A Method for Selecting E-Health Standards to Support Interoperability of Healthcare Information Systems

Funmi ADEBESIN[1, 2], Paula KOTZÉ[1, 2], Derek RITZ[3],
Rosemary FOSTER[1, 2], Darelle VAN GREUNEN[2]
[1] *CSIR Meraka Institute, P.O Box 395, Pretoria, 0001, South Africa*
Tel: +27 12 8413373, Fax: + 27128414720, fadebesin@csir.co.za
Tel: +27 12 8414791, Fax: + 27128414720, pkotze1@csir.co.za
Tel: +27 12 841 4418, Fax: + 27128414720, rfoster@csir.co.za
[2]*School of ICT, Nelson Mandela Metropolitan University, P.O Box 77000,*
Port Elizabeth, 6035, South Africa, darelle.vangreunen@nmmu.ac.za
[3]*ecGroup Inc., 17 Rankin Crescent, Toronto, M6P4H1, Canada*
Tel: +1 905 5150045, derek.ritz@ecgroupinc.com

Abstract: There is growing concern over the fragmentation and inability of healthcare information systems (e-health systems) to exchange pertinent healthcare information that can empower healthcare professionals to make informed decisions regarding the care of their patients. Standardisation is increasingly being seen as a means to ensure the interoperability of e-health systems. However, several e-health standards are being published, many of them without implementation guidelines. This paper describes a proposed method that could guide the selection of e-health standards (particularly for developing countries) to support the interoperability of e-health systems.

Keywords: E-health, interoperability, standards, implementation guidelines

1. Introduction

Although the use of Information and Communication Technologies (ICT) to support healthcare has the potential to improve healthcare quality and service efficiencies, it is difficult to realise this potential when healthcare information systems (e-health systems) are incapable of exchanging information. Currently, ICT usage in the healthcare sector is dominated by the implementation of silo systems, where each provider or facility has its own proprietary system that is incapable of exchanging information with the systems implemented by other providers [1].

Concerns over the fragmentation of e-health systems have dominated the global discourse of healthcare stakeholders in recent years. While electronic access to a person's banking information is possible from any region in the world, the same cannot be said for healthcare information [2]. The problem of fragmentation and inability of e-health systems to exchange crucial information about a patient for effective care coordination and improved quality of care affects is evident in both developed and developing countries. As such, several initiatives are taking place at national, regional and international level to address the problem. These initiatives include the United States public-private partnership to facilitate interoperability among e-health systems through the Healthcare Information Technology Standards Panel (HITSP) [3], the European Union e-health interoperability roadmap [4], World Health Assembly resolutions on e-health standards and interoperability

[5] and the World Health Organisation (WHO) and International Telecommunication Union (ITU) National eHealth Strategy Toolkit [6].

1.1 The face of modern-day healthcare is changing

The delivery of healthcare is very complex, not only because of the complexity of the human body, which is beyond the complete understanding of any single individual, but also because modern-day healthcare processes are complex and constantly changing.

Gone are the days when a single healthcare professional would be solely responsible for the care of all citizens in a designated region. It is now the norm for several healthcare professionals, including physicians, nurses, dieticians, psychologists and other allied professionals to be involved in the care of a single person [7]. As such, teamwork and effective coordination between and among the various role-players and the subject of care, i.e. the patient, is essential in order to provide him/her with the best possible care [8].

1.2 E-health and interoperability

According to the WHO, e-health can broadly be defined as "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" [9]. Various application areas of e-health include:

- *Electronic medical record* (EMR): The electronic record of the health-related information of an individual, which is created, managed and accessed by authorised administrative and healthcare personnel within a single health facility [10].

- *Electronic health record* (EHR): A comprehensive lifelong record of an individual's health information generated through one or more encounters in more than one healthcare setting [10].

- *Personal health record* (PHR): A partial or complete electronic record of an individual's health information generated through one or more encounters in more than one healthcare setting over the lifetime of the individual. A PHR is under the control of the individual or other legitimate persons, (e.g. a family member) [10].

- *Computerised provider order entry* (CPOE): An application that supports electronic ordering of medication, laboratory or radiology tests by physicians [11].

- *Electronic prescription:* An application used to support workflows related to prescription and dispensing of medications [12].

