Journal of Software Engineering Research and Development, 2025, 13:7, doi: 10.5753/jserd.2025.4624

Bridging Blockchain Technology to Electronic Patient Record Engineering: A Sociotechnical and User-centered Analysis

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Abstract Blockchain-based Electronic Patient Records (EPRs) are transforming clinical information management by enabling secure, transparent, and decentralized data storage. However, sociotechnical studies on the adoption and impact of collaborative work in healthcare with blockchain-based EPRs are scarce despite their influence on the engineering of these relevant systems. In this context, we conducted a sociotechnical and user-centered analysis to understand the perspective of healthcare professionals and patients on using a blockchain-based EPR and the role of this technology in meeting their requirements. To this end, we developed a Proof of Concept (PoC) of blockchain-based EPR, including its software architecture, and evaluated it through Focus Groups using real-world scenarios and user tests. Our study delivers a practical contribution to the software engineering of blockchain-based EPRs, including findings on the current use of EPR, collaborative aspects, practical adoption, lessons learned, and opportunities for improvement.

Keywords: *Blockchain, Electronic Patient Record, User-centered Design, Sociotechnical Analysis.*

1 Introduction

Electronic Patient Records (EPR) have been evolving toward an artifact for maintaining electronic information on the individual's health status and the care procedures history (Marin et al., 2003). In addition to the storage purpose, the requirement of data interoperability is another significant feature to enable proper communication between multiple health systems/stakeholders and ensure the continuity of care. On the other hand, one essential discussion arises around the privacy guarantee regarding patient data (da Conceição et al., 2018).

Given these considerations, blockchain technology has proven pertinent for EPRs due to its ability to provide a distributed database protected by cryptography and governed by a consensus mechanism (Bashir, 2017). These mechanisms enable a highly transparent, secure, resilient digital transaction record. The use of blockchain has proven effective in integrating with EPRs (Kassab et al., 2019), with studies exploring different architectural approaches, such as permissioned blockchain for smart hospitals (Gomes, 2022), self-sovereign identities for user-centric health data (da Conceição et al., 2018), and decentralized repositories using blockchain and FHIR (Fast Healthcare Interoperability Resources) standards (Vieira et al., 2023). Additionally, as the technology has matured, proposals have become more patient-centered, particularly in addressing data ownership and access control challenges (Chen et al., 2019; Duong-Trung et al., 2020).

However, considering the complex scenario around healthcare systems, the widespread adoption of blockchain-based EPR may still face significant challenges. In particular, the interaction between blockchain and EPR should address technical challenges and promote collaboration between stakeholders in addressing healthcare issues by leveraging existing social structures and systems. From this perspective, developing reliable, collaborative, and maintainable decentralized applications requires robust Software Engineering (SE) processes. Since SE is recognized as a sociotechnical endeavor, social aspects are increasingly regarded as a critical part of practice and research (Storey et al., 2020; Marchesi et al., 2020).

In this context, User-Centered Design (UCD) can play a fundamental role in improving user-focused EHRs, employing principles to prioritize the goals and requirements of system stakeholders throughout the blockchain-oriented SE process (Porru et al., 2017). UCD prioritizes end users' needs, limitations, and preferences at every stage of the development process (Brhel et al., 2015). Furthermore, UCD is particularly relevant in healthcare systems, where the complexity of interactions between professionals and patients demands a deep understanding of user needs and their contexts (Ratwani et al., 2015). This approach allows the evaluation of the system's technical aspects and an understanding of how it integrates with existing collaborative practices in the healthcare environment.

Indeed, the SE literature has predominantly evaluated blockchain-based EPR system proposals from a technical perspective (da Conceição et al., 2018; Fuentes, 2019; Shahnaz et al., 2019; Chen et al., 2019). However, EPRs are also related to critical user requirements that can directly affect their healthcare due to various medical services, workflows, and dataflows, as well as collaboration activities that impact system design (Marcu et al., 2016). In addition, blockchain-based EPRs may transform dimensions of society and systems collaboratively (Prinz, 2018; Lumineau et al., 2021). Hence, a sociotechnical orientation emerges as an insightful framework for investigating this phenomenon, given the ability to be aware of technological bias and consider the social context in the software development process (Bassan de Moraes et al., 2019).

In practical scenarios, the lack of user feedback and the distance between blockchain architects and industrial stakeholders can restrict the adoption of this technology (Wessling and Gruhn, 2018). To address this challenge, preliminary studies have integrated social and human aspects, research theoretical underpinnings, and blockchain-oriented software engineering approaches (Li et al., 2023; Faruk et al., 2022). Moreover, studies have started raising awareness on the sociotechnical effects of blockchain-based EPRs (Wong et al., 2018; Lee et al., 2020; Esmaeilzadeh, 2022; Murphy et al., 2021). These works have concentrated on introducing conceptual orientations, clarifying advantages and disadvantages, and gauging the perceptions of patients, health professionals, and developers in particular contexts such as telemedicine.

However, we noticed a lack of research covering how these systems impact sociotechnical aspects of collaboration, communication, cooperation, and coordination among healthcare stakeholders. This gap is particularly relevant because it reflects different problems: (1) misalignment between the actual requirements of healthcare professionals and implemented functionalities, hindering the adoption of blockchain technology; (2) communication failures between multidisciplinary teams, impacting the quality of care; (3) difficulties in implementing workflows that reflect the actual needs of cooperation between professionals and institutions, and (4) risks to privacy and data security due to a lack of understanding of collaborative dynamics. Understanding these sociotechnical aspects is critical to ensuring that blockchain systems provide technical security and support the collaborative practices critical for healthcare. Moreover, the studies did not explore a collaborative process using a Proof of Concept (PoC), missing user-centered around the blockchain-based EPR usage.

Given the previous motivation and the explained research gap, our study aims to provide a sociotechnical and user-centered analysis. We seek to understand the perspectives of healthcare professionals and patients on using a blockchain-based Electronic Patient Record (EPR). Additionally, we will explore the role of this technology in meeting their requirements, including critical issues related to patient data access control and privacy. As one can see, our novelty lies in understanding the practical implications of using blockchain-based EPRs and how these findings can be used to improve the engineering of these systems.

For this purpose, we followed a multi-method approach supported by Design Science Research (Vaishnavi and Kuechler, 2004) to guide the development and evaluation of a PoC of blockchain-based EPR. Drawing on a qualitative and exploratory research scope, we conducted Focus Groups (FGs) using Scenarios and User Tests as resources to guide the step-by-step of a user-centered evaluation. Two major issues were investigated around our blockchain-based EPR: i) communication, coordination, and cooperation constructs outlined in the 3C Collaboration Model (Fuks et al., 2008); and ii) the *used technology* in the healthcare professionals and patients' view.

This study provides theoretical and practical contributions to the SE of blockchain-based EPR. We obtained a comprehensive set of sociotechnical findings from healthcare practitioners and patients. These findings have implications for the current use of EPRs, collaborative aspects, practical adoption, lessons learned, and opportunities for improvement. Additionally, we propose a PoC of patient-centered blockchain-based EPR and architecture that drives the data access control through a layered storage structure. This proposal reflects how blockchain technology can meet requirements for privacy and security, which are considered particularly important concerning patient data (da Conceição et al., 2018).

This paper is organized as follows: Section 2 overviews brief theoretical concepts covering blockchain, EPR, and the 3C collaboration model. Section 3 outlines the research design. Section 4 describes the proposed blockchain-based EPR. Subsequently, Section 5 presents the results from the data analysis of the experiments. Section 6 presents discussions contextualizing the findings with state-of-the-art knowledge. Section 7 presents the related works. Subsequently, Section 8 summarizes potential threats to the study's validity. Finally, Section 9 concludes with final thoughts and future work.

2 Background

In this section, we present a theoretical baseline for this study. Section 2.1 introduces the definition of blockchain, its structure, and the main components involved in this technology. Section 2.2 covers the general concepts of EPR. Finally, we briefly explain the 3C Collaborative Model in Section 2.3.

2.1 Blockchain

Blockchain is a peer-to-peer (P2P) network consisting of a distributed ledger that stores append-only transactions performing only insertion operations, with no changes or deletions of data stored between different machines (Xu et al., 2019). In this network, transactions are grouped into data structures called blocks, which serve as containers for storing and organizing these transactions. The blockchain structure works as a chain of these blocks, so each new validated block is interconnected with the last block added to the network through a cryptographic hash. As depicted in Figure 1, each block is linked to the previous block using this cryptographic hash generated according to 1) the content of the current block and 2) the cryptographic hash of the previous block (Van Mölken, 2018).

Furthermore, each block comprises a set of transactions organized in a data structure defined as a Merkle Tree. Transactions are grouped into pairs, and the hash of each transaction is stored in a parent node, and their respective hashes are stored one level above the tree. This behavior occurs successively up to the root node of the Merkle Tree (Narayanan et al., 2016).

