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BLOCKCHAIN AS A QUALITY MANAGEMENT TOOL IN HEALTHCARE INSTITUTIONS: ENSURING DATA INTEGRITY AND PATIENT SAFETY

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Abstract: The study adopts a conceptual research design that combines a structured synthesis of the scholarly literature with a comparative review of selected international initiatives. This approach enables the identification and clarification of the key mechanisms through which blockchain can be integrated into quality management practices. The results of the study highlight four key dimensions of blockchain's contribution to quality management: transparency and traceability, security and trust, automation and efficiency, and practical information sharing through a common record for all authorised actors. In parallel, the study delineates constraints associated with standardisation, interoperability, cost, privacy, and scalability, which collectively shape both feasibility and operational performance. The findings indicate that blockchain can serve as an organisational mechanism for structuring and reinforcing quality processes by enhancing auditability and supporting evidence-based decision-making; however, its practical impact depends on appropriate governance arrangements and effective integration with existing systems and workflows.

Keywords: *digitalisation, QMS, medical system, data integrity, data protection, traceability, interoperability.*

JEL code: *I10; I18; O33; L86*

Introduction

The quality of healthcare services is one of the central pillars of the sustainability of modern healthcare systems. In a context marked by the growing volumes of data, accelerated digitisation, and societal demands for greater transparency, healthcare institutions are increasingly required to implement innovative solutions that guarantee the integrity, traceability, and security of patient data and clinical processes.

Quality management in medical institutions has as its fundamental objective to guarantee patient safety and organisational performance, through standardised processes, risk control and continuous improvement. However, a persistent and significant vulnerability in healthcare systems concerns unauthorised alterations or inadvertent errors in medical records, which may undermine clinical decision-making and erode patient trust. In this context, blockchain technology, initially established through use in the financial sector, is increasingly demonstrating its relevance in the medical field, where the requirements for traceability, accountability, and process control are particularly high. Beyond its function as a distributed ledger, blockchain can support quality management by creating a unified record of critical events, reducing the risk of inconsistencies and reporting errors.

In this context, blockchain technology that initially was developed and widely adopted in the financial sector became increasingly recognised as relevant to healthcare, where requirements for traceability, accountability, and process control are especially stringent. Beyond its role as a distributed ledger, blockchain can strengthen quality management by enabling a shared, tamper-evident record of critical events, thereby reducing inconsistencies and minimising reporting errors [1–3]. Concurrently, by safeguarding the integrity and verifiability of records, blockchain enhances audit and compliance capabilities, thereby facilitating the demonstration of adherence to regulatory standards and applicable requirements [4,5]. Thus, blockchain can be seen as an operational support

for increasing patient safety and improving the continuity and transparency of quality processes in medical institutions.

Conceptual approach to blockchain technology

Blockchain technology has undergone an accelerated development in recent years, becoming intensely discussed both in the scientific environment and in practice, amid its ability to support more transparent, secure and less dependent systems on intermediaries. Through its decentralised architecture and transaction validation mechanisms, blockchain provides prerequisites for increasing trust between participants and improving the traceability of information and data flows [1,6,7]. The literature deals with this field from a variety of conceptual and applicative angles: from theoretical clarifications and explanatory models on the functioning and governance of distributed networks, to analysis methodologies and evaluation tools.

The adoption of blockchain in organisations, including healthcare institutions, is not without its challenges, as it involves aligning technical, organisational, and regulatory requirements. Firstly, there is a need for standardisation and interoperability so that the blockchain can work coherently with existing systems and flows. At the same time, initiatives of this type involve implementation, training and maintenance costs, and the benefits must be demonstrated through quality and safety indicators [1]. A major challenge is privacy, as healthcare data is sensitive and must be protected through strict access controls and legal compliance policies. Last but not least, scalability is a concern: the solution must handle large volumes of events and users without affecting process speed or operational reliability.

An open quality framework (OQB) supported by blockchain in the context of Industry 4.0 strengthens trust among actors in the production chain by providing a common, verifiable record of quality-relevant events [8]. Through greater transparency and traceability, organisations can more clearly track the origins of materials, process steps, and control points, identifying deviations and defect causes more quickly. As a result, quality decisions become better informed and faster, reducing the costs of non-quality and the risk of delivering non-compliant products. In the medium term, this approach supports continuous improvement and increases the robustness of both products and production systems.