- *Clinical decision support* (CDS): An application that provides healthcare providers with essential patient-specific information and/or knowledge that has been intelligently filtered and presented at the appropriate time to enhance healthcare delivery [13].

- *M-health:* An application area of e-health where mobile devices and wireless technologies, such as wireless fidelity (WiFi), global positioning system (GPS) and Bluetooth, are used to support medical and public health practices [14].

- *Telemedicine:* An application area of e-health that can be defined as "the delivery of healthcare services, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities" [15].

The benefits of e-health include the availability of information whenever and wherever it is needed, enhanced clinical decision-making, better legibility, reduction in medical errors and cost reduction. However, e-health is more than the adoption of technology [16], since several factors could affect the degree to which its benefits can be maximised. These factors

include the presence of appropriate legislation, the ability of healthcare systems to exchange information and effective change management.

Interoperability in the healthcare context is "the ability of health information systems to work together within and across organisational boundaries in order to advance the health status of, and the effective delivery of healthcare for individuals and communities" [17].

Contemporary healthcare delivery, where teamwork and care coordination are mandated, calls for e-health systems that facilitate access to patients' healthcare information as and when required, so that healthcare professionals are empowered to make informed decisions regarding the patients in their care.

1.3 Why e-health interoperability is important

Interoperability facilitates timely access to necessary information about a patient. Multiple systems are able to share information about a patient, thus reducing the need to recapture the same information in every system. Healthcare professionals that have been authorised to access patient information can make informed decisions and provide personalised care to patients. Interoperability can also lead to better care coordination, improvement in patient safety and reduction in overall costs of healthcare delivery [18, 19].

1.4 The role of standards in enabling e-health interoperability

Standards are the specifications for products and services used to outline their acceptable functionalities, performance, safety and efficiencies. They provide assurance to consumers of products and services regarding to the ability of these products and services to perform according to specifications [20, 21].

In the healthcare sector, standardisation is key to enabling seamless exchange of healthcare information [1, 22]. Furthermore, standards reduce the complexity associated with information sharing among multiple systems. Other benefits include reduction in the risk of single vendor lock-in and the potential to drive the uptake of new technology innovations by providing common platforms for their dissemination [23-25].

Despite the important role of standardisation in the quest for interoperability in the healthcare sector, e-health standards have not been widely embraced. This is especially true for African and other developing countries. Some of our earlier work [26, 27] explored the challenges associated with e-health standardisation internationally and in Africa.

2. Objectives

The objective of this paper is to describe a proposed method, called the *Standards Selection Method for e-Health Interoperability (SMeHI)*, which could guide the selection of e-health standards in order to support the interoperability of healthcare information systems. This will be particularly valuable to African and other developing countries, where the lack of expertise and adequate standardisation skills is prevalent [26, 27].

3. Method for Selecting E-health Standards to Support Interoperability

In the National eHealth Strategy Toolkit [6], the WHO and ITU recommend that e-health initiatives should be driven by national health priorities. This is to ensure the coordination of efforts and alignment with national objectives. Similarly, e-health standards adoption should be coordinated at a national level, preferably through an interoperability governing body [28].

SMeHI draws on recommendations from the WHO and ITU in their National eHealth Strategy Toolkit [6], as well as experiences from the European Union in their implementation of the European Patients Smart Open Services (epSOS) project, which aims to enable cross-border interoperability of EHR systems across Europe, in order to improve

the quality and safety of healthcare for its citizens when they travel to another European country [29, 30].

Determining appropriate standards to support interoperability for any given healthcare context is not trivial. Merely providing a list of e-health standards, with which the developers and vendors of healthcare systems must comply, will not guarantee the interoperability of such systems. It is essential to have a set of guidelines that describes how the standards should be applied in a coordinated way to address the interoperability requirements of a specific healthcare domain. These guidelines, often referred to as *profiles*, form interoperability building blocks that specify how system actors will utilise standards as they interact with each other to meet a specific clinical requirement [31].

The European Union recommends a three-layer approach to e-health standards specifications, where the uppermost level address business requirements or use cases, the intermediate level is formed by interoperability building blocks of implementation guidelines or profiles, while the lower level is represented by the standards that are utilised in the profiles or implementation guidelines [30]. This approach enables the specification of e-health standards that are capable of addressing real-world clinical requirements.

