InoculLedger: A Secure and Scalable Distributed Ledger for Efficient Vaccine Supply Chain Management

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***Abstract*—The Vaccine Supply Chain (VSC) is a crucial component of the Healthcare Cyber-Physical System (H-CPS), enabling seamless coordination among various entities to ensure the timely delivery of safe and effective vaccines. Given the extensive number of interactions and the stringent requirements for monitoring environmental parameters, the VSC features a highly complex architecture with intricate operational dynamics. This complexity, coupled with the reliance on multiple centralized systems, often results in lack of transparency, making it challenging to monitor the vaccine movement withing the supply chain network as well as recording the temperature excursions.**

To address these challenges, we propose a novel blockchain-based system that provides a transparent and secure mechanism for storing and accessing vaccine records. By leveraging the IOTA Tangle data structure, our system meets the high throughput demands of the application while ensuring data integrity and scalability. A proof-of-concept implementation was developed and analyzed to evaluate its scalability and adaptability for real-world deployment, demonstrating its potential to revolutionize the VSC by enhancing transparency and efficiency.

***Index Terms*—Distributed Ledger Systems, Blockchain Healthcare, Vaccine Supply Chain Management, Tangle Data Structure, Vaccine Tracking**

I. Introduction

Vaccines are preparations that are administered to train our immune systems to fight against a particular infectious or malignant disease. A pharmaceutical supply chain is an interconnected network of processes and entities that are actively involved to ensure manufacturing, storage, distribution, and delivery of pharmaceutical products. Vaccines are highly sensitive to temperature and require strict monitoring. One of the most used vaccines is the influenza vaccine for flu, the hepatitis B vaccine for providing protection against hepatitis B, and some other immunizations fall under this category [1]. Immunizations like COVID-19 need to interact with freezing temperatures around -70°C in terms of storing vaccines for long periods. It is important for these vaccines to not exposed to temperatures beyond the recommended range, which might result in early expiration and potentially some serious consequences for the consumers [2]. Because of internationalization and the variety of concerned entities, the VSC has become more complex and maintaining and tracking all interactions among different entities is quite challenging. As shown in Figure 1, standard VSC procedure shows interactions between different entities when vaccine moves through the supply chains.

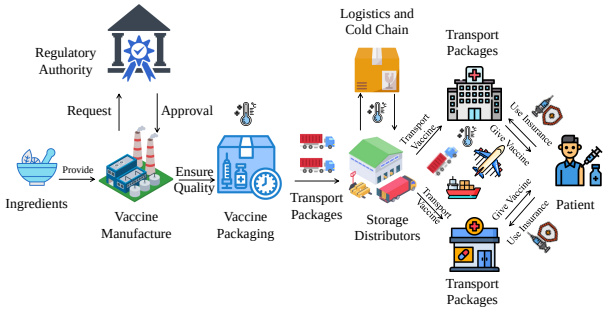

Fig. 1. Typical Vaccine Supply Chain Process

The Pharmaceutical Supply Chain (PSC) is a key element of the Healthcare Cyber-Physical System (H-CPS), facilitating the timely delivery of essential medication with appropriate quality standards. The PSC supports global collaboration among organizations and enables the implementation of cost-effective and efficient strategies in pharmaceutical logistics [3]. Both the VSC and PSC share the fundamental characteristics, such as stakeholder involvement and risk management. Stakeholders are responsible to ensure product safety and quality, while maintaining a steady supply of essential medicines and vaccines.

