

State of Digital Health Communication Infrastructure in LMICs: Theory, Standards and Factors Affecting Their Implementation



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1 Introduction

A robust communication infrastructure is required to support healthcare data sharing required to facilitate patient-centred care. Components that make up the digital health communication infrastructure (DHCI) include software and digital health applications, the hardware, network, security and personnel that use the infrastructure to capture, process, store and or share health data/information [1–4]. Actually, in a digital health information-sharing environment, communications engage people and things including the physical backbone that supports the digital health applications [3]. However, in low and middle-income countries (LMICs) constrained by resources, there are only limited components of the DHCI and are often in a poor/inadequate state [1, 5, 6]. Furthermore, proper management of these DHCI components is required to realise its full potential in supporting patients and the public. Nevertheless, the skills required to develop, deploy, maintain and use digital health technologies are greatly lacking which has continued to hinder LMICs' from reaping the expected benefits from their digital health implementations [7].

Several reasons have been given for the poor state of these DHCI components including limited funding, lack of technical skills, inadequate legal and governance frameworks leading to uncoordinated implementations, and limited political support among others [6–8]. These challenges can be categorised into financial, technical

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and management/governance problems, both internal and external. The challenges have resulted in diverse implementations of digital health (DH) systems that lack interoperability [6, 8, 9] and therefore are unable to support secure, reliable healthcare data sharing on time [7]. The telecommunications domain has conceptualised the use of standards as a solution to the problem of interoperability of communications systems [10]. Similarly, health systems have adopted the standardisation approach to address such gaps.

Standardisation means different things in different domains [11]. While standardisation implies the use of the standard to some, to others, it means adopting the same procedures or methods to harmonise work processes for compatible outputs [11]. Whereas the international standards organisation considers standardisation to be the “activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context” [12]; Rowlands [13] suggest that it should cover development and consistent implementation of the standards and technical documents. Therefore, this study infers that standardisation of digital health (DH) could mean developing and using standards for harmonised processes and interoperable health information system outcomes. Standardisation consists of formulating, issuing and consistently implementing standards [14, 15]. Whereas formulating and issuing standards are standards development activities, implementation covers deploying the standards, using them and monitoring to ensure that every participating entity is compliant.

Developing a standard that may be accepted among implementing entities requires adhering to universally acceptable principles of standards development. However, it should be noted that standards development is a complex process. For example, the TU-T [10] argued that DH standardisation is one of the most challenging areas of standardisation. Balancing the sometimes-diverging expectations of all digital health stakeholders and driving consensus is a difficult task requiring negotiation expertise to arrive at a consensus. The difficulty in developing quality standards is exacerbated by colossal legacy systems and technologies that are still in place, massive data quantities in various formats, multiple areas of technologies and complexity caused by competing/overlapping standards initiatives [10, 16].

Different standards development organisations (SDOs) agree on several principles of standardisation, including openness, transparency, representation, impartiality, consensus, market need and net benefit, timeliness, internationality, compliance, coherence, availability, and support [13, 17, 18]. *Openness* means the standards development processes are open to any interested party on a non-discriminatory basis. *Transparency* means information on current work (standards development) programs, such as proposals and how to participate, is available to all interested parties. *Representation* refers to the balanced participation by those significantly affected by a resulting standard (stakeholders). *Impartiality* is concerned with not privileging or favouring the interests of a particular entity or group of stakeholders. *Consensus* refers to the general agreement (absence of sustained opposition) on a standard. *Market need and net benefit* mean a standard is produced only when needed and there are possible benefits. *Timeliness* refers to the urgent need for a standard. The *internationality* principle recommends that relevant international standards be

used in preference to national and sub-national standards where they exist. *Compliance* means any standard being produced should comply with relevant regulations, including the natural law of competition. *Coherence* means standards that are developed should be consistent with developments in other sectors, e.g., the health sector's DH standards being consistent with ICT standards. *Availability* refers to the readiness with which such a developed standard is accessible. Finally, *support* means approaches to disseminating supplementary knowledge associated with a standard should be considered during its development. Any process that satisfies these principles of standardisation is considered suitable to guide a domain's standards development. Therefore, this study argued that if an LMIC followed and made due consideration to standardisation principles during the development of DH standards, then the developed standard would be suited to guide the standardisation of the DHCI for Uganda's health system.

The use of a standard entail consistent implementation, compliance monitoring and maintenance of the standard [13]. Consistent implementation is achieved through the adoption and consistent use of the standard for its intended purpose. It is claimed that any consistent use of a health standard is ascertained by ensuring effective use across a health system [19]. Achieving a level of standardisation that will deliver interoperability of DH systems "involves both a process for establishing and maintaining the standards and an organisational infrastructure for implementing that process" [14]. There is a need for frameworks and theories that support standards development, implementation and monitoring of compliance that is suited for the resource-constrained health systems common in LMICs. However, there is scanty literature on frameworks or theories that can be adopted to support digital health standardisation. Besides, existing standardisation frameworks are based on procedures and processes that have been proven to work in high-income countries. Actually, common digital health standards like DICOM, HL7, and FHIR among others were developed and piloted in developed countries, but all countries are being encouraged to adopt them. Authors and some standards bodies have recognised the need to adapt/contextualise standards having realised that the contextual environment affects their implementation success.

To better understand the scope of standardisation of the DHCI in Uganda, an example of a resource-constrained health system, this study first reviewed the literature to determine what concepts and constructs that can be borrowed to construct a comprehensive DHCI standards framework that covers the full scope of standardisation to include standards development, implementation and compliance monitoring. Secondly, the study explored DH stakeholder experiences and views regarding the existence and use of those concepts and constructs in Uganda's DHCI environment to identify any challenges and gaps in standardisation.

2 Literature Review

To better understand DH standardisation in low-resource settings, we reviewed current practices of standardisation in select countries and theories/frameworks of standardisation to inform our exploration of the status of DHCI standardisation in Uganda's health system.

