

# Barriers and Challenges to the Adoption of E-Health Standards in Africa

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## Abstract

*Purpose: Although standardization is seen as the key to ensuring interoperability of healthcare information systems, the large numbers of standards available can make the selection decision difficult especially for a developing nation. This paper reports on a study of e-health standards development and the level of African countries' participation in the development process. We explored the factors that restrict the adoption of e-health standards by African countries and provide ways of overcoming the barriers.*

*Method: We conducted literature study of e-health standards, their development, and the degree of participation by African countries in the process.*

*Results: The study revealed that African countries' active participation in e-health standards development is limited to the International Organization for Standardization (ISO), with no evidence of active involvement in other international standards development initiatives. Several factors were found to contribute to limited participation in the development and adoption of e-health standards by African Countries.*

**Keywords: E-health, healthcare information systems, interoperability, standards, standard development organizations**

## Introduction

The costs of healthcare delivery around the world continue to grow at an alarming rate, without corresponding improvement in the quality of care rendered [13]. Despite the economic recession, the United States' 2010 health spend per person was \$8402; with an overall spending of \$2.6 trillion. This accounted for nearly 17.9% of the gross domestic product (GDP) [48]. Data from the Organization for Economic Co-Operation and Development (OECD) [45] on total healthcare expenditure as a percentage of GDP in its member countries show similar trend. For example, Canada's total healthcare expenditure per GDP in 2010 was 11.3%; Italy's was 9.6% while Iceland spent 9.3% of its GDP on healthcare. South Africa's national healthcare expenditure accounts for 8.5% of its GDP [41] while Sierra Leo-

ne has the highest healthcare expenditure per GDP in Africa, at 13.1% [51].

This paper adopts the World Health Organization (WHO) definition of *e-health*, which is "the cost-effective and secure use of information and communications technologies in support of health and health-related fields, including healthcare services, health surveillance, health literature, and health education, knowledge and research" [50].

The adoption of e-health offers many benefits to healthcare consumers, providers, as well as managers and policy makers. From a consumer's perspective, e-health facilitates access to quality healthcare services, especially to people in remote and under-resource communities. Consumers can receive better and safer healthcare, since relevant health information is available to care providers when required. Consumers also become active participants in ensuring their well-being through access to reliable, accredited health information [7].

For the provider, e-health supports informed decision making through the availability of accurate health information, access to medical knowledge databases and best practises. Multidisciplinary teams of care providers can share health information and coordinate health interventions in an effective manner, thereby eliminating unnecessary duplication of efforts. Medication errors and adverse drug reactions can be averted through the use of e-prescription systems that flag alerts when an order is made for medications to which a patient is known to be allergic. Furthermore, time spent clarifying and re-writing illegible prescriptions is freed up and can be better utilized [7].

Policy makers benefit from e-health through access to accurate and reliable information upon which healthcare investment decisions are based. Thus, health service interventions are directed to where they are most urgently needed. Managers can better monitor and evaluate health intervention programmes through access to national health data summaries [7].

E-health has the potential to positively influence the quality of care, and improve healthcare service efficiencies. However, its widespread adoption is being hindered by a number of factors, including the high cost of acquisition, especially at the initial stage [1]; resistance

to change on the part of healthcare professionals [40]; security, privacy and confidentiality concerns [1, 39]; and lack of technical skills [1].

The major barrier to e-health adoption is the inability of healthcare information systems (HISs) to interoperate in order to share information [34]. Standardization is seen as the key to achieving interoperability [10, 35]. However, the e-health standardization arena is fraught with many challenges, the chief of which is the huge number of available standards, with many of them competing and overlapping, and some even contradicting one another [10, 35].

In this paper, we explore the e-health standards that support the interoperability of heterogeneous HISs, their development processes, as well as African countries' participation in the development process.

