



UNIVERSITY OF NAIROBI

Department of Computing and Informatics

**USE OF BLOCKCHAIN TECHNOLOGY IN VACCINE
DISTRIBUTION TO ENHANCE VACCINE SAFETY IN KENYA**

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DECLARATION

I declare that this research project is my original work and has not been presented in this University or any other for assessment.


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This research project has been submitted for examination for the award of Master of Science in Distributed Computing Technology with my approval as the University Supervisor.

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ABSTRACT

Recent history has seen COVID-19 emerge as one of the deadliest communicable diseases. Following its high levels of severity, inaction, and spread, the World Health Organization, WHO, declared the disease a global pandemic and called on nations to take action to contain the virus.

The world response to COVID-19 pandemic through development of vaccines has been tremendous having developed two vaccines with an efficacy rate of more than 90% in few months. One of the main hinderances to fighting a pandemic is the use of counterfeit vaccines. The biggest challenges identified in vaccine distribution is how the vaccines will get to every living person while maintaining their safety and efficiency and how to prove that the vaccines delivered for injection are authentic.

Therefore, the aim of this research was to explore how the different factors to be considered to ensure the effectiveness of the vaccines and safety to the public is upheld. It also aimed at finding out how to control counterfeit vaccines from entering the vaccine supply chain.

This research finds that the use of immutability and proof of origin features of Blockchain technology greatly enhances traceability of the vaccines within the supply chain. It is imperative that the granular information collected at the various stages of the vaccine supply chain should be intuitive and accessible to all parties and be used to measure the safety of the vaccines.

Key words: Distributed Ledger Technology, Blockchain, Supply Chain, COVID-19

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List of abbreviations

ICT – Information Communication and Technology

HIPAA – Health Insurance Portability and Accountability Act

DSCSA - The Drug Supply Chain Security Act

WHO - World Health Organization

EPI- Expanded Programme of Immunisation

GAVI - Global Alliance for Vaccination and Immunisation

GPS - Global Positioning System

CPU - Central Processing Unit

RDBMS - Relational Database Management System

API - Application Programming Interface

JSON – JavaScript Object Notation

HTTP - HyperText Transfer Protocol

IoT - Internet of Things

CI/CD – Continuous Integration/Continuous Delivery

Chapter 1 Introduction

1.1 Background

1.1.1 Blockchain technology

Blockchain is a distributed ledger technology and the most disruptive technology in Information Communication and Technology (ICT) that helps store a specific and verifiable record of every single transaction that has ever been made. Blockchain is cryptographically secure, immutable, and updateable only via a consensus among the participating nodes (Bashir, 2017).

Blockchain was first introduced in 2008 by Satoshi Nakamoto, through concept of Bitcoin cryptocurrency (Nakamoto, 2008). He acknowledged using a digital signature to provide a secure peer-to-peer transaction but challenged its double-spending problem since it still required a trusted third party.

Before Blockchain, the Central Bank acted as the regulator for financial transactions. The adoption of Blockchain allowed these transactions through an untrusted network of nodes (Mirabelli & Solina, 2020). Blockchain technology was later adopted in other sectors such as: healthcare, government among many others.

Reliability, transparency, and immutability are the main properties of Blockchain technology, and these have defined its success. (Mirabelli & Solina, 2020).

There has been a lot of literature and proposals on Blockchain but minimal applications in the actual context (Mirabelli & Solina, 2020). Recent studies also show that Blockchain is still in its early stages and has not been adopted in some sectors.

1.1.2 Hyperledger Fabric and Ethereum

Hyperledger fabric and Ethereum are the leading blockchain platforms. The two platforms have different visions regarding use cases and applications.

Hyperledger fabric is a modular blockchain framework and an effective standard for enterprise blockchain platforms by the Linux Foundations. It is intended as a foundation for developing enterprise-grade applications. It uses plug-and-play components, which makes it suitable for multiple use cases. (Androulaki, et al., 2018).

Hyperledger Fabric has advanced privacy controls. It only allows approved data to be shared among the permissioned network nodes. It uses smart contracts, shared among the nodes, to document the business processes to be automated with self-executing terms between the parties written into lines of code. The transactions within the Hyperledger fabric are trackable and irreversible therefore, creating trust between organisations. In return, companies can make informed decisions quicker, thereby saving time, reducing costs and risks. (Androulaki, et al., 2018).

Ethereum is a public or permissionless, blockchain-based distributed computing platform and operating system.

Due to the sensitivity of data in the vaccine supply chain, Ethereum, a permissionless platform does not qualify for this use case.

1.1.3 Contribution of vaccination to global health

Vaccination has significantly impacted global health by eradicating various infectious diseases, including smallpox and rinderpest.

Creation of the World Health Organization (WHO), the Global Alliance for Vaccination and Immunisation (GAVI), and the Expanded Programme of Immunisation (EPI) saw a dramatic

enhancement of worldwide handling of vaccination against many childhood infectious diseases. A disease like measles has been successfully controlled, while Polio has almost been eradicated. Despite the success in dealing with contagious diseases, infections like pneumonia and diarrhoea claim an average of 6.6 million children yearly. At least half of these deaths could be prevented by vaccination (Greenwood, 2014).

Since 1984, there have been no indigenous cases of Polio in Kenya, and in 2005, Kenya was certified Polio free. However, the vaccine has still been administered in Kenya since countries still report polio cases.

1.1.4 Vaccine efficacy

Vaccines help the body remember a microorganism to fight it off when the need arises. They are vital in controlling the spread of diseases but do not guarantee complete protection as they are not foolproof (Mandal, 2021). Double-blind clinical trials best measure vaccine efficacy. It prevents the participants and researchers from knowing the treatment until the clinical trial is over.

Knowing the efficacy level of a vaccine means it has been tried in stern clinical conditions. However, vaccine efficacy does not equal vaccine effectiveness.

According to (Mandal, 2021), vaccine efficacy can be expressed as follows:

$$\text{Efficacy} = ((\text{ARU}-\text{ARV})/\text{ARU}) \times 100.$$

Where

ARU – Attack Rate between the Unvaccinated

ARV - Attack Rate between the Vaccinated

1.1.5 Vaccine effectiveness

Vaccine effectiveness is the realistic view of vaccine performance. It measures the overall benefits vis a vis adverse effects of a vaccination program. A vaccine might prove efficacious but be less effective.

Vaccine effectiveness is mainly affected by how well target groups in the population are immunised, difficulties in storing, administering, cost, accessibility, availability, stability, and manufacturing (Mandal, 2021).

Vaccine effectiveness can be expressed as follows:

$$\text{Effectiveness} = (1 - \text{OR}) \times 100$$

1.1.6 The COVID-19 epidemic

An outbreak of the novel coronavirus SARS-CoV-2 originating from the Republic of China spread to many other countries prompting the World Health Organization (WHO) Emergency Committee to declare it a global pandemic on January 30 2020 (Velavan & Meyer, 2020).

At the time of this research, there was roughly 4.3 million confirmed cases of infection and about 300,000 deaths. The virus caused fear for a global economic crisis and depression. Social distancing, self-isolation, and travel restrictions are the main ways of naturally controlling the virus from spreading, leading to a reduced workforce across all economies. It also led to schools closing and decreased need for supplies and manufactured goods. The food sector was not spared either. There was an increase in demand for food supplies due to panic buying and stockpiling (Manjula Bai, 2020).

The pandemic prompted scientists to design anti-SARS-CoV-2 vaccines. Over 150 official vaccine projects had been launched by December 2020, with at least 50 of them being at the human experimentation stage and a few of them having been administered to the public.

As of March 21 2021, WHO had announced three primary vaccines; Pfizer COVID-19 vaccine (BNT162b2) and two versions of AstraZeneca/Oxford COVID-19 manufactured by the Serum Institute of India and SKBio and Ad26.COV2.S by Johnson & Johnson (WHO, 2021).

1.2 Problem statement

The development of the various vaccines at a pandemic speed raises questions on their effectiveness in controlling the spread of COVID-19 and their future side effects. The vaccines have different conditions that should be met to be effective.

For example, the Moderna vaccine requires a temperature of -20°C for long-term freezing. It can also be stored up to one month in a regular refrigerator with temperatures between $2-8^{\circ}\text{C}$ (Moderna, 2020). In contrast, Pfizer's vaccine can be kept up to 5 days under standard refrigeration but will require a much colder environment of up to -70°C for long-term freezing (Businesswire, 2020). However, for the vaccines to maintain their efficacy, it is critical to store them properly.

A press statement by the Kenya's cabinet secretary for health, Mutahi Kagwe, warned Kenyans that some could be paying for water instead of the COVID-19 vaccine. The message raised concerns regarding the authenticity of the vaccines being distributed in the country.

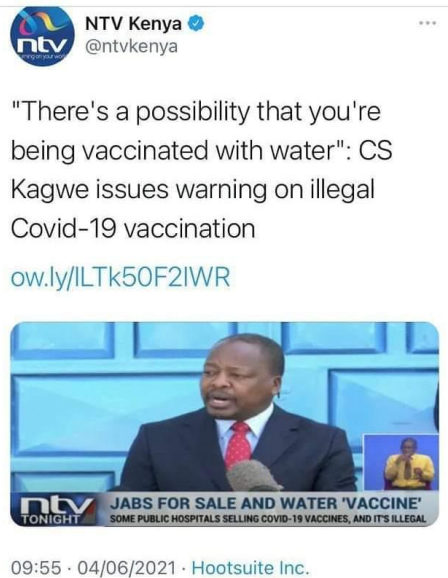


Figure 1: NTV Kenya’s tweet with a warning from Kenya’s Cabinet Secretary of Health, Hon. Mutagi Kagwe’s.

In a press release by a Kenyan free newspaper, People Daily, dated September 9 2021, quacks masquerading as Kenyatta National Hospital Medics charged as much as KSh. 3,500 for administering fake jabs assumed to be from Johnson & Johnson. According to a statement presented to the Milimani Law court in Nairobi, the exercise took place on various dates between July and August 2021. The victims reported the matter to the police after realising their names did not appear in the list of vaccinated people in the ministry of health records. At the time of the reporting, it was still unclear how many fake doses were distributed and how many members of the public were affected.



Figure 2: A screenshot from a Kenyan newspaper, People Daily, reporting fake J&J COVID-19 vaccines.