Within the supply chain, blockchain can support much more rigorous traceability by consistently recording the stages the product passes through – from the origin of raw materials, through processing and packaging, to transport, storage, and delivery to the end user [1,9]. Such a common record enables rapid identification of the point where a deviation occurred, thereby reducing investigation time and enabling the application of corrective measures or targeted product recalls. In addition, access to verifiable information reduces disputes among participants and limits informational asymmetries, as each actor has access to the same data. As a result, trust between partners increases, and the credibility of quality and compliance processes is strengthened throughout the supply chain. Blockchain can strengthen transparency and trust among actors, as it provides a common, verifiable, and easy-to-track record of steps and transactions along the chain. Especially in the agri-food sector, where there are many intermediaries and risks of non-compliance, this increased visibility reduces information asymmetries and limits disputes over origin, quality, processing or transport conditions [10,11]. As a result, cooperation between manufacturers, processors, distributors, retailers and authorities becomes more efficient, based on credible data and clear traceability. Additionally, by tracking material flows and responsibilities, blockchain can support circular practices, making it easier to implement and monitor them consistently.

In industry, blockchain, the integration of processes with IoT sensors, and the use of machine learning techniques enable continuous quality supervision based on automatically collected and updated data [12]. Critical parameters such as temperature, humidity, vibration, pressure, process times, or energy consumption can be continuously monitored without reliance on periodic manual checks [8]. In this way, blockchain supports quality management by ensuring the traceability and integrity of records, which facilitate auditing, demonstrate compliance, and clarify responsibilities throughout the production flow. In parallel, machine learning algorithms can analyse these data streams in real time to identify deviations and anomalies, and the resulting signals can trigger rapid

and documented interventions. By combining these technologies, the organisation reduces the risk of errors and data manipulation, shortens the reaction time to non-conformities, and strengthens continuous quality improvement.

Technically, blockchain is presented as a decentralised ledger system that records and validates transactions on a peer-to-peer network, enabling two parties to exchange without a central authority [6]. The aim is for participants to gain trust, security, transparency, and the assurance that the data cannot be further modified.

To highlight the economic logic of how blockchain works and how it can support coordination, traceability, and trust among pharmaceutical value chain actors, Figure 1 summarises the main steps in recording, validating, and confirming transactions in a decentralised network.

