WHITEPAPER On

Blockchain Technology to Respond Quickly in Future Pandemic Situations by Ensuring Proper Distribution, Authenticity, and End-to-End Traceability of the Vaccines

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ABSTRACT

In the context of global pandemics, the knowledge we got from the most recent pandemic i.e., the COVID-19 pandemic can play a vital role in how efficiently we carry out the idea in other vaccination programs or pandemics. While we try to slow down the outbreak, the success rate will highly depend on the quick response of performing a successful vaccination program. In this case, some of the obstacles that may arise include but are not limited to the risk of counterfeit vaccines, not transporting the vaccines in an expected way throughout their journey, and the possibility of altering sensitive data, e.g., changing production or expiration dates. In this context, we propose a Blockchain-based solution that can be used as a model to respond quickly during global pandemics like COVID-19. The proposed solution ensures end-to-end traceability and transparency in the distribution of the vaccines while maintaining a cold chain, i.e., a temperature-controlled supply chain. As we have seen, the government is highly concerned about managing healthcare during and after the COVID-19 pandemic, building trust and reducing costs by implementing a secure and transparent system that helps to flatten the curve will have a promising impact on both public health and the economy of our country. Moreover, a system like this will help to increase revenue by reducing the loss of sales due to counterfeit vaccines. The private blockchain can have a promising impact on the supply chain environment and its relative sections.

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THE PROBLEM

The devastating pandemic known as COVID-19 has taught us some lessons in a hard way, as people around the globe are still dying because of the coronavirus. The vaccine is proven to be the best chance to get rid of the virus. Maintaining the quality of the vaccine in any pandemic is very crucial and can raise trust issues while questioning the whole system. People may question the authenticity of the vaccine they are receiving, which can cause chaos if remain unanswered.

Having a long history of counterfeit or substandard drugs which is about 20% of the total sales per year [1], Bangladesh has already seen the illicit trade of medical equipment and fake coronavirus certificates during the pandemic [2,3]. Whenever a pandemic starts, there is a huge risk that counterfeit vaccines may rise in the market, creating chaos in the vaccination program anytime when the supply of vaccines will not meet the demand. We propose a system with end-to-end traceability that would ensure the authenticity of the vaccine for current and future pandemics.

Throughout the paper, we will use COVID-19 as the reference for the pandemic. Let's look at an example. Ali, a citizen of Bangladesh is listed for the COVID-19 vaccine supplied by 'X' Pharmaceuticals Ltd and monitored by the government. However, he has a few concerns before taking the vaccine, such as:

- The vaccine is originally supplied by 'X' Pharmaceuticals Ltd.
- No unauthorized person in the supply chain was able to possess the vaccine.
- A strict cold chain was maintained i.e. the vaccine was constantly stored at 2°-8° Celsius throughout the journey.

PROPOSED SOLUTION AND METHODOLOGY

We are proposing a system that can be used as a model to fight future pandemics. In this paper, we are taking the example of the COVID-19 pandemic about how a blockchain-based temperature-controlled supply chain can maintain the proper quality and authenticity of the vaccine. In case of future pandemics, our scalable system can be easily implemented and modified accordingly. Our system has two fundamental responsibilities:

- i. Firstly, we propose to use a blockchain-based supply chain for end-to-end traceability of the vaccine.
- ii. Secondly, we propose to use a cold chain to monitor the temperature of the vaccine throughout the journey.

METHODOLOGY

In Bangladesh, according to a health ministry statement, the vaccines are sent to civil surgeons in all of the 64 (administrative) districts, as practice goes, the vaccines will be transported to distributors for allocation to hospitals, clinics, and vaccination centers [6,7].

