A Blockchain-based Approach to Detect Counterfeit Drugs in Medical Supply Chain

Shabnam Sabah, A S M Touhidul Hasan* and Apubra Daria

Abstract The production and circulation of counterfeit drugs in the supply chain is an earnest and progressively vital issue. However, the existing supply chain management system fails to guarantee genuine medicines to the patient. To ensure authentic medicine and to mitigate supply chain issues, we propose a blockchain-based approach to ensure authentic drugs for the patients. The blockchain-based distributed system will empower all the stakeholders, including patients, to know and trace the authenticity of the medicine. To make the process faster, we have adopted the Hyperledger Fabric platform to develop peer-to-peer distributed applications for drugs supply chain. Besides, smart contracts make the supply chain management system automated, more robust, and transparent to detect counterfeit drugs so that patients can get original products produced by a legitimate manufacturer. The experimental analysis demonstrates that the proposed system runs smoothly on a Hyperleadger Fabric platform, and each transaction can handle efficiently with the distributed smart contracts.

Key words: Blockchain, Supply Chain, Hyperleadger Fabric, Smart contracts

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1 Introduction

Supply Chain Management (SCM) is the progression of goods and information through numerous providers like manufacturers, distributors, retailers, and clients. It helps to check the traversal of products and information without any difficulties. However, the existing pharmaceutical supply chain cannot ensure authentic medicine to patients. Counterfeit drugs are sold across all the distribution channels from drug stores to top hospitals in Bangladesh. Nowadays, in developing countries, counterfeit drug production and circulation have become a significant concern and cause a severe threat to public health. In developing nations, 30% of medicines sold are found counterfeit [17]. In 2020, a total of 18 individuals were charged for manufacturing and selling counterfeit drugs. Counterfeit medicines are made in the capital's Chawkbazar, Fakirapool, Uttara, and Tongi of Gazipur and afterward are supplied to various known medicine shops [15]. World Health Organization (WHO) specified counterfeit drugs as falsely and intentionally mislabelled with identity [12].

Numerous strategies have already been used to detect counterfeit drugs in Bangladesh. A startup company called "Panacea" proposed an approach where a pharmaceutical company prints a unique code on each medicine strip to verify the originality of the product. Reneta, the fourth largest pharmaceutical company in Bangladesh applied Panacea's technology to Maxpro and Rolac to ensure the authenticity of the medicine [9]. In 2018, The Directorate General of Drug Administration (DGDA) of Bangladesh has launched six international standard mini-labs in different districts to enhance its capacity to check the sale of fake medicines [4].

However, from the existing method, a patient cannot know whether the drugs are produced precisely by following the actual drug manufacturing code or not from the existing pharmaceutical drug supply chain. At the production time, a manufacturer can use harmful/inactive ingredients or active ingredients with a small/large amount. Besides this, drugs can be produced with unsafe substances or mislabelled by an invalid manufacturer. Moreover, it fails to trace the drug as medicine ownership changes from time to time.

To mitigate the supply chain issue and ensure authentic and genuine medicine, we propose a blockchain-based approach to detect counterfeit drugs in the pharmaceutical supply chain. In the proposed system, we have integrated a hash function and digital signature for user validation and message authentication so that all authentic people can join in the transaction, and it will ensure the trustworthiness of the ledger. A pharmaceutical laboratory has been introduced to detect original or fake drugs. An observer (i.e., independent pharmaceutical laboratory, public, or organization) witnessed the supply chain to observe the medicine after its distribution into the market and challenge its authenticity. A tracking system has been proposed to detect real or fake drugs based on unique QR code verification. We have applied Hyperledger Fabric-based [3] smart contracts to assure an efficient, protected, and trusted environment for authentic and genuine medicine supply activities for the general people.

The paper is organised as follows: Section 2 provides the related work. Section 3 presents the proposed blockchain based drug supply chain model. Section 4 presents the tracking system. Section 5 discusses the experimental results. Section 6 presents the conclusions and future works.

