A Software Architecture Based on the Blockchain-Database Hybrid for Electronic Health Records

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Abstract. Blockchain applications are regarded as a disruptive technology in the health area for working in a decentralized manner, with inherited features such as immutability, privacy, scalability, and security, and with users managing their data. We present a software architecture based on blockchain and a document-oriented database to manage and store electronic health records (EHRs). This software architecture was designed and implemented to manage EHRs of patients in the process of motor function recovery and assist the research on virtual reality and neurofunctional recovery (BRAINN_VR) at the Brazilian Institute of Neuroscience and Neurotechnology (BRAINN). This solution allows BRAINN_VR researchers to analyze data while respecting the patient's privacy. We evaluate the network performance of our solution to validate EHR insertions using four scenarios with varying data block size, network latency, and jitter. The consensus performance reached shows the feasibility of our architecture. Our software architecture has the potential to provide seamless interaction between multi-institutional research laboratories, health institutions, and patients.

Keywords: blockchain · eletronic health records · software architecture

1 Introduction

People seek various medical facilities throughout their lives to receive treatment, answered by diverse professionals, hospitals, and clinics. These multiple events generate information in various formats that make up one's lifetime medical

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record. When a medical history is organized and provides instant access to accurate and up-to-date information, it can improve the overall quality of health services, creating benefits such as error prevention, security, and easy information access. Electronic health records (EHRs) can offer medical record availability, and their services are widely recognized in the literature [4]. However, their full potential has rarely been achieved because they depend on the success of technological factors such as usability, regulation, infrastructure, training, and interoperability [11,13].

This study focuses on one of the critical factors of EHRs, namely, the software architecture (component-and-connector structures) that defines the software elements (components) by delineating their features and the interactions (connectors) between the structural parts [7]. These interactions create the desired EHR software behavior that requires consideration of all stakeholders (e.g., patients, researchers, and health professionals) and software characteristics (e.g., scalability, interoperability, performance, reusability, and security). These prerogatives affect software development principles such as standards, data modeling, software maintenance, rules of thumb, and empirical practices, all of which are fundamental for decision making toward a specific direction and evaluating the EHR's success. While EHR factors such as usability and performance can be evaluated early during the system adoption phase, many other essential aspects are hidden by the underlying software, making them challenging to create and evaluate, such as the software architecture that is the foundation for solid software to meet all requirements.

In recent years, blockchain-based EHRs have aroused interest in the health sector [1,10,14,21,25,26] for their capability to provide the underlying software architecture. With the adoption of such EHRs, patients can manage their data [15]. Moreover, medical records can be added and shared but not changed or deleted. Blockchain-based EHRs aim to allow all interested people who previously did not know or trust one another to share data in a secure and tamper-proof way.

Adopting blockchain to EHR creates a distributed data storage system with security access and validation that replaces centralized systems. However, only authorized entities with explicit permission, such as doctors, hospitals, and other health insurers, can access patient records to serve their purpose. There is a trend toward merging blockchain and databases (blockchain-database hybrid), with one feature incorporated by the other and vice versa [23]. For example, concurrency control techniques are being used to increase the performance of blockchains, and, at the same time, blockchain security features are being incorporated into the blockchain-database hybrid [23]. Examples of this approach are BigchainDB [19], Blockchain Relational Database (BRD), and ChainifyDB. These blockchain databases combine the key benefits of distributed databases (i.e., high throughput, low latency - latency is the amount of time a network packet takes to travel from the sender to its destination -, and rich querying) and traditional blockchains (i.e., decentralized control, immutability, and creation and movement of digital assets) with an emphasis on scale. An asset in this work is a tangible (patient,

patient data, patient responsible, admin, medical record and institution) or intangible (access) resource owned by the entity (i.e., patient, institution, laboratory). For example, patient and institutional data.

