

A Conceptual Model for Adaptation of eHealth Standards by Low and Middle-Income Countries

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Background and Purpose: Electronic health (ehealth) is the use of information and communication technology to support healthcare. It is used to driving efforts to achieve sustainable development goals (SDGs) particularly “good health and well-being for all”. Nonetheless, just like other technologies, ehealth has rapidly gained ground in low and middle-income countries (LMICs) although with scanty government intervention. In fact, governments in LMICs have only lately developed ehealth strategies. Much as ehealth offers the promise for improved and affordable healthcare and service delivery, its success is still dependent on the specifications (standards) to support interoperability and information exchange. Regrettably, standardization efforts in LMICs are greatly curtailed by resource constraints.

Methods: We reviewed literature on ehealth standardisation in LMICs using four African countries as our case studies. The objective of the study was to explore the challenges of ehealth standards development and or adoption by LMICs and posit that adaptation of existing international ehealth standards is a better option for LMICs. Qualitative analysis was used to derive key themes.

Results: Our study findings indicate several challenges to ehealth standardization in LMICs including delayed standardisation efforts and unregulated penetration of ehealth, slight industry involvement, inadequate funding for the standardisation process, insufficient human resources, less to none participation in the international standards development process, and inadequate technical infrastructure for standards participation among others.

Conclusions: This study recommends adaptation of international ehealth standards to local context of individual LMICs to help streamline both patient data and health information sharing. To achieve this, we developed the ehealth standards adaptation model. The model offers better opportunity to fast-track ehealth standardisation efforts in LMICs, as such creating an enabling platform for ehealth systems interoperability and support for health information exchange.

Keywords: Adaptation Model, eHealth Standardization, Standards

1 Background and Purpose

Technological advancement in LMICs has always preceded the regulation. Governments and regulatory bodies are slow to develop or adopt standards and regulations to guide technological adoption, implementation, usage, access, security and privacy. While innovators continue to develop solutions for health problems in LMICs, they need to use and follow standards that should guide them to develop products suitable for use in resource-constrained environments. Standards are specifications necessary for proper co-existence and interoperability of systems; essential for meeting national and international regulations and critical for safe operation of devices without causing harm to people or equipment [1] [2] [3]. In health, standards are needed to foster effective health information exchange, co-existence and interoperability of systems [2] [3] [4]. In addition, standards for ehealth aim at provision of reference criteria that a solution (product or service) must meet; provision of information that enhances safety, reliability,

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and performance of such solutions, product or services; assure stakeholders about their reliability and guarantee choice of technology, solutions and services [2] [5]. Notwithstanding the benefits of ehealth standards, many LMICs are still slow in adopting ehealth standards [6]; as such they have lagged behind in the implementation of interoperable ehealth systems. For this reason, pilot ehealth projects in LMICs including Uganda, have failed to scale-up [7] [8] and remain standalone, that is, non-interoperable health systems. This has hindered attainment of one vital goal for ehealth, that is, access to health information whenever and where required by authorized persons [9] [10]. To address such gaps, various studies on ehealth in LMICs suggest priority areas to include; e-Health standards, ICT and health policies, e-legislation, e-Health infrastructure, ehealth education and ICT competence [6] [11] [12] [13].

Given the background above, this study focuses on adapting ehealth international standards to address the LMICs' ehealth interoperability initiatives. Using Uganda as an example of LMICs, several ehealth interoperability challenges have been observed key ones being the lack of ehealth standards and guidelines [14] [15]. However, developing standards for the complex ehealth environment is more challenging than for general innovations [16]. As such, our study suggests, paying more attention to developing ehealth standards that can be adapted to address LMICs' ehealth interoperability challenges. We note, however, lack of a powerful process to develop ehealth standards [17] or even contextualise existing international standards to meet requirements of resource constrained environments in LMICs. Existing adaptation models only consider technology adaptation, quality adaptation, and content adaptation [18] [19] [20] among others, but none presents ehealth standards adaptation model. While some of the international ehealth standards are applicable in LMICs, others require adaptation to support the unique resource requirements or use cases [12]. The concept of "Adaptation" also called co-shaper refers to adjustment of existing international standards to suit a country's specific needs and deployment of such adjusted standards [5]. The need for adaptation of ehealth standards by LMICs is heightened by the demand to fast-track the standardisation of ehealth to ensure interoperability of already existing ehealth implementations; and the need to promote innovation of standardised ehealth technologies [6] [11] [12]. To this end, we reviewed the challenges of ehealth standardization in LMICs and suggested that adaptation of existing international ehealth standards is a better option. In fact, Kern [21] argues for standards adaptation for new regularly emerging technologies; and [22] recommends adaptation to meet a country's specific needs.

