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BLOCK CHAIN FRAMEWORK FOR PHARMACEUTICAL SUPPLY CHAIN MANAGEMENT

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ABSTRACT

Despite blockchain's great potential to solve traditional supply chain problems, there is a lack of research on its application in pharmaceutical supply chains (PSCs). Therefore, the purpose of this study is to further develop a conceptual framework for use in the pharmaceutical business and to offer crucial insight into the relationship between PSC and blockchain technology. The innovative conceptual framework that has been suggested offers manufacturers, authorities, and governments helpful guidance on how to apply blockchain technology in the pharmaceutical sector.We also examine the challenges and future research directions of applying blockchain technology in the pharmaceutical industry. By enabling visibility and immutability of each link in the network, blockchain technology may be used in supply chain management to give assurance, security, traceability, and transparency to the chain.

Keywords: Pharmaceutical supply chains, Blockchain technology, implementation, Systematic literature review, Conceptual framework

Introduction

Pharmaceutical supply chains (PSCs) supply drugs to a variety of customers, such as biotechnology firms, health regulatory organizations, pharmacies, and hospitals. PSC is now at the top of various government's priority due of the ongoing COVID-19 pandemic and geopolitical conditions. The World Health Organization (WHO) estimates that approximately 10% of pharmaceuticals in use are substandard, and over 50% of drugs offered online are fake (WHO 2017). These drugs containing toxic, dangerous ingredients are on the rise in the pharmaceutical industry posing increased risk to public health.Within the pharmaceutical supply chains (PSC), the Food and Drug Administration (FDA) in the United States is the regulatory organization in charge of overseeing the efficacy, safety, and quality of medications.urged those involved in the drug and medical supply chain to work together to create an electronic system that may be used to track prescribed medications through their physical movement by 2023. However, despite stringent regulations by regulatory authorities and other industry-led initiatives, pharmaceutical breaches continue to increase, putting millions of people at risk and predicted to result in billion-dollar healthcare fraud.The low effectiveness of PSCs is caused by a lack of coordination among supply chain participants and stakeholders. Lack of Transparency and visibility of drug supply within PSCs are essential causes of the rise in drug resistance, disease progression, and death. Fortunately, global sourcing and online markets make it easier to procure and supply medicines in different countries; however, they pose an increased health risk without the ability to trace the origin. Even with stringent standards and the latest technologies (e.g. holograms, barcodes, RFID tags) to maintain the integrity of pharmaceutical products, counterfeiting remains a major challenge for global PSC.Using the principles of cryptography, the peer-to-peer network achieves immutable recording of self-executive transactions through the usage of blockchain, a shared digital ledger. Blockchain has a lot of potential to be implemented in the pharmaceutical industry because of its unique intrinsic attributes, like decentralization, immutability, and auditability. It has been successfully implemented in other industries like finance, energy, and food and agriculture, and decentralization has the potential to upend the health care hierarchy by enabling the development of new systems that help patients manage their data. The most accurate data for precision medicine could be provided by blockchain technology, preserving individuals' sovereignty and ownership over their personal information.Additionally, the Blockchain's high data transparency can enhance confidence in medication distribution, conditions, documentation, and end-to-end visibility-particularly in the context of cold chain management. Blockchain has a lot of potential for pharmaceutical supply chains, according to several research.A thorough or organized evaluation of the literature on blockchain's use to PSC interface is still lacking, nevertheless. Most notably, there isn't a structure in the body of existing literature for potential Blockchain application in PSC. Therefore, the purpose of this study is to provide a

conceptual framework and perform a comprehensive review of Blockchain use in PSC. The analysis establishes the direction for further studies and the creation of an implementation framework. This study offers scholars and practitioners a comprehensive grasp of the relationship between PSC and Blockchain.