SMeHI, as illustrated in Figure 1, consists of the following five processes, which are elaborated in sections 3.1 to 3.5:

1. Determine interoperability objectives and priorities.
2. Develop business use case specifications as user stories.
3. Extract key business functions from the user stories.
4. Identify applicable implementation guidelines that support the interoperability.
5. Extract the underlying standards from the implementation guidelines.
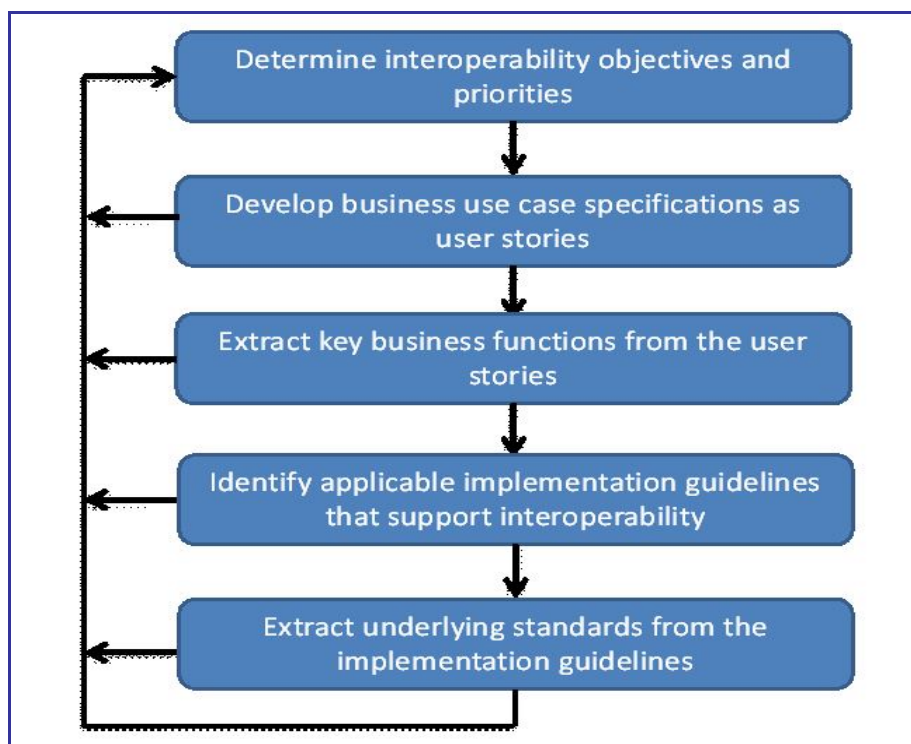

Figure 1: Proposed Standards Selection Method for e-Health Interoperability (SMeHI)

It should be noted that the steps in SMeHI are implicitly iterative. This is mainly due to the dynamic nature of the healthcare domain and the need to accommodate changes in health priorities and their associated interoperability objectives.

3.1 Determine interoperability objectives and priorities

The first step in standards selection is to carefully articulate the interoperability objectives that should drive e-health initiatives at national, provincial or regional level. This is to ensure that all activities are geared towards the realisation of the objectives. Relevant stakeholders should be involved in determining these objectives and the objectives should be prioritised, taking into account regional, national and/or local health priorities. Examples of interoperability objectives could include the following:

- To utilise the same unique identifier for every patient across all healthcare facilities in the city/province/country.
- To ensure that any update to a patient's demographic information at any healthcare facility is replicated in the shared electronic health record (EHR) system, whether national, provincial or regional based.
- To facilitate access to a patient's clinical information by authorised users in order to support continuity of care.

The outcome of this process is a prioritised list of interoperability objectives and priorities.

3.2 Develop business use case specifications as user stories

A business use case documents an organisation's business processes in terms of a sequence of actions that provide observable value to a business actor or stakeholder [32, 33]. Business use cases are typically specified through narrative text (as user stories) and/or graphically using, for example, unified modelling language (UML) sequence diagrams [32]. Typically, multiple use cases would be required to address regional, national and/or local health priorities. The use case specifications could reflect healthcare guidelines (e.g. the national maternal care guidelines or the childhood immunisation guidelines), as well as health indicator data that is required for monitoring and evaluation of healthcare programmes (e.g. the total number of antenatal patients who were tested for HIV at the first visit).

