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Blockchain-Based Traceability of Counterfeited Drugs

Bipin Kumar Rai, ABES Institute of Technology, India*
https://orcid.org/0000-0002-9834-8093

Shivya Srivastava, ABES Institute of Technology, India

Shruti Arora, ABES Institute of Technology, India

ABSTRACT

In the healthcare industry, providing a vital backbone for services is critical. The supply chain is a complex network that crosses organizational and geographical borders. In the healthcare business, counterfeit pills are one of the primary reasons for the harmful impact on human health and financial loss. Thus, pharmaceutical supply chains and end-to-end tracking systems are the recent research in healthcare. In this paper, the authors propose blockchain-based traceability of counterfeited drugs (BBTCD) that implements tracking of counterfeited drugs using smart contracts on the Ethereum blockchain. They offer a solution to fully decentralize the tracking by storing BBTCD on IPFS (inter planetary file system) to provide transparency and cost-effectiveness.

KEYWORDS

Blockchain, Counterfeit, Decentralised, Ethereum, Supply Chain

INTRODUCTION

The suppliers of raw materials, manufacturers, retailers, hospitals, distributors, clinics, and patients are contained as an agent in the healthcare supply chain. The necessity of data, centralized organizations and the competition in the market between the partners and other factors are responsible for the difficulty in supply throughout the process. It is complex due to COVID-19 (Chambliss et al., 2012) and the challenge of countering fake drugs as they can quickly soak the healthcare sector.

Some healthcare drugs are produced and illegally designed to increase financially in the market, which affects human health while they seem genuine(Chambliss et al., 2012). Medicines with no proper ingredients, inaccurate amounts of API, repackaging of expired drugs, a lower degree of rank, and poisonous substances are examples of medications that lead to harmful side effects like organ failures and even death.

In India, CDSCO (Central Drugs Standard Control Organization) is an administrative office assigned to recognize the materials for producing drugs through a loyal API provider. The re-packager gets a bundle of the drugs from the manufacturer. A few parts of the item are sent to merchants. Others

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*Corresponding Author

depend on switching the medications built on item requests or secondary suppliers (if the number of items is exceptionally vast) who will change the items to the stores. In the end, patients usually medicate on doctor's prescribed medicine allotted by stores. The whole process does not need a third party because of the supply chain (Musamih et al., 2021).

Demand for drugs has increased quickly in recent years and has been widely exported to the market on profit margins (Musamih et al., 2021). Poor healthcare facilities, public and private sector corruption, and restricted access to effective medicinal products are the critical causes of counterfeit and second-rate drugs. For this reason, we need dominant and constant monitoring of healthcare items in the supply chain market (Marucheck et al., 2011).

Several governments worldwide help to improve the demand for tracking and tracing counterfeited drugs. The traceability of drugs has turned out to be an essential part of the healthcare supply chain that authenticates tracking and tracing of healthcare products in the supply chain (Conti et al., 2018).

In the healthcare industry, counterfeit drugs are a significant problem that concerns patients who consume drugs. The information gathering of drugs is resolved by open-source intelligence (OSINT) based solutions (Rai et al., 2021), and the medical prescription and Report Analyzer (MPRA) proposed model helps patients to analyze the data and prescribed medicines by providing handwritten text data from images (Kumar Rai et al., 2021).

Hospitals and pharmacies are knowledgeable about the complications in analyzing the materials used in drugs; this is a significant cause in the healthcare sector for patient illness. The PcPbEHR system designed an algorithm for a healthcare information system that maintains the security and privacy of patient data (Rai, 1 C.E.), and electronic healthcare records (EHR) help to maintain the safety of patient information with the support of chained hashing (Rai, 2022).

In this paper, we propose blockchain-based traceability of counterfeited drugs (BBTCD) that implements tracking of counterfeited drugs using smart contracts on the Ethereum blockchain. We propose a solution to fully decentralize the tracking in healthcare by storing BBTCD on IPFS (Inter Planetary File System) to provide transparency and cost-effectiveness.

BACKGROUND

We have tried to showcase all the research work done before to place our piece against the problem statement.

