

Compliance with Interoperability Standards in Implementing Digital Health in Low and Middle-Income Countries

Daniel Irongo ^{a,*}, Funmi Adebisin ^a, Rosemary Foster ^b

^a Department of Informatics, University of Pretoria, South Africa

^b School of Public Health, University of Cape Town, South Africa

Background and Purpose: Low- and Middle-income Countries (LMICs) bear over 70% of global mortality and morbidity, compounded by systemic healthcare challenges. In response, many LMICs have adopted Digital Health (DH) to transform patient management and overall care. However, the transformative potential of DH is constrained by poor interoperability among diverse systems, which undermines effective data sharing and informed decision-making. This study explores the factors that hinder compliance with interoperability standards in DH implementations in LMICs.

Methods: A Systematic Literature Review (SLR) was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, with peer-reviewed articles retrieved from PubMed, Scopus, and ScienceDirect. The search, covering the literature from January 1, 2015, to January 30, 2025, was refined using relevant keywords. Out of 865 screened articles, 38 underwent full-text assessment, and 22 met the quality criteria for analysis.

Results: The analysis, structured using the Technology-Organisation-Environment (TOE) framework, identified key barriers. Technological challenges include inadequate Information Technology (IT) infrastructure, limited standardization, fragmented systems, and adaptation difficulties. Organizational barriers involve weak leadership, poor governance, limited technical capacity, and resistance to change. Environmental obstacles include outdated regulations, weak compliance monitoring, data security concerns, and financial constraints.

Conclusions: These findings underscore the need for a coordinated, multi-level approach to enhance interoperability compliance in DH, thereby improving healthcare outcomes in LMICs. Targeted interventions are essential to drive sustainable DH implementation in LMICs.

Keywords: Compliance, Digital Health, Interoperability standards, Low- and Middle-income Countries, LMICs.

1 Introduction

Low- and Middle-income Countries (LMICs) account for over 70% of global mortality and morbidity rates [1-3]. These high disease burdens are further stressed by systemic healthcare challenges, including a shortage of skilled personnel, weak governance, and inadequate information systems infrastructure [4-6]. In response, several LMICs have implemented health sector reforms to enhance healthcare service delivery [7-9]. A significant aspect of these reforms involves using digital health (DH) interventions to improve healthcare delivery, leveraging the increasing network connectivity and mobile phone usage.

DH is defined as the development and application of digital technologies and data to enhance health outcomes [10-12]. According to the World Health Organization (WHO), DH encompasses various domains, including Electronic Health (eHealth), Mobile Health (mHealth), the Internet of Things (IoT), and Artificial Intelligence (AI). Furthermore, Al Meslamani [13], Kabore et al. [14] and Ramnath [15] note that DH encompasses many technologies, including big data, robotics, machine learning, remote monitoring, genomics, smart wearables, blockchain, telehealth, and telemedicine. The rise of DH holds significant promise for transforming healthcare delivery in LMICs by facilitating more efficient patient management, remote care, chronic disease management, operational efficiency, care coordination, and robust data management and analytics [16-18].

Despite their transformative potential, DH solutions implemented in LMICs are often not interoperable, thereby hampering effective data exchange and limiting the capacity to enhance healthcare delivery [19-21]. Interoperability in DH, as defined by Kawamoto et al. [22], Kobusinge [20], Kramer and Moesel [23], and Torab-Miandoab et al. [24], refers to the capability of DH to share and utilize data to advance healthcare objectives. An interoperable DH solution is crucial for facilitating the seamless and secure exchange of data, which enhances informed decision-making and improves healthcare delivery, underpinned by established interoperability standards [22, 25].

Interoperability standards are the most critical drivers of DH interoperability, ensuring seamless exchange and use of data across fragmented and varying vendors' DH solutions [26-29]. These standards consist of technical specifications that define common protocols, data formats, guidelines, and languages for interoperability [26, 29, 30]. Notably, standards such as Fast Healthcare Interoperability Resources (FHIR), Health Level Seven (HL7), and Aggregate Data Exchange (ADX) have been adopted across several LMICs to enhance healthcare delivery [25, 31, 32].

Compliance with interoperability standards is essential for the successful implementation of DH solutions that could transform healthcare delivery [27, 33-35]. However, LMICs often face inadequate compliance with interoperability standards due to various technological, organizational, and environmental factors [27, 33-35]. Despite frameworks provided by the International Telecommunication Union (ITU) and the WHO advocating for the use of interoperability standards, many LMICs struggle with adherence [36, 37]. Additionally, Bincoletto [38], Jonnagaddala et al. [39], Nsaghurwe et al. [21], and Pine [40] highlight the scarcity of literature addressing the factors hindering compliance with interoperability standards in DH implementation within LMICs.

This study reported in this paper conducted a systematic literature review (SLR) to provide an overview of current knowledge of factors that hinder compliance with interoperability standards in the implementation of DH in LMICs and to identify gaps in existing literature. It is anticipated that the findings from the SLR will offer valuable insights for policymakers, healthcare providers, technology developers, researchers, and other key stakeholders. These insights can guide the development of targeted interventions to enhance the effectiveness of DH and transform healthcare outcomes in LMICs. The paper is structured as follows: Section 2 outlines the research methodology, Section 3 presents the results, and Section 4 discusses the implications of the findings, with the conclusions in Section 5.

2 Materials and methods

This study was based on the PRISMA guidelines by Page et al. [41]. The primary research question addressed in this paper was: "What are the factors that hinder compliance with interoperability standards in implementing digital health in low and middle-income countries?" Peer-reviewed research papers were retrieved from three electronic databases (i) PubMed, (ii) Scopus and (iii) ScienceDirect. The selection of these databases was based on their prior utilization in similar studies, including those by Alunyu et al. [42], Higman et al. [43], and Palojoki et al. [44], as well as their comprehensive coverage of DH and interoperability standards in LMICs.

The study's primary objective, to synthesise and document factors that hinder compliance with interoperability standards in implementing digital health in low and middle-income countries, guided the identification of keywords. The primary keywords were "digital health", "interoperability standards", "compliance", "low- and middle-income countries", and "factors hindering". Synonyms and related terms for each keyword were generated to ensure a comprehensive search.

For "digital health", associated terms included "health information systems", "eHealth", and "health information technology". For "interoperability standards", the related term was "interoperability". For "compliance", the associated terms were "adherence" and "conformity". For "low- and middle-income countries", synonyms included "developing countries", "LMICs", and "resource-constrained countries". Finally, for "factors hindering", the related terms were "barriers" and "challenges". These terms were combined using Boolean operators, "OR" to include synonyms and "AND" to connect different keywords. The resulting search phrase was: ("digital health" OR "health information systems" OR "eHealth" OR "health information technology") AND ("interoperability standards") AND ("compliance" OR "adherence" OR "Conformity") AND ("low- and middle-income countries" OR "developing countries" OR "LMICs" OR "resource-constrained countries") AND ("barriers" OR "challenges" OR "factors hindering").

The search phrase was tested and refined in PubMed, Scopus, and ScienceDirect to fine-tune search terms, maximise the retrieval of relevant studies, and minimise irrelevant results.

2.1 Inclusion and exclusion criteria

The inclusion and exclusion criteria were meticulously defined to ensure a comprehensive and the retrieval of relevant literature, capturing diverse studies that shed light on factors hindering compliance with interoperability standards in DH implementation within LMICs, as illustrated in Table 1:

Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Peer-Reviewed Articles: Only peer-reviewed publications, including original research, case studies, and reviews, were considered to ensure quality, reliability, and diverse perspectives.	Topic Relevance: Studies that did not discuss interoperability standards in DH were excluded, ensuring that the SLR addresses the core issues pertinent to DH implementation.
LMIC Focus: Studies focused on LMICs, as classified by the World Bank, recognizing their unique DH implementation challenges would differ from high-income countries.	Geographic Scope: Studies not focused on LMICs were excluded to maintain the study's relevance to LMIC-specific challenges and contexts.
Interoperability Barriers: Included studies specifically addressed barriers, challenges, or obstacles to compliance with interoperability standards in DH implementation.	Language: Articles not published in English were excluded to maintain access and consistency in the analysis.
Digital Health Scope: Research covered various DH domains, including eHealth, electronic health records (EHRs), health information exchanges (HIEs), telehealth, and mHealth, ensuring a comprehensive view of interoperability challenges.	Publication Date: Articles published before 2015 were excluded to ensure the review reflects the most recent developments and trends in DH interoperability.
Language & Publication Date: Only English-language articles published between January 1, 2015, and January 30, 2025, were included to ensure relevance while capturing recent developments.	

