

Leveraging Blockchain Technology For Enhancing Medication Traceability And Pharmaceutical Supply Chain Integrity In Clinical Pharmacy

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Abstract

Blockchain technology is revolutionizing the face of industries worldwide and is especially revolutionary in the use of the pharmaceutical supply chain. This decentralized, immutable ledger system improves traceability of medication for integrity and fight against counterfeit drugs. The challenges in the pharmaceutical supply chain are many, from fragmented processes and counterfeit medications to strict regulatory standards. Blockchain addresses these issues in a secure, transparent framework for real-time drug traceability, from manufacturing through distribution. This paper discusses the capability of blockchain technology in changing the traceability of medication and managing supply chains within clinical pharmacy. The major implementations are Medledger, on Hyperledger Fabric, which provides tamper-proof transactions as well as more visibility in supply chains. Other uses of blockchain with IoT showed the capability of blockchain in tracking environmental

conditions of transport to assure quality drugs. Although the benefits of blockchain are very numerous, its adoption still faces major hurdles, including technological limitations such as scalability and interactivity, regulatory hurdles, and resistance from stakeholders who are very adapted to traditional systems. Here, strategies toward overcoming the issues will be put forward, in which the problem of standardization, interoperability, and mutual cooperation among the multitude of stakeholders should be emphasized.

Keywords Blockchain technology, Medication traceability, Pharmaceutical supply chain, Counterfeit drugs, Supply chain transparency, IoT integration, Clinical pharmacy.

1.Introduction

Blockchain technology refers to the type of decentralized digital ledger system applied in recording transactions across a distributed network of computers in such a manner that recorded transactions cannot be altered. Its characteristics range from providing transparency, security, and immutability, which makes it pretty vital for applications as diverse as cryptocurrencies and supply chain management and smart contracts. The underlying principle of blockchain is the consensus mechanism, where members in the network agree over the validity of some transactions by not having an authority centralize it. Ruoti (2019), Yaga et al. (2018).

It has a central process-a chain of blocks holding transaction data. Each block has a unique linkage to the preceding one. This configuration provides that a block being added into the chain pretty much makes impossible information it includes to change in ways other than influencing a whole sequence of blocks running down through the rest by consensus majority majority of all such participants across networks (Ruoti, 2019; Yaga et al., 2018). Blockchain technology offers more security because it applies the cryptographic techniques to parts of hash functions and asymmetric-key cryptography in ensuring that only authorized users gain access and amend the data to ensure data integrity (Yaga et al., 2018; Vaghasana & Suliya, 2023).

Blockchain technology has diverse applications and usage that are immense in number. In supply chain management, for example, blockchain will facilitate traceability and transparency to such an extent that every stakeholder will be in a position to track movement in real-time thus reducing fraud and errors (Sabeti et al., 2018; Paliwal et al., 2020). Blockchain can further offer the mechanism of smart contracts as self-executing contracts with the terms of the agreement written directly into code. This can balance out the processes, decrease the number of middlemen needed to reduce many costs and make it more efficient (Martinez et al., 2019). However, with such vast potential, technology remains very juvenile, and most organizations are struggling to understand its capabilities and implement them correctly (Herold et al., 2021; Mathivathanan et al., 2021).

Further, the hype related to blockchain technology has caused it to be overperceived and even misconceived by many; consequently, it is applied to some projects that might not necessarily benefit from this technology (Spencer-Hicken et al., 2023). While exploring ways through which organizations could implement blockchain within their systems, readiness must be evaluated as well as the unique needs of a business model that may allow them to succeed with the integration process (Johnson et al., 2020; Park & Sung, 2020).Currently, research and innovation in this space is concentrated on the practical nature of blockchain to remove the blockages which is affecting its adoption rate, especially amongst the industries of supply chain management (Xie, 2023; Queiroz et al., 2019).

Such systemic complexities emerge through traceability of medication, as well as in maintaining the integrity of the clinical supply chain, from several systemic clinical pharmacy issues. The main challenge is the complexity and fragmentations of the supply chain itself. There are several distinct entities in the pharmaceutical supply chain, including manufacturers, wholesalers, distributors, and pharmacies, which operate within their own systems and processes. This non-integrated nature makes it very challenging to trace drugs accurately and in real-time as they move through one entity to the other. According to Rahaman et al., health care is a complex supply chain network, and because of its lack of information sharing and central control, it is difficult to track products within the said network. Rahaman et al. 2022.

Lastly, one of the dangers that puts at risk traceability of medications is drugs counterfeits. One major percentage of the world supply of drugs is within the scope of counterfeit drugs, especially from developing countries and can pose major threats to patients and further threatens public trust, World Health Organization said. The concept of blockchain has emerged as a solution to this problem: it allows for a transparent and immutable record of transactions along the supply chain. However, it also presents several challenges in its use. For instance, blockchain integration is a total overhauling of the current systems and processes that may face resistance from the stakeholders who are used to the traditional methods (Haq & Muselemu, 2018; Sarkar, 2023).