Ellis Soliman et al. (2019) defines their application using an inimitable smart contract which merges with the Ethereum blockchain through Newcastle university and establishes a centralized management platform (Solaiman et al., 2021). Benedikt Notheisen et al. (2016) give three schemes of recent research: First, they present the irreversibility of transactions to decrease the risk of transaction failure. Second, they introduce an independent transaction database with more security for registration and transactions. Third, they provide reliability, transparency, and records of every market's asset (Notheisen et al., 2017). Nakka Murali Krishna et al. (2020) introduce a supply chain system that uses a distributed public ledger for secure transmission and tracking (Krishna & Kumar, 2020). National Urban Security Technology Laboratory (2016) gives data on 20 assets and inventory systems. Commercial merchants provide a solution, product, and technology from the market but cannot cover all retail merchants (FDA, 2014).

Mr Daryl Woodfield, DAF (2019) studies blockchain in more detail, specifically how the DOD supply chain influences DOD assets in cyber security. Their descriptive study states that to prevent counterfeit products, they need to analyze related work done through blockchain in the healthcare sector and then conclude what best algorithms are designed for the DOD supply chain for DOD assets in cyber security (Woodfield, 2019). Arnab Banerjee et al. (2019) propose a solution for tracking and tracing to upgrade the performance of tasks for the recall and return of products. They simplify the penetration process, gathering and obtaining information through a transversely multifaceted supply chain through a centralized system (Banerjee & Venkatesh, 2019). Victor Zakhary et al. offer permission and non-permission blockchains for data management of assets of drugs. Governmental administrations manage permission blockchains (Zakhary et al., 2019).

Jonathan Chiu et al. (2018) work on non-permission blockchains to provide more security. Their primary focus is the PoW protocol (Chiu & Koeppl, 2018). Ashar Ahmad et al. (2021) help to solve the problems and challenges that are faced in classifying and processing various blockchain mechanisms (Ahmad et al., 2021). Jiang Wang (2002) talks about the US stock market for the exchange of stock and data capacity (Wang et al., 2002). Abdullah Al Omar et al. (2017) offer blockchain-based secure data storage for patients' healthcare information management. It is a centralized system (Al Omar et al., 2017). Haya R Hasan et al. (2018) give a POD solution using blockchain for the shipment of raw materials that are used in the Ethereum innovative contract network for tracking and tracing of products and done with higher accuracy, security, integrity, reliability and invariability (Hasan & Salah, 2018).

Rai, B.K. (2022) talk about current technologies used in the market. These blockchain technologies are used from a technical and application standpoint and interfere with actual and future problems. (Yang et al., n.d.; Utz M. et al., 2019) introduce a local market for financial implications, the issue of reimbursement, and incentivizing grid nature in the marketplace (Utz et al., 2019).

Nishara Nizamuddin et al. (2019) provide a sale and digital publication of assets using blockchain technology (Nizamuddin et al., 2019). Alexander Djamali et al. (2021) offer a methodological solution for providing a high frequency of data and efficiency that uses a Merkle tree and influences Merkle 12 proofs for confirmation of data integrity, privacy and security (Djamali et al., 2021). Francesco Maesa et al. (2017) introduced a blockchain-based protocol, a widely evident policy for exchanging rights. Therefore, any handler can use resources and knowledge about policy at all times paired with resources (Di Francesco Maesa et al., 2018).

Dounia Marbouh et al. (2020) track data of new, death and recovery cases and prepare a report from authentic sources that helps to plan, build and evaluate an Ethereum-based blockchain system (Marbouh et al., 2020). Fran Casino et al. (2019) offer a complete analysis of blockchain-enabled applications in a variety of industries, including supply chain, business, healthcare, IoT, privacy, and data management, as well as important topics, trends, and upcoming research areas (Casino et al., 2019). Roman Beck et al. (2017). They provide tangible benefits for managing assets, a physical partnership of support, financial services, and everyday activity (Beck et al., 2017).