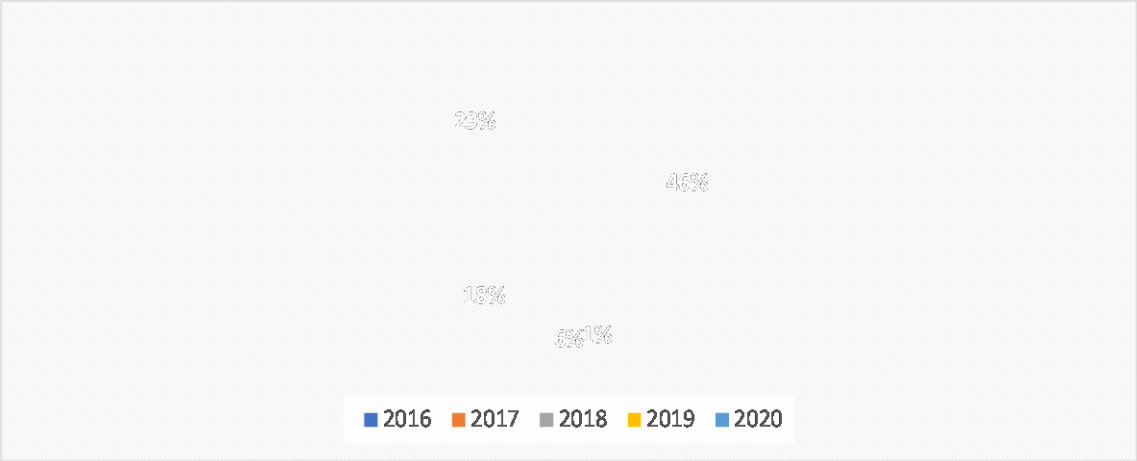

Figure 1: Proportions of research on blockchain in the health care sector.

Block chain Technology

1. Blockchain in Pharmaceutical Industry
2. Prevention of counterfeiting
3. Product distribution
4. Tracking and tracing
5. Safety and security
6. Data Governance
7. Data Quality
8. Pharmaceutical Turnover

1. Blockchain in Pharmaceutical Industry

Blockchain technology is employed in the pharmaceutical sector for a variety of reasons. One of the main challenges is security, which is solved by using cryptographic technology to validate transactional data blocks. Security elements unfold in different paradigms. With this technique, serial numbers are authenticated by verification checks installed across the supply chain system. In order to combat drug theft, drug traceability has also been improved. Digital signatures are used for quality control, and data miners, blockchain chain codes, and health information are sent from the producer to the pharmacy to ensure constant quality.

2. Prevention of counterfeiting

Pharmaceutical products are given security features and serial numbers so that consumers may verify them and tell them apart from fakes. The transparent and chaincode-based transactions of the blockchain technology also improve security. The pharmaceutical sector depends on transparency and trust since, in the absence of both, the counterfeiting industry flourishes, putting the general population at risk from tainted or substandard medications. Blockchain technology improves safety and saves lives when it comes to quality control and the identification of counterfeit medications. The Anti-Counterfeit Medicine System (ACMS) is one method that can be used to stop counterfeiting, among others.

The Ethereum blockchain and the Interplanetary File System (IPFS) networks are used by ACMS in the following ways:

- To stop cloning, establish ownership requirements for both retail and non-retail medications.
- Create Ethereum smart contracts to take use of IPFS and administer ACMS practically. networks as well as the Ethereum blockchain
- Put the small business initiative into action.
- Examine and assess the suggested system.
- Clients create a chaincode when a transaction is initiated; peers verify the signature; the endorsements are gathered and forwarded to ordering services, where transaction validation is the final step. This way, the ACMS effectively avoids fraud.

Product distribution

The existence of several dealers and middlemen creates a formal practice opportunity that reduces supply chain effectiveness. Blockchain has been praised for its ability to stop the sale of subpar medications.

Drugs that don't meet quality standards are seized and their introduction into the pharmaceutical supply chain is looked into. Pharmaceutical distribution is made easier by ledger systems, chaincodes, and serialization—the process of assigning numbers to pharmaceutical items so they may be identified and distinguished from one another. Blockchain data is strictly controlled to prevent illegal access that can compromise security measures. The Internet of Things (IoT) in the pharmaceutical distribution system enhances efficiency.

3. Tracking and tracing

Naturally, goods in transit should be tracked and traced from dispatch to destination. Delivery delays hamper business operations in general, but problems can lead to loss of life or exacerbation of illness in the pharmaceutical and health industries.

The pharmaceutical supply chain has benefited from the application of blockchain technology. For regulatory compliance, patient health, and corporate operations, drug tracking and traceability are critical. Pharmaceutical commerce and patient management are made possible by the timely delivery of items in transit to their intended destinations, made possible by sophisticated and secure tracking and tracing technology.An international registry was created to facilitate the distribution of drugs around the world. While this technology has great potential for large pharmaceutical companies, smaller companies should benefit as well.

