Trace and Track: Enhanced Pharma Supply Chain Infrastructure to Prevent Fraud

Archha(✉), Bithin Alangot, and Krishnashree Achuthan

Amrita Center for Cybersecurity Systems and Networks,
Amrita School of Engineering, Amritapuri Campus,
Amrita Vishwa Vidyapeetham, Amrita University, Coimbatore, India
archa91@gmail.com, bithina@am.amrita.edu, krishna@amrita.edu

Abstract. The menace of counterfeit drugs has prompted the regulatory authorities to mandate trace and track systems to verify the provenance of drugs as it travels across the supply chain. Here, we propose a highly scalable and enhanced trace and track system for pharma supply chain. Our novel idea of using an IoT framework known as GDP (Global Data Plane) integrated with blockchain helps in communication and management of data between untrusted parties. The blockchain maintains an immutable record of drugs each party holds and transactions the parties make amongst themselves. This makes it hard to introduce counterfeit drugs into the supply chain.

Keywords: Supply chain · Blockchain · IoT

1 Introduction

The pharma industry provides critical health care service by supplying life saving drugs to people. But the recent surge of counterfeit drug supply in the market has raised issues of mistrust among the people. The statistics show that this issue is especially prevalent in the developing countries. There are many cases of counterfeit drugs reported worldwide, for example, the anti malarial drugs that were bought in Southeast Asia or the usage of toxin diethylene glycol in the manufacture of fake paracetamol syrup [4]. Many of the pharmaceutical companies and government do not publish information regarding counterfeit drugs as it might harm their sales [12]. They also believe in the philosophy that "as much as possible should be done behind the scene and that no great publicity should be sought because it could damage public confidence in medicines" [4].

In order to counter menace of counterfeit drugs, the regulatory authorities (such as the FDA) has mandated to implement trace and track system into the pharma supply chain. The Drug Quality and Security Act (DQSA) details the requirements to build a system to trace some prescription drugs that are distributed in United States. The key recommendations of the system are: (1) to include unique product identifiers by manufacturers and repackagers with lot granularity, (2) support tracing, verification and notification by manufacturers,

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wholesale distributors, repackagers and dispensers, (3) include details on wholesale as well as third party logistics licensing [6]. The pharma companies take help from companies such as Tracelink Inc. [16] to implement a trace and track system which follows all the compliance put forth by the regulatory authorities. The companies provide services over the cloud which allow to deploy the system over a global scale. But applications (especially IoT applications) build over the cloud if not properly implemented can lead to lot of drawbacks as mentioned by Zhang et al. The trace and track system can be considered as a large scale IoT infrastructure with barcode or RFID readers which are connected to the cloud over the internet.

In this paper, we propose to build a highly scalable and trusted trace and track system for the pharma industry that trace their drugs across the distribution lifecycle. Here, we model the whole system into a large scale Internet of Things (IoT) infrastructure where IoT devices such as barcode readers, smartphones and so on scan the serial numbers or RFID tags integrated into the drug package. In order to manage the IoT applications and devices across the distributed infrastructure we use an IoT framework called GDP [3]. We also design a controller for the GDP leveraging blockchain technology to track the transaction between different entities. A single entity cannot make any changes to the transaction record without the knowledge of others. This will bring in more accountability into the system and in turn eliminate the possibility of inclusion of counterfeit drugs into the distribution cycle by malicious entities.

Contribution of our paper:

- Propose a scalable trace and track system for pharmaceutical industry using GDP IoT framework.
- Integrate blockchain into the trace and track system to create a trusted environment amongst different entities in the supply to prevent fraud.

The paper is structured as follows. Section 2 overviews the related works. Section 3 describes the background knowledge of the GDP framework and blockchain technology. Section 4 proposes the trace and track system and the paper concludes with Sect. 5.

2 Related Works

For fraud detection many trace and track systems have been developed to be used as part of the supply chain cycle of various products such as with drugs. The Tracelink is a pharma supply chain trace and track system. It introduced Life Sciences cloud on Amazon Web services to provide a scalable solution to trace drugs on a global level if needed [16]. This is further enforced by techniques to neutralize data format and transport preferences allowing partners to integrate under a uniform level. Bosch Packaging Technology [2] is another such system. It provides the mass serialization services in food and pharmaceutical companies. It makes use of an open standard for data format GS1 application identifiers to represent the data. Data is encoded into 2D matrix code and printed on the product in a human readable format. A camera reads this and stores the information in a centralized database unlike our decentralized approach for tracking. Recently IBM and Maersk [9] released a system that uses Hyperledger Fabric to implement a tracking system for shipping industries. Our solution offers more flexibility and trust than the existing systems as we are using the GDP framework that better supports the IoT infrastructure along with the blockchain controller using Tendermint to improve security and privacy.