2 Methods

To conduct our study, we surveyed various literatures including specific country ehealth policy and strategy documents on ehealth standards in LMICs. We identified four African countries to represent LMICs. We conducted desk reviews of published and unpublished literature on the standardisation of ehealth systems in Rwanda, Malawi, Kenya and Uganda. The qualitative analysis method was used to synthesise the data we collected; the aim was to derive common themes on the challenges of ehealth standardisation, as well as to deduce sound conclusions regarding the state of e-health initiatives in LMICs, that is the standards that support interoperability and integration of ehealth systems.

3 Results

From our literature reviews, we derived a number of ehealth standards challenges as discussed below;

Little participation in international ehealth standards development: Standardisation can be at national, regional, international or industry context, where stakeholders agree upon a repeatable way of doing something [23]. The standards are grouped as formal, informal, official, voluntary, industry, private or open standards [17] [24]. This study considered formal de jure standards. These types of standards are developed by standards development organisations (SDOs), the bodies mandated within the industry, nation, and region or internationally to develop the standards. Table 1 presents LMICs participation in some of the international ehealth SDOs (using February, 2018 data).

Table 1. eHealth Standardisation Organisations

SDO	LMICs Participation	
ISO–TC215 Health informatics	27/59	(45.8%)
GS1	66/113	(58.4%)
European Committee for Standardization	0	(0.0%)
International Health Terminology SDO - SNOMED	3/31	(9.7%)
Institute of Electrical and Electronics Engineers (IEEE)	Individuals	N/A
National Electrical Manufacturer Association (NEMA)	0	(0.0%)
International Electrotechnical Commission (IEC)	41/85	(48.2%)
Health Level Seven (HL7)	Individuals	N/A
Clinical Data Interchange Standards Consortium (CDISC)	Individuals	N/A
Regenstrief Institute	0	(0.0%)

Lack of a formal standardisation process suitable for LMICs: SDOs have a formal process for standards development and approval [25]. The process can be summarised into five stages of demand for standards, organization and management of the workgroup, development and implementation of standards, education and support services, testing and evaluation of standards, and conformance monitoring and review [21] [22] [26]. The process presents a structured procedure of producing standards /specifications based on outlined principles [23].

High penetration of ehealth systems: Electronic health implementation in LMICs started in the 1980s – 1990s. Evolving of ehealth technologies followed, but their penetration in the health sector has remained largely unregulated. Much of these implementations remain isolated and fragmented [12] [19] [27] [28]. The reviewed LMICs in Africa have small, fragmented and generally donor led health information systems (HIS) and technologies [12] [13].

Delayed ehealth standardisation efforts in LMICs: LMICs including Uganda have multiple health sector challenges, including shortage of health professionals and facilities. Hence, the individual LMICs moved quickly to adopt ehealth solutions to curb various shortages in the health sector. A review of ehealth in Uganda, Kenya, Rwanda, and Malawi revealed similar patterns in adoption of ehealth, for example the computerised health records (CHR), hospital management systems (HMS), health information system (HIS), health management information system (HMIS), among others; ehealth strategies and corresponding standardisation efforts (see Table 2).

