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Review

Health organization challenges in health data governance implementation: A systematic review

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Abstract: Health data governance is essential for optimal processing of data collection, sharing, and reuse. Although the World Health Organization (WHO) has proposed practical guidelines for managing health data during the pandemic, the Organization for Economic Cooperation and Development (OECD) found that many countries still lack the use of health data for decision-making. Therefore, this research aimed to identify and assess the challenges faced by health organization in implementing health data governance from various countries based on research articles. The challenges were assessed based on key components of health data governance from practitioner and scientist perspectives. These components include stakeholder, policy, data management, organization, data governance maturity assessment, and goals. The method used followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines for collecting and reporting. Data were collected from several databases online with large repositories of academic studies, including IEEE Xplore, ScienceDirect, National Library of Medicine, ProQuest, Taylor and Francis Group, Scopus, and Wiley Online libraries. Based on the 41 papers reviewed, the results showed that policy was found to be the biggest challenge for health data governance. This was followed by data management such as quality, ownership, and access, as well as stakeholders and data governance organization. However, there were no challenges regarding maturity assessment and data governance goals, as the majority of research focused on implementation. Policy and policymaker awareness were identified as major components for the implementation of health data governance. To address challenges in data management and governance organization, creating committees focused on these components proved to be an effective solution. These results provided valuable recommendations for regulators and leaders in a healthcare organization to optimally implement health data governance.

Keywords: systematic review; electronic health data; health data governance; data governance; health organization

1. Introduction

Electronic health (eHealth) was recommended by the World Health Organization (WHO) in 2005 to improve the progress of the health sector in each country (WHO, 2005). The definition of eHealth has expanded along with advancements in technology and increased knowledge. In health sector, eHealth is regarded as a state of mind, a way of thinking, an attitude, commitment to network, and global thinking to enhance health care locally, regionally, and worldwide (Shaw et al., 2017). In economic aspects, eHealth improves the efficiency of health organizations in terms of time and resources for clinical and administrative services (OECD, 2010). Furthermore, it provides timely data to allow decision-makers to identify areas of focus, address challenges, and forecast trends (WHO SEAR, 2015). In health sector, eHealth improves the quality of life, including patients and the general population (WHO SEAR, 2015), thereby enhancing innovation (OECD, 2010).

In 2015, WHO published data showing that approximately 70 countries had successfully adopted eHealth (WHO, 2016), indicating a significant growth in global acceptance (Tse et al., 2018). However, the WHO South-East Asia Regional (SEAR) describes several challenges to implementing eHealth for countries in the region. These challenges include the lack of eHealth policy and strategy, uncoordinated investment in ICT in health, absence of cooperation and collaboration across sectors, poor ICT infrastructure, and limited public sector capabilities (WHO SEAR, 2015).

Health data collected from various sources, such as national and global, have complex structures (Oktaviana et al., 2022), a lack of standards, and high privacy issues (Hripcsak et al., 2014). To address these challenges, there is a need to strengthen data governance concerning collection, reporting, partnership, analysis, dissemination, privacy protection, and data security for national health monitoring (Yao and Park, 2020). Health data governance plays a crucial role in enabling health workers to create report (Khurana, 2021), guarantees the truth of the report, and establish standard data for collecting and sharing (Dagliati et al., 2021). Some research found health data governance is essential to meet the requirements for universal health coverage (Ndlovu et al., 2023) and increase research (J. Li et al., 2021; Walters et al., 2022).

WHO and the Open Data Institute (ODI) have proposed practical guidelines in health data governance for countries (Boyd and Tennison, 2021a). However, only five of the 24 Organization for Economic Cooperation and Development (OECD) member countries surveyed have the maximum score in health data governance (Bienassis et al., 2022). The World Bank has also surveyed 80 countries to evaluate the use of health data in monitoring national health (World Bank, 2021). The results showed that over 60% of countries have not achieved optimal use of health data for monitoring and decision-making (World Bank, 2021).

Extensive research on health data governance has been conducted by several countries, resulting in the development of a framework for specific purposes. Tiffin et al. (2019) proposed a health data governance framework for non-high-income countries to promote privacy. Similarly, Khurana (2021) developed a framework to ensure health data quality in India. In another high-income country, some research suggested a health data governance for health research purposes (Ali et al., 2021; De Freitas et al., 2021; Jones et al., 2020a; Murtagh et al., 2018), while two studies focused on healthcare organization in China (Li et al., 2019; Wang et al., 2022). Although numerous investigations have been carried out, several countries and health organizations were unable to implement health data governance (Ndlovu et al., 2023; Were and Moturi, 2017). It was also found that some studies pertaining to certain countries have identified challenges in implementing health data governance (Hassan et al., 2021; Munung et al., 2021; Osakede, 2021; Were and Moturi, 2017; Wang et al., 2021). This shows the need for investigation focusing on identifying general challenges to implementing health data governance.

Based on the background above, this research aimed to determine the challenges faced by health organization in implementing health data governance in various countries. The investigation was carried out using the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) as guidelines for collecting and reporting (Page et al., 2021). This research combined data governance frameworks from the academic and practitioner literature to construct key components (Alhassan et al., 2018; Jang and Kim, 2021; Khatri and Brown, 2010; Ladley, 2020; Winter and Davidson, 2017; Zorrilla and Yebenes, 2022) and practical approaches (DAMA International, 2017; OECD, 2015; The Data Governance Institute, 2020). The results provided practical and theoretical knowledge to regulators as well as leaders in a healthcare organization to optimally implement health data governance.

This research is divided into six sections. The first section serves as the introduction, which explains the research background. The second section is the literature review, discussing health data and governance. Meanwhile, the third section describes the systematic review framework as research methodology. The fourth and fifth sections focus on data extraction and the results of research questions, while the sixth section presents the conclusions of this research.