2.2 Screening process and quality assessment

PubMed, Scopus, and ScienceDirect databases were filtered to retrieve only papers published between January 1, 2015, and January 30, 2025, ensuring relevance while capturing recent developments. The database search retrieved a total of 1,007 records, including PubMed (651), Scopus(204), and ScienceDirect (152). All identified studies were imported into EndNote 20.6 for meticulous reference management. Following an initial screening, 142 duplicate sources across the three databases were deleted. Thereafter, the remaining 865 sources were screened to ensure that they met the inclusion criteria. Titles and abstracts were assessed against predefined inclusion criteria, leading to the exclusion of 646 records; three were non-English, six were editorials, 623 were review articles, and 14 were published before 2015. This resulted in 219 articles that underwent full-text assessment for eligibility. Upon detailed examination, 181 articles were excluded due to inadequate and out-of-context discussions on compliance with interoperability standards. Thereafter, the remaining 38 papers were assessed for quality using the following quality assessment (QA) questions:

1. Does the paper adequately discuss technological, organizational, or environmental factors that hinder compliance with interoperability standards in digital health implementation?
2. Does the paper explore the different dimensions or components of these hindering factors within the Technology-Organization-Environment (TOE) framework?
3. Does the paper analyse how these hindering factors impact the successful implementation and scaling of interoperable digital health solutions in LMICs?

For QA1, papers that only mentioned factors hindering compliance with interoperability standards were awarded a score of 0, those that provided a limited explanation were awarded 0.5, while those that provided an adequate discussion were awarded 1. For QA2, papers that did not categorize factors under the TOE framework were awarded a score of 0, those that partially mapped factors to at least one TOE dimension were awarded 0.5, and those that comprehensively categorized factors under all three TOE dimensions were awarded 1. For QA3, papers that did not discuss the impact of non-compliance were awarded a score of 0, those that provided at least one impact were awarded 0.5, while those that discussed two or more impacts were awarded 1. Thus, a paper could have a maximum score of 3. Only sources that obtained at least 1.5 were considered for inclusion in the SLR. Following the QA process, a total of 22 papers were included in the final analysis. Figure 1 illustrates the source selection process.

We analyzed these 22 papers using descriptive statistics to examine paper distributions by year of publication and document type. Qualitative content analysis was used to extract concepts and map the identified factors to the TOE framework. The results of this analysis are presented in Section 3.

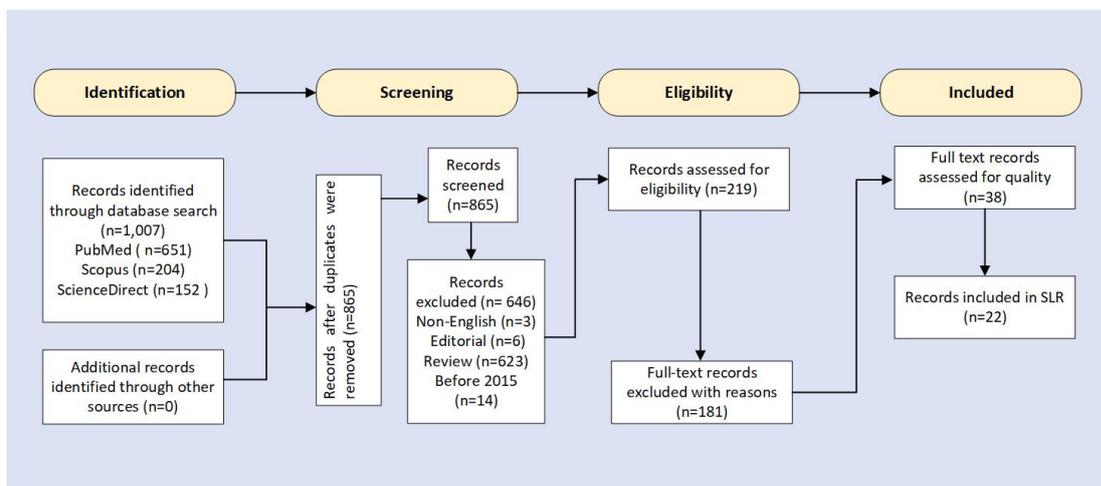


Figure 1. SLR screening process

2.3 Ethical Considerations

This SLR involved the analysis of existing literature and did not require ethical approval as it did not involve primary data collection or interaction with human subjects. However, ethical considerations were taken into account by ensuring proper citation and acknowledgement of all sources used in the review as prescribed by Taquette and Borges [45].

3 Results

This section presents the findings derived from the analysis of the 22 studies included in the SLR.

3.1 Basic quantitative analysis results

The descriptive statistical analysis of 22 papers included in the SLR by publication year revealed that a single paper was published in 2015 and 2018, respectively (see Figure 2). The number of publications increased to two in 2020 and 2022, respectively, followed by a notable rise to five in 2021. In 2023, the number of publications reached four, before peaking at six in 2024. The analysis further shows one publication in 2025. This is because the sources included in the SLR were retrieved on January 30, 2025.

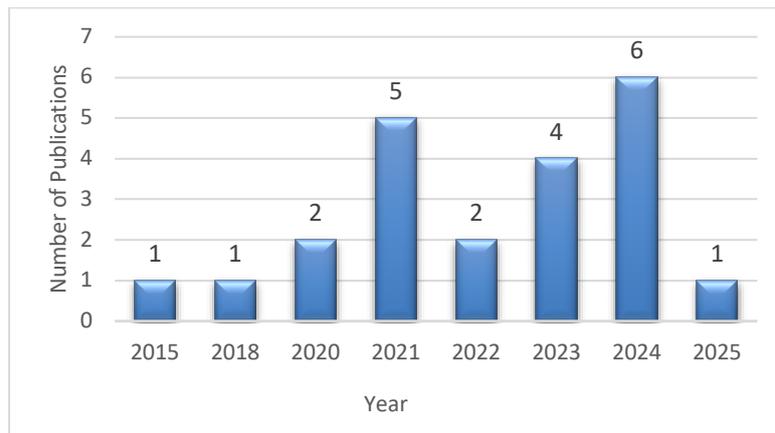


Figure 2. Number of publications per year

The analysis by document type revealed that the majority of the papers (19) were journal articles, while the remaining three were conference proceedings. The analysis by source databases showed that 13 (59.1%) of the papers were retrieved from PubMed, six (27.1%) from Scopus and three (13.6%) from ScienceDirect.

3.2 Basic qualitative analysis results

The qualitative analysis of the 22 selected studies followed a structured approach to identify barriers to compliance with interoperability standards in DH implementation across LMICs. Data were systematically extracted and organized in Excel, with key study characteristics including publication details, study setting, findings, and reported challenges recorded in separate columns. Through initial coding, descriptive labels were assigned to frequently mentioned challenges, capturing patterns across multiple studies. These codes were then reviewed and grouped into broader themes, reflecting common obstacles such as technical constraints, organisational limitations, and regulatory gaps. To ensure a structured interpretation, the TOE framework was adopted as an analytical model for categorizing these themes into interdependent domains.

The TOE framework, developed by DePietro [46], explains how organizations adopt and implement technological innovations based on three key contexts: technological, organizational, and environmental. This framework was selected for its capacity to provide a comprehensive analysis of the multifaceted factors that impact interoperability in DH implementations [46]. It offers a structured approach to identifying and understanding barriers across these three dimensions [46].

1. Technological Context – Encompasses internal and external technologies relevant to the organisation, including system capabilities, infrastructure, and interoperability standards.
2. Organisational Context – Includes internal factors such as structure, resource availability, management processes, and organisational capacity to support technology adoption.
3. Environmental Context – Covers external influences such as regulatory frameworks, policy fragmentation, market conditions, and socio-economic factors that impact technology implementation.