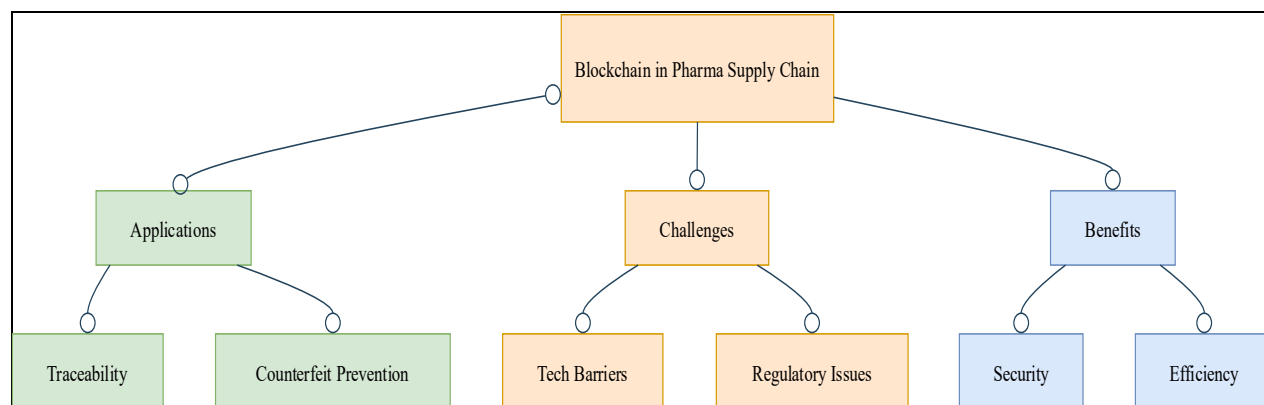


Figure 1. Key Applications of Blockchain in Pharmaceutical Supply Chain.

The second critical challenge would be to comply with the regulatory standards. The pharmaceutical industry is highly regulated, and any system implemented for traceability of medications should comply with different laws and regulations. This makes it a little challenging to introduce new technologies such as blockchain since they do not have regulatory frameworks established on how they can be used in the healthcare industry. To medication traceability, absolute interoperability of multiple systems involved and complete peer-to-peer records would be required. Still, it remains a hard requirement in the real world (Durneva et al., 2020). Data security and privacy should not be disregarded either.

Patient data is sensitive in nature in the health sector, and any system to track medication must provide security and privacy of this information from unauthorized access and breaches. Blockchain technology can offer some advantages for this purpose by enhancing security in its decentralized approach. However, it still faces severe challenges of scale and vulnerabilities that may arise due to the design of the blockchain itself (Putro, 2023). This mainly means that in the pharmaceutical supply chain, there is a missing consistency, making it another problem to efficient traceability. It is possible to have different users of systems and technologies of choice yet the stakeholders are still maintaining diverse systems for the data format and protocols; it may deny the whole chain the easy system needed to share the information with

inevitable effects on the integrity of traceability of medicines. According to Yazdi, traceability is fast emerging as a pressing need in the pharma sector. However, much has to be achieved before that by addressing issues relating to standardization and interoperability (Yazdi, 2023).

2. Current Applications of Blockchain in Pharmaceutical Supply Chains:

2.1 Existing Implementations of Blockchain in Pharmaceutical Supply Chains

One such example is the Medledger system, where a blockchain platform by Hyperledger Fabric is used so that secure transactions between actors in the pharmaceutical industry are enabled in a very efficient manner. This system will trace the medication through the supply chain while ensuring that all transactions are tamper-proof. Medledger removes the need for trusted intermediaries; hence, it is more effective and secure apart from providing a safe traceability framework that could significantly reduce the chances of fake drugs Zhu (2023) Uddin et al., 2021).

Another key development is the blockchain framework by Uddin et al., where the complexities of the pharmaceutical supply chain have been identified. Their research indicates the necessity of an efficient traceability system that traces ownership and movement from raw materials suppliers to the ultimate consumers of pharmaceutical products. The proposed architecture uses Hyperledger Fabric and Hyperledger Besu while underlining the flexibility of blockchain technology in order to meet the specific needs of the pharmaceutical sector (Uddin et al., 2021).

In Nigeria, for instance, a pilot study examined whether it was practicable to employ blockchain technology integration in the drug's logistics network for reducing drug counterfeitness and ascertains through interviews some of the interested parties, who come from either different pharmaceutical organization and regulatory entities to know whether blockchain technology has any utility at the level of drugs traceability. This type of initiative indicates the scope for blockchain to further enhance the legitimacy of the pharmaceutical supply chain, particularly in places with a high incidence rate of counterfeit drugs (Labaran & Hamma-Adama, 2021).

