

Implementing Healthcare Innovation via ISO Standards: An Exploratory Literature Overview

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Abstract: The healthcare sector faces increasing pressure to improve quality while reducing its environmental impact. This study presents an exploratory semi-systematic literature review investigating the implementation of the most important ISO standards (9001, 14001, 45001, 26000, and 50001) in healthcare organizations, focusing on implementation of drivers, barriers, and the role of digital technologies. Through analysis of peer-reviewed articles from Web of Science published between 2010 and 2024, the study aimed to examine driving forces and barriers affecting ISO implementation in healthcare settings, while also investigating the potential role of digital technologies in addressing implementation obstacles. While ISO 9001 dominates implementations, driven by desires for process optimization and improved patient care, significant barriers persist, including lack of commitment, financial constraints, and administrative burdens. Despite limited explicit discussion of technological solutions in the literature, digital technologies could facilitate ISO implementation, particularly through integration with healthcare-specific ISO standards. However, technology adoption might exacerbate existing challenges related to training and organizational commitment. Understanding the implementation dynamics provides healthcare organizations with insights for decision-making regarding ISO adoption. Furthermore, the findings can support policymakers in developing targeted initiatives for smoother ISO standard implementation across the healthcare sector, laying the groundwork for future research in this important area.

1 INTRODUCTION


The healthcare industry stands as a fundamental pillar of societal well-being and economic development, representing one of the largest service sectors in OECD countries with projections indicating continued growth in the coming decades (Weisz et al., 2020).


Nonetheless, its growth might contribute to climate change (Weisz et al., 2020). Indeed, the global healthcare sector's annual greenhouse gas emissions are comparable to those of 514 coal-fired power plants (Mominkhan et al., 2023). In OECD


countries, the healthcare sectors account for 5% of national carbon dioxide emissions (Mominkhan et al., 2023). Furthermore, the healthcare sector's contribution to pollution, in turn, has negative consequences for public health (Eckelman et al., 2018).


In response to these challenges, many healthcare organizations have turned to standardized management systems. Indeed, various standards for healthcare operations have been established by the International Organization for Standardization (ISO).


Implementing ISO standards has been linked to positive outcomes in healthcare, including greater

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patient satisfaction and safety and enhanced profitability since they provide a robust framework for process management and continuous improvement (Villa-Gallón et al., 2024).

A recent study conducted by Creixans-Tenas et al. (2019) identified the ISO standards with the most significant implications for healthcare, which are: ISO 9001 (Quality Management System, ISO 14001 (Environmental Management System, ISO 45001 (Occupational health and safety management systems), ISO 50001 (Energy Management System), and ISO 26000 (Guidance on Social Responsibility), (ISO 2010; ISO 2015a; ISO 2015b; ISO 2018a; ISO 2018b). Indeed, potential benefits of ISO implementation are well known, as demonstrated in literature. For instance, quality following ISO 9001 adoption, educational institutions realized sustained improvements in service (Arribas Díaz et al., 2018). Integrated ISO systems can lead to operational efficiency in the manufacturing sector (Fahmi et al., 2021), as well as improved operational processes and customer relations in the food industry (Agus et al., 2020). Furthermore, simultaneous implementation of ISO 45001 and ISO 14001 can reduce administrative overhead and lead to more robust management systems (Pauliková et al., 2022).

Nevertheless, obstacles to ISO implementation remain significant in healthcare organizations. Such is the case of constraints on resources, high costs related to certification, or opposition within organizations, (Carrillo-Labela et al., 2020; Mitchell & Fakhruddin, 2022). Such challenges largely depend on the heterogeneity of organizational types, sizes and missions, creating various degrees of needs and capabilities for implementing ISO standards.

A possible solution to address such issues might lie in digital technologies. For instance, Artificial intelligence (AI) or Machine Learning (ML) can transform healthcare, leading to a future with increased personalization, precision, predictive capabilities, and portability (Channapatna 2023).

Previous reviews have focused on specific aspects: Rakhmawati et al.'s (2014) comprehensive review of ISO 9001 in healthcare revealed that while quality management standards are widely adopted, there is no clear evidence of their effectiveness in driving broader sustainability outcomes. Similarly, Sherman et al.'s (2020) systematic review identified a critical need for standardized approaches to measure and improve environmental performance in healthcare, but did not explore how existing ISO frameworks could fulfil this need.