BLOCKCHAIN FOR DRUG TRACEABILITY

The centralized system is commonly used in tracing the traditional healthcare sector. Openness is required in supply chain management, maintaining privacy by permitting the central handler to change data without third-party involvement. Blockchain offers integrity, privacy, security, clarity, and recoding of all transactions (Chambliss et al., 2012). Blockchain technology is a distributed ledger, decentralized system and interoperability property that makes it more unique and helps secure transactions and traces our assets. In the market, straightforwardness and tracing are used in different fields. In the supply chain, complex information is termed straightforwardness. Such as the name of the supplier and so on is demonstrated in the supply chain (Ahmad et al., 2021) as granular data are connected with tracing, which helps select any component.

BLOCKCHAIN-BASED TRACEABILITY OF COUNTERFEITED DRUGS (BBTCD)

Considering the current situation, we propose a decentralized solution, BBTCD. It is a multichain system that allows users to deploy its smart contract on the Ethereum blockchain. Our proposed solution has three major stages.

Stage 1 in which the stakeholders visualize the intelligent contract, the decentralized storage system and on-chain resources with the help of software devices that consist of a front-end layer denoted by a DApp (Decentralized Application), which is connected to the smart contract, on-chain resources, and decentralized storage system by an application program interface (API) such as Infura and Web3.

Stage 2, the already authorized function, will get started when stakeholders interact with the smart contract, and then a decentralized storage system will access the data file.

Stage 3 at the end, they meet with the on-chain resources for the required information such as logs, IPFS hashes and transaction

SYSTEM ARCHITECTURE

Every entity of BBTCD must first be registered on the blockchain network. The components shown in figure 1 are:

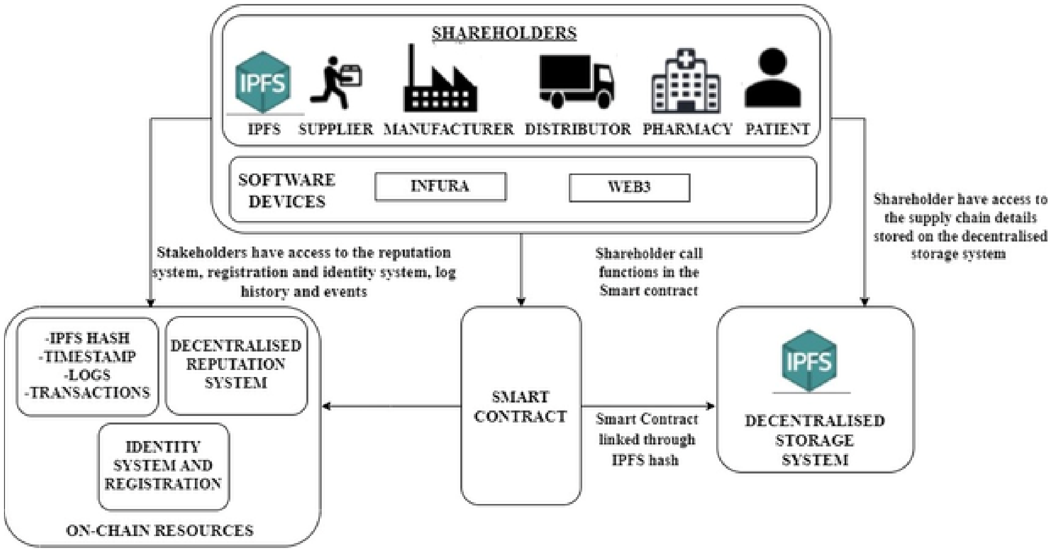
- **Stakeholders:** support the agencies like the CDSCO team, distributors, suppliers, and patients. These agencies are dependent on the participation of the supply chain market. Stakeholders also have access to tracing and tracking information like records and login information. These stakeholders have a direct concern about healthcare services.
- **Decentralized Storage System:** IPFS helps in verifiable, accessible, programmable and efficient transactions for storing data in the supply chain. The integrity of the decentralized storage system is maintained by uploading files with the help of the Secure Hash Algorithm (SHA). These uploaded files are stored in the blockchain through intelligent contact, with minor changes reflected in the SHA.
- **Ethereum Smart Contract:** manages the decentralized storage system and the deployment process, an essential key factor for recording transactions and collecting data. That helps in providing access to the participants and all the stakeholders. In this process, a modifier is used to remove non-specific transactions and add specified parties with the help of intelligent contact. The stakeholders approve complex transactions as it has all the suppliers' accessing information.
- **On-chain Resources:** refer to those available inside the blockchain network. These resources can work on public keys and are used by third parties. These resources are used for storing and enabling transactions to track and trace intelligent contracts. Rai, B. K. et al. (2022) discuss different platforms for managing it.
- **The distributor:** bundles all the smart contracts and takes a backup of all the packages to start the delivery process. They supply a lot to pharmacies for secure transmission and transfer limited stock to valuable parties.
- **Sale:** contact between the pharmacist and the patients are the sequence diagram's final phase. The pharmacy will start selling the medicine Lot box here and will be announced to all supply chain partners. The IPFS will then upload a picture of the sold drug package and send a hash to the smart contract. The patient will get the medication Lot box, which marks the end of the drug Lot selling phase.

