An Ontology for Regulating eHealth Interoperability in Developing African Countries

Deshendran Moodley[1], Christopher J. Seebregts[1,2], Anban W. Pillay[1], and Thomas Meyer[1]

[1] UKZN/CSIR Meraka Centre for Artificial Intelligence Research and Health Architecture Laboratory, School of Mathematics, Statistics and Computer Science, University of KwaZulu-Natal, Durban, South Africa
[2] Jembi Health Systems NPC, Cape Town and Durban, South Africa

Abstract. eHealth governance and regulation are necessary in low resource African countries to ensure effective and equitable use of health information technology and to realize national eHealth goals such as interoperability, adoption of standards and data integration. eHealth regulatory frameworks are under-developed in low resource settings, which hampers the progression towards coherent and effective national health information systems. Ontologies have the potential to clarify issues around interoperability and the effectiveness of different standards to deal with different aspects of interoperability. Ontologies can facilitate drafting, reusing, implementing and compliance testing of eHealth regulations. In this regard, we have developed an OWL ontology to capture key concepts and relations concerning interoperability and standards. The ontology includes an operational definition for interoperability and is an initial step towards the development of a knowledge representation modeling platform for eHealth regulation and governance.

Keywords: eHealth regulation, Interoperability, Standards.

1 Introduction

Health information technology and eHealth are increasingly being used in an effort to improve health service delivery in low and middle-income countries (LMICs) despite significant challenges, risk and limited proven benefits [3,6,24,25]. The need to improve interoperability [19] and the adoption of eHealth and interoperability standards in low resource settings have been identified as fundamental challenges to build coherent and sustainable national health information systems [13,9,33,1]. In these settings national health information systems are expected to evolve incrementally with systems maturing in line with available funding and regional priorities. The middle-out architecture approach proposed by Coeira [5] for developed countries also appears to be the most appropriate approach for developing countries [20]. The approach entails providing leadership, policies and regulations at the

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national level, but delegating autonomy to provincial or regional levels for system selection, procurement, deployment and maintenance [20]. Health information exchanges, similar to the recent deployment in Rwanda [7,2], are essential to bridge the gap between disparate regional systems. For countries adopting a middle-out architecture approach, an effective governance framework and regulatory environment, including appropriate strategies, policies, guidelines and legal structures are central to the effective and equitable implementation and integration of health information systems within the country [16,27,32].

An effective regulatory environment and governance framework is also crucial to manage the complex relationships and dependencies between national government and the different stakeholders, including international donors, private sector, commercial software development organizations and non-governmental organisations. Such a framework must protect the rights, privacy and safety of patients and allow the national government to maintain control but must simultaneously promote innovation, open architectures and systems while discouraging closed technologies that result in vendor lock-in, whether proprietary or open source. eHealth regulations can provide a powerful legal mechanism to help developing countries encourage interoperability and harmonization of health information systems with a national computing platform that support common standards and data interchange formats.

The need for an overarching legal and regulatory framework for eHealth has recently been articulated by, among others, the Agenda for Action on Global E-Health [9,18], the World Health Assembly [33], the International Telecommunications Union [15], and the World Health Organization (WHO) together with the International Telecommunications Union (ITU) in their eHealth Strategy Toolkit [34]. Governments in developing countries such as South Africa, Ghana, Kenya, Uganda and Rwanda have responded to these calls and many now have eHealth strategies in place[1]. Most of these eHealth strategies identify the need for appropriate legal structures and an eHealth regulatory framework. However, the development of appropriate eHealth guidelines and regulations is still under-developed in sub-saharan Africa [12] and often limited to general provisions in the national health act supplemented with a few telecommunications regulations. Usually, there is little or no legal or regulatory framework specifically targeting eHealth or health information and HIS. Few other examples of eHealth regulations exist and examples from developed countries are not necessarily appropriate in low resource settings where the healthcare priorities, resourcing and capacity to adopt technology are often different [30].