Indeed, an overview focusing specifically on healthcare remains unexplored. In addition, an

exploration of how technologies might foster ISO implantation is also needed. Considering this, the aim of this exploratory review is to provide an overview of the primary factors leading to ISO implementation or hindering as well as exploring which digital technologies can overcome implementation issues. Hence, this research aims to address the following questions:

- What are the primary factors promoting and hindering the adoption of the most relevant ISO standards (14001, 45001, 9001, 26000, and 50001) in healthcare institutions?
- What technologies can healthcare organizations employ to effectively overcome ISO implementation barriers?

Understanding these implementation dynamics is important for developing effective strategies that promote widespread ISO adoption in the healthcare sector, thus overcoming its environmental challenges.

The subsequent sections of this paper are structured as follows: first, the Methodology section details the systematic approach used for literature selection and analysis; second, the Results and Discussion section presents and discuss the key findings, followed by conclusive remarks.

2 METHODOLOGY

To answer the abovementioned research questions this study adopted an exploratory semi- systematic literature review. A semi-systematic review merges the exhaustive nature of systematic reviews with the interpretative adaptability of narrative ones (Snyder, 2019). To ensure methodological soundness and clarity, the researchers strictly adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Page et al., 2021).

The research focused exclusively on Web of Science as the primary academic database. Keywords selection encompassed the most relevant ISO standards according to Creixans-Tenas et al. (2019). Hence, the study concentrated on five specific ISO standards: ISO 9001, ISO 45001, ISO 14001, ISO 26000, and ISO 50001, all contextualized within the healthcare domain.

Only English peer-reviewed articles and reviews published in academic journals were considered, aligning with recommendations from scholarly research that emphasize the superior utility of such publications (Ceulemans et al., 2015; Saunders et al., 2009). To ensure contemporaneity and relevance, the temporal boundary was defined from 2010 to 2024,