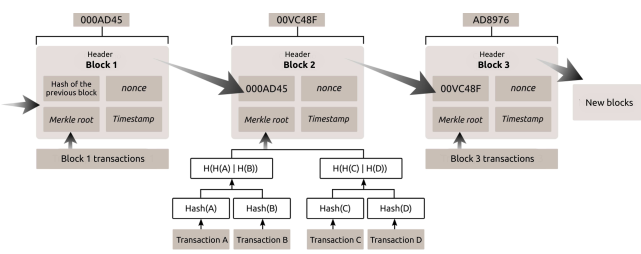

Figure 1. Simplified representation of a blockchain (Rocha et al. (2021)).

By expanding the use of blockchain, new generations of this technology enabled the development of different business rules, covering sectors such as government, health, science, and education (Raval, 2016). In particular, this capability became widely explored due to the development of smart contracts approached by the Ethereum platform in the so-called second generation of blockchain technology (Buterin, 2013). In summary, smart contracts are scripts that execute business logic at the top of the blockchain when certain conditions are met (Bashir, 2017). As stated by Xu et al. (2019), 'smart contracts are programs deployed as data [...] and executed in transactions on the blockchain [...] can contain and transfer digital assets managed by the blockchain and invoke other smart contracts stored on the blockchain. Smart contract code is deterministic and immutable once deployed'.

Smart contracts can automate and manage legal contracts between different parties based on previously defined interaction protocols and innovate the development of blockchain systems in several use cases and areas. This quickly growing interest in smart contracts empowered the development of Decentralized Applications (dApps). One of the main features of these applications is that no single server or entity controls them as in a client-server model. Furthermore, dApps are based on using blockchain as storage and processing by implementing smart contracts (Metcalfe, 2020).

DApps have been helpful in many different industries. Apart from financial-oriented dApps, areas such as healthcare can get much help from this technology. It can benefit actors such as providers, patients, payers, research organizations, pharmaceutical supply chains, and other processes related to issues of record management, interoperability and data exchanges, security, data provenance, and data privacy, etc (Yaqoob et al., 2019). These data management problems and their respective blockchain-based applications have been discussed as quite insightful in the literature (Clauson et al., 2018; Zhang et al., 2017; Soni and Singh, 2021).

2.2 Electronic Patient Record in Brazil

As stated by the Brazilian Federal Council of Medicine (BRASIL, 2002b), the patient record is a single document composed of various information, signs, and registered images. These records are created from facts or situations concerning the patient's health and the care procedures provided. This medical history allows communication between professionals of a multidisciplinary health team, which guarantees continuity of respect for the individual. As one can expect, this artifact requires a minimum set of information that the health team must compulsorily fill in. Among this information, the following ones stand out: complete identification of the patient (name, gender, date of birth, mother's name, place of birth, and address), anamnesis, physical examination, complementary exams with diagnostic results and hypotheses, prescribed treatment and daily evolution of the patient. In addition, there must be a legible name, signature, and number in his/her class registration (BRASIL, 2002b,a).

With the advances of digital transformation in the healthcare sector, the patient record as an artifact has also been tackled as a relevant target of several improvements and innovations. A critical advance in this matter comes from the diffusion of Electronic Patient Records (EPR) for properly maintaining electronic information about individuals' health status and the care received during their lifetime. Thus, EPR stores all essential information for the communication of the multidisciplinary team and the patient, in which there is a guarantee of safety and management of the health service (Habib et al., 2019; Kashyap, 2020; Bharti et al., 2021).

However, implementing an EPR is not simple, both from social and technical perspectives. For example, according to Jenal and Évora (2012), 'the implementation of information systems in a hospital, in addition to being complex, involves a very high cost and a significant workforce commitment, and it is expected that the implemented systems work properly'. In this context, one must claim the need to extend those considerations to domains of relevance for user-centered studies while broadening the scope of the themes and lenses made possible through caring in a sociotechnical fashion (Toombs et al., 2018). For this purpose, we highlight the relevance of addressing communication, coordination, cooperation, and collaboration constructs among healthcare stakeholders regarding the actual actions of care work, their perceptions, and how these practices change in the face of new technologies.

2.3 3C Collaboration Model

Social and technical factors are inseparable, as an information system comprises a set of technologies, organizational processes, and people integrated (Oliveira et al., 2020). As discussed by Klein (2014): 'Sociotechnical theory makes explicit the fact that the technology and the people in a work system are interdependent [...] Technology affects the behaviour of people, and the behaviour of people affects the working of the technology'. Then, as much as software systems are intrinsically technological, their analysis and implementation become incredibly insightful when grounded on a sociotechnical approach since they are deployed to solve societal problems.

However, fostering communication, motivation, and leadership through collaborative software is difficult, as it involves factors such as the old and complex human behavior (Kujawski, 2003). In this regard, the use of technologies by society generates changes that affect interpersonal relationships and communications in several niches, from business to political issues (Cukierman et al., 2007).

In line with the previous arguments, one can notice the relevance of adequately analyzing the behavior of people and groups when interacting with software so that it becomes possible to design and build effective collaborative systems. In particular, recent studies have covered a range of theories and collaboration models to provide interdisciplinary insights into this matter, including how and why people work in a group. Among these models, we highlight the 3C Collaboration Model (Fuks et al., 2008), which considers communication, coordination, and cooperation constructs for understanding collaborative aspects of technological solutions.

In summary, communication involves exchanging messages and negotiating commitments through tools that process the interaction. Moreover, coordination deals with managing people, tasks, and resources to manage conflicts of interest and organize activities to be carried out in a specific order and period. Then, cooperation joins operations in the shared workspace. Finally, collaboration is the interplay between communication, coordination, and cooperation.

3 Research Design

For this study, we approached a research scope supported by Design Science Research (DSR), which has gained widespread acceptance as a research approach in SE. We designed our DSR protocol in five steps based on Vaishnavi and Kuechler (2004).

During the **Problem Awareness**, we firstly conducted a *ad-hoc* literature review to identify related work and theoretical background to underpin our aim. Also, we accomplished an extensive document analysis to complement the academic findings with the Brazilian patient record regulatory guidelines, including regulatory documents. For this method, we followed the 8-step process suggested by Bowen (2009) for document analysis: (1) gather relevant texts, (2) develop an organization and management scheme, (3) make copies of the originals for annotation, (4) assess the authenticity of documents, (5) explore document's agenda and biases, (6) explore background information, (7) ask questions about document and, finally, (8) explore content.

We also documented the findings of Problem Awareness in a previous study (Soares et al., 2021a). In this study, we examined the potential and challenges of complying with Brazilian health informatics regulations, conducting a technical evaluation in light of the technical requirements established by the Brazilian Society of Health Informatics (SBIS) and data privacy issues raised by the Brazilian Data Protection Law (LGPD). These analyses contributed to advancing the understanding of the possibilities of how the adoption of blockchain-based EPRs would be operationalized following the Brazilian regulatory framework, including the effect on organizations and individuals.

Then, we proceeded to the **Suggestion** phase, designing a software architectural model as a 'tentative design' (Beck et al., 2013) for our artifact. For this architectural model, we identified different layers, assets, and roles to be further depicted as a web application for our blockchain-based EPR. Enlighted by these requirements, we advanced to the **Development** phase, where we focused on the implementation of the PoC of blockchain-based EPR, respectively: 1) a smart contract with the business rules to be executed in the blockchain; 2) an Application Programming Interface (API) for communicating with the smart contract deployed on the blockchain; 3) an integration layer connecting with distributed storage systems, and 4) a front-end interface of a web application to enable use by healthcare professionals and patients in the experiment.

Our empirical analysis was conducted during the **Evaluation** phase. In a prior work, we performed a preliminary computational experiment (Soares et al., 2021b) to assess an off-chain strategy to address scalability challenges in blockchain-based EPR systems. In particular, this paper extends that research by developing a Proof of Concept (PoC) for the latest architecture version and empirically exploring the sociotechnical perceptions of multiple healthcare stakeholders regarding a blockchain-based EPR proposal. This sociotechnical and UCD perspective, focusing on integrating healthcare stakeholders' views on blockchain-based EPR systems, was not covered in our previous publications. Drawing on the use of Focus Groups (FG), we investigated the: i) communication, coordination, collaboration, and cooperation constructs outlined in the 3C Collaboration Model (Costa et al., 2014); and ii) the *used technology* in the view of the participants in terms of cooperative work, that is, the blockchain-based EPR as a web application.