The VSC represents a crucial network of operations connecting various entities involved in vaccine production, transport, storage, and administration. The process begins with capturing the raw ingredients from the ingredient supplier. Later, the manufacturer will involve in research and development of the vaccines and must follow the approval from regulatory authorities to mass produce the vaccine. These large batches of vaccines produced at the manufacturing units

will be sent to repackaging to smaller packaging and then be sent to the distributors. These distributors are responsible for sending these to end healthcare hubs and clinics to be made available to the end consumer. A critical component of the VSC is the cold chain, which encompasses a series of refrigerated manufacturing, storage, and distribution processes designed to preserve vaccine quality. This includes specialized refrigeration equipment at production facilities, temperature-controlled transportation methods, and appropriate storage facilities at distribution hubs and clinics. Maintaining precise temperature control is essential, as minor deviations from the allowed range can degrade the vaccine efficacy. By leveraging advanced technology like IoT, the cold chain ensures the vaccines remain effective from production to administration. Along with this VSC also improves accessibility, optimizing stock management, reducing wastage, and ensuring timely vaccine delivery.

VSC has faced many challenges due to its complex nature of interactions and large number of participating entities leading to an obscure network. The COVID-19 pandemic has exposed critical vulnerabilities and challenges in the global VSC [4]. One of the major limitations is lack of resources to maintain storage environment at different steps of the supply chain. Some specialized vaccines require different temperature ranges, such as the Rota-virus lifespan may reach up to 30 mounts when stored below 25 in Celsius degree [5]. Effective data management and tracking are vital aspects of the VSC since they enable real-time monitoring and prediction to ensure the secure and effective distribution of immunizations. The main challenge in this subject is the integration of diverse data systems across the supply chain. Blockchain technology is a recent technology which can provide a clear and permanent record of immunization delivery and help improve the administration of stocks.

Different technologies have contributed to enhance VSCs for safe and secure distribution of vaccines. The Internet of Things (IoT) is one of these technologies that can facilitate continuous monitoring of environmental parameters remotely. Generally, the IoT architecture comprises three distinct layers: the sensor layer, the network layer, and the cloud layer. Sensor Layer provides a monitoring system for environmental parameters such as temperature and humidity, which is important for sensing surrounding conditions data during storage and transportation procedures and sending the data to the network layer. Further, the network layer's responsibility is to gather data from the sensing layers and provide it to the cloud layer for future processing. The cloud layer provides essential computation and storage capabilities in the IoT architecture. One of the IoT applications that can be presented in terms of smart healthcare is the Internet of Medical Things (IoMT) [6]. Due to the limitations of IoT devices, utilizing complex encryption mechanisms is not a reliable option. Blockchain technology, especially IOTA Tangle, can improve data security and integrity. IOTA Tangle delivers a decentralized ledger that can rapidly record and authenticate VSC data and provide transparent records. It facilitates the monitoring system of the immunization data and observing the distribution of vaccines to consumers [7]. Entities in cold supply chain can gain more reliable and efficient management of immunizations and contribute to ensuring public health. The IOTA Tangle can create a data structure established with Directed Acyclic Graph (DAG). This technique verifies any new transaction verification with two previous transactions, unlike blockchain with a linear sequence of blocks. IOTA Tangle provides characteristics such as immutability and security like blockchain. However, IOTA Tangle was designed as a solution for IoT because of its fee-less architecture and scalability [8].

II. Related Research

IOTA Tangle has been a developing technology which has provided highly promising solutions over many domains of Smart City applications such as Smart Healthcare, Smart Agriculture, and others. One of the main characteristics of IOTA Tangle is scalability and provides fee-less transaction cost that makes it suitable for applications with very large microtransactions such as IoT. VSCs which have problems due to their complexity can benefit from utilizing IOTA Tangle as a solution. Many studies are being conducted in using IOTA Tangle as a solution for supply chain and ensuring safety of the products.

The proposed system in [9]–[11] makes use of blockchain systems by utilizing smart contracts to ensure real time transparency and accuracy in pharmaceutical supply chain (PSC). These systems allow monitoring of environmental condition and tracking the medication journey from manufacturers to consumers. However, in our current proposed system, InoculLedger uses IOTA Tangle as the distributed ledger to assure scalability and increase transaction throughput allowing it to handle large numbers of transactions.