It was even worse in Uganda. Experts confirmed that more than 800 people from several companies in the Kampala area had received water for the COVID-19 vaccine between May 15, 2021, and June 17, 2021 (Monitor, 2021).

This research focuses on how blockchain can be used in vaccine distribution to ensure vaccine transparency and effectiveness as the vaccines move from inception to injection.

1.3 Research Objectives

1.3.1 Main Objective

The core objective of this study is to address the lack of transparency in vaccine distribution by developing and implementing a blockchain-based application. This application will enable

the public to access relevant information about the vaccine and determine its effectiveness before it is administered.

1.3.2 Specific Objectives

The specific objectives of the research are:

1. To establish how to provide consistent data on vaccine distribution using blockchain technology.
2. To develop a blockchain-based system whose features support the provision of authenticity and safety in vaccine distribution in Kenya.
3. To measure how effective a blockchain-based system is compared to the current manual system.

1.4 Research Questions

1. How can blockchain technology impact vaccine distribution in Kenya?
2. What is the impact of creating a blockchain-based application for vaccine distribution?
3. How will the platform be tested?

1.5 Justification

The world response to the COVID-19 pandemic through the development of vaccines has been tremendous, having developed two vaccines with an efficacy rate of more than 90% in a few months. The use of counterfeit vaccines would also hinder the efforts to fight the pandemic. One of the biggest challenges identified is how these vaccines will get to every living person and maintain their safety and efficiency. The other challenge is how to verify that the vaccine is not fake.

Among the factors that affect the effectiveness of vaccines are how they are handled and stored, how they are administered, the target groups, accessibility, stability, and manufacturing. There is, therefore, a need to monitor these factors during the distribution of the vaccines.

Blockchain technology can be vital in monitoring the vaccines during distribution. The data will be collected at various stages and saved in a distributed immutable ledger, thus ensuring only the vaccines that meet the required conditions are released for administration to the public.

1.6 Scope

The scope of this study is limited to vaccine distribution in Kenya, and the challenges faced that overall affects the effectiveness of the vaccines. The study involves understanding the challenges regarding traceability, transparency, and effectiveness that vaccines distribution faces and developing a Blockchain-based platform to solve the identified challenges.

1.7 Limitation

Various countries including Kenya had imposed travel restrictions to control COVID-19 from spreading. Therefore, this research focussed on Kenya and the data that was available in Kenya.

Chapter 2 Literature Review

In this section, the research dives into literature about the technology that the pharmaceutical industry has adopted and how these technologies affect the supply chain. It also explores the interests posed by Blockchain technology and how the features it provides can provide authenticity and safety of vaccines within the supply chain.

2.1 Introduction

The Healthcare sector has various problems that can be solved using blockchain properties; immutability, fraud avoidance, and data sharing capability between organisations without trust (Bell, et al., 2018). Hospitals can use blockchain technology to trace their assets. The collected information can improve patient safety and overall efficiency.

The pharmaceutical industry can use blockchain to control counterfeit and unapproved drugs from entering the supply chain. Smart contracts can be defined for drugs, packed in pill containers that can be integrated with the Global Positioning System (GPS) to log chain-of-custody, thus allowing frictionless recall of such medicines as they can easily be tracked within the supply chain.

Blockchain can be used within clinical trials to eliminate fraudulent results and malicious deletion of data, thus enforcing integrity. Blockchain can also store unchangeable logs of subject consent on tests. By defining a chain-of-custody in the pharmaceutical industry, the industry is expected to save up to \$200 billion (Bell, et al., 2018).

Many areas within health insurance can also benefit through blockchain technology by keeping a trusted record of events for their patients. These areas include automating underwriting activities, improved reporting, definition, and enacting contracts (Bell, et al., 2018).

2.2 Existing work

2.2.1 The MediLedger project

The MediLedger blockchain project was announced in 2017 by two conglomerates, Pfizer and Genentech. The project aimed to explore how blockchain can trace prescription medicines. The project's scope was to assess the viability of a blockchain-based solution for compliance with The Drug Supply Chain Security Act (DSCSA).

MediLedger leverages the immutability property of blockchain to create an audit trail model that shows the manufacturer of a drug and the change-of-hands from inception to the patients, thus preventing fraud and theft of pharmaceuticals (Bell, et al., 2018).

The main goal of the MediLedger was to prevent counterfeit medical products from entering the supply chain. According to (Bagozzi & Lindmeier, 2017), an estimated 10 percent of the medical products circulating in medium and low-income countries are substandard. These products have a tragic impact on patients and their family members and threaten antimicrobial resistance, thus making medicines less effective.

Emphasising interoperability between healthcare providers, MediLedger has enabled health providers to meet the healthcare standards of the pharmaceutical supply.

2.2.2 Blockpharma

Blockpharma is another blockchain based solution developed to deal with counterfeiting and traceability issues of vaccines. It allows consumers to quickly verify the authenticity of the packaging of any drug before purchasing. This information is relevant to patients in determining whether the drug they are purchasing is falsified or not. Blockpharma also used machine learning to improve the recognition of counterfeit medicines (Blockpharma, 2016). Blockpharma has managed to weed out the 15% of all fake drugs in the world (Daley, 2019).

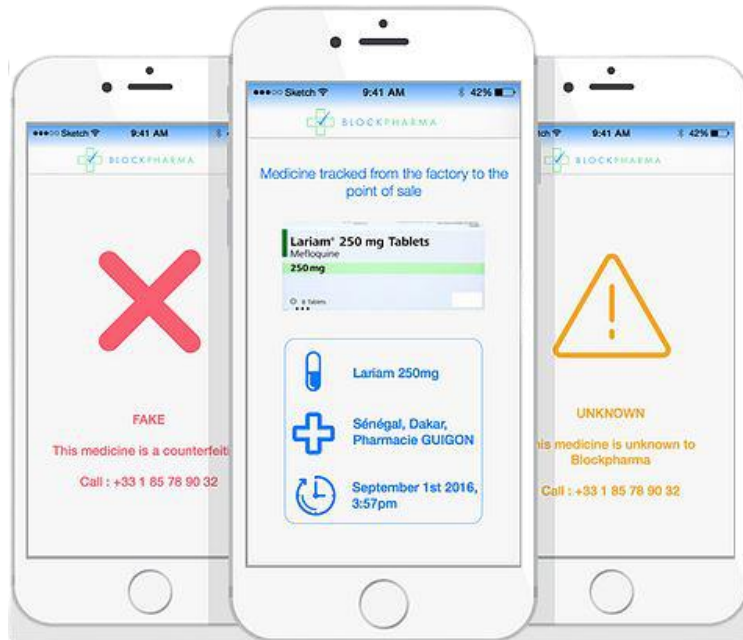


Figure 3: Blockpharma application showing the authenticity status of drugs

Source: (Blockpharma, 2016).

2.2.3 Tierion

Tierion used blockchain technology to audit records, documents, and medicines to keep a clear audit trail. It uses blockchain credentials and timestamps to uphold proof of origin in a medical distribution. Tierion also proposed a multi-network coin to improve the versatility of Bitcoin and its application in medical distribution (Daley, 2019).

2.2.4 IBM digital health pass

A computer hardware company, IBM, is one of the technology companies that put efforts during the COVID-19 pandemic period to offer a solution to ensure the trust of vaccines from inception to injection. In an article published by (IBM, 2021), 77% of U.S. citizens are cautious of the safety and efficacy of vaccines. A whole-of-government tactic is critical to increasing speed, transparency, and accountability across the vaccine distribution system. IBM developed a network for vaccine distribution aimed at helping manufacturers to monitor adverse events proactively and manage to recall vaccines where need be. Distributors using the system can get

real-time visibility of the vaccines and better respond to issues in the supply chain. Vaccine dispensers can also use the application to manage their inventory and monitor their safety, thus boosting the confidence level of vaccines among citizens.

2.2.5 Embleema

Embleema is a health records blockchain, founded by Robert Chu, which gives patients complete control over their health data. Embleema connects key stakeholders in the healthcare industry securely. It provides for the secure sharing of patients' data and puts them at the forefront of the healthcare system (Sturman, 2020).

According to an interview by Healthcare Global, (Sturman, 2020), the founder and CEO of Embleema pointed out the major benefits that blockchain technology has to the healthcare sector to be:

1. A ledger of where to find a patient information
2. Smart contracts to determine who can access the patient information and under which conditions.
3. Security keys to ensure only authorised parties' access patient data under the terms provided by the patient.

The data developed by Embleema can help drive positive patient outcomes as it makes it easy and faster to monitor who received a certain drug, the efficacy level of the drugs and theory adverse effects.

2.2.6 BurstIQ

BurstIQ was developed in Colorado State in the U.S. BurstIQ leverages blockchain technology to help companies in the healthcare sector securely manage vast amounts of patients' information. BurstIQ ensures strict constancy to Health Insurance Portability and

Accountability Act (HIPAA) guidelines while storing, sharing, or licensing medical data. It generally improves how medical data is used and shared (Daley, 2019).

2.2.7 FactFactor blockchain

Factom has created a blockchain application to store health-related digital records securely. It has designed Security chips that hold patient information and keep it as private data, making it only accessible to authorised people (Daley, 2019).

2.3 Conclusion

The current works have focused on how blockchain can securely store and share information about patients, manage the distribution of vaccines, improve drug tracking and ensure immutability and transparency. However, there exists a gap in enabling the public to have access to relevant information of any vaccine prior to being administered to them.

The focus of this research is to find out how blockchain technology can be used to ensure the public can easily differentiate original vaccines from counterfeit and how to check whether they will be safe after taking a specific vaccine.

2.4 The nature of the end-product

This research seeks to create a new product that will use blockchain technology to monitor the safety of vaccines as they move from inception to injection and ensure the vaccines have an intended effect on the persons to be injected.

The developed product will be called Vaxx from the name vaccine.

