A blockchain-enabled framework for improving traceability and coverage analysis of vaccine supply-chain reducing the anomalies

Adarsh S
Research Scientist
Kerala Blockchain Academy
IIITM-K, Thiruvananthapuram
Email: adarsh.res16@iiitmk.ac.in

Shon G Joseph
Senior Scientist
Kerala Blockchain Academy
IIITM-K, Thiruvananthapuram
Email: shon.joseph@iiitmk.ac.in

Franklin John
Research Scientist
Kerala Blockchain Academy
IIITM-K, Thiruvananthapuram
Email: franklin.john@iiitmk.ac.in

Lekshmi M B
Research Engineer
Kerala Blockchain Academy
IIITM-K, Thiruvananthapuram
Email: lekshmi.mb@iiitmk.ac.in

Asharaf S.
Professor
IIITM-K, Thiruvananthapuram
Email: asharaf.s@iiitmk.ac.in

Abstract—Tracing the vaccines from the manufacturing labs till the health centres administering doses to child is a cumbersome process with the involvement of large number of stakeholders and with multiple levels of book-keeping mechanisms. This work primarily focusses on the problem of traceability of immunization vaccines from manufacturing facility, through the distribution mechanisms in cold storage network and the vaccine handling/administration facilities, till the end consumer in the Indian context. The proposed research named, Immunochain is a state-of-the-art big data and block chain technologies powered, mobile/web enabled vaccine traceability solution for immunization programs in India. It is vendor neutral, scalable, replicable and reusable across different immunization programs in any geographical context. Experiments and pilot testing on Indian geography indicates that the proposed approach outperforms some of the existing approaches in vaccine traceability and record management systems.

Index Terms—blockchain, hyperledger, supply chain, smart contracts, big data.

I. Introduction

Immunization is the simplest and the most effective approach to protect humans from many serious diseases. Successful immunization programs are essential for the economy too, as it can save a large amount of public money spent on controlling many disease outbreaks and healthcare activities. Further, it ensures a healthy and productive workforce for nation building. India's immunization programme is the largest in the world, with annual cohorts of around 26.7 million infants and 30 million pregnant women [1]. Even though our governments have attempted major immunization programs

covering the entire nation, monitoring and measuring the effectiveness with relevant data has always been a challenge. With the large number of stakeholders involved in the immunization programs, the collection and analytics of credible data is definitely a non-trivial task. Some of the major dimensions of this problem are related to sanctity, completeness, timeliness and integrity of the data collected from the field. Hence most of the immunization programs have given very limited focus on monitoring and evaluation. This often leads to lack of clarity on the effectiveness of the past programs leading to poor plans for further/corrective actions resulting in many adverse effects in our public healthcare systems. This proposed works aims at building a blockchain-enabled framework for improving traceability and coverage analysis of vaccine supply-chain reducing the anomalies in the existing system. The research outcome was built as a solution termed as Immunochain and got selected for the Grand Challenges India program jointly funded by Bill & Melinda Gates Foundation and Department of Biotechnology. The major contributions of this paper are:

- Critically examines the problems with the existing system of record keeping and traceability with the Mission Indradhanush Program.
- Proposes a blockchain framework for traceability and coverage analysis which is supported by mobile applications.
- Experimentally verify the usefulness of the proposed framework with on-field implementations.

The remainder of this paper is organized as follows: Section II discusses some of the recent and prominent approaches in immunization program, Section III introduces the technologies

used in this approach, in Section IV, the proposed method is discussed, in Section V, the experimental setup is detailed and in Section VI the results are presented and a detailed analysis is given. Conclusions and future work are also discussed accordingly.

II. RELATED WORK

The Government of India has come up with Mission Indradhanush program that aims at improving the immunization program in India and the operational guidelines are defined in Intensified Mission Indradhanush [2]. A detailed study is done by INCLEN Trust International [3] to analyse the procedures undergone for storing the vaccines, supply the vaccines and improve vaccine coverage in three Indian states. The steps taken for training the health officials and the methods opted for Cold Chain and Logistics Management are mentioned in [4], [5]. In [6], a blockchain based solution is proposed for managing electronic health records to ensure scalability, security and confidentiality. A lightweight blockchain architecture is proposed in [7] for health care data management by dividing the network participants into clusters. The various challenges in addressing key management, mining attacks, mining incentives etc and various opportunities and research challenges in implementing blockchain in healthcare applications is discussed in [8].