The lack of appropriate governance has contributed to the uncoordinated implementation of electronic medical record systems and mobile phone pilot applications outside of the national HIS in several developing countries. To alleviate concerns regarding interoperability with existing public health systems and wastage of scarce government and donor resources some national governments have

[1] http://www.HingX.org/eHealthStrategy

established moratoria to curtail new implementations and/or have implemented eHealth-specific regulations to try and curtail this practice. Several developing countries in Africa have embarked on intiatives to develop national enterprise architectures, interoperability frameworks and related technologies [8,11,29,21,7] with several examples of interoperability guidelines and policy documents being developed at national level[2].

In recognition of this need, the WHO convened an international working group to develop guidelines aimed at improving data standardization and interoperability [35] and international standards organizations, e.g. HL7 and the International Standards Organization (ISO) have begun to consider ways to make standards more accessible in low resource countries. More recently, the WHO [33] and others, e.g. [1] have begun to research and develop guidelines for the selection of relevant standards that are appropriate in LMICs from among the plethora of overlapping standards that are available from a number of international standards development organizations. Regulations will play an important role in entrenching an agreed set of standards within a particular legislative domain.

In this paper, we present our initial eHealth governance ontology that focuses on interoperability and standards. The ontology aims to clarify core concepts in this domain and is part of a broader project to develop a knowledge representation and modeling platform for eHealth governance and regulation. The platform aims to facilitate greater coordination between government needs and eHealth implementations and to assist with drafting, refining, reusing, implementing and compliance testing of eHealth regulations and other instruments of eHealth governance.

2 Developing an Ontology for Regulating eHealth Interoperability

The ontology for regulating eHealth interoperability is envisaged as a core component of a modelling platform for facilitating the drafting of policies for the regulation of standards, assessing their impact on interoperability and allow for a better understanding of the choices of standards available. We have approached the development of the ontology from three usage viewpoints.

(i) Policy and Legal

Policies and legal instruments must be consistent with existing policies and laws as well as international best practice. Language needs to be harmonized and, in the case of technical regulations, such as those for interoperability and standards, sufficient technical detail is required to ensure that the provisions can be effectively implemented and enforced. The ontology should provide legislators with a clear understanding of the core technical issues and approaches around interoperability and the impact of regulations on the design and implementation of software systems.

[2] http://www.HingX.org/interoperability

(ii) *Regulation and Compliance*

The ontology should provide support for evaluating different vendor proposals during the software procurement process and determining compliance of final implementations. It should also support the evaluation of existing systems for compliance to standards and provide a clear upgrade path to mature systems to advanced levels of compliance.

(iii) *System and Software Development*

The ontology should allow for the translation of regulations into concrete technical software requirements that can feed into software design, development and deployment.

2.1 Ontology Design Approach

In order to clarify the issue of interoperability in the eHealth domain, we developed an OWL ontology of the key concepts and the relationships between them. Our focus was on eHealth regulations, systems and standards. Ontology development followed a middle out design [31], i.e. a combination of a bottom up and top down approach.

In developing the interoperability regulation ontology, we analysed a real world regulation from Brazil, viz. *Ordinance # 2.073/11 - GM: standards and interoperability* [4], as a case study to ground our ontology. This ordinance is one of five regulations pertaining to eHealth in Brazil. Other ministerial acts regulate the national health card system, the use of the national health number and funding for the development of interoperability solutions.

The ordinance deals specifically with interoperability and standards. In this work, we only considered the standards part of the ordinance. Table 1 shows English language extracts (direct translations from the Portuguese) from the ordinance as well as the concepts that refer to standards, to be modelled in the ontology. Even though it is clear that the intent is towards adopting specific standards to deal with certain aspects of interoperability, these aspects are not explicitly stated. In general interoperability is loosely used and not qualified. One exception is Section 4.3 where "semantic interoperability" is associated with the use of SNOMED-CT. It is not clear what types or levels of interoperability exist. Even though systems can be evaluated in terms of the standards which they implement, one cannot infer from this what level of interoperability they will support.

