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Mitigating Factors Affecting Secure Interoperability of Medical Systems Using DLTs in Healthcare

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Abstract: The need for more people in the world to connect with one another via use of networked computerized distributed information systems is on the rise in different sector as well as in the medical sector. With many medical information systems being complex and private owned, networking such systems to aid interoperability in order to allow secure sharing of the electronic medical records remains a challenge. This calls for secure connections of different medical system platforms that will aid easy and timely sharing of electronic medical records across different medical facilities. Distributed ledger technologies such as enhanced blockchain is one of the such technologies that when implemented in the healthcare sector have ability to support secure sharing of electronic medical records. The study used exploratory and a survey-based descriptive research design. Information was gathered through both a literature review and a questionnaire survey involving a sample of twenty (20) companies specializing in the development of medical systems software. For this survey, two (2) domain experts from each company were purposefully selected as respondents, totaling forty (40) respondents. The response rate was substantial, with seventeen (17) companies participating, contributing a total of thirty-four (34) domain experts, representing an 85% response rate. The aim of the study was to explore the factors that are hindering secure interoperability and sharing of electronic medical records across different medical systems. The findings revealed that technical factors like data formats, syntax, organization and protocols are the factors affecting structural interoperability levels while data meaning, models codification schemes and data definition standardization are the factors affecting semantic interoperability. Other factors include financial, organizational, human, cultural, security and privacy. The study proposes integration of Distributed Ledger Technologies (DLTs) into the medical systems to mitigate the factors that affect secure interoperability of medical systems and to enhance secure sharing of electronic medical records (EMRs) across medical systems.

Keywords: Interoperability, Structural interoperability, Semantic interoperability, Medical System, Distributed Ledger Technologies, Healthcare, Blockchain

1. INTRODUCTION

Information communication technology (ICT) is critical and valuable to health sector in our society. ICT systems support medical processes by storing, processing, and communicating critical and sensitive data and information [1]. Distributed ledger technologies (DLTs) like Blockchain technology have been penetrating every aspect of ICT and its use has been growing rapidly in recent years with the use of cryptocurrencies in the finance sector [2].

In developing countries, the adoption of ICT in healthcare has proliferated over the years and continues to increase [3], however the health sector has not been fully automated to use eHealth or medical systems some health institutions are still using the manual processes [4]. According to [5] some of the major challenges that affect the full use and hinder full potential of eHealth or medical information systems in the healthcare industry include: the fragmented patients data that is distributed in different hospitals databases across various healthcare facilities, inconsistent patients health or medical records which makes it difficult to track, access and manage patients data, untimely access to patients records, lack of medical systems interoperability and lack of data security in transmission of patient data across different medical systems platforms and geographies which compromises its privacy and security . These eHealth information systems challenges can be solved by use of distributed ledger technology which will allow the sharing of patients' data, electronic medical records and information across different eHealth and medical systems platforms and medical facilities [6].

Distributed ledger or a shared ledger or distributed ledger technology (DLT) is a technological infrastructure and protocols that allows users to simultaneous access, record, validate, share, and synchronize data and transactions updating across a networked database in a distributed network consisting of numerous participants [7]. It can also be understood as a range of technologies with comparable structures but can be executed in various ways with different rules. DLT uses cryptography to securely store data, cryptographic signatures and keys to allow access only to authorized users. The technology also creates an immutable database, which means information, once stored, cannot be deleted and any updates are permanently recorded for posterity [8]. These unique features of DLTs make them suitable for the applications in the healthcare sector.

Healthcare Information and Management Systems Society [9] defines interoperability as the ability of different information systems, devices and applications (systems) to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize the health of individuals and populations globally. Medical data exchange system architectures, application interfaces and standards should be designed in a manner that enable data to be accessed and shared securely across different healthcare facilities despite their medical enterprise system platforms [10].

Interoperability of medical systems is categorized into four levels namely: Foundational which is Level 1: this level establishes the inter-connectivity requirements needed for one system or application to securely communicate data to and receive data from another. Structural which is Level 2: which defines the format, syntax and organization of data exchange including at the data field level for interpretation. Semantic Level 3: this level provides for common underlying models and codification of the data including the use of data elements with standardized definitions from publicly available value sets and coding vocabularies, providing shared understanding and meaning to the user. Lastly, Organizational level which is Level 4: this level includes governance, policy, social, legal and organizational considerations to facilitate the secure, seamless and timely communication and use of data both within and between organizations, entities and individuals. These components enable shared consent, trust and integrated end-user processes and workflows [9].