## Background

A standard is an agreed-upon, repeatable way of doing something; it is seen as the key to achieving interoperability of healthcare systems. A standard could be formal, proprietary or open [10]:

- *Formal standards* are developed by national or regional standard development organizations (SDOs). The adoption of formal standards could be mandatory through government regulations, or voluntary. Participation in the development and modifications to formal standards typically has financial implications for members.
- *Proprietary standards* are developed for private use by profit-driven industry organizations. Specifications for such standards are typically not disclosed and are subject to copyright law.
- *Open standards* are developed by non-profit organizations. Participation in the development and modifications to these standards are open to all interested stakeholders. The standard specifications and necessary documentations are made available for public use free of charge or at a nominal fee.

E-health standards cover a very wide spectrum of technology; ranging from those that deal with patient data content, to electronic medical devices.

The full extent of e-health standards cannot be covered in a single article, hence we limit our discussion to the standards that support the interoperability of heterogeneous HISs. These standards enable secure, effective and timely exchange of patient data in order to provide quality care [52]. Other e-health standards, such as those focusing on mobile health applications and the interoperability of medical devices, are not the focus of this paper.

E-health interoperability standards can be classified into the following categories:

- *Identifier standards*: these are standards that deal with unique identification of various entities, such as, patients, healthcare providers and healthcare institutions. Examples of these standards include the identification of subjects of healthcare standard (ISO / TS 22220:2011) [29] and the provider identifier standard (ISO/TS 27527:2010) [27].

- *Messaging standards*: these standards specify the structure and format of messages to facilitate secure transmission and receipt of the messages between healthcare providers. They also specify the acknowledgements that should be sent by the recipient of a message, as well as the warnings that should be generated when the message has not been delivered or if it is declined [54]. Health Level Seven (HL7) version 2 messaging standard [17] is the most common way of exchanging healthcare information worldwide [8].
- *Structure and content standards*: these are standards that provide specification for the structure of the data element in electronic health records (EHRs), referral letters or discharge summaries. The standards also specify the data types, field lengths and the content of data fields in these documents. This is to ensure that healthcare data is presented in a consistent manner by software applications [54]. Examples of structure and content standards are the HL7 clinical document architecture (CDA) [14], the American Society for Testing and Material (ASTM) continuity of care record (CCR) [4], and the HL7/ASTM continuity of care document (CCD) [16], which is the harmonization of both the HL7 CDA and ASTM CCR standards.
- *Clinical terminology and classification standards*: these standards support the description of medical conditions, symptoms, diagnosis, and treatments using common language in order to prevent ambiguity in the interpretation of healthcare information that is transmitted electronically [54]. Examples of clinical terminology and classification standards include the Logical Observation Identifiers Names and Codes (LOINC) [38] coding system for laboratory test reports, the International Classification of Diseases (ICD) [53] codes for classifying diseases, health conditions and causes of death, and the Systematized Nomenclature of Medicine – Clinical Terms (SNOMED-CT) [8] clinical terminology standard.
- *Electronic health record standards*: these are standards that define the architecture of computerized medical records, such as the electronic medical records (EMRs) and EHRs. Examples of EHR standards are the requirements for an electronic health record architecture standard (ISO 18308:2011) [28] and the ASTM standard for the description of reservation/registration-admission, discharge, transfer (R-ADT) systems for EHR systems (ASTM E1239-04:2010) [5].
- *Security and access control standards*: these standards enable the secure transmission and delivery of healthcare information so as to ensure that personal healthcare information is protected from unauthorized access [54]. Examples of e-health specific security and access control standards are the ISO privilege management and access control standards (ISO/TS 22600, parts 1 – 3) [24-26] and the ASTM standard guide for user authentication and authorization (ASTM E1985-98:2013) [3].

## Materials and Methods

We conducted literature study of e-health standards development by standards development organizations (SDOs) to ascertain the level of participation of African countries in standards development process, as well as the associated 'costs' of such participation, and the adoption of standards, especially as it relates to e-health interoperability standards.

The literature study was conducted as part of a project, driven by the South African National Department of Health, to develop a normative standards framework for e-health, as part of the ten strategic priority areas identified in the eHealth Strategy South Africa 2012-2016 [42] document. This is also in alignment with the World Health Organization (WHO) and International Telecommunication Union (ITU) National eHealth Strategy Toolkit [54], which identifies standards and interoperability as one of the enabling environments for any country's e-health plans and initiatives.