Some of the related works in the existing system relating to the vaccine supply-chain traceability ,

A. electronic Vaccine Intelligence Network (eVIN)

The Government of India introduced electronic Vaccine Intelligence Network (eVIN) through the United Nations Development Program (UNDP) in 2015 which was rolled out in 12 out of 36 states and union territories in India. The primary aim of eVIN is the real-time tracking of stocks of vaccine at the cold storage facility and monitoring of storage temperature.

B. RCH Portal

RCH Portal [9] got established in wake of providing quality healthcare to pregnant women and thus reduce the infant mortality rates (IMR), maternal mortality rates (MMR) in India. An initiative under the National Health Mission (NHM) of the country, the project envisions to track all the key information with respect to RCH related services including family planning, maternal health, child health and immunization. The portal early identifies the reproductive lifecycle of women and help to track the health conditions during her pregnancy journey.

III. TECHNOLOGIES USED

The following section summarizes the technologies used.

A. Blockchain technology

Blockchain Technology is introduced through a white paper [10] written by an anonymous named Satoshi Nakamoto. Blockchain technology is a distributed ledger technology(DLT) in which the ledger is shared among multiple nodes. The ledger refers to a means for recording transactions

and in the case of blockchain technology, ledger refers to a chain of blocks. Blocks are containers that store transaction details and various other relevant details of the block. Each block is chained to the previous block by embedding the block with a piece of information from the previous block. Thus forming a chain of blocks - blockchain. It is the hashing technique in cryptography that helps blockchain in safeguarding the transaction/information from tampering or any fraudulent events. Each block in blockchain points back to the previous block by including its hash. In other words, a block contains the previous hash of its predecessor block indicating its connection. Thus any attempt to edit the older blocks will immediately be made apparent to the network participant (nodes). The blockchain system is decentralized, referring to no centralized authority for controlling the blockchain network. A fully decentralized system is known as a public blockchain [11]. In such systems, anyone can join the network and it is publicly available. Bitcoin and Ethereum are examples of public blockchains. An important aspect to achieve decentralization is consensus mechanisms. Consensus is a set of rules (algorithm) followed by a blockchain network in order to reach an agreement about which copy of the blockchain should they keep. In other words a method for maintaining a single truth in the network. In contrast to the public blockchain network, a private blockchain network is configured in such a way that only restricted parties can join the network and participate in reading or writing data. A consortium blockchain can be considered as a combination of both public and private blockchains. A partially decentralized network, consortium blockchain is a semi-public system that is, in a way, a hybrid between public and private blockchains controlled by certain pre-selected nodes.

B. Hyperledger

Hyperledger is an open-source collaborative effort created to improve cross-industry blockchain innovations. The Linux Foundation has hosted Hyperledger as a global collaboration, supported by many leaders in the areas of Banking, Finance, Supply Chains, Internet of Things, Manufacturing, and Technology. Hyperledger provides a greenhouse structure that can nurture new ideas, provide support with essential resources, and distribute the results worldwide. Hyperledger has played an important role in ensuring inter-operability, longevity, transparency, and support for promoting blockchain technologies so as to enhance commercial adoption.

C. Smart Contracts

Smart contracts are self-executing program modules which can run on the blockchain networks without the involvement of any intermediaries or trusted-third parties [11]. The important rules and regulations for the immunization process can be converted into smart contract and deployed over the blockchain network to avoid discrepancies and malpractices over the traceability and administration of vaccines.

IV. Proposed Method

The proposed method aims at building big data and blockchain technology powered, mobile/web enabled immunization effectiveness solutions for immunization programs in India. As it is essential to trace the details of vaccines administered for a child and also the availability and usage of vaccines at various geographical locations, the proposed solution serves as a solution that can store the details on blockchain which ensures traceability and immutability. In the current scenario, the tracking of vaccination details are done through physical record keeping which is a cumbersome process. As the availability of vaccines at various health centres is not uniformly tracked, there is a chance of shortage of vaccines which may lead to inadequate vaccine administration for the child. Immunochain can address the problem of traceability of immunization vaccines from regional centers, through the distribution mechanisms in cold storage networks and the vaccine handling/administration facilities, till the end consumer.

