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A BLOCKCHAIN-BASED SYSTEM FOR PREVENTING DRUG COUNTERFEIT

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ABSTRACT

The drugs industry is one of the most popular industrial areas, which suffers from counterfeit and loss of integrity. For instance, the proportion of counterfeit drugs in the world reached 10-15%. This paper proposes a secure Blockchain-based system for reducing drug counterfeit. The proposed system was implemented using the NodeJS language with a hyper ledger fabric platform. We analyzed network overheads to assess how many network messages we need to reach a consensus on a single block. The results show that to reach a consensus in a system of N peers, 2N*(N-1) messages are required. In addition, the proposed system has high performance in terms of less time needed to validate and append transactions into BC system.

Keywords: *Blockchain, Counterfeiting, Hyper Ledger Fabric, Consensus, Smart Contract.*

1. INTRODUCTION

The process of counterfeiting means faking something original, with the aim to break down, rob, or modify the original, for using it in illegal deals or to trick people into believing that the fraudulent things are the same as the original. Counterfeit goods are fakes or unauthorized versions of the original product. Counterfeit products are often produced with the intention to take benefit of the top value of the fake product [1] [2]. The quality of counterfeit materials is often bad and dangerous, and one of its main negative results is a large number of deaths, especially in pharmaceutical production [3]. Counterfeiting of drugs reduces the government tax and pharmaceutical companies' revenues, and poses serious health risks to humans. The World Health Organization (WHO) estimates that counterfeit drugs make up 15 percent of global drug market [9][21].

The first step in solving counterfeit medicines is the recognition of this problem by manufacturers and governments, and seeking practical solutions that limit this phenomenon. After investigating and following up on the methods used by counterfeiters of medicines, it was found that the main reason of drug counterfeiting is the lack of drug supply chain systems that take into account the manufacturing, transportation and supply processes of drugs, which ensure drug delivery to the consumer in a safe way, and this motivates counterfeiters to continue these illegal acts that harm society as a whole. Therefore, several anti-counterfeit mechanisms for drugs have been proposed, but unfortunately, they have not been proven to be efficient or help in solving these problems [8][9].

Recently, a new technology called the Blockchain (BC) has appeared and used in several domains like education, health care, smart cities and real estate, which made it a good candidate to solve the issue of counterfeit drugs [4][5] [9] [10]. Because BC technology has a great potential for improving security, privacy and transparency in the above domains [9][20][24][25]. Therefore, a broad range of researchers started to utilize BC technology and implement it in various areas for solving trust issues between trustless individuals in different applications, reducing counterfeit drugs, etc. [6][7][19]. The rest of this paper is organized as follows. Section 2 presents the background of BC technology and related works. Section 3 presents the proposed BC-based system for preventing drug counterfeit. Section 4 shows Simulation results and discussion. Finally, the conclusion is presented in section 5.

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2. THEORETICAL BACKGROUND

Blockchain is a technology, which has many attractive features like decentralization, distribution and immutability that can maintain a list of secured and linked blocks using several cryptographic and security techniques like hashing, digital signature, private and public keys. There are three main types of Blockchain networks: public BC, private BC, and hybrid BC. Public Blockchain is an open system where anyone can engage, which was introduced for the first time in 2008 by Satoshi Nakamoto's to underpin BITCOIN [11]. BC removes the appearance of any third-party or central authority for management or coordination, then utilizes the decentralization way of distributed systems in its full form [12][22][23].

On the other hand, private BC has defined rules and permissions on network nodes and it is completely managed by a central organization that allows specific nodes or participants to engage in the network [12]. Finally, the hybrid BC, which mix private and public BC, in this system the consensus is specified by a group of authenticated organizations that are pre-selected and has special permissions, these organizations give read and access permissions for participants to engage in the BC system [12] [13].

Several research papers based on BC technology have been proposed to address the issue of drug counterfeiting. Haq et al. [6][7][14] proposed a BC-based system to prevent drugs counterfeiting, where both sender and receiver in the system share the public key. The proposed system goes through many stages starting from manufacturing process following by transportation and ending delivery a drugs to medical centers, pharmacies and patients. Kumar et al. [8][15] proposed a quantitative analysis on cracking down the fake drug industry based on BC technology in India. The proposed framework comprises Pharma department, extraction unit, manufacturer, distributer and patient. Their proposed system uses smart contract and can track the drugs from manufacturing to delivery steps. The system uses Internet of Things (IoT) devices like sensors to monitor the temperature of the drugs store and send gathered information to BC system. The results shows that the system performance is good in terms of high throughput and low latency time as the number of transactions increased up to 1600 transactions.

Botcha et al. [16] proposed a BC-based system for Enhancing traceability in pharmaceutical supply chain using Internet of Things (IoT) to reduce drugs counterfeit. The main advantage of the proposed system is the integration of BXC technology and IoT to address the problem of drags counterfeiting. Pandey et al. [17] produced a securing e-health system for counterfeit medicine penetration based on BC technology. The framework of the proposed system follows the rules and standards of the pharmaceutical industry in India. The system was simulated using a hyper ledger fabric platform, and its performance was compared with other existing methods. Singh et al. [18] developed an IoT system based on BC technology for temperature monitoring and counterfeit pharmaceutical prevention. The proposed system uses sensors to monitor temperature in order to store drug at an acceptable temperature to protect it from spoilage. Table one show a comparison between different research studies.

