizational performance, optimizing costs, and strengthening standards of care (Ahmed, 2022; Hidayah et al., 2022). This is especially relevant in European health systems, where the WHO Regional Office for Europe (2024) reports limited implementation of national quality and patient safety plans, insufficient patient involvement in governance, and uneven digital integration. In response, it advocates a "whole-system quality" approach based on integrated planning, clear standards, workforce development, digital capacity, and stronger patient participation in decision-making. This systemic approach closely aligns with TQM principles of stakeholder involvement, data-driven improvement, and organization-wide integration of quality.

### 3.5. Applying TQM Principles

Healthcare organizations can significantly enhance their overall performance and achieve sustainable results by applying TQM principles. TQM is a structured approach focused on identifying and addressing areas for improvement, fostering teamwork, and building an organizational culture oriented toward excellence and long-term sustainability (Zehir & Zehir, 2023).

The ASQ (2025) identifies eight fundamental TQM principles: customer focus, total employee involvement, a process approach, system integration, a strategic and systematic approach to management, continuous quality improvement, fact-based decision making, and effective communication within the organization. However, scholarly literature often emphasizes three central postulates: a focus on user satisfaction, continuous quality improvement, and the involvement of all employees within an organization (Lazibat et al., 2023). TQM principles provide a framework for achieving organizational excellence in healthcare, but their implementation must be adapted to contextual specificities, organizational culture, and the level of participation of all stakeholders.

#### 3.5.1. Customer Focus

In the application of TQM in healthcare organizations, the principle of customer focus is essential for understanding quality from the perspective of the end user – the patient. In healthcare, patient-centeredness stems from the fact that healthcare is a service sector whose outcomes directly affect the physical and emotional well-being of patients and their families. Patient satisfaction is therefore not only an indicator of quality but also an ethical imperative for healthcare institutions, especially in a dynamic and highly regulated environment (Singh & Rathi, 2019).

Within the philosophy of TQM, patient focus is a foundational principle in healthcare. TQM systematically aims to increase user satisfaction, which, along with improvements in service quality, is linked to greater market share and stronger organizational performance (Ahmed, 2022). Higher patient satisfaction leads to better operational and overall results for healthcare institutions (Grossu-Leibovica & Kalkis, 2022). At the same time, patient satisfaction, as a central element of patient-centered care, is increasingly used as a key performance indicator in hospital systems (Abdallah et al., 2025).

What most distinguishes the TQM concept from traditional approaches is the integration of "soft" organizational dimensions such as leadership, employee involvement, and customer focus, alongside standard technical components. According to Alkhaldi and Abdallah (2022), there is a growing consensus among researchers and practitioners that patient satisfaction is a key indicator of health system performance, highlighting the need for its systematic monitoring and analysis.

### *3.5.2. Process Approach*

In healthcare institutions, particularly hospitals, effective process management is of critical importance due to the specificities of the setting, which involves a combination of tangible and intangible elements of the healthcare service. The complexity arises from the fact that a number of interrelated organizational units participate in care delivery. It is therefore necessary to ensure a high level of coordination, safety, and hygiene standards, especially in the context of clinical processes that can have direct consequences for patients' lives and health. In this sense, process management serves as a mechanism for aligning the system with patients' expectations and perceptions during and after a healthcare intervention.

According to the ASQ (2025), a process approach entails understanding, managing, and continuously improving organizational processes to achieve desired results, with an emphasis on efficiency and effectiveness in operational performance. The sustainability of operational and quality performance depends strongly on process management, as it provides the structure needed to deliver the same quality of service at any time (Zehir & Zehir, 2023).

Within the standard EN 15224:2016 (European Committee for Standardization, 2016), three fundamental processes are recognized in healthcare organizations: clinical, research, and educational, with clinical processes identified as the central carriers of healthcare services. They encompass all activities related to the interaction between patients and healthcare professionals and form the foundation of quality management systems in healthcare. In line with the standard's guidance, effective and systematic management of clinical processes contributes to the implementation of evidence-based medical practices, the timely identification and mitigation of risks, and the assurance of continuity and safety of care.