Suppose, 'X' Pharmaceuticals Ltd, one of Bangladesh's biggest pharmaceutical companies, is the original supplier of the AstraZeneca vaccine in the country, and Ali, a citizen from Sylhet is listed as one of the customers. We start tracing after the vaccine lands in Bangladesh. Let's look at the sample supply chain:

'X' Pharmaceuticals Ltd(Original Supplier) - Civil Surgeons - Distributor Y - Distributor Z - Hospital/Clinic - Customer(Ali)

VACCINE DISTRIBUTION PROCESS:

- 1. Say, 20 thousand vaccines need to be delivered to Sylhet at some point. First of all, 'X' Pharmaceuticals Ltd will tag the vaccines and vaccine lots with unique codes. For simplicity, say, we tag the master box with a unique QR code "SYL-100". If there are 5 sub-boxes inside the master box, we tag them as "SYL-100-A", "SYL-100-B", "SYL-100-C", "SYL-100-D", "SYL-100-E".
- 2. Now, if the sub-box "SYL-100-A" contains 4000 vaccines, we can uniquely tag every vaccine inside this box as "SYL-100-A_0001", "SYL-100-A_0002", ..., "SYL-100-A_4000". These codes will be stored using an unclonable QR code, thus the physical copy of the original QR code will not be possible [10].
- **3.** Every distributor in the middle needs to scan the QR code of a box to confirm the delivery. The vaccines within it will automatically be scanned. So, if someone confirms that he received the box "SYL-100-A", that means he also received the items in that box e.g., "SYL-100-A_0001", "SYL-100-A_0002" etc. This can be done with a few lines of code.
- **4.** To maintain the cold chain, the boxes will be equipped with some internet of things (IoT) devices to observe the temperature. Thus, any unsafe fluctuation in the system can be recorded easily. An indicator device will be also added for ease of monitoring. Suppose, the indicator will be **Green** if it is stored at 2°-8° celsius. If the temperature is not maintained even for a moment the indicator will go **Red**. Once it is changed, it will never go back to the previous state. We propose the box be transparent in order to see the indicator from the outside of the box.
- **5.** When Ali receives the vaccine, he only takes the vaccine if it ensures these 3 major concerns:
 - He scans the QR code from the vaccine and checks the supply chain to ensure if it was the original product of 'X' Pharmaceuticals Ltd.
 - The QR code of the vaccine will be on the cork in such a way that if anyone tries to open the bottle, the QR code will be ruined which ensures that no unauthorized person opened the vaccine.
 - When he sees the indicator inside the box is green that means it has maintained the cold chain.

HOW FEASIBLE IS THE SOLUTION?

We will calculate the estimated cost and see how our solution reacts in different situations.

COST ESTIMATION

Our variable costs include internet of things (IoT) devices i.e., a temperature sensor, transmitter, and indicator which will be inside of the boxes. The current total price of these machines is around \$20-\$50. Some additional fixed costs e.g., transportation cost, freezing cost, etc can be managed. The blockchain-based solution will eliminate unnecessary middlemen, which can help the system to save money.

HANDLING CRITICAL SCENARIOS

Let's see how our solution responds to the following scenarios.

Q1: What prevents an unauthorized person from opening any box?

<u>Ans</u>: The QR code of the will be ruined, as it is unclonable, it couldn't be copied and replaced, so if a dishonest person in the middle tries to open it illegally, he would not be able to sell it to the next person anymore and can be tracked down.

Q2: What if someone shows the indicator of another box?

Ans: If the customer scans the vaccine bottle they will know its parent box.

Q3: How will the customer check if the vaccine is real?

Ans: The QR code of the vaccine will be in such a way that before taking the vaccine, he will scan the QR code and verify the supply chain. He could check the box it is from and the indicator. These can be done within a short time and should not affect the fact that it takes some time before the temperature of the vaccine increases to room temperature.

Q4: What if someone tries to replace the indicator?

Ans: The unclonable QR code associated with the indicator will be ruined.

WHY IS BLOCKCHAIN USED?