Table 1: Studies With Their Contribution, Strengths And Limitations

Authors	Contribution	Advantages	Limitations	Technologies
[25]	They Proposed a further use case of Blockchain technology in healthcare. and explained how Blockchain can be used to add traceability and visibility to drugs supply and overcome the issue of counterfeiting.	-They Proposed new framework and implementation for the drugs system using Blockchain. -Used Ethereum Blockchain.	-The authors do not present any evaluation criteria to show the system accuracy. - Suffers from lack of full immutability. -The authors did not explain the main functionalities in their	- Smartphone application. - Permissioned Ethereum network.

			system like consensus algorithm.	
[15]	Proposed placing import and export operations of medicines in India on the Blockchain system for it is ability to deal with sensitive matters such as fraud and counterfeiting. The proposed Blockchain system will track the life chain of a drug from the moment it is manufactured until it reaches the consumer.	- A new framework and actual system work were presented. -The third part does not exist in order to the implemented of smart contract.	-The degradation of system performance. - The lack of confidentiality.	- Hyperledger Fabric v1.0 - CouchDB. -Linux. -Caliper benchmarking.
[16]	Reviews the integration of the Internet of Things with the Blockchain to reduce drug fraud and counterfeiting.	-Enhance the transparency using the IoT technology.	-No evaluation results included. -IoT security problems.	- Private Blockchain.
[17]	They proposed a complete health network system to treat counterfeit medicines and discover them inside India using Blockchain technology, and they also presented the results of their system and compared it with other systems.	- Implemented real system and compared it with other existing system. - High secure without any need for third party. -They explain all the elements of Blockchain technology used in their system in detail.	- Reducing the number of ordering or committing nodes can generates an attack.	- Hyperledger fabric. - Windows 11 64-bit PCs. - Permissioned Blockchain network. -PBFT algorithm.
[18].	They introduced a health system based on Blockchain technology combined with the Internet of Things technology to track the drug from it is manufacture until it is arrival to the user	-Each thing in the system is traceable and no need of third party and there is a smart contract. - Digital water mark QR code for the best security. - They explained the entire system core in the best brief way.	-The raft consensus algorithm limitations make it suitable only for small networks so bad performance for other sizes of network. - They	- Permissioned Blockchain. - BloXroute. -Raft consensus algorithm. -IoT. -Cloud storage. -Elliptic Curve Diffie–Hellman Key Exchange and Digital Ring Signature.

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	in addition to monitoring it is temperature.		did not evaluate their system with the other related system.	

We can summarize that limitations of the Blockchain system are below:

1. Cost when choose the validators.
2. The complexity of the government rules.
3. The Network coverage in the third countries issues.
4. The illiteracy in using the system.

3. THE PRPOSED METHODOLOGY

The phenomenon of counterfeit medicines in the world has huge negative effects on several sectors like health, governments and pharmaceutical industry. This phenomenon has caused severe financial losses to governments and pharmaceutical companies as well as losses in human lives. Because the traditional systems to combat this phenomenon could not prevent it or reduce it. Therefore, the Blockchain technology can deal with this issue by tracing and controlling all stages of drug manufacturing process. In this respect, this section presents and describes the proposed system BC-based system for preventing drug counterfeit.

3.1 General Overview of Drug Supply Chain Management

The general overview of drug supply chain with Blockchain system is in Figure 1 in which participants can manage, control and updates the whole supply chain processes. All data and information related to the participants of the system suppliers, manufacturer, distributors, hospitals, doctors, pharmacy and patients are stored in the Blockchain-based system. Each user of the system participants can create and broadcast their transactions and communicate with the BC system via client application. This supply chain system uses a private BC, which ensures that only authorized users be able to add or view the data by using their proof of authority concept as shown in the general overview of drug supply chain management Figure 1.

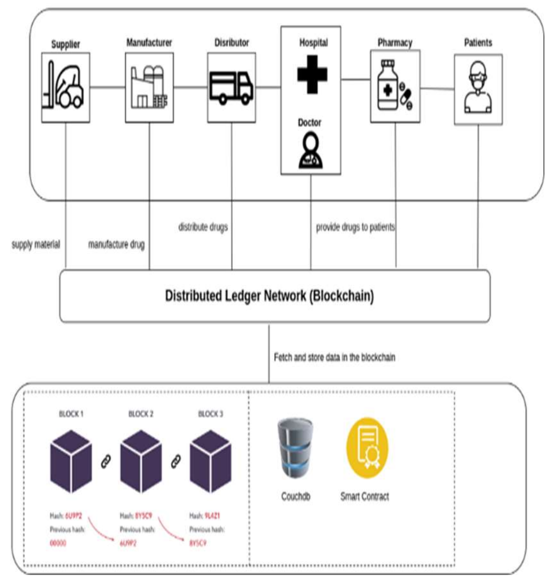

Figure 1: Overview of drug supply chain management system with Blockchain.

