Blockchain Technology in Healthcare: Readiness of Different Types of Stakeholders

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Abstract

With the advent of the Digital Transformation, Healthcare Systems have switched from paper to electronic health records (EMR). However, there are few critical issues related to data governance (e.g., transparency of data, traceability, immutability, privacy and security) that need to be addressed in the upcoming years. Blockchain (BT) is a decentralized digital ledger and an innovative technology with the potential to address such issues.

A pivotal role when implementing a blockchain-based solution, in healthcare as in other fields, is played by the stakeholders involved in the digitalization process, and in their

respective readiness, that can be defined as the availability and capacity of the various stakeholders to adopt the new technology, both individually and collectively.
Readiness represents a factor that affects the correct implementation of blockchain-based solutions and is commonly declined in the literature by means of different dimensions: motivational readiness, engagement readiness, technological readiness and structural readiness.
Readiness is particularly important for those stakeholders who are nodes of the blockchain network, as they have the fundamental role of keeping and exchanging the information necessary for its operations.
However, in the literature we have not encountered any work analyzing the differences between stakeholders that are nodes and those that are not-nodes of the BT network, not only in terms of type but also in readiness.
This work aims at identifying what is the difference between the readiness dimensions of stakeholder-nodes respects stakeholders-non-nodes in BT-based projects applied to EMR and how readiness impacts blockchain-based projects, especially when it concerns the stakeholders that are nodes of the BT network and those that are not.
The chosen methodology is the multiple case studies; three different projects have been selected that use BT in different ways to manage EMRs.
Through semi-structured interviews, it was possible to identify the stakeholders interested in these projects, determine which of these represent nodes of the network and which non-nodes, and identify the different dimensions of readiness that characterize them.

Keywords – Blockchain, Electronic Medical Records, Healthcare Organizations, Digitalization

Paper type – Academic Research Paper

1 Introduction

Digital technologies represent a possible tool to achieve a better healthcare quality (EUR-Lex, 2020). The results of "Digital Transformation: Shaping the future of European healthcare" research performed by the Deloitte Center for Health Solutions (2020), highlighted that the most used technologies in healthcare are connected to the electronic medical record (97% in the Netherlands, 74% in Portugal, 69% in Italy) and the electronic prescription systems (97% in the Netherlands, 13% in Germany, 67% in Italy). Data is, in fact, the core element of this digital transition, which revolutionized economy, society, and health [4]. Through digitalization, healthcare organizations can integrate and improve care, increase quality and make data flow more accessible.

Although there are significant differences among the requirements and objectives of the different digital health systems, there are three main criticalities characterizing most of them.

First, the health structures often use non-homogeneous application architectures, even within their operating units. Moreover, the data extracted from different devices are often heterogeneous and hard to integrate with each other automatically. In this context, obtaining a complete picture of the complete health history of a patient is challenging, and the resulting fragmentation generates inefficient coordination of care, lack of interoperability and potential lack of essential information in case of emergency (Yaeger *et al.,* 2019; Zhang *et al.*, 2018).

Secondly, patient information is generally contained in electronic health records, mainly organized within centralized systems and, for that reason, vulnerable to a single point of failure and information loss, due to natural disasters or information thefts following cyber-attacks (Yaqoob *et al.,* 2021). It's worth recalling that last September, ransomware attack caused a network failure at the University Hospital of Düsseldorf (UKD), which also caused the death of one patient (Ciampanu, 2020).

Finally, current data management systems cannot ensure transparency, reliable traceability, immutability, audit, privacy, and security when managing EMR (Yue *et al., 2016)*.

Blockchain Technology (BT) has the potential to address those issues (Chen e*t al.,* 2019; Gordon, 2019; McGhin *et al.*, 2019; Farouk *et al.*, 2019). It is an extremely innovative technology, able to aid the simplification of health data management operations: on the one hand, it allows unprecedented efficiency and reliability in data management (Islam *et al.*, 2016; Chukwu, 2020; Syed *et al.,* 2019; Esposito *et al.*, 2018), on the other, it offers a wide range of important integrated functions, such as data access flexibility, security, privacy, decentralized storage, transparency, immutability, authentication, disintermediation, verifiability, programmability, interconnection (Omar e*t al.,* 2018; Hasselgren *et al.*, 2020).