While Walmart's blockchain pilot is more on food traceability, the insights gained from this pilot are applicable to the pharmaceutical sector. It showed how products can be tracked at an item level rather than just batch level, which would give detailed visibility throughout the supply chain. For pharmaceuticals, this capability is important because knowing the exact provenance of a medication can prevent counterfeit products from reaching consumers (Kamath, 2018; Francisco & Swanson, 2018). Apart from this, studies have also been conducted under several research projects related to blockchain implementation in drug traceability. Zhang et al. had proposed a blockchain-based framework for life cycle assessment with IoT and big data analytics for increasing the sustainability of the supply chain. In this approach, importance is given to credible data acquisition, traceability throughout the chain for high quality and safe products (Zhang et al., 2020).

More importantly, Kshetri emphasized the use of blockchain in making supply chains more transparent and accountable, relevant to the pharmaceutical industries. Through the decentralized and immutable record of transactions, blockchain helps reduce the risks that may be found in a product recall and safety vulnerabilities (Kshetri, 2018).

In the literature, there is acceptance of issues in implementing blockchain into pharmaceutical supply chains. Labaran and Hamma-Adama found the specific drawbacks to blockchain in Nigeria as involving a low level of awareness and regulatory constraints in adopting blockchain technology among various stakeholders, which they recognized should be improved through structural intervention that shall facilitate integration with the already defined pharmaceutical framework of supply chain (Labaran & Hamma-Adama, 2021).

2.2 Impact of Blockchain Implementations on Medication Traceability and Supply Chain Integrity

Another wonderful influence of blockchain in traceability of medication is counteracting the spread of fake drugs. The pharmaceutical industry has had the issue of introduction of fake products in the chain, which, as a matter of fact, holds a tremendous danger to patients' safety. Blockchain technology allows the possibility of building a secure system for the management of drugs, able to prove at all sales points that a given drug is genuine. According to Gami, Hyperledger Fabric secures the records of the drug supply chain, hence allowing one to trace the authenticity and origin of the pharmaceutical supplies Gami (2023). This ensures that the consumer receives only authentic medicines for better patient safety and confidence in the health care system.

Through this integration, blockchain technology has improved the visibility of the pharmaceutical supply chain as a whole. Old supply chains are typically non-transparent; it is not uncommon for stakeholders not to see how medicines move. In contrast, the blockchain is shared and tamper-proof; every transaction is, in real time, updated and thus traceable through to the end-users. Elangovan et al. point out that blockchain addresses some of the major issues in the pharmaceutical industry, including the delivery of substandard or counterfeit drugs, by creating a safe and secure platform for supply chain management (Elangovan et al., 2022). Increased visibility not only enhances traceability but also makes it easier to recall defective products, thus reducing risks to patients.

Improvement of traceability-Blockchain technology provides a means of supply chain integrity through data accuracy and minimizing opportunities for fraud in the supply chain. Blockchain operates in a decentralized manner, thereby preventing any form of control or manipulation by an individual over the entire system. Kumar points out that blockchain enhances safety, security, transparency, and trust among supply chain partners. Such aspects are efficient in ensuring that the pharmaceutical supply chain remains legitimate (Kumar, 2022). Blockchain is helpful in enabling a transparent transaction record that can be verified to ensure good stakeholder trust very essential for smooth collaboration in the pharmaceutical industry.

The use of blockchain allows for adherence to regulatory standards. Since pharmaceutical businesses are strictly controlled, record and report accurately and correctly, storing an immutable history of transactions via blockchain in a safe environment would ensure that the information is available to be viewed readily in the case of an audit or review by regulatory bodies. This is very relevant in the case of drug serialization, where it is essential to track batches of medications correctly to ensure compliance with regulations aimed at keeping counterfeit drugs from entering the market (Haq & Muselemu, 2018). Through streamlining compliance processes, blockchain technology can reduce the administrative burden on pharmaceutical companies and improve overall operational efficiency.

Blockchain technology can also be used to make supply chain operations more efficient. As pointed out by Rijanto, blockchain adoption will accelerate supply chain processes by cutting down the time and resources involved in verifying transactions and record-keeping (Rijanto, 2021). It will save the pharmaceutical companies a lot of costs and improve their service delivery to the patients. Further, integration of blockchain with other technologies such as IoT can further enhance supply chain operations through real-time monitoring of medication conditions during transportation, thus ensuring that products are stored and delivered under optimal conditions (Sylin et al., 2018).

However, these benefits notwithstanding, the successful implementation of blockchain in pharmaceutical supply chains is not without challenges. Adoption issues include stakeholder resistance, lack of awareness, and regulatory uncertainties. Yet the more pharmaceutical firms become aware of the advantages offered by blockchain, the higher the inclination will be for the adoption of this technology by the supply chain

management practices. For instance, blockchain in the context of the cold chain network has been mooted as offering guarantee about the integrity of temperature-sensitive medicines and is, in turn, one of the specific ways to which blockchain can be applied as a solution for the particular kind of supply chain challenges (Sarkar, 2023).