Two smart contracts manage the entities such as patient and drug lot:

BBTCD_Parent Smart Contract

It is deployed only once and is responsible for adding, updating and deleting drug lot information. It also deploys other smart contracts.

Figure 1. System architecture of blockchain for counterfeited drugs



BBTCD_Patient Smart Contract (BBTCD_PSC)

BBTCD_PSC is deployed as per the patient and is responsible for checking drug information. PSC allows the patients to give information about the drug, whether it is counterfeit or not. Its functioning includes storing records on IPFS.

The sequence of movements shown in figure 2 is as follows:

1) A manufacturer will request CDSCO initiates the drug manufacturing process. After approval from CDSCO, the manufacturer will start the manufacturing process.
2) On IPFS, the image of the drug lot is uploaded by the manufacturer, and then IPFS sends respective data to the smart contract so that participants access those images later. Then, the distributor will get the drug lot for packaging.
3) The image of the packaged drug will be uploaded on IPFS, which will be sent to the smart contract by the distributor. Then, all packages are sent to the pharmacies.
4) In the end steps of the sequence diagram, only two participants will interact: the pharmacy and the patients.
5) Pharmacy will sell drugs, and an event will be declared in the supply chain to all participants. Sold drugs image is uploaded on IPFS, which will send data to intelligent contract by the IPFS.
6) All transactions are recorded and can be accessed by all participants in the supply chain.

The workflow of the proposed BBTCD is shown in figure 3. An API supplier is responsible for delivering the raw materials to manufacture drugs approved by the Indian agency CDSCO. CDSCO checks the raw materials and approves or denies the lot manufacturing. Sometimes the manufacturer needs a re-packager for sending a drugs Lot. Distributors receive their packages of packaged products and then send them to hospitals and dispensaries. When the quality of lots is substantial, we move some packaging to the secondary distributor. In the end, dispensaries and hospitals allow the drugs to the patients as prescribed by their doctors.