2.5 Conceptual design

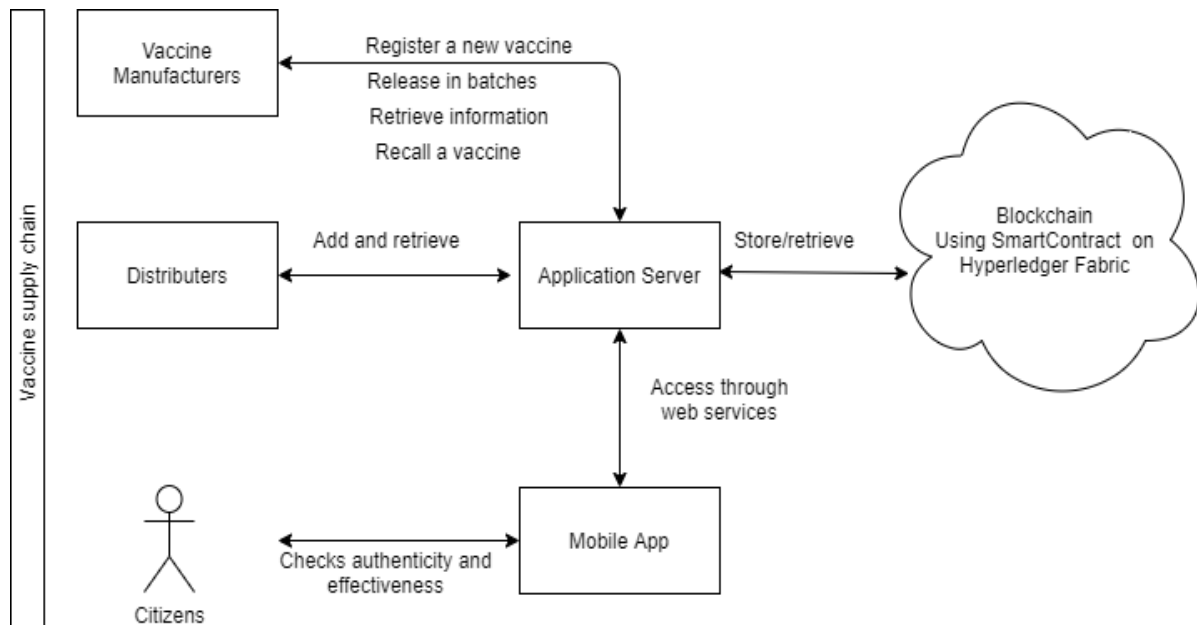


Figure 4: Blockchain-based vaccine distribution application, Vaxx

The manufacturers of the vaccines will add a new vaccine to the blockchain supply chain application and design the efficacy level obtained. The vaccines will then be packed in batches, labeled, and released to the supply chain. The other players in the supply chain will receive the vaccines and record any required information based on the vaccine. The data collected at the different supply chain stages will be verified before registering.

At the vaccine dispensing centres, the public will have access to the batch information in which the vaccine is, and they will use the identification number to authenticate the vaccine. They will also be required to key in any information that will be used to check how effective the vaccine will be on them. Vaxx will also be able to tell if a vaccine was properly handled during distribution based on the safety indicators.

Chapter 3 Methodology

3.1 Research design

This research primarily used exploratory research design and analysed examples that are insight-stimulating. This was due to lack of sufficient data on the use of blockchain technology in vaccine distribution to maintain the safety of the vaccines during distribution. The method required intense study and exploration into the area of blockchain in smart contracts and applications in other areas. It served to identify the current capabilities of blockchain technology, its benefits, and its ideal for the research.

Later, a prototype was designed, developed, and tested to evaluate whether the stated objectives were met.

3.2 Population

The population targeted for this research included the leading players of the vaccine supply chain and the citizens. The players of the vaccine supply chain include manufacturers, distributors, companies or government institutions, transport companies, vaccine dispensing centres, and dispensing officers.

GlaxoSmithKline and AstraZeneca were considered COVID-19 vaccine manufacturers. The information collected from the manufacturers was relevant to understanding the different vaccine safety metrics and how they should be maintained across the supply chain.

Vaccine dispensing centres at various levels were also considered. Large, medium and small private and public institutions were supposed to offer handling and storage information for the different vaccines. This data was useful to determine how the vaccines were handled and whether they were effective.

Vaccine dispensing officers were used to shed more light on public awareness and the behavior of the public during vaccine administration.

3.3 Sampling

This research used the probabilistic sampling technique to a large extent. A random cluster sampling technique was used to select the citizens who provided information regarding the vaccination exercise and their general knowledge of their received vaccines.

This research used both probabilistic and non-probabilistic sampling techniques. The study also had some elements of a non-probabilistic approach. It used purposive sampling to select respondents from the medical and pharmaceutical industries.

This research considered a sample size of 20 respondents.

3.4 Data collection technics

3.4.1 Document review

At the time of this research, there was a lot of helpful information available regarding COVID-19 that were very useful for this research. Healthcare data sensitivity also made document review a vital data collection technique. Various documents were collected, reviewed, and gave more information about the different data points necessary to build the project.

3.4.2 Interviews

Interviews were conducted to evaluate the guidelines provided by the manufacturers and how well they were met along the vaccine supply chain to ensure authenticity and safety were maintained. The interviewees also gave more information about the various types of vaccines and their varied guidelines to preserve their safety. It also gave more details regarding the effects of the multiple vaccines if the conditions were not met.

The research used a random sampling technique to select responders at the various stages of vaccine distribution to improve the accuracy of the responses. The respondents included the vaccine manufacturers, logistics companies used, dispensing centers, and vaccine dispensers.

The research also used semi-structured interviews to ensure enough feedback was collected. A list of pre-determined, standardised, and identical questions was prepared for every interviewee, but the order of the questions varied based on the direction of the interview. The interviewees were also allowed to share their thoughts on the system that is currently in place and how they thought that could be improved.

3.4.3 Questionnaires

Questionnaires were prepared using Google Forms to gather feedback from various professionals within the supply chain and to the public who were not available within the region due to COVID-19 safety guidelines provided by the Ministry of Health.

3.5 Ethical consideration

This research focused on healthcare information, which is deemed private and confidential, especially among the persons who receive the vaccines. Therefore, the respondents were requested to offer information that they were comfortable sharing.

Chapter 4 Results And Discussions

This chapter puts together the results from the research conducted and the steps followed to develop the prototype, Vaxx.

4.1 Research results

75% of the selected respondents shared their feedback. It can be seen that the public relied on Government directives to trust the vaccines that were administered to them. At the time of the research, companies dealing in high-risk activities like the media organised for their staff members to be vaccinated. This served as a verification to many respondents. Some respondents also used the vaccines side effect to verify the vaccines administered to them were genuine.

Below is a discussion of some of the responses from the research:

4.1.1 Should COVID-19 be administered to the public?

The question was relevant to determine whether the public had enough knowledge on the importance of taking the COVID-19 vaccine. The respondents, including those who had not been vaccinated at the time responded positively to this question. Those who had not been vaccinated, were open to the idea that the vaccine should not be forced to the public. Instead, they should take the vaccine at will. This was entirely in fear of the unknown side effects from the vaccines.

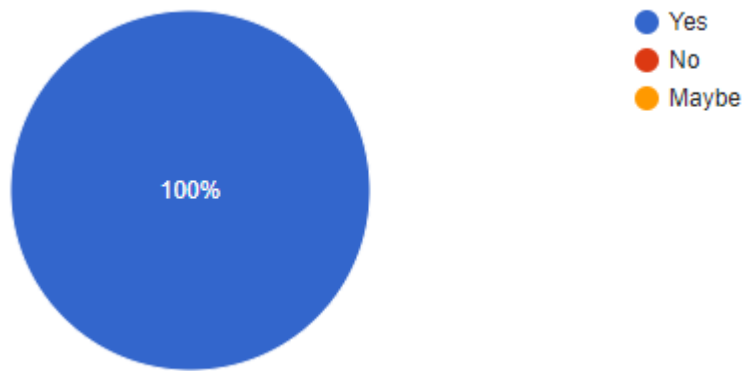


Figure 5: A graph showing responses on whether COVID-19 vaccine should be administered to every citizen

4.1.2 Vaccine safety checks before injection

Various COVID-19 vaccines had various conditions that had to be met to maintain their safety during supply chain and effectiveness on administration. All the respondents knew some of the conditions with a good percentage knowing all the conditions that needed to be met.

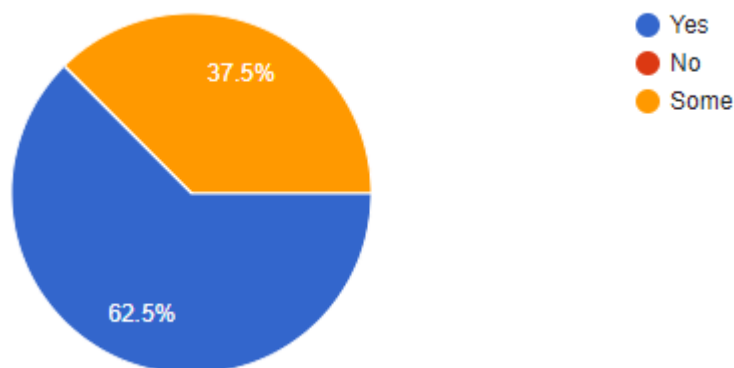


Figure 6: Pie chart showing respondents knowledge of vaccine safety.

The government of Kenya had done a good job on public sensitisation as it formed the basis of the responses shared by the respondents. Companies that offered critical services like health centres, media and food processing plants had also encouraged their members of staff to get

vaccinated. Some companies even organised for vaccinations of their members of staff through the Ministry of Health.

4.1.3 Type of vaccine taken

At the time of this research, AstraZeneca was the only vaccine that was readily available in Kenya. 100% of the responders had received AstraZeneca.

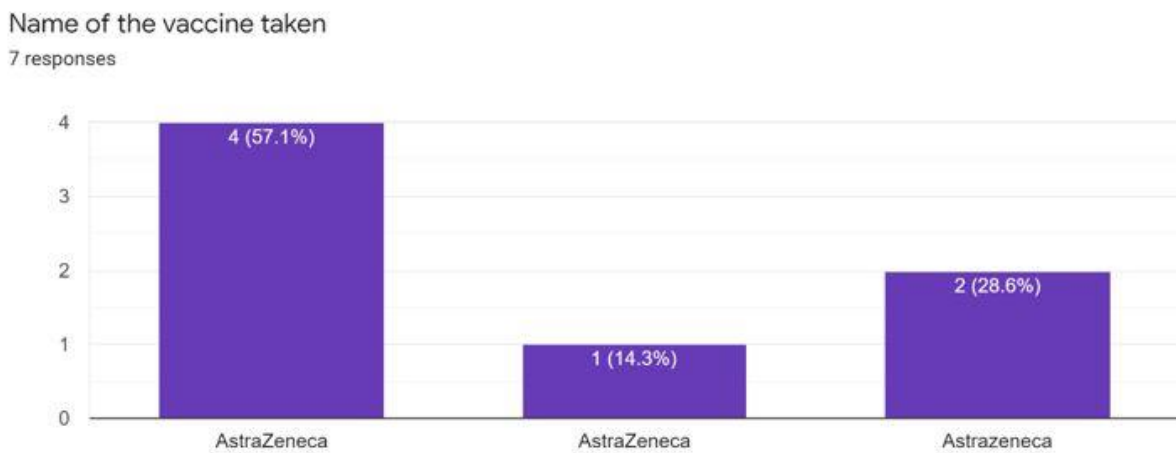


Figure 7: Bar graph showing the vaccines that the respondents had taken at the time of this research.

