PriMera Scientific Surgical Research and Practice
Volume 4 Issue 5 November 2024
ISSN: 2836-0028

Blockchain-Based Solution for Ensuring Authenticity in the Pharmaceutical Supply Chain

Type: Review Article
Received: August 05, 2024
Published: October 30, 2024

Citation:
K Anitha Kumari., et al. "Blockchain-Based Solution for Ensuring Authenticity in the Pharmaceutical Supply Chain". PriMera Scientific Surgical Research and Practice 4.5 (2024): 30-40.

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Abstract

Background: In the realm of pharmacology, a significant and urgent issue confronting us today is the rampant spread of counterfeit drugs. Pharmaceutical companies have faced increasing challenges in tracing products along the supply chain over the last decade, providing an entry point for counterfeiters to infiltrate markets. The proliferation of fake medications poses a serious threat to global public health, resulting in adverse effects. According to the World Health Organization, some countries experience as much as 30% of medication sales attributed to counterfeits. In less developed nations, the problem is even more severe, with one in ten medicines being identified as fraudulent or non- compliant. The detection of these counterfeits is complicated due to their intricate journey through networks, creating vulnerabilities. To effectively combat forgery, a comprehensive approach is imperative to monitor the entire delivery process. The utilization of efficient blockchain technology holds the potential to authenticate medications and safeguard public health.

Methods: This proposal introduces a pharmaceutical supply chain management system utilizing advanced Hyperledger Fabric technology to securely store medication records in a network. The framework addresses the issue of counterfeit drugs by establishing a drug ledger that meticulously records all network transactions, thereby establishing an intelligent healthcare ecosystem within the supply chain. Central to this system are smart contracts, essential components that confer specific access rights to the drug ledger. These contracts ensure that only authorized entities have control over access to sensitive information. Through the integration of Hyperledger Fabric and smart contracts, the system aims to create a supply chain characterized by transparency, resistance to tampering, and efficiency, effectively combating counterfeit drugs and enhancing the integrity of medication distribution. Ultimately, these improvements contribute to bolstering patient safety and optimizing healthcare outcomes.

Results and Conclusion: Ensuring confidentiality at the chain code layer is achieved through user-specific access controls in Attribute-based access control (ABAC). To evaluate the framework's performance, the blockchain benchmarking tool, Hyperledger Caliper, quantifies crucial metrics such as transactions per second, transaction idleness, and asset usage. This process provides valuable insights into the efficiency and effectiveness of the system.

Keywords: Private Blockchain; Hyperledger fabric; Supply chain; Chain code; Access control

Introduction

Counterfeit drugs present a significant challenge to the global pharmaceutical industry, characterized by deception, mislabeling, and subpar quality that disregards regulatory standards. The World Health Organization (WHO) reported that underdeveloped countries can experience up to one-tenth of purchased drugs being counterfeit and of poor quality. These counterfeits often contain inaccurate ingredient quantities and are susceptible to contamination, posing health risks. Exploiting reputable pharmaceutical brand names, counterfeit drug manufacturers infiltrate the legitimate supply chain, enabled by advanced technology's global distribution. Both the FBI and the International Anti-Counterfeiting Coalition (IACC) recognize counterfeiting as a major criminal activity due to rising global infections. Illicitly circulated drugs lack legitimacy, often originating from unregistered manufacturers. Urgent comprehensive measures are needed to combat this issue and ensure public health safety. The use of counterfeit drugs has led to increased fatalities, as reported by WHO [16]. These medications not only fail to aid patient recovery but also pose grave threats to human well-being. Complex networks facilitate their distribution, making it challenging to identify these fraudulent substances. Circulating obscure medications worsens patterns of misuse. Oversight lacks qualified organizations, spanning production to dissemination. This approach ensures transparent and accountable medication handling, incorporating cutting-edge tech. Secure supply chains and management are vital. The solution involves monitored delivery at each stage, from sourcing to reaching consumers. Blockchain technology emerges as an innovative solution for real-time tracking [11, 15, 18, 19].