Figure 2. Sequence diagram of blockchain for counterfeited drugs

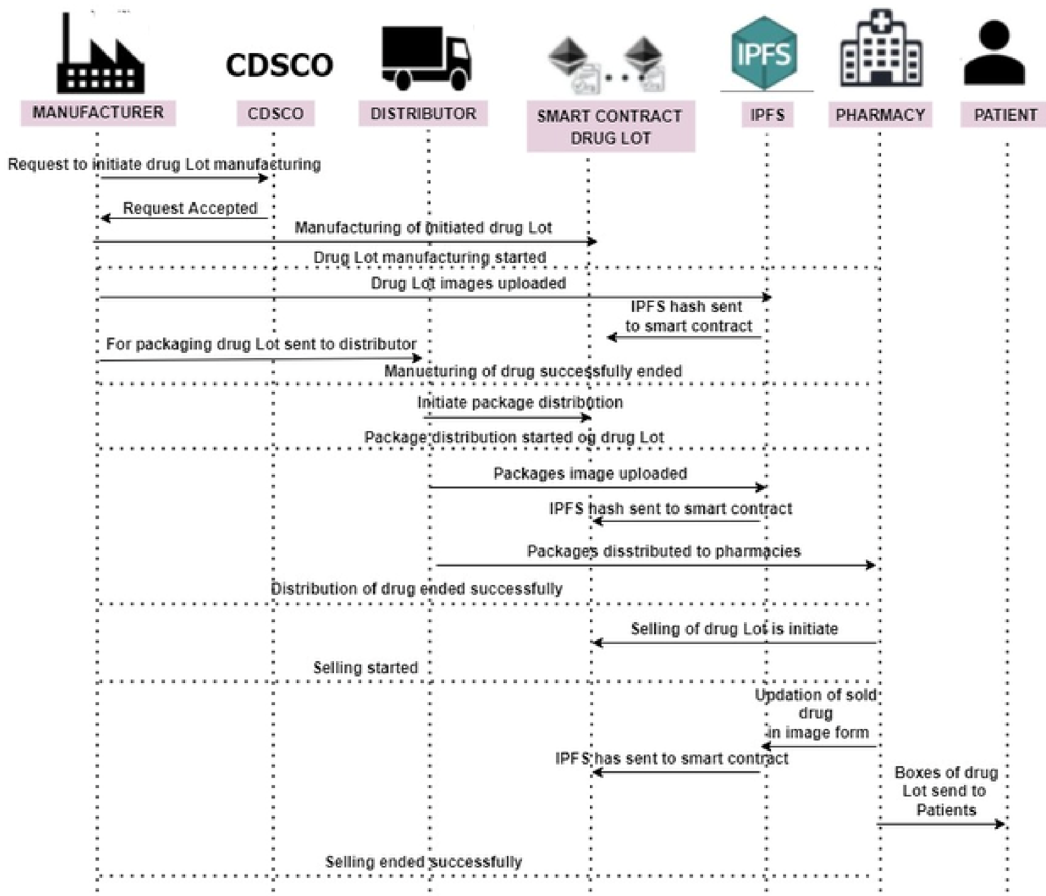
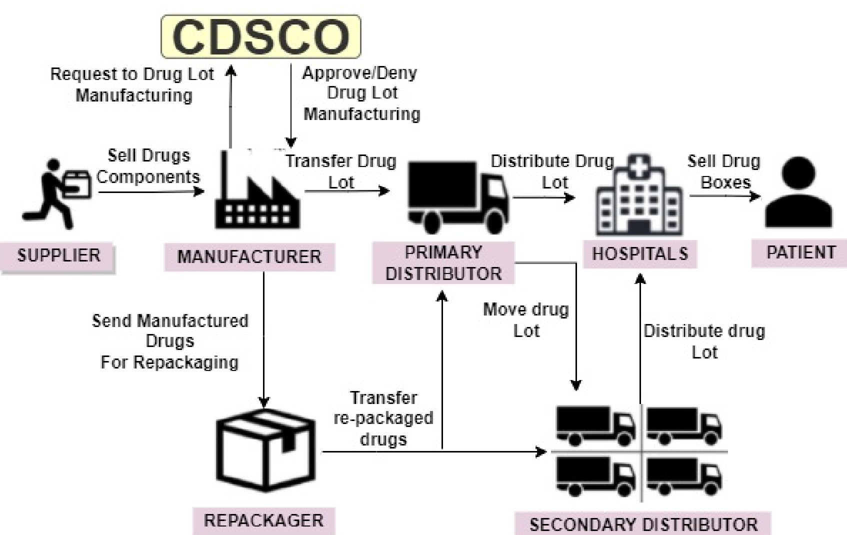


Figure 3. Workflow diagram of blockchain for counterfeited drugs



IMPLEMENTATION

We use Remix IDE for the compilation and testing of the smart contract. In this, an intelligent contract is first deployed with the manufacturer's help, where all the details of the manufactured drugs are defined. The system is decentralized, which helps prevent our system from hacking, modifying, removing, and accessing data.

The current smart contract has the address of Ethereum and is installed using the ownerID gateway. There is only a single ownerID because the drug lot is in a smart contract, and once the owner changes, an event is formed and recorded on the database, which helps us track and trace the source of the drug lot, but the ownerID is a pathway, not a mapping.