4.2 Discussion and interpretation of the research questions

The research conducted shows that there was a lot of information regarding COVID-19 and the different sources offered different kind of information that created mixed feelings to the public regarding its safety. A good number of the responses relied on government sensitisation and their employers to build trust of the safety of the vaccine.

There was no means to personally authenticate the vaccines that were being distributed and to validate their safety prior to the vaccine being administered to them. The responders relied on the aftereffects of the vaccine to validate them. This was however not a good way to do it

because people react differently to the different vaccines. Therefore, there was need to find a better way of verifying the vaccines before injection.

The government of Kenya had a portal, through the Ministry of Health to register every person who has taken the vaccine. The system did not however give any information to the public except a downloadable certificate indicating that the vaccine had been administered and the date on which it was administered.

4.3 Functional requirements

4.3.1 Disease registration

Vaccinations are conducted to prevent spreading of diseases or managing the effects of the disease in case of infection. Details including the name of the disease and background information will be required to be registered on the system. This will provide a validated-on-demand information portal for any registered diseases.

4.3.2 Vaccine registration

Pharmaceutical companies that create vaccines should be registered on the system with relevant details captured. Whenever they release a vaccine, the vaccine information including their name, the disease they are meant to treat, their efficacy level among others should be captured. This information should be enough and unbiased and aimed at leading the public to make better decisions.

The safety indicators of the vaccines will be a very paramount information that will be captured. For example, if a vaccine is not safe for a specific set of people, it should indicate very well. These data will be used by the public to determine the safety of the vaccines and whether it is fit for them.

4.3.3 Vaccine distribution

As vaccines move from the manufacturers to the public, they could be handled by different people or companies. This information should be captured and stored. The information will be critical to show the various steps the vaccine took before getting to the public.

During distribution, the safety indicators will be measured and in case of any violations, the vaccines should be marked unsafe.

4.3.4 Vaccine safety check

Vaccine safety checks should be done at different points when the vaccines are changing hands. The vaccines are packed in batches and at the dispensing centres, they might be in fractions of the batches. This information should be captured and should help inform the public of the safety of the vaccines during distribution and at the time of injection.

4.3.5 Vaccination

During vaccination, the details of the person receiving the vaccine should be captured and stored on the system. The information including their name and identification using government issued documents should be captured. The information will be relevant for record keeping and in case of tracing and call backs.

4.4 Non-functional requirements

- **Efficiency** – Vaxx should be able to work as expected at all times. It should take in required information, process it and give a desired outcome.
- **Reliability** – Reliability defines that the system should always be available and in a proper working condition. The system must always ensure integrity of data and have a zero or close to zero failure rate. Maintaining 99.9% uptime will be ideal.
- **Failure detection and recovery** – As a computer-based system, different failures and their consequences are anticipated. To mitigate this, an error logging and reposting

system will be put into place. For recovery, both manual and automated procedures will be used depending on the situation.

4.5 System analysis and design

4.5.1 Flow chart

4.5.1.1 Checking for vaccine safety

The flow chart below illustrated the steps used by the citizens to check for vaccine safety. The users begin by checking whether the vaccine they are about to take is authentic. They then proceed to viewing vaccine history if the vaccine is authentic. The vaccine history shows the steps the vaccines took from inception to the current storage. The user can go further to verify the safety of the vaccine by checking their conditions alongside the safety indicators provided by the vaccine manufacturer.

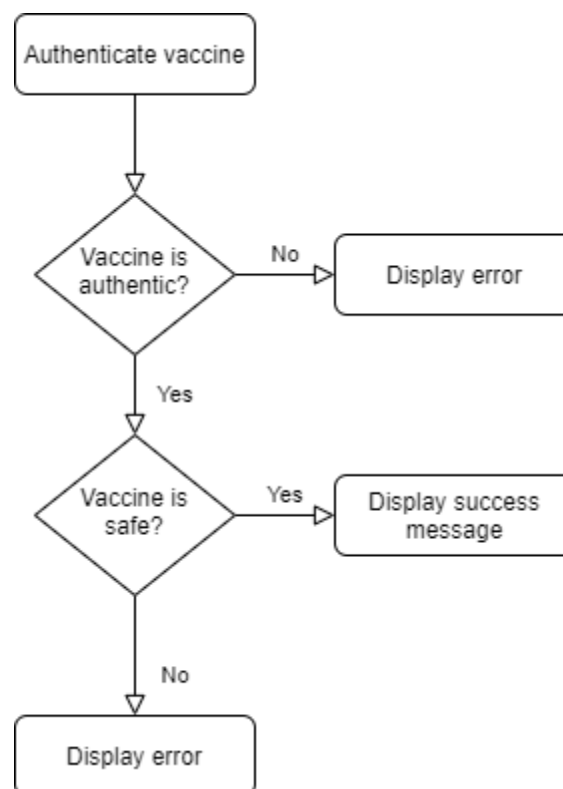


Figure 8: A flow chart diagram showing the steps used by the citizens to authenticate and verify vaccine safety.

4.5.1.2 Vaccination flow chart

Figure 9 below shows the vaccination process flow. Vaccination only happens after verifying vaccine information from the Vaxx application database and the Vaxx blockchain. The web and blockchain applications must have similar data for the vaccination to be approved.