Let's dive into details of how blockchain can enable more transparent and accurate end-to-end tracking:

- 1. Using Blockchain to enhance the supply chain: A blockchain-based supply chain enhances traceability, increases efficiency and speed by eliminating middlemen, and reduces disruptions. When vaccine lots flow from one distributor to another, the tagged QR code is scanned and recorded on the blockchain. It creates a history of every item throughout the supply chain i.e. from its source to the end customer. Without blockchain technology, the information can be compromised, may lack verifications, and raise trust issues.
- **2. Using blockchain to protect sensitive data:** We can remove the possibility of altering sensitive supply chain data, e.g., changing production or expiration date. If we use a conventional or cloud database, any dishonest person can change it. Blockchain is designed to be immutable i.e. if we add any data to a blockchain, it cannot be changed.
- **3.** A counterfeit vaccine can be traced to its source using the blockchain trail: If an organization or distributor finds any counterfeit product, blockchain permits the organization and its supply chain partners to trace the product, find suppliers involved with it, and determine production and shipment batches related to it. So, in this case, blockchain can be more suitable for pandemic remedies like COVID-19 vaccines.

WHY PRIVATE BLOCKCHAIN?

Our proposed system will be administered and monitored by the government. If we do not use a private blockchain, anyone in the world would be able to see the transactions. The government may want to introduce the system only to its related parties such as suppliers, distributors, end consumers, etc. Usually, supply chains require private blockchains among known parties, so that members of a supply chain can find out the source and quality of their inventory [11]. Therefore, only known parties can be allowed to participate in such a blockchain. We choose Hyperledger Fabric for the development of our proposed system.

MARKET AND PARTNERS

MARKET

For COVID-19, Bangladesh has a budget of 1.68 Billion USD and around 72% of people have received at least one dose so far according to Wikipedia [5]. To vaccinate 160 million people, Bangladesh will face a cost of around 2 Billion USD. So, it's a huge market. According to the officials of the Bangladesh Pharmaceutical Industry Association, the annual sales of counterfeit or substandard drugs in the country is over Tk 1,500 crore

which is 20% of the total sales [1]. Though pandemics like coronavirus are recent, the history of faking drugs and vaccines is not and if that happens, it'll cause tremendous destruction to the country's health and economy.

PARTNERS

Here, the notable partners can be: 'X' Pharmaceuticals Ltd (as suppliers), Directorate General of Drug Administration (DGDA), and the government itself. Their roles, responsibilities, and incentives are mentioned below:

- 'X' Pharmaceuticals Ltd. will gain profit if their supplied vaccines are sold. If counterfeit vaccines are in the market at a low price, it would be a huge loss for them.
- Directorate General of Drug Administration needs manpower to monitor counterfeit drugs and vaccines. If they implement the proposed solution, it will reduce human error and hardship of paperwork, saving both time and money.
- The distributors in the middle will be penalized if they are involved in any distribution of counterfeit vaccines.
- If the government uses the proposed solution to implement a transparent way to distribute the COVID-19 and other vaccines, the public health and economy will be improved.

By implementing a private blockchain i.e. Hyperledger Fabric, the partners will act as organizations with peers. Every party can access data on which they have permission. The government will act as a founding member so that it can monitor everything.

COMPETITION AND RISKS

COMPETITION

We consider 3 types of competitors here such as:

- 1. Very direct competitors: Very direct competitors are other blockchain solutions that have the same goal. In this case, we currently have no other blockchain solutions in the market that have the same goal as us.
- **2. Direct competitors:** Direct competitors can be referred to the products or services that have the same goal. The Government of Bangladesh has launched a web application named "Surokkha" so that people can get the vaccine [13,14]. However, Surakkha and our solution can both work side by side. Still, let's look at the different properties between these two solutions:

Feature	Surokkha Application	Our Proposed Solution
Supply chain	Traditional Centralized	Blockchain-based and temperature controlled
Cost	Comparatively Higher	Comparatively lower because of deduction of middlemen
Transparency, traceability, and verification	Rare and difficult	Visual and applicable

Tracing back to counterfeit vaccine producer/supplier	Not applicable	Applicable
Verifying original vaccine	Rare and difficult	Visual and applicable

3. Indirect competitors: Indirect competitors refer to those who deliver completely different products or services but share the same target audience. In this case, maintaining a food chain, drug chain, product authentication, etc can be examples of indirect competitions. As we are dealing with worldwide pandemics like COVID-19, we must need to take vaccines. Thus, the indirect competitors, in this case, can be taken care of.