For this reason, we defined our research approach as ***sociotechnical*** because it integrates both social and technical aspects in the study of blockchain-based EPRs, which includes understanding the impact of blockchain technology on collaborative work in healthcare, considering the per-

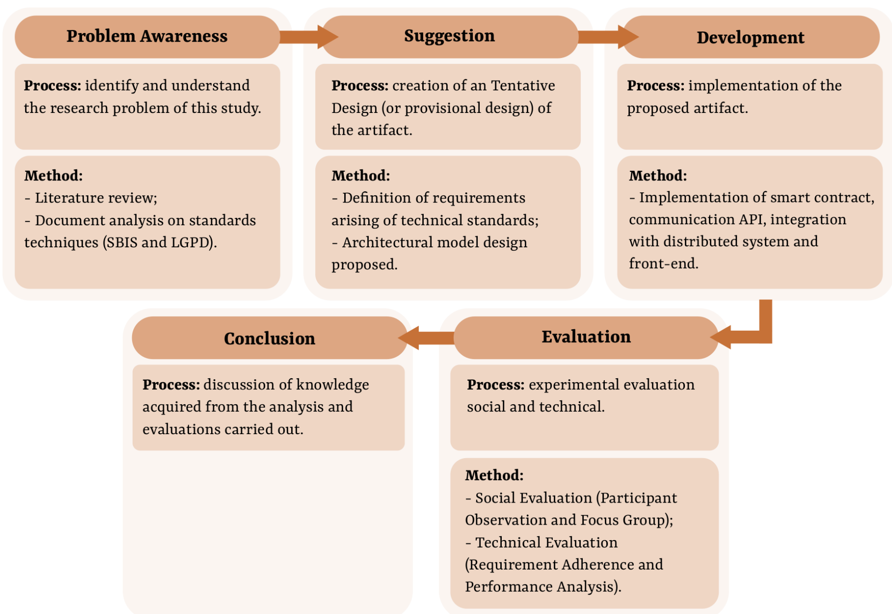

Figure 2. Overview of the Research Design.

spectives of health professionals and patients, and analyzing the sociocultural implications through the use of FGs. By incorporating sociotechnical principles, such as UCD, collaboration models, and stakeholder engagement, we ensure that blockchain-based EPRs can be technically feasible and aligned with the healthcare ecosystem's needs, values, and practices.

Regarding the qualitative data analysis derived from the FGs data, we employed the Thematic Content Analysis as an interpretive method to identify, analyze, and describe the significant patterns or themes (Bardin, 1979; Braun and Clarke, 2006; Cruzes and Dyba, 2011). In the first step, the first author transcribed the recorded audio of the FGs. Then, through the notes and transcripts, this author read them several times to apply the *open coding*. Hence, this author performed *axial coding* to identify patterns and group the speeches and observations on the topics and subtopics addressed. Finally, after merging the themes and subthemes, the other two co-authors meta-reviewed the codes and evaluated the resulting data to materialize the information and clearly understand the contributions. We approached the ATLAS.ti[1] tool to support the encoding process. Additionally, we used the systematic-emergent (Onwuegbuzie et al., 2009) for occurrence analysis to verify if the themes that emerged in the first FG also occurred in the second FG and vice-versa.

In the **Conclusion** phase, the knowledge of this research effort was discussed and consolidated as an academic paper.

3.1 Focus Groups Configuration

We opted for Focus Groups (FG) as the primary method for data collection due to their capability of collecting insights (convergences and divergences) through group interactions (Krueger, 2014). Our aim with the FGs was to investigate the sociotechnical and usability perceptions of users who experimented with scenarios together (and sequentially) with the proposed blockchain-based EPR. We organized two FGs for this aim, each with four different stakeholders representing the respective roles addressed (which will be detailed ahead of time) by our artifact. The first FG occurred on 02/06/2021 and lasted 100 minutes, while the second was on 04/06/2021 and lasted 112 minutes. Eight participants contributed to 212 minutes of discussion, accomplishing 32 transcription pages (Arial font, size 12).

We prospected participants through LinkedIn (containing experts with specific roles), Instagram (sending direct messages to those who have yet to answer us on LinkedIn), and a professional network of authors. We sent invitations individually by email to the available participants, consisting of a brief description of the project, the data collection stages, and the FG's estimated duration. Table 1 summarizes the characterization of the participants, evidencing their background and roles in this study.

Due to the social distance imposed by the COVID-19 pandemic, we used the Google Meet[2] as a video-conference tool to conduct each FG remotely. We did not find significant damage, as 1) the user's physical reaction could be observed through the webcam, 2) the interaction with the artifact could

Table 1. Characterization of Participants.

	ID	Age (years)	Highest Degree	Graduate Course	Occupation	Experience (years)
FG1	P1	24	High School	Computer Science	Operation Support	-
	HP1	25	Bachelor Degree	Medicine	Doctor	1
	HI1	29	Master Degree	Nursing	Scholarship	7
	ML1	32	Specialization	Biomedicine	Biomedical	2,5
FG2	P2	27	Bachelor Degree	Computer Science	IT Supervisor	-
	HP2	40	PhD	Medicine	Doctor Professor	16
	HI2	35	Master Degree	Nursing	Urgency and Emergency Cell Advisor	14
	ML2	25	Bachelor Degree	Biomedicine	Biomedical	1,5

be noticed through screen mirroring, and 3) the group discussion could be synchronous. The first author of this study acted as a moderator in each FG, seeking to encourage positive or negative comments rather than having a position of power or influence (Krueger, 2014). Extensive and descriptive responses were also encouraged in line with the good practices (Boyce and Neale, 2006). The FGs followed the 5-step process in Figure 3.

In **Step 1**, the moderator (the first author of this paper) overviewed the study's procedures to the participants. Participants read and signed the informed consent form to consent to participate in this research and fulfilled a background characterization form (**Step 2**). Subsequently, we carried out the FG itself in two sessions (**Step 3** and **Step 5**, respectively). In **Step 3**, we explored the current use of EPRs to understand their general perceptions of the processes, privacy issues, sharing, benefits, and information losses using current EPRs (paper-based and non-blockchain-based). The questions were related to how the current communication and collaboration occur between a medical team and how they handle information from different parties.

In **Step 4**, the moderator presented a brief explanation of the blockchain technology and the proposed solution, including a basic workflow composed of four scenarios derived from the current Brazilian standards for EPR (BRASIL, 2002b). We guided this explanation with a slide presentation, allowing the participants to comprehend fundamental concepts and clarify doubts. As all the participants declared to understand the proposal, they sequentially accomplished the workflow according to their respective roles. These tasks were based on the four scenarios presented in Figure 3 and were detailed in our repository (Soares et al., 2024). In addition, we used Participant Observation and Think-Aloud (Cooper et al., 2004; Rubin and Chisnell, 2008) to manifest whatever came into their mind as they completed the task.

After each participant interacted with the EPR, the moderator retook the FG to discuss the user's experience with the blockchain-based EPR in the **Step 5**. We elaborated guiding questions to empirically uncover the perceptions of the participants about two significant lines: i) the communication, co-

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[2]https://meet.google.com/

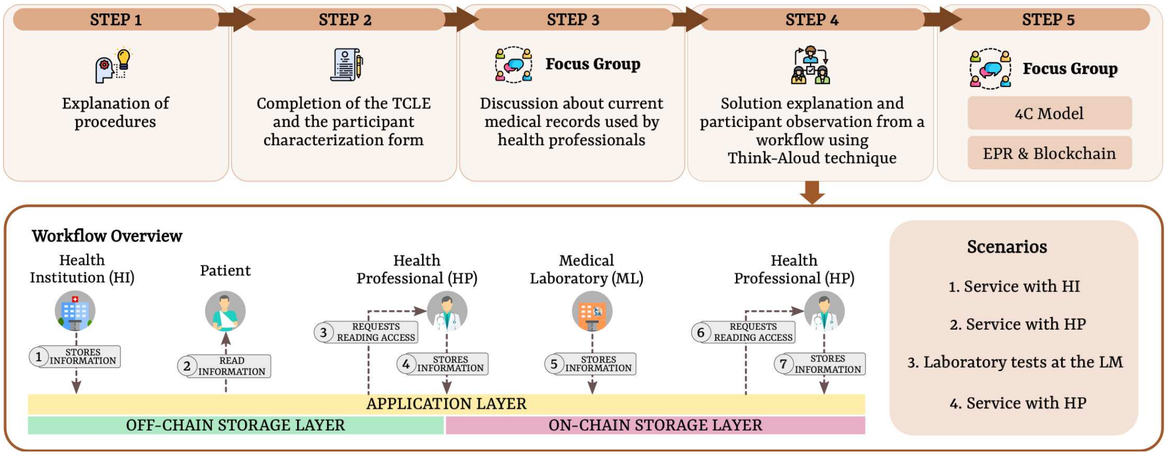

Figure 3. Focus Group Planning.

ordination, and cooperation constructs outlined in the 3C Collaboration Model (Fuks et al., 2008); and ii) the blockchain-based EPR as the *used technology* to empower collaboration. The questions aimed to evoke discussions about how the proposed solution can improve the cooperation related to the patient's diagnosis, what critical aspects can be mitigated through blockchain-based EPR, and the perceptions regarding the view of the patient. The second group of questions covered data privacy, access control, immutability, and the availability of medical records when using blockchain-based EPR. Documents used on all phases are available on the repository (Soares et al., 2024).