Blockchain technology efficiently manages and monitors production network interactions via a secure digital record system. It organizes executed transaction details into blocks, functioning as a distributed database. Each block stores transaction info, timestamp, date, cost, and participants. Decentralized across the network, independent nodes validate transactions without direct communication. Blocks contain previous and current hash codes, interlinked, and secured through cryptography. Robust algorithms empower mining nodes to validate blocks without data compromise. Approved blocks integrate into the blockchain network, ensuring tamper resistance and transparency. The network comprises interconnected blocks adhering to defined storage rules. Miner nodes collaboratively create new blocks, forming independent transaction chains. This distributed framework captures transaction data, maintaining a historical record [20].

Blockchain is divided into three types: private, public, and consortium. In public blockchains, miner nodes independently validate and oversee transactions, participating in consensus for integrity (e.g., Ethereum, Bitcoin). Private blockchains ensure confidential info and transactions, accessible only to authorized members. This aligns with consortium networks where a single admin adds authorized members. Multichain networks resemble private blockchains [12].

Blockchain emerges as a prime solution for managing the complex pharmaceutical supply chain. Some companies already adopted it for enhanced security in inventory management, while others transition for the same reasons. Increased node participation minimizes network failure risks. This approach uses Hyperledger Fabric to robustly manage the supply chain, enabling real-time monitoring, mitigating counterfeiting concerns, and prioritizing secure medication delivery and consumer well-being.

Our proposed framework's operational mechanics are as follows: Firstly, an innovative blockchain-based pharmaceutical supply chain framework is established to seamlessly and securely exchange information among stakeholders like suppliers, manufacturers, distributors, pharmacies, hospitals, and healthcare facilities. This collaborative use of the blockchain network efficiently shares crucial data [7]. Next, a sophisticated access control mechanism is integrated, powered by smart contracts that employ attribute-based access control. It enforces strict restrictions on unauthorized users. The framework uses a command-line terminal interface for streamlined handling and monitoring of medication inquiries. Transaction validation and verification adhere to well-defined guidelines within the access control policy and transaction history. A plethora of transaction records are systematically stored in CouchDB, addressing the challenge of information overload by ensuring separate storage for each blockchain network node, optimizing data management. The ultimate goal is to empower consumers, especially patients, with transparent and ethical medication access from the process's start, fostering an environment of accountability. The framework's development and effectiveness are thoroughly evaluated using Hyperledger Caliper, a cutting-edge benchmarking tool for in-depth smart contract performance assessments. This tool analyzes throughput, latency, and resource consumption within the active blockchain network during smart contract usage [8, 9].

Related Works

The use of blockchain technology in the pharmaceutical supply chain has been extensively studied and documented. This analysis examines insights from these studies. Blockchain securely stores and transmits data, benefiting organizations by enhancing security, efficiency, and decentralization. While blockchain originated with Bitcoin, its applications have expanded beyond finance, particularly in healthcare. However, blockchain's role in healthcare is evolving. Healthcare experts are actively keeping up with advancements and research. This compilation highlights current blockchain applications in healthcare, showcasing its potential to shape the industry's future.

Blockchain and Machine Learning-Based Drug Supply Chain Management and Recommendation System for the Smart Pharmaceutical Industry" was developed in 2020 by Abbas, Khizar, Muhammad, Afaq, Ahmed Khan, Talha, and Song, Wang-Cheol. The system consists of two core modules. The first employs Hyperledger to establish an efficient drug supply chain management system capable of seamless pharmaceutical distribution. The second module employs AI, utilizing N-gram and LightGBM models, to suggest optimal medications to industry customers. An implementation challenge is the real-time testing of the AI model and recommendation system within pharmaceutical companies [1, 14]. "Drug Supply Chain Management System with IoT and Blockchain Integration," authored by Jianfeng Shi, Dian Yi, and Jian Kuang in 2019, utilizes IoT devices to capture drug product status. Blockchain technology ensures transparent, tamper-proof data sharing across the supply chain and incorporates a consortium- based permission control mechanism for data security. A limitation is its suitability for small organizations, accommodating a predetermined number of transactions within a short time for heightened security [2]. The work titled "Blockchain Technology for Detecting Falsified and Substandard Drugs in Distribution: Pharmaceutical Supply Chain Intervention," authored by Patrick Sylim, Fang Liu, Alvin Marcelo, and Paul Fontelo in 2019, presents a Distributed Application (DApp) using Swarm as the Distributed File System, functioning on smart contracts.