2.3 Limitations of Current Blockchain Applications in the Pharmaceutical Sector

2.3.1. Technological Limitations

One of the significant technological limitations is scalability. Most existing blockchain implementations fail to process a large number of transactions that occur in the pharmaceutical supply chain. According to Elangovan et al., blockchain technology can provide an immutable record of transactions, but the current infrastructure may not be able to handle the fast processing of large-scale data required for a comprehensive supply chain management Elangovan et al. (2022). Interoperability among different blockchain systems can also be a problem. In this case, the same supply chain participants may use several different blockchain platforms; therefore, information exchange and interoperations may become challenging (Agbo et al., 2019). The second type of technological challenge facing blockchain adoption is the amount of energy that the networks consume, particularly proof-of-work consensus algorithms. Such an enormous amount of energy use raises issues regarding sustainability as an industry with more and more carbon footprint concern reduction (Kumar, 2022). Lastly, the complexity in implementing blockchain solutions may not make organizations open up to it as it mostly entails a whole transformation of what already exists within an organization (Treiblmaier, 2018).

2.3.2. Regulatory Challenges

Regulatory compliance is another major obstacle to the adoption of blockchain in the pharmaceutical industry. The pharmaceutical industry is heavily regulated, and the introduction of new technology needs to comply with stringent data privacy, security, and patient safety laws. The strict laws the European Union places on data privacy may be used against the underlying nature of blockchain, which allows for transparent forms of record-keeping that would eventually lead to sensitive information on patients" (Kayhan, 2022).

2.3.3. Operational Limitations

It is very operational cumbersome to integrate blockchain technology with the present supply chain. Most organizations lack infrastructure and expertise for effective implementation of blockchain solutions. According to Uddin et al., the multiplicity of stakeholders involved in the pharmaceutical supply chain and varying levels of technological readiness within these stakeholders make it complicated for the digitization of tracking and tracing processes (Uddin et al., 2021). This may lead to stakeholder resistance, motivated by fear of altering their structured workflows. Another aspect is that blockchain applications are data input dependent on correctness and timeliness. If the data entered into the blockchain is wrong, the entire system will be compromised. The reliance on data quality requires strict data governance frameworks that most organizations are not yet prepared to do (Sarkar, 2023).

2.3.4. Stakeholder-Related Challenges

The last point of significance is that the stakeholders are critical to ensure successful implementation of blockchain in pharmaceutical supply chains. There can be disintegrated efforts and different levels of application in different sectors, because stakeholders cannot get together for a common objective. Mackey et al. emphasize that widespread collaborations among the players in this regard, i.e., between the pharmaceutical firms and the authorities alongside the technological experts, is almost non-existent though there exist multitudes of prototype and pilot phases (Mackey et al., 2019). Similarly, disparate trust levels in people may serve to be another potential barrier between resource as well as information sharing toward which effective block chain implementation hinges on.

3. Benefits of Blockchain for Medication Traceability

3.1 Blockchain's Role in Enhancing Medication Traceability

3.1.1. Improved Data Integrity

One of the most important reasons blockchain improves traceability of medication is that it has an immutable record of every transaction. Once data has been input, a participant can modify or remove only by consent from the network stakeholders. Transactions are stored securely in a decentralized ledger. This characteristic is essential to maintaining the integrity of the medication records because it eliminates tampering and fraud. Blockchain technology makes sure that the supply chain partners are provided with safety, security, transparency, and trust necessary to mitigate the risk associated with counterfeit medicines Kumar (2022). Authenticity of medicines can only be assured through verification at every stage of the supply chain.

3.1.2. Enhanced Transparency

Blockchain technology increases the transparency of the pharmaceutical supply chain because it ensures that all parties have real-time access to the same information. Shared visibility helps stakeholders track the flow of medications from production to delivery, done through manufacturers, distributors, and pharmacies. As mentioned by Elangovan et al., blockchain provides a distributed shared data platform, hence immutable, trustworthy, and transparent. This requirement can be for effective drug traceability (Elangovan et al., 2022). This not only ensures better inventory management but also the quicker response towards recalls and safety alerts and ultimately enhances the overall safety of the patient.

3.1.3. Secure and Efficient Tracking

Because blockchain is decentralized, it can track medications in a secure manner without the need for a central authority. This is particularly important in combating counterfeit drugs, as it allows verification of each transaction along the supply chain. As per Sarkar, at each transfer point, blockchain technology will ensure the arrival of legitimate medicines to real stakeholders, which develops a decentralized system of drug tracing that can assure security and trust (Sarkar, 2023). Blockchain thus diminishes fraud chances by having cryptographically secured record for each transaction and thus provides only authentic drugs to consumers.

3.1.4. Regulatory Compliance

The drug also satisfies the traceability requirement of the blockchain technology at the regulatory requirements. The pharmaceutical industry is strict, with strict regulations and strict mandates in place for record keeping and reporting accurately. Blockchain technology provides an immutable, transparent record of transactions, which makes traceability easier to abide by such stringent requirements. It follows that blockchain shall help solve some of the identified problems in tracing products in a pharmaceutical supply chain, thus assisting in compliance with laws aimed at preventing counterfeit drugs (Uddin et al., 2021). Such is an essential feature to safeguard the integrity of the supply chain and ensure the safety of every drug.