Higher level abstract concepts (top down) was informed by our previous work in designing interoperability solutions in developing African countries [7,19], the Interoperability Framework developed by the Australian National eHealth Transition Authority (NEHTA) [22], the European Commission report on ICT standards for health [17] and a recent survey on standards and interoperability of African health information systems [1].

Table 1. Example extracts dealing with eHealth Standards in the Brazilian eHealth Ordinance (translated from the Portuguese)

Ordinance # 2,073 of 31 August 2011 - TRANSLATED		
ANNEX		
Chapter I	Standard	Translated extract from CATALOG SERVICES
Article 1	SOAP	For **interoperability between systems** will be used the SUS Web Service technology, the standard SOAP 1.1 (Simple Object Access Protocol) or higher
CHAPTER II		
Section 4.1	OpenEHR	For the definition of the Electronic Health Record (EHR) will use the openEHR reference model
Section 4.2	HL7	To establish **interoperability between systems**, aiming at integrating the results of examinations and inquiries, we will use the standard HL7 - Health Level 7
Section 4.3	SNOMED-CT	In terms of clinical coding and mapping of national and international terminologies in use in the country, aiming **support semantic interoperability** between systems, will be used terminology SNOMED CT, available at http://www.ihtsdo. org / SNOMED-CT
Section 4.5	CDA	To define the clinical document architecture is used standard HL7 CDA
Section 4.6	DICOM	For information relating to representation of imaging will be used DICOM standard
Section 4.7	LOINC	For coding of laboratory tests will use the standard LOINC (Logical Observation Identifiers Names and Codes).
Section 4.9	ISO 13606-2	Towards **interoperability of knowledge models**, including archetypes, templates and management methodology, we will use the standard ISO 13606-2.
Section 4.10	IHE-PIX	To the intersection of identifiers of patients of different information systems, will be used to specify integration IHE-PIX (Patient Identifier Cross-Referencing).

3 An Ontology for eHealth Interoperability: Regulations, Systems and Standards

This section describes the key concepts, relations and modeling decisions taken when developing the ontology. The ontology is represented in OWL and was developed using the Protégé software tool.

3.1 Overview of the Ontology

Figure 1 shows the high level concepts and relations between regulations, the health system and software. Each country has a health system, e.g. the Brazilian Health System, which provides health services and which, in turn, are supported by one or more health software system services. This distinction between health service and software service is important in the health domain as there is often confusion between the service from the health perspective and the service from the computer system (IT) perspective. Furthermore, different health services may deal with different data elements, which use different data standards, e.g. a lab service may use LOINC, while a radiology service may use DICOM (see Sections 4.6 and 4.7 in Table 1).

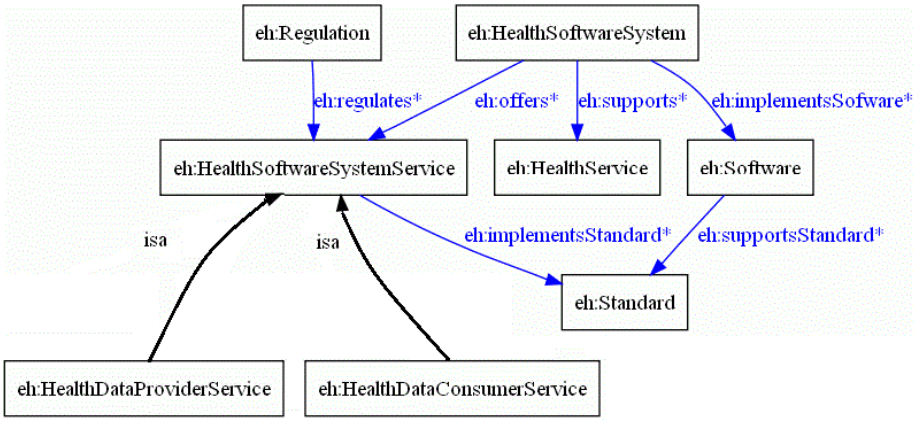

Fig. 1. Key concepts and relations in the ontology

A health software system supports one or more software system services, regulated by one or more regulations. Since the current focus is on interoperability and health data exchange, we broadly categorize services as being either data provisioning or data consuming. Other types of services may be added to the ontology in future. A health software system service implements one or more eHealth standards. We are more concerned with the interaction between services rather than the internal data