4. Safety and security

Because drugs are valuable assets, security is important to protect them. The cryptographic aspects of blockchain technology are the basis for safety and security in the medical industry. Comply with compliance and regulatory compliance capabilities, and cryptographic technology that improves drug security.Security has been strengthened against theft and the introduction of counterfeit medicines. Unauthorized drug changes will also be reduced, preventing drug addicts from changing drugs, thereby reducing quality. Supply chain systems are governed by safety and security

measures that sound the alarm in case of a breach.

5. **Data Governance**

Blockchain technology provides advanced transaction systems that require strict monitoring and control measures and data-security. Therefore, while maintaining specific application domains and management considerations, blockchain and data management (DG) are complementary in many ways. Supply chains and data management have benefited from the use of blockchain and IoT technology. IoT has also been used to ensure regulatory compliance for pharmaceutical products.

6. **Data Quality**

The Internet of Things (IoT) has been used to meet GDP regulations and ensure consistency when transporting medical devices (such as temperature control) using sensors in each package. By guaranteeing the high quality of all data, blockchain technology can help solve these problems.

The new block is verified after all nodes verify that the data is valid. However, blocks with low quality scores are not added. Every transaction that a user makes on a blockchain requires the network to perform a series of special operations and monitoring.

These are meant to ensure that the transaction is fair. This transaction is then announced to all other nodes on the block and updated continuously.

7. **Pharmaceutical Turnover**

By strengthening supply chain processes, reducing waste, and ensuring the efficient distribution of goods, blockchain can help reduce medical turnover. Pharmaceutical companies can save money and patients can get their medicine on time.

Research Methodology

1. **Identification of data sources**

Data identification is a critical stage in the SLR, attempting to clearly define the scope and quality of the study. Here the keywords are identified for searching relevant information from multiple data sources. The pilot search results for apparent keywords: 'Blockchain' and 'Pharmaceutical supply chain' received only 20 and 86 hits from Web of Science and EBSCO databases, respectively. Scanning through these limited papers thoroughly, other keywords were identified. In the Blockchain review articles, other synonyms or technical names such as 'distributed ledger', 'shared ledger' and 'Smart contracts' were found to be commonly used.

Similarly, the pharmaceutical and healthcare industries closely collaborate and associate with each other. In the pharmaceutical sector, the words medicine', 'pharmaceutical' and 'drug' are often used interchangeably. Two commonly used online databases, namely Scopus and Web of Science, were used to identify peer reviewed, high quality (based on ranking, citations, impact factor, etc.) papers for conducting the SLR.

Both databases are commonly used to screen data sources and are proven to provide reasonably comprehensive results. The choice of two different databases was to capture the inter-disciplinary work comprehensively.

Predefined inclusion criteria comprised papers published between 2010–2021 to capture a decade long horizon. Although the first Blockchain-related paper was

published in 2014, a more significant time span was selected to capture the broader growth of the PSC. Only peer-reviewed academic journals were included, while conference proceedings, books, book chapters and other grey literature (e.g. newspapers, white papers, HTML links, etc.) were excluded.

This exclusion of the 'grey literature' in SLR studies helps to focus on the quality publications. Given the interdisciplinary nature of the study capturing the nexus between Blockchain and the pharmaceutical industry, papers published inwider journals (beyond operations and supply chain discipline) were considered to ensure the study is holistic and unbiased.

2. Data extraction & synthesis

The data extraction & synthesis stage helps to filter highly relevant papers. After removing the duplicates and excluding literature from the two selected databases; each paper was carefully synthesised by considering the title, keywords, and abstract to select 119 papers that were found to be relevant to the study. Following an iterative process, a full-text assessment of the selected paper identified 65 papers for final assessment, adapting a PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) approach, a systematic method to visualise the study selection process.

Text mining is used in this study for the data synthesis activity. Text mining of selected papers was conducted to validate the search strings identified in the previous stage and provide further support for the data analysis.

Presents the most important words or phrases identified in the selected database by their term frequency and inverse document frequency (TF-IDF). TF-IDF is a measure of significance and provides information regarding the number of occurrences of a given word or phrase in the selected dataset.

It is noticeable that Blockchain, healthcare, supply chains, smart contracts appear as the most frequent words or phrases through text mining/analysis.

Furthermore, most of the identified words and phrases strongly correlate with identified search strings for data identification. This retrospective validation of the preidentified search strings provides confidence in the reliability of the process followed for data identification and analysis. Furthermore, data sources were (text) mined for extracting patterns to develop suitable themes using the clustering and correlation approach.

3. Data analysis and Dissemination

The data analysis and dissemination stage consist of descriptive and thematic analysis. The former analysis aims to provide a brief overview capturing the depth and spread of the subject under study.