3.1.5. Integration with IoT and Other Technologies

Also, blockchain can be combined with other technologies, for example, Internet of Things, to further advance the traceability of medication. For instance, with the use of IoT devices to track the conditions under which medications are transported and stored, blockchain would be able to give real-time data on the temperature, humidity, and all other critical factors that affect drug quality. This integration enables

an advance tracking system whereby, on top of ensuring that drugs are authentic, they are also kept and transported under the best conditions (Juturi, 2023).

3.2 Potential Improvements in Patient Safety and Regulatory Compliance Through Blockchain

Table 1. Enhancements in Patient Safety.

Key Area	Description	Citation
Counterfeit Drug Prevention	Blockchain technology enables secure tracking of medications across the supply chain, verifying their authenticity at every transaction point. This significantly reduces the risk of counterfeit drugs reaching consumers and enhances patient safety.	(Ettaloui, 2023)
Improved Recall Efficiency	Blockchain allows rapid identification and notification of affected medications during recalls. Its immutable records enable efficient tracing and removal of unsafe products, improving regulatory compliance and minimizing risks to patients.	(Sharma, 2023)
Enhanced Data Integrity	Blockchain's tamper-proof ledger ensures data integrity, providing accurate patient records and medication histories. This reliability prevents data manipulation, supporting better-informed clinical decisions and enhancing patient safety.	(Charles et al., 2019)

3.2.2. Improvements in Regulatory Compliance

1. Simplification of Compliance Processes: The blockchain technology is supportive for simplifying the compliance processes because the whole transactions provide transparency and traces in audit forms. This actually becomes helpful to the regulatory bodies as they may obtain verification compliance data without undergoing much hassle on the side of pharmaceutical companies. According to Charles et al. (2019), blockchain can enable regulation through smart contracts that have predefined protocols to check automatically the process of compliance. In this way, effective regulation is achieved, and risks related to non-compliance are eliminated.

2. Compliance to Regulatory Norms: The pharmaceutical sector is very demanding regarding the need for regulation requirements. This could involve requirements like data protection and patient confidentiality requirements. Blockchain will help the pharmaceutical companies to meet the requirements of the GDPR and HIPAA as blockchain provides safe data management solutions that enable the protection of information about patients, but with utmost transparency (Ettaloui, 2023). This will be able to serve all the requirements of winning patients and regulatory bodies confidence.

4. Allows Safe Data Sharing: This is because, being decentralized, the blockchain will afford safe data sharing between participants, without compromising any integrity. This becomes very important in clinical

research, considering the stringent regulation involved with standards compliance. This will thus make it easy to share information across researchers, regulatory bodies, and healthcare service providers, making better patient care possible in the long run. However, issues about data sharing and compliance are issues that must be appropriately controlled over those keeping and enforcing the rules already existing (Ettaloui, 2023).

3.3 Comparison of Blockchain and Traditional Methods in Ensuring Traceability

3.3.1. Decentralization and Data Integrity

Traditional traceability systems have a strong dependency on central databases, which become easily vulnerable to data tampering and loss. Conversely, blockchain works in a decentralized network where all the participants share the same information. Through decentralization, no participant would be allowed to alter the data unless consent has been received from the network, hence ensuring integrity of data. This is because traceability information is lacking in completeness and reliability as traditional traceability systems for drugs are centralized Zhu (2023). Since blockchain technology is a distributed ledger, all transactions are assured to be secured and verifiable, which enhances traceability data a lot in regard to authenticity and reliability.

3.3.2. Enhanced Transparency

Blockchain offers a clear record of all transactions; this means that the stakeholders trace the flow of goods in real-time in the supply chain. This kind of transparency is of extreme importance to win the trust of consumers and other stakeholders. For example, Wang and Chen show that blockchain can substitute the traditional centralized databases where traceability information is stored in a safe manner, and the non-repudiation of information sources is ensured (Wang & Chen, 2022). Traditionally, consumers do not have clear information about the source and handling of the products, which leads to safety risks. The openness of blockchain means the customers can check the genuineness of the products, hence improving safety and trust.

3.3.3. Security and Anti-Tampering Features

The cryptographic security characteristics of blockchain offer an excellent defense against tampering and fraud. A transaction is recorded in a block that is cryptographically linked to previous blocks making it virtually impossible to change previously written records without being detected. Deng and Feng pointed out that the anti-tampering capabilities of blockchain are highly beneficial to applications in food traceability to ensure the authenticity and reliability of traceability data (Deng & Feng, 2020). In traditional systems, the potential for data manipulation can undermine the entire traceability process, which leads to safety risks and regulatory non-compliance.

3.3.4. Efficiency and Cost-Effectiveness

The traceability process would be made easy by blockchain technology, which means less time and fewer resources to follow the product's history. In traditional traceability methods, paper work and data entry through the manual method create cumbersome processes with errors and inefficiencies. Helo and Hao mention that blockchain reduces workload, ensures traceability, increases efficiency, and decreases costs (Helo & Hao, 2019). Blockchain can also facilitate faster and more accurate traceability by automating data recording and verification through smart contracts, thus being very helpful in industries that require timely information.

