Blockchain based mobile-patient medical records management system

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Abstract. The study outlines a blockchain-based mobile app-based patient records management system that aims to store and exchange all data in a more safe and open manner. The system was developed using Android Studio based on flutter SDK. Since flutter is a free and open-source software development kit that facilitates the creation of mobile apps that run on several platform, technological study based on flutter programming language has been chosen to be utilized for the implementation. The extendable, scalable, and adaptive nature of the language is more effective. Safekeeping and updating of medical records on paper is a major challenge. Additionally, these can be easily lost and swapped. Other existing electronic record systems lack robust security and in cases of emergencies can pose a delay. Thereby, this project proposes leveraging features of the blockchain technology by developing an easy-to-use mobile app, so that healthcare establishments can overcome the limitations identified in current systems while revolutionizing the healthcare system. To ascertain the issue's scalability, rigorous testing was carried out. The system architecture, user requirements, interface designs, necessary sequential patterns and the development process have been documented in this paper.

Keywords: DApp, Mobile-EHR, IPFS, Ethereum, Blockchain.

1 Introduction

The latest advancement in technology influences every aspect of human existence and alters the way we previously used and perceived things. As with other areas of life, the healthcare industry is benefiting from the innovations brought about by technological advancements. Improvements in security, user experience, and other areas of the healthcare industry are the primary outcomes of technological progress. Electronic health records (EHRs) and electronic medical records (EMRs) provided these advantages. They do, however, have problems with data integrity, user ownership of data, and other similar concerns. The utilization of cutting-edge technology, such as Blockchain, may be the key to solving these problems. This technology has the potential to create a safe, tamper-proof environment for keeping sensitive healthcare data such as patient records.

Medical records have been traditionally kept in a paper-based system or otherwise manually until the widespread use of electronic storage media. This paper-based system for keeping track of patients' medical histories was not only slow and prone to errors, but also lacked security, proper organization, and was easily subject to alterations. Another challenge faced was that patient's medical records could be duplicated throughout several facilities they attend. Thereby, blockchain might be seen as a public record that can be seen by anybody due to the inherent openness of the technology [1].

In recent years, the public health sector has been one of the industries that has made significant progress toward digitization. The worldwide public health system, which is still plagued by inefficiency and deficiencies, has been brought to the attention of the by public opinion, which has underlined the need for a drastic reform in the workings of the system. These vary from the outdated handling of patients' healthcare records to the frequent mismanagement of such records to the seemingly endless wait times for medical visits. The administration of medical records is gradually transitioning away from the use of paper files and toward the use of digital records that contain the same information as their paper counterparts. These digital records are made possible by advancements in technology. It typically takes between 7 and 15 working days to satisfy requests for clinical records in Mauritius, which is plainly unacceptable when dealing with something as essential and priceless as a patient's health.

After identifying these gaps in the Mauritian context, this paper discusses the proposition, design, development, and evaluation of a system that addresses the outlined issues with EHRs whilst also catering for productivity, boosting decision making, and improving efficiency of resources available.

Therefore, the central aim of this project is to boost health care worker productivity by digitizing patient health data while guaranteeing security. Furthermore, EHRs provide more complete patient information, enabling practitioners to make well-informed care decisions more quickly, aiding in treatment improvement and reducing safety issues. This approach allows for more efficient use of resources.

Although, the use of blockchain technology in the healthcare industry faces major challenges, including technical obstacles and questions pertaining to ownership. As time passes, technical challenges like slow processing speed and the need to duplicate enormous amounts of data will be conquered. However, the key impediments to the use of blockchain technology in healthcare will be ownership issues, namely public vs private. A recommendation could be the blockchain initiative that is being supported by the Estonian government. This project makes it possible for businesses to develop their own blockchain solutions and establish a whole new environment for medical innovation. Nevertheless, the existence of a public blockchain does not guarantee that information will be accessible to each and everyone.