BT is, indeed, a decentralized digital ledger that offers the opportunity to record and share information (Hussien e*t al.*, 2019). This data is held on the network through a series of nodes. Any entity connected to the blockchain can be classified as a node. Nodes are a critical component of the infrastructure of a blockchain because they act as further validation for the ledger, allow anyone to transparently view transactions/data conducted or held on the network and their connection is described by blockchain architecture (Hussien *et al.*, 2019). If the nodes involved in blockchain are already known to the network, then the blockchain is referred to as permissioned, such as Hyperledger Fabric (Androulaki, 2018). When a system is open to the public, any individual or organizational node can be a member of the network; hence, this blockchain is referred to as public, such as Ethereum (Founder *et al.*, 2018) and bitcoin (Nakamoto., 2008; Hussien *et al.*, 2019).

Because of these characteristics, BT seems to be the leading solution to address the healthcare critical issues described above. Nevertheless, it is worth noting that the introduction of new and emerging technologies in any sector can give rise to some problems and challenges (Khan *et al.*, 2021).

The literature unison confirms that blockchain requires a strong synergy among the stakeholders (Lee *et al.*, 2012): not only clinical staff, patients, management, but also suppliers and BT experts, need to be put in place. Therefore, when implementing a BT project, it is essential to assess the stakeholders' readiness, i.e., the availability and capacity of the various stakeholders concerning the adoption of the new technology, both individually and collectively (Savage *et al.,* 2010). Specifically, the literature shows that four dimensions of stakeholders' readiness play a pivotal role: motivational readiness, engagement readiness, technological readiness and structural readiness (Balasubramanian et al., 2021).

However, to our best knowledge, the literature has neglected one important difference between stakeholders: all nodes can be stakeholders, but not all stakeholders are nodes. This means that not each readiness dimension may be as important for every stakeholder and hence that not necessarily all the stakeholders should score high whatever the readiness dimension is analysed. To put it differently, for implementing a BT project, it is important to distinguish if there are differences between nodes stakeholders and not-nodes stakeholders in terms of readiness dimensions. This is indeed our paper's objective, which we deem extremely important in a BT project, in order to avoid assessing readiness dimensions whose role is not critical for a specific type of stakeholder. On this regard, the research questions underlying this research are the following:

1. What is the difference between the readiness dimensions between stakeholders-nodes and stakeholders-non-nodes in BT-based projects applied to EMR?

2. How does nodes-stakeholders' readiness and non-nodes stakeholders' readiness affect the implementation of BT-based projects applied to EMR?

2 Background

The fundamental basis of BT is the nodes that constitute its network and that orchestrate all the information necessary for its operation. In the literature, the nodes of the projects implemented with BT are usually referred to as stakeholders or as interested and involved actors on various levels. The distinction between node and stakeholder is not clear and thoroughly defined; very often, it is not even considered that if it is true that all the nodes of the BT network are stakeholders, not all stakeholders are nodes.

Previous studies in the healthcare field have highlighted a plurality of relevant stakeholders for implementing BT-based solutions. For instance, patients (Patel, 2019; Siyal *et al.*, 2019, Yoon, 2019, Khatoon, 2020; Tandon *et al.*, 2020) and Governments (Bell *et al.*, 2019; Dhagana *et al.*, 2019) have sometimes been included as stakeholders. Moreover, business entities (Radanovic and Likic, 2018), regulatory bodies (Nugent et al., 2016), and service providers (Kuo et al., 2017) have been included as actors with a stake in the BT system development.