Interoperability of information systems has evolved over the years, starting with the use of middleware in web services using technologies like firewall and protocols like hypertext transfer protocol (HTTPs) to support sharing of electronic medical records via the web across different health facilities located in different geographical areas but this is faced with a challenge since this type of web configurations inhibits smooth communication of different middleware making interoperability impossible [11]. Other web systems use XML and JSON as marshalling technology for packaging parameters to be communicated over the internet in a technology neutral format [12]. These technologies have still not fully address the structural and semantic interoperability levels which remains unsolved due to use of distinct data formats, protocols and standards which still remains to be software platform and vendor dependent [13]. This paper suggests the use of distributed ledger technology (DLT) based systems to solve the challenges of structural and semantic interoperability levels of medical systems.

Using DLTs different medical systems, devices and applications can securely access, exchange, integrate and cooperatively use medical data in the process of coordinating and organizing electronic medical records (EMRs). DLTs supported medical system interoperability will aid different medical systems and medical devices from different vendors and manufacturers to securely share and exchange electronic medical records between applications, databases and other computer information systems.

2. MATERIALS AND METHODS

This study applied survey-based descriptive and exploratory research design. Exploratory research was carried out through reviewing existing literature on factors affecting secure interoperability of medical systems in the healthcare sector that was published between the periods of (2017 - 2023) years. The study cited the factors that affect secure interoperability of medical systems at structural and semantic interoperability levels. A survey-based descriptive research design was employed to gather information from domain experts, specifically medical system software developers in Kenya. Forty (40) questionnaires were distributed to twenty (20) medical systems software development companies in Kenya and subsequently Thirty-four (34) responded by filling and returning the questionnaire, providing data from two experts in each of the seventeen (17) out of the twenty (20) purposive sampled medical system software development companies in Kenya, which was 85% response rate. The subsequent sections show the steps and process that followed during the review of existing literature.

I. Research Questions Addressed

RQ: What are the factors that are affecting secure interoperability of medical systems at structural and semantic interoperability levels?

II. Inclusion and Exclusion Criteria

This literature review only includes research that address the issue of interoperability of medical system with a focus on structural and semantic interoperability levels. Additionally, studies on the application of DLTs by the medical systems in healthcare sector and the studies from the years 2017 to 2023 are the ones included for the review. Review type research, discussions, uses and applications of DLTs in other sectors, non-relevant publications and any work that are not empirical are excluded.

III. Data Sources

The literature review included the review of ten electronic databases and electronic libraries. The libraries reviewed include; IEEE Xplore, Google Scholar, PubMed – NCBI, Elsevier Science Direct, Mendeley, PNAS, Springer link, Web of Science (WoS), Medline EBSCO, and ACM Digital Library.

The researcher conducted the advanced search for the relevant publications from the electronic libraries and databases using the query string(s) defined below:

(Distributed ledger OR Distributed Ledger Technologies OR “DLTs”) AND (medical systems OR healthcare OR eHealth OR e-health OR health* OR health systems* OR medical information systems OR *health information systems* OR medical*)

The researcher constructed the search string based on the research domain and the defined research question.

Due to a lack of advanced search options for some libraries and databases like Google Scholar, Mendeley, PNAS and Springer Link, they returned many non-related results that were not meeting the inclusion - exclusion criteria. Therefore, the researcher only included the first 100 most relevant results from these four databases. This search in the online digital libraries was conducted in January 2023. The researcher intentionally made the search query as broad as possible in order to consider as many results related to the systematic research questions as possible. The summary of the search in all databases and libraries returned 4777 results and the results returned for each database search are presented in Table 1.

Table 1 Summary of Search Results

Database / Library	**Number of Results**	**Number of Suitable results after detailed screening**
IEEE Xplore	17	10
Google Scholar	3562(100)	12
PubMed – NCBI	30	5
Elsevier Science Direct	18	8

Mendeley	167(100)	7
PNAS	202(100)	2
Springer link	745 (100)	1
Web of Science (WoS)	10	2
Medline EBSCO	20	4
ACM Digital Library	6	1

IV. Selection of Studies

The selection process started with 501 publications gathered from online digital databases and digital libraries. Based on the inclusion-exclusion criteria, the publications were either included in the review or not and a total of 52 papers were reviewed. The researcher was interested in how the distributed ledger technology (DLT) is used in providing structural and semantic interoperability of medical systems in the healthcare sector and finding out what are the factors that are affecting secure interoperability of medical systems at structural and semantic interoperability levels. Later the researcher suggests the use and integration of DLTs to mitigate the challenges identified.