Another significant technical challenge for blockchain's distributed ledger solutions is meeting the requirements of the existing HIPAA privacy regulations while simultaneously keeping data that has been spread over the network. The distributed ledger infrastructure has to be built in a manner that prevents it from being broken into using cryptographic techniques. Only in January 2018, 433,192 people were affected by data breaches that occurred as a result of traditional systems. These breaches may have been averted by using solutions that are based on blockchain technology.

Adopting the blockchain technology for the storage of electronic health records would offer a wide range of benefits, including enhanced health data security, efficient management of information, smooth interoperability between relevant organizations, reliability/integrity of information, and transparency. By leveraging the features of blockchain, hospitals can overcome the limitations of paper-based systems while revolutionizing the current healthcare system. The proposed technology has many desirable characteristics that will significantly enhance EHR systems, namely: interoperability through version control, security via file-level permissions, and immutability via versioning where all participants contribute to a system that is immutable and becomes growingly secure.

The paper is structured as follows, section 2 discusses some key literature in the blockchain and EHR domain. Section 3 provides a detailed outlook of the overall project design and development process. Section 4 demonstrates the application with few key screens, and section 5 ends the paper with a conclusion.

2 Relevant Literature

2.1 Background of Blockchain

A proposal published by scientists [2] in 1990, defined the term digital timestamping which today is known as the distributed ledger. Years later this model was implemented and introduced by Nakamoto [3] as blockchain which became a very popular technology. As a Distributed Ledger Technology (DLT), blockchain is often referred to as a next-generation database architecture that allows information to be accessed, recorded, and shared with several copies of the same ledger [4]. Some of the major advantages of the blockchain technology is that it is decentralized, immutable, traceable, and most importantly provides a framework to achieve transparency all while keeping the data's integrity intact. These advantages can be leveraged for a proper EHR and m-health platform which has been proposed in this paper.

The blockchain technology has the potential to define the next generation of applications and solutions. However, there are some hurdles that have been limiting its progress and widespread adoption. Despite a couple of ground-breaking research areas such as healthcare, finance, insurance, or real-estate amongst others are yet to fully expand and adopt blockchain. A blockchain's data accessibility can either be permissioned or permissionless. The permissioned blockchain is a blockchain whose security, validity, and integrity is guaranteed by a trusted third party. No centralized entity may interfere with the implementation of the consensus rules in a permissionless blockchain, therefore the security and integrity of the blockchain can be trusted to the vast majority of its independent peers. Equally important, a majority vote from the peers is needed to alter the consensus rules [5]. Gaps identified for this issue are mainly due to lack of comprehensive and developer-friendly documentation. However, recently some scalable and innovative elements such as Ganache, Polygon, or Solana have been established. These help in building a community around and consequently more robust applications.

2.2 Blockchain for EHR

Amongst other domains where blockchain stands out the health care industry might be the one with great potential. There has been a recent surge of innovation in healthcare outcomes, thanks in large part to the fervor and financial backing of the industry. Authors [6] demonstrated that there are several barriers to the adoption of blockchain, such as security and accuracy concerns. The preservation and circulation of records involves institutional rules and technological problems. Therefore, most short-term suggestions centre on raising people's consciousness, encouraging critical thinking, and garnering support. An example of this is the collaboration between the government of Estonia and the Dutch IT firm Guard Time to implement a blockchain-based patient character validation system [7].

All inhabitants have a smart card that ties a blockchain-based identification to EHR information. All DSE refreshes are hashed on the Blockchain and are recorded. This technique implies that an unchangeable review trail is included in the EHR information, and that the library is not malevolently altered. Appointment preparation, time stamping, and encrypted and signed blocks are only some of the website modifications that will be recorded in immutable history logs that will be kept in current patient files and on the hospital's website.