The application of the TOE framework has been established in various studies examining factors that influence technology adoption in similar contexts. For instance, Al Hadwer et al. [47] conducted a systematic review that emphasized organizational factors impacting cloud-based technology adoption, underscoring the framework's utility in understanding readiness and capability. Similarly, Anthony Jnr [48] investigated telehealth adoption during public health emergencies, utilizing the TOE framework to explore the determinants that influence implementation. Assaye et al. [49] assessed readiness for big health data analytics in Ethiopian health sectors through the TOE analytical lens, while Ngongo et al. [50] examined the determinants of mHealth adoption in Kenyan hospitals, revealing the interplay among technological, organizational, and environmental factors.

This study applied the TOE framework to systematically analyse the barriers to interoperability in DH implementation in LMICs. These barriers are categorized into technological (e.g., legacy systems, lack of standardization, and infrastructure limitations), organizational (e.g., governance weaknesses, resource constraints, and limited technical capacity), and environmental (e.g., regulatory gaps, fragmented policies,

and market dynamics) factors. By structuring these challenges within the TOE framework, this study provides a deeper understanding of interoperability constraints and informs strategic interventions to enhance compliance in LMICs. Based on the synthesis of the sources included in the SLR and guided by the TOE framework, successful compliance with interoperability standards requires a balance between technological capabilities, organisational capacity, and external environmental factors (see Figure 3).

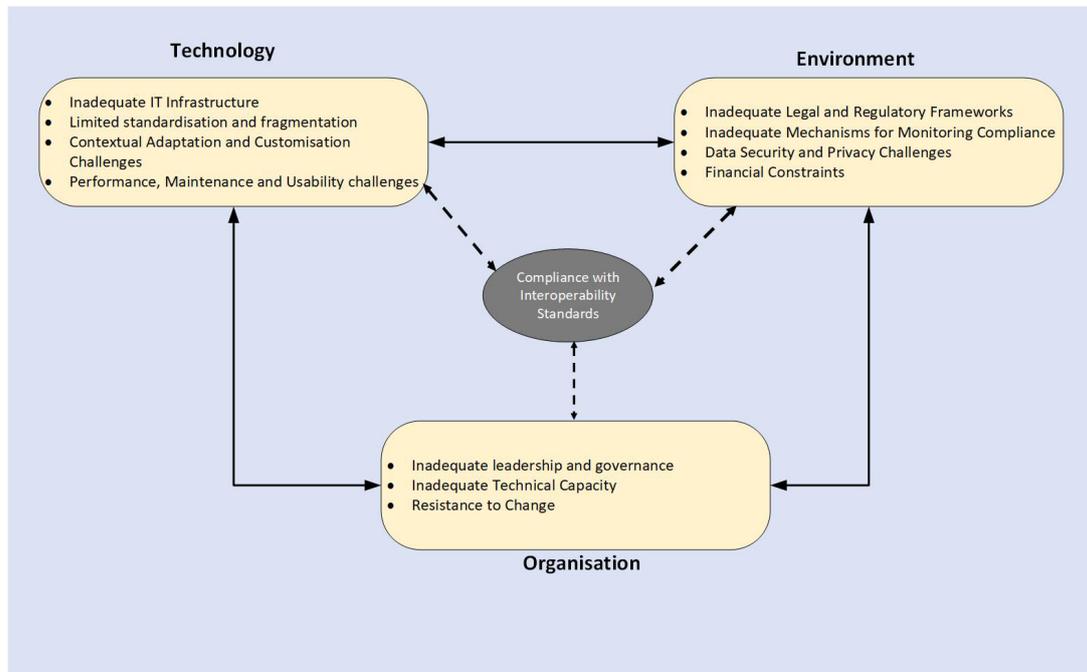


Figure 3. A conceptual framework of the factors that hinder compliance with interoperability standards using the TOE framework

3.2.1 Technology Factors

- **Inadequate IT infrastructure:** One of the technological factors that was found to hinder compliance with interoperability standards was inadequate IT infrastructure in LMICs. Inadequate IT infrastructure entails deficiencies in the foundational technological systems required for seamless data exchange and compliance with interoperability standards in DH. This factor was identified from seven sources included in the SLR [39, 51-56]. Studies reported that many LMICs have to contend with insufficient hardware, outdated software, unreliable network connectivity, and unstable electricity, which collectively hinder compliance with interoperability standards [39, 51-56]. It was further noted by Bagyendera et al. [51] that inadequate internet connectivity, limited server capacity, and a lack of data analysis tools in several health facilities across LMICs significantly impede data collection, storage, and sharing. Additionally, Jonnagaddala et al. [39] emphasised that such infrastructural weaknesses limit the ability to adopt and sustain interoperable systems, thereby hindering effective compliance with interoperability standards in LMICs.
- **Limited standardization and fragmentation:** Limited standardization and fragmentation were additional technological factors found to hinder compliance with interoperability standards. Standardization ensures uniform technical protocols for compatibility and interoperability, while fragmentation arises from a lack of coordination, leading to isolated and incompatible systems. These closely interlinked factors were highlighted by three sources included in the SLR [39, 51, 52]. LMICs were reported to have a limited availability of universally adopted standardised data formats leading to inconsistent data structures across DH, complicating the consolidation and exchange of data across platforms [39, 51, 52]. Furthermore, Bille et al. [52] emphasized that LMICs are characterised by variations in medical terminologies that amplify challenges with complying with interoperability standards, resulting in inconsistencies in the recording of diagnoses, treatments, and procedures. These discrepancies increase

the risk of misinterpretation, data mismatches, and disruptions in care coordination, which ultimately impact treatment outcomes.

Additionally, Bagyendera et al. [51] and Bille et al. [52] noted that LMICs have a high prevalence of fragmented, independently deployed DH solutions, which create isolated data silos, further hindering seamless information exchange and compliance with interoperability standards. Bagyendera et al. [51] and Bille et al. [52] attribute the high prevalence of fragmented DH in LMICs to limited centralised governance, inconsistent funding sources, and the adoption of donor-driven vertical programs that prioritise specific health interventions over integrated system development.

- Contextual adaptation and customisation challenges: Contextual adaptation and customization challenges were also reported as key technological hindrances to compliance with interoperability standards in the implementation of digital health in LMICs across two sources in the SLR [57, 58]. The contextual adaptation and customization challenges relate to the limited ability to modify interoperability standards during DH implementation to fit the local context in LMICs. It was reported that interoperability standards, such as HL7 and FHIR, which are widely used in LMICs, have not been adequately adapted to local contexts, leading to misalignment with the specific interoperability requirements and challenges of these settings [57, 58]. It was also observed that DH solutions deployed in LMICs have frequently been designed for developed contexts, with limited consideration for local cultural and operational interoperability requirements, creating technical challenges in adaptation and compliance with standards [57, 58].
- Performance, maintenance, and usability issues: Several sources [54, 57, 59, 60] identified technological challenges, such as performance, maintenance, and usability issues, as significant barriers to compliance with interoperability standards in LMICs. Several DH solutions in LMICs face limited optimization in terms of performance, usability, and availability, creating obstacles to effective implementation and adherence to interoperability standards [57]. Examples include slow Electronic Medical Record (EMR) response times due to inadequate servers at health facilities, complex DH interfaces that hinder navigation, and unreliable internet connectivity, which disrupts access to cloud-based platforms in rural facilities [57]. Additionally, frequent technical malfunctions in DH solutions, often caused by poor system design and inadequate testing, disrupt seamless data exchange and undermine user trust, thereby reducing compliance with interoperability standards [59]. The lack of sufficient maintenance of IT infrastructure, including networks and hardware, exacerbates these challenges, contributing to unstable environments that further compromise interoperability [54]. Moreover, LMICs often rely on outdated DH solutions, making it difficult to comply with evolving interoperability standards due to the need for regular updates and rigorous testing [60]. The dominance of proprietary technologies developed by multiple vendors in many LMICs also restricts interoperability, as these vendors maintain market dominance, which leads to widespread non-compliance with established standards [60].