Narrative 1 provides a hypothetical example of a simple user story. The business use case illustrated by this story is aligned with the Millennium Development Goal 5, which is aimed at improving maternal health [34].

Narrative 1: A business use case illustrating patient registration

Lusanda is a 23-year old female. She is 22 weeks pregnant with her first baby. Lusanda was recently transferred from her company's head office to one of the regional offices, which is located in another province. She had been receiving antenatal care at one of the local community health centres close to the head office. Two weeks after settling down at her new home, Lusanda decided to visit a community health centre (CHC) located not far from her new home, with the aim of continuing her antenatal care at the centre.

At the CHC, Lusanda was first seen by Beatrice, the registration clerk. Lusanda told Beatrice that she has just relocated to the area and wished to continue her antenatal care at the centre.

Beatrice asked Lusanda for her national identity (ID) number, which is used as unique identifier for all patients throughout the country's public healthcare facilities. Beatrice logged into the local EMR system using her login credentials for authentication. Because Lusanda had been previously registered on the national programme at the other facility, Beatrice used Lusanda's ID number to search for her EHR on the national/shared EHR system. Lusanda's EHR was returned to the local EMR following its authentication and Beatrice was able to view Lusanda's demographic data based on her access rights and privileges. Beatrice used the demographic data on the national/shared EHR system to populate a new record for Lusanda on the centre's local EMR system. Access to the national/shared EHR system ensured that Beatrice did not have to recapture the same demographic data about Lusanda on the local EMR. Beatrice also updated Lusanda's demographic data on the national/shared EHR system to reflect her new residential address.

In the example, the national government aims to facilitate access to the health records of pregnant women in order to support quality maternal care. The user story exemplifies the

interactions between the patient and the registration clerk, as well as interactions between the clerk and the national/shared EHR system through the local EMR. Figure 2 provides an illustration of the business use case sequence diagram and the interactions between the various actors.

3.3 Extract key business functions from the user stories

Following the definition of business use cases through the user stories, the key business functions or 'technical use cases' are extracted. For example, the key functions that are associated with patient registration in Narrative 1 are:

- *Authenticate user:* This user authentication is done at local level, i.e. by the local EMR system.
- *Resolve the patient identifier:* The unique patient identifier (ID number) will be transmitted by the local EMR to the national/shared EHR system in order to determine whether the patient has a record on the system.
- *Authenticate system:* The national/shared EHR system need to verify whether the local EMR system is accredited to access patient records. This is to ensure that patients' records are only accessible to 'trusted' systems.
- *Display patient record:* If the patient has a record on the national/shared EHR system, it will be returned to the local EMR.
- *Create new local patient record:* The local EMR is populated with a clinical record based on the returned shared health record data.
- *Update patient demographic record:* Any new demographic data not on the national/shared EHR is captured on the local EMR and then transmitted to the patient's record on the national/shared EHR for update.

3.4 Identify applicable implementation guideline(s) or profiles that support interoperability

As stated in section 3, it is not sufficient merely to list the set of e-health standards with which applications must conform. Guidelines, defining how these standards can be applied in a coordinated manner, are required to ensure that the ensuing applications or systems are able to exchange information. The majority of the published e-health standards do not have implementation guidelines. The situation is further complicated by the fact that the interoperability needs of a given healthcare context require the combination of a number of standards.

In addition to the scarcity of technical expertise that challenges developing countries, lack of implementation guidelines, as well as gaps and conflicts between standards that have been published by different standards development organisations (SDOs), make it extremely difficult for developing countries to incorporate e-health standards into applications or systems [26, 27].