MedRec, a collaboration between the MIT Media Lab and Beth Israel Deaconess Medical Center, was the EHR's second implementation. This stage offers a distributed method for keeping tabs on how rights, abilities, and specifics are shared throughout Wellness frameworks [8]. Patients will be able to control who has access to their health information and make the best-informed decisions possible with the use of Blockchain technology. Whether or not the actual health data is placed on the Blockchain, these rights may be exchanged to allow for a more automated approach to knowledge sharing for clinical and research reasons. While rights for external space and accounting paths may be kept on the Blockchain, all clinical data must still be stored in EHR frameworks, which necessitates extra programming components to enable true interoperability [8]. Because of its usefulness in verifying drug concepts, the engineers working on the MedRec project are currently attempting to bring it up to date by incorporating new data sources, information providers, and end users. This proof of concept demonstrates how blockchain technology might improve scientific research and the dissemination of discoveries by facilitating the easy and trustworthy sharing of data collected over time. When used to EHRs, blockchain technology improves the security of data storage, transfer, management, access control, and confidentiality. Rapid delivery of treatment to patients and assistance in navigating the complex health care system are both made possible by interoperability of clinical insurance. Therefore, it has been determined that blockchain technology may be used to address issues with EHR deployment. However, further study is needed to validate blockchain-based EHRs properly.

3 System Design & Development

After performing a thorough literature review analyzing the existing systems and identifying gaps to be resolved, the next step was to start development of a system that addressed the problems. This section mainly discusses the design and development of the system, where gathering of the system requirements was crucial so that the development of the application could start as per the specifications.

3.1 Development Methodology

For the implementation of the proposed system, most prominent development methodologies were explored and compared such that a basis on the better method could be employed. There is no generally applicable system development approach. Additionally, this consideration was useful since a number of alternate methodologies have emerged, each with their unique benefits but also drawbacks. After the comparison, the waterfall development methodology was preferred due to its simplicity, granularity, and firsthand experience. The main stages in development entailed: requirements gathering, designing the system, scripting, testing, and deployment of the DApp, with maintenance and documentation of the process involved. The diagram below shows the main stages of a development-based project that were practiced during this project.

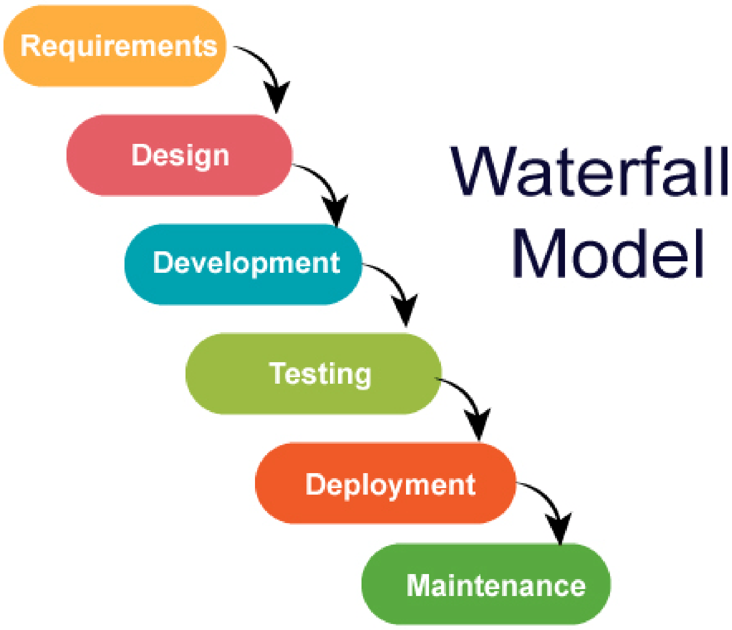

Fig. 1. Phases of the waterfall model [9]

Release Plan

A release plan plays a critical role in maintaining a structured and planned approach to development of software. Schedule and sequences of releases are outlined that define the delivery of features. The following are details of a release plan according to the waterfall model.

EHR System with Blockchain V1.0

For the first version of the system, the following features were focused on:

- Finalizing the blockchain type.
- Pick the best proceedings for development of the system.
- Creating a simple user interface.
- Login of the system.