2 Related Work

An automated supply chain management system is a process where a person can track and trace products' life cycles efficiently. Numerous approaches were proposed for detecting fake medicine in the medical supply chain with the integration of blockchain technology as a decentralized database [2, 5, 11, 13]. A drug supply chain management and recommendation system based on machine learning and blockchain were proposed to observe and track the medicine delivery process [1].

Sylim et al. [16] proposed the pharmacosurveillance blockchain system, which can just distinguish movements of drugs that follow official circulation chains known to the regulatory agency but cannot track distorted medicines that are circulated through routes apart from official conveyance chains. Numerous blockchain-based techniques are introduced to manage the records of the supply of drugs in a secure way [7, 18]. Huang et al. [6] proposed a blockchain-based system called "Drugledger" for medicine traceability and regulation which guarantees both privacy and authenticity of traceability data and meanwhile accomplishes finally stable blockchain storage with time going by.

Jangir et al. [8] introduced a new structure by applying Etherium based distributed ledger technology and smart contract for the pharmaceutical supply chain management that help in achieving user privacy, immutability, data transparency, high availability, non-repudiation, no single point of failure, real-time tracking of the medicine, and demand-supply management. Kumar et al. [10] resolved the issue of drug safety utilizing blockchain, which depends on PKI and digital signature and encrypted QR (quick response) code security.

However, the above mention approaches have remarkable drawbacks in terms of detecting fake drugs. Authors assumed that drugs are made properly by a legitimate manufacturer. Authors used only QR code verification, Near Field Communication (NFC) tags, and machine learning methods along with blockchain to detect the fake drug. However, from all of these an end-user cannot know whether the drugs are produced precisely by following the actual drug manufacturing code or not. Besides this, medicines can be produced with unsafe substances or mislabelled by an invalid manufacturer.

3 Methodology

This section presents the blockchain-based secure pharmaceutical drug supply chain model. Figure 1 shows the proposed secure pharmaceutical drug supply chain model based on blockchain. The proposed system is divided into four parts: Ingredient

Verification, Drug Sample Verification, Drug Delivery & QR Code Verification, and Observation And Revoke.

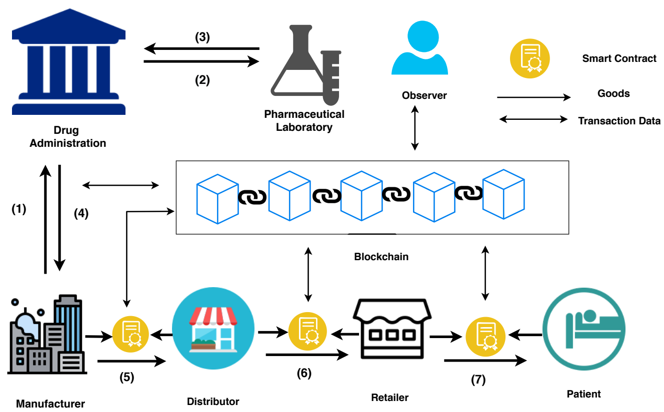

Fig. 1 Secure Pharmaceutical Drug Supply Chain Based On Blockchain

3.1 Ingredient Verification

The ingredient verification process ensures that the ingredients are authentic and original. Figure 2 shows the ingredient verification process. In this process, In this process, the manufacturer requests permission from the drug administration to produce a drug in a batch (e.g., a batch has N drugs.) and sends drug ingredients to the drug administration for verification. After getting those ingredients, drug administration adds the ingredients information into the blockchain. For ingredient verification, drug administration selects one pharmaceutical laboratory from several pharmaceutical laboratories that work under them and sends the ingredients to the selected pharmaceutical laboratory. After the ingredient checking, the laboratory gives the ingredients test result to drug administration. Afterward, drug administration adds the ingredient test result into the blockchain. Based on the ingredient test result, drug administration permits the manufacturer to produce the drug and generates a unique QR code for each drug of that specific batch and includes them into the blockchain. The manufacturer then produces N units of a drug in a batch after getting approval from the drug administration and appends the unique QR code to every drug packet of that batch at the time of packaging and labeling. In our proposed system, to add each transaction into blockchain, we have used the Practical Byzantine Fault Tolerance (PBFT) consensus algorithm which is permissioned voting based that allows our distributed system to reach a consensus even when a small number of nodes demonstrate malicious behavior (such as falsifying information).