3. DISCUSSION

The study revealed that today, most healthcare organizations have adopted electronic medical records (EMR) technology. A decade ago, EMR adoption in hospitals hovered around 73%. Now, roughly 98% of hospitals are using a government-certified EMR. While the increased adoption is a step toward achieving interoperability, it also reveals a new challenge. There are hundreds of EMR systems on the market today, each with its own unique set of technical specifications[14].

Different medical systems used by different health facilities use different data formats, specifications, and semantics, further fragmenting patient information and complicating health information exchange. Due to the varying data standards, former attempts to promote interoperability have been ineffective. For example, electronic medical records (EMRs) - a primary source of healthcare data - produce disparate and non-standardized data, making it difficult to access, share and analyze patient information across systems [15].

The findings indicate that distribute ledger technology research in healthcare is increasing and it is mostly used for data sharing, managing health records and access control [16]. The findings indicated that 78% of the most commonly used DLT in the medical sector is Blockchain. This is used with aim to provide security and privacy of electronic medical records.

The findings further revealed that the most challenges related to interoperability of medical systems are financial costs at 74% of the revealed articles, Technical challenges which includes the system designs, data structures and architectural accounted for 48% of these challenges. The findings further shown that 31% was due to identifying and implementing standards. Unrealistic end user expectations accounted for 26% and patients matching 21%. The results are shown in the figure 1.

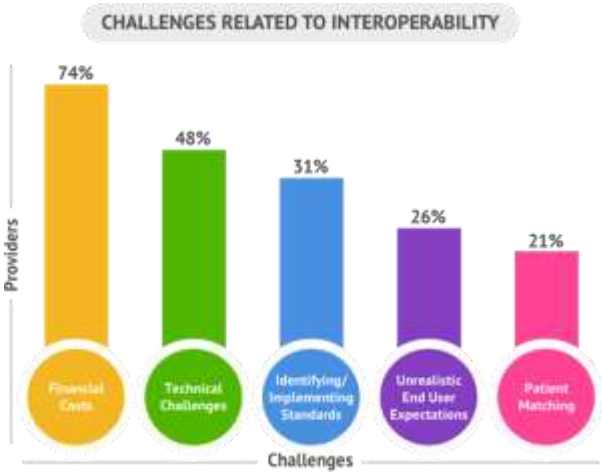
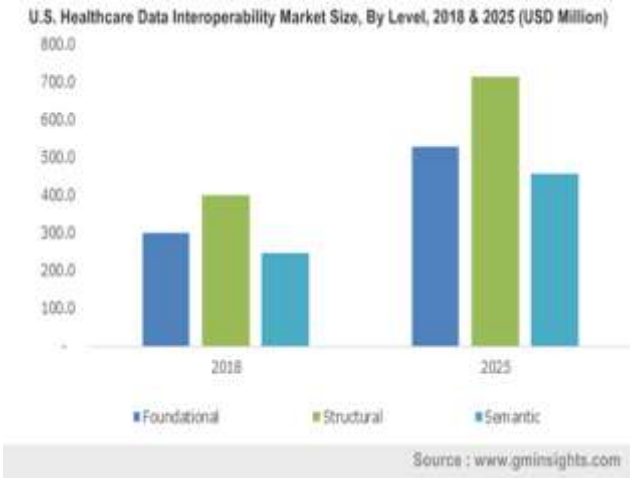


Figure 1: Challenges related to interoperability

Additionally, 55% of the reviewed articles revealed that common research problems addressed in the area of DLTs dealt with structural designs in the form of frameworks, architectures or models of Blockchain which is one of the DLT types [17]. 94% of the reviewed articles also show that technical details about the used DLT elements are not given in most of the analyzed publications and that most research does not present any prototype implementation or implementation details on medical systems and secure access and sharing of electronic medical systems [18], [19]. Often even with a prototype implementation, no details about DLT elements are given, hence the need to conduct a research on DLT prototypes with the aim of providing interoperability of medical systems. Some of the key methodologies and methods used in this area include the exploratory, descriptive and systematic literature review (SLR).

Current trends of DLT research in healthcare from the reviewed articles 82% indicate that it is mostly used for data distribution, health records and access control, but rarely for other scenarios, such as providing interoperability of medical systems that are design and developed by different vendors [20], [21]. Therefore, much potential for DLTs is still



unexploited. The findings as published by Global market insights [22], show that U.S. healthcare data interoperability market size by level forecast between the year 2018 to 2025 revealed that structural and semantic interoperability level

factors are the highest contributors and deterrents of medical system interoperability as shown in Figure 2.

Figure 2: U.S. Health Data Interoperability Levels Indicators by Global Market Insights

In addition, Emergen Research [23] report also support that in the year 2021, structural and semantic interoperability levels lead in the solution in healthcare market in US billions as shown in the figure 3.