3.2.2 Organizational Factors

- Inadequate leadership and governance: From an organizational perspective, 11 sources [39, 51-55, 61-65] identified inadequate leadership experience and weak governance structures as significant impediments to compliance with interoperability standards in LMICs. Several public health and ICT sector leaders across LMICs were found to frequently demonstrate limited political will and commitment to enforce policies and guidelines that mandate compliance with interoperability standards [39]. Additionally, governance structures in LMICs are frequently reported to be insufficiently developed to support the formulation and enforcement of digital health interoperability standards [54, 64]. Furthermore, LMICs were found to generally have limited well-established leadership frameworks, governance mechanisms, and dedicated regulatory bodies to ensure adherence to organizational policies, procedures, and best practices necessary for interoperability compliance [54].

In addition, it was reported that healthcare organizations in LMICs frequently struggle to align their internal processes and structures with the requirements necessary for compliance with interoperability standards [62, 63]. Specifically, LMICs were noted to exhibit inconsistent organizational practices, coupled with unclear roles and responsibilities concerning interoperability standards, leading to fragmented implementation processes and weakened compliance efforts [63]. Similarly, a survey by Kiwanuka et al. [61] reported that only 46% of respondents perceived DH governance at the facility level to be strong. This was attributed to the absence of formal guidelines and an overreliance on ad-hoc measures at facilities, which create inconsistencies and inefficiencies in

data governance practices [61]. It was also emphasized that governance guidelines in LMICs are often inadequate, unclear, or undocumented, making it challenging to ensure the integrity and reliability of health data, an essential factor for compliance with interoperability standards [51]. Poorly defined governance structures and mechanisms in LMICs were reported to contribute to weak coordination, ineffective enforcement of leadership and governance regulations, and the inability to ensure compliance with interoperability standards [53].

Furthermore, the lack of adequately structured frameworks and guidelines to support the adoption and standardization of digital health interoperability in LMICs was reported [52, 63, 64]. Studies observed that governance frameworks in LMICs are often insufficient to facilitate the systematic adoption of interoperability standards, resulting in inconsistencies and incomplete compliance [63, 66]. Additionally, in several LMICs, interoperability governance guidelines were noted to exist primarily as informal mental models rather than structured documents, making compliance more challenging [51]. The absence of well-documented interoperability procedures was identified as a barrier to effective communication and coordination among key stakeholders in LMICs, including government agencies, healthcare institutions, technology providers, and policymakers [52, 64]. These gaps were reported to have slowed progress in the implementation of interoperable DH solutions and led to inconsistencies in the application of standards, ultimately weakening overall compliance efforts.

- **Inadequate capacity:** 14 sources [39, 51, 53-57, 59, 61-63, 66-68] identified inadequate capacity in LMICs, characterized by knowledge gaps, insufficient training, and a shortage of skilled personnel, as a substantial obstacle to compliance with DH interoperability standards. Many LMICs face a shortage of skilled personnel with the expertise needed to manage and implement interoperability standards [57]. A shortage of skilled personnel in LMICs is reported to hamper the development, monitoring, and compliance with DH interoperability standards [55]. Moreover, awareness of interoperability principles was found to be insufficient not only among healthcare professionals in LMICs but also at the institutional level [39]. Specifically, a limited understanding of Enterprise Architecture (EA) and interoperability standards among key stakeholders, including government bodies, healthcare organizations, and IT professionals across LMICs, was highlighted, impeding the effective implementation of interoperability initiatives [39]. LMICs were further reported to experience a shortage of staff responsible for managing DH and data at healthcare facilities, leading to operational disruptions and undermining efforts to maintain consistent interoperability [51, 56, 66, 67]. Several clinicians in LMICs frequently use shorthand or submit incomplete information, resulting in poor data quality and inaccurate entries that undermine the integrity of health records, which is crucial for effective interoperability [67].

Another key dimension of inadequate capacity is the scarcity of structured and consistent training programs for healthcare workers, IT professionals, and policymakers involved in DH implementation [53, 61, 62, 66, 67]. A survey revealed that while 70% of healthcare workers had received training on various healthcare topics including patient privacy and confidentiality, fewer than half had been trained in DH and interoperability standards [62]. Moreover, LMICs were found to exhibit a limited availability of training and educational programs for healthcare providers, regulators, and other key stakeholders, especially regarding the importance of interoperability and adherence to DH standards [53]. It was further noted that LMICs have not integrated DH interoperability courses into existing health professional training curricula, creating an educational gap and hindering the development of essential knowledge and skills required to ensure compliance with interoperability standards [61, 66, 67]. LMICs were also observed to have a shortage of health professionals trained in key interoperability areas such as medical coding, with those trained often possessing outdated knowledge, further hindering the progress towards interoperability [61, 67].

- **Resistance to change:** Resistance to change in LMICs is significantly driven by insufficient involvement of both users and management in the decision-making and DH design processes [52, 61, 63, 65]. Inadequate stakeholder involvement in DH design in LMICs was observed to result in misalignment with operational requirements, workflow disruptions, resistance, and non-compliance with interoperability standards [61, 65]. A survey of healthcare stakeholders in an LMIC revealed that only 36% of participants felt engaged in DH planning, while 52% reported insufficient management participation, leading to misaligned systems and resistance to interoperability standards for data exchange and use [61]. Healthcare professionals in LMICs were also found to rely on traditional record-keeping methods, with frequent resistance to DH due to concerns about usability, workload, and workflow disruptions, hindering digital transformation and compliance with standards [52]. LMICs were further noted to lack sufficient national strategies to raise awareness about DH

interoperability standards, leading to high resistance and inconsistent adherence across healthcare facilities [63].

3.2.3 Environmental Factors

- Inadequate legal and regulatory frameworks: Six sources [52, 63-65, 69, 70] detailed inadequate legal and regulatory frameworks as one of the factors hindering compliance with DH interoperability standards. Numerous legal and regulatory frameworks in LMICs are inadequately designed to meet the specific requirements for interoperability, particularly concerning data exchange, privacy, and the ethical use of health data, thereby impeding compliance with DH interoperability standards [53, 61]. Several LMICs were indicated as having outdated legal and regulatory guidelines that fail to address the complexities of DH systems, leading to inconsistencies in data sharing, weak enforcement of standards, and regulatory gaps, thereby hindering compliance with interoperability standards [61, 71]. The inadequacy of clear, enforceable operational, legal and regulatory frameworks for DH in LMICs leads to inconsistencies in data sharing, weak enforcement of standards, and regulatory gaps, thereby hindering compliance with interoperability standards [39, 53, 68, 71]. The absence of clear and enforceable operational, legal and regulatory frameworks for DH in LMICs leads to inconsistent implementation and adherence to DH interoperability standards, resulting in fragmented DH systems that impede effective data exchange and compromise patient care [34, 39, 53, 68, 70]. For example, the frequent absence of clear frameworks for patient control over personal health data in LMICs is indicated to pose a significant challenge to data sharing and collaboration across DH systems, hindering compliance with DH interoperability standards [53, 69].
Additionally, a slow evolution of legal and legislative frameworks in LMICs was highlighted as a hindrance to aligning these frameworks with evolving standards, thereby hindering compliance [53]. LMICs were also noted to face challenges in developing standardised, scalable, and interoperable DH systems due to diverse cross-border legal and regulatory frameworks across these settings, leading to non-compliance with interoperability standards [34].
- Inadequate monitoring of compliance: From the studies analysed in the SLR, eight sources [55, 57, 61, 63, 64, 66, 68, 71] identified inadequate monitoring of compliance with interoperability standards as an additional barrier to achieving DH standards compliance in LMICs. Regulatory frameworks in LMICs were found to have insufficient mechanisms for monitoring compliance with interoperability standards, which directly contributes to low adoption and weak enforcement [61, 63, 64, 68]. LMICs were further reported to have weak institutional capacity characterized by insufficient staffing and limited structures dedicated to monitoring compliance with interoperability standards [55, 61, 63]. Specifically, a lack of an adequate framework for monitoring compliance with interoperability standards, specifying stakeholders, enforcement mechanisms, risk assessment procedures, and procedures for escalation in cases of non-compliance was noted in LMICs [55, 57, 63, 66]. Limited awareness among key stakeholders about monitoring compliance with interoperability standards was also found to hinder the prioritisation of these standards in DH planning, routine implementation, oversight, and inclusion in DH guidelines [61, 71]. It was further highlighted that several LMICs perceive monitoring compliance with interoperability standards as the responsibility of health development partners, who serve as the principal funding entities for many digital health initiatives in these contexts [57, 61].
- Data security and privacy challenges: Based on analysis of sources included in the SLR, six [34, 53, 61, 65, 70, 72] indicated that ensuring compliance with interoperability standards is severely challenged by pervasive data privacy and security issues. The legislation in LMICs was noted to be deficient in addressing data confidentiality, ethics, and privacy concerns, particularly related to the secure collection and transfer of personal data across DH systems, hindering compliance with standards [61]. A scarcity of regular data audits and secure data handling was highlighted in LMICs, raising the risk of unauthorized access to sensitive health data, thereby eroding trust across DH stakeholders and hindering adherence to interoperability standards [70]. At the health facility level, although several LMICs were found to have physical security measures like security personnel and locked server environments, there were concerns about the limited availability of measures to ensure data security and compliance with interoperability standards [61, 70]. Evidence further indicated that in LMIC health facilities, data privacy and security measures are typically adopted directly from governing bodies such as Ministries of Health, but rarely adapted to local contexts or integrated with interoperability compliance measures [61].