The proposed system in [12] makes use of blockchain and encrypted QR codes in order to enhance traceability and security for the medicine supply chain, which is utilized for authorized access to data and chain storage to record all manufacturing and distribution transactions. Also, CryptoCargo that is proposed in [13] makes use of Ethereum blockchain systems integrated with IoT with the assistance of smart contracts in order to track products in pharmaceutical supply chain along to avoid counterfeiters. However, our proposed system InoculLdeger provides cost-effective transactions that can be scalable to the VSC industry.

The proposed system in [14] makes use of IOTA Tangle to improve efficiency, security, and transparency in the dairy supply chain field, which offers cost efficient transactions by reducing the processing time. This also enhances security using cryptographic protections to sustain counterfeiters and data manipulation. Unlike our current proposed InoculLdeger which utilizes IOTA Tangle in terms of VSC associated with cold chain management since the immunizations are very sensitive to environmental changes, and it requires monitoring to ensure consumer safety.

TABLE I
COMPARISON BETWEEN OUR PROPOSED SOLUTION WITH OTHER EXISTING SOLUTIONS

Aspect	Traditional Blockchain Applications	Ethereum Blockchain & IoT Applications	InoculLdeger (IOTA Tangle-based)
Platform	[✓]	[✓]	[✓]
Business Functions	[✓]	[✓]	[✓]
Mechanism	[✓]	[✓]	[✓]
Scalability	[✗]	[✗]	[✓]
Cost	[✗]	[✗]	[✓]
Security	[✓]	[✓]	[✓]
Access Control	[✓]	[✓]	[✓]
Real-time Decision	[✓]	[✗]	[✓]
Throughput	[✗]	[✗]	[✓]

III. NOVEL CONTRIBUTIONS

A. Problems addressed in the paper

Problems addressed in the current VSC systems are:

- Centralized authorities in current VSC lead to several security threats and are prone for Single Point of Failure (SPOF).
- Detection delay of vaccine condition can risk the efficiency of vaccines.
- Ensuring proper storage and transportation for vaccines is critical, yet it is challenging with traditional systems.
- Ethereum and other blockchain solutions are expensive and might not scale enough for a higher VSC with billions of transactions.
- Vaccine authenticity is highly concerning to consumers due to counterfeit vaccines and mishandled doses.

B. Novel Solutions Proposed

Below are the novel solutions proposed in InoculLdeger:

- Enabling P2P network among trusted nodes significantly addressed the security threats.
- Immutable nature of IOTA Tangle guarantees vaccine data security.
- Implemented InoculLedger leveraging IOTA platform which is cost-effective compared to other blockchain platforms.
- Designed Smart Container can provide continuous monitoring and alerting mechanism to effectively manage the vaccine environment during transport and storage.
- Developed InoculLedger immutable record of all transactions provides fool-proof way of authenticating vaccinations before administering.

IV. ARCHITECTURAL OVERVIEW OF INOCULLEDGER

An architectural overview of the proposed InoculLedger system, using IOTA Tangle for the VSC is illustrated in Figure 2. The important entities participating in the InoculLedger system are as follows: Smart Vaccine Containers equipped with IoT devices at different tiers of the supply chain. These containers perform the task of collecting environmental data continuously in terms of temperature and humidity during transportation. It is assumed that each package is dedicated to carrying vaccines under the same conditions of storage, which in turn allows for easy tracking of consignments. The environmental parameters data collected at these containers will be transmitted to the leveraged distributed ledger to create an immutable record.

Decentralized Application (dApp) interacts directly with stakeholders such as manufacturers, distributors, and regulatory authorities like the FDA. This leverages the communication among them and allows data input from smart contracts. The IOTA Tangle structure will store immutable logs of all environmental data and deviations to ensure complete transparency for all entities in the supply chain. The immutability feature of this distributed system permanently records violations in storage conditions making vaccines safe and compliant. This data can also be processed to provide insights into vaccine demand. This analysis can also assist all stakeholders in making informed decisions while deploying necessary adjustments in near real-time to maintain the VSC without disruptions.