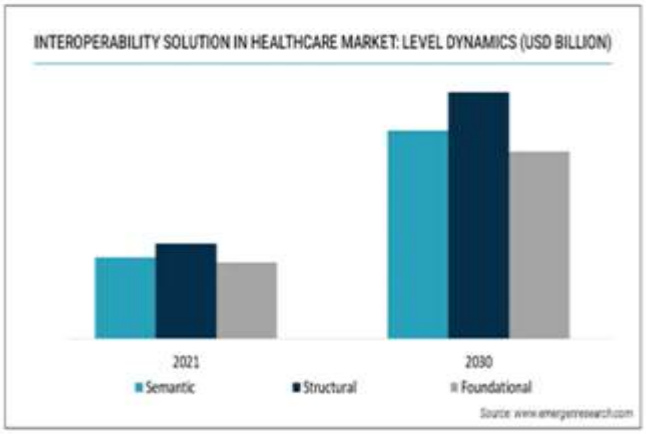


Figure 3: Interoperability Solutions in Healthcare Market by Emergen Research

The study shows that some of the challenges that hinder interoperability of medical systems include structural based factors like data formats, syntax, organization and protocols of the enterprise medical systems which are vendor and platform dependent. These factors affect the structural level of medical systems interoperability. Medical data can be inputted into medical systems in many diverse formats which includes text, numeric, string, special characters, multimedia, which is encoded to be understood by only the medical practitioners and specific to a health facility medical system. Some of these data formats are universal and others are single system based [24]. Data Syntax is defined as a set of rules defining the way in which data is put together with appropriate identifiers, delimiters, separator character(s), and other non-data characters to form messages [25].

Data organization is based on different database structures and models that are implemented by different health facilities to support their medical systems. Data in the databases can be organized and modeled in form of relational databases, hierarchical databases, network based databases, NoSQL databases and object oriented databases [26]. These data organizations and models will vary if the systems are centralized, distributed, cloud or IOTs and AI based [24]. System protocols are a set of procedures and technological measures to ensure secure and efficient operation of information within an organization [27]. These protocols determine how different medical systems are going to exchange data and manage access of the electronic medical records.

Semantic interoperability is the ability of computer systems to exchange data, with unambiguous meaning [28]. It is a requirement not only for medical data be shared between different systems or applications, but for them to be understood. Semantic interoperability refers to the transmission of the meaning of data [29]. Some of the semantic based factors that affect medical systems interoperability include data meaning, models codification schemes and data definition standardization are the factors affecting medical interoperability at the semantic interoperability level. Data codification allow system users to reduce large quantities of information into a form that can be more easily handled, especially by computer information systems [30]. In healthcare data codification needs to be done in a more systematic manner to ensure similar interpretation of the coded data and avoid misinterpretation which in turn can lead to misdiagnosis. Coded medical data stored in the medical systems are used by many entities outside the health facility for a variety of purposes including research, insurance of patients, public health, development of health policy, quality and safety monitoring patients [31]. Data Standards are information artefacts developed in community-driven consensus processes that specify uniform features, criteria, methods, processes and practices for a certain domain [32]. Healthcare standards offer health information technology (IT) developers, EMR vendors, and healthcare organizations the means to ensure medical systems and devices can exchange data successfully.

To address these structural and semantic interoperability issues, stakeholders should embrace the use of DLTs to aid secure sharing of electronic medical records. The DLT based medical system will automate workflows, minimize document errors, and, most importantly, collect, store, and deliver medical information in a way that is private, secure, and follows all industry and HIPAA protocols. Adopting health data standards in a consistent and comprehensive manner will be key to enabling meaningful healthcare interoperability at all levels. Consequently, a data architecture and data structures that works for one health facility may not work for another health facility, hence there is need also to consider a technology that will aid data interoperability of medical systems at different interoperability levels. Since data is encrypted as it is stored in different databases, integration of DLTs to aid medical systems to share data should be considered as a solution to solve the structural and semantic interoperability challenges across medical systems.

Consequently, the results from the survey based descriptive study concurred with the literature review findings. The medical system software developers indicated that some of the factors that affect interoperability of medical systems can be classified as semantic, technical, organizational, legal/regulatory, security and privacy, human, financial, and cultural aspects as shown in Figure 4.