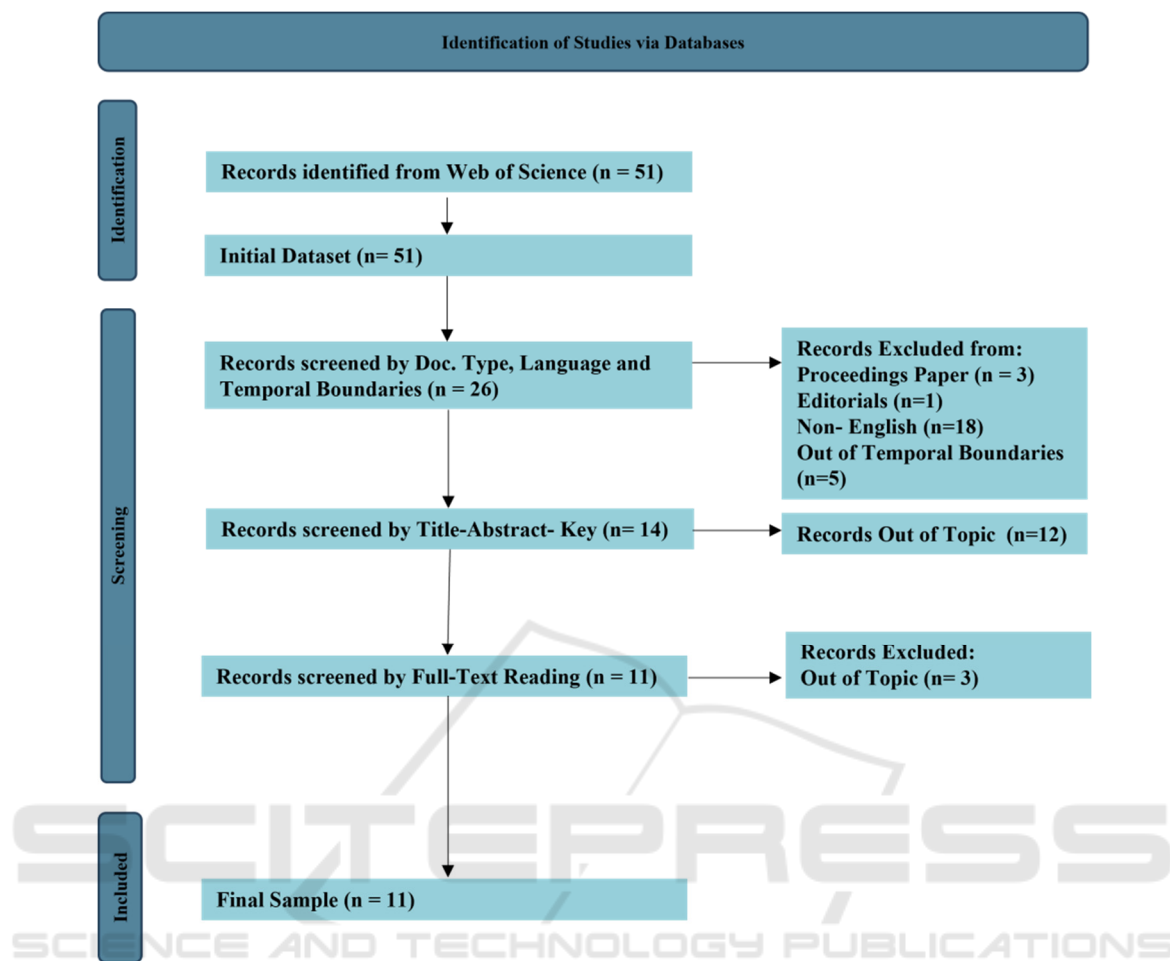


Figure 1: PRISMA Flowchart.

coinciding with the issuance of ISO 26000 in 2010. Studies were selected if there are explicit mentions of challenges, barriers, drivers, or benefits related to ISO standards in healthcare contexts.

An initial search generated 51 potential studies, which were subsequently refined through progressive filtering. Document type, language constraints and temporal filter further narrowed the selection to 26 articles. Examination of titles and abstracts culminated in 14 studies, with a final selection of 11 articles after full text reading. The selection process is illustrated in figure 1.

3 RESULTS AND DISCUSSION

Among the 11 articles analyzed, the overwhelming majority (9 out of 11) mentioned ISO 9001:2015 as the most important standard to be implemented in healthcare. This dominance of ISO 9001 reflects a

traditional focus on quality management in healthcare organizations, driven by patient safety concerns and regulatory requirements. While such focus demonstrates a clear understanding of its immediate benefits for patient care, it also suggests that healthcare organizations may need guidance in recognizing the value of other ISO standards that could complement their quality management efforts. Indeed, this inadvertently overshadows other crucial aspects of healthcare operations that could benefit from standardization.

The complete absence of ISO 26000:2010 implementation studies in the sample is particularly noteworthy, implying an important gap between healthcare organizations' social responsibilities and their management practices. Healthcare organizations bear significant social responsibility towards both patients and employees, and ISO implementation could help achieve sustainable development objectives (ISO 2010). This gap is especially concerning given healthcare's central role in

community wellbeing and social equity. The lack of ISO 26000 adoption might indicate either limited awareness of the standard's potential benefits or challenges in translating social responsibility principles into concrete healthcare practices. Indeed, current approaches to promoting ISO standards in healthcare appear to be too narrowly focused on operational aspects while overlooking broader societal impacts.

The limited exploration of ISO 14001:2015 and ISO 50001:2018 in the literature (found in only 3 articles) suggests that environmental and energy management remain secondary priorities in healthcare organizations' standardization efforts. This finding is particularly relevant given the healthcare sector's significant environmental footprint. Organizations might benefit from an integrated implementation framework that demonstrates how environmental and energy management standards can support and enhance quality management objectives, rather than competing with them for resources and attention. Dion et al. (2023) demonstrated that adopting ISO 50001:2018 guidelines can lead to better energy efficiency in hospitals, providing concrete evidence of potential benefits. However, the limited adoption of these standards might indicate a disconnect between healthcare organizations' environmental impact awareness and their willingness to implement systematic solutions. Seifert's (2018) findings regarding barriers to ISO 14001:2015 implementation - particularly lack of commitment and awareness - point to deeper organizational challenges. These barriers might reflect broader institutional resistance to environmental initiatives in healthcare settings, where immediate patient care concerns often overshadow longer-term sustainability goals. This suggests a need for better integration of environmental management with core healthcare operations.