One example of efforts aimed at bridging the gap between standards definition and the development of implementation guidelines is the one spearheaded by Integrating the Healthcare Enterprise (IHE) [35]. IHE is involved in the development of implementation guidelines or *IHE profiles,* which specify how these standards should be combined to address real-world clinical needs. The profiles undergo extensive testing by relevant stakeholders [30], this is to ensure that the standards used in the profiles do not conflict or contradict one another.
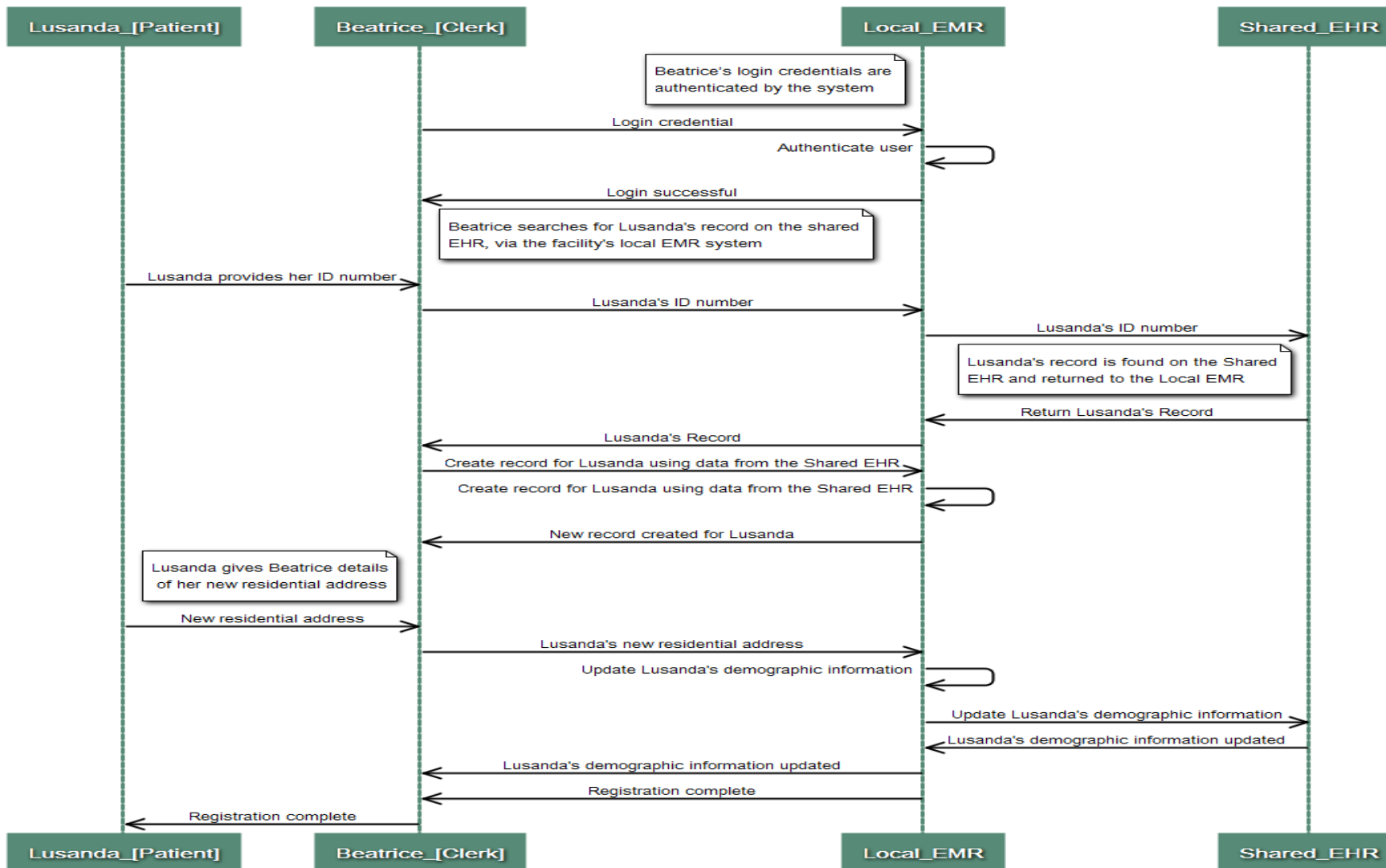
Figure 2: Business use case sequence diagram for patient registration

IHE profiles do not specify new standards but stipulate the coordinated use of existing standards from other SDOs, such as ISO [36], HL7 [37] and NEMA [38]. Requirements for extensions or clarifications to any of the existing standards are typically referred to the applicable SDO [39, 40]. IHE has published profiles for many clinical domains. These include profiles for cardiology, laboratory, pharmacy, radiology and general IT infrastructure profiles [41], which can be freely accessed from the organisation's website [42]. IHE profiles are used in this paper to illustrate the concept of implementation guidelines.