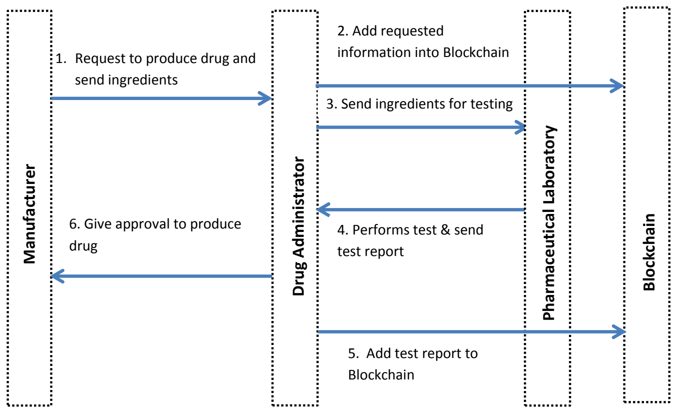

Fig. 2 Ingredient Verification Process

3.2 Drug Sample Verification

The drug sample verification process ensures that drugs are authentic.Figure 3 shows the drug sample verification process. In this process, the manufacturer sends the particular batch of a drug to the drug administrator (DA) for sample verification, and after the verification, DA includes the information into the blockchain. DA selects a pharmaceutical laboratory from a pool of laboratories for drug sample verification. The laboratory performs various types of tests on that particular batch of a drug to detect the counterfeit. There are three types of tests to detect counterfeit drugs which are given below.

- Thin Layer Chromatography (TLC) distinguish the counterfeit drug, and it is one of the efficient ways to determine the material in the drug, quantity of substances and adulterations [12].
- Analytical Techniques might be applied when fake drugs are more sophisticated and require more sensitive tools to identify active ingredients in the medicine. This technique includes near-infrared spectrophotometer, nuclear magnetic resonance, and mass spectrometry [12].
- Visual Inspection is another rapid and straightforward strategy to recognize counterfeit drugs. It compares the original drug in terms of drug packaging and labeling. If there is no original drug to analyze, features such as altered/diverse packaging and non-uniform coloring of the drug can show that it may be counterfeit. In this way, authentic makers should give an exact depiction of the drug's physical qualities, and its materials to simplify the visual assessment [12].

After the test, the laboratory gives the sample test report to the DA, and the DA appends the smple test report into the blockchain. If the sample test report returns that

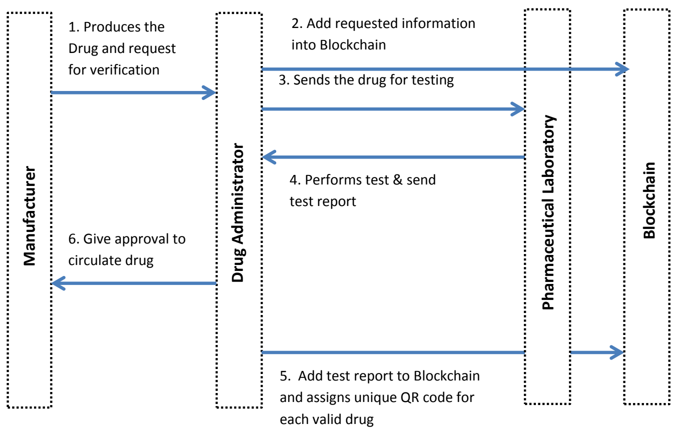

Fig. 3 Drug Sample Verification Process

the specific batch of a drug is counterfeit, the DA does not allow the manufacturer to circulate the drug in the supply chain. Otherwise, the DA acknowledges the manufacturer to distribute the authentic drug's in the supply chain and stores the unique QR code of each drug into the blockchain as a valid QR code.