We also studied the factors that mitigate against the adoption of e-health standards by African countries. The paper reports on our findings and suggests ways to overcome the barriers identified.

## Factors Affecting the Adoption of E-Health Standards in Africa

The literature analysis on the adoption of e-health standards revealed that the slow pace of the adoption of standards (both by developed and developing nations) is due to several factors. The factors include the large number of standards that are being developed by the various SDOs, the fact that e-health standards do not address one unified area of technology, the existence of conflicting and overlapping standards, the difficulty of combining standards from different SDOs, and the high cost of converting to new standard-based solutions [9, 10].

However, our analysis of the literature revealed that developing countries also face additional challenges when compared to developed countries, including:

- Limited participation in standards development process.
- Lack of involvement of diverse users of standards in the development process.
- Lack of understanding of the importance of standards at national level.
- Lack of foundational infrastructure.
- Lack of human resource capacity for standards development.
- Lack of implementation guidelines.

Each of these aspects is briefly discussed in the remainder of this section.

### Limited participation in standards development process

There are several e-health standards development initiatives by organizations around the globe. This section reports on our findings on the prominent organizations that are involved in e-health standards development and

the participation of African countries in their standards development process..

### The International Organization for Standardization (ISO)

The International Organization for Standardization is the world's largest developer of standards, with 164 national standards bodies across the globe as members. ISO standards are developed by working group members within the various technical committees, which are made up of national member bodies. ISO offers three categories of membership, giving varying degrees of access to its standards, and participation in their development [30]:

- *Full membership* provides a country with voting rights; the country can influence the standards development process, as well as the policies and strategic direction of ISO. A country with full membership may choose to be part of any technical committee either as a P-member (participating member), or an O-member (observer member). Participating membership of a technical committee requires a country to have a 'mirror committee' at national level, to facilitate consensus building among the country's stakeholders, as well as to coordinate active participation in the work of the committee.
- Countries with *correspondent membership* participate as observers in ISO standards development process, i.e. O-member. Such members have no voting rights; neither do they have any influence on ISO's policies and strategic directions.
- *Subscriber membership* allows access to a number of ISO standards. Such a member is unable to take part in standards development either as participating or observer member; and have no influence on ISO's policies and strategic directions.

The type of membership that a country holds affects its ability to shape the direction of ISO, and the type of standard it develops. Currently, from the 164 national standard bodies that are represented at ISO, 111 countries hold full membership. However, only 20 of these countries are from Africa [31].

ISO's Health Informatics technical committee, TC 215, develops standards for the healthcare domain. TC 215 has 58 member countries, but participation by African countries in this technical committee is minimal, with only three countries (Kenya, South Africa and Tunisia) as participating members; while Zimbabwe is holding observing membership in the committee [32]. Limited participation of African countries in this committee could be as a result of the cost associated with each type of membership [33], as well as the high cost of sending a delegation to attend meetings that are held bi-annually.

There are significant cultural and environmental differences between developed and developing nations. Low level representation of African countries in standards development means that the continent's ability to influence the development of standards that address their peculiar needs is greatly reduced [33].

### World Health Organization

The World Health Organization (WHO) publishes and maintains the ICD coding system [53] for classifying diseases, health conditions and causes of death, the Anatomical Therapeutic Chemical Classifications Systems

with Defined Daily Doses (ATC/DDD) codes [55] for classification of medicines, and the Statistical Data and Metadata Exchange – Health Domain (SDMX-HD) [46], a standard for the exchange of healthcare indicators, among others. The WHO also collaborates with International Health Terminology Standards Development Organization (IHTSDO) in order to enable cross mapping of SNOMED-CT terminologies (discussed later in this section) with ICD codes [56]. Although participation in WHO e-health initiatives and standardization activities is open to member states, the costs associated with sending delegations to these events could limit participation, especially for a low resourced country.