RISKS

No business or technology is beyond risks. Blockchain is no exception. We have identified a few risks such as:

- i. Strategic Risk: Blockchain is certainly not a universal solution. Being a new technology, it may take some time to cope up with the other technologies. Thus the acceptance of blockchain over other technologies should be considered.
- **ii. Operational and Technical Risk:** Changing from one solution to another can be hard to adapt sometimes. For example, if someone in the middle of the supply chain ruins the QR code by accident, he won't be able to scan it for transactions.
- **iii.** Lack of Expertise: If a problem occurs in the system e.g. while distributing the vaccine, it should be considered that people with blockchain expertise are limited.
- iv. Reputational Risk: If an organization in the chain neglects to incorporate blockchain into its system, it might result in a poor customer experience.
- v. Smart Contract Risks: Smart contracts are self-executing agreements between the dealers being written into lines of code. Some risks in smart contracts are data confidentiality risk, consensus method risk, legal risk, risk due to mapping evidence from physical to digital, value transfer risks, etc.
- vi. Non-Cooperation Risk: If a syndicate forms in such a way that organizations would not participate in the supply chain, the system will lose control. Then the government has to find alternative organizations, which might be difficult.
- vii. Conflict Between Governing Bodies: The government may be pressured not to introduce the system since many corrupted people have their self-interests and want their self-fulfillments.

ARCHITECTURE AND GOVERNANCE

GOVERNANCE

The governance of our proposed solution is organized into 3 essential areas. Let us discuss each of these areas.

Business Network Governance

The supply chain business-specific legitimate and financial policies are governed by the business network governance structure. They include the following items:

- A network related unified charter that includes business outcomes, participants' contribution (cost and ecosystem), and their incentives. Here, every participating organization wants to pass the verification of counterfeit vaccines in order to reduce loss and save reputation.
- The proposed business model is a consortium-led ecosystem with a set of founding members. ('X' Pharmaceuticals Ltd, the government and governmental bodies), and non-founding members (Other distributors, hospitals and customers).
- Founding members can order and endorse the transaction for validation. Non-founding members can only endorse transactions.
- Business contracts (purchase orders, letters of credit, commercial invoices, and others) between buyers, suppliers, and distributors are managed by using smart contracts.
- SLAs for shared services, e.g., reporting, auditing, tracking, and tracing of vaccines, including penalties in quality of service, are coded on blockchain.
- Business operations and security standards to make sure participants' and their data's security, privacy, integrity, and execution are part of the digital supply chain network.
- Risk identification and mitigation policies are included in the proposed supply chain network.

Network Membership Governance

- Set up rules for every type of participant, the authority to invite entities to join the network, and onboarding and offboarding of new distributors, suppliers, buyers, and governmental bodies.
- The rights of access and operations to data and transactions (purchase orders, letters of credit, commercial invoices, and others) in the blockchain.
- Membership and network participation fee structures for every sort of participant and their roles.
- Management of decentralized and shared network services, including track and trace, verify and purchase order processing, and transportation.
- Penalties for not delivering services and quality as well as neglecting the charter of our proposed network.
- Communication agreements to share the right information with the right participants at the right time in the supply chain for trust and transparency.

Technology Infrastructure Governance

The technology infrastructure governance for our proposed network includes all the rules and regulations listed below:

- Private blockchain technology i.e. Hyperledger Fabric assessment, selection, and deployment.
- Setting up blockchain nodes (a system with a copy of the distributed ledger connected to the network).
- System management, test, and deployment of chaincodes of Hyperledger Fabric (decentralized applications) for network services and Infrastructure operations i.e. server, storage, and network.
- Security and access of nodes as well as shared services chaincodes. For example, a distributor in the middle will only have access to see transactions that are relevant to him.
- Independent execution of incentives, penalties for quality assurance, risk management & infrastructure service.
- Scalability, capacity, monitoring, incidence, and performance management policies of the network.

- The management of change, upgrade, and release of the technology.
- The management of high availability, disaster recovery, and project continuity using strong architecture.
- Perform technology adoption and risk assessment, which requires keeping up with technology evolution. We propose to use Hyperledger Fabric v2.2 which is a part of the long-term support (LTS) release of Fabric v2.x.