Any blockchain software requires a consensus protocol to validate the data entries, the most famous of which is Proof of Work (PoW) because of its integration with Bitcoin [3,6]. A consensus is a mechanism used to achieve the necessary agreement on a single data value among the nodes. PoW offers the most robust protocol based on brute force, demanding high computer performance to validate the data. Another protocol is Byzantine fault tolerance (BFT), in which each node needs two-thirds of the votes from all nodes to perform a data commit [3,9].

This paper describes a software architecture to provide medical record availability to multi-institutional research laboratories and patients. More specifically, we developed a software architecture based on a permissioned blockchain (private) using BigchainDB to manage and store EHRs using eighth assets. Permissioned blockchain has an identity provider that controls the identity of the entities. This study describes how our software architecture provided a feasible environment for our healthcare and research context. We also evaluated the network performance to validate the transactions by using four scenarios with varying EHR sizes, network latency, and jitter - it is a variance in latency when a data packet is transmitted and when it is received; the variance is caused by network congestion or route changes -. The significant contributions presented in this paper are:

- The software architecture designed and implemented allows to manage EHRs of patients in the process of motor function recovery and assists the research on virtual reality and neurofunctional recovery (BRAINN_VR) at the Brazilian Institute of Neuroscience and Neurotechnology (BRAINN). This solution allows BRAINN_VR researchers to analyze data while respecting the patient's privacy; and
- Evaluation of the performance of this software architecture using network parameters considering real network adversities that of a real environment. Network adversities are issues that can cause delays in the transmission of data. We simulated a network between five universities in different Brazilian regions (north, northeast, midwest, southeast, and south).

The solution was developed to manage and store EHRs with inherited blockchain features such as data availability, immutability, privacy, scalability, security, and users' data management. This solution can provide seamless interaction between multi-institutional research laboratories, health institutions, and patients. Our research aims to develop new body-tracking devices and interfaces for virtual and augmented reality to assist patients during motor function rehabilitation. In BRAINN_VR project, we collected kinematic data and analyzed them to identify patterns and correlations.

The remainder of this paper is organized as follows. Section 2 presents related work. Section 3 describes our software architecture and the transactions comprising an actor sender, an actor recipient, and an amount of health data. Section 4

presents the method used to evaluate our solution, which applied different parameters (data block size, network latency, and jitter), and a scenario with five Brazilian regions in our evaluation. Section 5 describes the tests and discusses the results. Finally, Sect. 6 presents the concluding results and future work.

2 Related Work

EHR is one the most popular subject espouse to apply blockchain in the healthcare area [1,2,10,14,16,20,21,25,26] for their capability to provide the underlying software architecture. Moreover, blockchain-based EHRs adoption allows patients to manage their data [15,16]. However, few studies present empirical results to substantiate their claims.

MedRec developed by Azaria, Ekblaw, Vieira, and Lippman [5] is based on Ethereum's blockchain to create a system that represents the ownership and viewing permissions of data shared by members of a peer-to-peer network. MedRec uses smart contracts to create the representation of medical records that are stored within specific computer nodes. Smart contracts permit trusted transactions and agreements to execute autonomously when certain conditions are met without the need for a central authority. SQLite database was used to implement their prototype. The contracts keep metadata about the record ownership, permissions, and data integrity. This study does not present performance analysis; however, the validation is based on the PoW algorithm, in which miners compete in solving a computational hard puzzle [12]. This algorithm requires a long processing time and high energy consumption of the computers. MedRec is a working prototype focused on evaluating the technology and implementation of blockchain prior to any real use.

Roehrs et al. [22] described the prototype and evaluation of the OmniPHR architecture model based on their blockchain and openEHR interoperability standard. This studies focus on EHR and Personal Health Record (PHR)[1] which is an emerging trend in healthcare context. The data follow a proprietary or an open standard and then is converted using a middleware. OmniPHR focus on creating a distributed architecture that is scalable, elastic, and interoperable. They list some studies that deal with implementing blockchain technology into EHR. The authors evaluated the network performance considering a scenario with ten super peers and thousands of competing sessions transacting operations on health records simultaneously, but without taking care of network adversities related to communication performance.