3.3.5. Regulatory Compliance

One advantage of blockchain technology is that it allows for an open and non-changeable ledger of transactions. Traceability systems that are more centralized in their management of data usually cannot be effective in maintaining very strict regulatory standards. In the opinion of Charles et al., blockchain

improves compliance with regulatory standards because it provides auditability by making the process easier to verify compliance with safety standards (Charles et al., 2019). This is particularly important in the pharmaceutical industry, where regulatory compliance is critical for ensuring patient safety.

5. Challenges and Barriers to Blockchain Adoption

4.1 Technical, Regulatory, and Organizational Challenges in Adopting Blockchain in Clinical Pharmacy

Table 2. Technical Challenges for the Adopting Blockchain in Clinical Pharmacy.

Challenge	Description	Citation
Interoperability	Ensuring seamless integration between blockchain systems and existing healthcare technologies, such as electronic health records (EHRs), is crucial. The lack of standardized protocols and open standards hinders effective data sharing and traceability.	(Puneeth & Parthasarathy, 2023)
Scalability	Blockchain networks struggle with scalability when processing large transaction volumes typical in healthcare. Performance degradation can lead to delays and inefficiencies, posing challenges in clinical settings where timely data access is vital.	(Shaikh et al., 2023)
Data Privacy and Security	Although blockchain enhances security, its immutable nature raises concerns about handling sensitive patient information. Privacy-preserving mechanisms are needed to protect patient data while enabling traceability and secure transactions.	(Rahmaty, 2023)

4.1.2. Regulatory Challenges

The pharmaceutical industry is very heavily regulated, and any new technology will have to abide by stringent laws related to data protection, patient privacy, and medication safety. According to Louis and Maheshwari, the main issue in implementing blockchain in healthcare is the regulatory burden, as "regulatory bodies may require a high level of validation and verification for blockchain systems, slowing implementation" (Louis & Maheshwari, 2023). As of now, there are not clear regulations defining the usage of blockchain technology in healthcare. Ambiguity will be there because of this vagueness and organizations are unable to find guidelines for implementing blockchain in healthcare settings. This point is highlighted by Baysal et al. that a lack of defined structures for implementing blockchain in healthcare has become an obstruction (Baysal et al., 2022).

Table 3. Organizational Challenges for the Adopting Blockchain in Clinical Pharmacy.

Challenge	Description	Citation
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Organizational Readiness	Adopting blockchain technology requires adequate infrastructure, resources, and expertise. Many organizations may lack the technical capabilities or understanding, leading to resistance from employees who see the technology as disruptive to workflows.	(Saif et al., 2022)
Change Management	Transitioning from traditional systems to blockchain involves significant process and system changes. Effective change management strategies are necessary to overcome resistance and facilitate smooth adoption within organizations.	(Rahaman et al., 2022)
Trust and Collaboration	Blockchain depends on collaboration among diverse stakeholders, including manufacturers, distributors, pharmacies, and regulators. Building trust in this competitive and confidential industry is critical for successful implementation.	(Puneeth & Parthasarathy, 2023)

4.2 Lessons from Blockchain Implementations in Other Industries

4.2.1. Value of Pilot Programs and Incremental Implementation

One significant lesson learned about blockchain-adopting industries is that pilot programs ought to be instituted. Hoek explains that pioneers in the adoption of blockchain in the supply chain have benefited because they conducted a pilot study of feasibility and known challenges before widespread implementation Hoek (2019).

4.2.2. Interoperability and Standardization Requirement

Interoperability is a challenge cutting across all sectors with blockchain implementations. Most blockchain projects fail because of the lack of standardized protocols and integration with existing systems, according to Rijanto (2021).

4.2.3. Compliance and Regulation Issues

Regulatory compliance is more critical in finance and healthcare sectors, whose industries are highly bounded by data handling rules and patient privacy regulations. Chang et al. suggest how policies have to be developed to help in adopting the technology and using it without misappropriation, such as money laundering or fraud (Chang et al., 2020). In clinical pharmacy, stakeholders have to navigate through several regulatory complexities for blockchain solutions that adhere to all laws regarding patient data protection and medication safety. Early regulatory engagement can, therefore, facilitate a better understanding of requirements to ease the transition.

4.2.4. Building Stakeholder Trust

Trust is very essential in achieving successful adoption, especially in the collaborative environment that is supply chain. Scott et al further note that it may build the trust among participants as it develops an

open, transparent, and immutable record of transactions in a decentralized blockchain (Scott et al., 2017). In the clinical pharmacy setting, building stakeholder trust between the manufacturers, distributors, pharmacies, and regulatory body is paramount while entering into potential collaborations. It would alleviate most of the concerns and therefore bring buy-in by involving stakeholders in the design and implementation of blockchain-based solutions.

4.2.5. Change Management

What often couples with the transition into blockchain technology is some form of change regarding work processes and workflows. As Ucha puts it, for successful transition, the organizations need to be prepared to handle change management successfully (Ucha, 2024). In clinical pharmacy, that might mean training employees, updating protocols, and getting past issues of resistance to new technologies. Having covered stakeholders, training, and the provision of support for a prolonged period, one is able to implement the entire process of changing with the solutions provided by the blockchain.