ASSET TOKENIZATION

Asset Tokenization refers to a process of converting real assets into digital assets on blockchain that enables fractional ownership of assets [8]. In our proposed solution, the vaccines can be referred to as assets. Let's assume that an organization in the supply chain holds a certain amount of vaccines at a certain time. There may be multiple investors in the organization. So, we split the vaccines into smaller assets, let an investor take some assets, tokenize them and build its digital representation on the blockchain. These tokenized assets i.e., vaccines are managed by smart contracts that enable the purchase and sale of the digital version of the vaccines in a way that protects the ownership of every investor.

First, we need to decide if we want to use a *fungible (every asset is identical)* or a *non-fungible (every asset is unique)* token for this task. We propose to use fungible tokens because all the vaccines carry the same value. Moreover, it's easy to manage, and the implementation in the blockchain is straightforward.



Fig: Asset tokenization of vaccines in the supply chain

ARCHITECTURE

In our proposed system, the architecture can be shown as the following where the suppliers and distributors can trace the product's information at any time within the network:

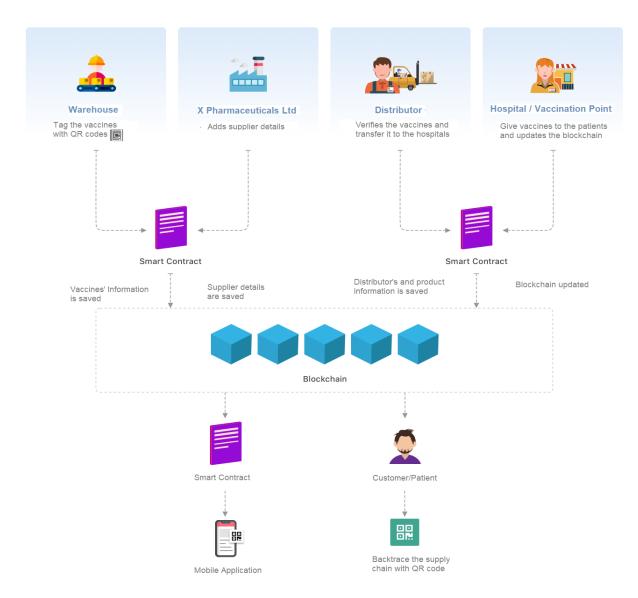


Fig: A transparent supply chain to prevent counterfeit vaccines.

We propose to use Hyperledger Fabric as the private blockchain. Here is why:

- i. Every organization and member is known in the chain [9].
- i. Scalability, trustworthiness, and performance are present.
- ii. Users can query over an immutable distributed ledger.
- iii. Strong and secure architecture with the protection of private data.

Let's look at the diagram below:

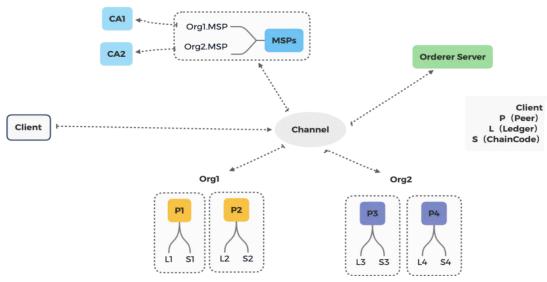


Fig: A runtime architecture of the Hyperledger Fabric

VALUATION AND DISTRIBUTION

In Bangladesh, a total of 1,952,506 Cases and 29,127 Deaths were counted till April 23, 2022 [4] due to coronavirus. According to the SANEM, Bangladesh's poverty rate may double to 40.9% from that prior to the onset of the pandemic [12]. As soon as we solve this problem, the country's economy will be saved and people won't die every day either because of pandemics like COVID-19 or poverty.

The officials of the Bangladesh Pharmaceutical Industry Association stated that the annual sales of counterfeit or substandard drugs in the country are over Tk 1,500 crore which is 20% of the total sales [1]. So, proper distribution of vaccines, the featured drug, can save both lives and money. Moreover, the idea and technology can be used in other vaccination fields besides COVID-19 which can save money in the future.