MedHypChain [17] is an architecture based on permissioned blockchain Hyperledger for a data-sharing system for healing the COVID-19 situation. The authors analyzed their solution's latency, execution time, and throughput, considering peers up to 10,000 transactions. The performance evaluation was done using the Hyperledger caliper tool. However, they do not consider network adversities related to communication performance. Their study also presented a comparison between diverse blockchain-based healthcare systems. They presented

[1] https://www.iso.org/obp/ui/#iso:std:iso:tr:18638:ed-1:v1:en:term:3.20.

a study case in which medical service is implemented based on MedHypChain. This service stores data of patients using sensors. According to the authors, MedHypeChain can handle up to 20 nodes for 1000 concurrent transactions and four nodes for 10,000 concurrent transactions.

The review paper by Kuo, Kim, and Ohno-Machado [18] presented benefits, pitfalls, and applications in healthcare domains. They covered key challenges, including issues like confidentially, scalability, and transaction performance. According to the authors, when using the PoW algorithm, Bitcoin reaches about 3.3 transactions per second on average due to the required computation workload. They highlighted that this is an important issue when creating a real-time healthcare application based on blockchain. The authors suggested the adoption of BigchainDB as a plausible solution to deal with speed, as we did in our study.

Many studies have described how EHR can be based on blockchain technologies. However, unlike related work that uses blockchain platforms like Ethereum, Hyperledger, or Chord algorithm, our work use BigchainDB. Moreover, none of the previous research compared the network performance considering realistic network inferences or designed to create EHRs for patients in the process of motor function recovery that can be accessed and managed by healthcare services and research laboratories.

The Brazilian Ministry of Health incentives the computerization of medical records. Our work advances the creation of patient records, treating the entire process as assets with their respective owners. Patients, medical and research institutions will reach a consensus via a vote-based protocol and data stored in a document-driven database.

3 Software Architecture for Electronic Health Records

In our software architecture for EHR, the actors are the entities that send, receive, and/or treat the messages. They are as follows:

- Patients: anyone who receives healthcare services;
- Health institutions: anyone or any facility that provides healthcare (e.g., laboratories, medical facilities, nurses, etc.); and
- Research laboratories: university facilities that provide the infrastructure to store and validate transactions and receive permission to access all data for conducting research anonymously.

Patients and health institutions use a web application on a webserver to interact with the EHR system inside the blockchain. Their privileges are taken care of by services offered by the certificate authority (research lab) that assigns a public and private key to each user. Our EHR solution uses BigchainDB to deploy a blockchain-like decentralized application using off-the-shelf technologies. Each blockchain node uses a local MongoDB (https://www.mongodb.com/) database and the Tendermint protocol (https://tendermint.com/) to communicate and reach a consensus between the nodes. BigchainDB uses the BFT protocol to

ensure the system continues to work, even if up to a third of the blockchain nodes fail. Figure 1 depicts the actors interacting with the developed blockchain-database hybrid, the architecture of which is provided by the research laboratories of Brazilian universities (Federal University of São Paulo (UNIFESP), University of Campinas (Unicamp), São Paulo State University (Unesp), and Federal University of São João del–Rei (UFSJ)). Other nodes can be added to increase capacity and throughput. This software architecture just focused on private blockchains instead of public blockchains due to data security and privacy issues, as well as due to the specific domain of healthcare targeted by BRAINN_VR project. Private blockchains address emergencies, giving access to EHRs to health professionals not previously authorized.