2.1 *Current Practice of Standardisation by the Country's National Standardisation Bodies*

Although criteria for selecting best practices in public health include relevancy, community participation, stakeholder collaboration, ethical soundness, replicability, effectiveness, efficiency, and sustainability [20]; this study assumed comprehensive stakeholder participation/collaboration, ethical soundness, and possible replicability of standards practices from countries that have made progress in standardising digital health. We reviewed current standardisation practices in similar peer countries in the region intending to highlight commonalities in practice and gaps in standards' development, consistent deployment, and effective use. Three high-income, two upper-middle-income and three lower-middle-income countries (as of 2021 World Bank classification) were reviewed. Table 1 presents a summary of the standardisation practices from this review.

Overall, the current standardisation practice in the reviewed countries shows commonalities in the standards development/adoption process. Notably, these countries have adopted similar standardisation processes with cycles that broadly include developing the standards proposal, discussion by a technical committee, seeking public input/contributions, and approving and publishing the standards. However, the review also shows that standardisation activities in the reviewed countries do little to support deployment and consistent implementation and ensure continued compliance/use of the standards. Existing gaps in the standardisation process are consistent in the areas of research and preliminary activities of determining the need and scope of the proposed standard, stakeholder engagement, promotional activities, maintenance activities, criterion, and or tools compliance monitoring strategies, and guidelines on how to deal with non-compliance with the standards.

2.2 *Theory and Frameworks for Standardisation*

The study used (1) Baskin et al's. [21] six dimensions of standards, (2) Fomin's Process Model of how successful standards emerge, (3) Three technology adoption theories i.e., Technology Adoption Model (TAM), Technology, Organisation, and

Table 1 Current practices of standardisation in eight countries

Country (income status)	The practice of standardisation to show how they got here: through activities of standards adoption, development and or implementation	What they are doing to ensure effective use
Estonia (high-income)	Involves preparation and determining standards to develop/translate into Estonian ones → Commenting/ providing feedback on and approving standard translations → Publishing/ reprinting the standard	• No data
Gap	• Standards are considered a matter of the state, and difficult to attract stakeholders to participate in the process • Lack of promotional strategies and funding plan • Lack of mechanisms/tools to support the continued use of the standards • Lack of criteria for monitoring use and or dealing with non-compliance	
Australia (high-income)	• Involves research on standards to be developed → Standards development → adherence to a methodology for standardisation (orchestration of a complex, adaptive standards ecosystem) → Accreditation → Commissioning → Promotion → Continued funding	• Conformity assessment—compliance monitoring
Gaps	• Lack of a documented standardisation process • No information on monitoring use or criteria for dealing with a lack of non-compliance	
New Zealand (high income)	Involves making a proposal for the needed standard → Forming a committee to draft the standard → Drafting the standards → Consulting the public and building consensus → Committee ballots to approve the standard → Publishing the standard → appointing accreditation bodies	• No data
Gaps	• Lack of mechanisms/tools to support the continued use of the standards • Lack of criteria for monitoring use and or dealing with non-compliance	

(continued)

Table 1 (continued)

Country (income status)	The practice of standardisation to show how they got here: through activities of standards adoption, development and or implementation	What they are doing to ensure effective use
Thailand (upper-middle-income)	A standard work program is published every six months → Collaboration with regional and international standardisation bodies to develop standards → Host standards information centre → Promote country standards → and appoint accreditation bodies	• Accreditation and conformity assessment are delegated
Gaps	• Limited rigour in the standards development/adoption • Limited human resource capacity and stakeholder engagement in developing the standards • Lack of standards, promotional strategies, and a funding plan • Lack of mechanism for enforcing conformity and criteria for dealing with non-compliance	
South Africa (upper-middle-income)	Involves conducting a preliminary investigation regarding the standards to be developed → A proposal for the standard is developed → A technical committee discusses the standard → Public is consulted to contribute during the standards inquiry stage → Publication of the standards → Conduct promotion activities to facilitate the correct application of standards	• Assess implementors' conformity with the standards
Gaps	• It does not stipulate resources required to support the standards development process • Limited stakeholder engagement as only high-level implementers get to know standards under public review • Missing a plan for collaborative agreement on stepwise/phased/ planned implementation of the standard • Lack of promotional strategies and a funding plan • No data on compliance enforcement	
Sri Lanka (lower-middle-income)	• Involves standards development → Publication of the standards → Dissemination of standards information and promote adoption of standards	• Conformity assessment through testing, inspection and certification
Gaps	• Lacks guidelines on preliminary activities leading to standards development • Not clear about the level of stakeholder involvement in the standards development process • Lack of guidelines on standards review (maintenance) mechanism	

(continued)

Table 1 (continued)

Country (income status)	The practice of standardisation to show how they got here: through activities of standards adoption, development and or implementation	What they are doing to ensure effective use
Kenya (lower-middle-income)	Involves drafting the standards by the technical committee → Public is invited to review the draft standard → Technical committee improves the standard → Approval—The proposed standard is put up for adoption	• Testing of goods and services that implement the standard
Gap	• Limited user involvement in the standards development/ determination process; only high-level implementers get to know the standards are under public review	
Tanzania (lower-middle-income)	A proposal for establishing a standard is made → Establishing the necessity for standards → Preparing a draft standard → Public consultations → Approval → Gazetting the standard	• No data
Gaps	• Limited attempt to build consensus among stakeholder groups • Limited stakeholder engagement and only high-level implementers get to know standards under public review • No data on measures of compliance enforcement	

Environment (TOE), and the Internet Standards Adoption (ISA), and (4) the European Statistical System (ESS) Standardisation Process.

Baskin et al. [21] posed pertinent questions that are critical to understanding standardisation activity. The scope of the questions is summarised into broad themes; why seek a standard? What is the category of product or service to be standardised? When in the product cycle to standardise? Which is the appropriate Standards Development Organization (SDO)? How will consensus be reached? and where will the standard be used? This study re-categorises the questions into three main overarching questions: why is there a need for a standard (what is the standard for)? what is the most suitable process for standards development in resource-constrained environments? and how should the standard be applied for maximum impact? These three broad questions give rise to the concepts of *setting standards context*, *standards development process*, and *standards implementation and monitoring compliance with the standards*. These constructs are expected to span the full scope of the standardisation process as advocated by Rowlands [13], who call for the development and consistent implementation of standards and other technical documents.