Finally, the stakeholders, including the government and healthcare entities, oversee the complete vaccine life cycle. They might then intervene with real-time feedback or suggestions based on data provided by the system to help deliver vaccines safely to the final endpoint with the same quality, which is the Vaccination Center where the patient is administered the vaccine. All of these integrate InoculLedger for a safe, transparent, highly efficient supply chain system for vaccines using the technology of IOTA Tangle.

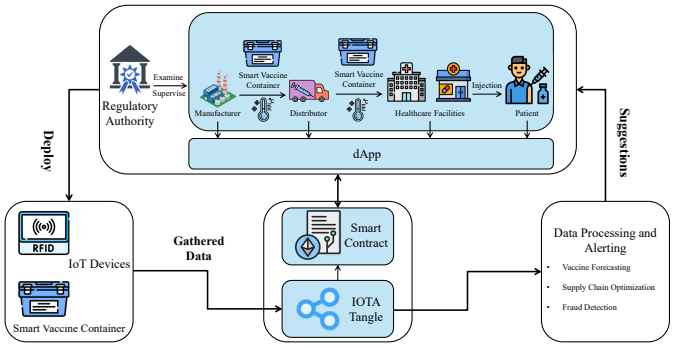

Fig. 2. Proposed Framework

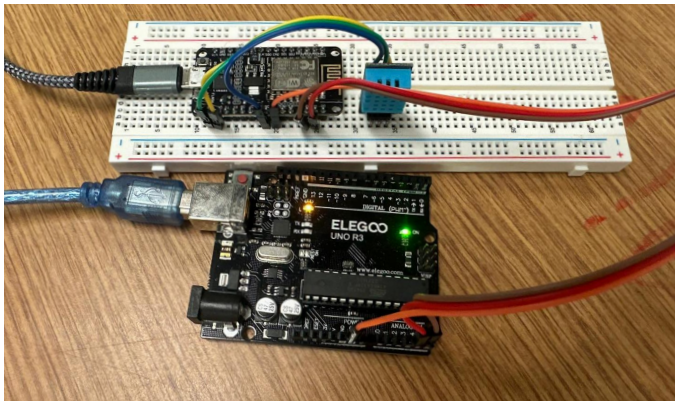

Fig. 3. Designed Smart Vaccine Container for InoculLedger

A. Smart Contract Desgin

InoculLedger smart contract introduces a pivotal role to ensure transparency and efficiency in terms of VSC by tracking the procedures of all stages, which are production by manufacturers, vaccine certification, ensuring the temperature by cold chain providers, vaccine distribution, and providing immunization for patients by vaccination centers. Each entity in the procedures is involved to a wallet address to enable Role Based Access Control Mechanism. Producing vaccines is an important component where manufacturers can produce packages in batches. Authorities, such as the FDA, have an essential role in certifying these batches when the batches meet the needed standard before continuing any further procedures. Cold chain providers and logistics roles are to maintain the temperature range from manufacture till it reaches distributors and ensure integrity by tracking multiple temperature readings and timestamps. When batch temperature deviates from the temperature range, the contract will alert stakeholders to enhance real-time monitoring and prompts corrective actions. Next, the contract will witness the process of vaccine distribution, where the immunizations are passed on to healthcare facilities that serve them to patients. The designed smart contract provides accountability among the parties involved.

V. Implementation and Validation

A. Implementation

The NodeMCU ESP8266 IoT platform is utilized to represent smart vaccine containers. It is an appropriate option because of its capability to connect to Wi-Fi and support various sensor interfaces. The core environmental parameters that are considered within the implementation of InoculLedger are temperature and humidity. For sensing temperature and humidity DHT11 sensor is used. Also, an Arduino UNO Rev3 is used as the smart vaccine container. Implemented container hardware is shown in Figure 3.