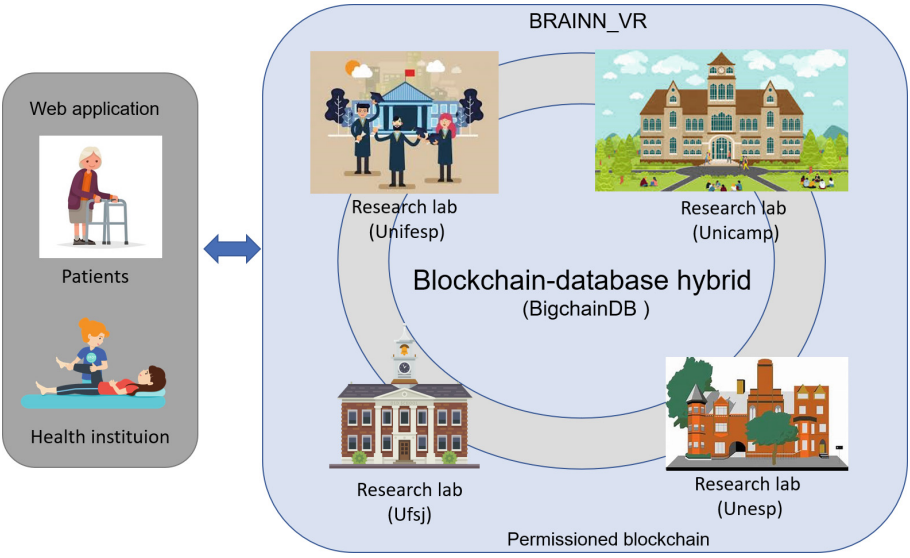

Fig. 1. Actors interacting in the EHR based on the blockchain-database hybrid.

The software architecture has eight types of assets that are created with distinct features but work in an integrated way. Figure 2 shows the relationship between the assets. The black arrows show the common data between the assets used to bond them together. The green arrows indicate the provided private key used to create the asset - if the private key is not public key pair, the asset is not created. The red arrow depicts a medical record transferring to a patient, becoming the asset owner. An attachment (e.g., video, sound, and image) can be part of a medical record. Just medical record assets can be transferred. The assets depicted in Fig. 2 are:

– Patient: it has an identifier (CPF - a Brazilian individual taxpayer registry identification) used to perform searches. Its public keys are also stored to perform transactions and encryption;

- Patient Data: contains information such as name, date of birth, and gender, among others. The patient only creates this asset, and when it needs to be updated, the patient must create a new asset of this type with the new information;
- Patient responsible: the patient can link other people to be co-responsible for his/her information. An example is the father and mother of a child, a patient with a child, or a patient with a disability;
- Institution: contains information about a health or research institution that uses the system. It also keeps its public keys;
- Medical record: holds the patient's EHR;
- Access: created after the creation of the patient EHR and when the patient wants to give someone else access to their record. It stores the EHR identifier and all public keys that have access to the EHR;
- Attachment: stores the notes of the files linked to the patient's EHR. These notes can be made through a file system or using some mechanism within the files or some mechanism within the database; and
- Admin: it is linked to all created assets. This asset is created only at blockchain setup time. It stores the public keys of the nodes configured to perform consensus.

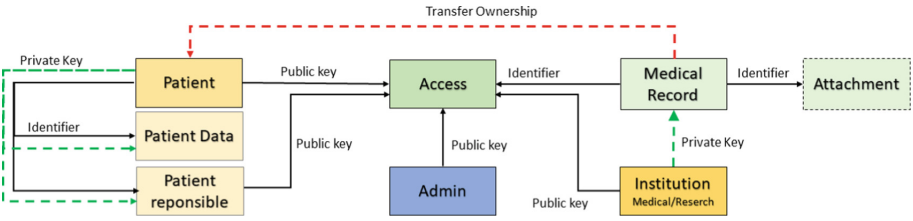

Fig. 2. Types of assets and relationship.

Transactions register the movement of assets between the actors (e.g., patients, therapists, nurses). BigchainDB provides an application programming interface to make transactions and register, issue, create, or transfer assets. Every transaction comprises an actor sender, an actor recipient, and an amount of medical data. The owners manage assets and can give access to other actors. The following steps are executed during the asset creation process: initially, an actor creates an asset and sends it to the blockchain (1), which asks the Tendermint (2) to reach a consensus using the BFT protocol. After the consensus, the current block is confirmed (3). Now the asset is sent to MongoDB (4). Then, the block is confirmed (5). The applications then receive the message that the asset was successfully created (6). This architecture guarantees the data's security and immutability to all actors.