Fomin's [22] *process model of standardisation* integrates separate lines of inquiry to standardisation activities, including Simon's theory of artefact design, Weick's sense-making concept and Latour's negotiation in socio-technical networks, organise them into a hierarchically organised web of standardisation events. Their model conceptualises standard development as a process where two or more actors come to agree upon and adhere to a set of technical or operational specifications of an

ICT system, its parts or its functionality, either tacitly or as a result of a formal contract [23]. Since it's an agreement between parties, it has social and community-dependent aspects [22]. The standard development is conceptualised in the "context" of the design as a set of related activities that lead to the understanding of what is articulated between actors, why, and how they reach agreements due to communications between them [22]. Actors, in this case, the DH stakeholders participate in the activities that include showing a (signal) willingness to develop a standard; participate in formulating the principal concept and scope of DH standards that make sense for them; agree on the exact content and form of the standard; develop a contractual agreement for "gives" and "takes" concerning the standardisation process and its outcomes, and agree upon what "conforming" to the standard specification means. This model presents a rigorous process of standards development that satisfies the principles of standards development, including transparency, openness, and consensus-building.

Concepts from the technology adoption theories that were explored include; (1) how the 'perceived usefulness' and 'perceived ease of use' from TAM [24, 25] can inform the formulation of context-relevant DHCI standards. (2) How organisation characteristics (characteristics and resources of the organisation), technology characteristics (all technologies that are relevant to the organisation and attributes that determine their rate of adoption), and environment characteristics from TOE influence adoption to use of the standards and implementation [26]. These TOE constructs can inform the standards' adoption and consistent use. (3) ISA was used to study the perception of DH stakeholders in Uganda regarding adopting standards in the country's health system. According to Hovav [27], Internet standards adoption is a function of the utility of the standard's characteristics (individual perspective) and the environment in which the adopter operates (community perspective). ISA's framework acknowledges that besides the features of the standard having high utility (useful features), successful adoption requires a conducive adoption environment [27]. Both dimensions must be of high quality for the standard to be fully adopted. Useful features of a standard may appeal differently to potential adopters.

The European Statistical System (ESS) standardisation process has five major stages, including establishing the need for a standard, developing the standard, adopting the standard, disseminating, applying the standard, and maintaining/reviewing the standard [28]. In addition to standards development, as currently followed by SDOs, ESS has activities that this study considered foundational to inform the standardisation of the DH in LMICs; some of them are critical to success when implementing standards. The activities include establishing the need for a standard, standards dissemination, application, monitoring and conformance assessment. Therefore, adapting these components of the ESS framework can facilitate an LMIC, like Uganda to; (1) produce consensus-based DH standards and (2) support the standards' implementation and consistent use.

Finally, Kern [29] argues that continual changes in the organisation, technology, and innovation warrant periodical reviews. In this case, it would warrant a periodic review of the standards for DHCI. Therefore, establishing and managing the life

cycle of DHCI standards should be core elements of the national infrastructure, as recommended by Stroetmann [30].

As evidenced in this review, several countries' current DH standardisation practices lack rigour, especially for the implementation and compliance monitoring stages. Besides, our literature review did not find a comprehensive framework or theory in the digital health domain to support the full scope of standardisation. Thus, the researcher used concepts from the reviewed Fomin's Process Model, the technology adoption theories, and ESS to explore DH stakeholder experiences and views in Uganda regards the existence and use of standards relevant to the DHCI.

3 Methods

A scoping literature review followed by an exploratory survey of the DHCI standardisation environment in Uganda was conducted. The exploratory study adopted a cross-sectional study design to explore the state of DHCI standardisation in Uganda as a case of resource-constrained health systems in LMICs. We explored the standardisation process to identify factors affecting standardisation of the electronic communication infrastructure that should support health information exchange in Uganda's health system. The case study explored the four top health system levels in Uganda, i.e., Health Center IVs, District Hospitals, Regional Referral Hospitals and National Referral Hospitals. Both qualitative and quantitative data were collected from purposively selected key respondents from the four top health system levels and the national level.

Study Site Selection: Government-owned and private, not-for-profit health facilities were considered in the study. They included one national Referral Hospital (NRH), Three Regional Referral Hospitals (RRH), Three District Hospitals (DH), twenty Health Centers Fours (HC VI), and two private health facilities (a hospital and an HC IV), which were purposively selected from four regions of Uganda. A health facility was considered in this study if;

- (i) It has implemented some form of eHealth, e.g., electronic medical records, Health Information Systems, Mobile technology for surveillance,
- (ii) It is an Infectious Disease Institute (IDI) site,
- (iii) It is located in a rural, peri-urban or urban setting representing the disparity in urban–rural resource differences in Uganda, and
- (iv) It is among Uganda's four top health system levels, i.e., NRH, RRH, DH, and HC IVs.

Besides, national views regarding the state of eHealth technologies and standards in Uganda were obtained from policymakers at the Ministry of Health, Uganda National Bureau of Standards (UNBS), the Ministry of ICT, other government departments, and healthcare implementing partners in Uganda.

Participant Selection: Conditions for selecting a participant to be included in the study were (i) being an implementer and/or supervisor of eHealth at the health facility

level. Those included were In-charge/Medical directors of health facilities and ICT/Data/Record Officers at health facilities. (ii) Users of eHealth technology at health facilities like the Medical Officer/Clinician, Laboratory Technologist, Nurse, and Pharmacist. (iii) Policymakers and health implementation partners in Uganda. They were drawn from various ministries, departments and authorities (MDAs), partner groups, healthcare trainers, and researchers. Only those that consented to give us interviews were finally interviewed.

Field Survey: The study collected both qualitative and quantitative data using interview guides and questionnaires. Semi-structured interviews were used to investigate current challenges to standardising eHealth communication infrastructure and technologies in the top four levels of Uganda's health system. The choice of qualitative interviews were based on the argument of Hege and Vibeke [31], who suggested that they stand out as a well-suited method to grasp the socio-technical complexity and rapid changes that characterise the e-health sector. To further benefit from the informed and technical expertise of DH policymakers, health development partners, researchers/trainers, eHealth implementers and users at the healthcare level, the study also used focus group (FG) discussion. Whereas national-level participants, officers in charge and ICT officers of health facilities responded to the interview questions, clinicians, nurses, pharmacists and laboratory technologies at health facilities filled in the questionnaires.