2. Literature review

2.1. Health data

Hovenga and Grain (2013) defined health data as a patient health document, which is stored in a medical record, in the form of registration details, disease symptoms, diagnosis, treatment and care plan, as well as treatment outcomes. The health documents include genomic data, diagnostic images, and laboratory test results (Vayena et al., 2018). Health data include physical and mental health, sexual behavior, economic conditions, and family health history (OECD, n.d.).

Health data is categorized into two types, namely clinical and administrative data. Clinical data relate to patient health (National Cyber and Crypto Agency, 2020; Tekieh et al., 2017), while administrative data include basic and social identity, finance, admission approval, authorization to release information, health insurance-related data, and informed consent (National Cyber and Crypto Agency, 2020; Tekieh et al., 2017). In traditional health systems, most health data are generated through the application of information technology (I.T.) such as Clinical Information Systems, picture archiving and communication systems (PACS), Hospital Information Systems (HIS), M-Health, Telemedicine, laboratory examination tools, pharmacy, Personal Health Record (PHR), and other medical image data collection (Handayani et al., 2018). With the recent advancement in information technology, collection can be made by individual and non-healthcare institutions, such as PHR, telemedicine providers, patient community platforms, health data banking, and independent research (Kariotis et al., 2020). Moreover, the summary of the electronic health data resource is shown in **Figure 1**.

Clinical data originates from three sources, namely clinical, patient, and machine generated. Moreover, clinical generated data are obtained during clinical treatment and inputted by clinicians or through laboratory investigations in the form of diagnosis (Tekieh et al., 2017). Patient generated data are health status provided to monitor their conditions, for example, the use of a smartwatch (Tekieh et al., 2017). Meanwhile, machine generated data are obtained directly through remote ECG, laboratory, or radiology machines (Tekieh et al., 2017).

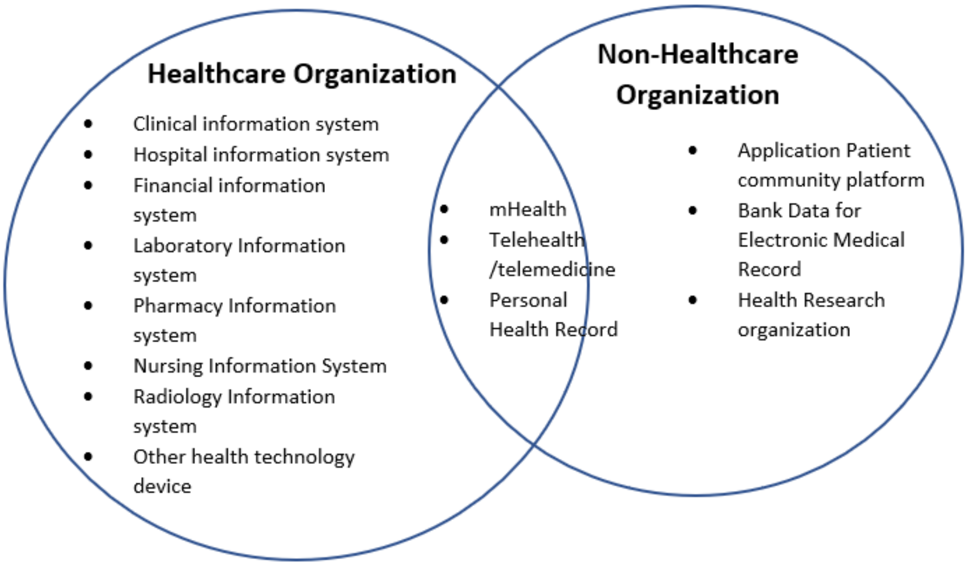

Figure 1. Source of electronic health data.

2.2. Data governance

Data governance is a process aimed at establishing and implementing accountability measures for data management (Hovenga and Grain, 2013; Rosenbaum, 2010). It shows the allocation of decision rights and accountability regarding an enterprise's data assets (Alhassan et al., 2018). Other studies define data governance as information-related process decision-making that follows an agreed-upon model describing the allocation of the authority to take specific actions on information, based on circumstances, and required steps (The Data Governance Institute, 2020). The main objective is to establish data access, determine information available for subsequent processes, and ensure adequate management (DAMA International, 2017).

In this research, health data governance is defined as an accountability process where clinical and administrative management is carried out. Specifically, health data governance determines the allocation of authority on specific information based on certain circumstances and required steps for further processing. This multifaceted approach is a strategy to maximize health data advantages and minimize risk (OECD, 2015; Tiffin et al., 2019). It also includes health data sustainability tools (Tiffin et al., 2019), policy or management decision-making (OECD, 2015; Tiffin et al., 2019), quality assurance during data collection (Rivera et al., 2020), and preservation of patient and community data to promote public trust in health system (Evans et al., 2020; Rivera et al., 2020).

Data governance operates through three phases, namely planning, operation, and control (DAMA International, 2017). In planning, data governance requires principles (Zorrilla and Yebenes, 2022) and goals as key components (DAMA International, 2017; Jang and Kim, 2021). These principles serve as guidelines for the implementation of data governance (Zorrilla and Yebenes, 2022), defining, and creating some related policy (Khatri and Brown, 2010). In the health sector, policy is a component of data governance, serving as goals (Vayena et al., 2018; Winter and Davidson, 2019a), including data privacy and universal health coverage policy (Vayena et al., 2018).

For effective operation, data governance body is required in organization with some roles and responsibilities (Jang and Kim, 2021; Winter and Davidson, 2017; Zorrilla and Yebenes, 2022). This body ensures effective operation by creating standards and procedures to confirm data quality (DAMA International, 2017). Organization also manages access data issues as a component to guarantee ethics and privacy, meeting all management aspects through a compliance process (DAMA International, 2017; Jang and Kim, 2021). Data management is responsible for achieving the objectives of organization (DAMA International, 2017), serving as an essential component (Jang and Kim, 2021; Zorrilla and Yebenes, 2022). In the health sector, data management has focused on technology standards for inter-organization data exchange (Winter and Davidson, 2017).