4 Suggestion and Development: Proposed Blockchain-based EPR

As stated in Resolution Nº. 1638/2002 from the Brazilian Federal Council of Medicine, "the health institution and doctor is responsible for keeping the medical record". This resolution also prescribes that outpatient clinics, infirmaries, and emergency services must adequately treat patients' health data. Given this scenario, we generalized and identified four primary roles: Patient (P), Health Professional (HP), Health Institution (HI), and Medical Laboratory (ML). In this way, we considered a typical healthcare workflow in which all these roles interact.

Medical data are generated in different formats and from several sources, and when associated with a patient, this data mirrors their clinical history. In line with the current Brazilian regulation (BRASIL, 2002b), a patient record requires a minimum set of information that must be completed, such as complete identification of the patient (name, gender, date of birth, mother's name, place of birth, and address), anamnesis, physical examination, and additional tests with results and/or diagnostic hypotheses and prescribed treatment and daily evolution of the patient. In addition, the health professional must have a legible name and signature.

We created an illustrative figure visually representing the software architecture, as shown in Figure 4. Hence, this architecture proposes a generic digital asset called `Record` to represent the data from the patient record. We defined the attributes that compose this digital asset, considering the participants who will handle it and the type of record. Also, our study follows the features of the Fast Healthcare Interoperability Resources (FHIR) for modeling records to facilitate a complete integration in the future. This pattern describes formats, data elements, and APIs for exchanging health records. In this regard, this study aims to address semantic and technical interoperability to promote the ability of heterogeneous and distributed systems to work together, sharing information with a mutual understanding of its meaning. Therefore, the tables in the database are inspired by a subset of these features (FHIR, 2019), which are:

- *Patient Resource*: provides patient information;
- *Practitioner Resource*: covers individuals involved in healthcare and their responsibilities;
- *Medication Administration Resource*: details medicine and vaccine administration;
- *Observation Resource*: central for diagnosis and progress monitoring;
- *DiagnosticReport* and *Media Resources*: present comprehensive investigation results and;
- *QuestionnaireResponse Resource*: captures responses to diagnostic inquiries.

As shown in Figure 4, the `Record` is primarily composed of the `recordID`, `patientID`, `heID`, being the last two attributes references for the patient that holds the information clinics and the Health Entity (HE) that registered the `Record`, respectively. In this case, HE refers to HP, ML, and HI. In turn, record types (based on the FHIR features) are represented by the `recordType`. For example, the `recordType` indicates whether the `Record` is an Anamnesis, Exam, Observation, or Medication. For each resource type, specific attributes would demand the creation of new attributes to cope with each type of record stored. For example, the Medication type record must be recorded, such as dosage, daily frequency, and other information. Finally, the `media` is the file generated from the compilation of information (*e.g.*, the result of a laboratory exam). We recognize the existence of an extensive list of FHIR-based resources (FHIR, 2019). Despite posing as restrictive, we selected only a subset of attributes matching a generic healthcare workflow that would be useful for experimentation.

Following a layered pattern, our architectural model is

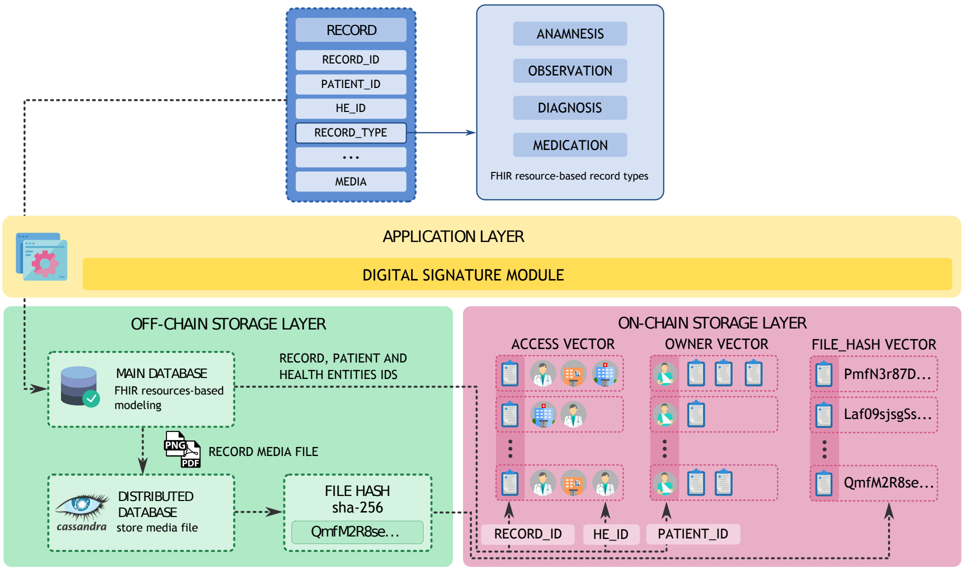

Figure 4. Overview of the Software Architectural Model.

based on two storage strategies using blockchain technology: on-chain and off-chain. As defined by Shukla and Samet (2020), on-chain storage refers to all raw data stored in the blockchain. In turn, an off-chain strategy is related to outsourcing raw data storage outside the blockchain with pointers and/or references stored in it. Figure 4 overviews our software architecture model.

The **On-chain Storage Layer** refers to the information and operations stored and performed on the blockchain. Initially, we implemented a smart contract using the Solidity language, which stores references from each patient's records to associate them with ownership of such documents. The `RecordControl` smart contract performs functions related to the storage, such as the inclusion of the owner to the record, the inclusion of users or entities that can access a private record, and the search and removal of a record by ID. In general, the smart contract stores references of each stakeholder in the network that may have access to a patient's record.

Our approach also covers an **Off-chain Storage Layer** of medical record-related data to maintain the privacy of sensitive data and mitigate concerns about blockchain scalability limitations. In other words, through the `Record`, the On-chain Storage Layer stores pointers to the full-content records in the Off-chain Storage Layer, which consists of a Traditional and a Distributed Database. The `Record` inserted in the network through the Application Layer is stored in the Main Database, which is represented by a table containing the attributes (columns) shown in Figure 4. The `Record` has `heID` and `patientID` as keys (identifiers) that relate the medical record to the tables that represent the health entity that inserted it and the patient who holds the clinical information. In turn, the media file generated or attached to the registry information is stored in a Distributed Database (in our case, Apache Cassandra). The Off-chain Storage Layer converts the media file to a hash using the SHA-256 algorithm, which will be stored in the On-chain Storage Layer. Consequently, the hash will be stored immutably in the blockchain. This technique allows future integrity checks of the original `Record` stored, serving as its 'fingerprint'.

Finally, the **Application Layer** has an interactive interface between the user and the On-chain and Off-chain Storage Layers. Thus, it is possible to make requests to the stakeholders and other further features to satisfy the requirements, such as using a digital signature. This layer enables other parties to access data from blockchain storage. In other words, it allows the Patient, HP, ML, or HI to interact with the application through the following operations: (i) Insert Record, which enables the participant to send a Registration to the network. Only the HP, ML, and HI can insert a `Record` since only these entities are legally responsible for issuing these documents; (ii) Read Record allows the HP, HI, ML, and Patient to read a Network Log. In this case, this request returns the clinical data for viewing; (iii) Authorize Access, the Patient grants access to a specific Record for the network's HP, ML, or HI. In this case, a third party will not choose to view the record. The Patient himself has the exam history list and will release the one that best suits the current situation to the doctor. The Patient can also disallow the reading of a `Record`, and (iv) Digitally Sign allows the doctors to carry out their digital signature of the documents they registered.

This last feature is performed through the *Digital Signature Module*, which adapts the proposal to the security requirements of current regulations. It allows health information in electronic media to be issued with the same legality as physical media documents. The legality of these signed documents must follow the specifications of the Brazilian Public Key Infrastructure (Infraestrutura de Chaves Públicas Brasileiras - ICP-Brasil, in Brazil), a hierarchical chain of trust that enables the issuance of digital certificates for the virtual identification of the citizen (GovBr, 2022).

Due to space constraints of this paper, we provide details of all layers, including the development of Off-chain and On-chain Storage Layers and the presentation of the interface screens for our PoC of blockchain-based EPR and its source code, on the supporting webpage of this research (Soares et al., 2024).

5 Evaluation

Regarding the data analysis, the (1) **audio transcription** produced 32 pages of transcripts, and after reviewing them, the (2) **open coding** resulted in 22 codes. We used thematic coding to identify the codes considering perspectives involving the 3C Collaboration Model and blockchain-based EPR. Then, the (3) **axial coding** step identified 17 sub-themes, and (4) **merge results** steps aggregated them into four main themes. In Table 2, we overview the four themes and 17 subthemes in which FG1 and FG2 discussed 88.3% of all subthemes found in each, and FG2 discussed 86.6% of the subthemes that FG1 addressed. Therefore, we observed a convergence in the results shown by both groups. These results evidence considerable reliability, which may have been impacted by the realities experienced by professionals in current health systems.