The heavy focus on quality management with limited attention to environmental, energy, and social responsibility standards, raises questions about the healthcare sector's readiness to address its broader societal impacts. This imbalance might need to be addressed through policy interventions, enhanced awareness programs, or revised implementation frameworks that better integrate different ISO standards.

3.1 Barriers and Drivers

Nearly half of the analyzed articles signaled lack of commitment, awareness and knowledge of either the top management or employees, as the predominant form of barrier to ISO implementation. Indeed,

efficient fulfilment of standards can be realized only with a strong level of commitment (López-Púa et al., 2023). The fact that this barrier persists across different types of institutions suggests potential systemic issues in how ISO standards are introduced and promoted within healthcare organizations. This could indicate a need for more sector-specific implementation approaches that account for healthcare's unique organizational dynamics.

ISO implementation can also become very financially demanding (Dion et al., 2023; López-Púa et al., 2023). Financial demands come in the form of certification fees, training the employees and logistics. Securing funds in the context of public hospitals, for the purpose of financing certifications, can be problematic (Veronese et al. 2020). This is particularly significant for public healthcare institutions, where the competing demands of immediate patient care needs and long-term quality improvements create complex resource allocation challenges. The variation in financial challenges between public and private institutions suggests a need for differentiated support mechanisms and implementation strategies.

The numerous administrative tasks required for obtaining certification may also impede ISO implementation (Franchina et al., 2023; López-Púa et al., 2023).

As mentioned at the beginning, the diverse nature of healthcare organizations can create obstacles in implementing ISO standards. Indeed, Different organizations may have distinct experiences (López-Púa et al., 2023; Nurcahyo et al., 2020) and may implement ISO standards in their own unique ways (López-Púa et al., 2023). While this diversity complicates standardization efforts, it may also shed light onto how ISO standards can be adapted to different healthcare contexts. The organizational changes triggered by ISO implementation suggest that these standards act not just as management tools but as catalysts for broader institutional transformation (Johannessen & Wiig, 2020).

Additional hurdles in ISO implementation include insufficient training (Silva et al., 2017; Seifert 2018; Franchina et al., 2023) and limited understanding among stakeholders about green operations and comparative energy costs, especially in relation to energy management systems (Dion et al., 2023).

Moreover, the ability to access various IT systems has been recognized as an impediment to implementing ISO 9001:2015 (Avruscio et al., 2022). Institutions are primarily motivated by the potential for internal management enhancement and process optimization (Avruscio et al., 2022; Corsi et

al., 2020). This manifests through the establishment of better-quality processes, systematic internal audits, and robust risk management approaches (Franchina et al., 2023).

The drive for continuous improvement emerges as a recurring theme across multiple studies (Franchina et al., 2023; López-Púa et al., 2023; Silva et al., 2017), suggesting its fundamental role in ISO adoption.

From a patient-centric perspective, healthcare organizations are motivated by the potential to enhance patient satisfaction (Dion et al., 2023; López-Púa et al., 2023) and improve patient safety through better diagnosis processes and measurement quality (Farfán-Vargas et al., 2024; Huf et al., 2024). The economic dimension also plays a significant role, with institutions seeking cost efficiency and improved staff productivity (Dion et al., 2023). External factors, such as governmental requirements, can also serve as catalysts for ISO implementation (Nurcahyo et al., 2019).

Furthermore, the standards' implementation is viewed as a strategic tool for enhancing competitiveness (Farfán-Vargas et al., 2024) and promoting sustainability in healthcare systems (Silva et al., 2017).

3.2 Digital Innovations and ISO Standards in Healthcare

Despite the potential of digital technologies to facilitate ISO implementation in healthcare, this review reveals limited explicit discussion of technological solutions in the current literature. However, some studies highlight both existing applications and future needs. The implemented technologies range from basic digitalization and automation processes to more sophisticated IT systems (Huf et al., 2024). Telemedicine emerges as a notable technological application in healthcare settings pursuing ISO compliance (Farfán-Vargas et al., 2024), representing an interesting convergence of quality management and digital innovation. This intersection suggests that digital technologies might serve dual purposes: facilitating ISO compliance while simultaneously modernizing healthcare delivery. However, the limited explicit discussion of technological solutions in the literature points to a potential disconnect between quality management practices and digital transformation initiatives in healthcare organizations.