Uniqueness of the System

- The implementation of unclonable QR code that cannot be physically copied [10].
- Maintaining a cold chain i.e. temperature-controlled supply chain.
- It can also be used in varieties of vaccination programs other than COVID-19.

CONCLUSIONS AND FUTURE WORK

As this paper is being written, we don't know how many people are dying across the country due to the current pandemic. To prevent future devastating conditions, COVID-19 showed us that having a model with our proposed solution of distributing vaccines securely at hand can have a promising impact to shorten the duration of the pandemic. Our future scope as project expansion is to implement the system in other countries as well. **The GitHub repository link of this project:** https://github.com/Risvy/VSN-A-Hyperledger-Fabric-Project

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APPENDIX

1. Registration: A user can create an account by providing necessary information e.g., name, email address, role about him/her, or the organization he/she is representing. The important point is users need to choose their role to complete the registration.

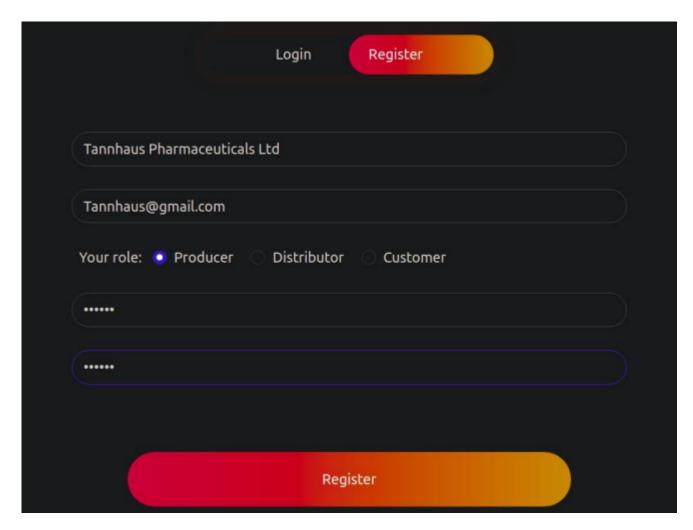


Fig A.1: Registration

- 2. Login: A registered user can log into the system by providing an email, password, and role.
- 3. Adding Information about a vaccine: Only a registered user whose role is producer can add vaccine information. Say, we tag a vaccine with the number: 10021.

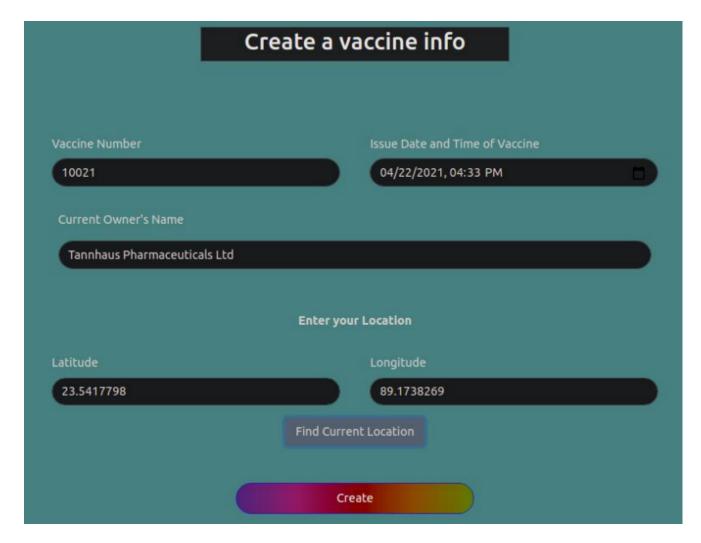


Fig A.2: Vaccine Creation

4. Generating a QR code: A QR code containing the vaccine number will be automatically generated after the vaccine information is added.

The QR code for this vaccine has been generated.



Fig A.3: Generated QR Code

5. Changing Ownership: A registered user whose role is distributor or producer can change ownership of a vaccine. However, A user cannot change ownership of a vaccine that doesn't belong to him/her.