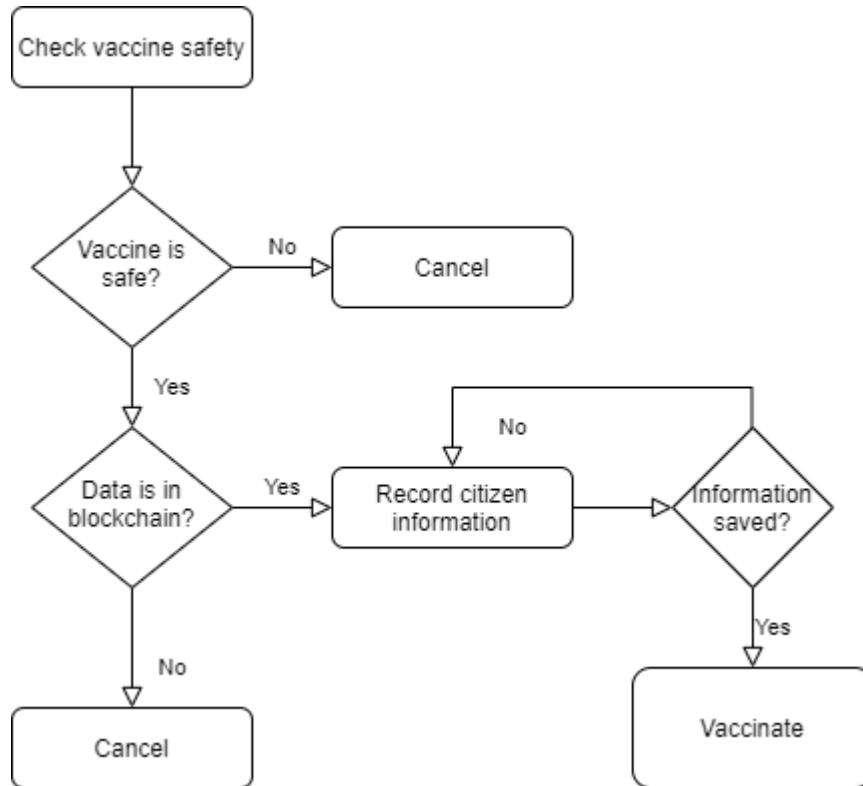


Figure 9: Vaccination process flow conducted by vaccine dispensers

4.5.2 Use case diagram

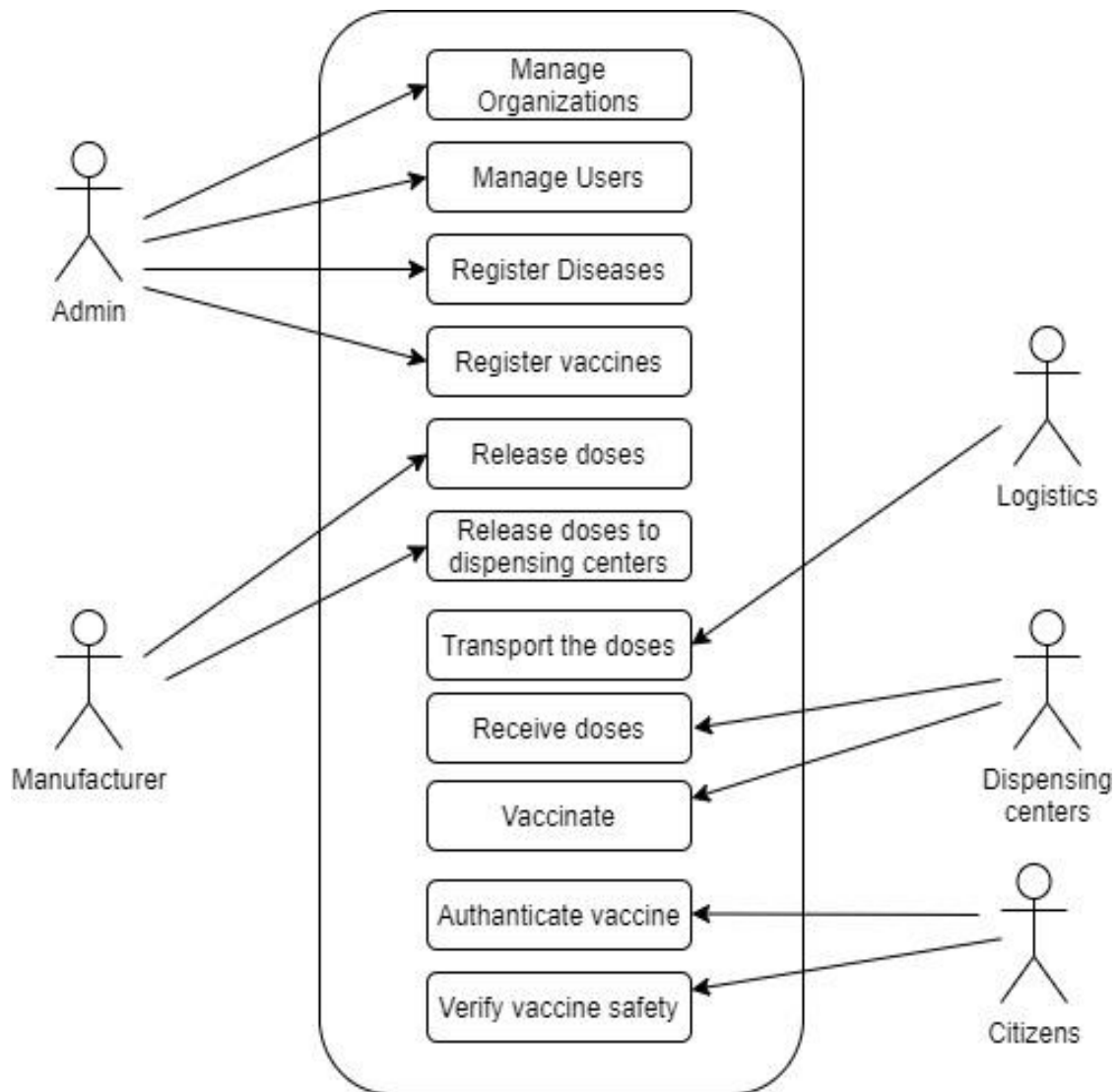


Figure 10: Interaction of various use cases in the system.

4.6 System implementation

This section gives details on how Vaxx application was developed. It shows the software and hardware resources used, the tools and the tools, programming languages and frameworks used.

4.6.1 Development methodology

The Vaxx application development utilized the DevOps software development methodology. DevOps is a software development culture that brings together the developers (DEV) and operations (OPS) teams therefore enhancing collaboration. DevOps utilizes Continuous

Integration/Continuous Delivery (CI/CD) to synchronize deployments and reduce overall time to market of the application being developed (Synopsys Editorial Team, 2017).

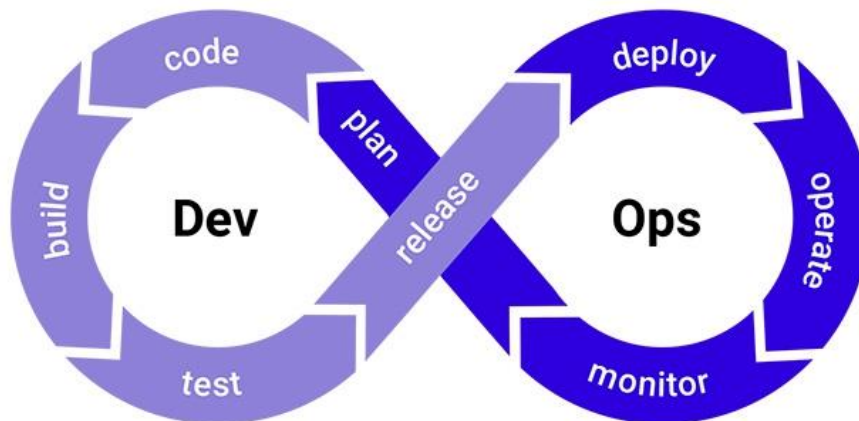


Figure 11: Steps involved in DevOps software development life cycle

Source (Synopsys Editorial Team, 2017).

4.6.2 Hardware resources

- HP Elitebook Laptop
- Processor – 2.3 GHz, 8CPUs
- RAM – 16GB
- Hard disk – 1 TB (SSD)

4.6.3 Software resources

- Android Studio
- Microsoft Visual Studio Code
- GIMP
- Apache2
- PHP
- Laravel 8
- MySQL

- Express JS

4.6.4 Implementation technology

4.6.4.1 Android Operating System

Android has an average market share of 72.78%, making it the most popular mobile operating system. This means that more people will have access to the platform making it more valuable and reliable.

4.6.4.2 PHP

PHP is the most common scripting language suitable for web application development. PHP was used to develop the Vaxx web application using Laravel 8 framework.

4.6.4.3 MySQL

MySQL is a popular database system that is open source and cross-platform. Therefore, Vaxx considered it for database management.

4.6.4.4 Node JS

Nodejs is perfect to run JavaScript based application. Since the smart contract is built in JavaScript, it was necessary to use NodeJS to expose the JSON APIs to make it possible for the system to communicate with the blockchain technology used.

4.6.4.5 Hyperledger Framework

Hyperledger fabric and Ethereum are the leading available blockchain platforms. The two platforms have different visions when it comes to use cases and applications. Hyperledger fabric is a permissioned platform while Ethereum is. Due to the sensitivity of data in the vaccine supply chain, Ethereum, being a permissionless platform does not qualify for this use case.

4.7 Data input

This section illustrates the various data variables required on different modules for Vaxx to work optimally.

4.7.1 Vaccine registration

The vaccine information collected will include name, description, the vaccines efficacy levels, and the key parameters necessary to verify their safety. This information include:

- Vaccine name
- Vaccine code name
- Summary
- Description
- Efficacy level
- Disease
- Manufacturer
- Safety indicators

4.7.2 Doses release

All doses are grouped into boxes called batches and the batches are coded. The doses information required include:

- Batch number
- Number of doses
- Date of manufacturing
- Date of expiry
- Vaccine
- Safety status

4.7.3 Citizen information

The information collected about the citizens will include their bio data and contact information. The fields include:

- First name
- Last name
- ID number
- Phone number
- Date of Birth
- Gender

4.8 Architecture

A client-server architecture was used in development of the prototype. The client can access the system using their computers or laptops depending on the tasks that they are undertaking on the system. The clients and the server communication are done through HTTP requests. At the server side, the system has a MySQL database that stores all data moving through the system and a blockchain that saves all store related changes.

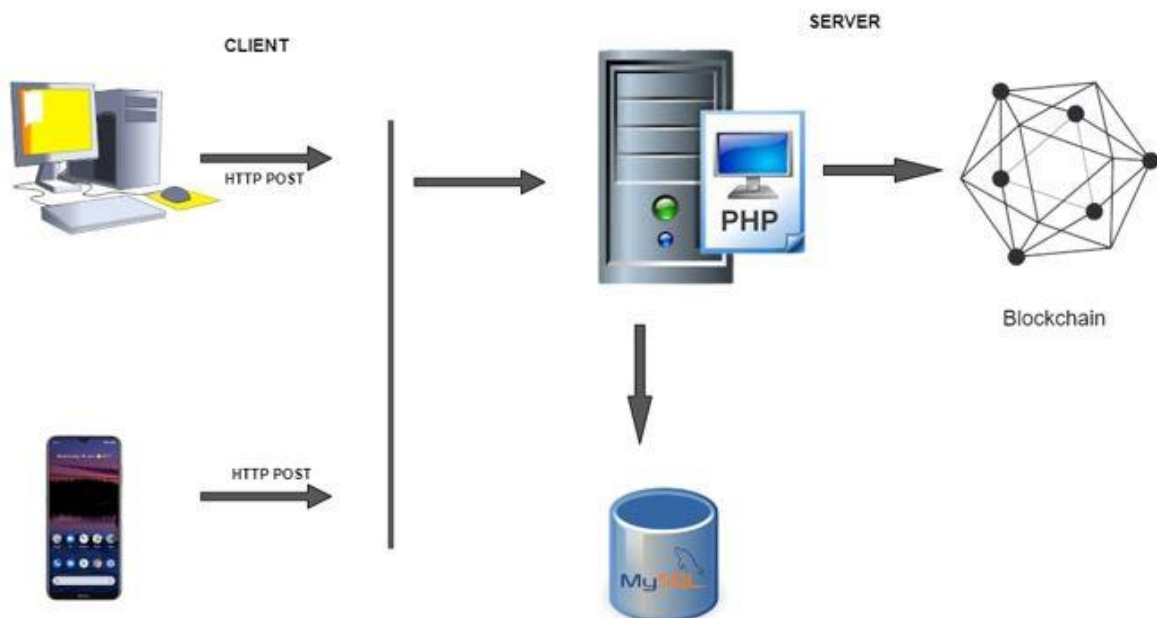


Figure 12: System architectural diagram

4.9 System testing

System testing was vital to find out whether the system complied to the requirements specified above. The system was tested under the following scenarios.

4.9.1 Unit testing

The software development methodology required segmenting the system into modules, developing the modules, and finally testing them to ensure they meet the set requirements. Additionally, input validations were done to ensure data collected at different points was valid.

4.9.2 Integration testing

The main integration modules included Hyperledger fabric running on docker, node modules for Service Oriented Architecture and mobile application integration using JSON APIs. These integrations were tested before, during and after each module was integrated to ensure the system flow works as expected from onboarding vaccines to vaccine injection.

4.9.3 Acceptance testing

A beta testing of the Vaxx application was carried out on a set of users. Some users posed as manufacturers, some as logistics companies administrators, some as vaccine dispensing officers in two dispensing centres and some as the public, who were getting injected the released vaccines. Whenever there was a mismatch of information between the data in the system and that in the blockchain, the system would block the batches from being administered to the public.

One manufacturer, one vaccine, two vaccine batches, one logistics company, two dispensing centres and 10 citizens were considered during this test.

The citizens were set to have varied conditions that were identified as key indicators of vaccine safety.