In the current scenario, the vaccine manufacturers generate a batch number for vaccine packages and distribute it to vaccine stores. In the vaccine stores, the receival of vaccines are recorded manually on record books and then they are distributed to the health centres. In the health centres, the respective health officials have to note down the details of the vaccines administered to the hospital's record keeping book and to the beneficiary's vaccination/RCH book. In these record keepings, it seems to be difficult to track the details of the vaccines that are administered for a particular child. Also, tracking the information related to the availability/usage of vaccines at various health centres or geographical locations is tedious as the data has to be collected by verifying the different entries in various record books. Hence the proposed solution projects on digitizing the vaccination details and beneficiary details there by ensuring the availability of data for various analysis and future reference.

Immunochain will store the beneficiary details and vaccine details in the blockchain thereby ensuring the traceability of the vaccines administered for each beneficiary. The system can also trace the availability/usage of vaccines at each health centre. The manual data entry process can be avoided by generating QR codes, which can be scanned for obtaining the details. The system proposes the usage of two blockchains - one for storing the vaccine details and the other one for storing the beneficiary details. The vaccine chain stores the details of the vaccines which includes the transactions based on vaccine registration, receival of vaccine stocks, transfer of vaccine stocks and vaccine stock updation. The beneficiary chain stores the details of the beneficiary which includes the transactions based on beneficiary registration and vaccine administration.

The smart contract layer will provide a trustworthy and traceable platform for vaccine administration processes for reliable data capture and management. This will make it easier to maintain accurate, timely and accessible data to be shared between different stakeholders involved in the whole immu-nization process under the Universal Immunisation Program (UIP). Unifying the data kept in various physical ledgers, into a distributed digital ledger will provide huge value to the people and officials with regards to record keeping of immunization details and for the long term. This can avoid a lot of human effort and errors involved, as well as duplication of records. For example, when a vaccination is administered for a child, all the required records and reports can be automatically filled in, without requiring to duplicate the data through human effort. This will also ensure the availability of these data, in case of loss of physical records due to unforeseen circumstances like a natural disaster. This data combined with their immutable identity stored on the blockchain, can potentially become a digital record/proof of diseases that a citizen is vaccinated for, throughout their lifetime, starting from their birth.

Real time data of the vaccine administrations available through Immunochain can be visualized using different reports/charts/comparisons, that provide insights to healthcare officials regarding various aspects with respect to the available data points. This can be coverage analysis based on location, vaccines, dates of administration. This data has a pivotal role in improving the effectiveness and coverage of the immunization process. The following subsection elaborates on the solutions proposed by Immunochain.

A. Blockchain system

Immunochain maintains two unique chains of data: a beneficiary identity chain and a vaccine chain. These chains ensure trusted and tamper-proof data to all the involved stakeholders. Hyperledger Sawtooth can serve as the blockchain framework for this purpose. Hyperledger Sawtooth is an enterprise blockchain platform for building distributed ledger applications and networks. The design philosophy targets keeping ledgers distributed and making smart contracts safe, particularly for enterprise use. It offers a flexible and modular architecture separating the core system from the application domain, so smart contracts can specify the business rules for applications without needing to know the underlying design of the core system. It provides an extremely modular and flexible platform for implementing transaction-based updates to a shared state between untrusted parties coordinated by consensus algorithms. Hyperledger Sawtooth supports a variety of consensus algorithms, including Practical Byzantine Fault Tolerance (PBFT) and Proof of Elapsed Time (PoET). From this, PBFT can be chosen as the consensus algorithm for both the blockchains. It ensures transaction finality and higher energy efficiency compared to other consensus mechanisms in the blockchain.

B. Big Data analytics platform

Big data technologies are primarily used for storing, processing and managing large amounts of data. The use of big data infrastructure helps in generation of various kinds of automatic reports, live updates and data analysis based on requirements. In Immunochain, big data infrastructure is used

to handle the bulk volume of vaccine administration related data. Apache Cassandra can be used for the database management system for the proposed method. Apache Cassandra is a free and open-source, distributed, wide column store, NoSQL database management system designed to handle large amounts of data across many commodity servers, providing high availability with no single point of failure. Cassandra was designed as a best in class combination of both systems to meet an emerging large scale, both in data footprint and query volume, storage requirements. As applications began to require full global replication and always available low-latency reads and writes, it became imperative to design a new kind of database model as the relational database systems of the time struggled to meet the new requirements of global-scale applications. Systems like Cassandra are designed for these challenges.

C. Immunochain mobile application

Immunochain mobile application provides the health officials with the options for vaccine registration, stock management, vaccine administration and report generation. Before a child is administered with a vaccine by an authorized official, the Immunochain mobile application can be used to scan and establish the identity data from both the child and vaccine identity chains. This establishes a connection and the data will be recorded along with the time stamp on the big data infrastructure.