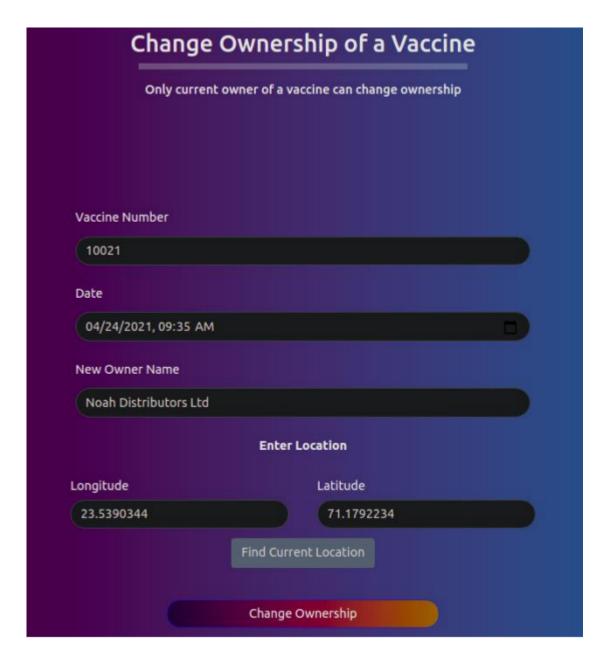


Fig A.4: Change Ownership

6. Scanning QR code: A registered user can upload a QR image to know the QR code content which is the vaccine number.

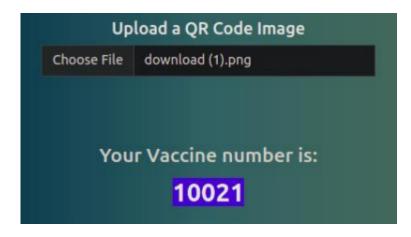


Fig A.5: Scanning QR Code

7. **Searching the detailed info:** A registered user can search the detailed information about a vaccine after giving the vaccine number. Then the system will show him the full supply chain of that vaccine.



Fig A.6: Timeline

A Full sample supply chain timeline for distributing the COVID-19 vaccine in Bangladesh

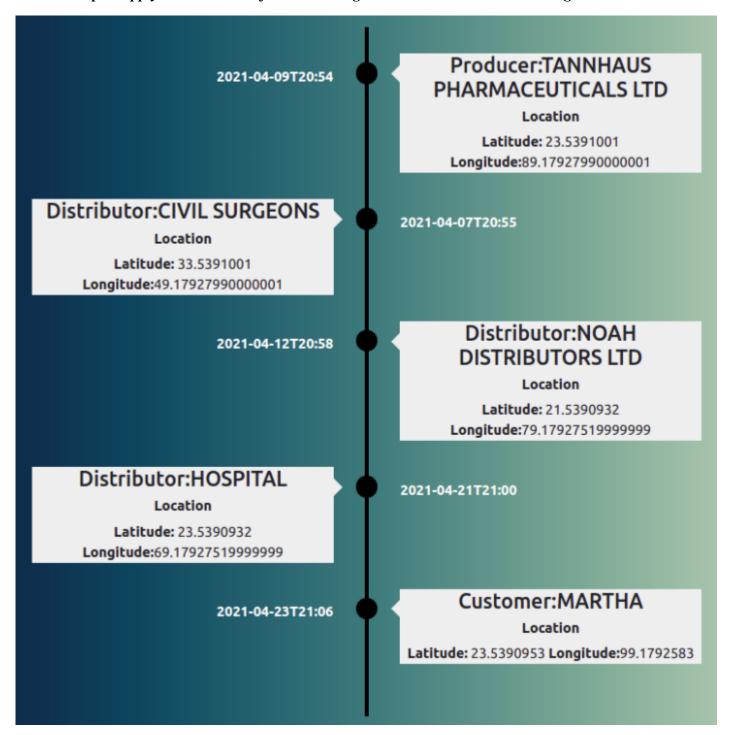


Fig A.6: A Sample COVID-19 Vaccine Supply Chain Timeline