4.9.4 Test cases

4.9.4.1 Web application test cases

Table 1: Test cases for the Vaxx web application

#	Module	Test	Expected Results	Actual Result
1	Login	A registered user can login and access the dashboard while an invalid user is locked out of the system	Access the system backend	Passed
2	Organisation management	Register and update organisations and their contact persons	Ability to add a new organisation and their contact persons	Passed
3	Disease management	Register diseases for which vaccines will be released.	Register and manage disease information	Passed
4	Vaccine management	Vaccine registration and editing	Register new vaccines and manage vaccine information	Passed
5	Vaccine management	Register and update safety indicators	Ability to add new, edit and delete vaccine safety indicators	Passed
5	Vaccine batches management	Register new vaccine batches into the system	Ability to register new batches for registered vaccines.	Passed
6	Users' management	Register, edit and delete system users	Onboarding and managing users information	Passed

4.9.4.2 Mobile application test cases

Table 2: Test cases done on the Vaxx mobile application

#	Module	Test	Expected Results	Actual Result
1	Login	Login and access to Vaxx mobile app.	Access the dashboard	Passed

2	Release vaccines	Release vaccines in batches.	Ability to select the batch, enter number of doses, select the logistics company, enter the safety indicator information and release the doses to another store.	Passed
3	Receive vaccines	Receive doses in batches	Ability to see vaccines on transit, select a collection, enter safety indicator values and submit the data	Passed
4	Vaccinate	Vaccine distribution to the public	Vaccine distribution center ability to register information of the person being vaccinated and the batch from which the dose belongs to.	Passed
5	Authenticate vaccine	Public validating a vaccine	Ability to check whether a vaccine is authentic or not	Passed
6	Check vaccine safety	Check vaccine safety based on the safety indicators	Ability of a citizen to key in vaccine batch number and validate the authenticity of a vaccine.	Passed
7	Vaccine history	Check vaccine history	Ability to pull vaccine history from the system from the day they were manufactured to the point of querying.	Passed

Description

The WHO Strategic Advisory Group of Experts on Immunization (SAGE) has issued interim recommendations for use of the Oxford/AstraZeneca COVID-19 vaccine (AZD1222).

Who should be vaccinated first?

Safety Performance Indicators -----

Age Pregnancy Status HBP Diabetes Temperature Add comma separated KPIs

Please add comma separated KPI values to populate the table below

KPI	Question	Access	Type	Best Case	Min Value	Max Value
Age	What is your age?	Citizens	Number	15	15	120
Pregnancy Status	Are you currently pregnant?	Citizens	True/False	false	false	true
HBP	Do you have HBP conditions	Citizens	True/False	false	false	true
Diabetes	Have you ever been diagnosed with Di	Citizens	True/False	false	false	true
Temperature	Whats is the current storage temperatu	Supply Chain	Number	19	17	24

Close Submit

Figure 13: Image showing how the safety indicators are being captured in the system

Release Vaccine ✕

Manufacturer

Vaccine

Batch Number **Doses**

Date of Manufacturing **Expiry date**

Figure 14: Release form for vaccines in batches

Chapter 5 Conclusion and Recommendations

This chapter summarises the findings and gives recommends future research. The conclusion is drawn from the results obtained from the research questions.

5.1 Existing approaches to measuring vaccine safety before administration

The results from the literature review conducted in this project indicate that the pharmaceutical industry has faced technological improvements. There has been a lot of work that has been done to do various automations on various aspects of the industry. Areas like securely transmitting and storing information about patients have been explored in depth. The developed countries like United States of America have also automated control of counterfeit vaccines from entering the supply chain through various projects.

While the developments cannot go unnoticed, there has not been any documented efforts for the citizens to authenticate and verify the safety of vaccines before they are administered to them.

5.2 Advantages of blockchain technology in vaccine distribution

- Transparency – Data in blockchain will always be available to authenticated users.
- Proof of origin – With the history provided about the vaccines, it will be easy to establish the path a vaccine passes from inception to the point of injection.
- Control of counterfeit vaccines throughout the supply chain – Having a single point to authenticate vaccines will block the counterfeit vaccines from entering the supply chain. This will also ensure that the efforts made to control diseases is not compromised.
- Single source of data – Currently, public sensitisation is the only verifiable source if information that is available. Having a blockchain based application will ensure that the

data is always available on demand and the public will not be misled from the varied content that is published online that is false and able to cause panic.

5.3 Contributions of the study

- To nations - Ability to control the vaccine supply chain and validate vaccines before they are allowed to enter the vaccine supply chain. The system will also help eradicate counterfeit vaccines from entering the vaccine supply chain which affects the efforts to control COVID-19 among other diseases.
- To manufacturers - Elimination of unfair competition and ability to call back vaccines with ease will be an advantage to the vaccine manufacturers.
- To the public – Improved awareness will lead to improved decision making based on verified information.

5.4 Limitations

The prototype developed uses manual input from users especially for the safety variables measured during supply chain. This poses a challenge of entering wrong information therefore, compromising data integrity during distribution.

At the citizen's end, while checking vaccine safety alongside the safety KPI's provided, there is a possibility of keying in incorrect information which will impact results.

While other diseases like Ebola and Polio have been a threat for years, this research only focused on COVID-19.

5.5 Future works

Currently, the system does not perform any actions when a vaccine is found to be unsafe. It can be expanded to include operations to be done whenever a vaccine in a specific store or in transit is found not to be safe.

The system also relies on manually input of data to make decisions. IoT can be integrated into the system to provide for fetching some key data that is sensitive and highly critical in determining vaccine safety. Some of this information includes temperatures.

The data collected in the system can also be expanded to other functionalities including recalling of vaccines whenever an issue is detected during supply and direct monitoring of the citizens who have taken a specific vaccine.

The research also focused majorly on COVID-19. It will be good to see how the system can be used with other diseases and vaccines.