3.3 Drug Delivery & QR Code Verification

The manufacturer sells the drugs to distributors after getting approval from the drug administration. Afterward, distributors sell the drugs to retailers, and the retailer sells the drugs to patients. At the time of purchasing, the user scans the unique QR code by using drug verification application. If the drug verification application returns authentic, then it indicates that the drug is authentic. Thus, in this way, a user gets an authentic drug from the supply chain. Every entity links up the new transaction as a new block in the blockchain ledger, as shown in Figure 4. The information of the delivered drug is stored in the blockchain by a smart contract. Every entity communicates with each other by sending digitally signed messages. The proposed structure utilizes blockchain capabilities and receives the original medicines and drugs' traceability from manufacturers to patients.

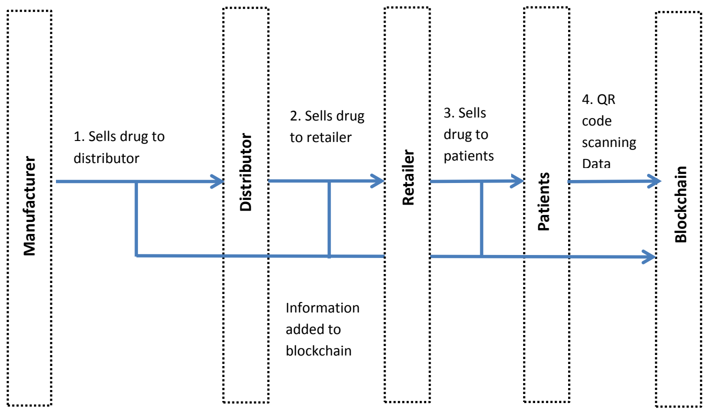

Fig. 4 Process of Circulating The Drug In The Market

3.4 Observation And Revoke

Drugs must be observed after their distribution into the market. To observe a drug any time from the market, the observer plays an important role. Figure 5 shows the observation and revoking process where after the distribution of the valid drug, any observer takes the valid drug from the market and their information from blockchain and tests the drug again from their pharmaceutical laboratory. Afterward, the observer compares the information stored in the blockchain with their test result. If any problem is found in that after comparison, then the observer claims to drug administration that the drug is counterfeit. If the number of this claim is maximum, then the drug administration will be automatically notified about the claim by the proposed system. Thereafter, drug administration re-tests the drugs by any pharmaceutical laboratory, which is selected from several pharmaceutical laboratories. Following the re-testing of the drugs, drug administration compares that claim with their re-test result. If that claim is proved correct by re-testing the drugs, drug administration will revoke the drug from the pharmaceutical drug supply chain. Subsequently, after the revoking, a unique QR code of a previously valid drug will be destroyed from the smart contract of drug administration.

4 Tracking System

In this section, we describe the tracking system. Drugs are tracked as they move along the supply chain, first when produced, and afterward, each time they are provided

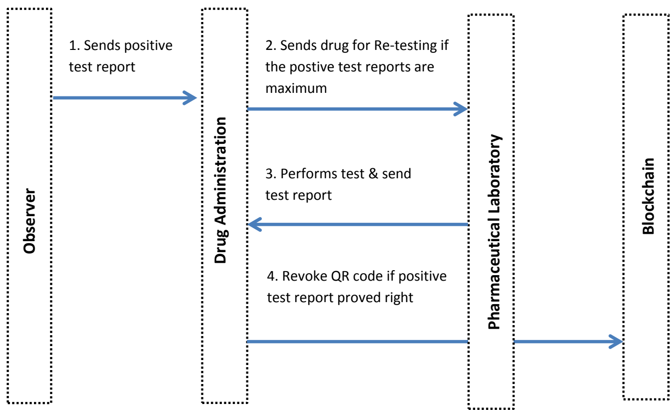

Fig. 5 Process of Observation and Revoke

to a buyer working at the next stage. The proposed mechanism can track whether a drug is valid or not based on unique QR code verification. The proposed tracking system can track the information on valid drugs and their ingredients. It can track the locations of verified drugs and track the locations where people are getting the maximum number of counterfeit drugs. All the supply chain entities can keep track of the verified drug's information, who is the manufacturer of that drug, where the drug is sold, and to whom it is sold. All this tracking information is stored in the blockchain as transactions to ensure they are immutable and available to every entity in the supply chain.