Facility-level data collection took place in January 2020; and due to the onset of the COVID-19 pandemic, interviews at the national level were conducted via online platforms. Two online platforms were used, i.e., Skype and Zoom and participants chose a preferred option. The interviews only focused on exploring the standardisation process, both the standards adoption, adaption, and development process, and identifying challenges to the process, including implementation and compliance monitoring process. The FG helped filter the challenges that emerged from the interviews.

Analysis: Quantitative data collected were analysed using MS Excel. Interview transcripts were systematically reviewed and coded in NVivo 12. Transcripts were coded for standards adoption, standards adaption/contextualisation, standards development, standardisation process/activities, stakeholder participation in the standards process, standards implementation, monitoring compliance with the standards, actors in standards implementation, standards monitoring tools, factors influencing standardisation process (research and development, adoption, adaption, development, implementation and compliance monitoring).

Ethical clearance: Makerere School of Public Health's Institutional Review Board provided ethical approval for this study. Also, the Ministry of Health, the eHealth problem owners in Uganda, granted the researchers permission to collect data from selected healthcare sites. The District Health Officers (DHOs), the Officer-in-charge of study health facilities, and the participants consented to the study.

4 Results

4.1 Demographics of Respondents

Responses reported in this paper are based on the participation of participants and respondents, as listed in Table 2. Of the expected 140 respondents and 90 study participants, 132 questionnaires were returned, and 56 interviews were completed, constituting a total response rate of 81.7%, which Mugenda and Mugenda [32] suggest is excellent for analysis. The researcher analysed and presented results from the 188 actual responses.

Subnational participants and respondents were spread over the regions of Uganda, as shown in Fig. 1. Northern Uganda had a 50% representation of the overall Regional Referral Hospitals (RRH) in the study districts of Uganda. Most of the IDI-supported District Hospitals (DHs) were in Uganda's West Nile and Western regions, represented by 66.7 and 33.3%, respectively. Discussions include upcountry (rural) experiences of the health facilities characterised by responses from Eastern Uganda, West Nile and Northern Uganda. Central Uganda covered the districts of Wakiso and Kampala, representing the country's urban and peri-urban settings.

On the distribution of Subnational participants/respondents by the type of health facility, Table 3 shows that 66.7% were from HC IVs, 22.7% from referral hospitals and only 10.6% from district hospitals.

Participation in the study as represented in Table 2, Fig. 1 and Table 3 reflects views representative of all categories of digital health stakeholders in Uganda, both

Table 2 The response/participant rate of the different categories of participants

Category of respondent/ participant	Expected responses	Actual responses	Rate
<i>Subnational respondents/participant</i>			
Facility administrator/ in-charge/medical director	28	19	68.9%
ICT/data/record officers	28	22	75.6%
Clinical medical officers	28	28	100.0%
Laboratory	28	28	100.0%
Nurses	56	51	91.1%
Pharmacists	28	25	89.3%
<i>National participants</i>			
Policy makers	10	5	50.0%
Health development partners	5	4	80.0%
Implementation partners	13	4	30.8%
HI researchers	6	2	33.3%
Total	230	188	81.7%

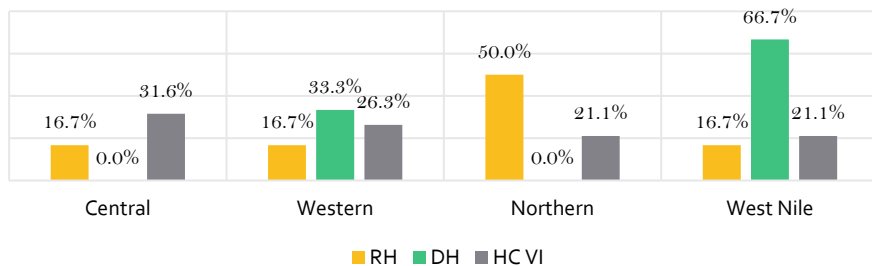


Fig. 1 Distribution of health facilities by region of Uganda

Table 3 Distribution of respondents by facility type

Facility type		Frequency	Per cent	Valid percent	Cumulative percent
Valid	HC IV	88	66.7	66.7	66.7
	Hospital	14	10.6	10.6	77.3
	RH	30	22.7	22.7	100.0
	Total	132	100.0	100.0	

at the national health system level and subnational levels. This study is considered representative of the actual state of digital health standardisation in Uganda at the time of data collection.

4.2 Standardisation Practice in Uganda

Two national-level participants, i.e., M04 (NITA-U Standards Officer) and M05 (UNBS Standards Officer), elaborated on developing standards in Uganda, stating that it is inter-sectorial and involves multiple Ministries, Departments and Agencies (MDAs). Figure 2 summarises their response into six main phases: preparatory, development, dissemination, implementation, monitoring, and review.

The activities start with determining the needs and priorities that can be addressed through standards, followed by standards' workgroup engagement to develop the standards and approval process. Once it has been approved, the standards are then declared national standards. For proper implementation and use of a standard, the responsible entity should disseminate and build the capacity (train) in its use. Once implementation is underway, the effects and impacts of the standard can be monitored. This monitoring may trigger the decision to review the standard and subsequently revise, confirm, withdraw the standards, or strengthen its implementation.

To better understand the standardisation process, participants were asked about their participation, majority of the respondents (61.4%) disagreed that they were

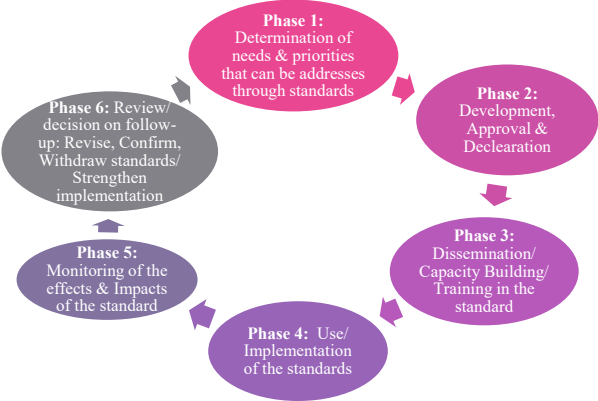


Fig. 2 Standardisation life cycle [33]

involved (see Fig. 3). Furthermore, 45.4% of the respondents said that the standardisation team is improperly constituted. In the participant’s expressions, the process follows the ‘PUSH’ methodology: “What I have seen before with the MOH [Ministry of Health] is that they use the push system. So, push in a way that we have generated this, of course, they have experts, consultants; they have the involvement of other IPs, so for you on the ground, what you feel whether that will be possible according to your experience some other person has more experience than you to decide for you” (W10, Facility Administrator). This may suggest that facility-level stakeholders are less involved in the process and, therefore, not knowledgeable about the activities of the standards committee.