Table 2. Examples of ehealth strategy development efforts in LMICs [8] [13] [29] [30] [31] [32]

Country	Start of eHealth implementation	eHealth Strategy	National eHealth Standardisation Body	
			Specialised	General
Uganda	1997 (HIS)	2012	Taskforce, Collaboration	UNBS, MoH
Kenya	2001 (CHR)	2011	Taskforce, Collaboration	KBS
Rwanda	1997 (HMIS)	2009	RITA	RSB, RITA
Malawi	2002 (HMIS)	2003	MoH	MBS, MoH

Common Standardisation Challenges: The following have been identified as the most common challenges to hamper adoption of existing ehealth standards in resource constrained-environments, particularly Uganda; little industry involvement [23] [33], inadequate funding for standardisation process, insufficient human resources [15] [23], inadequate technical infrastructure for standards participation [23] [34], competing and overlapping of standards [33] [34], and complexity of ehealth data / information and its components [23].

4 Discussion

The review of ehealth standardisation in LMICs revealed various challenges that continue to limit eHIS interoperability and deter health data / information sharing. Table 1 shows that LMICs' involvement is an average low of 23.3% only (participatory and observatory) in the seven common ehealth SDOs. Active participation remains greatly in developed countries (76.7%), and not LMICs [12]. Limited input from resource-constrained countries suggests developed standards may not be 'exact fit' for resource-constrained nature of the LMICs. Hence the need to develop and or contextualise these standards to meet individual country ehealth interoperability needs. We note however, that existing SDOs standardisation processes only emphasise development, adoption and implementation, and overlooking the need for adaptation, yet Kern [21] argues for standards improvement and adaptation for new regularly emerging technologies. Besides, [22] recommends adaptation to meet a country's specific needs. Also, the "standardization process takes too long for a fast-moving industry or product development" [25] like the ehealth environment. Regards LMICs, they lack resources to develop standards. Similarly, adopted international ehealth standards may not fully apply to LMICs due to varying resources environments. Thus, we argue that neither the development nor adoption of ehealth standards is a viable alternative for LMICs.

In the presence of unregulated mix of government, donor and private HIS unguided by standards, most HIS remain isolated, fragmented and noninteroperable [12] [13] [19] [27] [28]. Thus, there is need to urgently standardise HIS, communication systems, data structure, terminologies, security and privacy to support health data / information sharing. Unfortunately, delayed standardisation efforts continue to aggravate the interoperability problem. In fact, despite early entry of ehealth implementations in LMICs in 1980s and 1990s [8], they remain unstandardized and lack interoperability. The four case countries reviewed in this work, have only recently developed the ehealth strategies and or policy (see Table 2).

Since standardisation is a difficult undertaking, when done after the country has mature noninteroperable ehealth systems across health facilities [9], an alternative to development should be considered. In addition, the resource-constrained countries experience general standardisation challenges like, inadequate funding for standardisation; insufficient human resources; limited technical infrastructure for standards participation and complexity of ehealth data / information and its components [23] [24] [34]. These limit the possibility of LMICs developing contextualised ehealth standards. Therefore, this study suggests the need for LMICs to explore ehealth standards adaptation as a better alternative to development or adoption.

4.1 Adaptation Model for eHealth Standardisation by LMICs

LMICs should fast-track ehealth standardisation efforts to overcome interoperability challenges. Besides, they need to ensure interoperability of already existing multiple ehealth implementations. This study suggests the adaptation of the ehealth standards as a better option to fast-track ehealth system interoperability and data exchange. Although, there exist many adaptation models, including the technology adaptation model, the quality adaptation model, and the content adaptation model [18] [19] [20] among others the current literature presents no ehealth standards adaptation model. As suggested in [19], the components of existing technology adaptation and quality adaptation models were used to develop the ehealth standards adaptation model in Figure 1. This model was derived from the technology adaptation model and the quality adaptation model [27] [33]. The model's component relationships include; first, the standards-country fit, which represents choice of ehealth standards suitable for resource-constrained nature of LMICs and their long-term needs. Second, the standards-HIS (infrastructure) fit, which represents standards tailored to the resource needs of respective ehealth systems.