5 Experimental Analysis

In this section, we discuss about the experimental tools that we have used to develop the proposed system and also evaluate the performance of the proposed system and compared the results with Etherium.

5.1 Experimental Setup

We have developed the proposed system on Hyperledger Fabric. The proposed system is conducted on a desktop computer with the following specifications.

- CPU: Intel Core i5-3517U 1.90 GHz

- Physical memory: 8 GB
- Operating System: Ubuntu 16.04.e

In order to assess the performance of our system, we have collected the data for each transactions as follows.

- Transaction formation time (t_1) : The time when transaction was formed.
- Transaction end time (t_2) : The time when the blockchain affirmed the transaction.
- Transaction number.

We have evaluated the performance of the proposed system in terms of three metrics: execution time, average latency and average throughput according to [14] by varying number of transactions from 1 to 1000. We have also compared the results with Ethereum. A detailed description of these metrics are given below.

- *Execution Time* : It is the aggregate sum of time (number of seconds) that our system took to execute and confirm all the transaction in the dataset, for each set of transactions which is shown in Equation. 1 where n is the total number of transactions.

$$Execution\ Time = \sum_{i=1}^{n} (t_2 - t_1) \tag{1}$$

- *Average Latency* : The average latency can be specified as the average of latency of all transaction in a dataset, for a set of transactions, which is shown in Equation. 3. Latency can be defined as the difference between finishing time and deployment time for each transaction which is shown in Equation. 2.

$$Latency = t_2 - t_1, \text{for each transaction} \tag{2}$$

$$Average\ Latency = \frac{\sum_{i=1}^{n} (t_2 - t_1)}{n}, \text{for a group of transactions} \tag{3}$$

- *Average Throughput* : The average throughput can be determined as an average of throughput over the execution time, shown in Equation. 5. Throughput can be estimated as the number of successful transactions per second which is shown in in Equation. 4.

$$Throughput = \frac{n}{\sum_{i=1}^{n} (t_2 - t_1)} \tag{4}$$

$$Average\ Throughput = \frac{Throughput}{n} \tag{5}$$

5.2 Experimental Results

This section describes the result of evaluating the proposed system in three ways: evaluating execution time, evaluating average latency, and evaluating average throughput.

5.2.1 Evaluating Execution Time

We investigate the distinctions in execution time by changing the number of transactions in Figure 6 with Hyperledger Fabric and Etherium. The x-axis shows the number of transactions (ranging from 1 to 1000) and the y-axis shows the execution time (in seconds) for each group of transactions. The scale is linear. The execution time increments as the quantity of transactions in the data set develop. But Etherium fails to execute 1000 transactions, it only executes 980 transactions. The result shows that the execution time of Hyperledger Fabric is constantly lower than Ethereum in all data sets. The gap between the execution time of Ethereum and Hyperledger Fabric likewise becomes bigger as the quantity of transactions increase.