model of the software system. This allows for wrapping legacy systems with a standards compliant service interface, without having to completely re-engineer the legacy system.

3.2 Interoperability

In broad terms, we define interoperability as the ability of a sub-system to effectively interact with other sub-systems. Classification or levels of interoperability are usually linked to the types of heterogeneity that exists between systems. From a Computer Science perspective, early classifications differentiated between system, syntactic, structural and semantic interoperability [28]. As systems evolved toward open systems, and technologies that adequately deal with lower levels, e.g. XML and web-services, mature and are more pervasive, new levels of interoperability are being identified and older levels no longer prove challenging. A more recent classification suggests differentiating between syntactic, semantic, pragmatic and social world interoperability [26]. An investigation into interoperability issues specific to health information systems [10] identified three levels of interoperability, i.e. technical, semantic and process. A recent survey on interoperability and standards in African HIS can be found in [1]. What is clear is that multiple types of interoperability exist and even though specific types of heterogeneity have been emphasized in the health domain, there is still no consensus on the types of interoperability.

Drawing from our experience in developing architectures to facilitate interoperability in low resource settings [7,19] and the pragmatic approach taken in Australia's NEHTA Interoperability Framework [22] we note three pragmatic characteristics concerning interoperability:

- *Allow for different perspectives for different systems and settings*: Depending on the nature and maturity of the eHealth system, different countries will have different requirements and types of interactions between health software services. As such, countries will have their own interpretation of interoperability, which may differ.
- *Dynamic*: A country's health information system continuously evolves to increasing levels of maturity. New subsystems will appear, functionality will change and increase and new versions of data exchange and standards will be adopted to support improved interactions. Different subsystems will be at different levels of maturity and it is naive to assume that the system will ever reach a complete level of stasis. The degree of interoperability of a sub-system, in terms of its interaction with other sub-systems, is fundamentally affected by this dynamism.
- *Measurable along a continuum:* interoperability should be considered as a measure along a continuum, i.e. different sub systems could have different degrees of interoperability. Each country will define its own measures and levels and allow

for evolution of these as their health information system evolves and matures. This is similar to the five interoperability maturity levels identified in the Australian NEHTA Interoperability Framework [22, 23].

We use the concept "CompliantHSS" to allow for custom definitions of compliance for software services. The current compliancy types represent different levels of interoperability. For illustration, we define five interoperability levels in the ontology, i.e. technical, syntactic, partially semantic, semantic and organization (adapted from the 4 levels in [1]). We split semantic into partially semantic, i.e. the service has some support to enable semantic interoperability, but cannot be said to be fully semantically interoperable. The levels are incremental, e.g. any service that is semantically interoperable is also syntactically and technically interoperable. As such technical interoperability is modeled as the superclass of syntactic interoperability, which is a superclass of semantic interoperability, which in turn is a superclass of organization interoperability (Figure 2). Our approach measures the level of interoperability of a service based on which data exchange standards are implemented by a software service.

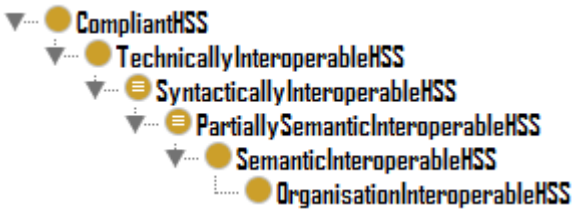

Fig. 2. Interoperability levels of software services

The five levels of interoperability defined above are used to illustrate compliance, but a country may define their own levels and these can differ between countries.