Two cases are presented: Hyperledger Fabric and Ethereum. Ethereum's PoW or PBFT consensus algorithms replace current ones for adaptability. The system lacks the ability to trace counterfeit drugs outside legitimate chains [3]. The importance of ontologies in blockchain design is argued by Kim in "Towards an Ontology-Driven Blockchain Design for Supply Chain Provenance" (2018). The paper discusses how ontologies enhance blockchain, focusing on agreements for provenance and traceability on Ethereum [4]. "Securing E-health Networks from Counterfeit Medicine Penetration Using Blockchain" by Pandey and Litoriya suggests a QR code framework. This QR code includes medication details, manufacturer info, dates, batch data, and logistics. QR coding prevents counterfeit drug infiltration, but extensive validation is crucial for large organizations [5]. "Utilization of Blockchain and IoT towards the Pharmaceutical Industry" by Premkumar and Srimathi explores blockchain in various sectors, not just healthcare, indicating its broad application. Researchers develop blockchain in smart grids, vehicle interactions, and cloud computing [6, 12].

Proposed System

Overview of pharmaceutical supply chain management system

Blockchain's decentralized and widely distributed nature significantly boosts pharmaceutical supply chain security and privacy. Figure 1 illustrates the comprehensive medication supply chain, including management components. Network participants oversee and update the entire chain, with user data securely stored. Assets managed include drugs, raw materials, orders, and records. Users access a client app-based terminal interface to execute transactions. Stakeholders track medication deliveries and verify details like expiration dates, pricing, and manufacturing dates [17].

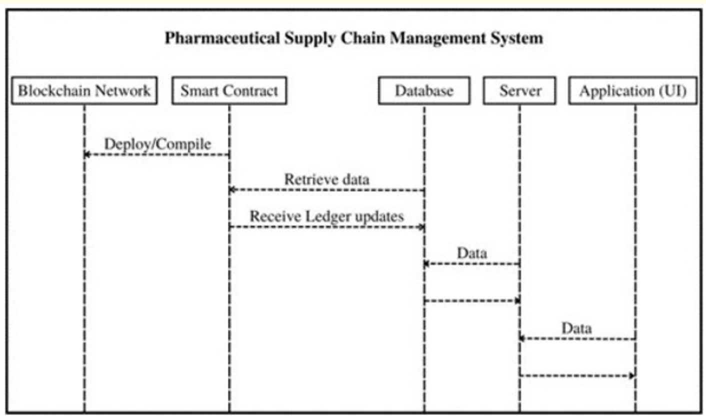

Figure 1: Sequence Diagram of Pharmaceutical supply chain management system.

In the framework, peer hubs calculate agreements for record consistency. The primary provider sends raw materials to the pharmaceutical company. If a producer orders raw material, any partner hub can approve it. Once approved, the provider receives the request. When the raw material request is ready for delivery, the provider confirms the order. Only a detailed medication information check by a client enables actions termed authorization rules in the blockchain network. Another instance: if a doctor wants to order from a drug company, they follow the same steps as the previous case in our proposed blockchain framework. Verification of the doctor, submitting the transaction proposal, manufacturer approval, doctor's confirmation, and event message for successful transaction inform order status [10].

Components of Hyperledger Fabric network

- Ledger: A distributed database shared and synchronized across multiple locations, entities, or geographies, accessible to various participants.
- MSP (Membership Service Provider): An abstract component offering authentication for clients and entities to engage in a Hyperledger Fabric network.
- Peers: They maintain records and execute chain code for read/write operations on the ledger.
- Ordering Service: A group of nodes responsible for sequencing transactions in a block. Independent of peers, it orchestrates transaction arrangement across channels based on a first come, first-served principle.
- Channel: A private blockchain overlay ensuring data confidentiality. Data within a channel is exclusively shared among channel peers, and valid communication requires proper validation through the channel.
- CA (Certificate Authority): The default Hyperledger Fabric CA issues PKI certificates for trust establishment between network participants and users.

- Organizations: Invited to join the blockchain network via a blockchain service provider, organizations incorporate their MSP into the structure.