### *3.5.3. Continuous Quality Improvement*

Continuous quality improvement (CQI) is the systematic, ongoing enhancement of healthcare operations that relies on patient feedback and the continuous evaluation of current processes and services, with the aim of improving all aspects of operations, enhancing quality, and increasing responsiveness to patient needs (Abdallah et al., 2025; Papadopoulos, 2011, as cited in Abdallah et al., 2025). As successive global developments unfold, the healthcare sector requires continual improvement and development of quality management systems to fast-track new developments, manage resources optimally, enhance service quality and care, and respond quickly and appropriately to patients' expectations and aspirations (Daqar & Constantinovits, 2020).

CQI initiatives have gradually been adopted as a key approach to strengthening quality at the system level (Endalamaw et al., 2024). They foster a culture of continuous learning, innovation, and improvement and are most commonly operationalized in practice through the PDSA (Plan–Do–Study–Act) / PDCA (Plan–Do–Check–Act) cycle, accompanied by the monitoring of process, outcome, and experience measures. Implementing CQI seeks to enhance core components of the health system, improve service delivery processes and outcomes, and ultimately prevent morbidity and reduce mortality.

The evolution of CQI in healthcare extends beyond the traditional PDSA/PDCA framework. Initiatives such as Lean Management (LM), Six Sigma (SS), and patient safety (PS)

programs can act as "micro-foundations" of business model innovation, that is, operational levers that catalyze organizational change and create additional value for patients and providers (Rosa et al., 2025). In private healthcare organizations, LM, SS, and PS each show a significant positive association with value-creation innovation (VCI), with SS exerting the strongest effect. Reported benefits include faster patient flow, reduced waiting times, fewer medical errors, increased safety, and improved patient experience, alongside more efficient resource use. The effectiveness of these approaches rests on an organizational culture of continuous improvement, particularly through Kaizen-based methods. VCI is defined as a set of value-creation strategies that leverage resources and organizational capabilities to enhance internal and external processes. As noted by Clauss (2017) and Castano (2014), in healthcare VCI is especially associated with standardization, process separability, and patient-centeredness.

Today, LM is one of the most widespread quality improvement approaches in healthcare, with uptake reported in approximately 86% of healthcare institutions (Abdallah et al., 2025). Its implementation involves identifying the value stream, defining value from the patient's perspective, systematically evaluating processes, and eliminating non-value-adding activities along the patient journey through the system (Alowad et al., 2021, as cited in Abdallah et al., 2025). Additionally, LM provides tools to streamline patient flow, reduce errors, and eliminate unnecessary costs and waste, ultimately enhancing patient satisfaction (Abdallah & Alkhaldi, 2019). Ilangakoon et al. (2022) note that the Lean approach enables the systematic identification and removal of inefficiencies, particularly in the healthcare supply chain and patient flow, while simultaneously improving quality of care.

Lean Six Sigma (LSS) is an integrated, TQM-oriented approach focused on continuous performance improvement. In healthcare institutions, it is applied primarily to reduce errors and strengthen patient safety. The methodology combines two complementary concepts, each based on distinct principles and tools: Six Sigma, which aims to identify and reduce variability to achieve stable and consistent processes, most commonly through the DMAIC framework (Define–Measure–Analyze–Improve–Control) and advanced statistical techniques; and Lean, which focuses on identifying and eliminating waste, empowering staff at all levels, and pursuing continual improvement through the Shewhart PDCA cycle (Ahmed et al., 2024). In practice, LSS in healthcare is predominantly implemented through DMAIC, with frequent use of process-oriented tools such as the Ishikawa diagram, process mapping, hypothesis testing, SPC, SIPOC, VSM, project charters, brainstorming, 5 Whys analysis, Pareto, and VOC. Reported measurable improvements often include shorter waiting times, reduced turnaround time (TAT) and length of stay (LOS), fewer unnecessary diagnostic procedures (MRI, CT, X-ray, etc.), and cost savings (Samanta et al., 2023).

These findings underscore the importance of CQI and innovation methodologies in achieving operational efficiency, safety, and sustainable quality of care in contemporary healthcare organizations.