The Medical Record asset is characteristic of multiple owners and is encrypted. When the asset is created and transferred to the patient, the system checks if there are other responsible parties (co-responsible parties); if so,

they must be registered in the asset as owners. Before the institution submits the asset to the blockchain, a session key is randomly generated and used to encrypt the asset symmetrically. Afterward, the session key is encrypted asymmetrically using the patient's public keys, co-responsible parties, institutions, and administrators.

Regarding multimedia files, we design their storage in a file system with only its pointer appearing in the database. This approach helps minimize indexing and searching problems in the database. In the model implemented, it is possible to create an attachment asset. We store the medical record's identifier and the pointer to the file in a file system or database table.

4 Evaluation

The transaction performance of medical records among health institutions, research laboratories, and patients is crucial to ensuring the adoption of blockchain-based EHRs. We evaluated the network performance to validate the task of creating and validating EHRs using four setups with varying data block size, network latency, and jitter (packet delivery). In these scenarios, consensus occurs by validating two-thirds of the blockchain nodes (BFT algorithm).

The laboratory setup consisted of five virtual machines (8 cores and 24 GB RAM) running on a Huawei FusionServer RH2288H V3 host server with 2x Intel Xeon E5-2690 v3 processors, 128 GB DDR4 RAM, and 2×2 TB hard disk. The virtual machines simulated five universities in five Brazilian regions (north, northeast, midwest, southeast, and south). Node 1 was the dispatcher responsible for creating the EHRs and performing the consensus. All the other nodes performed the consensus exclusively. We developed a shell script to handle 32 executions of creating EHRs to run in parallel. Multiple factors (i.e., the distance of a link, state of intermediate routers, and jitter amount) may cause packet delay on network links, affecting the data throughput between connected nodes. When the latency is very high, the throughput of a connection cannot be considered reliable. Generally, a network can be regarded as reliable when jitter is on the order of 10% of the average round trip time that is the amount of time it takes for a network packet to travel from a starting point to a destination and back again to the starting point.

We used the NetEm tool (https://www.linux.org/docs/man8/tc-netem.html) to emulate the network adversities in these regions. The simulation parameters were based on the report from the Brazilian Network Information Center [8], which allowed the definition of the threshold values to indicate the operational limits of the experiment. Table 1 depicts the scenarios that combine the major adversities related to the latency and jitter of data networks. These parameters hardly appear in isolation in the real environment. For each simulation, we created 20,000 EHRs and varied the packet sizes (i.e., 15, 20, 40, and 80 Kb). Each EHR creates the following three transactions: CreateEHR, which creates the EHR; CreateAcess, which defines the privileges of the created EHR to the

patient, co-responsible parties, institution, and administrators; and TransfertoPatient, which associates the EHR with the patient's property. A total of 20,000 EHRs requested 60,000 transactions.

Table 1. Test scenarios with varying latency and jitter for the creation of 20,000 EHRs.

Setup 1					
	Node 1(north)	Node 2 (northeast)	Node 3 (midwest)	Node 4 (southeast)	Node 5(south)
Node 1 (north)	latency (0 ms) jitter (0 ms)	latency (0 ms) jitter (0 ms)	latency (0 ms) jitter (0 ms)	latency (0 ms) jitter (0 ms)	latency (0 ms) jitter (0 ms)
			Setup 2		
Node1 (north)	latency (50 ms) jitter (6 ms)	latency (55 ms) jitter (6 ms)	latency (65 ms) jitter (7 ms)	latency (60 ms) jitter (6 ms)	latency (77 ms) jitter (8 ms)
			Setup 3		
Node1 (north)	latency (50 ms) jitter (4 ms)	latency (55 ms) jitter (4 ms)	latency (65 ms) jitter (5 ms)	latency (60 ms) jitter (4 ms)	latency (77 ms) jitter (6 ms)
			Setup 4		
Node1 (north)	latency (50 ms) jitter (2 ms)	latency (55 ms) jitter (2 ms)	latency (65 ms) jitter (4 ms)	latency (60 ms) jitter (2 ms)	latency (77 ms) jitter (5 ms)