Hence, the literature, while recognising the diversity in terms of type and interests between the involved actors, identifies a wide spectrum of actors as stakeholders, without taking into account if they are nodes or non-nodes of the blockchain network. For example, in a patient-centric project aimed at improving clinical record management, both the patient – i.e., the owner of clinical data - and hospitals – i.e., data managers - are undoubtedly stakeholders and nodes of the blockchain network. Conversely, the Government, even if recognisable as stakeholder aiming at both ensuring the privacy of its citizens and improving the efficiency of the process, is not necessarily a node in the network.

Savage (2010) and many others explains that when a BT project is implemented, the stakeholders' readiness, i.e., their availability and capacity of adopting a new technology, is important; and it is important in all its four dimensions: motivational, engagement, technological and structural (Balasubramanian *et al.,* 2021; Li *et al.*, 2012). The achievement level of each of the above different dimensions of readiness is an important element that impacts the BT implementation (Balasubramanian *et al.*, 2021).

Motivational readiness is necessary to appropriately address the changes concerning an existing service or circumstance - for instance, in clinical data management, the need to overcome problems related to the quality of service or privacy. Motivational readiness presents strong and different relationships with the stakeholders involved; end-users who receive assistance below expectations, regulatory bodies interested in providing an adequate service to their citizens, corporate entities that, by offering assistance, face the inefficiency of the health system daily.

Engagement readiness refers to the knowledge of new solutions and the explicit recognition of their benefits and potential challenges. For blockchain technologies, this includes knowing how to achieve results, the potential risks to current systems, the potential benefits, the difficulties associated with development costs, and the risks of failure.

Technological readiness is the individual or organizational predisposition to embrace new technologies. Factors contributing to this type of engagement include, for example, the availability and compatibility of existing hardware, software, networks, applications, and other information and communication technology (ICT) resources that facilitate the new technology. Technological readiness regards all the stakeholders, as it refers to the propensity to welcome new technologies and make integration with previous ones possible.

Structural readiness refers to the availability of non-technical resources - financial and human - to be invested in adopting new processes or technologies. Indeed, implementing BT requires valuable resources, such as time, money, and personnel. For the implementation of blockchain, a high level of structural readiness is essential both for government bodies and for the health and blockchain service providers who invest in these projects, but also for end-users, as consumers, regarding the availability and ability to use computers, smartphones and the Internet for daily activities.

We are adamant to claim that the above difference between node and non-node stakeholders within the network play a role when determining the factors that influence the possibility of implementing BT, as in the specific case of readiness in all its four dimensions.

The relationship between readiness and types of stakeholders involved in the implementation of BT-based projects – if nodes or not-nodes – is important to properly assess to what extent the single stakeholder is ready for adopting a new technology. However, the scientific debate does not provide indications. More specifically, we encountered only three studies about blockchain readiness assessment (Ozturan *et al.*, 2019; Vlachos *et al.*, 2019; Balasubramanian *et al.*, 2021), and only one of them (Balasubramanian *et al.*, 2021) involved healthcare. Furthermore, to the best of our knowledge, no work on readiness assessment has been published that considers the difference between the stakeholders in terms of node or non-node of the blockchain network.

3 Methodology

3.1 Case studies

We present here a multiple case study: as blockchain-based solutions in healthcare are a new phenomenon and there is a lack of quantitative data, we have chosen a qualitative approach.

We used the database provided by the Blockchain & Distributed Ledger Observatory of the Politecnico di Milano, which mapped the reality of the blockchain worldwide, to identify the state of the art of blockchain initiatives in the healthcare sector and to select the case studies to be analyzed in detail.

Starting from the database containing all the projects, we applied these selection criteria: the level of maturity of the project and their relationship with the medical record, such that we would include only cases with a close relationship with the medical record. The information availability and the general characteristics of the case contributed to the inclusion in the selected group.