The respective pharmacy lots and the smart contract have features like Name, Price, nBoxes and images. Three mappings occur for companies that have permission to access some entities such as suppliers, manufacturers, etc. For a complete result, the manufacturer and seller require smart settlement that needs several skills. Details contain the data about the manufacturer and take various inputs such as Name, Price, nBoxes, and priceofbox.

```
Creating a Lot in Smart Contract:
Input: Name, Price, nBoxes, priceofbox, IPFS_hash, CallerID, OwnerID
Output: The image has been uploaded and manufactured by declaring
an event.
Data:
Name: defines the name of the Lot
Price: specifies the name of the Lot
nBoxes: represents the entire number of boxes in the Lot
priceofbox: determines the price of each box in the Lot
IPFS_hash: defines IPFS hash function of the image in the Lot
ownerID: specifies the owner address of the Lot
Initialization:
if CallerID == ownerID then
  Update Name
  Update Price
  Update nBoxes
  Update priceofbox
  Add IPFS_hash
An event is released and declared when Lot has been manufactured.
An event is released and declared to the IPFS server when the Lot
image has been uploaded or else
Revert and show an error
Granting Lot Scale:
Output: Sale of Lot occurs, and then an event is declared
Initialization:
if CallerID == ownerID then
  An event release for the sale of Lot
or else
  Revert and show an error
Buying Lot:
Input: ownerID, Buyer, Seller, Amount_transfer, Price
Output: Lot is sold for that an event is declared
Data: ownerID: address of the current owner
Buyer: address of the buyer
Seller: address of the seller
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```
Amount_tranfer: The amount transferred to the function
Price: the price of the Lot
Initialization:
if  Buyer ¹ Seller Ù Amount_transfer = Price then
  Amount of the lot transferred to the seller
  Update ownerID by changing the seller address to the buyer address
  An event release and declaration for the sold lot
or else
  Revert and show an error
Buying Lot boxes:
Input: ownerID, the buyer. Seller, Amount_transfer, priceofbox,
nBoxesToBuy,
   Patient_boxes
Output: An event declares for the sold lot
Data: ownerID: address of the current owner
Buyer: address of the buyer
Seller: address of the seller
Amount_transfer: transferred amount to the function
priceofbox: the price of the box
nBoxes: defines the entire number of boxes in the Lot
nBoxesToBuy: represents the whole number of boxes in the Lot the
buyer wants to buy
Patient_boxes: number of boxes maps to the buyer's address
Initialization:
if Buyer ¹ Seller Ù Amount_transfer =nBoxesToBuy* Price then
Transfer the total amount of the boxes to the seller
Update ownerID by changing the seller address to the buyer address
Update nBoxes decreasing the sold amount by the seller
Update Patient_boxes by transferring the total amount to the
buyer's address
or else
Revert and show an error.
```

COMPARISON OF THE PROPOSED SOLUTION WITH EXISTING SOLUTIONS

We present a comparative analysis of the proposed solution for a traceable supply chain of pharmaceutical drugs with relevant existing solutions. The proposed solution is decentralized, an essential feature as it prevents any single entity from manipulating or modifying the data. Another important feature of our solution is resilience. Since the answer is decentralized, it eliminates a single point of failure. Blockchain offers an excellent data integrity and security solution due to its features, such as immutability. Therefore, once the information is added to the ledger, it cannot be removed or modified. Data security is maintained because it is stored in a decentralized way which makes no single entity capable of simultaneous manipulation of data.

As transparency of transactions is a crucial aspect of any supply chain, our proposed solution allows all participants to access and view verified transactions in a trusted environment.

CONCLUSION

Protecting drug traceability against counterfeit drugs in the healthcare supply chain is a big challenge. As a result, we designed a blockchain-based application to track and trace the healthcare supply chain in a distributed method. Our application uses blockchain technology which provides a secure channel in the supply chain for login and develops intelligent contracts using Ethereum, which stakeholders only access for check authentication of participants. Our proposed application is more stable than past works in this field. However, more work has to be done on our proposed application to achieve transparency and enhance the efficiency of the healthcare supply chain.

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Competing Interests

All authors of this article declare there are no competing interest.

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APPENDIX

The following abbreviations are used in the paper:
IPFS: Interplanetary File System
P2P: Peer to Peer
PSC: Patient Smart Contract
PSC: Parent Smart Contract
dApp: Decentralized Application
API: Application Programming Interface
CDSCO: Central Drugs Standard Control Organisation