#### *3.5.4. Communication, Strategic Alignment, and System Integration*

Effective TQM implementation in healthcare depends on leadership, open communication, strategic alignment, and system integration. In complex healthcare organizations, transparent communication between senior management and frontline staff, as noted by Ahmed (2022) and Laureani et al. (2024), helps employees understand the organization's vision, goals, and expectations, while also strengthening motivation, accountability, and participation in quality improvement initiatives.

A strategic and systematic approach further requires aligning the quality management system with organizational priorities, structures, culture, and processes to support long-term improvement and prevent the premature abandonment of good practices (Kavukoğlu

& İsci, 2024). Evidence also suggests that leadership commitment is a particularly strong determinant of successful TQM implementation in hospitals (Aburayya et al., 2020).

Within this framework, TQM views the organization as an integrated system in which functions, processes, and resources are linked toward common quality objectives. Rather than operating in isolated departments, healthcare organizations need cross-functional collaboration, employee involvement at all levels, and coordinated decision-making to ensure organizational effectiveness and the consistent delivery of quality care (ASQ, 2025; Hidayah et al., 2022).

### 3.5.5. Employee Involvement

Employee involvement is a critical aspect of TQM's success, as employees form the foundation of the organization and implementation ultimately occurs at the frontline (Ahmed, 2022). All employees, regardless of hierarchical level or role, should actively participate in quality improvement initiatives, with education, empowerment, and the development of a culture of accountability as critical success factors (ASQ, 2025).

TQM rests on the premise that every member of the organization, irrespective of hierarchy, is responsible for the continuous improvement of process and outcome quality. In healthcare institutions, characterized by high complexity and the need for rapid, precise coordination between clinical and administrative staff, employee involvement has a pronounced impact on operational efficiency and overall organizational performance. A study conducted in private hospitals in Malaysia found that employee involvement was identified as the most important component of TQM in improving organizational performance, surpassing even leadership and continuous improvement (Ramasamy & Avadaiyar, 2024). This finding supports the view that TQM, as both a methodology and an organizational culture, cannot function without teamwork, cross-functional collaboration, and open communication among employees.

According to Cavallone and Palumbo (2022), employee involvement, as one of the key "soft" TQM principles, is crucial for shaping an organizational climate that fosters excellence. However, its positive effects on organizational commitment and performance are not automatic; they are significantly amplified when adequate educational and motivational mechanisms are in place. Bakotić and Rogošić (2017) similarly argue that employee involvement should not be regarded as a mere technical tool, but as an organizational philosophy aimed at creating a climate in which employees have a genuine influence on decisions and activities related to their everyday work. In this sense, communication, employee empowerment, appropriate training, and recognition and reward systems stand out as key factors for successful TQM implementation.

Informed, motivated, and empowered employees act as drivers of continuous improvement and organizational excellence. Ramasamy and Avadaiyar (2024) emphasize that education and training are crucial for successful TQM implementation, especially in healthcare, where effective collaboration between clinical and administrative staff underpins continuous, integrated care. Educating employees in relevant tools and methodologies, such as statistical quality control, Six Sigma, and Lean, enhances their competence and understanding of quality management systems, thereby further improving the effectiveness of TQM initiatives. Such a workforce can reduce staff turnover, increase employee satisfaction, and strengthen the organization's overall orientation toward quality (Ramasamy & Avadaiyar, 2024).

### 3.5.6. Evidence and Fact-Based Decision-Making

The principle of fact-based decision-making rests on processes derived from accurate, verified data and objective analysis rather than assumptions or intuition. In this context, statistical tools and quality management methods play a pivotal role in ensuring the

objectivity and reliability of decisions (ASQ, 2025). In hospitals, where decisions are often made under time pressure, well-structured decision-making procedures support problem-solving and the choice of the best options, thereby helping to execute TQM practices across the organization (Zehir & Zehir, 2023).