5 Discussion

An effective software architecture to manage and store EHRs with inherited blockchain features should allow the building of applications tailored to the network. From the EHRs point of view, data block size, network latency, and jitter are quality parameters of the network. From the EHRs user's point of view, they experience the cumulative effect of these parameters. The software architecture supported a high volume of transactions (60,000) even with different setups. The combination of network latency and EHR size influenced the consensus time. Setup 3 was the worst scenario, averaging 41 EHRs per minute. Setup 1 was the best, with an average of 47 EHRs per minute. Blockchain network performance also depends on the consensus mechanism chosen. We chose the BFT algorithm in our scenarios, and the four fastest nodes were enough to reach the consensus.

Given our context, the main features of the architecture developed are as follows:

- It provides fast transaction validation using the resources of the research facilities;
- The database solution adopted inherits the features of modern distributed databases, such as linear scaling in throughput and capacity with the number of nodes, efficient querying, and full support to NoSQL query language, and a private blockchain;
- Patients can administer and own their health data, that is known as Personal Health Record (PHR), which is an emerging trend in healthcare context;
- It facilitates auditing because data are stored chronologically and cannot be deleted;

- It provides access to the patient's medical records regardless of where the care was performed;
- It integrates into a solution the useful features from blockchain and databases; and
- Research laboratories can have access to medical records without compromising the identity of patients.

Our performance evaluation did not cover the execution of business rules that health information systems have and users' interaction with the interface. Instead, we limited the tests to execute transactions using scripts. The test scenarios were defined to stress the EHR system shared by research laboratories without generating errors or crashes, such as time out.

Swan [24] identified the following technical challenges related to the blockchain implementation: (1) throughput, (2) latency, (3)size and bandwidth, (4) security, (5) wasted resources, (6) usability, and (7) versioning, hard forks, and multiple chains. We could find that our practical experience faced these challenges. We tailored the software architecture to our problem, but creating a facto standard requires more research in the future. Moreover, it must comply with legislation that changes significantly from country to country (for example, Brazilian General Data Protection (LGPD) in Brazil, Health Insurance Portability and Accountability Ac (HIPAA) in the USA, and General Data Protection Regulation (GDPR) in Europe).

Therefore, we surmise that our software architecture is a promising solution to be used in many healthcare and research contexts, similar to the one presented in this study, with little or no effort can be benefited from all the features (e.g., scalability, performance, security, and easy information access). Consequently, it can improve the overall quality of health services, develop new treatments and cures, and enable precision medicine.

6 Conclusions

EHRs must integrate data from multiple players, creating challenging security, privacy, and governance requirements. A significant challenge for EHRs is collecting patient information, even from the same patient, and carrying it from one care facility to another with a reliable software architecture that provides scalability, cost-effectiveness, and capacity to adapt new functionality with minimum changes.

This paper presented software architecture whose main aim is to assist the rehabilitation of patients in the process of motor function recovery. This software architecture is part of the research on virtual reality and neurofunctional recovery (BRAINN_VR) at the Brazilian Institute of Neuroscience and Neurotechnology (BRAINN). Patients benefit from medical history being accessible and credible, and healthcare can learn by analyzing patterns and correlations of treatments. This architecture was designed for application in research projects linked to the BRAINN VR initiative, with e-health solutions for telemonitoring and virtual reality for neurofunctional recovery. We developed the software

architecture based on a permissioned blockchain using BigchainDB to manage and store EHRs. The architecture was created considering the requirements of stakeholders and software characteristics, such as scalability, interoperability, performance flexibility, reusability, and security. Moreover, the solution developed is feasible to assist healthcare and research. Network performance was also evaluated to validate the EHR insertions using four scenarios with varying data block size, network latency, and jitter. It took 0.38 s on average to create one EHR.

This study evaluated the EHRs software architecture; then, others studies are needed to evaluate other key factors such as usability, regulation, infrastructure, and training. In future research, we plan to improve the software architecture by adding new features, such as data integration with healthcare professionals' tools, some of which have already been developed.

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