3.2 System Architecture of Proposed System

In this research, the system goal is to reduce the fraud and counterfeiting that accompanies the process of producing medicines by forming a reliable ledger that saves all the events related to medicine in our system. So, we can stop the manipulation and falsification that can occur to the drug data in terms of any modification in the materials, the date of issuance, or any other manipulation then the stakeholders in this process can see all the information related to any product of the medicine and prove that it is an original product that is not counterfeited in any way. Blockchain provides a great security mechanism for the supply chain industry and data immutability is one of the biggest advantages of this platform. Similarly, in the case of the medicine supply chain by storing the data in distributed peers and providing data immutability, the system can ensure that every detail and update process of the medicine is available on the ledger and any kind of information about any drug is verified by any stakeholders. Every stakeholder will be interacting with the Blockchain and will fetch or save the medicine-related data into the ledger. This data will not be deleted or tempered as it will be stored in different peers. In this supply chain system, a private Blockchain framework hyper ledger fabric will be used which will ensure that only authorized people will be able to add or view the data by using it is proof of authority concept, and this is what makes us sure that we can build our proposed system through it. The

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proposed system architecture comprises four main components: The front-end, back-end, hyper ledger network, and database. The end user can perform many transactions using the client-side application, which handles by the back-end server. The back-end server saves or retrieves the data from the database or the BC hyper ledger fabric depending on the type of transaction request type. The backend system uses a hyper ledger fabric SDK to interact with the hyper ledger network. The detailed architecture of the proposed system is shown in the figure 2. The stakeholders in the proposed system are five stakeholders and their main duties can be summarized as follows:

1. Manufacturer: It is a registered drug manufacturing, it will request the raw material of drugs from supplier, it will check the validity of these materials and add all things in the block then it will produce the medicines with unique QR for each one this information is recorded on the ledger maintained over a Blockchain network.
2. Supplier: Deliver the raw data using the transportations (distributor), (the transportation checks the validity of these raw material and add them on the block).
3. Distributor: it will check the authenticity of medicine from the supplier and manufacturer phase and add them to the block after the validation; it will not deliver or accept them from any phase if it's not authentic. It will deliver them after this process in each stage.
4. Medical sector (Hospitals/pharmacies and doctors): deliver the medicine for the patients.
5. End user/Patient: check the drug by scanning the QR code on the drug.