Evidence-based decision-making (EBDM) is an approach that relies on the best available and up-to-date evidence. In this approach, managers and decision-makers gather and appraise data from multiple sources, including scientific research, expert perspectives, empirical evidence, and stakeholder (including patient) preferences, to maximize objectivity and managerial effectiveness (Hedayatipour et al., 2024). Creating an EBDM culture that fosters critical thinking, active evidence seeking, and creative behavior has a positive and significant effect on performance. Although their findings stem from studies in primary care, the conclusions are applicable to broader health-system contexts. Similarly, Shrout and Gallagher-Ford (2021) note that integrating EBDM into practice can improve quality and safety of care, enhance clinical outcomes, and reduce costs. The importance of developing competencies for the application of EBDM is underscored by the study by Bastani et al. (2021), which indicates that skills in critical thinking, information interpretation, and understanding scientific evidence and practical experience are fundamental to the successful implementation of this approach. Such managerial empowerment contributes to evidence-informed decisions, optimal resource use, and the formation of an organizational culture oriented toward improving overall efficiency and performance.

Evidence-based practice (EBP) is a lifelong approach to problem-solving in clinical care that integrates the best available external evidence, clinical expertise, quality-improvement initiatives, and patients' values and preferences to achieve optimal health outcomes (Melnyk & Fineout-Overholt, 2023). Connor et al. (2023) report that EBP is associated with improved treatment outcomes, greater patient safety, and favorable economic impacts, including return on investment (ROI). They also highlight the importance of standardizing EBP implementation, evaluation, and terminology, underscoring the critical roles of leaders and practitioners in its ongoing integration and sustainability. However, Shrout and Gallagher-Ford (2021) note that fully actualized evidence-based cultures in which EBP is consistently implemented remain uncommon, emphasizing the importance of leadership, mentorship, and structured toolkits for sustainable implementation.

### 3.6. Challenges of Implementing TQM

The theoretical principles of TQM provide a strong framework for improving healthcare, but successful application depends largely on organizational context. When implemented effectively, TQM can lead to higher hospital care quality (Hidayah et al., 2022), reduced errors, optimal resource use, and improved quality management (Aggarwal et al., 2019). As a result, patient trust increases, costs decrease, and overall user satisfaction improves (Chletsos & Saiti, 2019). Ansari (2022) notes that these positive outcomes occur mainly in organizations with committed leadership, appropriate infrastructure, and strong organizational support. In such environments, TQM promotes better service quality, greater satisfaction among patients and staff, user loyalty, and growth in profitability and stakeholder value. However, Ansari warns of specific obstacles in healthcare organizations, especially hospitals, including multilayered bureaucratic hierarchies, departmental fragmentation, and complex, inter-linked management controls that often conflict with TQM's participatory and flexible approach. Additional barriers include insufficient leadership commitment, weak teamwork, ineffective or superficial training, limited employee empowerment, and the absence of clearly defined processes and procedures, as well as a lack of embedded quality control and continuous improvement philosophy (Ansari, 2022). These challenges extend beyond structural and process-related issues. Mandel and Cady (2022) caution that relying too heavily on technical methods and metrics in quality improvement, while neglecting employees'

emotional experience, can drain emotional energy, reduce engagement, and increase resistance to change. Because quality is deeply rooted in the identity, culture, and operational practices of healthcare organizations, sustainable transformation requires incorporating adaptive, socio-behavioral elements. Ignoring these aspects can trigger a "self-limiting spiral," where increasing formal control and improvement mechanisms paradoxically reduce effectiveness and motivation.

These circumstances point to the need for an integrated approach to TQM implementation that, alongside theoretical principles, encompasses an understanding of emotional dynamics, organizational culture, and everyday challenges in healthcare settings. In this context, Akmal et al. (2021) argue that difficulties in implementing TQM initiatives often stem not primarily from methodological weaknesses, but from constraints in operational control, insufficient adaptation to the specific context of health systems, and a lack of long-term strategic orientation. In conclusion, the authors warn that failures in quality improvement frequently arise from structural mismatches between the demands of these approaches and the inherent complexity of health systems themselves.