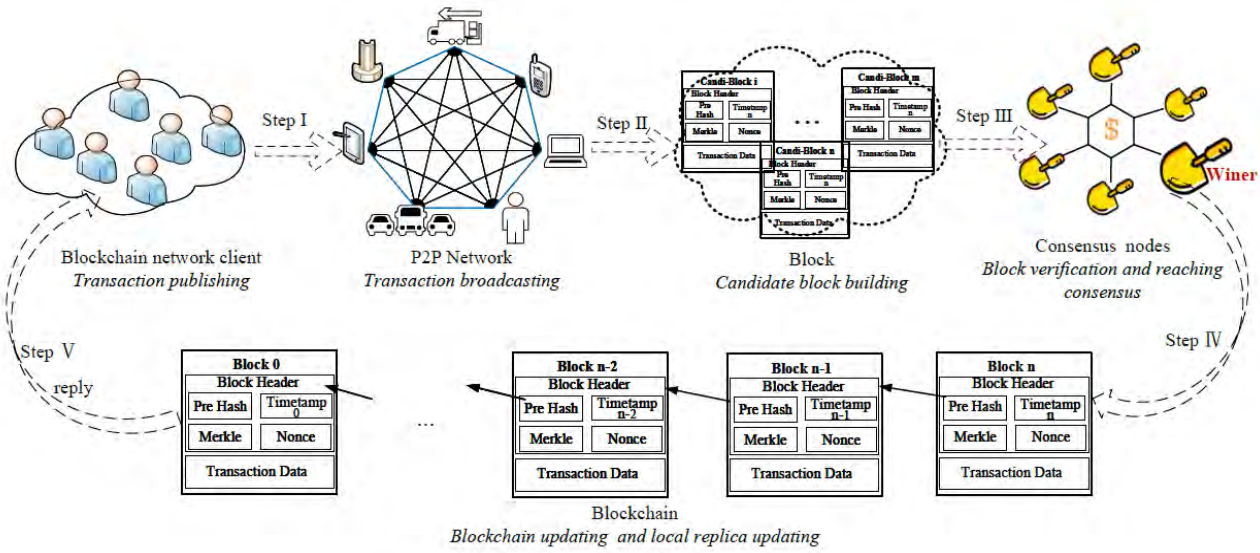


Figure 1. An overview of blockchain workflow

Source: [6], p.3

The figure illustrates a workflow in which blockchain can serve as a quality management tool, ensuring consistent, verifiable recording of relevant events (e.g., production, testing, shipping, receiving) throughout the pharmaceutical supply chain. By transmitting information to all participants and validating it through a common confirmation mechanism, a uniform record is created that reduces the risk of non-conformities, errors and contradictory reporting. Once confirmed, records are "fixed" in a chronological sequence, which facilitates traceability, auditing, and demonstrating compliance with regulatory standards and requirements. In this way, the blockchain supports rapid prevention and investigation of quality issues by providing a clear history of responsibilities and checkpoints.

Connections between blockchain technologies and quality management in healthcare institutions

As digital technologies evolve, they are increasingly integrated into quality management, becoming an essential support for monitoring, control and continuous improvement in almost all areas of activity [13,14]. The connections between blockchain technologies and quality management in healthcare institutions stem from the idea that patient safety and organisational performance depend directly on data integrity, process traceability, and the capability for auditing and compliance. In practice, many non-conformities and adverse events are driven by incomplete documentation, fragmented information flows, difficulties verifying changes, and the lack of a uniform record across actors. In this context, blockchain is approached not as an IT solution in itself, but as an organisational mechanism that can support the discipline of quality processes through verifiable ledgers, clear accountability, and controlled information sharing.

Figure 2 summarises, at a conceptual level, the main dimensions through which blockchain can support quality management in medical institutions.

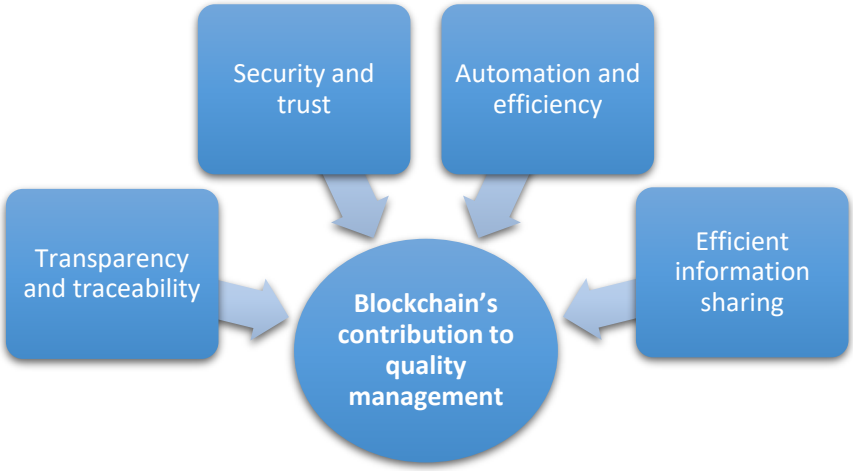


Figure 2. Key dimensions of blockchain as a quality management tool in healthcare institutions

Source: elaborated by the authors

At the heart of the model is the contribution of blockchain to quality, and four impact directions are grouped around it: transparency and traceability, security and trust, automation and efficiency, and efficient information sharing. Together, these dimensions indicate how blockchain can strengthen process control and patient safety by enabling verifiable records and more consistent collaboration among actors.

Transparency and traceability are enabled by the blockchain's creation of a coherent, verifiable history of key events that remains stable over time and can be consulted by authorised actors. Thus, each relevant step is documented in a manner that allows for quick tracking of "who-what-when-where" [1,4,8]. Consequently, when deviations or errors occur, the organisation can more effectively identify the point of non-compliance and establish clear responsibilities, which supports auditing, corrective action, and recurrence prevention.

Security and trust are strengthened because the information recorded in a blockchain becomes difficult to alter after validation, and any attempt at intervention would be easy to detect through the network's verification mechanisms [2,5,7]. This feature limits the possibility of "last" changes, reducing the risks of falsifying records, manipulating reports, or hiding errors. As a result, partners such as healthcare institutions, laboratories, suppliers and authorities can collaborate based on more credible records, which increases trust and facilitates auditing and demonstrating compliance.

Automation and efficiency can be supported by smart contracts, which turn certain quality and compliance rules into automatically applied procedures based on pre-established conditions [12,15]. In this context, routine validations, confirming the completeness of documentation or triggering alerts when deviations occur can be carried out without manual intervention, which reduces the dependence on repeated checks and reduces the risk of human error. In addition, by automating these steps, the institution can respond more quickly to non-compliances, shortening response time and improving control over critical processes.