3.3 Standards

The level of interoperability of a software system is determined by the standards implemented by the service interfaces that it exposes. A standard is managed by a standards organization and follows different processes for its development. The definition is shown in figure 3.

Different categories of eHealth standards have been modeled. Categories have been adapted from a European Commission report on ICT standards in the health sector [17, page 15, exhibit 2-1]. The report identifies seven categories of eHealth standards. Table 2 shows these categories and their mappings to concepts in the ontology, and the class hierarchy and sample instances are shown in figure 4.

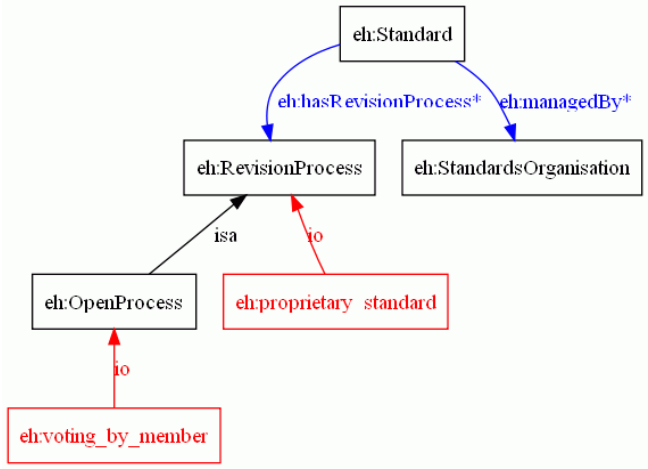

Fig. 3. Representing standards

Table 2. Categories of standards and equivalent concepts in the ontology (instances in bold are examples from the Brazilian Ordinance)

Standard category [17]	Equivalent concept in ontology	Example instances
Architecture	eHealthArchitectureStandards (expanded)	***OpenEHR,*** ***DICOM,*** ***ISO13606-2,*** ***IHE-PIX*** ***HL7***
Modeling	ModelingStandard	CEN TR 15300 Framework for Formal Modelling of Healthcare policies ISO 10746 ODP
Communication	CommunicationStandard (expanded)	SOAP1.1, XML
Infrastructure	InfrastructureStandard	***GeneralSOA*** CanadaHealthInfoWay ESB, OpenHIM
Data security	DataSecurityStandard	WSSecurity
Safety	SafetyStandard	CEN TR 13694 Safety and Security Related Software Quality Standards for Healthcare
Terminology and ontology	TerminologyAndOntologyStandard	***CID,*** ***LOINC,*** ***SNOMED-CT***