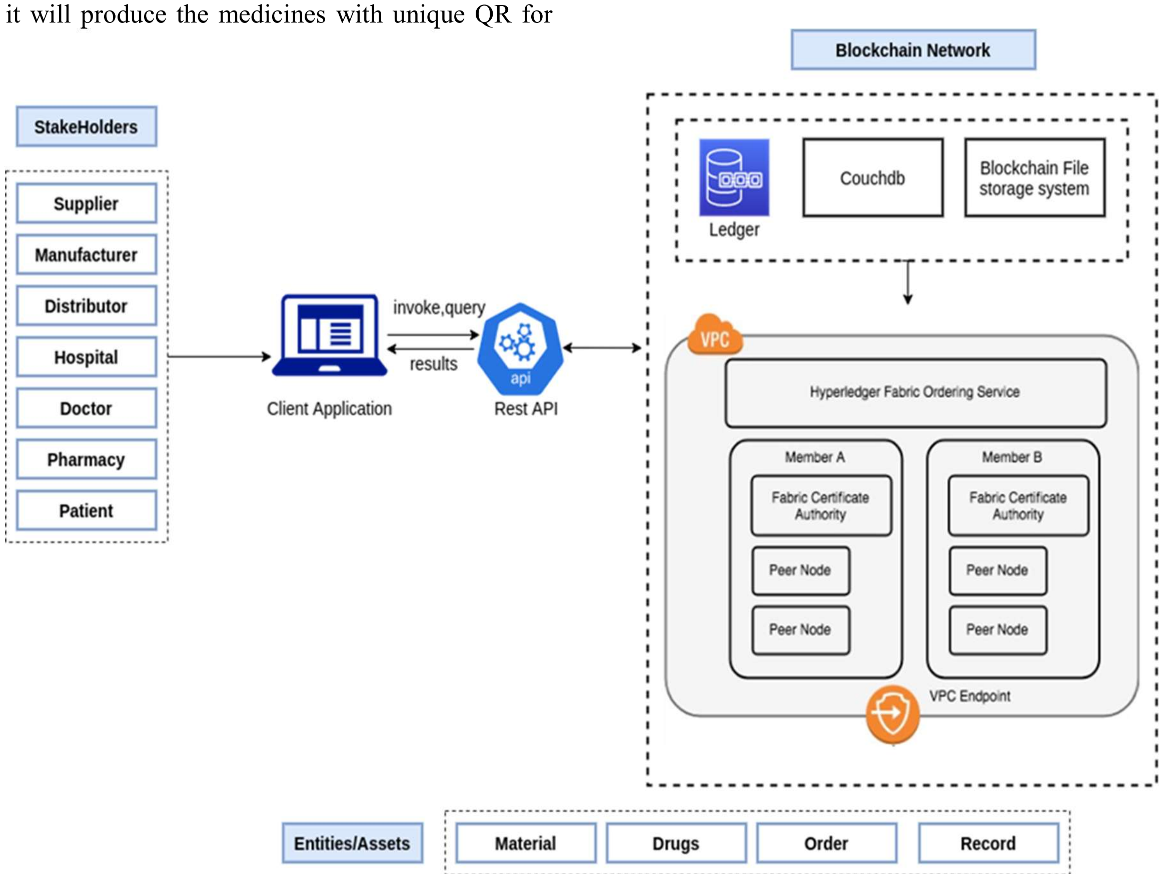

Figure 2: Architecture Of The Proposed System

3.3 Smart Contracts

On Blockchain systems, the purpose of a smart contract is to give system's participants the ability to execute an agreement between different parties without the need of third party. The smart contract consists of a predefined set of rules in which both parties have done an agreement with each other. The smart contract is immediately executed when the conditions match the same. Furthermore, smart contracts help the users to control the access rights and their assets among various parties. These smart contracts are stored and managed in the distributed ledger of the

Blockchain platform, where they are completely protected and secured from modification by editing or removing. It is triggered immediately by the proposed consensus algorithm of the Blockchain network. In our proposed system, the

smart contract is developed only for two peers (Validators) from four peers, who are called endorsement peers; those peers can validate the transactions.

The smart contract that stored in the Hyper ledger network has four main components: a model for representing the stakeholder's classes, a script for business logic, a set of access control rules in file for permission or reliability, and queries for reaching the ledger database (CRUD). In the proposed system, the smart contract is implemented in Golang language, which appeared in 2009 by Google. The interaction between smart contract program and the application SDK can be illustrated in the figure 3. A smart contract contains multiple types of transactions as shown in figure 4.