Recent evidence reveals a recurring pattern of contextual constraints on TQM effectiveness. Findings show that TQM loses traction in environments with multilayered command-and-control hierarchies, fragmented departments, and dense, interlinked management controls that conflict with TQM's participatory and agile orientation. Additional barriers include limited employee empowerment and involvement, superficial training, and the absence of clearly defined processes and a CQI/CI culture. Beyond structural factors, neglecting employees' emotional experience and relying solely on technical metrics can erode engagement and increase resistance to change. As indicated by Ansari (2022), Mandel and Cady (2022), and Akmal et al. (2021), effectiveness improves when TQM principles are explicitly tailored to the specific context of healthcare organizations and supported by a clear, long-term orientation.

### 3.7. Digitalization of Quality Management: Quality 4.0 and Healthcare 4.0

From a technical standpoint, the Fourth Industrial Revolution (Industry 4.0) is grounded in cyber-physical systems (CPS), entailing the integration of computing, communication, and control. It relies heavily on three technological pillars: the Internet of Things (IoT), characterized by the pervasive presence of uniquely addressable, cooperating objects (e.g., mobile phones, sensors, actuators), cloud and fog computing, which provide virtually unlimited computing, communication, and storage resources as utilities (on-demand and pay-per-use), and big data analytics, which extracts value from large and complex datasets (Aceto et al., 2020).

In healthcare systems, these technologies underpin the concept of Healthcare 4.0, denoting the transition to smart, digitally connected solutions (Marbough et al., 2023) such as IoT, cloud and fog computing, blockchain, and big data analytics (Aceto et al., 2020; Ilangakoon et al., 2022), terahertz imaging (THz) and artificial intelligence (AI) (Abbate et al., 2023; Al-Assaf et al., 2024). This digital transition is reshaping how healthcare professionals access data, analyze information, and manage knowledge (Abbate et al., 2023). Healthcare 4.0 represents a paradigmatic shift in healthcare, integrating physical healthcare systems with cyber systems to create a digital health ecosystem that benefits stakeholders (Sony et al., 2023). A synthesis of the literature suggests that implementing Healthcare 4.0 can positively affect healthcare service quality across interpersonal, technical, environmental, and administrative dimensions. At the same time, Healthcare 4.0 applications are associated with more precise diagnostics, stronger patient engagement, and improved system-wide communication, which can enhance care quality and service efficiency (Al-Assaf et al., 2024). However, the evidence base remains constrained by limitations in the existing literature (e.g., review scope and databases) (Sony et al., 2023), and the transition to digitally managed

healthcare services is still complex and requires further theoretical and managerial development (Abbate et al., 2023).

The Quality 4.0 concept represents a contemporary approach to quality management that augments traditional models like quality control (QC), quality assurance (QA), and TQM, with digital technologies, enabling a transition from reactive and proactive to predictive quality management (Sader et al., 2022). These technologies can improve clinical effectiveness, patient safety, and overall patient experience (Marbouh et al., 2023). Traditional TQM offers a holistic, people and process-centered framework involving suppliers and customers. Quality 4.0 does not discard these foundations, rather, it extends them by incorporating digital tools and advanced analytics, thereby broadening the scope of quality management and improving the efficiency and effectiveness of quality activities (Sader et al., 2022). This paradigm shift affects people, processes, and technologies within organizations, underscoring the importance of competencies, teamwork, and leadership (Ali & Johl, 2022).

Implementing Quality 4.0 depends on the aligned action of multiple organizational factors spanning the "soft" and "hard" dimensions of TQM (Ali & Johl, 2022; Ali & Waheed, 2025). Across industries, a comprehensive review of Quality 4.0 literature identifies several interrelated barriers to implementation (Mahin et al., 2024). The top obstacles include skill gaps, lack of resources, lack of leadership support and clear vision, high investment cost with unclear ROI (or cost of implementation), and lack of implementation knowledge and standardized frameworks. These barriers are interdependent (e.g., limited resources constrain training and exacerbate skill gaps; weak leadership support hinders resource allocation), suggesting a need for integrated strategies that address multiple linked challenges simultaneously. Mahin et al. further note that tacit knowledge has received less attention as an impediment, yet insufficient attention to capturing and transferring tacit knowledge may limit organizations' ability to realize Quality 4.0 benefits. They suggest knowledge-sharing platforms, a culture that supports knowledge exchange, and mentoring and training initiatives. They also call for additional empirical work, including longitudinal studies, to test the effectiveness of integrated solutions and to examine how tacit knowledge can be effectively transformed within Quality 4.0 frameworks.