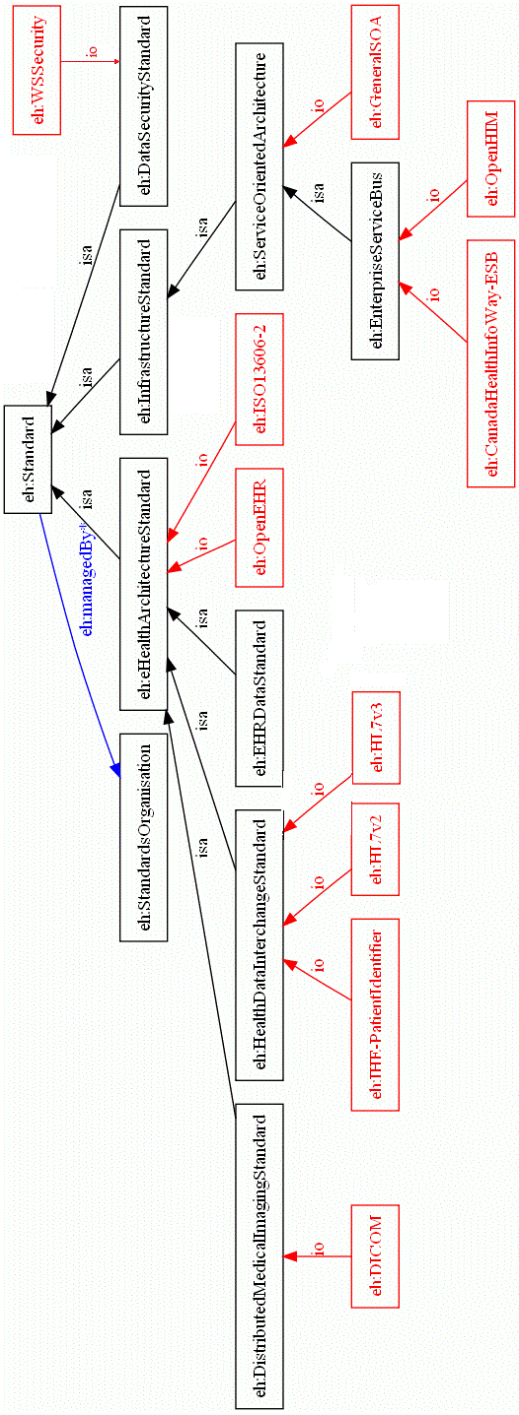

Fig. 4. Categories (types) and instances of standards

Table 3. Categorization of standards and mappings to levels of interoperability [1]

	Interoperability level			
Standard	technical	syntactic	semantic	organizational
Identifiers				
ISO/TS 22220:2011		X	X	
ISO/TS 27527:2010		X	X	X
Messaging / information exchange				
HL7 V2.X		X	X	
HL7 V3		X	X	
DICOM		X	X	
SDMX-HD		X		
Structure and content				
ASTM E2369-12		X	X	
HL7 CDA		X	X	
HL7/ASTM CCD		X	X	
HL7 CRS		X	X	
ISO 21090		X	X	
Clinical terminology and coding				
SNOMED		X	X	
LOINC		X	X	
ICD		X	X	
ICPC-2		X	X	
CPT		X	X	
Electronic health record				
ISO 18308:2011		X	X	X
System functional models				
HL7 EHR-System Functional Model, Release 1.1	X	X	X	X
Security and access control				
ISO/TS 22600				X

The ontology can support alternate and even multiple categorizations of standards and interoperability. For example a recent mapping between eHealth standards and levels of interoperability [1] (see Table 3) can be easily modelled in the ontology.

3.4 Knowledge Representation, Reasoning and Compliance Checking

A further benefit of the ontology, in addition to the consistent and explicit definition of concepts such as interoperability, is the ability to use algorithms for reasoning over ontologies to assist in matters such as compliance testing. More precisely, given an ontology that specifies different levels of compliance in a particular country, such algorithms (amongst other functions) can be used to:

- check whether a given health service meets a specific level of compliance;
- explain why a given health service does or does not meet that level of compliance;
- suggest measures for meeting that level of compliance, if it does not.

As an example, suppose that we have three levels of compliance for health software system services (HSS):

1. We define a service that is *syntactically interoperable* to be associated with the implementation of at least one syntactic interoperability standards, e.g. HL7v2 or HL7v3
2. We define a service that is *partially semantic interoperable* to be associated with the implementation of at least one semantic interoperability standard e.g. HL7v3 which supports the use of clinical terminologies and coding systems.
3. We define a service that is *semantically interoperable* to be associated with the implementation of the HL7v3 standard, as well as the medical ontology standard SNOMED CT.

