Communications on Applied Nonlinear Analysis
ISSN: 1074-133X
Vol 32 No. 2s (2025)

Hybrid Blockchain Network for Drug Traceability in Secure Pharmaceutical Supply Chain

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Article History:

Received: *05-09-2024*

Revised: *15-10-2024*

Accepted: *25-10-2024*

Abstract:

Several stakeholders are involved in the pharmaceutical supply chain (PSC), including those who provide raw materials, make and sell drugs, and oversee the industry, hospitals, pharmacies, and patients. An efficient traceability system is necessary to ascertain the present and all prior ownership of products because of the intricate nature of product and transaction flows in PSC. Furthermore, regulatory supervision and product safety can be significantly improved by digitizing the track and trace procedure. A permanent, trustworthy, responsible, and transparent system in the PSC can be achieved using blockchain-based medication tracing, which provides a distributed shared data platform. A hybrid blockchain network (HBN) based on secure pharmaceutical supply chain architecture (SPSCA) has been proposed for this research. The suggested system relies on smart contracts to record significant events and track how all the parties engaged in the supply chain perform their respective tasks. In this way, everyone concerned can remain informed of developments and protect the supply against manipulations of supply records and counterfeit pharmaceuticals. All parties involved benefit from a secure, immutable record of transactions due to the smart contract, which additionally guarantees the provenance of data and deals with mediators. Detailed methods and the system architecture that enable the solution's functioning are laid out here. We perform testing and validation to assess the system's efficacy in improving pharmaceutical supply chain traceability and provide cost and security evaluations.

Keywords: Blockchain, Pharmaceutical Supply Chain, Drugs, Traceability.

1. INTRODUCTION

The severe consequences of counterfeit medicines on human life and treatment efficacy constitute a major threat to public health [1]. According to the World Health Organization (WHO) [17], counterfeit medicines are deliberately and fraudulently mislabeled regarding source and identity. The components in counterfeit pharmaceuticals may be missing or wrong, the information on the box may be misleading, or the ingredients themselves may be partial or incorrect. An estimated 1-2% of drugs taken in developed countries are fake, according to the World Health Organization (WHO), whereas 10% of pharmaceuticals ingested in underdeveloped nations are either substandard or fabricated [3]. The counterfeit drug trade impacts hospitals, pharmacies, distributors, regulatory bodies, and global health efforts [2] [4]. It is possible because there aren't enough commercial or technical solutions for provenance and tracking [18].

Drug security is always at the top of the list since it impacts public health [8]. To ensure the safety of drugs, academics and businesspeople agree that it is essential to have a reliable system for

monitoring their production, distribution, and sale [16]. According to [5], previous traceability systems studies mostly focused on centralized or distributed architectures. With the use of web-based and IoT technologies, all product-related data is maintained in a single database in centralized traceability mode [6]. This allows for compliance with government regulations and meets customer demand. Concerns about data security and scalability, mainly when dealing with several partners that may have competing interests, have dogged this centralized approach for some time[12] [19].

Numerous researchers have devised distributed traceability modes to circumvent these limitations. When all parties (such as a manufacturer or logistics provider) utilize a separate database to keep track of the product's history, this is called a distributed traceability mode [10]. In the dispersed traceability mode, a common standard is used to establish data interfaces for exchanging data [7]. Nevertheless, small and medium organizations aren't the best fit for distributed traceability mode since it raises maintenance costs and makes reconfigurations more complex, mainly when dealing with system upgrades or updates [20].

Blockchain technology, a distributed ledger system that operates without a central authority, offers an efficient and trustworthy method for monitoring products. Blockchain technology, which underlies digital currencies, has been used in several sectors, including healthcare, supply chain management, finance, energy, commodities trading, and supply chain management [9] [14]. The permanent and secure nature of blockchain technology provides great promise as a practical solution to the problem of counterfeit medications by facilitating the tracking and provenance of pharmaceuticals [21,11].

The purpose of this research is to develop a smart tracking and tracing platform that uses blockchain technology and Internet of Things capabilities to provide smart medicine traceability. A blockchain-based data on-chain and off-chain system must be built to increase medicine transparency while retaining acceptable privacy. Services for quality control, transparency and auditability, risk analytics, and intelligent alarms are the goals of developing smart contracts.

2. LITERATURE SURVEY

Digital traceability (DT) of pharmaceutical medications across the supply chain is essential for optimum public health safety, as discussed in [6] [22]. The supply chain process in the pharmaceutical sector is vital. Medications are guaranteed to be authentic by lowering the probability of drug shortages or the availability of counterfeit drugs. Given the potential danger of illicit and counterfeit pharmaceuticals, this study assesses the need for digital traceability in the pharmaceutical supply chain.