EHR System with Blockchain V2.0

The following features were focused and delivered for the second version:

- Link the screens.
- Develop majority of the screens.
- Build test scripts and test users to vet the consensus mechanism.
- Implement the blockchain technology.
- Validations of input entries.

EHR System with Blockchain V3.0

The third version of the system released will be having all of the documented elements. Most prominent bugs found while initial testing of the app will be resolved with this release. In addition to a simplified user interface, features that change based on the user checking in will also be available. The system includes customizable features with the inclusion of blockchain technology. Moreover, imperative functionalities such as reading medical records and inputting prescriptions will be included. Finally, a separate set of unit tests will be carried out to ensure that the system is fully functional as per the standards set.

System Unit Tests

Unit testing will be employed to evaluate each functionality of the system. The tests are performed on every individual function to confirm whether it generates the required result as per the deliverables' requirements. This will be accomplished by providing input and determining whether the output produced by the system is genuine. After gathering the results, the features functioning properly will be documented and delivered as the final version of the DApp.

3.2 System Requirements

Prior to initiating the project, an initial concept encompassing the characteristics, functionalities, and behavior of the system was outlined. Moreover, before entering the development phase, it is essential to thoroughly document the system's behavior, features, and logic. Consequently, specific system requirements are collected using specialized tools, and methodologies. These requirements have a specific purpose of helping in understanding the intended performance and behavior of the technology. These are typically organized into groups such as model, service, task, or function. The comprehensive requirement tables, diagrams, and mock-ups demonstrated in this section depict the system's logic, decision-making processes, and design. This represents a fundamental step in the software development life cycle to be accomplished prior to designing, implementing, and testing the system.

Functional Requirements

Functional requirements outline functions or operations that the system is built to perform. In simpler terms, they represent the fundamental functionalities of the system which it should or should not do. The following table compiles the functional requirements of the proposed system.

Table 1. Functional Requirements.

Functional Requirement	**Description**
1. User Registration	The system should allow users to create an account.
2. Patient Health Records	Patients should be able to upload and view their previous health records.
3. Patient Personal Details	Patients should be able to upload and view their personal details.
4. Doctor Access	Doctors should be able to view: • health records and personal details of approved patients, • update and validate health records of patients.
5. Hospital Staff Access	Hospital staff should be able to: • view health records of patients stored in the system, • modify personal details of patients, • grant access to doctors to view medical records of patients, • revoke access to medical records of patients.

Non-Functional Requirements

Non-functional requirements refer to the characteristics or qualities that define the system's behavior and performance. These encompass aspects like security, performance, reliability, usability, efficiency, maintainability, and modifiability. They outline the specific attributes that the system should exhibit to meet user expectations and standards. These requirements go beyond the functional capabilities and focus on the system's overall effectiveness and user experience which are paramount in the acceptance of the system. The table provided below outlines the non-functional requirements for the system.

Table 2. Non-Functional Requirements

Non-Functional Requirement	Description
1. Security	The system should ensure secure storage and transmission of sensitive patient data. Pre-defined set of protocols through consensus mechanism on the blockchain.
2. Privacy	Give access to users with information only intended for their user role. Keep data to be collected minimal and private.
3. Performance	System should be able to handle heavy loads with no drop in performance. Response time to actions to a minimal.
4. Reliability	The system should be available with uninterrupted access to the users. Data integrity should remain intact with the decentralized network.
5. Usability	The user interface of the system should be easy to use, user-friendly, and intuitive to use.
6. Compliance	With the consensus algorithm, law, rules and regulations from the relevant respective parties international or local must be accommodated and respected.
7. Efficiency	Pertaining to optimal utilization of system resources and the ability to perform tasks in a timely manner.