Following the extraction of key business functions from user stories, the functions should be mapped to the appropriate IHE profile(s). The applicable IHE profiles for the business functions identified in section 3.3 are:

- *Resolve the patient identifier:* The Patient Identifier Cross Referencing (PIX) IHE profile [40] supports the cross-referencing of patient identifiers from multiple patient identifier domains. When unique identifiers are used, PIX is the applicable profile to search for a patient's demographic record. In situations where a combination of demographic data is used to identify patients, the Patient Demographics Query (PDQ) IHE profile, which enables applications to query a central patient registry using the patient's demographic data as the search criteria will be useful [40].

- *Authenticate system:* The Audit Trail and Node Authentication (ATNA) IHE profile establishes the security measures which, together with the security policies and procedures of an organisation, ensure the confidentiality of patient information, data integrity, and user accountability [40]. The Consistent Time (CT) IHE profile provides a mechanism to ensure that system clocks and time stamps of multiple computers in a network are well synchronised [40]. These two profiles provide support for system authentication.

- *Display patient record:* Patients' health records can be exchanged among healthcare applications using the Cross-Enterprise Document Sharing of Medical Summary (XDS-MS) IHE profile. This *content profile* supports the registration, distribution and access to patients' records across healthcare domains. The profile can be likened to an envelope and is used to hold a summary of the actual medical record that is intended for sharing among care providers. The XDS-MS profile can be used for the exchange of any format of medical document, including text, images and clinical codes [40].

- *Create new local patient record:* The clinical record (e.g. CDA) conveyed to the EMR via XDS-MS may be used to create a medical record on the local EMR which is aligned with the shared content on the EHR [40].

- *Update patient demographic record:* The applicable IHE profile for this function is the Patient Administration Management (PAM) profile. This profile enables the exchange of patient's demographic data among healthcare systems at the time of registration and subsequent updates to the data as and when required [40].

3.5   Extract the underlying standards from the implementation guidelines

IHE profiles make use of existing published standards, which can be general IT or e-health specific, to ensure the interoperability of systems and applications that implement a particular profile.

The standards that should be selected for implementation to support the interoperability objectives identified in phase 1, will be those standards that are underlying the IHE profiles identified in phase 4. The mapping between the business functions, the applicable IHE profiles and their underlying standards for our example is shown in Table 1.

Table 1: Mapping between business functions, applicable profiles and underlying standards

Business functions	Applicable profiles	Underlying standards
Resolve the patient identifier	PIX	HL7 Version 2.X
	PDQ	HL7 Version 2.X
Authenticate system	ATNA	DICOM Part 15 (Security and System management Profiles) Transport Layer Security (TLS) 1.0 (RFC 2246) ITU-T Recommendation X.509 Secure/Multipurpose Internet Mail Extensions (S/MIME) Version 3.1
	CT	Network Time Protocol Version 3 (RFC 1305) Simple Network Time Protocol (RFC 4330)
Display patient record	XDS-MS	HL7 Version 2.X HL7 Version 3 CDA Release 2.0 RFC 2616 ISO/IEC 9075 ebMS ebRIM ebRS
Update patient demographic record	PAM	HL7 Version 2.X

4. Summary and Conclusion

With the growing concerns over the fragmentation of e-health applications and their inability to exchange important patient information to support continuity of care, many stakeholders are looking to standardisation as the key to addressing the problem. However, due to the plethora of published e-health standards, the selection of an appropriate set of standards to support interoperability requirements of a given clinical context can be difficult, especially for developing countries where skills shortage is a major challenge.

The Standards Selection Method for e-Health Interoperability (SMeHI), as proposed in this paper, provides a step-wise approach to e-health standards selection by drawing on recommendations from the WHO and ITU, as well as experiences from developed countries that have taken huge strides to ensure improvement in the safety and quality of care provided to their citizens through the adoption of standards that supports the interoperability of e-health systems.

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