Architecture of the proposed system

Supply chain architecture

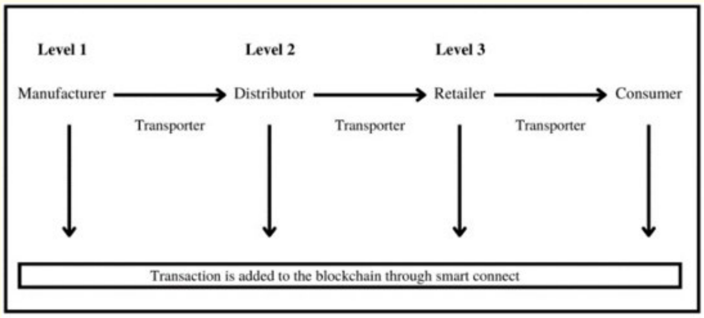

Figure 2: Supply chain architecture.

As demonstrated in the Figure 2, there are five partners/associations in this store network organization.

- Producers: Medication manufacturers, whether enrolled or future participants with the company, are categorized here. Notably, drug manufacturers like 'Sun Pharma' and 'Dr. Reddy's Laboratories' belong to this group.
- Wholesalers: This group consists of registered or prospective drug distributors who directly procure drugs from manufacturers. Notable examples include 'VG pharma' and 'Medico Labs,' prominent drug wholesalers within the 'Wholesalers' category.
- Retailers: Pharmacists or drug retailers fall under this category, receiving drug shipments from wholesalers.
- Consumers: Individuals purchasing medications from pharmacists.
- Carriers: Entities entrusted with transferring shipments between designated points. Renowned carriers like BlueDart or FedEx handle the transportation of drugs from manufacturers to distributors. Similarly, carriers play a role in transferring from distributors to retailers.

Smart contract

A concise explanation of smart contracts depicts direct asset exchange without intermediaries. A hallmark feature of blockchain, they are code enforcing party agreements, eliminating mediators. Code has predefined rules parties must follow. When conditions align, contracts execute automatically. They manage access and assets, stored safely on the blockchain, immune to tampering. Securely translating terms into code, smart contracts validate and enact through consensus. Challenges include learning Solidity, a complex language, making mastery demanding. Intermittent transaction execution among peer nodes hampers speed, requiring more effort. Selectively deploying contracts to specific nodes, not all, overcomes this. Defined node clusters enhance efficiency. Smart contracts use Java, Node.js, easing logic formulation in familiar languages beyond Solidity.

Smart contract architecture

The workflow required for the case study as depicted in Figure 3 is divided into the following three units:

- Company Registration.
- Drug Registration.
- Transfer Drug.

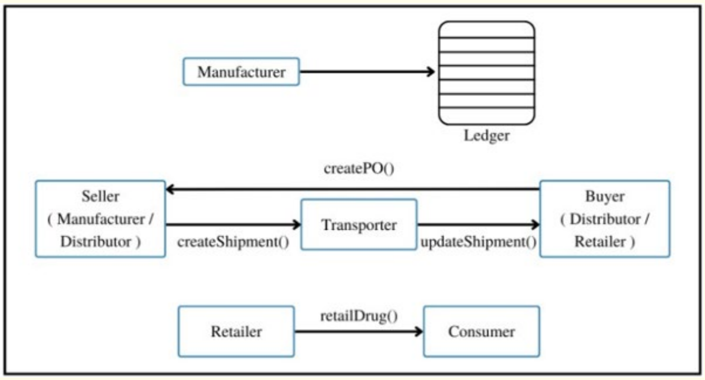

Figure 3: Smart contract architecture.

The work process needed for the contextual analysis is isolated into the accompanying three units:

- Company Registration
  All elements who wish to be important for the inventory network should be first enlisted or, in different terms, put away on the record.
- Drug Registration
  As a piece of this interaction, any medication produced must be enlisted on the record by the assembling organization.
- Transfer Drug
  A buyer raises a Purchase Order for specific medication cluster. It includes medication name, quantity, buyer details. Vendor initiates shipment using 'FedEx', creating a shipment item. It contains carrier info, origin, destination. Upon receiving, buyer becomes cluster owner. For consumers, only ownership transfer occurs, omitting Purchase Order and shipment process.