Further interrogation of stakeholders’ involvement in the standardisation process revealed that subnational stakeholders were not fully engaged in the standardisation process. As a result, participants felt left out of the process or even the decision to adopt DH technologies. A participant expressed this view on the need to include health facility-level users in the development/selection of standards and DH technologies, saying, “... I think for something to work in health, you need to involve the

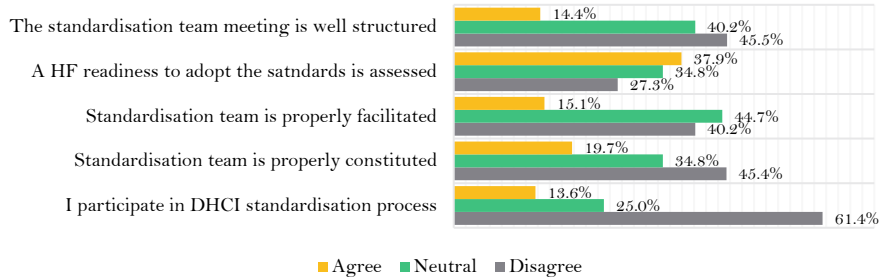


Fig. 3 Stakeholder engagement in the DHCI standardisation process in Uganda (n = 132)

lower cadres upwards” (N06, Medical Director). The lack/limited involvement of subnational levels in the standardisation process seems consistent to warrant a participant to believe that developing standards (SoP) is an MoH responsibility that does not include facility-level stakeholders. Participant W04, ICT Officer, stated, “... *most of the SOPs we are using, they nationally used, we are using national guidelines...*”. The participant further recognised the need for multiple stakeholder involvement in the standardisation process by saying, “*Health sector is sensitive; you can’t come up with your own. So, we follow national guidelines*” (W04, ICT Officer); and that the standards development team should have adequate time and resources to complete their standardisation tasks.

Respondents indicated that the team was improperly facilitated. Regarding support provided to the MoH for DHCI’s standardisation, only 40.2% agreed. They claimed that although health development partners (HDPs) like World Health Organisation (WHO) and United Nations International Children’s Emergency Fund (UNICEF) often offer support, they are insufficient to support the entire standardisation process. Also, health workers do not possess the required ICT standardisation literacy, knowledge, and experience to participate in the standardisation process. Nevertheless, HDPs provided technical support to the Ministry of Health during the standardisation process, including providing standards and guidance documents as mentioned by participant IP02: “*provide standards from other settings/countries, that can be used for benchmarking best practice*” (DP02, ICT Specialist).

Finally, regarding whether health facility readiness assessment is done before the proposed adoption of DHCI and standards, more respondents (37.9%) agreed, 27.3% disagreed, and 34.8% remained neutral. This may imply some assessment is done but is not extensive enough to be noticed by all health facility workers.

Regarding standards implementation and compliance monitoring practices being used in Uganda’s health system, results in Fig. 4 shows that only a small percentage of respondents agreed that there are guidelines for implementing DHCI at the facility (31.8%) and that implementers try to adhere to those guidelines (32.6%). The majority agreed that there is good communication and coordination between DHCI implementers (60.6%) that can be leveraged upon. Although a participant argued that some form of implementation is going on by saying, “...*you are blocked if you try to access certain sites which you are not supposed to*” (N06, Medical Director), the low agreement on whether implementers adhered to the standard/guidelines when implementing ICT in healthcare is evidenced by a participant who said, “*someone goes and develops a system without consulting us and knowing what problem we have and then tries to force us to use the system*” (M03, Assistant Commissioner Health Information Management).

Regarding monitoring compliance with standards for DHCI, subnational participants indicated they were not involved in the decisions to monitor compliance with standards for DH. Most of the respondents were non-committal on all four questions on compliance monitoring. Therefore, they could not be asked to narrate their experiences or state the activities of DH standards implementation and compliance monitoring. For example, one respondent said, “*There is an informal way of monitoring; occasionally, you come across something that has been done wrongly by*

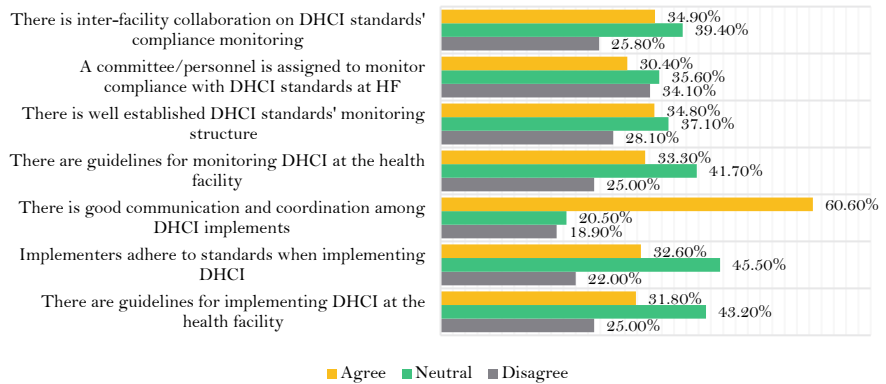


Fig. 4 State of implementation and monitoring compliance with standards for DHCI in Uganda (n = 132)

individuals, but there is no system which constantly monitors compliance” (N06, Medical Director), which means that the respondent could not identify any tools, criteria or mechanisms adopted to monitor DHCI and standards’ implementation and level of compliance with such standards. However, in the absence of an independent arm for monitoring and evaluation of DHCI, HDPs support the Ministry of Health as mentioned by participant W04, ICT Officer: “*The government does not have an independent arm attached to monitoring and evaluation. The health development partners bring in their M&E systems*” (W04, ICT Officer). Also, a national participant claimed that Uganda’s National Information Technology Authority (NITA-U) conducts assessments of implemented digital systems to ensure they comply with standards. “*NITA-U also conducts an assessment to compliance to standards once systems have been implemented*” (M04, Standards Officer). But this claim could not be collaborated by any participant from the MoH. Besides, no documented evidence exists regarding the findings of such claimed assessments.