3.3 System Architecture

Since the application is targeting both the healthcare industry and the general public, careful consideration of the features to be developed for the blockchain EHR system is essential. The system was developed while following best practices that ensured the quality of the user interface while also having a feature rich application. This was prioritized since the acceptance and comprehensibility were of the utmost importance for such an app. The main considerations for implementing the features of the application were as follows:

- Understanding the health regulatory compliance (required for the security and privacy requirements),
- Thoughtfully comprehending the diverse roles, access and requirements based on users' roles and duties,
- Develop a robust consensus mechanism,
- Ensure data interoperability, and
- Implementation of proper logs and auditing (with integrated IPFS).

Incorporating the main findings from the literature review, the following steps were carried out to begin development of the mobile app and blockchain network:

- Instantiating digital wallets to carry out transactions,
- Using Ganache to host the blockchain,
- Implementing the app using Dart language, and
- Setting up an IPFS to store the data.

Overall, an effective blockchain EHR system would give patients and doctors access to their relevant medical data on the blockchain network, make transactions, and have the application efficiently interact with the IPFS system. The diagram below portrays the architecture diagram and overall logic of the system.

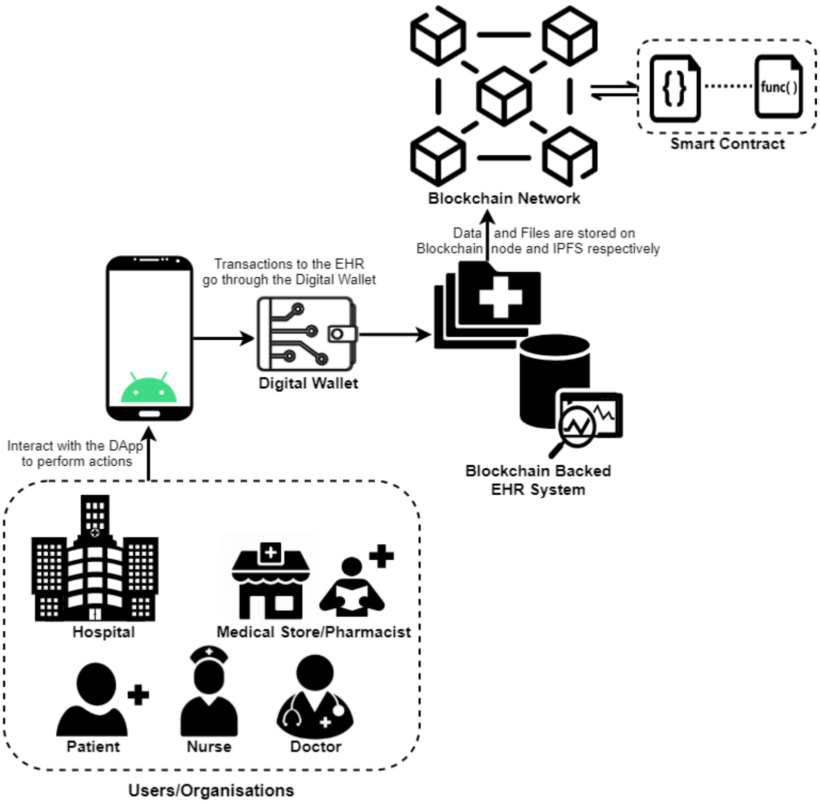

Fig. 2. Project Architecture Diagram

3.4 Implementation of System

The central aim for the project is to enhance healthcare worker productivity through the digitization of patient health data via the proposed EHR system. The system will leverage benefits from the blockchain technology whilst also ensuring transparency, security, and privacy for the healthcare industry. The goal of this project is to create an effective blockchain EHR system that provides patients and doctors with seamless access to their relevant medical data on the blockchain network. To initiate the development of the project the first steps include instantiating digital wallets for secure transactions, configuring Ganache and Truffle as the blockchain hosting platform, developing the app using the Dart programming language, and setting up an IPFS system to store and manage the data. While carefully considering the features to be developed, best practices were followed to ensure a high-quality and bug-free user interface in addition to a decentralized application that meets the needs of the diverse users.