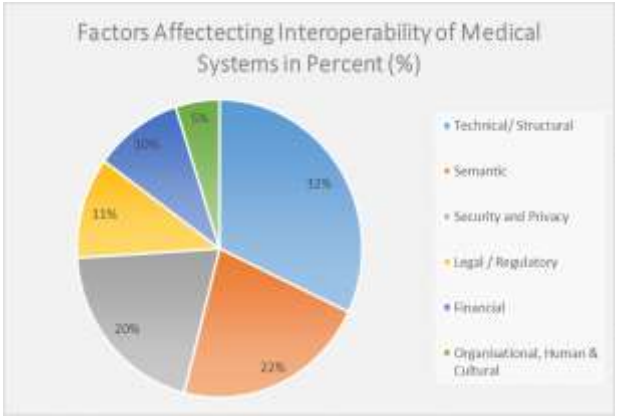


Figure 4: Categories of Factors Affecting Interoperability of Medical Systems

In this research, participants identified technical factors as the most significant. A notable 32% of respondents believe

that technical aspects exert the most considerable influence on the interoperability of medical systems. This classification includes essential components like data standards, interoperability protocols, data integration, scalability, and technical infrastructure, all recognized as key contributors to the broader challenge of achieving overall medical systems interoperability.

In this study, semantic factors emerged as the second most influential considerations, with 22% of participants highlighting terminology, vocabulary, data mapping, and ontologies as primary elements. This suggests that maintaining a uniform application of medical terminology and coding systems is crucial for ensuring shared meaning of data across various systems. Additionally, the creation of mappings between diverse coding systems or vocabularies facilitates the translation of data among systems with differing terminologies. Moreover, the utilization of ontologies and knowledge graphs proves beneficial in representing intricate medical concepts and relationships, ultimately supporting semantic interoperability.

Similarly, legal and regulatory factors were recognized as another obstacle to the attainment of interoperability in medical systems, as indicated by 11% of survey respondents. Healthcare regulations, exemplified by HIPAA in the healthcare sector, impose stringent requirements regarding the storage and sharing of patient data. Regulatory bodies may lag in establishing clear standards for interoperability, leading to potential challenges. The absence of such standards can impede innovation and introduce uncertainty for healthcare organizations. Varied regulations across regions and countries add complexity to compliance, thereby obstructing the seamless sharing of data. Consequently, finding a nuanced equilibrium between ensuring compliance with these regulations and promoting interoperability becomes a critical challenge in achieving interoperability. In a similar vein, financial considerations, marked by 10% of respondents as a concern, also pose a barrier to achieving interoperability in medical systems.

Organizational, human, and cultural factors, collectively representing 5% of responses, were identified as notable influences on medical system interoperability. Organizational aspects encompass healthcare policies and regulations, necessitating compliance with standards like HIPAA and ISO, which can impact the exchange of patient data across organizations.

Cultural factors, constituting the final 5%, include resistance to change, a prevalent sentiment in the healthcare industry due to its traditionally conservative nature, potentially impeding the adoption of new technologies and interoperable systems. Healthcare professionals may express reluctance toward embracing change, even in the face of potential benefits. medical systems.

4. CONCLUSION AND FUTURE WORK

This study investigated factors that affect interoperability of medical systems. Distributed ledger technologies presents a decentralized network and is regarded as having great potential for use in healthcare sector, because of the sensitive nature and need for privacy and security of data being processed and managed. DLTs also when used in medical systems has capability of providing system interoperability, trust, timely access to data when needed, solving the issue of data fragmentation and security of patients' electronic medical data.

The aim of the study was to carry out a literature review and survey-based study with the goal to revealing the factors that affect interoperability of medical systems. The highlight of these factors are data formats, syntax, organization and protocols. Consequently, the semantic based factors, technical, organizational, legal/regulatory, security and privacy, human, financial, and cultural factors were cited by the medical system software developers as key categories of factors that hinder interoperability of medical systems.

Further, data meaning, models codification schemes and data definition standardization are the specific factors affecting medical interoperability at the semantic interoperability level. To achieve the study objectives, the researcher defined research questions and using the predefined methodology the researcher narrowed down the analyzed literature to 52 publications. These were then further analyzed and 10 relevant online databases for publications published between 2017 and 2023 searched. The researcher collected data as prompted by the research question and assessed the publications using the predefined assessment criteria.

The study findings indicate that distributed ledger technology research and its employment in eHealth, and healthcare is increasing. Current trends of DLTs research in healthcare indicate that it is mostly used for data sharing, health records and access control, but rarely for other scenarios, such as providing medical system interoperability of medical systems located at various health facilities across different geographical areas. Therefore, much potential for DLTs is still unexploited in relation to solving interoperability challenges of medical systems. Future work can consider designing and developing frameworks and models for integrating DLT into medical systems with an aim to address interoperability challenges.

5. ACKNOWLEDGMENTS

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