4.3 Factors Affecting Implementation of DHCI Standards in Uganda

Overall, the study identified factors that affect development/contextualisation and or implementation of DHCI standards in Uganda’s health system. Identified factors extend the organisation’s preparedness for DHCI implementation to issues of the process followed in developing, implementing and monitoring compliance with the standards (as summarised in Table 4). These factors are explained in subsequent subsections as follows;

Table 4 Factors affecting standards implementation identified during the study

Aspects	Factors that influence standards implementation in Uganda
1. Organisational readiness	(i) Inadequate technical expertise and user skills
	(ii) Weak DH leadership/governance structure
	(iii) Financial constraints
	(iv) Unregulated implementations of health information systems (HIS) and other DHCI components not guided by DH standards
2. Standardisation process	(i) The MoH lacks a documented methodology for determining standards
	(ii) Limited involvement of lower-level carders in determining standards DHCI
	(iii) Limited sensitisation of facility-level users about the existence and need for DHCI standards
	(iv) Inadequacy of the reviewed/updated/contextualised standards
	(v) Poor documentation of DH standards for health facilities
3. Standards implementation process	(i) Sometimes the standards are difficult/confusing to understand for end-users
	(ii) Limited awareness of standards for ICT being used in healthcare processes
	(iii) Unreliable facilitating resources like electric power, financial, and human resources
4. Compliance monitoring process	(i) The lack of an agreed-upon level of adherence
	(ii) Lack of monitoring tool/criteria/mechanism agreed upon by stakeholders
	(iii) Lack of DH standards' monitoring structure

4.3.1 Gaps in organisation's Preparedness to Implement DHCI and Standards

- (i) ***Inadequate Technical Expertise and User Skills***: only a few respondents agreed that Uganda had adequate technical expertise in DH. This confirms the views of a participant who said, “*You know most people are not yet computer literate. It requires some training*” (C04, Facility Administrator). When another participant was asked to comment on computer literacy in the health sector, he/she stated that “*People here are not computer literate*” (C09, Data Officer), which inadequacy may extend to include relevant knowledge that contributes to the standards development/contextualisation process. Authors have recommended developing a policy on human resources development and skills training in LMICs [34, 35]. Besides, such policy and or training programmes should stipulate the required expertise, skills, competencies, and

specialised knowledge required to participate in the standardisation of DHCI (an eHealth standardisation project). Also, it should be clear about investing in human capital development, continuous professional development, and any incentives to motivate health professionals.

- (ii) **Weak DH Leadership/governance structure:** One participant (DP01, ICT Specialist) noted a challenge of leadership structure to decide whether DH innovations should be considered. The complexity of multiple innovations led to having multiple systems with different standards that could not be interoperable. In addition, there were challenges for individuals or agencies to move their agenda forward and not abide by the implementation of standards. The weak leadership resulted in siloed applications, as mentioned by M01, MoH's Health Information Specialist: *"Our biggest challenge has been siloed implemented applications at disease level that are not even speaking to each other.... most of these solutions are not also sustainable.....this is because HDPs implement systems without following the structures put in place for approval"* (M01, MoH's Health Information Specialist). The siloed systems were also facilitated by a lack of monitoring systems, as noted by participant IR01, Health Informatics Researcher. This finding aligns with the fact that only 32.6% (see Fig. 4) of the respondents agreed that implementers adhered to guidelines when implementing ICT in healthcare.
- (iii) **Financial Constraints:** very few respondents at the health facility level agreed that the standards development or review team had adequate resources to develop the DH guidelines. The same was echoed by participant M05 (a UNBS Standards Officer) at the national level that a significant amount of money was needed to implement the standards. Spring and Weiss [36] proposed a solution to this problem of financing the standardisation process.
- (iv) **Unregulated implementations of HISs and other DHCI components not guided by DH standards:** In addition, although one participant mentioned that the MoH developed the DH policy to guide DH standards implementation (M03, Assistant Commissioner Health Information Management), there are no guidelines, criteria or standards to guide the MoH and DH stakeholders' decisions on such implementation. Besides, this was confirmed in a literature review of DH standardisation in LMICs, which found no suitable frameworks low resources countries like Uganda can use to fast-track the standardisation of the DH CI [37].

4.3.2 Challenges that Relate to Standards Formulation

- (i) **The MoH lacks a documented methodology for determining standards:** or even scrutinising DH applications/technologies to be adopted across the different healthcare sites in Uganda's healthcare system. In addition, there is no implementation/compliance monitoring guide. However, several authors argue for the development of a mechanism to support standards development, implementation planning, validation, use, and conformance [38–41], including the

all-inclusive and established structure of stakeholders mandated to standardise the DHCI [42, 43].

- (ii) **Limited involvement of lower-level carders in determining DHCI standards:** Only 13.6% (Fig. 3) of the respondents at health facilities mentioned that they participated in deciding the guidelines for ICT to be used at the health facility level. Both national and subnational participants agree that all stakeholders have limited involvement in standardisation activities, including requirements elicitation. Notably, PM05 (UNBS Standards Officer) reported insufficient participation of key stakeholders while conducting review meetings or workshops and proposed vigilance by the Ministry of Health. Only one subnational participant agreed to participate in developing guidelines for ICT in health, stating that “*Yes, I have heard a chance to attend some of the meetings. Recently, I was part of the team that came up with the M&E health plan for the country*” (W04, ICT Officer). This affects the usage and acceptability of the developed artefacts, hence limited use (and/or abandonment) to support healthcare processes. The limited participation in the standards development process has caused health facility-level stakeholders to have a limited understanding of the standards (W04, ICT Officer), which could lead to little appreciation of the DH standards to support secure health data exchange, and, therefore, potentially low ownership and uptake of the standards [44].
- (iii) **Limited sensitisation of facility-level users about the existence and need for DHCI standards:** In fact, most users were not even aware of the standards for DH, as exemplified by a participant’s statement that “*To be honest, guidelines are not actually, like I said followed because not every staff are even aware of the guidelines*”—N11, Data Officer. Another participant even suggested that rather than just providing the guidelines, the MoH also need to train users. He said there is “*also a need for training of people from down here not just developing the guideline or pushing the information down without training people*” (N10, Medical Director). This suggests that health facility participants lack awareness, unlike at the national level, where participants could identify a few standards like DH security and privacy. In addition, there are inadequate ICT skills related to DH among healthcare professionals at health facilities (i.e., the officer In-charge health facilities, clinicians, nurses, laboratory technologists and pharmacists), both in terms of the numbers and skills mix/set. Furthermore, healthcare workers lack training, experience and expertise in the development and/or use of standards for DHCI.
- (iv) **Inadequacy of the reviewed/updated standards:** In addition to evidence that Uganda’s MoH has not officially adopted standards to support the electronic sharing and exchange of patient data specifically, one participant affirmed the importance of standards by saying, “*Confidently, yes, the guidelines can cover that. However, they seem to be repeated guidelines. I have never seen it before, yet things have changed. They should be, maybe evaluated*” (W10, Facility Administrator). This suggests significant improvement to existing guidelines,