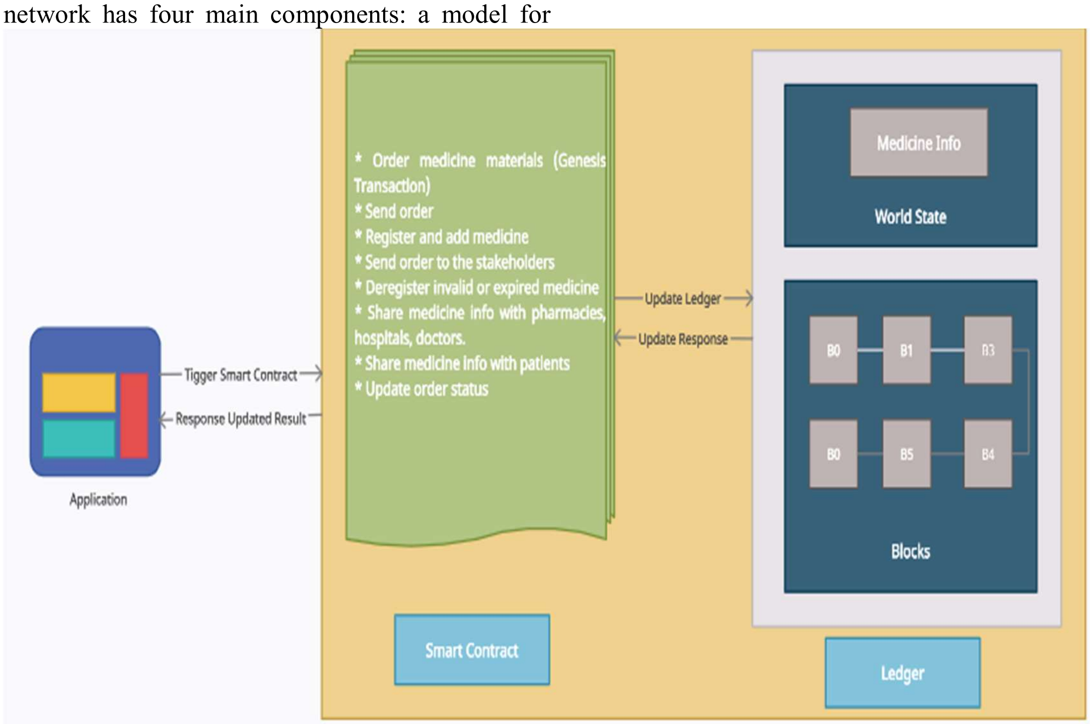

Figure 3: Smart Contract Interaction With The Application SDK

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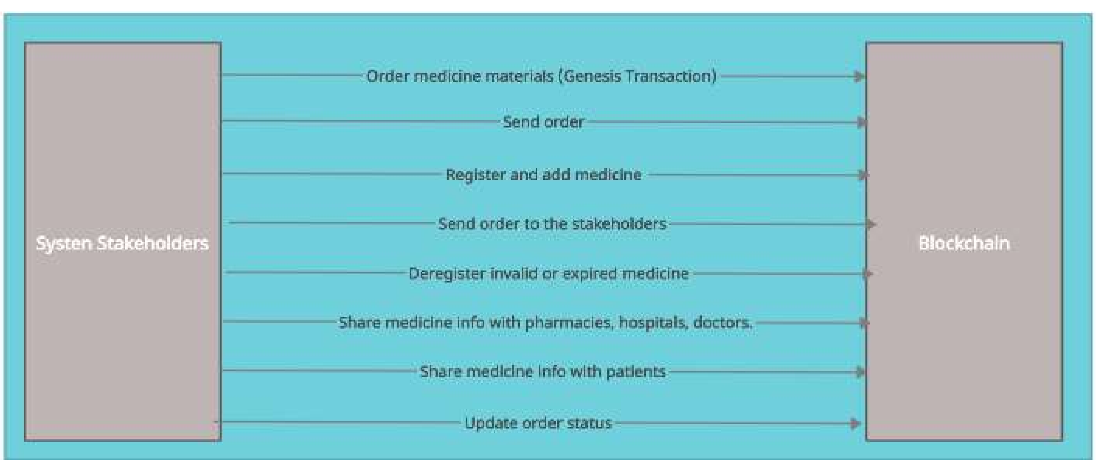

Figure 4: Transaction Types

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3.4 The Proposed Consensus Mechanism

The Transactions created by the stakeholders are grouped in a transaction pool with their timestamp and then sent to validators for validation, where the number of validators is four to obtain high level of transparency and achieve better synchronization in the system. The consensus mechanism is executed on the backend side to guarantee that all stakeholders came to common agreement in order to append the blocks into BC. In addition, the proposed consensus mechanism uses Kafka ordering service to preserve the order of transactions, which means that if the transactions are sent from the transaction pool in a certain order, the validator will write these transactions into a block in the same order, and all nodes in the system read them in that order. The proposed consensus algorithm contains three phases: an endorsement, an ordering, and committing as shown in the figure 5. The endorsement phase includes the execution of smart contract inside the Hyperledger SDK by two peers selected randomly by the ministry of health. The smart contract defines the rules that must be met by all stakeholders. The second phase starts with the arrangement of transactions using the Kafka validator service, which provides high throughput and reduces network bottleneck. The final stage in our algorithm is the verification or committing stage, which is carried out through two precise steps using two functions that have been programmed to verify that the block is secure by the complete consensus of all the validators, the system must obtain a consensus rate in the first and second function also equal to 75% to be accepted block and add them to the system successfully, else the block will be rejected.

Figure 5: The Proposed Consensus Algorithm [Annex-1].

3.5 Couch DB

The proposed system uses CouchDB as the BC ledger, which issues rich queries against data values rather than the keys. In addition to that, CouchDb is used to save a huge amount of transactions, and considered the most suitable choice to reduce data redundancy problem, and produces separate storage for every single node in BC network. Moreover, using CouchDB allows developers to deploy indexes with their chain code to make queries more efficient and enable them to query huge datasets.

3.6 Transactions Flow

This section describes the general transactional flow of the proposed system. First, the user or client initiates transaction by creating a transaction proposal for registration via SDK to generate a digital certificate. The certificate holds a public key and an entity (a hostname address) signed by a certificate authority like Comodo, GeoTrust. After the registration process is completed any stakeholder can propose a transaction using the generated certificate. The transaction is approved by the endorsing peer and then the peer returns the RW sets to the SDK. The RW sets send to the orderer in order to create a block after arranging the transactions. Finally, the blocks are sent to the validator for verification and then the peer executes the transaction, adds it to the ledger and notifies the user of the result as shown in figure 6.

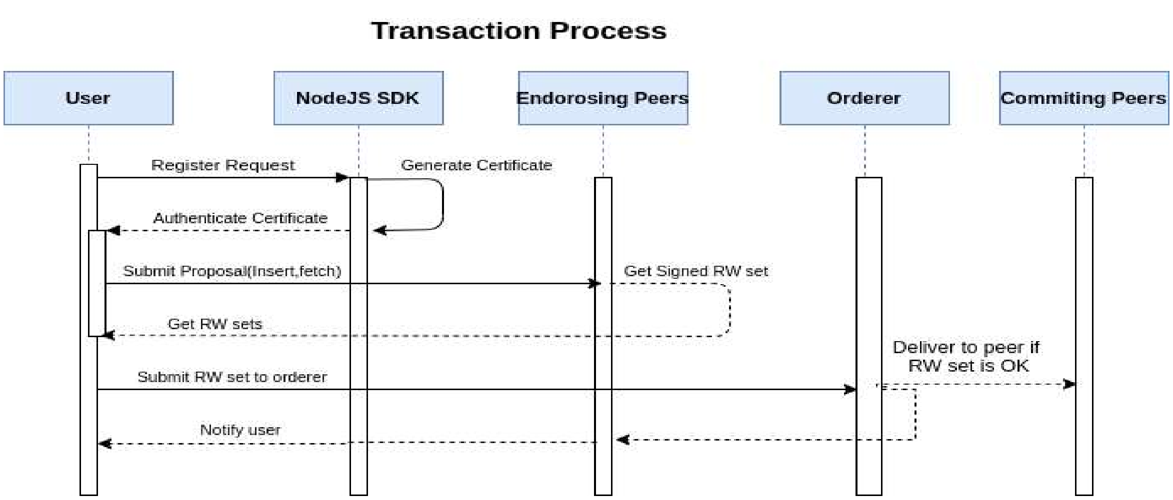

Figure 6: The transactions flow.