- **Financial Constraints:** Eight studies [39, 51, 52, 54, 59, 61, 63, 65] reported that financial constraints significantly hinder compliance with interoperability standards in the implementation of DH in LMICs. It was highlighted that LMICs have constrained healthcare budgets, making it difficult to invest in and sustain interoperable DH systems, thereby reducing overall compliance with interoperability standards [54, 59, 63]. A survey conducted among healthcare stakeholders found that only 38% of respondents believed that health facilities and the Ministry of Health had adequate financial capacity to support DH interoperability initiatives, such as infrastructure, hindering compliance [61]. Beyond initial investments, LMICs were reported to face significant operational costs to sustain the technical support needed to address ongoing DH interoperability challenges, ultimately deterring health facilities from maintaining these systems and hindering compliance [51].

The overall shortage of financial resources for DH in LMICs was cited as undermining regulatory oversight, as Ministries of Health struggled to secure adequate funding for continuous monitoring and enforcement of interoperability standards [52]. Additionally, the shortage of financial resources in LMICs was noted to hamper workforce capacity development, limiting the ability to effectively manage and evolve digital health systems in line with interoperability requirements [39]. Furthermore, LMICs were reported to frequently rely on donor funding, which undermines the long-term sustainability of DH initiatives, leading to fragmented services and difficulties in maintaining compliance with interoperability standards over time [65].

4 Discussion

This systematic review aimed to identify the factors that hinder compliance with interoperability standards in the implementation of DH in LMICs. Using the TOE framework [73] as a theoretical lens, the findings reveal a complex interplay of barriers across the technology, organizational and environmental dimensions. These challenges are not isolated but rather interrelated, suggesting that sustainable progress towards compliance with DH interoperability standards in LMICs requires integrated interventions that address each dimension simultaneously.

4.1 Technological Barriers

One of the most prominent findings from SLR is the pervasive inadequacy of IT infrastructure in several LMIC settings. Inadequate hardware, outdated software, unreliable network connectivity, and unstable power supplies significantly impede seamless data exchange, which is required for interoperability and compliance with standards [39, 51-56]. These infrastructural weaknesses not only limit the initial adoption of interoperable systems but also compromise their long-term sustainability. These findings echo previous research that underscores the critical need for robust and scalable IT systems to support digital transformation in LMICs [74-77].

Limited standardization and system fragmentation emerged as additional technological barriers. The lack of sufficient universally adopted data formats and consistent medical terminologies leads to isolated data silos, complicating efforts to consolidate and exchange information across DH platforms and compliance with standards [39, 51, 52]. The prevalence of independently deployed solutions further exacerbates this problem, making compliance with interoperability standards more challenging and increasing the risk of data mismatches and misinterpretation of clinical information. These issues have been highlighted in earlier studies that call for harmonized standards to improve health data quality and care coordination [28, 42, 78, 79].

Contextual adaptation and customization challenges also play a significant role. While interoperability standards such as HL7 and FHIR are widely used, they often are not sufficiently tailored to meet the unique cultural and operational needs of LMICs [56, 58]. This misalignment between global standards and local requirements creates technical difficulties that hinder both adoption and ongoing compliance. Additionally, performance, maintenance, and usability issues, exacerbated by poor system design and insufficient testing, undermine user trust and disrupt the consistent implementation of interoperable systems [54, 57, 59, 60]. Together, these technological challenges call for context-sensitive approaches that ensure both technical robustness and local relevance.

4.2 Organizational Barriers

At the organization level, the SLR highlights inadequate leadership and weak governance structures as major impediments to compliance with interoperability standards. A significant number of studies [39, 51-55, 61-65] reported that limited political will and fragmented internal processes contribute to the absence of enforceable digital health policies and guidelines. For example, survey data revealed that only 46% of respondents perceived digital health governance at the facility level to be strong [61]. This lack of adequate structured governance results in inconsistent adherence to interoperability standards, thereby slowing down the implementation of integrated DH systems.

Inadequate capacity further compounds these organizational issues. A shortage of skilled personnel, limited training opportunities, and insufficient knowledge about interoperability principles have been reported across multiple studies [39, 51, 53-57, 59-61, 63, 66-68]. This deficit not only hinders the development and monitoring of interoperable systems but also contributes to resistance to change. Stakeholder resistance, often driven by inadequate involvement in the decision-making processes and misaligned system designs, disrupts workflows and deters the adoption of digital solutions [52, 61, 63, 65]. These findings suggest that improving capacity through targeted training programs and enhanced stakeholder engagement is essential for overcoming organizational barriers.

4.3 Environmental Barriers

The external environment presents its own set of challenges. Inadequate legal and regulatory frameworks in many LMICs create significant uncertainty around data exchange, privacy, and ethical use of health data [52, 63-65, 70]. Outdated or insufficient regulatory guidelines contribute to inconsistent enforcement of interoperability standards, leading to fragmented DH systems, which could compromise patient care [39, 53, 68, 71]. The slow evolution of these legal frameworks, combined with challenges in standardizing cross-border regulations, further impedes the development of scalable and interoperable systems.

Closely linked to regulatory challenges is inadequate monitoring of compliance. Eight studies [55, 57, 61, 63, 64, 66, 68, 71] underscored that the lack of robust mechanisms for continuous oversight reduces accountability and allows non-compliant practices to persist. Moreover, pervasive data security and privacy concerns undermine stakeholder confidence in DH systems. Inadequate measures for secure data handling and insufficient adaptations of security protocols to local contexts pose significant risks for data breaches and unauthorized data sharing [34, 52, 61, 65, 70].

Financial constraints further complicate the environmental landscape. Limited healthcare budgets and reliance on donor funding restrict the necessary investments in infrastructure, human capital, and regulatory oversight [39, 51, 52, 54, 59, 61, 63, 65]. The cumulative effect of these financial limitations is a cyclical challenge that hinders the long-term sustainability of DH initiatives and compliance with evolving interoperability standards.

5 Conclusions

This SLR revealed that achieving compliance with interoperability standards in LMICs is a multifaceted challenge encompassing technological, organizational, and environmental domains. Overcoming these barriers requires a coordinated, multi-level approach that not only improves IT infrastructure and standardization but also strengthens governance, builds technical capacity, and modernizes regulatory frameworks. Such a holistic strategy is vital for creating resilient, sustainable DH systems that can improve patient care and health outcomes in resource-constrained settings.

The findings of this SLR have important implications for policymakers, healthcare providers, and technology developers working in LMICs:

1. Addressing Infrastructural Deficits: Strategic investments are critical to creating a robust technological foundation for interoperable DH systems.
2. Enhancing Organizational Governance and Building Technical Capacity: Comprehensive training programs and improved stakeholder engagement are essential for overcoming internal resistance and ensuring effective implementation.
3. Updating Legal Frameworks and Establishing Robust Monitoring Mechanisms: Alongside securing sustainable financing, these steps are necessary to create an enabling external environment.