3 Background

In this section, we discuss two main technologies used to build our trace and track system: GDP and Blockchain. The GDP is a framework which enables us to develop applications on top of IoT infrastructure with ease and Blockchain is a distributed ledger which is maintained in a decentralized manner by a group of untrusted people.

3.1 Global Data Plane

The growth of Internet and the development of communicative devices have led to high interactivity through computing platforms and services leading to the development of Internet of Things (IoT). The recent trend in easy availability of cheap IoT devices and economic model of cloud has accelerated the deployment of highly scalable IoT applications without much effort. Anyone with a sensor can start streaming data to the cloud from which it could be analyzed to get useful information. But connecting these IoT devices directly to the cloud has drawn in issues related to scalability, bandwidth utilization, latency, durability management along with privacy and security concerns as stated by Zhang et al. In order to overcome these issues related to the present IoT infrastructure they have come with a IoT framework called GDP. This framework handles data protection, preservation and distribution amongst the distributed edge servers and backend cloud nodes. GDP follows a data-centric architecture which advocate the use of a append-only log data structure as the fundamental storage abstraction for transferring and managing data [3]. A log abstract sensors, actuator and IoT applications; any read or write to the device is done via a log just like how a file abstract devices in Operating Systems. Logs are durable, lightweight and support multiple readers at the same time and can be migrated as necessary to meet Quality of Service (QoS) requirements.

The GDP is logically divided into different planes: Application Plane, Control Plane and Data Plane. The data plane contains the logs while control plane holds the program which need to communicate with both applications and logs. The controller application such as the one which decide the follow of data across the infrastructure or access controllers are placed in the control plane. The application plane contains the IoT applications which is used to interact with the IoT devices via log. In our trace and track system we are developing both the controller with blockchain backend and IoT application.

3.2 Blockchain

Blockchain was first introduced as a immutable public ledger for tracking transaction of cryptocurrency Bitcoin [15]. Its decentralized approach relies on the distributed network to validate the consensus for the transaction and prevents any single one authority to control it. The presence of a third party may monopolize the transactions, eliminating them reduces transaction costs and time delays. This feature of blockchain further adds reliability to the transaction as it prevents the occurrence of human errors. Also, the records are accessible from anywhere with any device and by anyone. Confidentiality of the data in the blockchain is maintained by encryption and hashing methods.

The research into the various consensus algorithms has led to diverse applications for blockchains [7,14] and to support uses apart from just cryptocurrencies. This is achieved by introduction of private blockchains. While the public blockchain implemented by Bitcoin application can be used by any user of the Internet it has its limitations. In applications which poses constraints on who has the authority to read the data, private blockchain is a more ideal alternative. It still maintains the property of blockchain and does not allow writes onto it based on a single party only. Private blockchain combines the advantages of public blockchain and maintains confidentiality provided by traditional databases.

The difference in the types of blockchains is brought about by the consensus algorithms they use. Consensus algorithm mainly defines a method whereby all the participants can come to an agreement on a matter in a fair manner in the best interest of the parties involved in the transaction. Many projects are developed based on different consensus algorithms like Proof of Work (PoW)[15], Proof of Stake (PoS)[18], Proof of Elasped Time (PoET)[10] and Practical Byzantine Fault Tolerance (PBFT)[13]. Projects like Hyperledger Fabric [8], Intelledger [10] and Tendermint [11] are designed on the basis of these algorithms.

There are several options to choose from with respect to consensus algorithms and blockchain frameworks. In our case study, the design prioritized privacy followed by scalability and also ensures more accountability. The combination of Tendermint blockchain framework and Tendermint Consensus Algorithm was found most suitable to cater to these requirements.

4 Pharma Trace and Track System

In this section, we introduce the trace and track system and its design details. The pharmaceutical supply chain consists of many unit processes that transform the input resources to medicines and medical equipments for distribution in the market. In each of the unit processes (manufacturing, registration, distribution etc.) fraudulent occurrences can lead to the development of substandard or counterfeit drugs. Pharma companies may not adhere to proper manufacturing technique; register products that do not meet quality requirement; hoard drugs to manipulate the market prices and so on. An example is when FDA discovered counterfeit versions of Avastin, a cancer drug, introduced in the U.S.

supply chain in 2012 [5]. Such activities adversely affect people's trust on pharma companies and the regulatory agencies.

The work flow at each stage of supply chain varies, hence, we will have to employ different approaches to tackle the different frauds. We focus on a solution to tackle fraud in the distribution stage as our first step. Currently, there are companies such as Tracelink [16], Axway [1] and VerifyBrand [17] which provide services to prevent or detect counterfeits. The present implementations makes use of distributed databases with central administrator while our blockchain approach help maintain the database among nodes that do not trust each other in a decentralized manner.