Drugs that do not contain the desired active components might cause injury or death to end-user patients since it is difficult to track the proper and active pharmaceutical ingredients throughout manufacturing. Due to its sophisticated characteristics, blockchain [13] can be a foundation for full drug traceability, from manufacturing to final consumption, and even detect counterfeit pharmaceuticals. The purpose of this article is to discuss how Blockchain technology and encrypted QR codes could resolve the medication safety problem.

The author proposes an architecture based on blockchain technology to guarantee openness and

transparency in the pharmaceutical supply chain. The architecture uses blockchain technology regarding decentralization, tamper-proofing, and traceability. A QR code on the blockchain for every product can be used to get complete information [23] and see what owns it, which helps find where counterfeit products came from. In addition, we provide verified certifications and lab results with every purchase. Medication administration authorities validate these reports to ensure the product's dependability. Consequently, in contrast to conventional and other blockchain-based systems, the created system provides strong protection against the sources of counterfeit goods.

Adopting a multi-perspective framework that integrates aspects of the technology-organization-environment (TOE) contexts for enterprises, the authors determined the critical success factors necessary to implement a system to generate value for pharmaceutical supply chain stakeholders and the entire pharmaceutical supply network [15]. This article identifies and ranks three important technological, organizational, and environmental success factors. This study adds to the existing knowledge on medication traceability by shedding light on how businesses can profit from this issue.

The author suggested a permissioned blockchain network-based solution for the pharmaceutical supply chain that would be visible and secure. Automated transactions between suppliers and distributors are an additional part of the planned effort [24], which aims to reduce supply chain risk, verify information adequately, and trace products' origin. The suggested system has been tested and validated using Hyperledger Calliper and Hyperledger Fabric. In the final phase, they measured the proposed work's throughput, transaction delay, and network load.

3. PROPOSED WORK

Figure 1 is a schematic representation of the pharmaceutical product supply chain that is blockchain-based and uses traceability, efficiency, and searchability. Our framework is a three-tiered supply chain built on blockchain that is visible and verifiable. The supply chain's bottom layer consists of all the parties involved. Customers are provided with traceability services via the top layer, which consists of blockchain data and smart contracts, while the intermediate layer is the blockchain network. Specifically, a collective blockchain network and a peer-to-peer network are established by the many parties involved in the supply chain, including producers, distributors, warehouses, and retailers. Each participant in the big-scale blockchain network can build a unique network of nodes or blockchains.

In addition, the suggested approach has used a computationally secure authentication methodology based on Chebyshev polynomial functions to generate a secret hash code that ensures the validity of drug quantities across the supply chain. The following factors encourage all parties involved in the proposed framework to record product information on the blockchain.

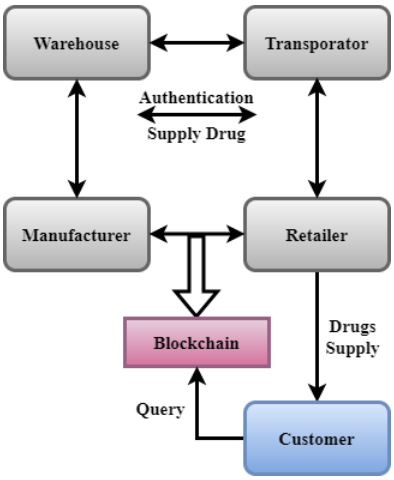

Figure 1: Effective Traceable and Supply Chain Architecture with Blockchain

The first benefit of keeping product data on the blockchain is that buyers have greater trust in the things they acquire. Furthermore, the linked data improves the efficacy of supply chain management. Lastly, the product details will align more with the rules' demands. Finally, the product data will align better with the specifications laid forth by the different rules. Blockchain technology can only guarantee data immutability after correct storage; therefore, consider that. The blockchain can serve as an unchangeable record of an incorrect entry if the party to a transaction provides incorrect data. Profiting from the supply chain's services, end customers can ask about product tracking information by querying the blockchain. Continuously captured on the blockchain is the product data with the following fields:

3.1. Security Framework

- Unforgeability -This security specification strives to be unforgeable to prevent fraudulent pharmaceutical products from being made through the supply chain network. This includes attacks launched by rational entities and any AI adversary using valid credentials.
- Robustness - the authentication method with the verifier requires valid credentials or a secret hash code so any hostile entity or consumer cannot pass it.
- Availability- it would be computationally difficult for any PPT opponent to perform DoS attacks to bring the servers or workstations down and prevent their intended users from accessing them.

3.2. Proposed Work Analysis

The suggested pharmaceutical supply model is explicitly built based on the system above architecture. A manufacturer, retailer, warehouse, transporter, and customer—along with their respective identities—are every participant in this creation. Figure 2 comprehensively illustrates the smart contract components and stakeholders shown in the suggested pharmaceutical supply chain solution. These stakeholders have public and private keys for Ethereum. The following is a description of the primary entities that are considered stakeholders.