The need for digital tools and innovative solutions to support ISO implementation is explicitly recognized (Dion et al., 2023; Franchina et al., 2023), suggesting an important opportunity for integration

with existing healthcare-specific ISO standards for digital technologies. For instance, while healthcare organizations are increasingly adopting digital medical technologies to enhance accessibility and flexibility (Senbekov et al., 2020), standards like ISO 13131 for telehealth services could complement quality management systems by ensuring patient safety in digital environments (ISO 2021; Meijer & Taylor, 2022). Similarly, as healthcare organizations implement sustainability-focused technologies such as real-time consumption monitoring software and renewable energy systems (Dion et al., 2023), they could benefit from integrating these with existing digital health standards. The healthcare sector's digital transformation, encompassing Internet of Medical Things (IoMT), telemedicine systems, and electronic health records (EHRs) (Rahim et al., 2024), suggests that a more integrated approach to ISO implementation could be beneficial. This could include combining traditional management system standards with healthcare-specific digital standards like ISO 11073 for remote patient monitoring (ISO 2008) and ISO 27799 for healthcare information security (ISO 2016). Such integration could create synergies that address both operational efficiency and digital innovation needs while ensuring compliance with quality, environmental, and safety requirements. This gap between the recognized need for technological innovation and actual implementation suggests an important area for future research and development. The limited discussion of digital technologies in the reviewed literature, coupled with explicit calls for more innovative tools, indicates an emerging awareness of technology's potential role in facilitating ISO implementation, even though concrete applications remain underexplored.

4 CONCLUSIONS

This exploratory review has provided an overview of the implementation dynamics of ISO standards in healthcare organizations, addressing the drivers, barriers, and potential role of digital technologies.

The dominance of ISO 9001:2015 demonstrates healthcare organizations' commitment to quality management yet also reveals potential gaps in addressing other critical areas. The notable absence of ISO 26000 implementation studies and limited adoption of environmental standards suggests healthcare organizations may be overlooking opportunities to address their broader societal and environmental impacts. This imbalance requires attention from both healthcare leaders, policymakers

as well as researchers to ensure a more comprehensive approach to standardization.

The prevalence of organizational resistance and lack of commitment indicates a need for more effective change management strategies specifically tailored to healthcare settings. Financial constraints, particularly evident in public healthcare institutions, necessitate innovative funding mechanisms and policy support. Administrative burdens could be mitigated through better integration of management systems and strategic use of digital technologies.

The relationship between digital technologies and ISO implementation emerges as a critical area for development. While technology shows promise in addressing certain implementation barriers, particularly administrative challenges, its successful integration requires careful consideration of organizational readiness and capacity. It is important to note, in fact, that technological solutions might exacerbate certain challenges, such as the existing issues with lack of training and commitment, if not properly managed.

Healthcare organizations must develop comprehensive strategies that align digital transformation initiatives with ISO implementation efforts. Healthcare administrators should consider developing integrated approaches that balance quality management with other ISO standards, while policymakers could work to develop targeted support mechanisms for public healthcare institutions. Technology providers might focus on creating healthcare-specific solutions that address ISO implementation challenges while minimizing additional training requirements.

Future research should examine successful ISO implementation strategies in different healthcare contexts, analyze the experiences of public versus private healthcare institutions, and investigate the barriers to implementing environmental and social responsibility standards. Empirical studies examining how digital technologies specifically address ISO implementation barriers in healthcare settings are needed. Additionally, scholars should assess the long-term impacts of integrated ISO systems on healthcare outcomes and evaluate digital technology's role in facilitating ISO implementation. Finally, healthcare administrators and policymakers could benefit from investigating how digital transformation might influence organizational commitment and training requirements in the context of ISO implementation.

Understanding of ISO implementation dynamics, coupled with strategic technological integration and targeted policy support, will be crucial for healthcare organizations to successfully balance quality

improvement, environmental responsibility, and social impact while maintaining operational efficiency in an increasingly complex healthcare landscape.

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