The literature identifies several key gaps, including inadequate IT infrastructure, fragmented governance, and a lack of scalable solutions for challenges such as power outages, unreliable internet, and technical expertise shortages. Furthermore, there is insufficient exploration of effective governance frameworks and compliance monitoring mechanisms. To address these gaps, future research should focus on evaluating the impact of capacity-building initiatives, public-private partnerships, and context-specific adaptations of interoperability standards. Additionally, future studies should investigate the development of scalable governance models and robust monitoring systems to ensure systematic compliance enforcement in LMICs, which will support the creation of sustainable and resilient DH ecosystems.

This review has limitations, in particular, the reliance on peer-reviewed literature, and the exclusion of non-English studies may have introduced publication bias and limited the generalisability of the findings. The use of quality assessment questions that were specifically aligned with the TOE framework could also have constrained the number of studies that met the QA criteria. Future reviews could benefit from broader inclusion criteria and the integration of grey literature to capture a wider spectrum of experiences and contexts.

Acknowledgements

The authors appreciate the University of Pretoria Library Information Specialist for assisting with retrieving sources from the electronic databases.

Statement on conflicts of interest

None

References

- [1] Bhattarai P, Shrestha A, Xiong S, Peoples N, Ramakrishnan C, Shrestha S, et al. Strengthening urban primary healthcare service delivery using electronic health technologies: A qualitative study in urban Nepal. *Digital Health*. 2022;8:20552076221114182. doi: 10.1177/20552076221114182.
- [2] Heine M, Hanekom S. Chronic Disease in Low-Resource Settings: Prevention and Management Throughout the Continuum of Care: A Call for Papers. *International Journal of Environmental Research and Public Health*. 2023;20(4):3580. doi: 10.3390/ijerph20043580.
- [3] Wilson E, Gannon H, Chimhini G, Fitzgerald F, Khan N, Lorencatto F, et al. Protocol for an intervention development and pilot implementation evaluation study of an e-Health solution to improve newborn care quality and survival in two low-resource settings, Malawi and Zimbabwe: Neotree. *BMJ Open*. 2022;12(7):e056605. doi: 10.1136/bmjopen-2021-056605.
- [4] Lawal FB, Omara M. Applicability of dental patient reported outcomes in low resource settings - a call to bridge the gap in clinical and community dentistry. *Journal of Evidence-Based Dental Practice*. 2023;23(1, Supplement):101789. doi: 10.1016/j.jebdp.2022.101789.
- [5] Mengiste SA, Antypas K, Johannessen MR, Klein J, Kazemi G. eHealth policy framework in Low and Lower Middle-Income Countries; a PRISMA systematic review and analysis. *BMC Health Services Research*. 2023;23(1):1-15. doi: 10.1186/s12913-023-09325-7.
- [6] Shagufta P, Zohra SL, Mohammad Afzal M, Henry BP, Caroline L. Application of primary healthcare principles in national community health worker programmes in low-income and middle-income countries: a scoping review. *BMJ Open*. 2022;12(2):e051940. doi: 10.1136/bmjopen-2021-051940.
- [7] Khattak AF, Rahman AU, Khattak M, Qazi M, Gilani H, Khan A. Toward Sustainable Healthcare Systems: A Low and Middle-Income Country's Case for Investing in Healthcare Reforms. *Cureus*. 2023;15(5):e39345. Epub 20230522. doi: 10.7759/cureus.39345. PubMed PMID: 37351239; PubMed Central PMCID: PMC10284437.
- [8] FardAzar F, Choopani A, Ahmadi A, Arkian S. Challenges of Health Care Reforms (HCRS) in Low and Middle-Income Countries (LMICs): A Qualitative Systematic Review 2021.
- [9] Holeman I, Cookson TP, Pagliari C. Digital technology for health sector governance in low and middle income countries: a scoping review. *Journal of global health*. 2016;6(2).
- [10] Wilson D, Sheikh A, Görgens M, Ward K. Technology and Universal Health Coverage: Examining the role of digital health. *J Glob Health*. 2021;11:16006. Epub 20211120. doi: 10.7189/jogh.11.16006. PubMed PMID: 34912559; PubMed Central PMCID: PMC8645240.
- [11] McCool J, Dobson R, Muinga N, Paton C, Pagliari C, Agawal S, et al. Factors influencing the sustainability of digital health interventions in low-resource settings: Lessons from five countries. *J Glob Health*.

- 2020;10(2):020396. doi: 10.7189/jogh.10.020396. PubMed PMID: 33274059; PubMed Central PMCID: PMC7696238.
- [12] Erku D, Khatri R, Endalamaw A, Wolka E, Nigatu F, Zewdie A, et al. Digital Health Interventions to Improve Access to and Quality of Primary Health Care Services: A Scoping Review. *International Journal of Environmental Research and Public Health*. 2023;20(19):6854. PubMed PMID: doi:10.3390/ijerph20196854.
- [13] Al Meslamani AZ. Why are digital health policies crucial? *Journal of Medical Economics*. 2024;27(1):167-9. doi: 10.1080/13696998.2024.2302254.
- [14] Kabore SS, Ngangue P, Soubeiga D, Barro A, Pilabré AH, Bationo N, et al. Barriers and facilitators for the sustainability of digital health interventions in low and middle-income countries: A systematic review. *Frontiers in Digital Health*. 2022;4. doi: 10.3389/fdgth.2022.1014375.
- [15] Ramnath VR. Chapter 12 - Global telehealth and digital health: how to support programs and infrastructure. In: Freeman AM, Bhatt AB, editors. *Emerging Practices in Telehealth*: Academic Press; 2023. p. 163-82.
- [16] Bonnechère B, Kossi O, Mapinduzi J, Panda J, Rintala A, Guidetti S, et al. Mobile health solutions: An opportunity for rehabilitation in low- and middle income countries? *Frontiers in Public Health*. 2023;10. doi: 10.3389/fpubh.2022.1072322.
- [17] Goldstein M, Archary M, Adong J, Haberer JE, Kuhns LM, Kurth A, et al. Systematic Review of mHealth Interventions for Adolescent and Young Adult HIV Prevention and the Adolescent HIV Continuum of Care in Low to Middle Income Countries. *AIDS and Behavior*. 2023;27(1):94-115. doi: 10.1007/s10461-022-03840-0.
- [18] Knop MR, Nagashima-Hayashi M, Lin R, Saing CH, Ung M, Oy S, et al. Impact of mHealth interventions on maternal, newborn, and child health from conception to 24 months postpartum in low- and middle-income countries: a systematic review. *BMC Med*. 2024;22(1):196. Epub 20240515. doi: 10.1186/s12916-024-03417-9. PubMed PMID: 38750486; PubMed Central PMCID: PMC11095039.
- [19] Ibeneme S, Ukor N, Ongom M, Dasa T, Muneene D, Okeibunor J. Strengthening capacities among digital health leaders for the development and implementation of national digital health programs in Nigeria. *BMC Proceedings*. 2020;14(10):9. doi: 10.1186/s12919-020-00193-1.
- [20] Kobusinge G. *Managing as Designing: Transforming Digital Healthcare Interoperability*. Americas Conference on Information Systems (AMCIS)2020.
- [21] Nsaghurwe A, Dwivedi V, Ndesanjo W, Bamsi H, Busiga M, Nyella E, et al. One country's journey to interoperability: Tanzania's experience developing and implementing a national health information exchange. *BMC Medical Informatics and Decision Making*. 2021;21(1):139. doi: 10.1186/s12911-021-01499-6.
- [22] Kawamoto K, Kukhareva PV, Weir C, Flynn MC, Nanjo CJ, Martin DK, et al. Establishing a multidisciplinary initiative for interoperable electronic health record innovations at an academic medical center. *JAMIA Open*. 2021;4(3):o0ab041. doi: 10.1093/jamiaopen/o0ab041.
- [23] Kramer MA, Moesel C. Interoperability with multiple Fast Healthcare Interoperability Resources (FHIR®) profiles and versions. *JAMIA Open*. 2023;6(1):o0ad001. doi: 10.1093/jamiaopen/o0ad001.
- [24] Torab-Miandoab A, Samad-Soltani T, Jodati A, Rezaei-Hachesu P. Interoperability of heterogeneous health information systems: a systematic literature review. *BMC Medical Informatics and Decision Making*. 2023;23(1):18. doi: 10.1186/s12911-023-02115-5.
- [25] Benis A, Tamburis O, Chronaki C, Moen A. One Digital Health: A Unified Framework for Future Health Ecosystems. *J Med Internet Res*. 2021;23(2):e22189. doi: 10.2196/22189.
- [26] Egwar AA, Ssekibuule R, Nabukenya J. Towards Adoption of Standards for Communication Infrastructure/Technologies in Healthcare Systems in LMICs: Theories, Practice and Evaluation. 13th International Conference on Health Informatics2020. p. 735-44.
- [27] Mamuye A, Yilma TM, Abdulwahab A, Broomhead S, Zondo P, Kyeng M, et al. Health information exchange policy and standards for digital health systems in africa: A systematic review. *PLOS Digital Health*. 2022;1(10):e0000118. doi: 10.1371/journal.pdig.0000118.
- [28] Wang K, Wang Y, Li Y, Fan X, Xiao S, Hu L. A review of the technology standards for enabling digital twin [version 2; peer review: 2 approved]. *Digital Twin*. 2022;2(4). doi: 10.12688/digitaltwin.17549.2.
- [29] Umberfield EE, Staes CJ, Morgan TP, Grout RW, Mamlin BW, Dixon BE. Chapter 9 - Syntactic interoperability and the role of syntactic standards in health information exchange. In: Dixon BE, editor. *Health Information Exchange (Second Edition)*: Academic Press; 2023. p. 217-36.
- [30] de Mello BH, Rigo SJ, da Costa CA, da Rosa Righi R, Donida B, Bez MR, et al. Semantic interoperability in health records standards: a systematic literature review. *Health and Technology*. 2022;12(2):255-72. doi: 10.1007/s12553-022-00639-w.
- [31] Lazarova E, Mora S, Maggi N, Ruggiero C, Vitale AC, Rubartelli P, et al. An Interoperable Electronic Health Record System for Clinical Cardiology. *Informatics*. 2022;9(2):47. doi: 10.3390/informatics9020047.
- [32] Smith NA, Sinden D, Thomas SA, Romanchikova M, Talbott JE, Adeogun M. Building confidence in digital health through metrology. *The British journal of radiology*. 2020;93(1109):20190574. doi: 10.1259/bjr.20190574.
- [33] Kiwanuka A, Nabukenya J. Requirements for Implementing Digital Health Terminology Standards in Uganda's Electronic Medical Records-Based Health Information Systems. In: Gehin C, Wacogne B, Douplik A, Lorenz R, Bracken B, Pesquita C, et al., editors. *Biomedical Engineering Systems and Technologies*. 1710. Cham: Springer, Cham; 2022. p. 202-12.