### ***European Committee for Standardization***

The European Committee for Standardization (CEN) is a non-profit standard development organization comprising of the national standards bodies of the 27 European Union countries, Croatia, The Former Yugoslav Republic of Macedonia, Turkey, Iceland, Norway, and Switzerland [12]. The main goal of CEN is to remove trade barriers across European countries through coordination of the development of European standards, which are in turn adopted as national standards by its member countries. CEN has cooperation agreement with ISO, with the aim of preventing the development of conflicting or parallel standards. With this agreement, an ISO standard could be adopted as a CEN standard, and a CEN standard could be adopted as an ISO standard [12]. Any of the CEN member countries can submit proposal for a new standard, typically through its national standard body. Participation in technical committees responsible for standard developments, as well as voting rights is also open to all of its member countries. Because CEN is a regional SDO, African countries are not involved in its standard development process.

### ***International Health Terminology Standards Development Organization***

IHTSDO is a non-profit organization that acquired the intellectual property rights to SNOMED-CT standard in 2007 [8]. SNOMED-CT is a highly comprehensive international and multilingual clinical terminology, with over 300 000 medical concepts that represent clinical information. It supports quality health care by enabling access to essential clinical information in a meaningful way. Each concept in SNOMED-CT is organized in a hierarchy, which is linked to other concepts through relationships. This allows clinical information to be captured at the required level of detail. SNOMED-CT also supports cross mapping to other clinical terminology and coding schemes, for example, the ICD-10 coding, thus enabling the re-use of coded data for purposes other than originally intended (for example, medical claims reimbursement) [8].

IHTSDO currently has 22 member countries [20]. All members are developed countries like Australia, Canada, Spain, United Kingdom and United States and there are none from Africa. The member countries are able to participate in the maintenance of SNOMED-CT. Non-member countries can use SNOMED-CT in software applications through an affiliate license, which could attract annual licensing fees, depending on the type of use and the wealth of the country [19].

### ***Digital Imaging and Communications in Medicines***

The Digital Imaging and Communication in Medicine standard (DICOM) was developed by the National Electrical Manufacturers Association (NEMA) to facilitate the exchange of digital medical diagnostic images, such as ultrasound, computed tomography (CT) scan and magnetic resonance imaging (MRI) scan between an imaging equipment and other healthcare applications [43, 49]. DICOM has been adopted as an international standard for medical images by ISO under the title ISO 12052:2006. DICOM standards are developed by members of its working groups (currently 28), established by the DICOM Standards Committee. Members of the Standards Committee include manufacturers of imaging equipment, suppliers of healthcare solutions, biomedical professional organizations, and other interest groups [44]. Although membership of and participation in DICOM standard development process is open to any stakeholder with an interest in DICOM, there is currently no representation from African countries in the committee [44].

### ***Health Level Seven***

HL7 is a non-profit, American National Standards Institute (ANSI) accredited organization that develop standards for the exchange of clinical and administrative data among heterogeneous healthcare applications. HL7 offers various categories of membership (individual, organizational, supporter/benefactor, caregiver, and student) and the degree of benefits enjoyed is dependent on the type of membership. HL7's 35 international affiliates are mainly from developed nations in Europe, United States and Asian countries, and none are from Africa [18].

### ***Logical Observation Identifiers names and Codes***

LOINC is a universal coding system for reporting of laboratory and clinical observations. LOINC was developed and is maintained by a group of researchers at Regenstrief Institute, a non-profit medical research organization based in the United States. The scope of LOINC codes covers laboratory observations, such as chemistry, hematology, serology, microbiology, and urinalysis, as well as clinical observations like vital signs, intake/output, electrocardiogram, endoscopy, and obstetric ultrasound. LOINC is provided free of charge by the developers [38].

### ***ASTM International***

ASTM International, formally known as American Society for Testing and Materials, is one of many SDOs active in the development of e-health standards. During its early inception, the organization was concerned with developing standards for the steel industry, but it has widened its scope to cover other areas of standardization, including e-health. ASTM standards are developed through a consensus process involving a cross-section of interested stakeholders. The ASTM committee on Healthcare Informatics (E31) was established in 1970 with the purpose of developing standards that govern the architecture, content, storage, security and communication of healthcare information. The committee meets bi-annually [6]. Members of the committee include vendors, clinicians, healthcare institutions and administrators, as well as patient advocates. Although membership of the committee is voluntary and open to any individual (at \$75 annual membership fee) or organization (\$400 an-

nual membership fee), our search did not yield any result on African countries' participation in its standards development process.