Among the soft dimensions, leadership commitment, customer focus, employee development, and analytical capabilities are prominent (Ali & Johl, 2022). Successful big-data analysis, particularly prescriptive analytics, is associated with achieving strategic quality objectives and risk reduction (Sony et al., 2020).

The success of Quality 4.0 initiatives hinges on leadership and on workforce capability built through training and continuous professional development (Sony et al., 2020). To address current and future quality management challenges, a new leadership paradigm is needed, one that incorporates quality maturity self-assessment and quality sustainability as key components (Antony et al., 2025). Moreover, successful implementation requires an organizational culture that supports standardized approaches, particularly within hierarchical systems, as well as a high degree of integration at all levels of the organization, including vertical, horizontal, and end-to-end integration, aligned with operations strategies based on continuous improvement (Sony et al., 2020). On the "hard" side, enabling dimensions include process management, continuous improvement, and product or service design (Ali & Johl, 2022).

Digitalization requires a well-defined strategy that includes setting clear objectives, strengthening organizational capabilities, upskilling the workforce, providing adequate technological infrastructure, optimizing processes, and managing change effectively (Aichouni et al., 2024). This strategy must ensure that the adoption of Industry 4.0 technologies aligns with TQM practices to enable effective and sustainable integration. Fostering a culture of innovation and continuous improvement, along with partnerships with technology suppliers, further supports successful integration. Tortorella et al. (2021) propose a problem-oriented

methodology based on QFD (house of quality) to prioritize Healthcare 4.0 digital applications in hospitals by combining managers' assessments of the frequency and relevance of operational problems with the current adoption level of digital applications. They argue that hospital digitalization is often limited to specific sectors or processes and that, given the complexity of hospitals, a systemic, problem-driven approach is necessary. Two case studies – a Brazilian public hospital and an Indian private hospital – demonstrate that ranking digital applications by their potential to address prioritized problems supports tailored implementation roadmaps and avoids one-size-fits-all strategies (Tortorella et al., 2021). Osama et al. (2023) identify 5G, IoMT/IoT (including wearables), AI, and edge and cloud computing as key enablers of Healthcare 4.0, supporting telemedicine and real-time monitoring. They emphasize that realizing these benefits depends on meeting requirements such as advanced data analytics, interoperability, security, and privacy, as well as managing massive data challenges. Overall, the review suggests that aligning these enabling technologies with the necessary network and data capabilities can support more proactive, personalized, and efficient digital health services (Osama et al., 2023). Building on these points, Balasubramanian et al. (2025) suggest that the successful scaling of AI-enabled digital health initiatives depends on supportive regulation, robust IT and data infrastructure, and cross-stakeholder cooperation, while also requiring attention to data privacy, model generalizability, and algorithmic bias. They also highlight adoption barriers such as data privacy and security concerns, limited model generalizability, and algorithmic bias, which must be addressed for the expected operational, quality, and societal benefits to materialize.

Integrating Industry 4.0 technologies with structured TQM processes strengthens organizations' dynamic capabilities, enabling effective responses to challenges and sustained improvements in the context of sustainability, while regular monitoring and evaluation ensure that this integration remains adaptable to changing market conditions and performance standards. At the same time, future research on Industry 5.0, with its emphasis on humanization, personalization, and ethics, raises new questions for the future of quality management (Aichouni et al., 2024).

#### 4. Discussion

Evidence to date suggests that applying TQM in healthcare organizations is a theoretically grounded and operationally sustainable approach that enables structured and comprehensive improvement of healthcare quality. In the face of increasingly significant challenges, including rising costs, demographic change, digital transition, and growing user expectations, TQM is an increasingly relevant integrative framework that addresses the needs of both organizational systems and users of healthcare services.