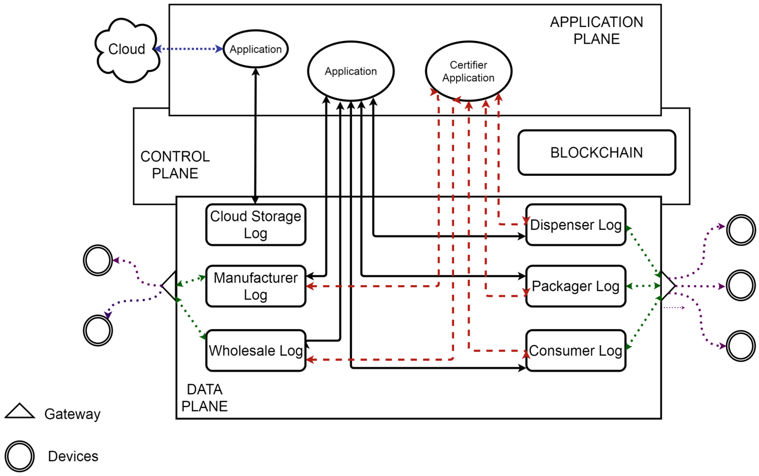

Fig. 1. Pharma supply chain infrastructure

In our implementation, we use GDP IoT framework proposed by Zhang et al. for efficient management and communication of data across the pharma supply chain. The whole supply chain infrastructure consist of sensors (RFID reader, Barcode scanner, Smartphones) that generate time series data that need to be stored and processed in a distributed manner. All data including information regarding the drug as well as transaction details are collected by the devices and stored in log files. The GDP framework is specifically designed to manage time-series data through its log based storage abstraction. The logs are signed with unique cryptographic keys for different devices, hence authenticity, integrity and non-repudiation is also incorporated.

The framework is logically divided into different planes as shown in the Fig. 1, such as the data plane, control plane and application plane. The data plane along with the application plane holds the trace and track application that we are going to build and control plane contains the controller that can detect counterfeit drug. The applications include querying the requested details of a medicine, taking care of data transfer from one log to another simultaneously with transfer of medicine from one participant to another. It also includes transferring relevant data to the cloud for further high end processing. The novelty of our approach is on the design of the GDP controller which uses blockchain to store verified transaction details on drug transfer. The design of controller workflow and role of blockchain in detecting fraud is further elaborated below.

While GDP help in storage and communication amongst different entities in a supply chain, the controller helps in tracing the drug as it travel across the entities of supply chain. When one entity transfers a set of drugs to another, the transaction details are sent to the controller. The controller in turn stores the details onto a private blockchain. For example, a transaction is recorded when a Distributor A transfers 100 units of a drug from manufacturer A to supplier B. The controller with the help of blockchain maintains the exact details of drugs that each entity hold thus making it very difficult to introduce counterfeits. The blockchain is maintained by all the entities that are part of the supply chain. The entities use a consensus algorithm to update the blockchain in order to avoid any inconsistency.

In blockchain, transactions are stored into as blocks which are linked using cryptographic hashes. A block consists of a header, set of transactions (that occurred during a time window) and a set of signatures from the participants to verify the transactions of the previous block. Each transaction will consist of a unique ID to identify the batch number, the source entity, and receiving entities, the quantity of medicines transferred and the timestamp. The header will consist of length of the chain, the last block ID as well as the hash of the previous chain state.

We have started the implementation of our trace and track system using Tendermint. Tendermint is divided into two sub components: a blockchain consensus engine and a generic application interface. Former, helps in the creation of blockchain and the later facilitates the communication between the trace and track controller and the blockchain [11]. The reason why we have chosen Tendermint is that it provide more accountability in case of occurrence of fraud. It is designed to provide the provenance of drugs to prevent introduction of counterfeit drugs into the supply chain while transactions happens between different entities. During distribution each of the product will have a unique hash representing a product state that can be tracked, but cannot be replicated. Due to the addition of transactions at each stage governed by consensus of its participants, the introduction of counterfeit drugs without other's knowledge is impossible.

5 Conclusion

Technologies for Healthcare today is a growing domain witnessing significant leaps in innovative use of science and engineering to enhance patient care. It is also a critical domain directly impacting health and well being. Pharma based healthcare industries serve large populations, and recently they have witnessed increasing instabilities in their supply chains by miscreants trying to introduce counterfeit drugs for additional profit. The increase in counterfeit drugs and the distribution of substandard drugs that can cause disability and loss of life have led to the implementation of trace and track systems over the pharmacy supply chains by the federal agencies around the world. In our work we have described a novel trace and track system that combines the advantages of GDP and blockchain technology. We utilize the GDP framework to build the IoT application that tracks the provenance of drugs. We also put forward the idea of using the blockchain technology in the controller application to ensure the trust among the different participants of the system. The blockchain by design imparts transparency, authentication, auditability to trace the origins of a product. Using the blockchain distributed design reduces the data tampering risks Further providing a unique identity to the blockchain makes it a cheap but error free operation.

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