3.7 Methodology Flow

This research concentrates on enhancing the working environment of the medical sector, which influences reducing fraud of Tax evasion, reducing the number of deaths caused by these counterfeit medicines. Blockchain technology will help us by adding traceability and visibility to drugs supply and overcome the issue of counterfeiting. The main goal of the research is to protect the health of each person by taking advantage of the technical characteristics of Blockchain as Immutability and decentralized.

1. Study and summarize Blockchain solutions that have been proposed previously to reduce counterfeiting on drugs, and indicate the strengths, weaknesses, and technologies in each proposal.
2. Describe the system stakeholders and study each entity's role with it is duties and the information that is of importance to the system and can be provided by this stakeholder. Then connect each stakeholder with it is related transactions.
3. Explain the importance of Blockchain as a solution for decreasing counterfeiting drugs and the suitable type that serves the problem at hand taking into reflection the nature of the environment.
4. Suggest a new framework and implement it with a suitable consensus mechanism along with the validation that must take place to create a comprehensive, secure, and trusted solution that meets the needs of the drugs industry.
5. Use a unique consensus algorithm that improves security.
6. Conclude the results of the experiment to evaluate the proposed system criteria.

4. SIMULATION AND RESULTS

In this section, the simulation results of the proposed system are discussed in detail.

1. Simulation Environment

The proposed system was implemented using Node JS 14.17.3 programming language with Microsoft Visual Studio Code 2019 16.0 software for user interface via React JS, WebStrom 3.5 for NodeJS, Postman 8.1.0 plus Swagger 2.0 for API Services manipulations, Wireshark 3.4.7 and SolarWinds (NPM) 12.4 for network performance analyzing. The experiments were conducted on HP laptop running Ubuntu 18.04 with core I7 10G, 16 GB RAM, 64-bit operating system, and X64-based processor. The proposed system used a specialized dataset for medicines provided by Kaggle, this dataset is called "drugsComTest_raw". The dataset contains 53,767 rows.

2. Results and Discussion

In this section, the overall performance of the proposed system is given. The system is tested and evaluated according to transaction latency, transaction endorsement time, transaction arrangement time Figure 8, 9 and validation and addition transaction time Figure 10.

4.2.1 Transaction Latency

Transaction latency defines the number of messages needed for a network to reach an agreement to add a block to BC system. The network traffic performance and the number of messages needed for a network to reach an agreement to add a block to BC system were tested using special software called Wireshark 3.4.7 (software monitors network traffic) is shown in figure 7. More messages mean that the process is slower than the other one. The system transactions is sent by Postman software to be recorded on Wireshark software. The committing phase starts after completing the endorsement and arrangement of transactions, by passing two messages (unique then verification) through all peers using the functions "CheckThenAppend", "SendUniqueMsg" and "SendVerfiedMsg". Only one peer node sends a validation request to all other peers in the network using "CheckThenAppend" function. Then the network peers verify the block and send unique messages to other peers to indicate that the verification has been done successfully using the method "SendUniqueMsg". The peers send a verification message when receiving 75% unique messages from network peers using the method "SendVerfiedMsg".

The final agreement is reached by exchanging several messages between the peers using three main methods "CheckThenAppend", "SendUniqueMsg" and "SendVerfiedMsg" , where the number of messages is 2N*(N-1), where N is the number of peers.

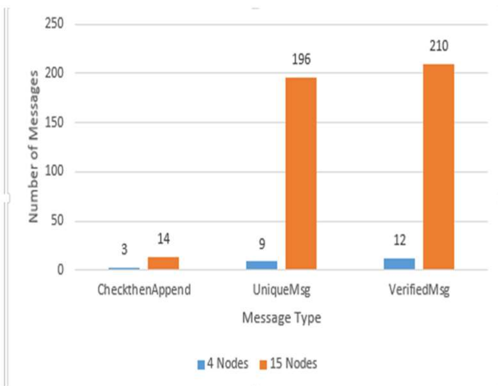

Figure 7: The number of messages to Reach Common Agreement for 4 Nodes and 15 Nodes.

4.2.2 Transaction Endorsement Time

Transaction endorsement time is the time required to invoke the smart contract and obtain the permission and confidential information of a client to enter the system as shown in figure 8. The results in figure 8 shows that the required time is too small, which indicates the efficiency of the proposed system.

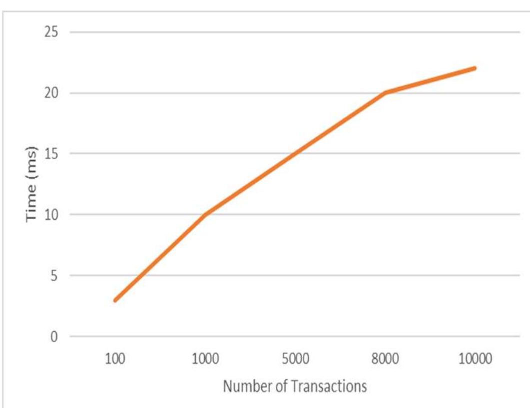

Figure 8: Transaction Endorsement Time.