The following statements, represented in the Manchester OWL Syntax for the Web Ontology Language OWL 2 (http://www.w3.org/TR/owl2-manchester-syntax/), represent a syntactically interoperable HSS (1), by defining the class `SyntacticInteroperableHSS` as:

```
Class: SyntacticInteroperableHSS
    EquivalentTo:
          HealthSoftwareSystemService and
          implementsStandard some
          SyntacticInteroperabilityStandard
```

Now, suppose we are told that X and Y are health software system services, and that X implements HL7v2 (we are not told whether or not Y implements some standard)

```
Individual: HL7v2
    Types: SyntacticInteroperabilityStandard

Individual: HL7v3
    Types: SyntacticInteroperabilityStandard

Individual: X
    Types: HealthSoftwareSystemService
    Facts: implementStandard HL7v2

Individual: Y
    Types: HealthSoftwareSystemService
```

A reasoning algorithm would then be able to give us the following information:

- X complies with a syntactic compliance level and since it is a health software systems service, it is therefore also a syntactic health software system service.
- We don't know if Y complies with a syntactic compliance level. But we know that if Y is made to implement either HL7v2 or HL7v3, it would become a syntactic health software system service.

The notions of partial semantic interoperability can similarly be represented in OWL 2. However, semantic interoperability is a little more complex as it can be achieved by implementing two standards and is defined as:

```
Class: SemanticallyInteroperableHSS
EquivalentTo:
     HealthSoftwareSystemService and (implementsStandard
     some SemanticInteroperabilityStandard or (imple-
     mentsStandard value HL7v3 and implementsStandard
     value SNOMEDCT))
```

Another example is to query for syntactically interoperable standards that are open:

```
SyntacticInteroperabilityStandard and hasRevisionProcess
some OpenProcess
```

Consider the ontology fragment in figure 5 below that represents software platforms. Two widely used software platforms OpenMRS and DHIS are shown as instances of EMR and health management information system software respectively. OpenMRS supports both the HL7 version 2 and version 3 standards.

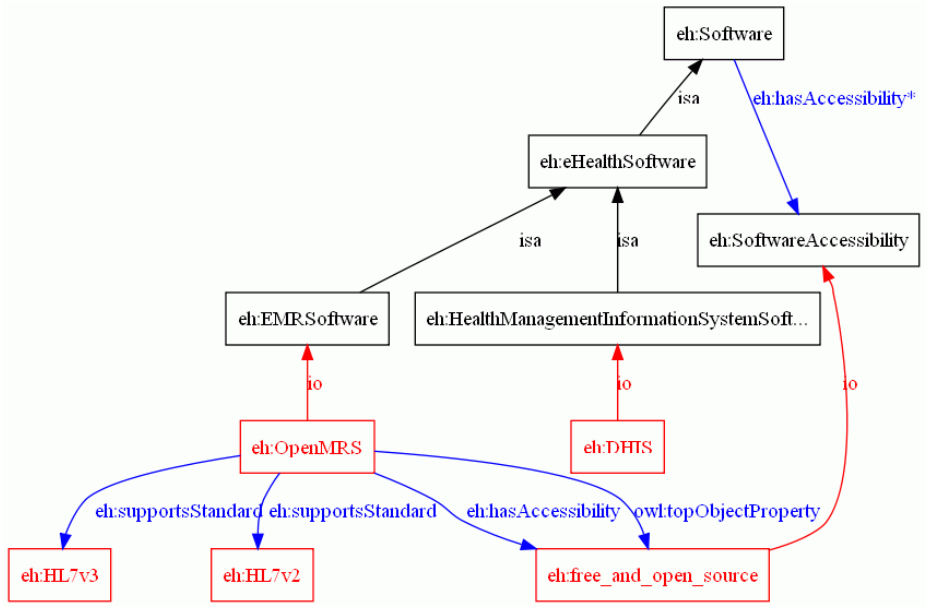

Fig. 5. Standard support for application software or platforms

Now suppose that we wanted to find all EMR software platforms that provides supports for partial or full semantic interoperability then:

```
EMRSoftware and supportsStandard some (PartialSemanticInteroperabilityStandard or SemanticInteroperabilityStandard)
```

will return `OpenMRS` since it supports `HL7v3` which is an instance of `PartialSemanticInteroperabilityStandard`.

Similarly a query to find only those platforms that are free and open source:

```
EMRSoftware and supportsStandard some (PartialSemanticInteroperabilityStandard or SemanticInteroperabilityStandard) and (hasAccessibility value free_and_open_source)
```

will also return `OpenMRS`.