The selected case studies are the following:

1. SAFE– [2020; Operating]
2. Medicalchain with the Groves Medical Group - [2018; Operating]
3. Hypertrust X-Chain - [2018; PoC]
4. Toronto Hospital Project - [2020; PoC]
5. IBM Canada project - [2019; PoC]

Following a detailed projects analysis and an initial contact with their respective representatives, aimed at verifying their availability to participate in the interviews, we selected SAFE, MedicalChain and HyperTrust X-Chain.

SAFE was born from the “MedTech Accelerator”, the flagship program of Mayo Clinic, and Arizona State University Alliance for Health Care. Its initial goal was to diagnose and monitor COVID-19, sexually transmitted diseases and some common ailments, such as flu.

The platform, currently used for COVID-19, connects patients, doctors and test providers through HealthCheck, an advanced smartphone and desktop application, which also allows verification of vaccination status. To ensure trust between all stakeholders and independently verify the accuracy of the information reported while keeping privacy intact, SAFE has relied on Hedera Hashgraph, a distributed ledger technology evolving from blockchain, which offers the same benefits as BT, but without its limits. The app includes voice / video telemedicine, services to allow the review, almost in real-time, of diagnostic tests and the option to request tests through interfaces / partnerships with Quest, LabCorp, and Mayo Clinic Labs and ePrescribing, through SureScripts.

Medicalchain is a platform, built in 2018, that allows the exchange and the use of medical data in a safe and fast way, without compromising the privacy of patients, thanks to asymmetric encryption. Healthcare professionals, doctors, hospitals, laboratories, pharmacists, and insurance companies can request permission to access and interact with medical records. Each interaction is verifiable, transparent, and secure, and recorded as a distributed ledger transaction. The platform is based on the Hyperledger Fabric architecture and, through permissions, allows different access levels, with the patients directly controlling who can access to which records and for how long. A smart contract is activated on this platform, which those entitled can allow third parties (e.g., doctors or other health professionals) to remotely access their medical reports through. Access can be granted in a limited form to specific files. Doctors can record, as ledger transitions, notes, scans, and lab results, and, likewise, pharmacists can add medications provided. Medicalchain also offers an innovative way to connect researchers and patients by sharing their data (anonymized), rewarding patients with personalized incentives (MEDTOKEN).

Eventually, with Hypertrust X-Chain, the CAMELOT Consulting Group offers a blockchain-based, patient-centered solution, particularly suitable for personalized treatments, which many stakeholders are involved in, such as in the case of self-transplant therapies. Hypertrust X-Chain orchestrates a distributed manufacturing process using a series of smart contracts, which act on a custom workflow model, stored on the ledger.

The system provides an end-to-end solution to automate, streamline and secure the supply chain for customized treatments, and inform interested parties about upcoming auctions. The system can be easily configured to manage the supply chain steps for autologous cell therapies such as patient enrolment, apheresis, and treatment appointments planning and monitoring, hospital pick-up appointments planning and monitoring, among others. Hypertrust X-Chain enables safe, efficient, and transparent workflow management for the entire autologous cell therapy process, with far-reaching benefits for pharmaceutical companies and all other stakeholders in the supply and data chain.

The research protocol was drawn up in a semi-structured way, in order to allow the interviewees to speak freely about their projects, stimulate thoughts and opinions on the topics related to the study.

3.2 Cross-case analysis

The three case studies and the analysis of the literature allowed us to categorize the main actors involved in blockchain-based projects into four broad categories: governments and regulatory bodies, health service providers (hospitals, health professionals, pharmaceutical companies, laboratories, etc.), blockchain-based solution providers, and end-users.

The case studies confirmed that not all stakeholders are nodes. In fact, all three interviewees identified the same stakeholders, but the substantial difference between the three projects is to be found in the number and type of nodes that make up the BT network; in SAFE, the network's nodes are mainly represented by patients and doctors, in MedicalChain, hospitals are included as well, while in Hypertrust, the network becomes even more extensive, incorporating a series of further actors that concern, for example, the drug supply chain (Table 1).