Furthermore, the system will facilitate secure transactions and provide access to files through the IPFS system. By prioritizing user acceptance, and comprehensibility this project attempts to contribute towards the advancement of healthcare industry by introducing new technology through blockchain innovation.
The following is a list of features and advantage over other existing systems that provide beneficial outcomes supporting the proposed EHR system:

- Roles and access for users will be verified patient, verified doctor, pharmacy, hospital admin.
- Access to the patient's electronic health record (EHR) will be granted on a time-limited basis to all persons involved in the care of the patient. The smart contract facilitates the transmission of the electronic health record.
- All of the data is encrypted, and it is never distributed to any other entities.
- A zero-knowledge protocol is one in which the prover validates a statement for the verifier without providing the verifier with any information on the assertion that is being validated. The use of zero-knowledge evidence helps to improve users' levels of privacy.
- Because of the intrinsic adaptability of Blockchain, the EHR framework may be used by a broad range of different medical software applications.
- Interactions between a range of parties engaged in a patient's care may be carried out in a patient-friendly and confidential manner using zero-knowledge proof techniques.
- It ensures that the patient is in control of their own electronic health record (EHR), which speeds up the procedures of approval and consent.
- The whole chain of custody is made public to all parties involved thanks to the blockchain technology.
- Decrease the number of unfavorable occurrences that take place and improve the overall quality of the care that is provided.
- As a result of the network's interaction with the Central Drugs Standard Control Organization, both pharmacists and medical professionals get timely notifications about any newly approved or banned pharmaceuticals.

The main logic for implementing the logic of the organizations and overall users have been encompassed in the smart contracts written in the Solidity language. The central smart contracts that process the system’s proceedings have been described briefly in the section below.

Smart Contracts

The sub-sections below briefly describe the smart contracts that form part of the EHR system. Overall there is a reliance on inheritance between multiple contracts as well for the smooth transfer of information.

Patient

The patient contract includes provisions for enrolling the patient with the network, update information, prescription and other records/uses. There is another built-in feature that retrieves the info for the patient individually as well.

Hospital & Pharmacy

These contracts processes registration of hospitals and pharmacies respectively on the network. There is also the patient agreement feature that performs the data retrieval process.

Doctor

The doctor contract serves several purposes, such as adding physicians to the network and providing payment for services. These screens are there in the registration process for physicians, when information like doctors' names, hospitals' locations, and wallet addresses are transferred around through a number of different variables.

Healthcare

The healthcare contract accommodates functions for all entities in addition to performing general CRUD operations for all the users and organizations. Finally, the verification and grant mechanism for patients and doctors has also been devised.

DApp on Flutter

For each deployed smart contract, there is a specialized Dart script that handles ingression of information over the mobile app. For processing of files, the IPFS system has to be instantiated with a connection established between the system and Ganache. A wallet management module has also been developed which manages the retrieval of relevant or requested wallet addresses for the eventual transfer of gas fees.

4 EHR System with Blockchain

This section will demonstrate the overall user interface of the system and discuss the main sections with their features.