- The sender entity is responsible for creating and initiating the smart contract and providing the pharmaceutical commodities (drugs) when the appropriate authentication has been completed.

- The receiving entity compensates the sending stakeholder entity in ether, and if the package arrives at the receiver entity unused, the funds are transferred to the sending entity.

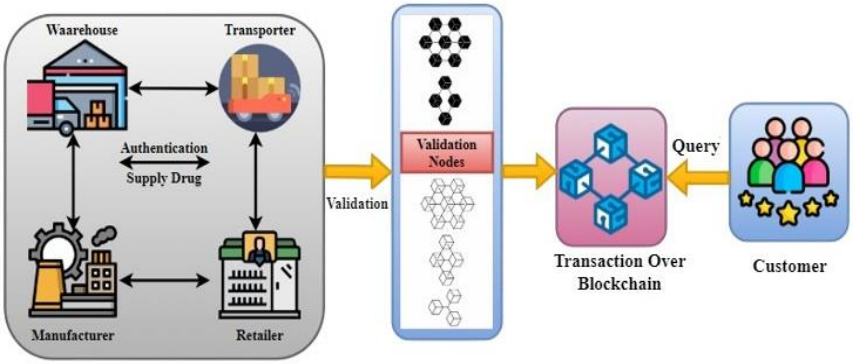

Figure 2: Hybrid Blockchain Network (HBN) based on Secure Pharmaceutical Supply Chain Architecture

3.2.1. Optimize the Pharmaceutical Supply Chain Transfer

There are two parts to this process. The first is the authentication method before pharmaceutical lots are sent via the supply chain. This step involves both the sender and the recipient stakeholder entities. Following authentication and verification of medication expiring per the supplied smart contract, the sending entity transmits a pharmaceutical product lot to the receiving entity in the second sub-phase.

3.3. Generating and Validating Transactions

The suggested pharmaceutical supply chain considers the important transactions that occur once a pharmaceutical lot is moved from one entity stakeholder to another. Once the validation process is complete, whenever one stakeholder entity initiates a transaction with another, the blockchain records every relevant interaction, such as delivering several beneficial items from the warehouse to the store. Subsequently, the transaction is sent by the sending stakeholder entity to the LVN, which verifies its legitimacy by the consensus rule by examining the signature of the sender and the Transaction ID.

3.3.1. Automated Traceability of Financial Transactions

There is a significant time cost in repeatedly running the graph creation function to trace the related transactions, which is the primary limitation of conventional approaches. We can streamline the search process by parallelizing activities while tracing transactions across the blockchain. In particular, we used parallel access by dividing the transaction into smaller pieces. In addition, the blockchain verifies each transaction several times for every newly produced chunk.

3.4. Traceability Analysis

This section demonstrates the many procedures used to confirm the legitimacy of the medication Lot. A unique smart contract is embedded into each medicine lot during production; this contract initiates events and records them on the distributed ledger. Each medicine lot has its own distinct Ethereum address. However, duplicating the Ethereum address for every medicine is tedious, error-prone, and

time-consuming. So, a Quick Response (QR) code is used, which can be readily scanned by cellphones. Smartphones can scan two-dimensional barcodes called Quick Response (QR) codes, which may store more than four thousand characters. You may create a QR code that maps to a specific Ethereum address every time it is scanned using an Ethereum QR code generator. Feed the Ethereum address into the generator, producing a unique QR code. The medication may be given to patients once the QR code is connected.

4. PERFORMANCE ANALYSIS

There are several important advantages to using a hybrid blockchain network to track drugs in the pharmaceutical supply chain. One of them is ensuring that the drugs move securely, transparently, and authentically.

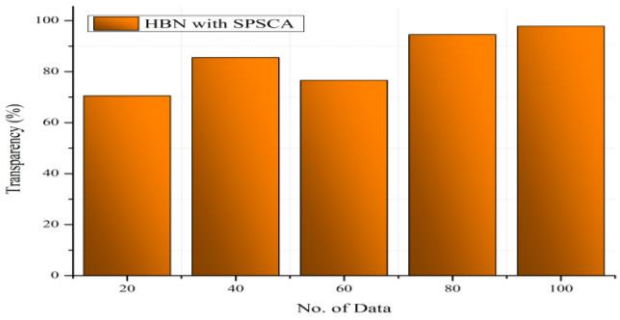

Figure 3: Transparency Analysis

Figure 3 shows the transparency analysis of the proposed work. A hybrid blockchain network creates an immutable, distributed ledger that records transactions and medicine transfers in real-time, improving pharmaceutical supply chain transparency. This system ensures regulators, manufacturers, distributors, and pharmacists get the latest pharmaceutical lifecycle information. For transparency, a hybrid system's public blockchain may contain shipping dates and basic tracking information, while the private blockchain might preserve sensitive data like proprietary equations or corporate details. Dual-layer openness ensures accountability and protects private data. Transparency improves monitoring and verification, preventing fake drugs, deception, and illegal supply chain modifications. Transparency helps stakeholders and consumers verify pharmaceutical products' validity and origin, boosting trust. Today's multinational supply chains are complicated and multi-party, making this crucial. People trust the supply chain more because blockchain may reduce disputes, errors, and ambiguities by providing a single source of truth.