D. Immunochain web application

The Immunochain web application provides a dashboard with vaccination analytics, beneficiary management and user management. The vaccination analytics provides various reports such as the count of vaccines administered, availability of vaccines in each station, details of the vaccines administered at a particular station, details of the beneficiary and the vaccines administered for the beneficiary etc. These reports can be used in analysis of usage of vaccines at various geographical locations and can be used in the study of improving the immunization programmes. The beneficiary management includes the registration of beneficiary, QR code generation which uniquely identifies the beneficiary, editing/adding child details and the immunization details etc. The user management defines the users and the roles which specifies the accessibility of the application.

E. RCH book mobile application

The RCH book mobile application can be used by the beneficiaries, similar to a vaccination counterfoil or RCH book, where the vaccination details of the child will get automatically updated.

V. EXPERIMENTAL SETUP

A. Immunochain Architecture

Immunochain provides a blockchain based solution that can track the vaccination processes involved from the vaccine manufacturer to the end user. In the normal scenario, the
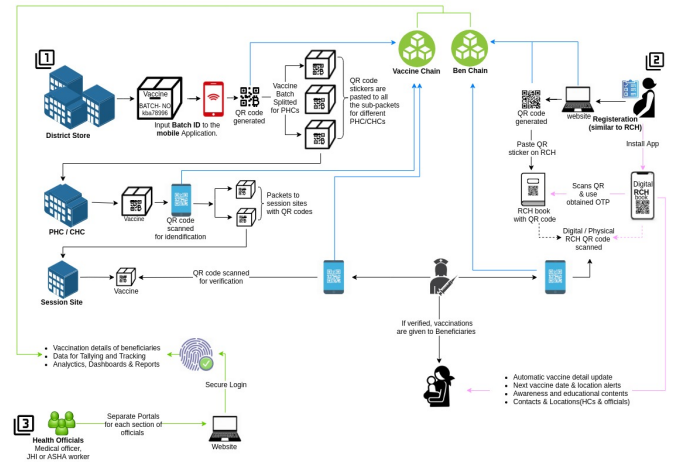

Fig. 1. Immunochain implementation workflow

vaccine manufactures will generate a batch number for each vaccine package and are initially distributed to the vaccine store and from there it is distributed to various health centres. From the health centres, the vaccine will be administered to the beneficiary. So it is essential to know the batch number of the vaccine that is administered for the child and also it is required to know the availability and usage of vaccines in each health centre. For tracking such information, the Immunochain maintains two blockchains -Vaccine Chain and Ben Chain. The Vaccine chain will store the transaction details related to vaccines which includes processes such as registering the vaccine at the vaccine store, receiving the vaccines at health centres or sub centres. The Ben chain will store the transaction details related to the beneficiary which includes beneficiary registration and vaccine administration. The whole process can be elaborated as follows:

The vaccine manufacturers issue the vaccines packages to vaccine stores. The vaccine packages have a unique batch number assigned by the manufacturer and it is an identification of the specific batch produced. In vaccine store, the vaccines will be registered to the system and generates a QR code which uniquely identifies the vaccine and the identity of the vaccine is stored in Vaccine chain. If the vaccine packages are sent to health centers then new QR code is generated which will be pasted on the vaccine package. The receiving health centre can confirm the receival by scanning the QR code and the vaccine receival information will be stored in the Vaccine chain. This data in the chain ensures the availability of the vaccine at that particular health centre. In some health centres there is chance of sending vaccines to sub-centres. In such case also separate QR codes can be generated and on scanning these QR codes, the sub-centres can confirm the receival. This information is also stored in Vaccine chain which ensures the availability of vaccine at the sub-centre.

In the beneficiary side, each beneficiary has to be first registered to the system which will generate a QR code to uniquely identify the beneficiary. The beneficiary registration details

is stored in the Ben Chain, which will be used for vaccine administration process and future tracking. The beneficiary can view the beneficiary details and vaccination details through the digital RCH book solution which is a part of Immunochain. The digital RCH book solution will contain the QR code of the beneficiary that can be used for future tracking and vaccine administration process.

During vaccine administration process, the system can identify the vaccine from the Vaccine chain and beneficiary from the Ben chain. The system will verify the vaccine data by scanning the vaccine QR code and will verify the beneficiary data by scanning the QR code available with the beneficiary's digital RCH book. The system allows vaccine administration after verifying the identity of vaccine and beneficiary. The vaccine details and beneficiary details in the chains are combined to ensure that the particular vaccine is administered for that particular beneficiary.