Based on the participants' speeches in the first FG session, we identified current challenges in using traditional EPRs (Section 5.1). Subsequently, from the second FG session to analyze our proposed solution, we gathered discussions on user perceptions regarding usability and collaborative aspects (Section 5.2), as well as the considerations of using EPRs based on blockchain technology (Section 5.3).

5.1 Current use of EPRs by health professionals and patients

Figure 5 summarizes the primary considerations concerning the current use of EPRs. One of the main drawbacks reported by the participants was the **lack of completeness and interoperability of information between different entities**. Regarding the entirety of the information, participant HP1 said that "never has this completeness registered, because I do not know what the other professional does [...] I did not see the evolution of patients or another regional hospital". Hence, it impairs the understanding of patient evolution. HP2 clarified that this challenge had been mainly in Brazilian public institutions since some information is more accessible in the private health system.

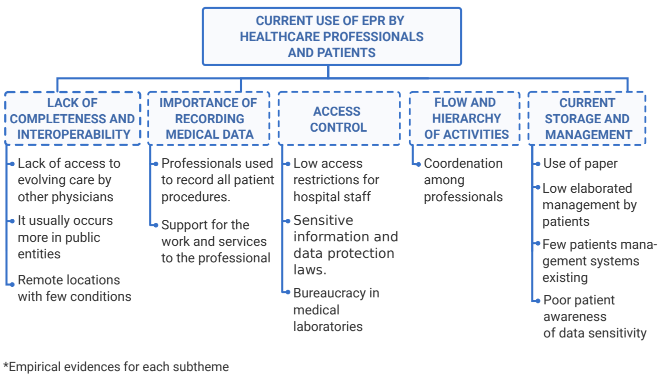

Figure 5. Overview about current use of the EPRs.

Moreover, there is a considerable effort to integrate data among entities and promote interoperability, as not all institutions use EPRs, and the health entities are usually in remote locations. Hence, this issue can harm communication among health professionals, as weighted by HP1: "We have difficulty forwarding data to another unit, precisely for this reason, because there is no integrated online system, and it makes communication very difficult".

This scenario imposes another necessary action related to the **importance of recording medical data to health professionals**. They are trained to write down all the procedures carried out with the patient to facilitate data sharing among professionals. Therefore, besides promoting the recording of patient information for proper health management, it also acts as a supportive tool for the professional's work. As HI1 mentioned: "the way we prove our service and what we are doing with the patient is from the record's annotation". Hence, even with much information being recorded, there must be effective ways to integrate it between professionals and institutions to mitigate the interoperability challenge.

In contrast, the patients' data availability in the current EPRs can raise several concerns about privacy and **access control by the patients to health professionals**. For example, to what extent does the patient have control over their medical data stored by healthcare entities? Covering this issue, HP1 mentioned that "there is no privacy for those who work at the hospital" and "professionals have access to data, for example, from what other doctors write in the medical record". At the same time, HP2 compared this Brazilian scenario to other countries, where only doctors can access records. Despite the importance of proper data sharing, fair access control of the data should also be necessary to comply with the requirements established by the Brazilian Data Protection Law. Also, proper access to information has been more bureaucratic and less common from the perspectives of ML1 and ML2.

Our findings showed that the current EPRs must also deal with the **flow and hierarchy of activities among health professionals to the patient records**. Depending on the processes, there is a specific 'coordination' of activities among health professionals. HI2 said that it must be possible to analyze the evolution of the patient in the context in which the doctor prescribes information to another doctor or nurse. The healthcare professional must act as prescribed throughout the day. In case of change, they would inform other professionals to carry out the activities correctly.

Another emerged discussion was about the **current storage and management of records by patients**. Despite the advancements in EPRs, paper-based records are still widely used, as confirmed by P1 and P2. For example, P1 said: "[...] I still keep the envelope because wherever I go, in health issues, I keep taking it". Also, we observed that their records are still not being completely managed. P2 mentions that s/he does not have a detailed method for managing all their records. For instance, s/he keeps their vaccination card. However, s/he only retains documents related to exams for a limited time before discarding them. Hence, these reports show us that: (i) patients may lose relevant medical information, leaving a particular 'gap' in the record of their medical history; (ii) there are still few systems that allow patients to manage their information and access control with whom they will share it; (iii) low awareness by the patient about the proper control of their sensitive data.

Table 2. Occurrence of Subthemes in Focus Groups

Theme	Subtheme	Occurrence in FGs	
		1	2
Current use of EPRs by health professionals and patients	Lack of completeness and interoperability of information between different entities.	✓	✓
	Importance of recording medical data to health professionals.	✓	✓
	Access control by the patients to health professionals.	✓	✓
	Flow and hierarchy of activities among health professionals to the patient records.		✓
	Current storage and management of records by patients.	✓	✓
3C Collaboration Model	Sharing and viewing patient information by professionals.	✓	✓
	Availability of medical records and prevention of information loss about the patient's segment.	✓	
	Awareness of health professionals and interprofessionalism among them.	✓	✓
Practical adoption and enablers of a blockchain-based EPR	Immutability, traceability, and information auditing increase security for all parties.	✓	✓
	Changes to the information within the medical record.		✓
	Access and availability of information.	✓	✓
Lessons learned and opportunities	Patient access control and the LGPD.	✓	✓
	Technology adoption barriers.	✓	✓
	Integration with automated systems.	✓	✓
	Medical care levels.	✓	✓
	Service Quality.	✓	✓

5.2 Analysis of the 3C Collaboration Model

Figure 6 depicts our findings about the 3C Collaboration Model evaluation. Given the discussion about **sharing and viewing patient information by professionals**, the participants highlighted positive feedback about how the solution could improve communication among health professionals based on patient data sharing. For example, HP1 informed us that it would be much easier to mitigate patient information loss if blockchain-based EPR were 'widespread' among providers. The only way to get evidence of successful communication is through speech and the actions and reactions of the receiver (Costa et al., 2014). Therefore, patient data loss can compromise communication between health professionals as the data may not reach the receiver properly. On the other hand, access and sharing of information speed up care and enable the exchange of information between doctor-doctor and doctor-patient (Mourão and Neves, 2007). Blockchain could facilitate this communication to mitigate data loss due to its distributed storage persistence.

In addition, HP2 emphasized that the solution: '[...] greatly aids the team as this interaction comes with the right dialogue.' HP2 also highlighted the importance of structured records in the EPR. As presented in Section 4, our proposal follows the FHIR standard for EPR implementation. This integration can contribute to organizing medical information, for example, in filling out the 'Anamnesis' form. Thus, semi-structured forms can improve interoperability between systems with standardized record structures. PS2 pointed

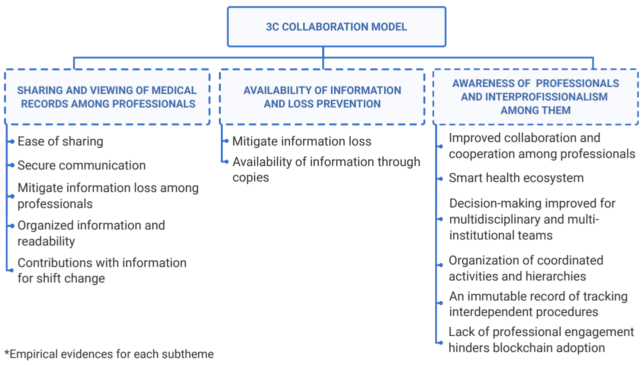

Figure 6. Overview about the 3C Collaboration Model insights.

out that another recurring issue is the doctor's handwriting, which is often illegible.

Hence, proper communication could also improve the 'shift handover' that occurs when healthcare professionals draw up the patient's care plan in the team's first communication, being one of the most critical moments of the day in the service (Schorr et al., 2020). This topic has been investigated in the literature since an adequate organization to share patient information among the medical team can facilitate the diagnosis. According to HP1, this proposal can help a professional to know another professional's opinion on diagnoses or what procedures should be done on the patient, for example. ML1 informs that the solution can improve access to patient information among different laboratories by demand. Thus, the solution can direct the analyst "when s/he will review the exam".

We noticed that this solution could also promote the *availability of medical records and prevent information loss about the patient's segment*. In this regard, HP1 emphasized that patients often forget important clinical information and frequently misplace or lose their exam records. However, since the information is available in several 'replicas' through the blockchain, this mechanism would facilitate communication between the patient and the doctor. If the patient lost some records, s/he could retrieve their information from other replicas distributed on the ledger.

Besides, the discussion led to a theme beyond the use of technology *per se*, which is the **awareness of health professionals and interprofessionalism among them**, which fosters effective cooperation and collaboration in managing medical data. The participants' speech brought this finding: "If this use is widespread, and the doctors are aware, I speak for my area, to put the data right in this system" (HP1) and "[...] helps a lot in this communication issue. However, unfortunately, because health professionals can still not act on this issue of interprofessionalism, which has always been urgent, I believe it". Interprofessionalism can be understood as a relationship of interdependence within a work environment, which requires collaboration among the agents composing that service in pursuit of a common goal (Araujo, 2021). It becomes clear that interprofessionalism depends on collaboration among professionals in handling medical data to develop work for the patient's health.