- [34] Ndlovu K, Mars M, Scott RE. Interoperability frameworks linking mHealth applications to electronic record systems. *BMC Health Services Research*. 2021;21(1):459. doi: 10.1186/s12913-021-06473-6.
- [35] Nyangena J, Rajgopal R, Ombech EA, Oloo E, Luchetu H, Wambugu S, et al. Maturity assessment of Kenya's health information system interoperability readiness. *BMJ Health & Care Informatics*. 2021;28(1):e100241. doi: 10.1136/bmjhci-2020-100241. PubMed Central PMCID: PMC8252685.
- [36] Olu O, Muneene D, Bataringaya JE, Nahimana M-R, Ba H, Turgeon Y, et al. How can digital health technologies contribute to sustainable attainment of universal health coverage in Africa? A perspective. *Frontiers in public health*. 2019;7:341. doi: 10.3389/fpubh.2019.00341.
- [37] Maina AM, Singh UG. Why National eHealth Strategies Matter - An Exploratory Study of eHealth Strategies of African Countries. 2020 International Conference on Electrical and Electronics Engineering (ICE3); 14-15 Feb. 2020;2020. p. 670-5.
- [38] Bincoletto G. Data protection issues in cross-border interoperability of Electronic Health Record systems within the European Union. *Data & Policy*. 2020;2:e3. doi: 10.1017/dap.2020.2.
- [39] Jonnagaddala J, Guo GN, Batongbacal S, Marcelo A, Liaw ST. Adoption of enterprise architecture for healthcare in AeHIN member countries. *BMJ Health Care Inform*. 2020;27(1). doi: 10.1136/bmjhci-2020-100136. PubMed PMID: 32616479; PubMed Central PMCID: PMC7333875.
- [40] Pine KH. The qualitative dimension of healthcare data interoperability. *Health informatics journal*. 2019;25(3):536-48. doi: 10.1177/1460458219833095.
- [41] Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *bmj*. 2021;372.
- [42] Alunyu AE, Wamema J, Kiwanuka A, Bagyendera M. Factors that Influence Potential Success of eHealth Standards Adoption in a Low-and Middle-Income Country: a review. *Journal of Health Informatics in Africa*. 2020;7(1):24-37. doi: 10.12856/JHIA-2020-v7-i1-274.
- [43] Higman S, Dwivedi V, Nsagurwe A, Busiga M, Sotter Rulagirwa H, Smith D, et al. Designing interoperable health information systems using enterprise architecture approach in resource-limited countries: a literature review. *The International journal of health planning and management*. 2019;34(1):e85-e99.
- [44] Palojoki S, Lehtonen L, Vuokko R. Semantic Interoperability of Electronic Health Records: Systematic Review of Alternative Approaches for Enhancing Patient Information Availability. *JMIR Med Inform*. 2024;12:e53535. doi: 10.2196/53535.
- [45] Taquette SR, Borges LM. Ethical Dilemmas in Qualitative Research: A Critical Literature Review. *International Journal of Qualitative Methods*. 2022;21:16094069221078731. doi: 10.1177/16094069221078731.
- [46] DePietro WE, Fleischer M. The context for change: organization, technology, and environment. In: Tornatzky LG FM, editor. *The Processes of Technological Innovation. Issues in Organization and Management Series*. First Edition ed. Lexington, MA: Lexington Books; 1990. p. 151-75.
- [47] Al Hadwer A, Taviana M, Gillis D, Rezaia D. A Systematic Review of Organizational Factors Impacting Cloud-based Technology Adoption Using Technology-Organization-Environment Framework. *Internet of Things*. 2021;15:100407. doi: <https://doi.org/10.1016/j.iot.2021.100407>.
- [48] Anthony Jnr B. Examining the adoption of telehealth during public health emergencies based on technology organization environment framework. *Journal of Science and Technology Policy Management*. 2023;ahead-of-print(ahead-of-print). doi: 10.1108/JSTPM-05-2022-0079.
- [49] Assaye BT, Endalew B, Tadele MM, hailiye Teferie G, Teym A, Melese Yh, et al. Readiness of big health data analytics by technology-organization-environment (TOE) framework in Ethiopian health sectors. *Heliyon*. 2024;10(19). doi: 10.1016/j.heliyon.2024.e38570.
- [50] Ngongo BP, Ochola P, Ndegwa J, Katuse P. The technological, organizational and environmental determinants of adoption of mobile health applications (m-health) by hospitals in Kenya. *PLoS One*. 2019;14(12):e0225167. Epub 20191213. doi: 10.1371/journal.pone.0225167. PubMed PMID: 31834891; PubMed Central PMCID: PMC6910672.
- [51] Bagyendera M, Nabende P, Nabukenya J. Critical factors influencing data use and utilization in health systems: a focus on data and interoperability standards for health information exchange (HIE) in Uganda's health care system. *Oxford Open Digital Health*. 2023;1. doi: 10.1093/oodh/oqad015.
- [52] Bille N, Christensen DL, Byberg S, Gishoma C, Villadsen SF, Calopietro M. A qualitative exploration of the early adoption of an electronic medical record system for type 1 diabetes management in Rwanda. *Digital Health*. 2025;11. doi: 10.1177/20552076241311057.
- [53] Saheb T, Saheb T. Digital health policy decoded: Mapping national strategies using Donabedian's model. *Health Policy*. 2024;147:105134. Epub 20240717. doi: 10.1016/j.healthpol.2024.105134. PubMed PMID: 39053416.
- [54] Yilma TM, Taddese A, Mamuye A, Endehabtu BF, Alemayehu Y, Senay A, et al. Maturity Assessment of District Health Information System Version 2 Implementation in Ethiopia: Current Status and Improvement Pathways. *JMIR Med Inform*. 2024;12:e50375. Epub 20240726. doi: 10.2196/50375. PubMed PMID: 39059005; PubMed Central PMCID: PMC11316158.
- [55] Alunyu A, Amiyo MR, Nabukenya J. Framework for standardizing digital health in resource-constrained settings: a case study of Uganda's digital health communication infrastructure. *Oxford Open Digital Health*. 2024;2. doi: 10.1093/oodh/oqae018.