4.2.3 Transaction Arrangement Time

Transaction arrangement time is the time needed to take the scattered transactions from the previous phase and add them into a queue for arrangement as shown in figure 9. Figure 9 shows that the process of arrangement is fast, which increase the efficiency of the system.

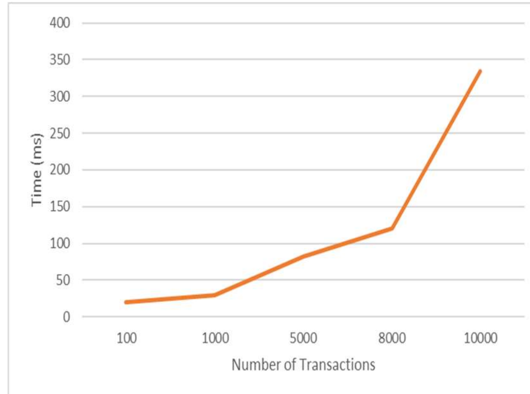

Figure 9: Transaction Arrangement Time.

4.2.4 Validation Time

The validation time of transactions has a great impact on the performance of the system. Figure 10 shows the validation time with different number of transactions. The results show in figure 10 represents the time required to validate blocks of different size. It is better to limit the number of transactions per block to an average number, because it affects the throughput of the system in terms of the number of transactions that are completed per time unit. Therefore, in the proposed system the size of the block were assumed to be 1000 transactions per each block.

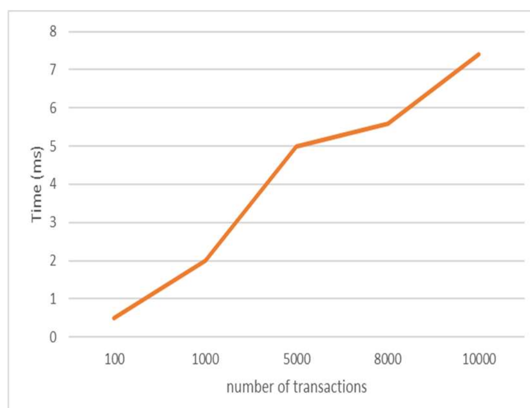

Figure 10: Validation and Addition Transaction Time.

4.2.5 Security and Privacy Analysis

This section tests our system versus security risks. We examine the system in terms of confidentiality, integrity, and availability (CIA).

Confidentiality and Privacy

Our proposed system used X509 certificate-based Public Key Infrastructure (PKI) for network peers and Universally Unique Identifiers (UUIDS) that generate a unique ID per transaction, this helps protect network nodes from not revealing their true identity to anyone in the system in any transaction. No one can retrieve drug information except in the case of obtaining a special drugID and a QR code that consisting of three fields: the name of the drug, the drug code, and an auto-generated number, this QR must be scanned over the drug packet, this will add another privacy level because not everyone has access to the drug QR code. The data is hashed and the access for confidential transaction kinds is allowed only for stakeholders that have permission.

Integrity

Every block includes a hash of it is content to guarantee integrity. In addition, every transaction list data also includes a hash of it is content to ensure it hasn't been altered. As we implement hashing techniques any difference in the block content will rescind the block then network validators will drop the block without adding it to the Blockchain. We imported the object-hash library in NodeJS and utilized the method "crypto.createHash (SHA256)" to hash the block content and then add the hash value to the block, most of the previous research did not specify the type of hashing algorithm, but a few reported that SHA256 is used. We imported "jsrsasign" library in NodeJS for signature keys and utilized the "crypto" method, the method "crypto.generateKeyPair ("EC")" to create the public key pair for the node. We used "ecdsa-secp256k1" to produce the signature scheme instance from "secp256k_pkcs8Scheme.

Availability

In general, the Blockchain system is distributed and decentralized, so if any node is crashed, the system will resume the job and serve the clients, also there is a distributed ledger for each node in the system. Our system is applying all rules of the Blockchain so the data will be available at any time.

4.2.6 Comparison between our Proposed System and other System

We have made several comparisons between our proposed system and some other systems in the same field.

Author	Difference between the previous proposal and our system
[25]	The system proposed in this research is based on Ethereum, unlike our system; there is still a need for a third party in their system because the smart contract is not programmed. Their system is still the traditional way of controlling from one side, and this does not explain the meaning of Blockchain technology.
[7]	In this work, the researchers designed a framework to solve the problem, but the work was not programmed, meaning there are no reliable results as we have. The role of the main consumer was not addressed in their system, unlike our system, which clarified the roles of all stakeholders and the elements of the Blockchain in detail.
[16]	They did not consider the degree of safety, but our system is based on the verification of the ID and QR code of medicines. The data here is collected by IoT sensors without regard to the roles of stakeholders in the system. Also, their system is a proposed theoretical system that has not been programmed and there are no real results.
[8]	The authors did not specify the characteristics of their system, nor the types of transactions that can be executed, or even the information of the validators, unlike our system, which explained all this. They programmed their system using Hyper Ledger, but the system has scalability issues.
[26] .	They did not provide a transaction that returns the full history of a particular drug, unlike our system that tracks the drug from the manufacturing stage to the customer's arrival. They did not clarify the type and details of the modification algorithm, how it will work with the system, and what the validators are for. Finally, this system penetrates the features of the Blockchain because it is implemented from one side.