The vaccine chain details and ben chain details can be used for various analysis and report generation that can be used for improving the Immunization programmes. These blockchains ensure trusted and tamper-proof data to all the involved stakeholders. The distributed ledger of the Immunochain running on top of the blockchain network ensures a single version of the truth of the immutable data with an easier audit process.

B. Implementation

A mobile application to handle the vaccine administration and vaccine management was developed as part of the Immunochain project. This application helps in the process of vaccine registration, stock management and vaccine administration. The application is available in Google Play Store named Immunochain. The source code of the project is available in the following public repository: https://github.com/Kerala-Blockchain-Academy/ImmunoChain/tree/master/immunochain-vaccinationclient/ImmunochainOfficial.

A mobile application similar to RCH book was developed for the use of beneficiaries and health officials. The application is available in Google Play Store named Immunochain-RCH. The source code of the application is published in the following public repository: https://github.com/Kerala-Blockchain-Academy/ImmunoChain/tree/master/immunochain-vaccinationclient/ImmunochainRch.

A portal was developed for beneficiary registration, management, analysis and reporting. This web-based application is hosted at https://immunochain.dev/. The source code of the project is available in the following public repository: https://github.com/Kerala-Blockchain-Academy/ImmunoChain/tree/master/immuno_dashboard.

The technical details of starting and using the application are available in the repository.

This research was field tested for 8 weeks under the supervision of Directorate of Health Services at Family Health Center in Kadakampally at Thiruvananthapuram District of Kerala State, INDIA from January 13 to March 2, 2020. A total of 345 beneficiaries were registered into the system and over 624 dozes of vaccines were administered to 326 children through this system.

VI. RESULTS AND DISCUSSIONS

With the implementation of the proposed system and the pilot testing, we have found some remarkable results in the following areas.

A. Traceability of vaccine batches

The availability of vaccine batches in each health centre can be easily traced as the data is stored in blockchain. Not only the vaccine details but also the beneficiary details are also stored in blockchain and hence mapping of Batch IDs of vaccines to the RCH ID of the beneficiary will provide the vaccine administration data. By implementing the proposed system, the beneficiaries of each vaccine can be identified. Further, each beneficiary vaccinated are mapped to the batch of vaccines they took. As the system provides immutable data, it can generate a trusted report of the vaccine usage at various locations.

B. Reduced Time and Effort

It takes, on average, about 45-50 mins for a parent/s to complete the vaccination for their child, after arriving at the health center. A large chunk of this time is spent for taking entry tokens where their data is searched and recorded, with health inspectors who capture their data and mark the vaccinations etc. With the help of the proposed system, this time can be significantly reduced to less than 10 mins, due to reduced efforts by not recapturing data that is already with the system. Scanning the QR code and verifying the data with the parents significantly reduces the time and effort involved.

TABLE I
VACCINE ADMINISTRATION PROCESSING TIME

Sl.No. Head	Time Comparison		
	Vaccination Process	*Existing*	*Immunochain*
1	Child Registration[a]	30-45 mins	10 mins
2	Vaccine Mapping[a]	10 mins	45-50 secs
3	Health official approval[a]	5-7 mins	25-30 secs
4	RCH Book Update[a]	4-5 mins	25-30 sec

[a]As per the conducted trial

Moreover the chances of errors during the manual process and updating multiple records and databases can be eliminated thereby ensuring trusted data records of vaccination which is a primary requirement of many further medical trials.

CONCLUSIONS AND FUTURE SCOPE

In this paper, a design of a blockchain based system, namely "Immunochain" for end-to-end Vaccine Supply Chain Traceability is proposed. A detailed study of existing methodologies and its shortcomings were done. Based on the study a software solution for supply-side traceability and consumption side data collection/integration is proposed. The proposed system addresses the problem of traceability of immunization vaccines

from regional centers, through the distribution mechanisms in cold storage networks and the vaccine handling/administration facilities, till the end consumer.

As a future strategy, the system can be used to track the beneficiaries of the COVID vaccines that come through CoVIN [12]. The system can work complementary to the supply side of the vaccine to track who received the vaccine doses. The system can also be extended to issue verifiable credentials for beneficiaries using blockchain-based identity management technologies for the universal immunization program.

ACKNOWLEDGEMENT

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