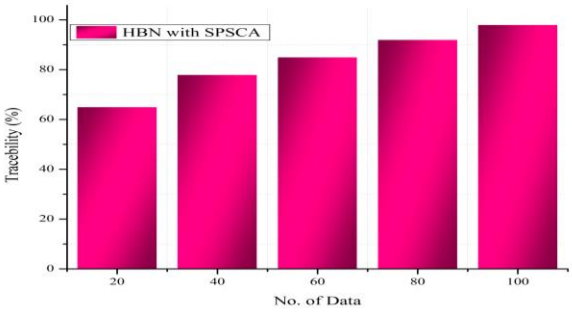

Figure 4: Traceability Analysis

Figure 4 shows the traceability analysis of the proposed work. Traceability is a major benefit of hybrid blockchain networks in the pharmaceutical supply chain. By documenting every transaction on an immutable ledger, blockchain technology makes drug manufacture to destination transparent. Time stamps and cryptographic security are used from packing to shipment to warehousing so authorized parties may easily access the audit trail. Several real-world advantages emerge from traceability. First, it helps identify issues like faulty items or phoney drugs to rectify them faster. Blockchain technology tracks hazardous batches during pharmaceutical recalls, speeding up the process and decreasing patient health risks. Second, traceability reduces regulatory violations and makes monitoring pharmaceutical safety and channel compliance simple. Traceability boosts operational efficiency. Real-time insight into drug locations improves logistics and inventory management. Supply chain managers can better schedule shipments and predict product expiration and shortages. This reduces waste and enhances medicine delivery.

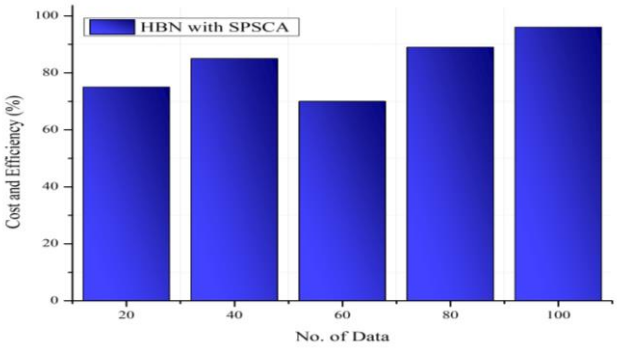

Figure 5: Cost and Efficiency Analysis

Figure 5 shows the cost and efficiency analysis of the proposed work. A hybrid blockchain network allows for more efficient and cost-effective management of pharmaceutical supply chains. By employing the optimal network for each data type, this technique has the benefit of reducing expenditures. Blockchains, both public and private, collaborate. Public blockchains that include thorough monitoring and compliance data are less expensive because they do not need a lot of computing power or security measures for sensitive data. Secure and anonymous user data storage is provided via private blockchain nodes. Logistical nightmares, labour-intensive audits, and intermediaries are cut in half by this hybrid approach to supply chain management. Payment clearance and quality checks are two examples of tedious but essential tasks that intelligent contracts may automate and streamline. The results are reduced personnel expenses and quicker, more accurate transactions. The trustworthy method of validating drugs using blockchain technology lessens the financial effect of counterfeiting. Due to customer hurt, brand damage, and substantial legal costs, the pharmaceutical business loses billions of dollars annually from counterfeit pharmaceuticals..

5. CONCLUSION

A hybrid blockchain network may completely transform the pharmaceutical supply chain by increasing visibility, audibility, and efficiency. Using the features of both public and private blockchains, authorized parties can securely and transparently share vital pharmaceutical data. This approach fosters a sense of responsibility and reliability. Improving the supply chain's ability to trace

a medicine from production to distribution can result in faster recalls, improved compliance with regulatory standards, and reduced counterfeit pharmaceuticals. The hybrid solution also reduces operational costs by automating operations, eliminating mediators, and streamlining transactions via smart contracts. Patients and industry stakeholders can expect the benefits of a more secure, efficient, and transparent pharmaceutical supply chain that employs a hybrid blockchain network.

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