5. CONCLUSION

In this paper we proposed a BC-based system for preventing drug Counterfeit. Due to the fact that the proposed system used X509 certificate-based Public Key Infrastructure (PKI) for network peers and Universally Unique Identifiers (UUIDS) that generate a unique ID per each transaction, the experiments demonstrate the usability and efficiency of the implemented system in terms of confidentiality, data integrity, privacy, and privacy of data. Moreover, the results show that to reach a consensus in a system of N peers, 2N*(N-1) messages are required. In addition, the proposed system has high performance in terms of less time needed to validate and append transactions into blocks.

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Annex-1

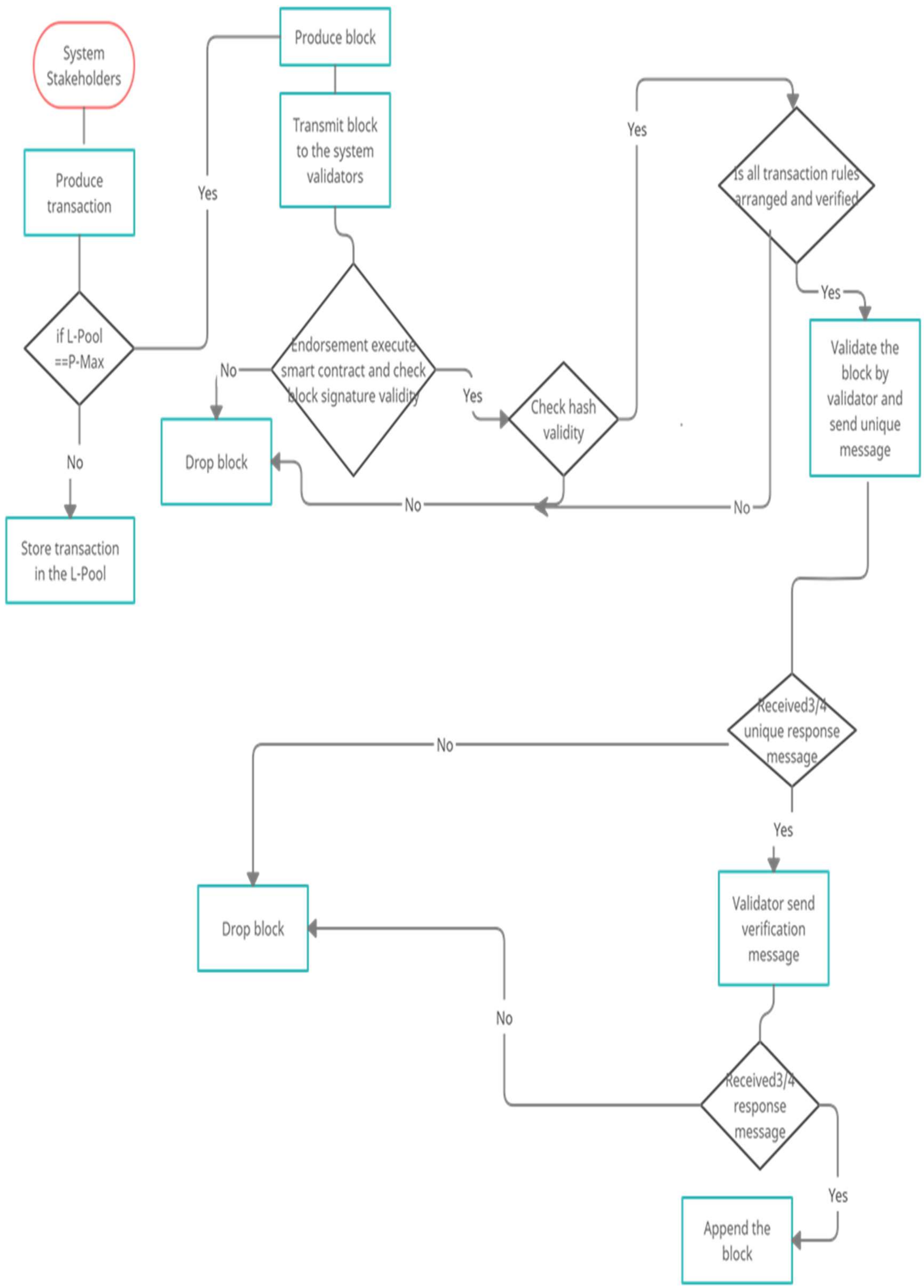

Figure 5: The Proposed Consensus Algorithm