4.2.6 Data Security and Privacy Features

Utilizing native data security features, which blockchain technology allows, will provide clinical pharmacy data security stronger in nature. For example, Halkiopoulou et al. emphasize that "a robust data protection framework may be established, safeguarding private information" while detailing how blockchain technology can be used to ensure the safe flow of data between applications (Halkiopoulou et al., 2023). Blockchain can be employed by clinical pharmacy to ensure the security of patient data and for the satisfaction of privacy regulations as it has the capability to encrypt and control access. The application will be trusted by stakeholders since security will be ensured by prioritizing it.

4.2.7 Continuous Learning and Adaptation

Blockchain technology is an evolving aspect thus needs open commitment to continuous learning and adaptation. According to Dabbagh et al., for one to keep with the current study and development going on in the block-chain, may position them on top (Dabbagh et al., 2019). On clinical pharmacy aspect, the different stakeholders need a chance of learning through sharing ideas, cooperation and innovation to have them stay productive and relevant through their applications on blockchain.

6. Future Prospects and Research Directions

5.1 Emerging Trends in Blockchain Technology for Clinical Pharmacy

5.1.1 Increased Traceability and Transparency

Most significant in this is blockchain technology. Its use enables greater traceability and transparency for drugs in the supply chain of the pharmaceutical. With blockchain comes an association of decentralization as well as a read-only immutable ledger. Hence, medicines are trackable in real-time, right from the manufacturer to end-users because every transaction can be recorded and verified. Saberi et al. stress that blockchain can be an important function for increasing the transparency of supply chains, which is an important tool in preventing counterfeit drugs and proving the legitimacy of drugs Saberi et al. (2018). This is a function of great importance in clinical pharmacy as the safety of patients depends on the purity of medication.

5.1.2. Blockchain with Telehealth Services

Blockchain technology, integrated with telehealth services, is another emerging trend. In addition to a rapid growth in telehealth, a need for a safe and efficient information sharing process among healthcare providers and patients will occur. Although Lussier et al. note innovations, including centralized pharmacy telehealth services, that will aid in adherence and improved patient outcomes, this does not place strong emphasis on blockchain (Lussier et al., 2021). This integration will most likely enhance clinical pharmacy

service delivery by providing ways of remotely monitoring patients' drug use and monitoring the patients themselves.

5.1.3. Smart Contracts and Automatization

Smart contracts play an essential role in pharmaceutical industrial applications since automatization would create an aspect where the lack of bureaucracy enhances productivity. It enables automatic transaction verification and compliance with regulations and entry into an agreement or contract on predetermined conditions. This is especially so in clinical pharmacy, where efficient and timely drug dispensing must be ensured. According to Queiroz et al., the smart contract has the potential of optimizing supply chain management and, thereby, an overall bettering of the efficiency of pharmaceutical services (Queiroz et al., 2019).

5.1.4. Emphasis on Data Security and Patient Privacy

With the increasing threat of breaches and issues of patient privacy, the technology of blockchain may be what brings robust security features to assist in protecting the sensitive health information that requires protection. Then, a patient's data will be kept safely inside the cryptographic security of the blockchain and become available to authorized parties. This is very relevant in clinical pharmacy as protection of such information aids in the preservation of trust and respect for regulations. Yoon provides implications of the blockchain technology over health data safety, and elaborates on a possibility that blockchain assures safe data management solutions (Yoon, 2019).

5.1.5 Interoperability and Standardization

As the maturity of the technology of blockchain happens, there grows an increased emphasis on standardization and interoperability. Interoperability will ensure effective communication between various blockchain systems so that data is shared and the full benefits of blockchain can be reaped in clinical pharmacy. This trend is supported by Dabbagh et al., where the authors emphasized the necessity of creating a uniform approach to blockchain implementation, starting with the creation of common standards and protocols, they argued, Interoperability will seamlessly integrate blockchain solutions to the existing systems of healthcare, making them more effective (Dabbagh et al., 2019).

5.1.6. Developing Regulatory Framework

With this emerging trend, blockchain-specific regulatory health frames will then influence how blockchain is adopted in clinical pharmacy. The more blockchain applications get publicized, regulatory bodies begin formulating their standards based on existing legislation but will also protect the security of patients. Stakeholder trust hence is paramount for the ever increasing adoption rate of the blockchain applications. Chang et al. suggest the need to foster policies that will enhance the uptake of blockchain with a sense of caution about potential misuse (Chang et al., 2020).

5.1.7. Sustainability and Ethical Concerns

This gives rise to further use of blockchain technology in pharmaceutical company affairs related to its sustainability and morality issues towards its sustainability and progress in more implementations from blockchain, one of the ethical sourcing practices, and cutting down on supply chain waste. According to Gruchmann et al., "blockchain proves that pharmaceuticals supply chains may operate sustainably with end-to-end visibility and accountability" (Gruchmann et al., 2023). This will be more in demand with the responsible practice in health care.