Table 1: Stakeholder vs Node

MAIN ACTORS		**CASE STUDIES**					
		SAFE		**MedicalChain**		**Hypertrust**	
		Non-nodes stakeholder	Node stakeholder	Non-nodes stakeholder	Node stakeholder	Non-nodes stakeholder	Node stakeholder
Governments and regulatory bodies		✓		✓		✓	
Health service providers	Hospitals	✓		✓	✓	✓	✓
	Doctors	✓	✓	✓	✓	✓	✓
	More	✓		✓		✓	✓

Blockchain-based solution providers		✓		✓		✓	
End-users	Patients	✓	✓	✓	✓	✓	✓

The interviews highlighted the differences between the readiness dimensions relating to stakeholders, both nodes and non-nodes, of each case considered (Table 2).

End-users (patients) are nodes in all three cases and they all agree in assigning greater importance to their motivational readiness, because the drive for change involves the realization of problems pertaining to poor service or the violation of patient privacy.

Regarding health service providers, doctors are nodes for all three cases, hospitals are nodes only for Medicalchain and for HyperTrust, and other entities - such as pharmaceutical companies and transport service provider- are nodes only for HyperTrust. As for doctors, hospitals, and other entities, the motivational readiness and the structural readiness are considered essential; having the awareness of the critical issues related to data management becomes necessary to explore the possibility of using BT as well as expressing any fears or concerns about the use of the technology.

As for the non-node stakeholders identified by all three cases, SAFE and Medicalchain agree on the importance of engagement readiness for the governments and regulatory bodies while, SAFE and Hypertrust agree on technological readiness relevance for the BT- based solution providers, and the importance of structural readiness for both.

The importance of governments' readiness for involvement is related to knowledge, awareness of new initiatives, and a clear recognition of their benefits and potential challenges that drive regulators to change legal frameworks. Structural readiness refers to the availability of financial and human resources that governments invest in the adoption of new processes or technologies.

Regarding BT solution providers, the importance of technological readiness is linked to the availability, ability, and deep-in knowledge of existing hardware, software, networks, applications, and other information and communications technology (ICT) resources and BT. Structural readiness, on the other hand, is linked to the availability of resources that would make it easier to implement BT.

Table 5 Readiness

CASE STUDY	**STAKEHOLDERS AS NODES**					
	Governments and regulatory bodies	Health service providers			End-users	Blockchain-based solution providers
		Hospitals	Doctors	More	Patients	
SAFE			✓		✓	
Medicalchain		✓	✓		✓	
HyperTrust		✓	✓	✓	✓	

CASE STUDY	**READINESS**																							
	MR	ER	SR	TR	MR	ER	SR	TR	MR	ER	SR	TR	MR	ER	SR	TR	MR	ER	SR	TR	MR	ER	SR	TR
SAFE		✓	✓						✓		✓						✓	✓					✓	✓
Medicalchain		✓	✓		✓			✓	✓		✓						✓	✓						
HyperTrust					✓			✓	✓		✓		✓			✓	✓						✓	✓

The case studies have, therefore, highlighted that the assessment of readiness (with a different specific weight depending on the type of stakeholder and the type of readiness) of both nodes and non-nodes is an essential variable for the implementation of blockchain.

On the contrary, only the stakeholders who are also nodes play a fundamental role in technological choice (Table 3). In fact, the technological choice depends on the ability of the nodes to send and validate transactions. If all nodes participating in the network can do this, a permissionless platform must be used, as in the case of SAFE, otherwise, if authorization is required to execute a transaction, a permissioned platform is used, as in the cases of Medicalchain and HyperTrust X-Chain.

Tabel 3 Technological Choice

Project name	Platform name	Permissioned/ Permissionless	Private/ Public
SAFE	Hedera Hashgraph	Permissionless	Public
MedicalChain	Hyperledger Fabric	Permissioned	Private
Hypertrust	Hypertrust X-Chain (supported BT: Hyperledger Fabric, Multichain, Quorum, Ethereum (private networks) and Hyperledger Indy)	Permissioned	Private

4 Discussion and conclusions

The goal of this study was to fill a gap in the literature related to the weight that stakeholders, nodes and non-nodes, have in the implementation of BT and the importance of their respective readiness.