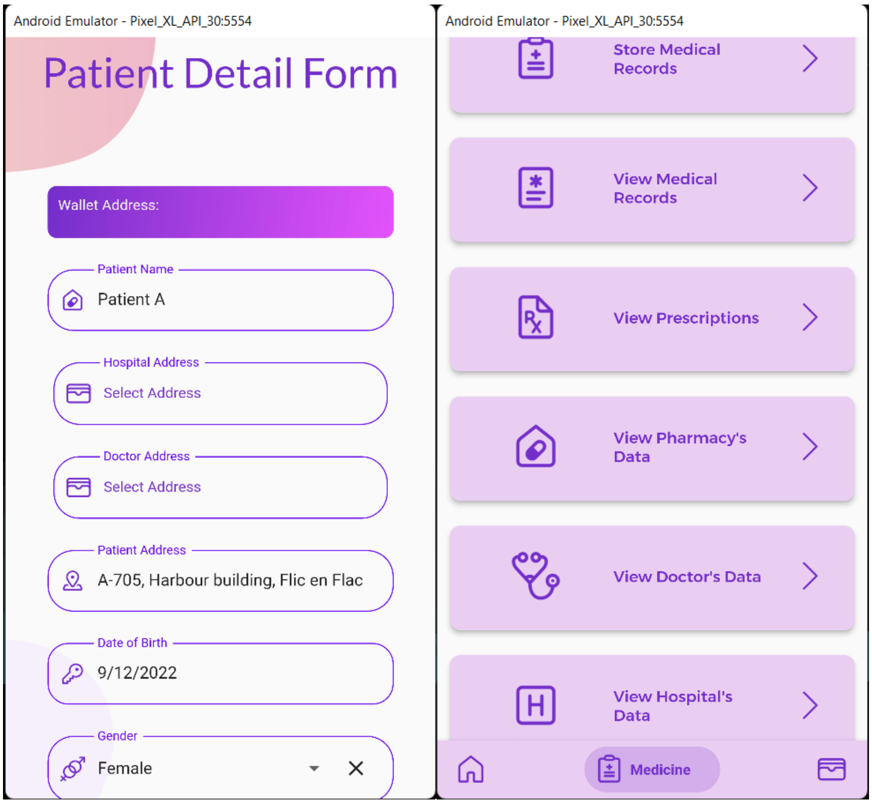

Fig. 3. Patient Details and Menu Options

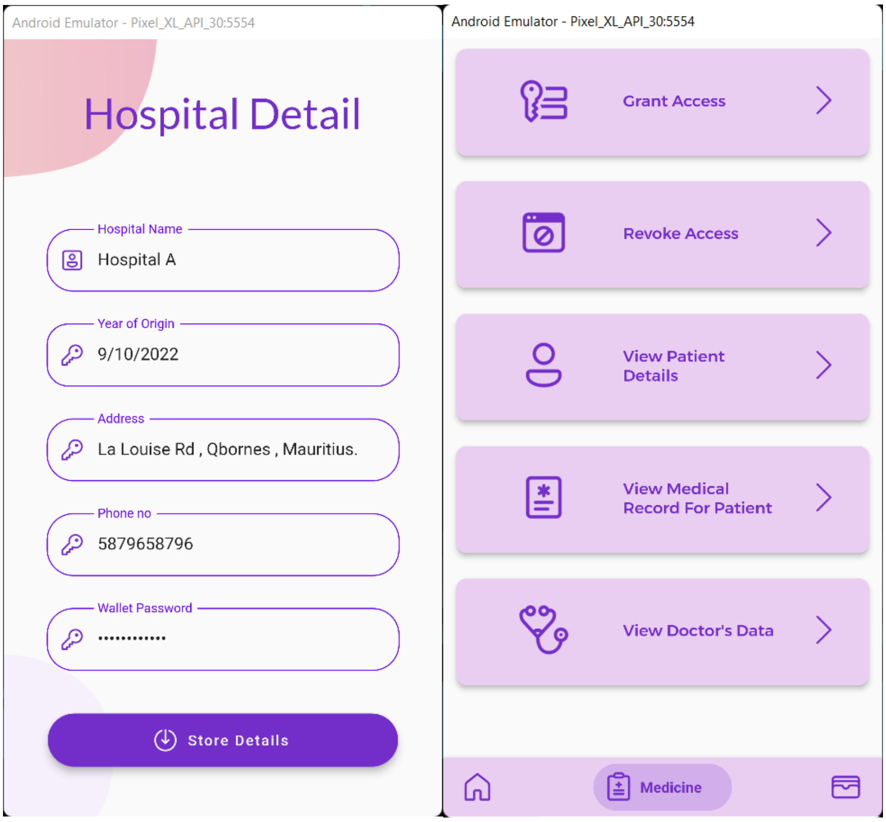

Fig. 4. Hospital Management and Menu Options

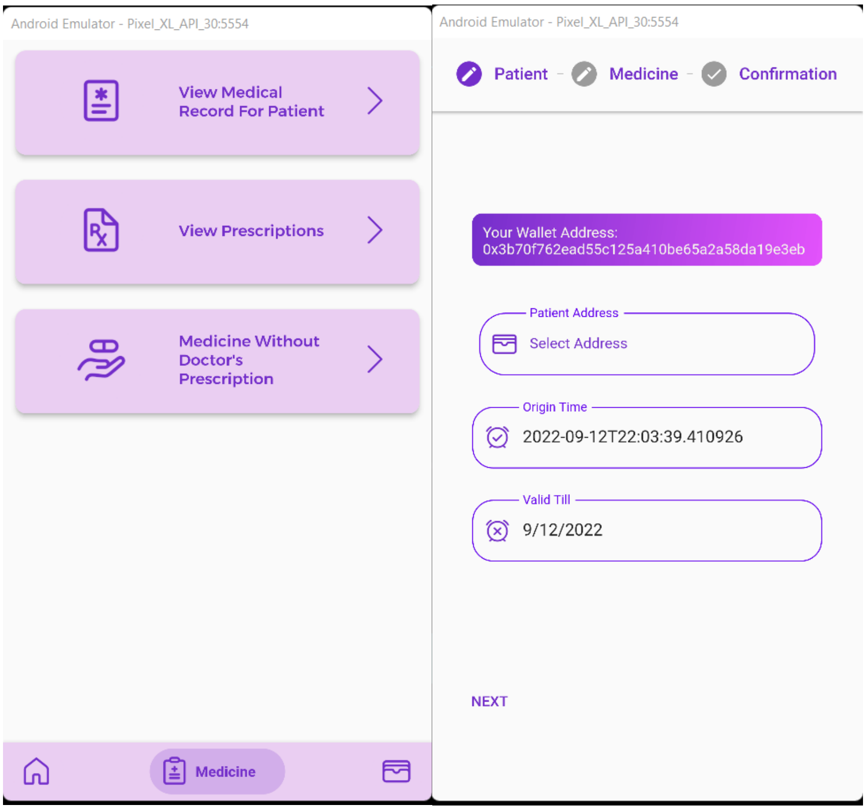

Fig. 5. General Patient Information

5 Conclusion & Future Works

Improvements in security, user experience, and other areas of the healthcare industry are the primary outcomes of technological progress. The digitization of health records means that cyber-security of medical records is becoming increasingly relevant. Thereby, the need for a blockchain based mobile EHR system is imperative. This project presented the development of a mobile-patient medical records management system using blockchain. The system was thoroughly tested through a series of unit tests. The smart contracts were also validated through tests using the truffle framework. As future considerations the application could be further tested in terms of performance, or usability. Concerning evaluation of the project, firstly the Mythril [10] framework could be used to assess its performance. Mythril has the capability to identify several security flaws, such as integer underflows, and other issues. Secondly, Hyperledger Caliper [11] benchmarking tool could also be used to measure and quantify the performance of the app in realistic environments. This platform helps in generating key references to reveal performance indicators. These details in return can be used to finetune the application. Furthermore, user acceptance testing could also be carried out in order to gather insights from the different user's perspective (Doctor, Nurse, Patient, Hospital). Alternatively, studying adoption of blockchain technology within the healthcare industry and its environment could also be another logical pathway [12]. Research backed frameworks such as Unified Theory of Acceptance and Use of Technology (UTAUT), Technology Acceptance Model 2 (TAM2), and Technology Organization Environment (TOE) Model can be considered. In terms of the limitations of this study, it is debatable whether the current network setup would be fully scalable for an organization [13]. Additionally, maintenance is another barrier since healthcare services continue to improve with new apparatus and sensors [14]. The system should be introduced in an environment where users are computer literate to minimize errors, otherwise training would be required.

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