### **Joint Initiative Council**

The Joint Initiative Council (JIC) is an alliance between global health informatics SDOs, with the primary goal of addressing the problems associated with gaps, overlaps and contradictions that could arise from the various standards that are developed by participating SDOs. JIC provides coordination for standards strategies and plans, and aims to make all standards available through ISO. Six SDOs currently participate in the work programs of JIC, namely, the Clinical Data Interchange Standards Consortium (CDISC), which develops standards relating to clinical research data interchange; CEN; GS1, which develops standards for improving supply chain management; HL7; IHTSDO; and ISO [37]. Participation in JIC activities requires an organization, among others, to be an international SDO and have a formal relationship with ISO [36]. Because Africa does not have a regional body that coordinates its standard development activities in the way CEN does, it is not represented at the JIC.

### **Lack of involvement of diverse users of standards in the development process**

E-health standards are typically developed by technical and standards experts in the various working groups of an SDO. However, the resulting standards from this highly technical specification process would be relevant to a diverse range of end-users, from the technically savvy healthcare application developers to policy makers in government, who may want to use the standards as a basis for the country's e-health strategy. The focus on technical specifications could result in standards that are not 'user-friendly', thereby making their application in the real world difficult [23].

### **Lack of understanding of the importance of standards at national level**

Largely, healthcare systems in Africa are paper-based. Where ICT is in use, it is mainly to support data capturing, storage, retrieval, and monitoring and evaluation of health programmes that are sponsored by external donors. Although governments remain a highly significant stakeholder in the healthcare sector, many African countries have no policies and strategies to govern e-health initiatives at national levels [2].

When compared to developed nations like the European Union, Africa has no known policy framework that governs areas of common interest at continental level. Notable in this regard is the European Patient Smart Open Systems (epSOS) project, which provides for the development of interoperable EHR systems across Europe in order to improve the quality of cross-border healthcare services for its citizens [11].

Furthermore, many of the high-level government officials who make policy decisions regarding e-health initiatives do not understand the important role of standards in effecting quality care; this is largely due to the technical nature of standardization [33].

### **Lack of foundational infrastructure**

Many African nations have a large number of its citizens living in rural areas. In the majority of cases, these rural communities lack even the most basic infrastructure, such as, electricity. There is also limited ICT infrastructure; broadband Internet connectivity is very low compared to developed countries. Foundational infrastructures, such as client and provider registries, as well as common terminology services are largely absent. Where ICT infrastructures are in place, they are neither standardized nor based on common platforms, making it difficult for them to interoperate [2].

### **Lack of human resource capacity for standards development**

African countries generally have low levels of human resources with the requisite expertise to participate in standards development [47]. The adoption of international standard by a country often requires localization of the standard to meet the specific requirements of the country. Limited technical expertise in African countries could affect their ability to effectively carry out standards localization. Furthermore, inadequate technical expertise could lead to an absence of, or ineffective government policies regarding the adoption of e-health standards [33].

### **Lack of implementation guidelines**

Many of the available standards do not have implementation guidelines [9]. The efforts to 'translate' standards to implementable systems often require interaction between experts. Inadequate implementation expertise could affect the ability of local developers to implement standards-based healthcare systems.