Moreover, some flows present coordination through predefined orders and hierarchies of activities according to the workflow of this proposal, as seen in Section 5.1. This feature aligns with what Fuks et al. (2008) states regarding coordination, a pillar where "the management of the tasks being carried out consists in managing interdependencies between tasks that are carried out to achieve a goal". For example, HI1 stated that a doctor can prescribe information to a nurse to perform procedures as defined. Coordination can also present interdependence of activities, meaning that the team is mutually interdependent. Our evaluation allowed participants to simulate activity coordination by executing steps. Each participant carried out their specific activities in such a way that their action influenced the actions of others. These activities can be found more on the support page (Soares et al., 2024).

In summary, HP had access to what the HI and ML had registered according to the scenario. In turn, HP performed its last activity based on the information contained in the previous records. In this way, it is possible to follow the order of the procedures being performed with the patient. The lack of assessment of the level of engagement among stakeholders in the current structures and the lack of cooperation, communication, coordination, and collaboration is one of the main obstacles to adopting blockchain in healthcare (Dhagarra et al., 2019). Therefore, our findings contribute to the literature by advancing the understanding of how blockchain may contemplate the 3C Model when integrating it with EPRs.

5.3 On the practical adoption and enablers of a blockchain-based EPR

As depicted in Figure 7, this section discusses the technical features users perceive that make blockchain-based EPRs viable.

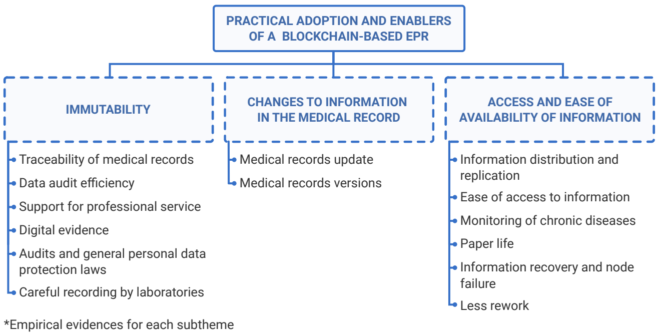

Figure 7. Overview about Blockchain-based EPR insights.

We verified that the **immutability, traceability, and information auditing increase security for all parties**. A relevant benefit enabled by blockchain is the traceability of actions in the patient's records provided by immutability, which can improve the efficiency of data audits, for example. In this regard, HI1 mentioned that immutability "guarantees patient safety and professional performance [...] Because the record is information. It is the support of their work". HP1 endorsed this argument by saying that the professionals would also 'protect' themselves with this resource.

HP2 clarified that errors could occur on both sides (*i.e.*, health professional and patient): '[...] sometimes there is a problem. The patient can say that s/he informed something, and it is not registered, or the opposite. The doctor says it is registered and has not been written there. Thus, the immutable information would be complex for someone to disagree with the records and procedures performed as the structure of interconnected blocks arranged chronologically and cryptographically. In particular, this solution is relevant to situations that have irregular behavior. In this way, the technology would be used to appeal in court, as mentioned above by HP1. The literature endorses this statement by presenting works that use so-called 'digital evidence' (Petroni and Gonçalves, 2018), which can now be registered on blockchain and retrieved for use directly in judicial bodies (Liu et al., 2019).

HI2 said that private hospitals usually conduct audits of the information, looking for wrong prescription records or "out of context". In that case, they identify errors, make corrections for the right version, and apply fines depending on the case (HI2). The use of blockchain would ensure greater security and complement existing audits. Specifically, data protection laws and health guidelines may establish formal requirements related to audits by responsible institutions. ML1 stated that laboratories would be more cautious in recording their results through immutability.

The participants also discussed the contrast between the immutability and the possibility of **updates to the information within the medical record**. In this case, it could happen if any reported error needs correction. For instance, HI2 informed that the "professional can change a certain issue within the medical record, the doctor prescribes it, a nurse schedules". Although the scope of the PoC of blockchain-based EPR in the present study does not allow modifications to the same document, it is possible to implement new functionalities to generate new versions with each modification of the record while maintaining the history of previous records. HI2 also highlighted that "every change that is performed, it has to be linked to the access password to that professional's credentials, right, because then he entered his access password, s/he changed it, and s/he is ethically responsible for the modification".

Our proposal can include this feature because the identifier of each professional who records the data is linked to the identifiers of the medical records. Additionally, each record is added chronologically and cannot be altered. However, we recognize security issues in this version of our PoC. As blockchain records are public, an attacker could observe transactions to collect valid identifiers of healthcare professionals and potentially use them in unauthorized access attempts. Since healthcare systems are particularly critical, future features are needed to add extra security mechanisms to mitigate such risks. However, this issue is not too problematic for this study, given that the main objectives of this study focused on evaluating sociotechnical aspects and collaborative characteristics of blockchain-based EPRs through a proof-of-concept implementation.

Furthermore, we have framed this artifact as a PoC, an initial implementation to demonstrate feasibility and gather user feedback rather than a production-ready system. In this direction, future work should advance this PoC by ensuring that professional credentials are adequately protected without compromising the traceability and auditability offered by blockchain.

We also analyzed the **access and availability of information** as another important subtheme raised by the participants, mainly because of the distribution and replication of data among blockchain nodes. P1 emphasized that the solution helps access information, as "regardless of what happens, it will be available to other network members. Then, even if I am not accessing there, it has registered". For HI1, this solution may be attractive to patients who are interested in always having their information, such as people with chronic diseases who require medical assistance. They could benefit from blockchain-based EPR to track their evolution on immutable records.

HP2 discussed that data availability is essential to prevent patient information loss and considers it a mechanism to increase security, given the importance of registered information. HI1 said there is much information loss, especially when medical records are on paper. HI2 emphasized that "this digital record is important [...] for example, after ten years, in the SUS[3] you no longer need to have this record on paper, the paper can be eliminated, it can go to an archive, so that will change, right, when I have this record". Information can still be lost or deleted when we use EPRs with traditional databases, while blockchain-based EPR allows data to be permanently recorded on the network.

[3]SUS (Sistema Único de Saúde, no Brasil) is the name of the Brazilian public health system created by the Federal Constitution Brazilian 1988.

Blockchain provides information availability because we can recover data from other replicas even if a node fails. Thus, there is no single point of failure as in traditional and client-server systems, where information is generally stored only on a central server. For example, HI1 recalled that s/he had to make handwritten notes of information in the system during the day. Still, everything that was noted would have to be entered into the system when it started working again. The emphasis of ML2 is in line with the same thinking about information availability, data loss, and possible rework: "I think this possibility is very good, you have your data in different places, and there is no dependency, and you do not have the record of just one and having to do it all over again".

5.4 Lessons learned and opportunities

From user testing with PoC of blockchain-based EPR, solution explanation, and brief technology concepts, we discuss some lessons learned and opportunities shown in Figure 8.

Patient access control and LGPD was one of the relevant subjects discussed by patients and healthcare professionals. In the patient's opinion, access control is an inherent capability due to the security and privacy of data enabled by blockchain. P1 raised the requirement to allow or deny access, which is an essential step in improving the security and privacy of patient data. However, excessive access control by patients can hinder the actions of healthcare professionals who do not have access, for example, in emergencies. Although blockchain is beneficial, some participants raised concerns about patient access control if they are not in ideal conditions to handle the solution. For example, HI2 presented the following scenario: "[...] suppose that P2 has not authorized anyone to look at their data, then suddenly they are in the emergency room, they take dipyrone and have a seizure, right? I do not have their medical history because they did not authorize it". In this solution, the patient fully manages their data and can choose who authorizes or denies viewing it. In particular, this blockchain-based EPR can be especially complex in emergencies, making it difficult for professionals who have not yet been authorized to access retrospective records. Thus, these circumstances complicate the "control around the patient and the conduct to be taken" (ML2).

ML2 suggested that a viable solution to the presented problem could be introducing additional rules and new smart contracts to address administrative issues. For example, the HI performed tasks similar to the HP in this experiment. However, we can extend the functionality of the HI to cover more rules and institutional requirements, making it capable of managing the PS working within it. Thus, all HI professionals can access the patient's medical records if s/he authorizes access control to their information. Another solution suggested by ML1 was the possibility of formal terms being sent to the blockchain, ensuring that an HI has authorization to access patient records. Furthermore, recording terms on the blockchain can ensure that patient decisions are shared with the multidisciplinary team and allow greater freedom of access for healthcare professionals to act in emergencies.