Transaction execution procedure

This section elucidates the conditional process in the pharmaceutical supply chain using a management framework. Users gain terminal access with registered credentials to interact with the blockchain. The administrator enrols participants, granting transaction initiation. To propose a transaction, users log in, submit requests, and peer nodes receive these proposals. Nodes fall into two categories: committers and endorsers. Endorsers validate and execute transaction proposals per smart contract criteria. Committers validate outcomes before adding to the ledger. Endorser peers, a specialized subset of committers, execute smart contracts for transactions, updating the ledger. In the simulated environment (RW set), they differentiate between read and written data—prior and post-transaction states. Endorser peers send endorsed transactions and RW sets to customers. Customers resend these to the consensus admin who forwards to committers, verifying and writing data to the ledger. The process concludes with updated ledger data. Committer peers notify customers of transaction status.

Implementation

Pre-setup

Generating all certificates and keys for our various network entities. To create a network according to a pharmaceutical organization's structure, and to bootstrap a channel, the following artifacts need to be generated.

- A genesis block containing certificates specific to each organization, which serves as the initial step in initializing the fabric blockchain.

- Configuration data for the channel, outlining its properties.
- Configurations for anchor peers for each organization, defining their role and positioning within the network.

Start network

Initiate the network deployment through automated scripts. Establish the Hyperledger Fabric Network by configuring the "pharmachannel" and incorporating the various peer organizations such as manufacturers, distributors, transporters, and retailers.

Start the chain code

Implement the PHARMANET chain code onto the Pharma Network and proceed to install the chain code across the peer organizations.

Attribute based access control

Dedicated terminal tabs will be established for each organization, enabling the invocation of functions on behalf of individual entities.

Web application

The Fabric API server employs a foundational API named "shim" or "fabric shim" for communicating with the chaincode. The website's server-side script triggers Fabric API calls to perform various actions concerning chain data. To operationalize the Fabric API server, it's launched initially, followed by setting up a web server. Subsequently, server-side code is crafted to interact with the API server, meeting diverse requirements for chain transactions. These include functions like "install," "instantiate," "invoke," and "query." Additionally, Table 1 offers an illustrative example of a smart contract designed for generating certificates and initiating network operations.

```
#To generate the needed certificates, the genesis block and
to start the network

function networkUp() {
 checkPrereqs
 # Generate artifacts if they don't exist
 if [ ! -d "crypto-config" ]; then
 generateCerts
 replacePrivateKey
generateChannelArtifacts
fi
# Start the docker containers using compose file
IMAGE_TAG=$IMAGETAG docker-compose -f
"$COMPOSE_FILE" up -d 2>&1
docker ps -a
if [ $? -ne 0 ]; then
echo "ERROR !!!! Unable to start network"
exit 1
fi
# Wait for 10 seconds to allow the docker network to stabilise
sleep 1
echo "Sleeping 10s to allow cluster to complete booting"
sleep 9
}
```

Table 1: Sample smart contract.

Result Analysis

Verify the chain code functionality

Register companies

To enroll a company within the network, individuals are required to furnish essential information including the company's name, location, identification, and designated role. In cases where an attempt is made to register a company using a name and identification that already corresponds to an existing entity, the system is designed to promptly generate an error message conveying the message, 'Invalid company details. A company with this specific Customer Relationship Number (CRN) already exists.'

Add the drug to the ledger

Manufacturers possess the capability to incorporate drugs into the ledger by furnishing specific details, including the drug's name, unique identification, manufacturer's name, and corresponding identification. In scenarios where a user endeavors to input a drug featuring an identical name and identification as an existing entry, the system is programmed to promptly issue an error message stating, 'A drug with the same name already exists within your records.' Furthermore, if a user attempts to introduce a drug using a Manufacturer CRN id that is deemed invalid, the system will promptly generate an error message communicating, 'Invalid CRN. No manufacturer is associated with the provided CRN.'

Create purchase order

Distributors can create purchase orders by entering crucial details like drug name, unique ID, distributor ID, and manufacturer ID. If a manufacturer tries to make a purchase, an immediate error message states, 'Buyer cannot be the manufacturer.' Similarly, unregistered users triggering purchase order creation receive an error message notifying their unregistered status.