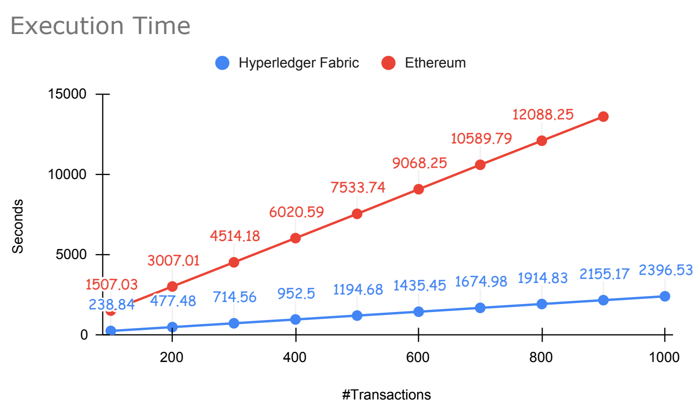

Fig. 6 Execution Time

5.2.2 Evaluating Average Latency

In Figure 7, we evaluated the average latency by differing the number of transactions with Hyperledger Fabric and Etherium. The x-axis shows the number of transactions (varying from 1 to 1000), and the y-axis shows average latency (in seconds) for each set of transactions. We observe that Ethereum fails to execute 1000 transactions, it only executes 980 transactions. The result shows that Hyperledger Fabric's average latency is constantly lower than Ethereum in all data sets. As the average latency is lower, it proves that each transaction takes less time in Hyperledger Fabric. On the other-hand Ethereum takes more time for each transaction.

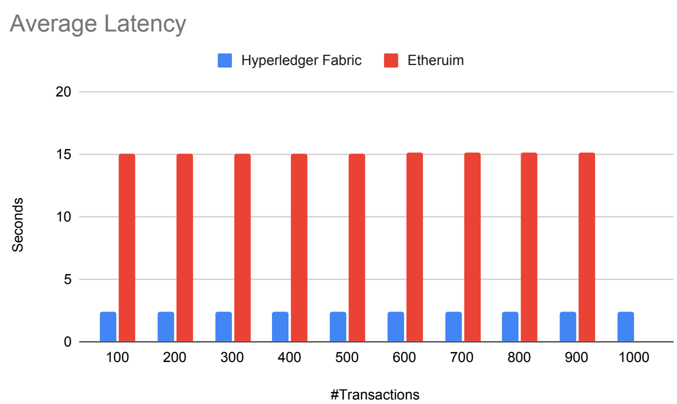

Fig. 7 Average Latency

5.2.3 Evaluating Average Throughput

We evaluated the average throughput by changing the number of transactions in Figure 8 with Hyperledger Fabric and Ethereum. The x-axis shows the number of transactions (ranging from 1 to 1000), and the y-axis shows the average throughput (in transaction per second (tps)) for each set of transactions. We observe that Ethereum fails to execute 1000 transactions, it only executes 980 transactions. The result shows that Hyperledger Fabric's average throughput is constantly higher than Ethereum in all data sets. In Hyperledger Fabric, the average throughput decreases as the quantity of transactions in the data set increases. We observe that in Ethereum when the quantity of transactions fluctuates from 500 to 900, the average throughput remains the same.

On a whole, we can say that our proposed system gives better performance in Hyperledger Fabric compared to Ethereum in terms of execution time, average latency and average throughput.

6 Conclusion

This paper proposed a blockchain-based approach by integrating pharmaceutical laboratories to detect counterfeit drugs in the pharmaceutical supply chain. The

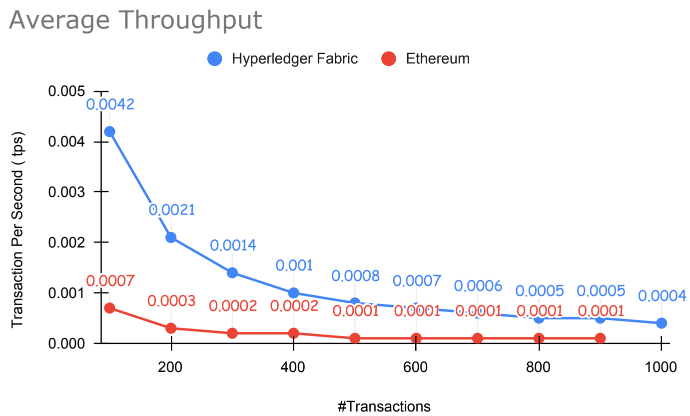

Fig. 8 Average Throughput

proposed supply chain can verify the ingredients of the medicine before and after production. Moreover, an observer of the supply chain can re-check medicine and challenge its authenticity from the blockchain's data. The supply chain is deployed on the Hyperledger Fabric for its faster transaction process. We compared the performance of the proposed system with Ethereum, and it shows that Hyperledger Fabric makes the system more robust and faster. In the future, we will build an integrated IoT device with a smart contract for the medical supply chain to verify and update each valid transaction.

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