Data governance is not a one-time project (Ladley, 2020) but an enduring practice, essential for organization to manage data as an asset (DAMA International, 2017; Ladley, 2020). Therefore, data governance maturity should be measured for organization to evaluate the current situation (Ladley, 2020; Zorrilla and Yebenes, 2022). The controlling phase establishes the fundamental guidelines for organization to identify the existing gap between the current situation and the desired goals (Zorrilla and Yebenes, 2022).

Stakeholders in data governance are all actors, such as individuals, groups, and organizations, who influence data and the value created (Micheli et al., 2020). In health data governance, stakeholders include the patient, healthcare industry, researcher/academia, government, media (Boyd and Tennison, 2021b), I.T. vendors, and community health organizations (Winter and Davidson, 2017). Others include hospitals, as central actors, and those who may not actively generate or use health data such as individuals with prescription aggregated data (Winter and Davidson, 2017). Based on the above explanation, this research organizes data governance components into stakeholders, policy, management, organization, maturity assessment, and data governance goals. The challenges encountered during implementation are analyzed and summarized based on data governance components.

3. Materials and methods

The literature review was conducted from November 2021 to February 2023 using a PRISMA framework as a guideline for collecting and reporting data in healthcare research (Page et al., 2021). **Figure 2** shows the framework details, including 41 papers that satisfy the review. Moreover, all processes included in the literature reviews are explained in the next section.

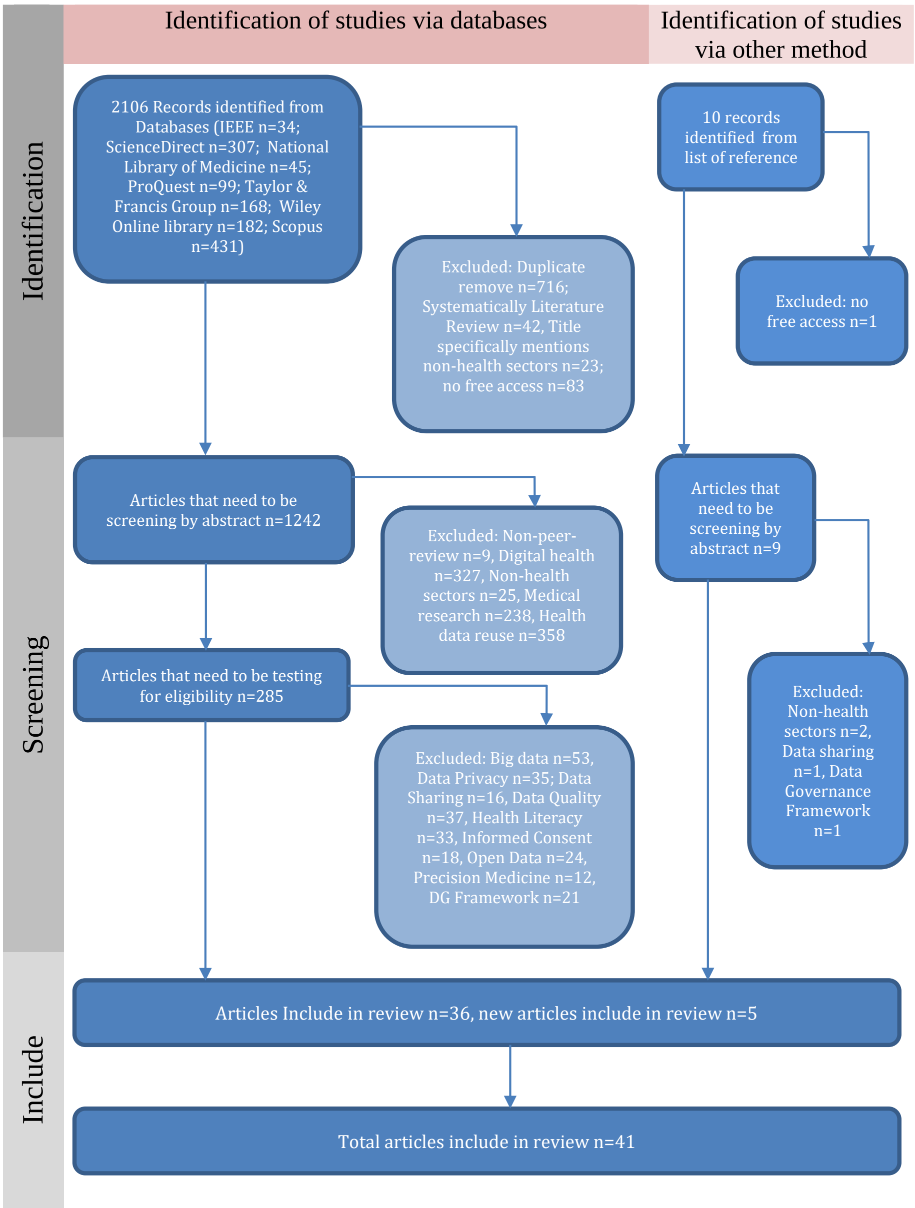

Figure 2. PRISMA framework for study literature review.

3.1. Database resource

The search was conducted in several databases online with large repositories of academic studies, including IEEE Xplore, ScienceDirect, National Library of Medicine, ProQuest, Taylor and Francis Group, Wiley Online libraries, and Scopus. These online databases are commonly accessed online for health, computer science, and information system research. For this research, 2106 articles were obtained from all repositories and only included fully accessible articles by author. A list of article references was also scanned to search for other related studies, leading to the addition of 10 articles.