- [56] Were MC, Savai S, Mokaya B, Mbugua S, Ribeka N, Cholli P, et al. mUzima Mobile Electronic Health Record (EHR) System: Development and Implementation at Scale. *J Med Internet Res.* 2021;23(12):e26381. doi: 10.2196/26381.
- [57] Ndlovu K, Scott RE, Mars M. Interoperability opportunities and challenges in linking mhealth applications and eRecord systems: Botswana as an exemplar. *BMC Med Inform Decis Mak.* 2021;21(1):246. Epub 20210821. doi: 10.1186/s12911-021-01606-7. PubMed PMID: 34419020; PubMed Central PMCID: PMC8379582.
- [58] Snidal SJ, Barnard G, Atuhairwe E, Ben Amor Y. Use of eCompliance, an innovative biometric system for monitoring of tuberculosis treatment in rural Uganda. *Am J Trop Med Hyg.* 2015;92(6):1271-9. Epub 20150406. doi: 10.4269/ajtmh.14-0413. PubMed PMID: 25846297; PubMed Central PMCID: PMC4458837.
- [59] Ding H, Jayasena R, Chen SH, Maiorana A, Dowling A, Layland J, et al. The Effects of Telemonitoring on Patient Compliance With Self-Management Recommendations and Outcomes of the Innovative Telemonitoring Enhanced Care Program for Chronic Heart Failure: Randomized Controlled Trial. *J Med Internet Res.* 2020;22(7):e17559. Epub 20200708. doi: 10.2196/17559. PubMed PMID: 32673222; PubMed Central PMCID: PMC7381046.
- [60] Walonoski J, Scanlon R, Dowling C, Hyland M, Ettema R, Posnack S. Validation and Testing of Fast Healthcare Interoperability Resources Standards Compliance: Data Analysis. *JMIR Med Inform.* 2018;6(4):e10870. Epub 20181023. doi: 10.2196/10870. PubMed PMID: 30355549; PubMed Central PMCID: PMC6231749.
- [61] Kiwanuka A, Bagyendera M, Wamema J, Alunyu A, Amiyu M, Kambugu A, et al. Establishing the state of practice about data standards in monitoring healthcare interventions for HIV in Uganda's EMR-based health information systems. *HEALTHINF.* 2021;5:200-1. doi: 10.5220/0010264302000211.
- [62] Ibrahim AM, Abdel-Aziz HR, Mohamed HAH, Zaghmir DEF, Wahba NMI, Hassan GA, et al. Balancing confidentiality and care coordination: challenges in patient privacy. *BMC Nurs.* 2024;23(1):564. Epub 20240815. doi: 10.1186/s12912-024-02231-1. PubMed PMID: 39148055; PubMed Central PMCID: PMC11328515.
- [63] Wamema J, Alunyu A, Amiyu M, Nabukenya J. Enterprise architecture requirements for standardising digital health in Uganda's health system. *Health Policy and Technology.* 2023;12(4). doi: 10.1016/j.hlpt.2023.100805.
- [64] Alunyu AE, Wamema J, Kiwanuka A, Bagyendera M, Amiyu M, Kambugu A, et al. Investigating the impediments to accessing reliable, timely and integrated electronic patient data in healthcare sites in Uganda. 2021.
- [65] Sibuyi IN, de la Harpe R, Nyasulu P. A Stakeholder-Centered mHealth Implementation Inquiry Within the Digital Health Innovation Ecosystem in South Africa: MomConnect as a Demonstration Case. *JMIR Mhealth Uhealth.* 2022;10(6):e18188. Epub 20220616. doi: 10.2196/18188. PubMed PMID: 35708756; PubMed Central PMCID: PMC9247812.
- [66] Moses B, Peter N, Brian G, Josephine N. Contextualizing Syntactic Interoperability Data Standards for Health Information Exchange in Uganda's Public Healthcare System. *Proceedings of the 10th International Conference on Information and Communication Technologies for Ageing Well and e-Health2024.* p. 267-75.
- [67] Kiwanuka A, Amiyu M, Nabukenya J. Constraints to and enablers for contextualizing digital health terminology standards in Uganda's health services: a qualitative case study. *Oxford Open Digital Health.* 2023;1. doi: 10.1093/oodh/oqad003.
- [68] Chuma K, Sibiya P. Digital Health Ecosystem Framework to Address Fragmentation of the Health System in South Africa. *Africa Journal of Nursing and Midwifery.* 2022;24(2):28 pages- pages.
- [69] Mbunge E, Muchemwa B, Jiyane Se, Batani J. Sensors and healthcare 5.0: transformative shift in virtual care through emerging digital health technologies. *Global Health Journal.* 2021;5(4):169-77. doi: <https://doi.org/10.1016/j.glohj.2021.11.008>.
- [70] Mbunge E, Millham RC, Sibiya MN, Fashoto SG, Akinnuwesi B, Simelane S, et al. Framework for ethical and acceptable use of social distancing tools and smart devices during COVID-19 pandemic in Zimbabwe. *Sustainable Operations and Computers.* 2021;2:190-9. doi: 10.1016/j.susoc.2021.07.003.
- [71] Jacob C, Lindeque J, Muller R, Klein A, Metcalfe T, Connolly SL, et al. A sociotechnical framework to assess patient-facing eHealth tools: results of a modified Delphi process. *NPJ Digit Med.* 2023;6(1):232. Epub 20231215. doi: 10.1038/s41746-023-00982-w. PubMed PMID: 38102323; PubMed Central PMCID: PMC10724255.
- [72] Sangiorgi L, Boarini M, Mordenti M, Wang V, Westerheim I, Skarberg RT, et al. SATURN: assessing the feasibility of utilising existing registries for real-world evidence data collection to meet patients, regulatory, health technology assessment and payer requirements. *Orphanet J Rare Dis.* 2024;19(1):336. Epub 20240912. doi: 10.1186/s13023-024-03341-4. PubMed PMID: 39267100; PubMed Central PMCID: PMC11391597.
- [73] Sadoughi F, Khodaveisi T, Ahmadi H. The used theories for the adoption of electronic health record: a systematic literature review. *Health and Technology.* 2019;9:383-400.
- [74] Nadhamuni S, John O, Kulkarni M, Nanda E, Venkatraman S, Varma D, et al. Driving digital transformation of comprehensive primary health services at scale in India: an enterprise architecture framework. *BMJ Global Health.* 2021;6(Suppl 5):e005242. doi: 10.1136/bmjgh-2021-005242.
- [75] Al Knawy B, McKillop MM, Abduljawad J, Tarkoma S, Adil M, Schaper L, et al. Successfully Implementing Digital Health to Ensure Future Global Health Security During Pandemics: A Consensus Statement. *JAMA Network Open.* 2022;5(2):e220214-e. doi: 10.1001/jamanetworkopen.2022.0214.
- [76] Yao R, Zhang W, Evans R, Cao G, Rui T, Shen L. Inequities in Health Care Services Caused by the Adoption of Digital Health Technologies: Scoping Review. *J Med Internet Res.* 2022;24(3):e34144. doi: 10.2196/34144.

- [77] Katchakis DG, Kouroubali A. A framework for eHealth interoperability management. *Journal of Strategic Innovation and Sustainability*. 2019;14(5):51-61. doi: 10.33423/jsis.v14i5.2521.
- [78] Alunyu AE, Nabukenya J. A conceptual model for adaptation of ehealth standards by low and middle-income countries. *Journal of Health Informatics in Africa*. 2018;5(2).
- [79] Sensmeier J. Interoperability: There is no Digital Health without Health IT Standards. In: Hübner UH, Mustata Wilson G, Morawski TS, Ball MJ, editors. *Nursing Informatics : A Health Informatics, Interprofessional and Global Perspective*. Cham: Springer International Publishing; 2022. p. 285-302.