including updates catering to new technology trends and contextual environments. Besides, to allow widespread appreciation, authors encourage that standards should be written in simple language, structure, and format with clear guidelines ensuring that they are simple, clear and unambiguous [39, 41, 45, 46]. In addition, it should be easily accessible, readable and understandable by domain experts. Also, often there is delayed updating of DH standards “*First of all, the updated one is not there*” (N11, Data Officer). “*...you see, the guideline sometimes may not state fully, and it may not cover everything...*” (N11, Data Officer). These responses suggest that some of the standards are not to date. Therefore, they must be reviewed, published, and easily accessible to all healthcare stakeholders, including technology developers.

- (v) **Poor documentation of DH standards for health facilities:** Most participants stated there are no guidelines for DHCI. Examples of their statements include; “*There are no guidelines*” (N02, Medical Director); “*There is a lack of guidelines on how to use ICT*” (N06, Medical Director); “*I have not seen some of the guidelines*”—W10, Facility Administrator; and “*No, they have not yet developed that*” (C04, Facility Administrator) among others. In addition, sometimes, the standards are not exhaustive but provide a limited depth/breadth, leading to a limited understanding of the scope of standards.

4.3.3 Challenges that Relate to Standards Implementation

- (i) **Sometimes, the standards are difficult/confusing to understand for end-users:** This suggests that some phrases in the standard may not be simple and clear enough to be comprehended by all. “*At times, they are those with technical terms, but people like me are in place to help people understand the SOPs*” (W04, ICT Officer). Therefore, the need to train/sensitise end-users at the facility level about their existence and how they should be followed.
- (ii) **Limited awareness of standards for ICT being used in health:** In fact, “*people think that they are health workers and they are not interested in computers...you understand. Because somebody is a nurse, it’s about patients...patients. So, they don’t know that they need computers*” (N12, Facility Administrator). This negative perception among healthcare workers may negate efforts to standardise DH systems in Uganda.
- (iii) **Unreliable facilitating resources:** resources like electricity required to power the DHCI devices and communication network hinder the standardised implementations of the systems. These and other challenges, such as limited finances and inadequate user skills, inhibit the implementation of DHCI. In addition, participants complained about insufficient supply from the main grid and that even where alternative sources/backups (generators, solar, UPS, etc.) exist, these cannot sustain the DH systems for a prolonged period.

4.3.4 Challenges that Relate to Standards' Compliance Monitoring

The identified gaps relate to the lack of governance structures to monitor compliance and tools for assessing compliance with DHCI standards and/or guidelines. The gaps include;

- (i) ***Lack of tool/mechanism that stakeholders have agreed upon to monitor compliance:*** "...there is no system which constantly monitors compliance" (N06, Medical Director). This lack of an agreed-upon mechanism suggests differentiated metrics for monitoring implementation and compliance with DH standards.
- (ii) ***The lack of an agreed-upon level of adherence:*** that constitutes compliance suggests results are dependent on the varied activities and convenience of the monitoring person
- (iii) ***Lack of DH standards' monitoring structure:*** Results show that health facility respondents were not aware of the standards monitoring structure. This could mean that the implementation and compliance monitoring team structure and activities are unknown to respondents because they are non-existent.

Overall, the study identified several gaps that hamper the establishment of a connected health system through a standardised DHCI. Consequently, participants in the survey identified several weaknesses (listed in Fig. 5) in existing implementations of the DHCI that stem from gaps in the standards development process, implementation lapses, and deficiencies in enforcing and monitoring compliance with the standards or guidelines.

Figure 5 shows that more (26.1%) respondents mentioned the digital literacy gap. These DH technology users worry more about their capacity to use existing DHCI and applications effectively. Also, 15.2% of the respondents point to the problem of the electric power required to run the ICT devices and technologies. One participant further highlighted the magnitude of the skills and power problem when he said, "We were supplied with smaller computers with cameras where you can capture real-time

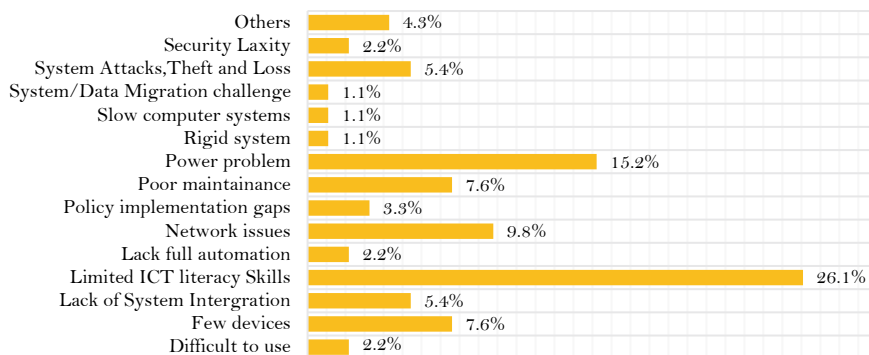


Fig. 5 Challenges of DHCI that exist in Uganda's health system (n = 46)

data. Information flow made communication easier. But this died a natural death due to power and capacity of staff to use the system” (WN05, ICT Officer).