3.2. Study inclusion criteria

A total of two inclusion criteria (IC) were identified as a guideline to review:

IC1: original paper, peer-reviewed, and written in English.

IC2: research article topic about challenges in health data governance.

The search criteria were not limited by year and country type of economy. However, stringency was applied to the English Language due to its widespread use in scientific research. The keyword string related to the research interest was used in the online database.

3.3. Study selection

The selection process included four steps:

- Step one. The search keywords used included “health” AND “data governance”, “health data governance”, and “clinical data governance”. The selection of the first search was performed on the title, keywords, and abstract, in line with the aim of this research. The inclusion of the string “clinical data” was selected based on frequent references in health research.
- Step two. Exploration and selection of title, abstract, and keywords of identified articles were conducted based on eligibility criteria. Meanwhile, non-peer-reviewed, duplicate, non-health topics, not fully accessed by authors, and systematic review articles were excluded.
- Step three. Complete or partial reading was conducted on articles not eliminated from the previous phase. Research methods with qualitative or quantitative, mixed methods, and case studies related to health or clinical data were included. Data integration, governance challenges, and barriers in health data were also associated with the research, which was used as a selection criterion.
- Step four. The reference list of articles from phase three was scanned to identify related articles. First, articles with titles containing the string “health data” and “data governance” or “health data sharing” were selected. Second, the selected articles were excluded from the previous search and the process was repeated in the third step.

All authors carried out these phases through repeated discussions. The assessment of the risk bias was carried out using Risk of Bias in Systematic Review (ROBIS) (Whiting et al., 2016). Differences of opinion were thoroughly discussed until a unanimous agreement was reached.

4. Results

4.1. Data collection process

A data abstraction form (available on request) was used to record standardized information from each paper, including article type, year, country, research methodology, topic, data, and challenges in health data governance. The assessment consisted of reading the full text and the extracted data. Subsequently, discrepancies observed were resolved through a discussion between the authors.

4.2. Data extraction

Information extracted from each article consisted:

- Demography of selected articles comprising (i) year of publication, (ii) countries included in health application research, (iii) distribution of health data, (iv) distribution of methods.

- Challenges and barriers in health data governance.

The first point aims to analyze the distribution of research related to the challenges in health data governance. During the analysis, a graphic distribution of the year was created to observe the progression of research annually. Research methodologies were distributed to determine the most popularly used in health data governance research. Subsequently, the distribution of data types, countries, and challenges were merged into one summary.

Figure 3 shows research on challenges in health data governance, spanning from 2013 to February 2023, and producing 41 papers. Research on these topics has increased due to high health data sharing and reuse during the pandemic. However, before the pandemic, several health organizations struggled with ICT adoption (Alshahrani et al., 2019; Gu et al., 2021). The majority of leaders did not use health data in decision-making during the pandemic, leading to low awareness of health data governance (Were and Moturi, 2017). To overcome these challenges, there is a need to share health data between organizations for effective monitoring and decision-making to combat the pandemic (Yao and Park, 2020). Although there are studies on health data governance, several organizations still have difficulty in implementation (Ndlovu et al., 2023). Therefore, research related to challenges in health data governance is required during the pandemic.

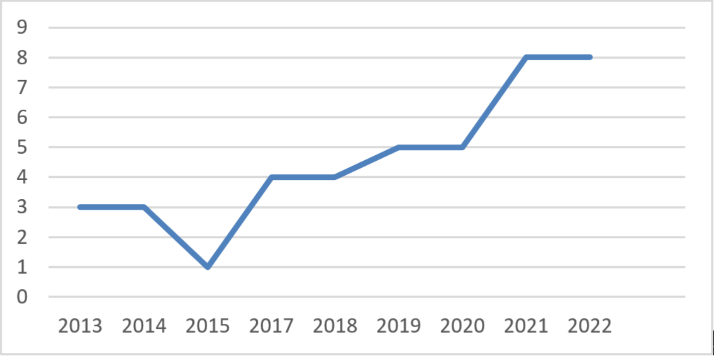

Figure 3. Distribution of articles per year.

Figure 4. Distribution of articles per research methodology.

Figure 4 shows the distribution of research methods, predominantly consisting of qualitative and case studies. Qualitative data were collected through interviews, policy analysis, and focus group discussions. In data governance research, the exploration focuses on various organizational functions and roles (Wende and Otto, 2007). Therefore, the use of qualitative methods allows for capturing the perspectives and interpretations of individuals with diverse interests and responsibilities (Sofaer, 1999).

Table 1 shows the summary of articles distribution based on data type and country. Research on challenges faced in health data governance was dominated by the United Kingdom, USA, and European Union, due to prolonged use of eHealth. These regions also have a policy that relates to health data governance, such as the General Data Protection Regulation (GDPR) in European Union Countries and the Health Insurance Portability and Accountability Act (HIPPA) in the USA.

Table 1. Distribution of the number country and data type.

Country name	Administrative data	Clinical data
Kenya	1	-
South Africa	2	-
Australia	1	1
Brazil	1	-
Canada	2	-
China	1	1
European Union	5	-
India	2	-
Ireland	1	-
Switzerland	2	-
United Kingdom	9	3
USA	8	-
Denmark	1	1
Sweden	1	-
Netherland	2	-
Norway	1	-
Poland	1	-

Table 2 shows several challenges in health data governance based on key components. The results showed that policy has twenty-five challenges, followed by stakeholders and data management, each with seventeen challenges, The last was data governance organization, comprising five challenges. However, there were no challenges in the data governance maturity and goals, as the majority of research focused on implementation. Research in health data governance is still rare, with only 15 countries conducting related studies due to the lack of Electronic Medical Records (EMRs) and Information Technology (I.T.) staff (WHO, 2016). The discussion and conclusion sections fully explain the result.

Table 2. The number of challenges in health data governance.