In contrast, the thematic analysis attempts to provide comprehensive insights based on the developed themes.

Based on implementation stages:

This theme attempts to capture developments through three stages adopted for implementing Blockchain: initiation, adoption decision, and implementation.

Based on drivers for Blockchain implementation:

This theme attempts to identify enablers or drivers for adopting Blockchain

technology in pharmaceutical supply chains.

Based on barriers to Blockchain implementation:

This theme summarises the barriers/challenges to implementing Blockchain in PSC.

Based on Blockchain applications:

This theme captures the broader applications of Blockchain within the pharmaceutical sector.

Blockchain implementation stages for pharmaceutical supply chain[41-52]

1. Initiation stage
2. Adoption stage
3. Implementation stage

1. Initiation stage:

The understanding of blockchain technology and its prospective advantages, including the justification for adoption, are captured during the beginning stage of blockchain.The external environment and technology initiatives drive the need for Blockchain adoption. Majority of conceptual studies in the pharmaceutical sector claim that the immutable and decentralised distributed ledger could stimulate a transparent, efficient, falsified-free pharmaceutical supply chain network. However, stakeholders won't be prepared to take chances to support the adoption of the Blockchain-based solution for the PSC without shared technological standards and other relevant rules.

propose a risk-based open government surveillance network on the circulation of medications within the PSC. To safeguard the legitimacy of the medications, the government and other supply chain partners may mandate that the transaction data be inspected.

The initial phase facilitates the conceptualization of a robust Blockchain. ecosystem for the PSC and additionally contributes to improving the acceptance of this technology by users

2. Adoption stage:

Organizations must assess their strategic, financial, and technological options in order to go from the initiation to the adoption decision stage.

This phase assesses the resources available inside the organization and distributes them to facilitate the adoption of technology. Since this is a strategic choice that will probably alter the organizational structure and resource needs, senior management support during the adoption decision stage is crucial in other technology deployment situations like RFID and IoT.

In order to create a blockchain-based culture within the organizations and gain relevant blockchain expertise, the assistance of the stakeholders is helpful at this point. For the stakeholders to demonstrate how Blockchain benefits the entire pharmaceutical supply chain financially, a cost model is required.

Large businesses may be convinced to participate in the pilot project for adoption by the long-term advantages of blockchain, which include enhanced supply chain efficiency, strong data security, and the ability to battle counterfeit medications. Furthermore, Blockchain platform firms must assist in resolving the technological challenges.

Blockchain offers interoperable interfaces with many systems and shares drug mobility, as opposed to connecting various healthcare information systems and pharmaceutical producers' ERP systems.

3. **Implementation stage:**

The practical application of Blockchain within a company or supply chain is known as the implementation stage. Starting a pilot project with a limited number of supply chain members to assess the feasibility of Blockchain in the PSC is a sensible idea. It was highlighted that conducting small-scale pilot projects can provide valuable insights and lessons. More stakeholders are drawn to this pilot project, which will probably persuade small enterprises to join the blockchain-based pharmaceutical sector ecosystem. The next step after pilot project success is to scale those initiatives up at the supply chain level. However, as was already mentioned, the obstacles that must be removed are those related to scalability, particularly with regard to transaction speed and multi-node compatibility.

If Blockchain is successful, users will adopt it more widely and it will require less money for implementation and technical problems. According to Bocek et al. (2017), adoption costs of Blockchain technology will decrease with market maturity. It's interesting to note that the pharmaceutical industry is expected to generate at least 1.6 billion dollars by 2025, which will aid in the adoption of blockchain technology.

Framework and future directions

It is observed from the selected past studies that Blockchain adoption in the PSC is still in its developmental stage. Due to the lack of empirical research, large-scale successful Blockchain-based platforms for the PSC are challenging.

Besides, practitioners have difficulty defining the steps to implementing Blockchain technology in the pharmaceutical sector, as research demonstrating a framework for implementation in such a specific sector is non-existent with in the supply chain management context. Therefore, following the insights generated from the thematic analysis, a conceptual framework of Blockchain implementation in the PSC is attempted.

The proposed framework is likely to benefit the successful implementation of Blockchain in PSC. Although conceptual, it can be retrospectively validated on Blockchain pilot studies within PSC or tested on the new initiatives in PSC attempting to implement Blockchain.

In the end, unique research gaps are identified, paving the way for future research directions in the selected area of study.

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