Efficient information sharing is enabled by the blockchain, which creates a common record consultable by authorised actors, so that manufacturers, suppliers, medical institutions and authorities operate based on the same verified data [3,16]. In this way, the differences between "what each party knows" are reduced, as there are no longer parallel versions of information or contradictory reports from separate systems. The consequence is better coordination of processes and faster decisions in critical situations, such as verifying provenance, confirming compliance, managing a recall, etc., with less risk of misinterpretation or bottlenecks caused by a lack of information.

Taken together, these dimensions highlight that blockchain can be leveraged as a tool to support quality management in healthcare institutions, not through its focus on technical infrastructure, but through its effects on process control and organisational discipline. By strengthening traceability, increasing trust in data, automating verifications and facilitating

collaboration between actors, blockchain contributes to reducing non-conformities and improving audit and reaction capacity. Consequently, this approach can support patient safety and compliance objectives, providing a more robust framework for evidence-based decisions and for preventing repeat errors.

The adoption of blockchain in organisations, including healthcare institutions, is not without its challenges, as it involves aligning technical, organisational, and regulatory requirements. Firstly, there is a need for standardisation and interoperability so that the blockchain can work coherently with existing systems and flows. At the same time, initiatives of this type involve implementation, training and maintenance costs, and the benefits must be demonstrated through quality and safety indicators [1]. A major challenge is privacy, as healthcare data is sensitive and must be protected through strict access controls and legal compliance policies. Last but not least, scalability is a concern: the solution must handle large volumes of events and users without affecting process speed or operational reliability.

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From the above, it can be concluded that the connection between blockchain and quality management in medical institutions is shaped by its ability to transform clinical and operational information into a more controllable, auditable, and credible record, which directly supports patient safety and compliance. Therefore, blockchain must be seen as a tool for disciplining quality processes, and its real impact depends on the alignment between infrastructure, regulations, costs and the ability of organisations to adapt their practices and responsibilities.

International experience in implementing blockchain in medical institutions

The adoption of blockchain in healthcare institutions has been explored through pilot projects and implementation initiatives in various countries, but the reported impact differs significantly from case to case. The results depend not only on technological maturity but also on local conditions: the level of hospital digitisation, interoperability between systems, the availability of standardised data, and the ability of organisations to change existing processes. At the same time, the regulatory framework directly influences how the solution can be designed and used, especially when sensitive patient data is involved. Therefore, blockchain does not automatically yield the same benefits everywhere, and the success of implementation is closely linked to alignment between infrastructure, governance, and the specific requirements of the health system, as further argued by the current experience of different countries in this field.

Estonia is frequently cited as an example of maturity in e-Health, as it has operationalised, at the national level, an electronic medical record system that integrates blockchain-inspired mechanisms to strengthen integrity and auditability. Since 2016, the Estonian approach has aimed to protect and verify the use of health data on a population scale (more than one million citizens) by combining national electronic identity with registers that allow access and changes to be tracked in a verifiable way[17]. From a quality management perspective, Estonia's experience demonstrates the feasibility of a scalable, publicly governed solution, supported by public-private partnerships, that strengthens process control, compliance, and trust among health system actors.

In the European Union, the experience of implementing blockchain in healthcare is heterogeneous mainly and still consolidating: initiatives are simultaneously influenced by standard rules at EU level and the legislative particularities of each member state, which explains the differences in approach and pace [18]. As a result, many approaches focus on readiness and compliance, security, consent, accountability and governance, before large-scale scale-ups, and benchmarking points to the need for harmonisation of rules and practices to facilitate interoperability

between systems [18]. A sore point remains the tension between the difficulty of modifying records and GDPR rights, which is why controlled architectures and mechanisms that limit the exposure of personal data are preferred. Thus, in the European Union, the adoption of blockchain in healthcare is advancing mainly through prudent, GDPR-compliant projects, and scaling up depends decisively on harmonising the legal framework and increasing interoperability between member states.

In the UAE, blockchain is promoted through a strategic government-level approach, oriented towards the efficiency of public services, ecosystem development, and international leadership, which has created a favourable framework for health projects and pilots[19]. In the healthcare sector, MoHAP has launched both a blockchain platform for storing and validating information about licensed medical and pharmaceutical institutions, medical personnel and drug data, and a blockchain system for sharing health professionals' assessment/credentialing information with licensing authorities, aiming to reduce time and costs and increase data integrity [20]. Thus, the UAE's experience shows that the benefits of blockchain for quality control and compliance materialise more easily when public strategies are doubled by transparent governance and consistent operational rules for sensitive data.