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6 Appendices

6.1 Figures

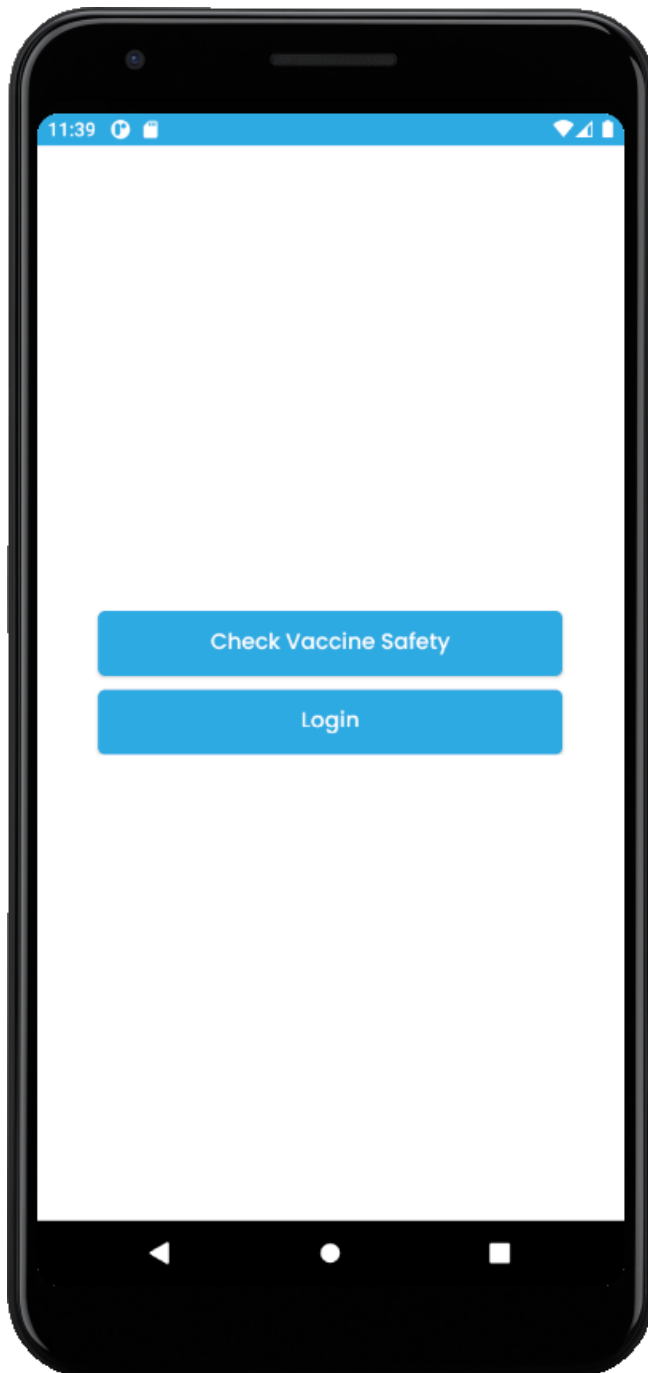


Figure 15: Vaxx mobile app homepage

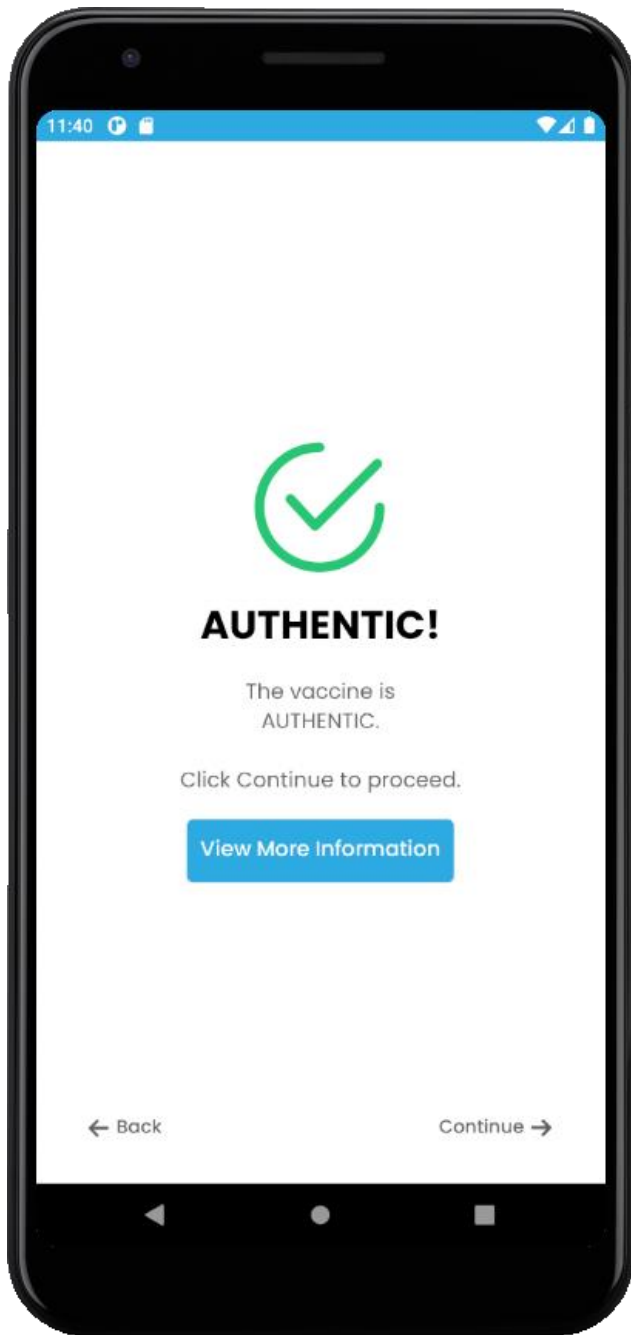


Figure 16: Figure showing a message from an authenticated vaccine

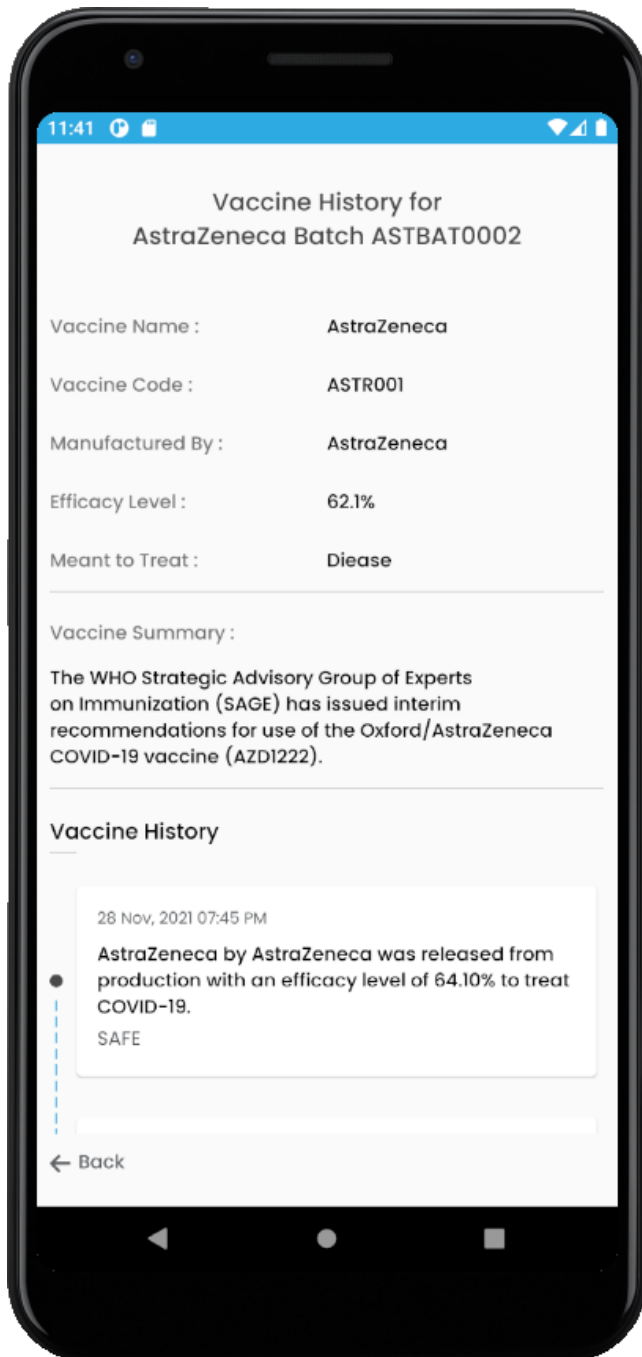


Figure 17: Figure showing a history of an AstraZeneca vaccine used a test case.

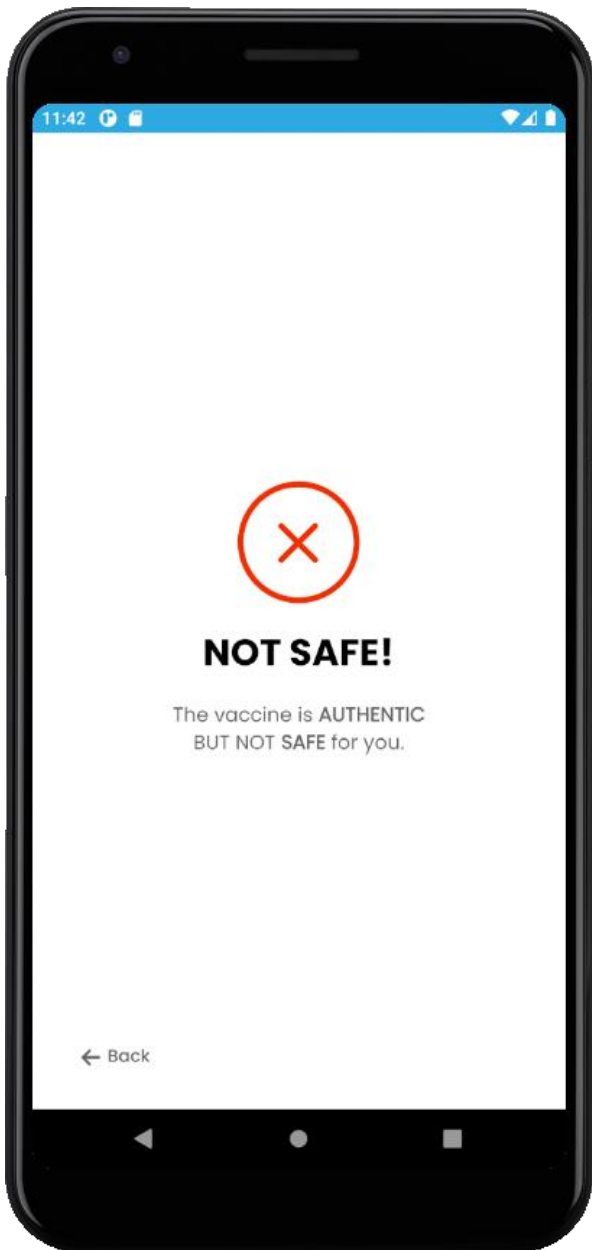


Figure 18: Image showing a message that displays when an authenticated vaccine fails safety check.

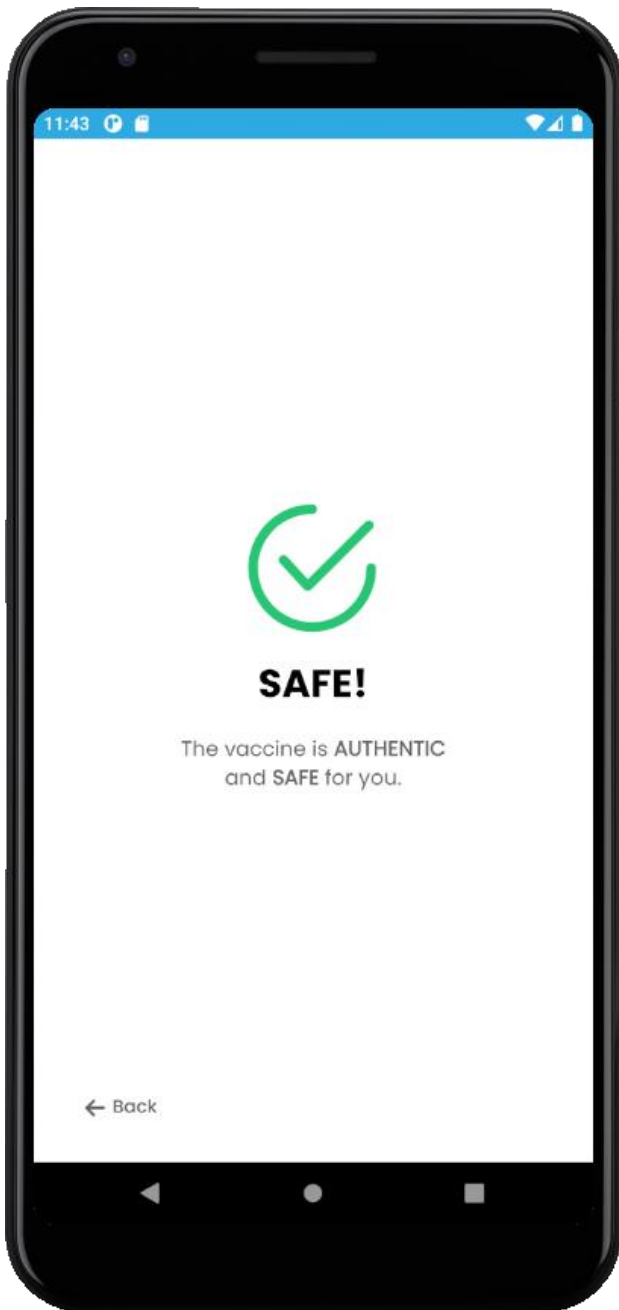


Figure 19: Vaxx app results for an authentic and safe to use vaccine conducted by a citizen.

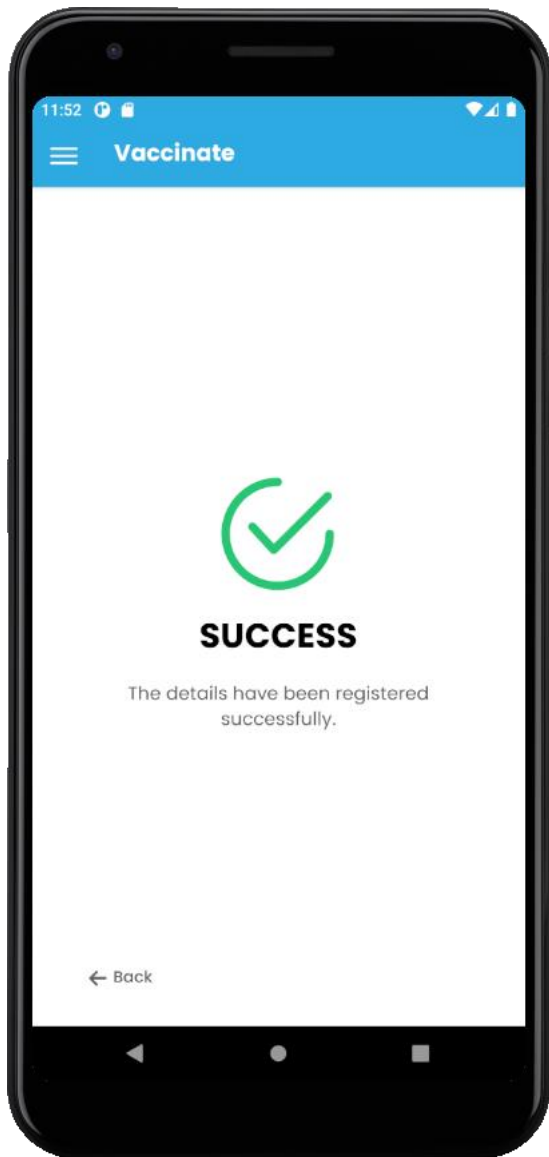


Figure 20: Image showing the success message after a dispensing officer has recorded details of a vaccinated citizen.