Furthermore, the InoculLedger smart contract, which is developed by Solidity, is implemented and deployed through Truffle Suite and MetaMask to simulate the proposed InoculLedger on IOTA platform. Truffle's environment enables complete testing and deployment environment. The Shimmer

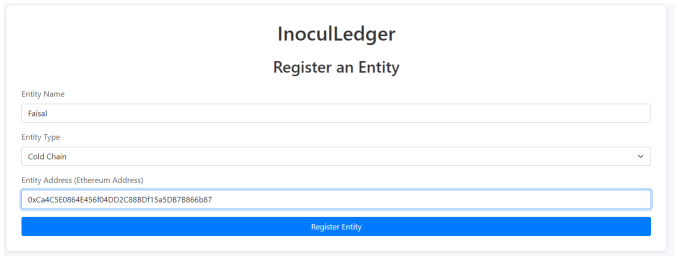

Fig. 4. Registration of Participating Entities from Designed DApp Interface

EVM testnet is used for testing the designed prototype. Shimmer EVM is a production grade staging network and a Layer-2 solution for IOTA to introduce smart contracts capability. All entities must undergo registration to participate in the network and a designed registration UI to interact with DApp is shown in Figure 4. Interacting with designed smart contract and certifying the vaccine can be seen at Figure 5.

Fig. 5. Certifying Vaccine in Designed InoculLedger Prototype

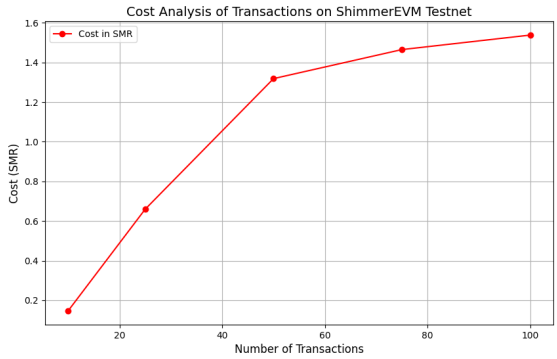

Fig. 6. Cost Analysis of Proposed InoculLedger

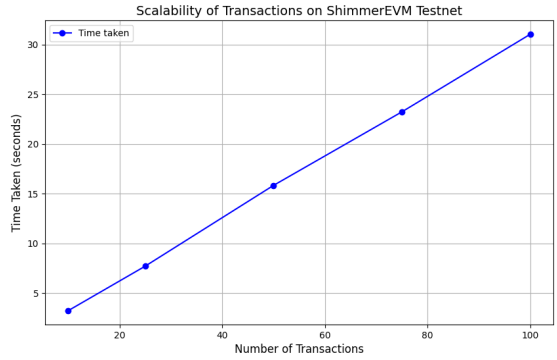

Fig. 7. Scalability Analysis of Proposed InoculLedger

B. Validation

Cost and scalability analysis of implemented InoculLedger are done to analyze the adaptability in real-world scenario. Results from the cost analysis are shown in Figure 6. As implemented application leverages IOTA blockchain, it supports large number of micro-transactions at minimal fee. With shimmer token at 0.0025$ as of 11th December 2025, the cost of transactions on implemented InoculLedger is very less making it a scalable solution to VSC. Throughput analysis is performed and the results are plotted in Figure 7. One of the major advantages of IOTA Tangle data structure compared to blockchain is the scalability. In IOTA, throughput of the network increases as the number of transactions increases. The results from Figure 7 clearly shows the proposed model can process large number of transaction data generated when deployed in real-world VSC.

VI. Conclusion and Future Research Directions

InoculLedger utilizes IOTA Tangle-based architecture to enhance vaccine tracking and management throughout the supply chain. It ensures real-time temperature monitoring and the integrity of vaccines from manufacturing to administration, all while significantly reducing transaction costs in favor of scalability and affordability. An intuitive interface eases the activities around shipment tracking and environmental monitoring, which allows stakeholders to have real-time oversight. In future research, we will include more complex interactions involved in the supply chain to provide a more complete solution. Also, introducing machine learning models to analyze the ledger data to automate processes will be implemented.

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