In Southeast Asia, a relevant direction for the use of blockchain in healthcare foresees the development of regional platforms for the exchange of Personal Health Records (PHR) through the Asia eHealth Information Network (AeHIN), to facilitate quick and controlled access to clinical information when the patient receives care in another country. The literature describes this solution as already implemented/piloted in countries in the region and positioned as the first PHR management platform for cross-region medical exchange through AeHIN [21]. In transnational trials, including scenarios involving the Philippines and Thailand, the patient explicitly grants the physician access authorisation prior to the consultation, and the history of interventions remains verifiable, supporting continuity of care and accountability of actors. The platform emphasises standardisation and interoperability so that data is clinically usable in different contexts, and user feedback emphasises the usefulness of the standardised format, the efficiency of data exchange, and increased trust in system security [21]. The experience of Southeast Asia shows that blockchain can serve as a "confidant" for cross-border exchange of medical data, especially when combined with interoperability standards and a clear model of consent and access. At the same time, the results on the use of blockchain in this region suggest that practical utility and scaling depend on regional governance and the alignment of procedures between different health systems, not just on the technology itself.

In South Africa, a relevant example is the piloting of a Hyperledger Fabric-based electronic medical record (EHR) system at Frere Provincial Hospital, designed as a decentralised platform for securely storing, managing, and sharing data between stakeholders, with a focus on transparency and access control [22]. In a quality management context, the central value of such a solution is that each access and update is auditable and verifiable, supporting the traceability of clinical decisions and the accountability of staff. The architecture clearly differentiates the institutional roles from those of the patient, and access is restricted to authorised users, thereby strengthening the integrity of processes and records through uniform validation and registration rules. From the perspective of quality control and patient safety, the authors emphasise that Fabric registries provide data permanence and integrity, reducing the risks of manipulation and increasing confidence in the authenticity of the information used in care [22]. Frere Hospital's experience shows that blockchain can serve as a "trust mechanism" for quality management through auditability, traceability, and protection of EHR integrity, but the impact at scale depends on infrastructure maturity, performance, and clear rules of use.

In the Republic of Moldova, discussion of blockchain technologies in healthcare is increasingly emerging in the context of digital transformation and innovation, but publicly available information suggests its actual use in medical institutions remains limited and poorly documented on a large scale. Instead, there is a more pronounced focus on strengthening digital infrastructure, interoperability, and data security requirements, which may be prerequisites for such solutions in the future.

International experience shows that blockchain can become a valuable tool for quality management in healthcare when integrated into well-governed architectures and processes that are oriented towards auditability, traceability, and data integrity. However, the results are not uniform: success depends on the degree of digitalisation, data interoperability and standardisation, as well as the maturity of the legal framework and the ability of institutions to adapt their operational procedures. The cases analysed indicate that the benefits are clearer where there is coordination at the national or regional level and strict rules on privacy and access, while a lack of harmonisation and compliance constraints can slow scaling. For the Republic of Moldova, this comparison suggests that the immediate priority is to strengthen digital infrastructure and interoperability, so that future implementations of blockchain can be realistically assessed through quality and patient safety indicators.

Conclusions and future research directions

Blockchain can be leveraged in healthcare institutions to support quality management by strengthening data integrity, process traceability, and audit and compliance capabilities, thereby reducing the effects of incomplete documentation and fragmented information flows. At a conceptual level, its contribution is explained by four dimensions that act in complementarity, through characteristics such as transparency and traceability, security and trust, and automation and efficiency, respectively, indicating how process control and patient safety can be strengthened through verifiable records and more coherent collaboration between actors. At the same time, comparisons of international experiences highlight that the effects of implementation are not uniform, and results depend on the alignment between infrastructure, governance, and the specific requirements of the health system, including the legal framework and the level of interoperability between systems.

Future research directions should focus on moving from the conceptual argument to operational validation by developing indicators that measure the effects on quality and safety, so that the benefits can be rigorously demonstrated relative to the costs of implementation and maintenance. At the same time, applied research is needed on standardisation and interoperability with existing systems, the design of governance and access policies for sensitive data, and testing scalability in real-world conditions, because without these, blockchain risks remaining an isolated solution with limited impact on the discipline of quality processes.

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