This study shows that the challenges are similar across health facilities in rural and urban settings, exemplified by the responses from both settings. In addition, the challenges apply across the entire health system levels surveyed, i.e., HC IVs, District Hospitals and regional referral hospitals. However, some health facilities have no connection to the primary electrical power grid. Examples are participants/respondents N12(Facility Administrator) and WN07(a Data Officer), who said, “...the lack of electricity. Power is not there.” and “it has taken long since Amin’s time, there has been no power this side” respectively, the power problem at their health facilities.

Other significant issues that emerged included network issues (9.8%), few ICT devices (7.6%), poor maintenance of the CI (7.6%), limited integration of DH applications (5.4%), security laxity leading to system attacks, theft, and loss (5.4%) and policy implementation gaps (3.3%) among others.

5 Discussion

The main findings of this exploratory study (1) confirm practices identified by similar studies in LMICs regards DH standardisation and (2) elicit factors that affect the implementation of DHCI standards in resource-constrained settings like Uganda’s health system.

5.1 Practice of DHCI Standardisation in Uganda, an Example of Resource-Constrained Setting

A key result from the study shows that Uganda has a standardisation process, although with gaps that limit its success in fast-tracking the already delayed standardisation of DHCI. As was shown in Sect. 2.2 of this chapter, these gaps are consistent with what other countries experience; both countries that have made progress in DH (Estonia, Australia, and New Zealand) and peer countries in the regions (South Africa, Kenya and Tanzania). This study refers to them as standardisation gaps and has developed three main categorisations: (1) gaps that relate to determining the need for a standard i.e., the context of the standards; (2) gaps in the standards formulation, and (3) weaknesses of the standards implementation process.

The gaps persist because Uganda does not have a documented procedure for streamlining DH standardisation. Furthermore, countries that have made progress in DH standardisation have not provided resource-constrained countries like Uganda with foundational models or frameworks for contextualising, which could be used to fast-track the formulation of suitable DH standards [47]. Therefore, this study

recommended structuring standardisation activities by developing a process or framework to aid less experienced standards developers to formulate suitable standards for their context. In addition, such a framework should be capable of empowering standards' implementors to collaborate in monitoring the compliance of digital health stakeholders with the developed DHCI standards.

Although, there was a framework, model or method to guide DH standardisation, limited stakeholder involvement in DH decisions and implementations, as reported in this study, might still entail failure. It has been claimed that the potential success of the protracted standards development process lies in stakeholder engagement that obeys the four cardinal principles (out of the 12 principles) of DH standards development, i.e., consensus-based, transparency and openness, balance, and due process [12, 28, 48]. Any process that satisfies these principles of standardisation is considered suitable to guide a domain's standards development. Overall, stakeholders' participation is critical to achieving all the above principles. Besides, stakeholder participation in standardisation gains knowledge, influence and network [48]. They gain knowledge of the upcoming standards and the underlying rationales; influence the upcoming standards and their requirements; and network with the other participants, often from different societal positions [48].

Although participants argued that DH governance at health facilities enforced the often-strict procedure of obtaining health data, there was a lack of clarity on structures for implementing standardised DHCI and monitoring compliance with the standards. There should be a strict mechanism that covers the full scope of DH implementation, starting from acquiring the DHCI, applications and technologies to secure the use of the DH systems to support HIE and patient-centred care. In addition, the study findings also show that stakeholders, especially facility-level stakeholders, are not involved in the current practice of standards implementation and compliance monitoring. Yet successful implementation and monitoring require stakeholder involvement.

5.2 Factors Affecting Implementation of DHCI Standards in Uganda

The study conceptualised that factors that affect the implementation of any standard start with gaps in standards development through implementation and compliance monitoring.

First, an inappropriate standardisation process has hampered the possibility of contextualising DHCI standards for Uganda. Despite the existing UNBS standardisation process, this study identified their weaknesses in fast-tracking the standardisation of DHCI. The existing process lacks a procedure for planning standardisation resources, training, measurement and evaluation plan. In addition, the existing DH environment is riddled with standardisation and other digitisation challenges that make standards development/adoption difficult for LMICs [16, 49]. Therefore,

existing processes/methods are unsuitable for fast-tracking DHCI standardisation in LMICs like Uganda [37]. Other factors that affect the standardisation process include limited participation of LMICs in global standards development, insufficient human resources, inadequate technical infrastructure for standards participation and financial resources factors [37, 50, 51]. The lack of a suitable process failed Uganda in adopting or contextualising standards.

Second the lack of officially adopted and contextualised standards for DHCI in Uganda's health system means that existing standards are not clear, used on the Adhoc as designated by NITA-U for all government MDAs. This problem is complicated by limited knowledge of the existence of NITA-U standards/guidelines for the acquisition and use of ICT by government ministries and departments [52].

Third, on factors that affect the implementation of standards for the DHCI in Uganda's health system, the study identified several gaps, including improper documentation, poor methods of disseminating the standards to health facilities and other standards implementers/users, delayed updating of standards, the complexity of the statements and specifications of standards, making them difficult to read or understand by end-users, limited awareness/enthusiasm over the adoption of standards for ICT to support healthcare processes, lack of tool/mechanism that stakeholders have agreed upon to monitor compliance, lack of agreed-upon level of adherence that constitutes compliance, and lack of guidelines for implementers to monitor themselves.

Standards implementation gaps extend from its development to monitoring of compliance. For example, the lack of a standard means we cannot implement and enforce compliance with what is non-existent. An improperly structured standard fails the implementers because it cannot be properly interpreted and applied. Those who attempt to apply the standard interpret it differently and consequently, it is implemented.

6 Conclusion

This study confirmed that existing processes are insufficient to fast-track DHCI standardisation and that several factors affect the implementation of existing standards for digital communications in Uganda. To ensure existing and future digital health information systems are effective in supporting patient-centred care and the general public, they must follow standards during data capture, processing, storage and sharing. Empirical results reveal factors that influence potential success in implementing DHCI standards extend conceptualisation, formulation, implementation and mechanisms to ensure compliant use, which this study refers to as standardisation gaps. We argue that for resource-constrained health systems to attain the benefits of digital health, they should address such standardisation problems. Our future works will address the identified gaps by adopting a rigorous process of determining

DHCI standards and collaboratively planning their implementation and compliance monitoring.

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