4 Discussion

We developed an initial ontology to regulate eHealth interoperability and standards. The design was informed by both a bottom up approach, by analyzing real world eHealth regulations in a developing country, in this case Brazil and modeling higher level abstract concepts and relations (top down) informed by previous experiences in designing interoperability solutions in African countries [7,19,1] and other standards and interoperability initiatives in Europe [17] and Australia [22].

The ontology provides an abstract conceptual model containing the necessary primitives for a country to define their own levels of interoperability. It is expected that each country will maintain their own version of the ontology, defining their own levels of interoperability, and additional categorization of standards. However, upper level concepts will be common across countries (ontologies), to facilitate reuse and sharing between countries.

The modeling approach and ontology described above has a number of potential uses.

Assist with drafting regulations
The ontology can assist with developing, refining and re-using eHealth regulations around standards and interoperability and may also be used to analyze existing or new regulations in order to identify gaps and areas of overlap. In addition, the ontology can be interrogated to provide examples of regulations to demonstrate the required functionality. The ontology provides a categorisation of standards and highlights the effect of different standards on interoperability. This allows regulators and policy-makers to compare the functionality of different standards at a higher level and evaluate the level of functionality and compliance required.

Bridge the gap between regulators and policy makers and software developers.
The ontology provides a more rigorous specification of regulated functionality which can potentially be converted directly into system specifications. Regulators and

software developers can agree on a common interpretation of interoperability and compliance to standards, resulting in more pragmatic regulations which balance patient and national health interests with pragmatic software design, development and deployment concerns.

Compliance and evaluation of software
The ontology will be useful for testing compliancy to eHealth interoperability regulations and for developing specifications for compliance testing. Existing systems and new software products can be objectively evaluated and developed to fulfill interoperability requirements. As described in section 3.4 the model can be used to automatically measure the interoperability of software systems and to identify paths for improving the interoperability of sub-systems

Contribute to the evolution of standards
The usage of standards can be evaluated in terms of its tangible benefit in enabling aspects of interoperability, identification of gaps to develop new standards or to enhance existing ones for specific settings and provides a more meaningful discussion on adoption and promotion of standards

Measuring Interoperability
The ontology and future models will assist national governments and regulators in low resource settings to control and strengthen their national Health Information Technology infrastructure in a more positive way. Although moratoria are effective at limiting the explosion of eHealth application variability, the ideal situation would likely be to regulate the industry at the level of the standards and functionality (eg interoperability) that systems are expected to achieve in order to be considered part of the national system and then leave it up to market forces to determine which applications are deployed in-country. This will potentially allow poor facilities to make use of low-cost systems and more top-end facilities to support applications with richer functionality to support their needs.

5 Conclusion and Future work

The ontology and conceptual model presented in this paper aim to provide a common interpretation and to bring clarity to the issue of interoperability in national health information systems. The ontology is a first step towards a broader knowledge representation and modeling platform for eHealth governance and regulation. Such a platform can facilitate greater coordination between government needs and eHealth implementations and to assist with drafting, refining, reusing, implementing and compliance testing of eHealth regulations and other instruments of eHealth governance.

We plan to test the ontology in the field by making it available for use in other African countries that are currently in the process of developing and applying eHealth regulations and, e.g. in Rwanda where an initial version of an health information ex-

change [7] has been deployed to facilitate interoperability between individual HIS and applications. Feedback from these processes will allow us to refine the current model.

There are many possible directions for further extension of the ontology. The ontology can be extended by incorporating existing legal ontologies such as LKIF [14] to capture other richer aspects of regulations, e.g. their intent and consequences.

The current ontology and case study deals specifically with interoperability as an example of a software system concern and its relationship to governance and regulations. The ontology can be expanded to incorporate regulations that deal with other eHealth system concerns such as information security, data access, patient identifiers, patient confidentiality and privacy.

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