The Model's three phases, include; the scanning phase, design phase and implementation and evaluation phases. The scanning phase, is the formative stage when assessment of a country's resources and existent international ehealth standards are done. The design phase handles adaptation and delivery of ehealth standards. This is the point where existent international standards are harmonized / tailored to make them relevant and accessible in a given context. Third, is the implementation and evaluation of adapted standards; these three phases have the following components:

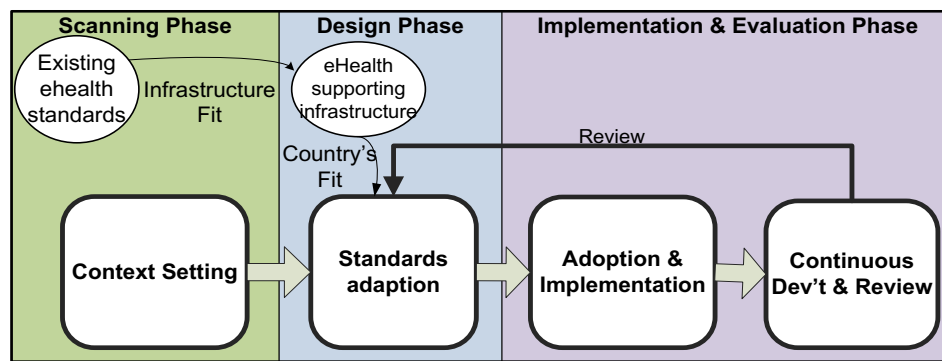


Figure 1. Model for ehealth Standards Adaptation

The context setting stage: This is the ground breaking and laying of the foundation to ehealth standards adaptation. All health stakeholders and consumers are sensitized on the strategic importance of ehealth standards. It includes, a country's ehealth strategies like the one that Uganda has already developed [15].

The standards adaptation stage: Although the existing international ehealth standards are extensive and accessible for ehealth implementation in resource-constrained environments (LMICs like Uganda), they may not fully apply to their ehealth sector [12]. This means, the standards need to be harmonised for such environments. This phase in our adaptation model will involve identifying ehealth stakeholders (actors), international standards for ehealth ecosystem, determining of methods/tools/instruments for adaptation of such standards, determining their fit for the country and its infrastructure. The country's and infrastructural fit depend on the individual country's ehealth resources.

The implementation and adoption stage: At this stage adapted / developed standards are introduced into the country's healthcare ecosystem. A standard must be implemented to derive its true benefits. Gaps in the standards implementation and compliance monitoring will stall success of ehealth. The implementation and compliance monitoring process are gradual and a responsibility of all stakeholders. Just like in other sectors of government, there is need for national standards body to monitor the implementation and compliance to agreed standards. Where no national institution has the competence to take binding decisions, a workgroup may coordinate such activities [35]. This requires the collaboration effort of many stakeholders to ensure compliance to both industry and government specifications.

The continuous development and review stage: The standards lifecycle require that there are periodic reviews. Depending on new ICT innovations, standards may need to be improved and adapted to the new technology [21]. Therefore, besides scheduled reviews, ad hoc reviews may be done if that particular standard is believed not to fit its purpose. The process confirms, revise or depreciate and replace a standard. Those ehealth standards that are either confirmed or revised to fit its purpose are then adopted for further use.

5 Conclusion

In conclusion, existence of ehealth standards cannot be disputed; however, there is a concern about LMICs participation in their development, adoption and implementation. In this research, we have identified various challenges facing ehealth standardization in LMICs and hindrances to their participation in international SDOs. We argued that the normal standardization process cannot solve these challenges and thus proposed a model for adaptation of ehealth standards by LMICs. Though, the study was limited to four African countries as the case studies, the proposed model can be used to fast-track ehealth standardization in all LMICs that have lagged behind in their standardisation efforts due to lack of common standardisation efforts and un-regulated ehealth penetration. Moreover, this study will provide an enabling implementation platform for ehealth system interoperability suitable for resource-constrained environments. In future work, we propose to empirically test and evaluate the usefulness of this model in LMICs using Uganda as our case study.

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