Create the shipment

Manufacturers can start drug shipments to distributors by providing vital details like drug name, unique ID, distributor ID, and transporter ID. Transporters ensure secure and efficient movement of drugs from manufacturer to distributor. If any organization other than the manufacturer tries to initiate a shipment, the system smartly generates an error: 'Unauthorized operation.'

Update the shipment

Transporters hold the authority to provide updates on the status of drug deliveries, indicating whether a particular drug has been successfully delivered or not. This process involves supplying essential information, including the drug's name, distributor identification, transporter identification, and the corresponding status of the delivery.

Sell the drug

Retailers can sell drugs they own. If a retailer tries to sell a drug not in their possession, the system generates an error: 'Unauthorized sale - not the rightful owner.' Furthermore, attempting to sell a drug with an invalid name or ID prompts an error: 'No matching drug with specified name and ID.'

Performance evaluation

The system utilizes Hyperledger Caliper, an open-source benchmark framework for assessing blockchain solutions. Developed by the Linux Foundation, it evaluates performance across various blockchain platforms like Fabric v1.0, Sawtooth 1.0, Iroha 1.0, Burrow 1.0, and Hyperledger Composer. The Caliper tool includes a range of performance metrics, such as success rate, transaction throughput, and latency (minimum, average, maximum, percentiles). It also offers insights into resource allocation like CPU usage, memory utilization, and I/O operations. Calculated metrics, each with a brief description of its significance, are provided below.

- Transaction Response Time: This metric gauges the duration it takes for a transaction to send a request and receive a response from a blockchain platform, thereby indicating the efficiency of the transaction process.
- Transaction Throughput: Measured within a specified timeframe, this metric quantifies the rate at which valid transactions are successfully processed and committed by the blockchain system under testing (SUT).
- Transaction Latency (Minimum, Maximum, Average): Transaction latency represents the time interval required for a transaction's impact to propagate through the network. This encompasses the full duration from the moment of submission to the point when the results become accessible across the network, with metrics including the minimum, maximum, and average latency times.
- Resource Utilization: This involves the efficient allocation and utilization of resources during the processing of transaction requests and responses. Assessment of resource utilization involves monitoring the extent to which the blockchain system employs CPU, memory, network, and input/output (I/O) resources within a defined time period.

Overview of the functionalities

The Table 2 shows the overall functionality of the supply chain, which can be performed by manufacturer, distributors, transporter, and retailer.

	Manufacturer	***Distributor***	***Transporter***	***Retailer***
Adding the drug	✓	-	-	-
Creating purchase order	-	✓	-	✓
Creating shipment	✓	-	-	-
Updating shipment	-	-	✓	-
Selling the drug	-	-	-	✓

Table 2: Overall functionalities.

Conclusion

In the realm of blockchain technology, authorized users engage collectively with an unaltered and permanent data source. Each transaction is meticulously duplicated across all chain blocks, ensuring an unmodifiable record. Blockchain has the potential to transform the traditional supply chain by incorporating security, automation, anonymity, persistence, traceability, and decentralization. The proposed system aims to address counterfeiting and authenticate pharmaceutical products. This is achieved by executing drug record transactions on a blockchain, fostering an intelligent healthcare ecosystem within the drug supply chain. The solution enables manufacturers, distributors, transporters, retailers, and consumers to collaboratively oversee, access, and ensure secure drug processes using transparent transaction logs. The integration of Hyperledger Fabric technology prevents data ownership monopolization and manipulation, ensuring data integrity and enhancing supply chain reliability.

Current & Future Developments

In terms of future steps, enhancing user accessibility can involve the development of smartphone applications, complemented by the implementation of QR code scanning to optimize system efficiency. To further elevate performance, the integration of RFID and IoT sensors presents an opportunity to meticulously monitor drug movement and status in real-time. Additionally, scaling up the network size and deploying the system within operational pharmaceutical companies could serve as a valuable avenue to rigorously test and validate the efficacy and reliability of our proposed solution.

Availability of Data and Materials

Not applicable.

Consent for Publication

Not applicable.

Funding

None.

Conflict of Interest

The authors declare no conflict of interest, financial or otherwise.

Acknowledgements

Declared none.

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