We have then shown that the importance of readiness for the implementation of BT projects was confirmed by our qualitative analysis. Using blockchain for secure data access and sharing is effective and reasonable if all parties involved in the process use it; indeed, BT is not owned by a single independent entity and all stakeholders must be part of the chain with a defined role.

The case studies revealed the existing relationship between each stakeholder, node or not-nodes, and between each type of readiness. This step is essential because it clarifies what factors need to be considered when implementing such solution and how stakeholders could facilitate or hinder the building of BT-based projects.

In this paper, it was also discussed the fundamental importance of nodes for technological choice, and the case studies clarify that from the SAFE project to Hypertrust, there is an increase in the complexity of the network in terms of actors involved, data exchange, and BT functionality. On this imagined scale, one can think of placing SAFE at a low level of maturity of technology adoption, Medicalchain at a medium level, and Hypertrust at a higher level (Figure 4).

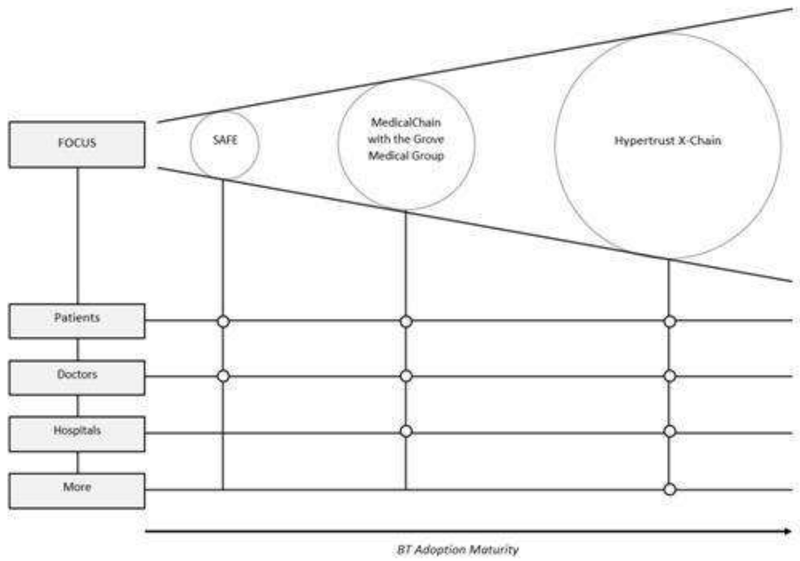

Figure 4 Adoption Maturity

However, a blockchain-based solution can evolve over time, as a consequence of the number and the type of the nodes joining the network, of stakeholders' need, and of the evolution of the external context. Taken together, our study shows that decisions about the BT form need to be taken not only during the startup phase of implementation, but also along the actual implementation and evaluation phases of the project.

Hence, it can be useful:

- to identify, *a priori*, the best solution for starting the implementation;

- to verify, *in itinere*, whether the initial form is still adequate or, according to the evolution, it should be modified;
- to evaluate, *a posteriori*, whether the chosen mode is adequate to the needs and characteristics of the collaboration.

It can also be useful for researchers and academics the *a posteriori* analysis because it may stimulate organizational learning within healthcare organizations and a better understanding of the complex phenomenon of blockchain-based solutions.

The analysis described in this research study is qualitative. We expect that with the increasing popularity and maturity of BT, novel data will be available for quantitative studies and further research should increase the rationality and the objectivity of our study.

For instance, during the selection of the case studies, two other cases were identified which are in the operational stage, as far as we know:

- The UAE Ministry of Health launches the Blockchain platform for medical data
- The HHS obtains ATO for a blockchain-based acquisition system.

It could be interesting both to broaden the investigation, analyzing these cases listed above, and gather more information with other interviews from the cases analyzed in this study.

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