Core TQM principles, such as customer (patient) focus, employee involvement, and continuous quality improvement (CQI), are clearly implemented in contemporary healthcare practice. Patient focus, a central TQM principle in healthcare, is especially important because user experience affects both satisfaction and measurable health outcomes. As the literature shows, patient satisfaction serves as a key indicator of health system quality and effectiveness, with benefits reflected in institutional reputation and operational results. (Abdallah et al., 2025; Alkhalidi & Abdallah, 2022; Chletsos & Saiti, 2019; Singh & Rathi, 2019; Aggarwal et al., 2019).

A process orientation is emphasized as a mechanism that enables the management of complex and interdependent clinical processes. Standardization, waste elimination, and clearly defined, protocol-driven activities ensure greater patient safety, process predictability, and more efficient resource use (Zehir & Zehir, 2023). Continuous quality improvement is recognized as an essential component of a sustainable and adaptable health system (Abdallah et al., 2025; Endalamaw et al., 2024). The integration of Lean, Six Sigma, and Lean Six Sigma (LSS) in healthcare organizations is associated with measurable improvements, such as reductions in errors, waiting times, and unnecessary procedures, as well as better

resource utilization (Ahmed et al., 2024; Rosa et al., 2025). Their effectiveness is further enhanced when implemented within an organizational culture of continuous improvement and innovation (Rosa et al., 2025). In this context, TQM is not merely a set of techniques but a management philosophy that encompasses the entire organization at all levels.

Environments with committed leadership, functional infrastructure, and strong organizational support are particularly conducive to positive TQM outcomes, while implementation is often hindered by bureaucratization, departmental fragmentation, and complex networks of interlinked management controls, including multilayered "command-and-control" hierarchies, as well as insufficient collaboration, limited employee empowerment, ineffective or superficial training, and the absence of clearly defined processes, procedures, and an embedded quality control and continuous improvement philosophy (Ansari, 2022). Beyond structural barriers, neglecting employees' emotional needs and focusing exclusively on the technical aspects of quality can reduce engagement and foster resistance to change (Mandel & Cady, 2022). TQM's effectiveness is further limited when core principles are not adapted to the specific context of healthcare institutions or when a long-term strategic orientation is lacking (Akmal et al., 2021). Leadership commitment, effective communication, and a participatory culture are foundational components of TQM implementation (Ahmed, 2022).

Digitalization is also reshaping the quality paradigm (Ali & Johl, 2022; Sader et al., 2022). The concepts of Quality 4.0 and Healthcare 4.0 introduce new tools and capabilities for personalized, predictive, and analytically driven quality management, while also requiring new competencies, systems, and strategies (Aichouni et al., 2024; Ali & Johl, 2022). Technologies such as the Internet of Things, cloud and fog computing, blockchain, big data analytics, terahertz technologies, and artificial intelligence enable more precise diagnostics, improved communication, and greater patient engagement, thereby increasing efficiency and quality of care (Abbate et al., 2023; Aceto et al., 2020; Al-Assaf et al., 2024).

Effective and sustainable digital transformation of quality management requires a clearly defined strategy that aligns the introduction of Industry 4.0 technologies with TQM principles (Aichouni et al., 2024). Key prerequisites for successful implementation include an organizational culture that supports standardized approaches, especially within hierarchical systems, and a high degree of vertical, horizontal, and end-to-end integration, consistent with operations strategies based on continuous improvement (Sony et al., 2020). A culture of innovation and continuous improvement, along with stable partnerships with technology providers, further supports the sustainability of the transformation (Aichouni et al., 2024). Leadership is critical to realizing the benefits of digital transformation in quality (Sony et al., 2020). Continuous staff education and the development of digital competencies are also necessary for the effective application of advanced technologies within quality management systems (Sony et al., 2020). The main discussion points from the reviewed literature are summarized in Table 1.