## **Overcoming the Barriers to E-Health Standards Adoption**

According to the WHO and ITU National eHealth Strategy Toolkit [54], a country's national e-health environment is composed of five enabling environment components and two ICT environment components (see Figure 1):

- The enabling environment components are:
  - *Leadership, governance, and multi-sector engagement*: this provides direction for and coordinates e-health initiatives at national level; ensures the alignment of e-health with health goals of the country; provides political leadership and facilitate engagement with relevant stakeholders.
  - *Strategy and Investment*: this provides for a responsive strategy and plan for a national e-health environment and aligns funding for e-health with national e-health priorities.
  - *Legislation, policy and compliance*: this ensures the development and adoption of national e-health policies and creates the legal framework for the protection of the citizens.
  - *Workforce*: ensures that the necessary e-health knowledge and skills are available through internal expertise, technical cooperation or partnership with the private sector, as

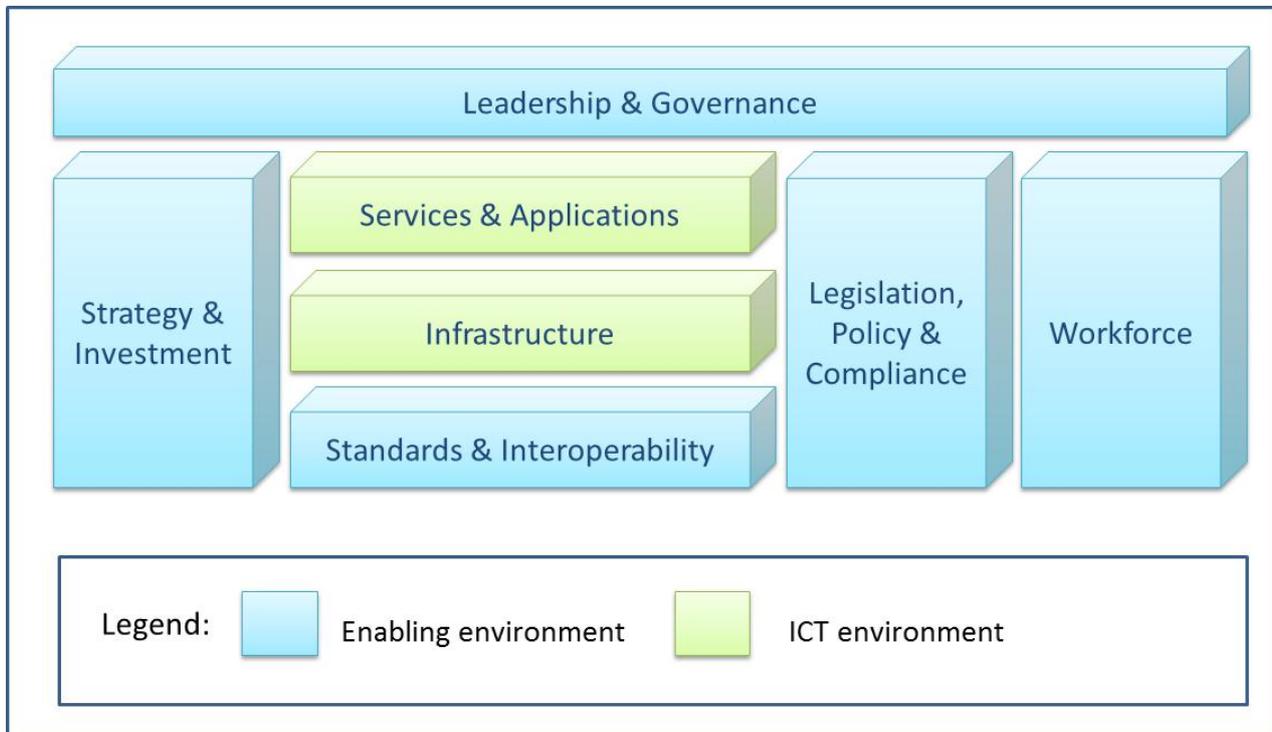


Figure 1 - E-health components (adapted from [54])

well the development of effective e-health education and training programmes to build an adequate health workforce.

sistent and accurate collection and exchange of healthcare information between and among care providers.

- *Standards and interoperability*: this enables the adoption of standards that facilitate con-

- The ICT environment components are:

- *Infrastructure*: this creates the physical infrastructure that forms the foundation for electronic exchange of health information across geographical and health-sector boundaries.
- *Services and applications*: this provides the tangible means for enabling services and systems.