Type of challenges	Number of challenges	Source
Policy	25	(Hripcsak et al., 2014; Khurana, 2021; Tiffin et al., 2019; Allen et al., 2014; Chen and Song, 2018; Di Iorio et al., 2021; Espíndola et al., 2018; Karz et al., 2018; Kim et al., 2013; Laurie and Nayha, 2013; Marelli et al., 2020; Marelli et al., 2021; Martani et al., 2021; Nomura et al., 2020; Shah et al., 2021; Pinto et al., 2022; Sethi and Laurie, 2013; Shidhaye et al., 2022; Thompson et al., 2015; Walji et al., 2022; Were and Moturi, 2017; Winter and Davidson, 2019b; Thiel et al., 2014; Martani et al., 2022; Shaw and Sekalala, 2023).
Stakeholder	17	(Khurana, 2021; Tiffin et al., 2019; Murtagh et al., 2018; Were and Moturi, 2017; Winter and Davidson, 2019a; Allen et al., 2014; Laurie and Nayha, 2013; Nomura et al., 2020; Sethi and Laurie, 2013; Thompson et al., 2015; Walji et al., 2022; Milne and Brayne, 2020; Shah et al., 2019; Sleigh and Vayena, 2021; Jones et al., 2020b; Wieland-Jorna et al., 2023; Paparova et al., 2023).
Data Management	17	(Khurana, 2021; Li et al., 2019; Were and Moturi, 2017; Winter and Davidson, 2017; Kariotis et al., 2020; Allen et al., 2014; Di Iorio et al., 2021; Karz et al., 2018; Nomura et al., 2020; Pinto et al., 2022; Walji et al., 2022; Winter and Davidson, 2019b; Shah et al., 2019; Foy et al., 2021; Dodd et al., 2017; Vayena and Blasimme, 2017; Piasecki and Cheah, 2022)
Data governance organization	5	(Murtagh et al., 2018; Winter and Davidson, 2019a; Foy et al., 2021; Dodd et al., 2017; Milne et al., 2021)
Data governance maturity	0	-
Data governance goals	0	-

5. Discussion

This section provides the summary of articles by grouping data governance components. Although six components were initially mentioned, only stakeholders, policies, data management, and data governance organization were explained in the discussion section. This is attributed to the focus of research on health data governance implementation in organization. Meanwhile, the remaining two components, namely data governance maturity and data governance goals were not exclusively explored. Based on the results, stakeholders and policies were found to drive the implementation of health data governance. In addition, policies from the government to support health data governance are also important, serving as basic regulations for implementation. Meanwhile, data management and governance organization were challenges faced at the early stages.

5.1. Stakeholders

The government requires health data for national health monitoring and decision-making. In low-income nations, the lack of government awareness is the biggest challenge in health data governance (Were and Moturi, 2017). Therefore, activities such as campaigning and training on health data governance can be carried out to increase government awareness (Were and Moturi, 2017). The silos such as interoperability and data interest between numerous government agencies also present additional challenges, further complicating the effective management of health data (Khurana, 2021). To overcome these challenges, ensure the availability of an Application Program Interface (API) for uniform datasets, facilitating data interoperability across government agencies (Khurana, 2021).

Effective data governance requires collaboration between business and Information Technology (I.T.) concepts. This is attributed to the increasing complexity of health organization, including I.T. language and medical jargon (Benfeldt et al., 2020; Sleigh and Vayena, 2021). Therefore, policymakers such as government and leaders in health organization, need a mix of knowledge to build health data governance. Other challenges include the difference in understanding among stakeholders (Milne and Brayne, 2020; Sleigh and Vayena, 2021) and the overlap in decision-making (Laurie and Nayha, 2013). This shows the need for good data literacy by data producers and users, particularly policymakers (Ladley, 2020) to facilitate understanding (Khatri and Brown, 2010; Ladley, 2020). Furthermore, having a standard for health data governance is required to enhance the understanding of combining I.T. and medical knowledge.

Health data generated from non-health organization provide challenges in data stewardship (Winter and Davidson, 2019a). This is attributed to the lack of clarity regarding who takes responsibility for the data generated by the patient through the eHealth application (Murtagh et al., 2018; Winter and Davidson, 2019a). Another challenge is the lack of mechanisms by which patients share and control their health data for non-clinical uses (Jones et al., 2020b; Shah et al., 2019). Therefore, organizations must provide patients with better data sharing and privacy information.

Healthcare clinicians such as doctors and nurses are also stakeholders in health data governance (Winter and Davidson, 2017). These clinicians collect health data daily through EMR (Oktaviana et al., 2022) for clinical purposes such as patient treatment (Walji et al., 2022). Low awareness of clinicians to collect EMR for non-clinical purposes becomes a challenge in health data governance (Walji et al., 2022). In addition, clinicians also have low motivation for good health data governance (Tiffin et al., 2019). This is because clinicians come from various universities with mixed learning backgrounds, resulting in low standard EMR and quality (Walji et al., 2022). To overcome these challenges, organization should provide clinicians with Hospital Information System (HIS) data entry training in the local language, ensuring an accurate and standardized health data collection process (Khurana, 2021). According to Ladley (2020), implementing data governance creates division, emphasizing that all stakeholders must have good data literacy. Increased data literacy in clinicians ensures that data assets are properly treated from the first time (Ladley, 2020). Moreover, leaders in health organizations also lack the initiative to establish health data governance (Thompson et al., 2015) due to a lack of understanding and knowledge (Allen et al., 2014; Nomura et al., 2020). Consequently, the provision of training in health data governance is a promising solution (Were and Moturi, 2017).