5.2 Collaborative Strategies for Advancing Blockchain Adoption in Clinical Pharmacy

5.2.1. Building Collaborative Networks

Such networks with the stakeholders involved would facilitate exchange in terms of knowledge, resources, and the best practices used when implementing the blockchain. According to Gross and Miller, a block works exceptionally when the various stakeholders' communities are aligned toward the goal using collaborative strategies that induce and support shared behaviors Gross & Miller (2019). Various stakeholders will interact to ensure overcoming any problems experienced by combining knowledge on best strategies and standardized methods to implement blockchains among providers.

5.2.2. Collaborative Pilot Studies

Collaborative pilot studies can be quite a very tangible way in which stakeholders experiment blockchain applications in clinical pharmacy. Balasubramanian et al. point out that the chief challenge that has confronted the acceptance of blockchain has been that of bringing together the different stakeholders on the same table for blockchain-related activities. Pilot projects give stakeholders the opportunity to test blockchain solutions in real-world settings, assess their effectiveness, and identify potential barriers to implementation. Such hands-on experience can foster trust and encourage broader participation in future initiatives (Balasubramanian et al., 2021).

5.2.3. Education and Awareness

Increased knowledge and awareness of the blockchain concept among stakeholders contribute to the growth of collaboration. Success in a blockchain-based HIE relies on the engagement of all stakeholders, such as patients and healthcare organizations, according to Esmailzadeh and Mirzaei study, Training, seminars, and workshops can be crucial for stakeholders in understanding the benefits and drawbacks of blockchain technology in order to facilitate a common agenda in implementing this type of clinical pharmacy in health care services (Esmailzadeh & Mirzaei, 2019).

5.2.4 Standardization of protocols

Amongst the factors involved in ensuring that interoperability across the blockchain systems is ensured lies standardization. According to Treiblmaier and Rejeb, some stakeholders need to be involved when developing standardized protocols may assist in smoothly implementing blockchain applications. The stakeholders, therefore, will have to identify together a uniform set of standards regarding the format of data and security as well as governance of data to facilitate better usability for blockchain in clinical pharmacy (Treiblmaier & Rejeb, 2023).

5.2.5. Overcoming Regulatory Challenges in Collaboration

Regulation has been the major challenge in the implementation of blockchain. The regulatory stakeholders can collaborate to identify a channel to present an approach for contacting the regulatory agencies to raise opinions on guidelines for the development of regulations that are amenable for blockchain implementation provided patient information and health data remain secure and confidential. This strategy, according to Özdemir et al., establishes trust with stakeholders since it allows the integration of blockchain technology in an efficient manner (Özdemir et al., 2020).

5.2.6. Patient Engagement

It is very important to engage patients as active stakeholders in the adoption of blockchain solutions to ensure that solutions meet the needs and preferences of patients. In a view of Esmailzadeh, active involvement of the patients along with a positive attitude is fundamental for the blockchain-based HIE's success, says Esmailzadeh & Mirzaei (2019). Discussing applications of blockchain technology by patients themselves might have further debated issues and preferences of the patients, making such solutions effective and user-friendly.

5.2.7. Leverage Governance Frameworks

There must be appropriate governance frameworks in place. Such a structure can make cooperation among stakeholders more fluid because guidelines in decision-making and solving conflicts could easily be established. Zhang argues that it is a must to study the process on how decisions are made in decentralized organizations and how the disagreement would be solved. That ensures that every voice is heard through a governance structure that includes multiple stakeholder groups, and in turn, may ensure that community interests are taken into account while making decisions (Zhang, 2023).

Conclusion

Blockchain technology can be said to form a part of very vital innovations that address very critical concerns in the pharmaceutical supply chain, such as counterfeit drugs, inefficiencies, and compliance with high regulatory standards. The decentralized and immutable nature will guarantee secure, transparent, and tamper-proof record keeping, which will improve traceability and integrity of medication at all stages of the supply chain. Blockchain real-time tracking of medicines reduces the risks associated with counterfeit drugs, enhances patient safety, and brings about confidence among the stakeholders. Other features include integration with other complementary technologies such as IoT and smart contracts, which enhance the utility of blockchain. The IoT devices facilitate real-time monitoring of storage and transport conditions in order to prevent damage to sensitive pharmaceuticals, while smart contracts automatically abide by all the rules and make processes simple. All these innovations open the door for an efficient and resilient supply chain, and manufacturers, distributors, and patients will reap the benefits accordingly. However, there are some key challenges that must be crossed to induce mass adoption of blockchain technology in clinical pharmacy. Firstly, issues concerning technological bottlenecks such as scalability and interoperability. Second, regulation uncertainty and stakeholder resistance to replace the existing systems will be conquered. Standardized protocols and frameworks will just be developed when that is done with considerable effort among industry participants, the bodies concerned, and the technology providers.

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Author contributions

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Conflict of Interest

Authors declare they don't have any conflict of interest.

Ethical Approval

Not Applicable

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