6.2 System sample code

Some sample code to demonstrate the Smart Contract that communicates with the Hyperledger fabric have been attached with the sample below.

6.2.1 Smart contract

The code below shows how to instantiate a Hyperledger fabric contract API, check if a vaccine store already exists before adding it to the blockchain. Figure 20 shown below displays a sample code on how to add a store to the blockchain and how to fetch a store record.

```
'use strict';

const { Contract } = require('fabric-contract-api');

class VaxxContract extends Contract {

  async storeExists(ctx, storeCode) {
    console.info('===== START : vaccineExists =====');
    const buffer = await ctx.stub.getState(storeCode);
    return (!!buffer && buffer.length > 0);
    console.info('===== END : vaccineExists =====');
  }

  async createStore(ctx, storeCode, batchNumber, organization, doses, safe) {
    console.info('===== START : createStore =====');
    const exists = await this.storeExists(ctx, storeCode);
    if (exists) {
      throw new Error(`The Store with code, ${storeCode}, already exists`);
    }
    const store = {
      storeCode, batchNumber, organization, doses, safe
    };
    const storeBuffer = Buffer.from(JSON.stringify(store));
    await ctx.stub.putState(storeCode, storeBuffer);
    return store;
    console.info('===== END : createStore =====');
  }

  async readStore(ctx, storeCode) {
    console.info('===== START : readStore =====');
    const exists = await this.storeExists(ctx, storeCode);
    if (!exists) {
      throw new Error(`The store with code, ${storeCode}, does not exist`);
    }
    const storeBuffer = await ctx.stub.getState(storeCode);
    const store = JSON.parse(storeBuffer.toString());
    return store;
    console.info('===== END : readStore =====');
  }
}
```

Figure 21: Sample code for creating a new store and reading a store record on blockchain

The smart contract uses allStores functions to fetch all the stores added to the blockchain and returns them as a JSON string. Figure 21 below shows a screenshot of allStores and vaccinate functions and from the smart contract

```
async allStores(ctx, startKey, endKey) {
  console.info('===== START : allStores =====');
  const allResults = [];
  for await (const { key, value } of ctx.stub.getStateByRange(startKey, endKey)) {
    const strValue = Buffer.from(value).toString('utf8');
    let record;
    try {
      record = JSON.parse(strValue);
    } catch (err) {
      console.log(err);
      record = strValue;
    }
    allResults.push(record);
  }
  console.info(allResults);
  return JSON.stringify(allResults);
  console.info('===== END : allStores =====');
}

async vaccinate(ctx, storeCode) {
  console.info('===== START : vaccinate =====');
  const exists = await this.storeExists(ctx, storeCode);
  if (!exists) {
    throw new Error(`The store with code, ${storeCode}, does not exist`);
  }
  const storeBuffer = await ctx.stub.getState(storeCode);
  const store = JSON.parse(storeBuffer.toString());

  let newDoses = parseInt(store.doses);
  newDoses--;
  store.doses = newDoses;

  const newStoreBuffer = Buffer.from(JSON.stringify(store));
  await ctx.stub.putState(storeCode, newStoreBuffer);
  return store;
  console.info('===== END : vaccinate =====');
}
```

Figure 22: Fetching all stores and vaccinating on the blockchain

6.2.1.1 Initializing blockchain

Communication to the smart contract is not done directly. The communications is secured using a Certificate Authority and users are created and authenticated on the client end to communicate with the smart contract. The figure below shows a function used to initialize the client application and authenticate it in order to communicate with the smart contract.

```
app.get('/initialize', async function (req, res) {
  var result = {};
  try {
    const ccpPath = path.resolve(__dirname, 'local_fabric_connection_profile.json');
    const ccp = JSON.parse(fs.readFileSync(ccpPath, 'utf8'));
    // Create a new file system based wallet for managing identities.
    const walletPath = path.join(process.cwd(), 'wallet');
    const wallet = await Wallets.newFileSystemWallet(walletPath);

    const identity = await wallet.get('appUser');
    if (!identity) {
      var result = {
        status: "00",
        stores: "Identity not found. Register App User before continuing"
      };
      res.status(200).json(result);
      return;
    }

    const gateway = new Gateway();
    await gateway.connect(ccp, { wallet, identity: 'appUser', discovery: { enabled: true, asLocalhost: true } });
    const network = await gateway.getNetwork('mychannel'); // Get the network (channel) our contract is deployed to.
    const contract = network.getContract('vaxxchain'); // Get the contract from the network.

    if (contract) {
      result = {
        status: "00",
        stores: "Contract is ready"
      };
    } else {
      result = {
        status: "01",
        stores: "Contract not found"
      };
    }

    gateway.disconnect(); //Always close the gateway
  } catch (error) {
    //console.error('Failed to evaluate transaction: ${error}');
    result = {
      status: "01",
      stores: "Contract not found"
    };
  }
  res.status(200).json(result);
});
```

6.2.2 Displaying all stores added on the blockchain

After initializing the blockchain client application, the functions can be called from the browser to return results. The function shown in the image below will fetch all stores from the blockchain application through the smart contract.

```

app.get('/api/all-stores', async function (req, res) {
  let startKey = req.query.startKey ?? "";
  let endKey = req.query.endKey ?? "";
  var result = {};
  try {
    const ccpPath = path.resolve(__dirname, 'local_fabric_connection_profile.json');
    const ccp = JSON.parse(fs.readFileSync(ccpPath, 'utf8'));
    // Create a new file system based wallet for managing identities.
    const walletPath = path.join(process.cwd(), 'wallet');
    const wallet = await Wallets.newFileSystemWallet(walletPath);

    // Check to see if we've already enrolled the user.
    const identity = await wallet.get('appUser');

    const gateway = new Gateway();
    await gateway.connect(ccp, { wallet, identity: 'appUser', discovery: { enabled: true, asLocalhost: true } });
    const network = await gateway.getNetwork('mychannel'); // Get the network (channel) our contract is deployed to.
    const contract = network.getContract('vaxxchain'); // Get the contract from the network.
    // Query transaction and return
    const batch = await contract.evaluateTransaction('allStores', startKey, endKey);
    result = {
      status: "00",
      stores: JSON.parse(batch)
    };

    gateway.disconnect(); //Always close the gateway
  } catch (error) {
    result = {
      status: "01",
      message: "Nothing found"
    };
  }
  res.status(200).json(result);
});

```

Figure 23: Function to return all registered stores on the blockchain with a start and end key showing the limits

```

1 {
2   "status": "00",
3   "stores": [
4     {
5       "batchNumber": "ASTBAT0002",
6       "doses": 0,
7       "organization": "LOGI-0001",
8       "safe": "1",
9       "storeCode": "RELA0001"
10    },
11    {
12      "batchNumber": "ASTBAT0002",
13      "doses": 0,
14      "organization": "LOGI-0001",
15      "safe": "1",
16      "storeCode": "RELA0002"
17    },
18    {
19      "batchNumber": "ASTBAT0001",
20      "doses": "1000000",
21      "organization": "ASZC-0001",
22      "safe": "1",
23      "storeCode": "STORE0001"
24    },
25    {
26      "batchNumber": "ASTBAT0002",
27      "doses": 399999,
28      "organization": "ASZC-0001",
29      "safe": "1",
30      "storeCode": "STORE0002"
31    },
32    {
33      "batchNumber": "ASTBAT0002",
34      "doses": 599999,
35      "organization": "HELT-0001",
36      "safe": "1",
37      "storeCode": "STORE0003"
38    }
39  ]
40 }

```

Figure 24: Image showing results from a query on all vaccine stores registered in the blockchain.

The image displays the status of the get request, “00” and an array of the stores in JSON format. To generate the above result, the link below was executed in the browser.

<http://domainname/api/all-stores/?startKey=0&endKey=10>

6.2.2.1 Vaccinating

When vaccination request is made through the Android application, the application invokes the api/vaccinate function shown in Figure 24 below. The function connects to the smart contract and hits the vaccinate function. The function verified the the data in the blockchain and if valid, reduces the doses by one.

```

app.get('/api/vaccinate', async function (req, res) {
  var result = {};
  try {
    const ccpPath = path.resolve(__dirname, 'local_fabric_connection_profile.json');
    const ccp = JSON.parse(fs.readFileSync(ccpPath, 'utf8'));
    // Create a new file system based wallet for managing identities.
    const walletPath = path.join(process.cwd(), 'wallet');
    const wallet = await Wallets.newFileSystemWallet(walletPath);

    // Check to see if we've already enrolled the user.
    const identity = await wallet.get('appUser');

    // Create a new gateway for connecting to our peer node.
    const gateway = new Gateway();
    await gateway.connect(ccp, { wallet, identity: 'appUser', discovery: { enabled: true, asLocalhost: true } });

    const network = await gateway.getNetwork('mychannel'); // Get the network (channel) our contract is deployed to.
    const contract = network.getContract('vaxxchain'); // Get the contract from the network.

    // Query transaction and return
    const store = await contract.submitTransaction('vaccinate', req.query.code);
    if (store) {
      result = {
        status: "00",
        store: JSON.parse(store)
      };
    } else {
      result = {
        status: "01",
        message: "An error occurred. Please try again later."
      };
    }

    gateway.disconnect(); //Always close the gateway
  } catch (error) {}
  result = {
    status: "01",
    message: "An error occurred. Please try again later."
  };
  res.status(200).json(result);
});

```

Figure 25: Client function to conduct vaccinations

6.3 Project Plan

Table 3: Research and project implementation plan

	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21
Preparation of thesis proposal						

Presentation of thesis proposal						
Data collection						
Data analysis						
Product Design						
Product Development						
Milestone 2 presentation						
Product testing						
Report writing						
Submission of thesis						
Presentation of thesis						

6.4 Budget

Table 4: Vaxx application implementation budget

Item	Description	Amount (KSh.)
Project Personnel	Data collection assistance	10,000
Administrative support	Facilitation and approvals to conduct this research.	10,000
Travel	Travelling during data collection	15,000
Tools and equipment	Laptops, data collection and data analysis tools	60,000
Miscellaneous	For emergency purposes	10,000
Total		105,000