Patients are the main subjects of health data (Winter and Davidson, 2017), who require transparent information about the use of their data for non-medical purposes, benefits, and other side effects (Jones et al., 2020b; Sethi and Laurie, 2013). Other stakeholders must ask for informed consent from patients to reuse health data for non-medical purposes. In some cases, this process is difficult to implement, as patients in nursing homes have limitations in giving consent (Wieland-Jorna et al., 2023). Therefore, a challenge in health data governance is creating a new type and process of informed consent that meets patients demands and conditions (Sethi and Laurie, 2013). This new process should be transparent and more flexible, complying with the data privacy policy (Jones et al., 2020b; Shah et al., 2021; Wieland-Jorna et al., 2023). **Table 3** shows the summary of the challenges from stakeholders and recommendations for solutions.

Table 3. Health data governance challenges on the stakeholder side.

Stakeholders	Challenges description	Proposed solution
Clinicians	Low awareness of using EMR for a secondary purpose (Walji et al., 2022).	Improve health data literacy (Ladley, 2020).
	Low motivation for good health data governance (Tiffin et al., 2019).	
Leader of a healthcare organization	Lack of initiative to establish health data governance (Thompson et al., 2015).	Building awareness of health data governance (Were and Moturi, 2017).
	Lack of understanding of health data governance (Nomura et al., 2020).	
Patient/citizen	Informed consent does not meet patients' demands (Sethi and Laurie, 2013; Wieland-Jorna et al., 2023).	Create a new type and process of informed consent (Sethi and Laurie, 2013).
	There are unclear mechanisms to share and control their health data for non-clinical use (Jones et al., 2020b; Shah et al., 2019).	Provide better information about data-sharing practices in privacy policies (Jones et al., 2020b; Shah et al., 2021).
Government	Lack of awareness of health data governance (Were and Moturi, 2017).	Building awareness of health data governance (Were and Moturi, 2017).
	The Silos between government agencies (Khurana, 2021).	Use API for data interoperability (Khurana, 2021).
	Have minimum standards in health data governance (Allen et al., 2014).	Create standards for health data governance (DAMA International, 2017).
Health organization partner	Different understandings of the concept of health data governance among stakeholders (Milne and Brayne, 2020; Paparova et al., 2023; Sleigh and Vayena, 2021).	Create standards for health data governance (DAMA International, 2017).
	Data decision-making overlaps between stakeholders (Laurie and Nayha, 2013).	Improve data literacy (Ladley, 2020).
	Unclear responsibility for managing data quality (Murtagh et al., 2018; Winter and Davidson, 2019a).	Define data quality management (Li et al., 2021).

5.2. Policy

Policy is a set of ideas or plans designed for a specific situation, agreed upon by a group of people or government (Cambridge Dictionary, n.d.). According to (DAMA International, 2017), policy is needed to help organization achieve data governance goals. The General Data Protection Regulation (GDPR) is the first policy related to health data governance in the health sector. Implemented in 2018, the GDPR serves as the main framework for data protection across the European Union (Marelli et al., 2021). The GDPR is not in line with current developments in digital health innovations including individual health data (Marelli et al., 2020, 2021). This phenomenon results in low levels of legal compliance when reusing personal health data (Di Iorio et al., 2021). To overcome this challenge, the legal framework should continue to be renewed to reflect societal values and address changing health innovation requirements (OECD, 2015). In addition, the GDPR establishes guidelines for project approval agencies using personal health data to ensure compliance with legal activity (OECD, 2015). A flexible legal framework made policy more adaptable to support health innovation.

Certain policy with a cautionary culture have led to a lack of public participation in digital health innovation (Khurana, 2021; Kim et al., 2013; Sethi and Laurie, 2013). Consequently, to increase knowledge about health data, benefits, protection, and data subjects' rights, there is a need to investigate various methods to engage the public in discussions about private health data and governance (OECD, 2015). This effort is expected to result in policies that aid in health data governance (Sethi and Laurie, 2013). In addition, public participation can be increased by including patients in reusing personal health data through the new informed consent format (Kim et al., 2013; Shah et al., 2021; Winter and Davidson, 2019b). This new format poses a challenge because patients need transparency and guarantees of the benefits of reusing personal health data (Hripcsak et al., 2014; Winter and Davidson, 2019b). However, there is a lack of clear policy to determine data reuse, extent of use, and access mechanism (Martani et al., 2022; Nomura et al., 2020).

Globally, policy differences are challenges in health data governance, including variations in regulating data access, privacy, and ethics for identical datasets (Allen et al., 2014; Chen and Song, 2018; Karz et al., 2018; Laurie and Nayha, 2013; Pinto et al., 2022; Shidhaye et al., 2022; Thiel et al., 2014). This difference makes data access procedures unclear and uncertain, as well as laws regarding the use of personal health data (Thompson et al., 2015). To address these challenges, an independent review committee is required to create new regulatory forms, ensuring the benefits of reusing health data (Winter and Davidson, 2019a). Members of this committee include scientists, citizens, health workers, and authorities (Wieland-Jorna et al., 2023), consistently verifying and reviewing access protocols for using health data to ensure innovation facilitation and patient privacy protection.

At the country level, some policies are not easily understood and implemented by health organizations (Thompson et al., 2015), with a lack of compliance monitoring mechanisms (Tiffin et al., 2019; Walji et al., 2022). To overcome these challenges, governments should make compliance with regulations related to health data a national goal (DAMA International, 2017). Consequently, the national health data governance roadmap was created to address the issue of reusing health data (DAMA International, 2017). In Kenya, specific challenges that were identified included the absence of policy, supporting resources, and funding to succeed in health data governance (Were and Moturi, 2017).

The government must develop regulations supporting health data governance (Were and Moturi, 2017), such as investment funds to prepare human resources with strong data governance skills (Were and Moturi, 2017), building national eHealth data infrastructure (Tiffin et al., 2019), and creating laws to reuse individual health data

(Tiffin et al., 2019). All stakeholders must also have good awareness and knowledge about health data governance through campaigns and training activities. However, not all healthcare facilities have the ability to use EMRs, requiring government intervention to facilitate good infrastructure. The use of health data for non-clinical purposes has risks such as privacy violations, showing the need for regulations to maintain risks. **Table 4** shows the summary list of health data governance challenges from policy perspective and recommendation solutions.