Another scenario discussed by the participants was regarding the **technology adoption barriers**. P2 highlighted the difficulty of dealing with technology and observed two chal-

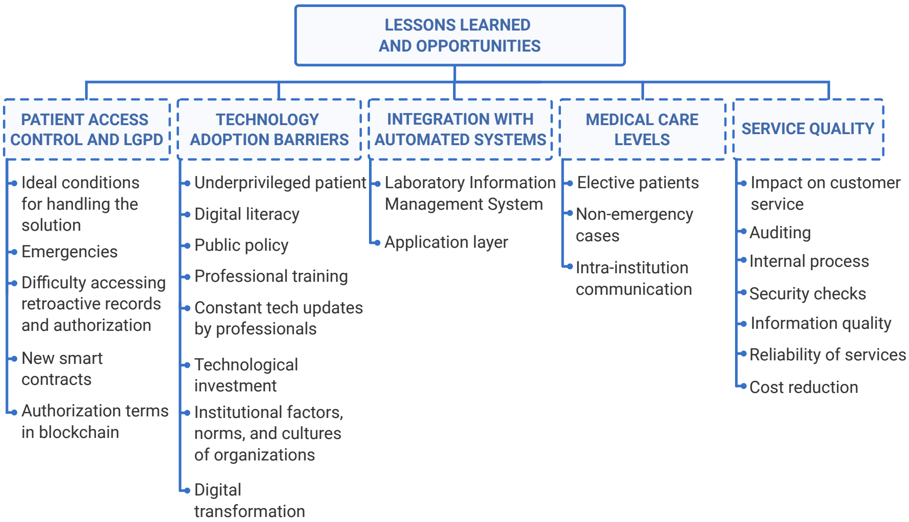

Figure 8. Overview about Lessons Learned and Opportunities insights.

lenging scenarios: 1) the patient can be unconscious, and 2) the patient can be conscious but does not know how to use and work with this technology. HP1 emphasized that "not all patients will understand this flow", especially in the case of "extremely poor patients who lack access to education".

In particular, this challenge may be related to the concept called 'digital literacy', the lack of formal literacy of some citizens that hinders their digital inclusion in society (Reddy et al., 2020). This problem requires effective public policies so citizens can take advantage of recent innovative technologies, which must be applied to patients and professionals. Therefore, HI1 endorses the necessity of resources for professional training and healthcare team empowerment to ensure the proper utilization of this record. Thus, professional effort and constant technological updating are fundamental as information in an organized hospital environment is the foundation of patient care management (Passos, 2019).

Petroni and Pfitzner (2021) present a specific example of the surgery scheduling process within the SUS to demonstrate how blockchain technology can enhance the efficiency and transparency of the system. The current process involves patients waiting in a virtual surgery queue without knowing their position, which is susceptible to political interference, causing delays among patients. In contrast, the process could be significantly improved with a blockchain network as doctors could suggest surgery and schedule a date for the patient on the SUS platform, which would be immutably stored in a smart contract. Patients could then view their position transparently. Using smart contracts would eliminate the possibility of political interference, leading to a fair and transparent system for all patients.

Still addressing the implications of digital transformation, P1 emphasized that the solution presented can solve this problem. However, the solution may not be perfect even if it is invested heavily from a technological point of view. Blockchain adoption still presents several challenges involving institutional factors related to organizational norms and cultures, existing laws, including governance (Janssen et al., 2020). Furthermore, quality infrastructure and adequately met technical requirements are fundamental for implementing the technology, as the satisfactory progress of the digital transformation also depends on quality infrastructure (Silva Brognoli and Ferenhof, 2020).

Additionally, we acknowledge that the way ML records occurred in the solution workflow was limited. Besides the EPR, there are Laboratory Information Management Systems (LIMS), systems applied to various types of information in analysis and different laboratory tests related to chemistry, hematology, and molecular biology, especially sample analysis (Lv and Yu, 2022). The implementation of LIMS was not the focus of this study. In this regard, participants suggested using blockchain-based EPR for **integration with automated ML systems**, such as LIMS. As reported by ML1, they typically "[...] send these results to the interface server, and the server retrieves them from the patient and sends them to the hospital system". Therefore, it becomes feasible to integrate LIMS into our solution through the `Application Layer` modules, designed to communicate with external APIs. The results generated by LIMS could be added to the `On-chain Storage Layer` and `Off-chain Storage Layer` (with their respective permissions) after the processing of the analyzed biological samples.

Professionals said that the use of this solution depends on the **medical care levels**. ML1 considered that the blockchain-based EPR is ideal for elective patients who undergo scheduled medical procedures. This caution arises from the need for mechanisms to handle emergencies regarding "intra-institutional" actions due to excessive permission to access patient data.

Additionally, we discussed the **service quality** that the use of blockchain provides to EPRs. Immutability is one of the main advantages of the blockchain, as it provides traceability and auditing of information. This feature influences the quality and integrity of data, the reduction of manual errors (Larry, 2021), and the quality of processes. As discussed by Zhang et al. (2019), blockchain implementation in healthcare can significantly impact other areas, such as customer service management, internal processes for quality assurance, safety checks, or external partnerships.

ML1 suggested recording access to a specific prescription to improve information auditing. For example, each professional access to a patient's medical record would be stored on the blockchain, as ML1 considers: "[...] we can audit that and see who was the last person to access it". An initial requirement in our solution is the chronological insertion log, as each record is stored with date and time. Additionally, the user who accessed a record can also be registered for future reference. ML1 emphasized that medical laboratories would be more careful than they already are in processes where records are immutable. These characteristics allow patients to perform necessary checks on their procedures, even in cases of potential errors. ML1 also reported witnessed cases where a laboratory erroneously recorded conclusions about the patient's health. Therefore, they considered that this solution would "force" the laboratory to pay proper attention to the process. In this respect, blockchain in healthcare can improve the quality of information, as stakeholders can access complete data, increasing reliability and patient satisfaction due to data auditability. From an institutional perspective, immutable systems with timestamping can enhance organizations' auditing and reporting capabilities.

6 Discussion

First of all, we can argue that the current *communication challenges* among health professionals and institutions may be partially derived from the lack of completeness and interoperability of data. In line with this, Esmaeilzadeh (2022) emphasized that using incomplete, duplicated, and inaccurate data could affect continuity throughout the patient care process, given the quality of data in the Health Information Exchange (HIE) databases. As we discussed, specific situations such as the lack of data standardization and public health entities' technological precariousness can intensify this challenge. Murphy et al. (2021) also mentioned that a province's disjointed system could create a significant data-sharing barrier.

Regarding *privacy of information*, we noticed a gap in elaborated restrictions on the privacy of patient data. Reinforcing this discussion, medical records could be manipulated or removed by any entities in HIE initiatives, posing a critical risk to the reliability of HIE databases (Esmaeilzadeh, 2022). On the other hand, countries such as Canada have defined a complex set of permissions related to accessing information due to past experiences with privacy violations (Murphy et al., 2021), and policies and training processes were implemented so that professionals could manage data correctly.

Another finding is that patients are not sufficiently aware of the *management of their medical information*, which is still widely recorded only on paper. We verified the participants' low level of care related to their sensitive data. This fact is also underpinned by Lee et al. (2020), which exposed that the group of patients investigated did not have concerns about the leakage of health information. The authors also enlisted considerations of why this phenomenon can occur, such as i) the patients tend to trust hospitals and medical doctors in South Korea, ii) there have been few accidents of health care information leakage so far in South Korea, and iii) patients are unaware of the risks resulting from the leakage of health data. Of course, patients' behavior regarding their trust in health entities may vary for each country. For example, Brazil and South Korea have considerably different socioeconomic realities, as well as when compared to Canada, earlier discussed by Murphy et al. (2021).

About *3C Collaboration Model* (Fuks et al., 2008), participants reported that our solution could facilitate the sharing and visualization of medical information between them. The blockchain could enable secure communication, mitigate information loss of records, and promote collaboration, information organization, and readability. This issue brings a discussion toward an interoperable structure for collaborative healthcare systems. In the work of Esmaeilzadeh (2022), 71% of respondents said that the blockchain could enhance collaboration among various entities in the healthcare industry. The more systems are decentralized, the greater the need to improve interoperability between them. Hence, our results argue that professionals' individual and collective awareness promotes interprofessionality and improves collaboration and cooperation for better decision-making.

The decentralization and data replication across multiple blockchain nodes increases the *availability of information*. As each node in the blockchain has some responsibilities, such as reading, writing, and entering information, it is possible to review the history of interaction between healthcare professionals and patients in real time (Esmaeilzadeh, 2022). Considering the software development perspective, a large amount of data should not be stored on the blockchain as it can cause a significant speed decrease (Lee et al., 2020). For the technical respondents from this study, it is appropriate for real data to be stored at each institution. At the same time, data generation, research, and exchange must be allowed via blockchain. Indeed, multiple scenarios caused by the intrinsic characteristics of blockchain must be weighted when dealing with a large amount of data. For instance, patients' data might not be processed (including genomics, critical organs, etc.) when blocks exceeding the size limit are rejected. Another challenging scenario would be the high volume of information in large-scale situations that can lead to an 'information overflow', performance degradation, and high latencies, making it even impractical (Mazlan et al., 2020).