**Table 1**  
Main Discussion Points

Discussion point	Main finding	Sources	Implication
TQM in healthcare	TQM is discussed as an organization-wide management approach, rather than a narrow quality-control tool.	<a href="#">Hidayah et al., 2022</a> ; <a href="#">Hu et al., 2024</a> ; <a href="#">Zehir &amp; Zehir, 2023</a>	TQM in healthcare should be treated as a managerial and operational framework.
Core principles and outcomes	Patient focus, process management, CQI and fact-based decision-making recur as key TQM elements and are linked to quality and organizational performance.	<a href="#">Alkhalidi &amp; Abdallah, 2022</a> ; <a href="#">Endalamaw et al., 2024</a> ; <a href="#">Hedayatipour et al., 2024</a> ; <a href="#">Bastani et al., 2021</a> ; <a href="#">Zehir &amp; Zehir, 2023</a>	TQM should be considered in terms of both healthcare quality and performance.
Implementation conditions	Leadership, communication, employee involvement, training, and a participatory culture shape implementation success.	<a href="#">Ahmed, 2022</a> ; <a href="#">Aburayya et al., 2020</a> ; <a href="#">Laureani et al., 2024</a> ; <a href="#">Ramasamy &amp; Avadaiyar, 2024</a>	Formal adoption is insufficient without organizational support.
Lean, Six Sigma, and LSS	These methods are associated with shorter waiting times, fewer errors, less variation, and better resource use.	<a href="#">Abdallah et al., 2025</a> ; <a href="#">Ahmed, 2022</a> ; <a href="#">Rosa et al., 2025</a> ; <a href="#">Samanta et al., 2023</a>	They work best as part of a broader quality approach.
Barriers	Common barriers include bureaucracy, fragmentation, weak teamwork, limited empowerment, poor training, unclear processes, constraints in operational control, and insufficient adaptation of TQM to the specific context and complexity of healthcare systems.	<a href="#">Akmal et al., 2021</a> ; <a href="#">Ansari, 2022</a> ; <a href="#">Mandel &amp; Cady, 2022</a>	TQM becomes less effective when it remains procedural and is not adapted to the context.
Quality 4.0 and Healthcare 4.0	Digital tools may improve monitoring, coordination, and data use, but their effects depend on skills, infrastructure, leadership, and alignment with TQM principles.	<a href="#">Aichouni et al., 2024</a> ; <a href="#">Mahin et al., 2024</a> ; <a href="#">Sader et al., 2022</a> ; <a href="#">Sony et al., 2020</a>	Digitalization should enhance quality management, not replace its organizational and human foundations.

*Note.* Authors' synthesis based on reviewed literature. CQI = Continuous quality improvement, LSS = Lean Six Sigma.

## 5. Conclusion

This review indicates that TQM remains a relevant framework for the systematic improvement of healthcare quality. Its value lies in combining patient focus, process orientation, continuous improvement, and employee involvement within an organization-wide approach to better safety, efficiency, and service quality. The literature also shows that Lean, Six Sigma,

and Lean Six Sigma can strengthen these effects by delivering measurable improvements in operational and clinical processes.

However, the impact of TQM depends on the context. Implementation is strengthened by leadership commitment, effective communication, a participatory culture, workforce capability, and alignment between quality goals, organizational structures, and daily practice. It is weakened in bureaucratic, fragmented, and tightly controlled settings, especially where improvement remains procedural rather than culturally embedded (Ansari, 2022; Mandel & Cady, 2022; Akmal et al., 2021). The growing relevance of Quality 4.0 and Healthcare 4.0 further suggests that digitalization can enhance TQM, but only when supported by adequate skills, infrastructure, and strategic integration.

This paper has several limitations. As a narrative review, it is interpretive and may not capture all relevant studies. Its conclusions are based on existing literature rather than original empirical research, which limits causal inference. The reviewed studies also differ in methodology, sector, and geographical context, constraining direct comparison and generalizability. Additionally, the limited focus on Croatian and regional healthcare settings reduces the immediate applicability of the findings to local systems.

Future research should examine more closely the organizational and contextual conditions under which TQM succeeds in different health systems, particularly in relation to digital transformation. Further empirical work is needed on the integration of TQM with Quality 4.0, including the development of validated process, outcome, and sustainability indicators. More broadly, TQM should be explored as an organizational model but also as a possible framework for shaping health system quality policy.

The article is relevant to UN Sustainable Development Goals:



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