Table 4. Health data governance challenges on the policies aspect.

Policy challenges	Challenges description	Proposed solution
Lack in policies	Some policies are not in line with current developments in digital health innovations that include individual health data (Marelli et al., 2020, 2021).	Continue to renew the legal framework to reflect societal values and address changing health innovation requirements (OECD, 2015).
	Have low legal compliance when reusing health data (Di Iorio et al., 2021).	Establish guidelines for project approval committees using health data (OECD, 2015).
	The policies with a cautionary culture lead to a lack of public participation in digital health innovation (Khurana, 2021; Kim et al., 2013; Sethi and Laurie, 2013).	Investigate ways to engage the public in discussions regarding health data and governance to raise knowledge of health data, advantages, protection, and subject data rights (OECD, 2015).
No policies	There is no policy to support resources and funding to succeed in health data governance (Were and Moturi, 2017).	Create a national policy to support health data governance (Were and Moturi, 2017).
	Have no mechanism for compliance monitoring (Tiffin et al., 2019; Walji et al., 2022).	Define regulatory compliance as a data governance goal (DAMA International, 2017).
	No policy guarantees the benefits of reusing personal health data (Hripcsak et al., 2014; Kim et al., 2013; Shah et al., 2021; Winter and Davidson, 2019b).	Create an independent review committee to recommend a new policy to guarantee the benefit of reusing health data (Winter and Davidson, 2019a).
	There is no policy for patients to control their health data in healthcare (Shaw and Sekalala, 2023; Martani et al., 2021).	
	There is no clear policy to determine who can reuse the data, to what extent the data can be used, and the mechanisms of access (Martani et al., 2022; Nomura et al., 2020).	
	There are differences in regulation in data access, data privacy, and ethics for the same health data set (Allen et al., 2014; Chen and Song, 2018; Karz et al., 2018; Laurie and Nayha, 2013; Pinto et al., 2022; Shidhaye et al., 2022; Thiel et al., 2014).	
	Unclear procedures and uncertain laws in the reuse of health data (Thompson et al., 2015).	
	Some policies are not easily understood and implemented at the country level (Thompson et al., 2015).	

5.3. Data management

Data Management Association (DAMA) defines data management as developing, implementing, and overseeing strategies, policies, programs, and procedures for controlling, protecting, delivering, and increasing the value of data and information assets (DAMA International, 2017). According to previous research, data governance operations need to be based on data management (Jang and Kim, 2021) to address several challenges such as ownership, access, and quality (DAMA International, 2017; Zorrilla and Yebenes, 2022). The suitability of the measured data for different applications is referred to as data quality (DAMA International, 2017). Meanwhile, the authorization to retrieve, edit, copy, or move data from I.T. systems is known as data access (DAMA International, 2017). Despite the ambiguous concept, data ownership is attributed to the producer and steward (Abraham et al., 2019).

In this research, data quality was identified as a challenge in data governance (Karz et al., 2018; Khurana, 2021; Walji et al., 2022) due to identical collection using different procedures (Khurana, 2021). In addition, the clinicians who input the data do not have the same knowledge about filling in the EMR (Walji et al., 2022). Although health sector has several standards, health information systems are still based on the need for reporting and analysis (Pinto et al., 2022; Li et al., 2019). When each organization does not use the same data standards (Winter and Davidson, 2017), there will be interoperability problems (Winter and Davidson, 2019b). Another cause of data quality is low accuracy (Foy et al., 2021) and incomplete information during collection process (Walji et al., 2022). To overcome these challenges, there is a need to develop a HIS using global standards such as the International Classification of Diseases (ICD) (Li et al., 2019), ensuring the integration of all health workers (Khurana, 2021). Furthermore, having data quality management enables hospitals to have complete, accurate, and useful health data for reporting and analysis (Khurana, 2021).

In data access, the implementation of the GDPR increases challenges associated with health data for non-medical use due to privacy concerns (Di Iorio et al., 2021). However, when the GDPR is ignored, the public needs assurance that health data is used for a limited purpose, based on committee data approval (Dodd et al., 2017). The public is concerned about losing control of their health data when used for non-medical purposes (Vayena and Blasimme, 2017). Health data of patients in healthcare are difficult to access and control (Kariotis et al., 2020). This is because the implementation of data access control ensures well-governed and compliant with legal standards (Tiffin et al., 2019), providing a solution to data access control. The two levels of data access control include procedure and technology. To address the procedure aspect, a Data Access Committee is established for data evaluation (Khurana, 2021; Tiffin et al., 2019). Meanwhile, the technology aspect entails the installation of firewalls, separating storage for sensitive data, and securing digital environments for health applications to ensure safety (Tiffin et al., 2019).

Karz et al. (2018) have shown the differences in data access procedures and requirements for reusing health data nationally as an additional challenge in health data governance at the macro level (Karz et al., 2018). Once the data is collected, it must adhere to the principles of Findable, Accessible, Interoperable, and Reusable (FAIR). This principle is applied throughout the data processing, ensuring sustainability and accessibility for authorized end-users (Tiffin et al., 2019).

Data ownership is the most critical challenge in health data governance. In many countries, government and management do not have data ownership (Were and

Moturi, 2017) due to the inability to implement strategic initiatives (Allen et al., 2014; Were and Moturi, 2017). Therefore, enhancing data literacy within the government can raise awareness of health data assets (Ladley, 2020).