As noted in the Toolkit [54], the adoption of e-health standards ensures that healthcare information is accessible to authorized users as and when required. However, one of the main barriers to the adoption of e-health standards relates to the difficulty of selecting the 'right' standard from conflicting standards, and the large number of standards. For example, both the ASTM CCR and HL7 CDA standards were developed to support the exchange of clinical documents. Which one should be used?

In recent years, several initiatives were undertaken by SDOs to coordinate and harmonize existing standards to assist with such difficulties, as well as with future standards development efforts [37]. An example of such initiative to harmonize competing standards led to the development of the HL7/ASTM CCD [16] from the ASTM CCR and HL7 CDA standards.

As stated earlier, there is limited participation by African countries in e-health standards development process. One reason for this limited participation has to do with the overall costs of such participation. Many of the SDOs charge fees for the various types of membership; and attending meetings of the technical committees could be

costly, especially for a low resource country. In addition, the implementation of many standards in software solutions attracts licensing fees. The transformation of the standards development process at the international level is long overdue. To improve the level of participation in standards development, SDOs should significantly reduce membership fees for African and developing countries. Furthermore, the cost of accessing standards should not be prohibitive.

There are on-going efforts by SDOs to make access to standards more affordable. For example, IHTSDO provides licenses for the use of SNOMED-CT free of charge to 40 countries classified as low economies, 26 of these countries are from Africa [19]. Likewise HL7 started granting free licenses to its published standards since the beginning of April 2013 [15].

As stated earlier, the absence of implementation guidelines for many of the published standards makes it difficult for countries with limited technical expertise to incorporate e-health standards in the applications they develop. Integrating the Healthcare Enterprise (IHE) is addressing this problem through the creation of profiles that guide the implementation of interoperable systems. IHE is not an SDO; rather it is an initiative by healthcare professionals and industries working together, with the aim of promoting the coordinated use of e-health standards, such as DICOM and HL7, to address a particular clinical requirement [22]. However, participation in IHE activities is largely dominated by multinational organizations, healthcare professional organizations from developed countries as well as regional/national bodies from Europe, Asia-Oceania and North America [21]. There is a need for Health Informatics stakeholders from Africa

and other developing countries to be involved in IHE activities so that their special interests can be represented.

Standards that are not user-friendly are not likely to be widely adopted. While we acknowledge that it is impractical to involve the entire standards user group in the standards development process, it is essential that technical experts take cognizance of the diversity of standards user groups. To ensure that resulting standards are 'usable', standards under development should be subjected to some form of heuristic evaluation using guidelines similar to those proposed by the International Federation of Standards Users (IFAN) [23]. Adopting a user-centered approach to standards development and the application of general usability principles, such as, consistency especially in the use of terms and definitions, simplicity and easy comprehension, will facilitate easy understanding by the non-technical users of standards.

Inadequate human resource capacity remains a critical challenge to the adoption of e-health in general, and e-health standards in particular. The WHO-ITU eHealth Strategy Toolkit [54] and the Draft Policy for Harmonization of eHealth Initiative in Africa [2] both recommend the development of effective health ICT workforce, capable of designing, building, operating and supporting e-health services. This workforce should lead to professionals with the requisite technical expertise to participate in standards development, as well as the localization of international standards to fit a country's specific need. This will enable African countries to leverage ICT in healthcare delivery.

As an important stakeholder in the healthcare domain, African governments need to play an active role in the adoption of e-health standards. At national level, there should be policies governing the acquisition of e-health solutions. Investment in foundational ICT infrastructures should be prioritized to facilitate the deployment of standards-based interoperable solutions.

## Conclusion

Standardization is the key to ensuring that healthcare information systems are able to exchange and share the essential patient information required for continuity of care. However, significant barriers impede wide-spread adoption of e-health standards, especially by African countries. These barriers include lack of understanding of the importance of standards at a high level, limited participation in standards development, unusable standards, cost barriers to accessing standards, lack of foundational infrastructures, and limited human resource capacity for standard development.

Overcoming these barriers will require transformation of standards development process at an international level and the adoption of a user-centered development approach. African governments would have to prioritize investment in basic infrastructure and the development of human resource capacity. Governments should also play more active role in standards adoption through appropriate national policies and guidelines.

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