In our study, we interpreted that the *coordination* was performed when the stakeholders executed the activities hierarchically and orderly. From this perspective, we found that blockchain could ensure the traceability of activities by recording process information chronologically and imminently. Reinforcing this finding, Esmaeilzadeh (2022) stated that 'coordination of care' can also impact and overcome interoperability conflicts between entities and professionals who share interdependent activities. Consequently, this problem should affect the 'relationship of trust' between the entities involved. However, although blockchain presents itself as a prominent solution to problems related to lack of trust, it is essential to engage stakeholders so that the technology is effectively adopted (Dhagarra et al., 2019).

Different implications also emerged on the *interplay between EPRs and blockchain*. For example, we can highlight 'data immutability,' one of the most discussed issues, which enables the traceability of medical records, increases efficiency in future audits, and generates digital evidence to support medical doctors and patients. According to the study of Esmaeilzadeh (2022), 76% of the respondents mentioned that immutability might benefit data integrity, data integration, helping with data storage and aggregation, and data consistency. Moreover, as data immutability improves data integrity, it can also enhance decision-making by professionals because of achieved data quality.

Although our blockchain-based EPR implementation addresses immutability and access control as *security aspects*, we acknowledge that additional security levels must be explored in future work. As presented, an important concern is the potential exposure of professional identifiers through the public nature of the blockchain, which could allow malicious actors to harvest valid credentials for unauthorized access attempts. Despite this proposal's current linkage of professional identifiers to medical records, a more robust security framework is needed to protect against credential harvesting and identity-based attacks.

These security enhancements may be necessary before deploying blockchain-based EPR systems in the real world. In this direction, future work would investigate authentication mechanisms and credential encryption schemes as future research, always seeking to maintain blockchain's transparency benefits. Additional mechanisms to blockchain technology, such as rate limiting, anomaly detection, and multi-factor authentication, can mitigate potential security risks.

We also pointed out a set of *lessons learned and opportunities for blockchain-based EPR improvement*. Firstly, patient access control and general data protection laws are vital issues and require proper attention in future work. Participants in this study were concerned about 'excessive access control', considering that complete control by the patient can limit the actions of healthcare professionals during emergencies. On the other hand, Lee et al. (2020) affirmed that patients have a behavioral standard toward their medical data since they usually expect medical doctors to be able to consult their information without their consent. Despite these potential conflicts, our study's participants suggested storing formal terms on a blockchain, granting access to doctors and the complete institution or most of them. The authors also discussed that health professionals could access their information without their consent in an emergency. Specifically, they could share information like rare blood types, allergies, and organ donor information in the system or as needed.

Finally, regarding the *used technology* and the difficulty of dealing with blockchain (and its adoption barriers), we can highlight that underprivileged patients and digital literacy are relevant issues that demand attention. In addition, organizations must adapt their factors, norms, and culture to properly introduce technologies such as blockchain without negatively impacting those involved. Wong et al. (2018) stated that blockchain technology would need to shift from focusing on information to one on 'value' and 'trust'.

7 Related Work

Wong et al. (2018) highlighted blockchain adoption in healthcare as a complex sociotechnical system, emphasizing the need for thorough impact evaluation as the technology matures. The authors underscored the importance of understanding blockchain's value generation and information-sharing potential among stakeholders. Meanwhile, Hollingsworth et al. (2022) explored sociotechnical and clinical considerations for patients with inflammatory bowel disease (IBD), advocating a user-centered approach. These works introduced relevant aspects of adopting blockchain in the healthcare area. However, they did not present empirical experiments, primarily philosophical ones.

Bautista et al. (2022) investigated patient-centered blockchain identity management during the COVID-19 pandemic, focusing on interoperability and patient perceptions through FGs. Lee et al. (2020) examined awareness among patients, healthcare professionals, and developers on blockchain-based Health Information Exchange (HIE). The authors used semi-structured interviews based on the Promoting Action on Research Implementation in Health Services (PARiHS) framework, highlighting concerns about data integrity and patient data sharing. In contrast, our study explores collaborative aspects in multidisciplinary blockchain-based EPR implementation, encompassing diverse stakeholders in healthcare workflows, and emphasizes collaborative constructs instead of information exchange.

Similarly, Esmaeilzadeh (2022) applied the PARiHS framework to explore medical doctors' perspectives on blockchain benefits, focusing on technological features, collaborative ecosystems, and system performance through in-depth interviews. Different from our approach, their study employed individual interviews, possibly missing nuances present in practical collaborative settings. Finally, Murphy et al. (2021) investigated barriers to data sharing in a Canadian jurisdiction and explored blockchain's potential in improving provincial and national information exchange, focusing on regulatory challenges and data access policies.

8 Limitations

We present this study's limitations following the standards for the quality of conclusions indicated by Miles (1994) to qualitative research, discussed below.

Confirmability. The participants representing the patient have a computer science background, which allows them to quickly identify and anticipate the technical perspective due to their previous knowledge. Furthermore, this proposal does not aim to fully address potential security vulnerabilities related to the exposure of professional identifiers through the public nature of the blockchain. Such advances require a security analysis with dedicated research, from implementing new architecture versions to specific experimental configurations to evaluate these vulnerabilities. In this regard, we reiterate the need for future research focusing on robust security mechanisms.

Dependability. As the number of steps, the long duration of the experiment, and the required amount of time to carry out the FG could cause fatigue and jeopardize the participants' engagement, we conducted a pilot experiment to verify the flow of the defined steps and optimize them, eliminating redundant activities. In addition, knowing they are being studied, participants can be influenced during testing due to the Hawthorne effect (McCambridge et al., 2014), generating behavioral change. To mitigate these circumstances, participants received an overall explanation of the approach.

In addition, the FGs were performed remotely (virtually outside a controlled environment), which can affect the participants' answers due to interference, such as noise, configuration, or the influence of the computational environment. To minimize these effects, we previously created and tested the credentials for each participant, then sent an email instructing them to access the platform, including step-by-step.

Credibility. Despite the restricted group, we invited three different real health specialties, presenting a reasonable level of heterogeneity and fulfilling the requirements for executing the proposed health workflow. In this case, several subthemes of the FGs were discussed in both groups, generating a certain degree of convergence. In this case, we observed that themes discussed by the FGs converged as we identified that FG1 and FG2 discussed 88.3% of the subthemes in common, and FG2 addressed 86.6% of them discussed by FG1.

Transferability. The reduced number of participants and FGs can be considered a limitation. The FGs had four participants each to ensure workflow with the stakeholders predefined in the proposal. However, we acknowledge that the number of FGs was limited due to the complexity of gathering a group of healthcare professionals with different specialties, which also represented an important achievement of our work. They represented various specialties, from public and private hospitals and laboratories, with experiences ranging from 1 to 16 years, which generated relevant discussions by sharing their experiences. The optimal size for an FG should allow the effective participation of the participants and adequate discussion of the themes (Pizzol, 2004). About the number of FGs, Debus (1994) suggests at least two sessions for each variable considered relevant to the topic in question or until the information obtained is no longer new.

9 Conclusion

While integrating Electronic Patient Records (EPRs) and blockchain seems enlightening in healthcare, sociotechnical studies are still scarce in the Software Engineering (SE) literature addressing this domain. Given this research gap, we conducted a sociotechnical and user-centered analysis to understand the perspective of healthcare professionals and patients on using a blockchain-based EPR and the role of this technology in meeting their requirements.

We argue that understanding how blockchain technology affects the collaborative work of healthcare professionals and using EPRs is fundamental for advancing the engineering of blockchain-based EPRs. Following a Design Science Research protocol, we developed a PoC of blockchain-based EPR and evaluated it through Focus Groups (FGs) using real-world scenarios and user tests to guide the user tasks.

Our findings clarify that the successful adoption of blockchain technology in healthcare depends on its technical feasibility and sociocultural and organizational considerations. Hence, the sociotechnical approach is reasonably justified in integrating these social aspects into the design and development of blockchain-based EPRs, from requirements engineering to their development and maintenance. Taking a holistic approach encompassing both technical and social aspects, we can reinforce that such systems meet users' needs, comply with ethical and legal standards, and promote positive outcomes for healthcare delivery.

Therefore, our paper provides theoretical and practical contributions to the SE of blockchain-based EPRs by delivering a set of sociotechnical findings that emerged from enriched discussions between healthcare practitioners and patients. These findings surrounded the current adoption of EPR, the application of the 3C Collaboration Model to understand the practical implementation and adoption of a blockchain-based EPR, lessons learned, and opportunities for improvement. Additionally, we detailed a PoC of patient-centered blockchain-based EPR and its software architecture to control data access through storage layers. Valuable implications for patient data security and privacy arise from this proposal, as well as the potential benefits of blockchain in collaborative work and use involving EPRs.

For future work, using the Technology Acceptance Model to determine stakeholders' willingness to adopt blockchain-based EPRs could be useful. Furthermore, other workflows, including new participant roles representing other healthcare ecosystems, could also be investigated.

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