Several countries have used GDPR to create exclusive ownership of personal health data for individuals (Shah et al., 2019; Nomura et al., 2020), providing the right to object to data processing, withdraw consent, and be contacted in case of a data breach (Shah et al., 2019; Nomura et al., 2020; Piasecki and Cheah, 2022). Although health data is a public good, the GDPR presents challenges in cross-border healthcare organizations' health data governance (Nomura et al., 2020). In Japan, national health data governance has been implemented with a people-trust method (Nomura et al., 2020) to increase public trust and participation. The Japanese government also provides a national infrastructure for public health data (Nomura et al., 2020). Through this method, patients can access their health data, facilitate participation in treatment decisions, and provide effective assistance in recognizing treatment-related health risks (Nomura et al., 2020). For research purposes, patients can actively provide informed consent (yes/no) (Nomura et al., 2020), reducing exclusive health data ownership. Moreover, the summary of this component's challenges and recommendations for solutions are shown in **Table 5**.

Table 5. Health data governance challenges from data management.

Data management challenges	**Challenges description**	**Proposed solution**
Poor data quality	The same health data was collected more than once (Khurana, 2021).	Use HIS with global health data standards (Khurana, 2021).
	Lack of data standards when creating a health information system (Pinto et al., 2022; Li et al., 2019; Walji et al., 2022; Winter and Davidson, 2017; 2019b).	Use global health data standards like ICD (Li et al., 2019).
	Difference procedures in data collecting (Karz et al., 2018).	
	Low data accuracy (Foy et al., 2021).	Define data quality management (Li et al., 2021).
	Incomplete data (Walji et al., 2022).	
Difficult to access data	Lack of data privacy control (Di Iorio et al., 2021; Dodd et al., 2017; Kariotis et al., 2020; Vayena and Blasimme, 2017).	Create data access control (Tiffin et al., 2019).
	There are differences in data access procedures (Karz et al., 2018).	Implement Findable, Accessible, Interoperable, Reusable (FAIR) principles for data sustainability (Tiffin et al., 2019).
The issue in data ownership	Do not have data ownership (Allen et al., 2014; Were and Moturi, 2017).	Define data owner in health organization (Ladley, 2020).
	Exclusive health data ownership (Shah et al., 2019; Nomura et al., 2020; Piasecki and Cheah, 2022).	Use a people-trust-oriented approach in the national health data governance framework to reduce exclusive health data ownership (Nomura et al., 2020).

5.4. Data governance organization

Data Governance Organization is organizational structure (DAMA International, 2017; Khatri and Brown, 2010), comprising various roles such as data access committee, ownership, producer, custodian, and customer (Khatri and Brown, 2010; Ladley, 2020). The models of data governance organizations might be centralized, decentralized, or federated (DAMA International, 2017; Khatri and Brown, 2010; Ladley, 2020). In a centralized model, one data governance organization covers all activities in business units, while a decentralized model has one data governance organization for every business unit (DAMA International, 2017; Ladley, 2020). Organization can mix centralized and decentralized models when one data governance is applied for every business unit within subject areas (DAMA International, 2017; Ladley, 2020).

In health sector, blockchain technology, a distributed peer-to-peer architecture to share and process health data, faces challenges in achieving the GDPR compliance (Foy et al., 2021). This is attributed to the difficulty of determining the organizational paradigm for data governance (Winter and Davidson, 2019a), as patients' health data are stored using conventional health systems. Moreover, it is also difficult to include patients directly in the system due to infrastructure problems and individual capabilities (Dodd et al., 2017; Milne et al., 2021; Wieland-Jorna et al., 2023).

Based on this research, several recommendations were provided as solutions to the data governance organization challenges. Firstly, all stakeholders should be represented on the data access committee (Dodd et al., 2017; Khurana, 2021; Tiffin et al., 2019) to enhance transparency, clarity, and flexibility (Khurana, 2021; Tiffin et al., 2019). Secondly, regular updates should also be provided to enhance public confidence, participation, and understanding of reusing health data (OECD, 2015). The summary of these challenges and recommended solutions for health data governance are shown in **Table 6**.

Table 6. Health data governance challenges from data governance organizations.

Data governance organization challenges	**Challenges description**	**Proposed solution**
Lack of a model of data governance organization	Difficult to include patients/citizens as a data access committee (Dodd et al., 2017; Milne et al., 2021; Murtagh et al., 2018). Data governance organizations' models find it challenging to meet data privacy compliance (Foy et al., 2021; Winter and Davidson, 2019a).	Making health data reuse regulations more transparent, clear, and flexible (not rigid) (Khurana, 2021; Tiffin et al., 2019).

6. Conclusion

In conclusion, this research showed that the first challenge in health data governance was policy component. However, some data governance related to policy was identified as a barrier, including unclear and rigid policies. This showed that the implementation of policy on health data governance required proactive efforts from regulators and leaders in healthcare organizations.

The second challenge was found to be stakeholders component, playing an essential role in data lifecycle, from creators and owners to users. Specifically, policymakers as users of health data, pose a significant challenge in driving the implementation of health data governance. Addressing this challenge requires a strategic focus on building awareness of health data governance among policymakers.

The third challenge is data management, particularly when efforts are directed toward enhancing the quality of health data and access. Furthermore, establishing health data governance organization that complies with policy is also challenging. A key solution to address challenges in data quality management and access is the creation of a specialized committee within health data governance organization. The implementation of data quality management committee is also essential for establishing health data standards. Meanwhile, data access committee would develop a clear procedure that guaranteed privacy issues. This practical knowledge can be used by healthcare leaders to optimize their health data governance.

Despite the effort to make a complete review of challenges in health data governance, this research has some limitations. These include the inability to obtain all articles due to limited access from the university. The analysis of challenges was based on six data governance components discussed in the discussion section. As research on health data governance progresses toward implementation, challenges related to data governance maturity assessment and goals have not been identified. Therefore, future research is recommended to examine the maturity assessment model for health data governance as well as the concept of micro and macro-level health data governance objectives.

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