

# Interoperable Electronic Health Records (EHRs) for Ecuador

Silva R\*, Medina JA, Dáher JE, Alvarado RM, Recalde T, Noboa C, Martillo I, Burgos F, Vargas Y, Falconi S, Ramirez AM, Chan GJ and Alvarez P

Programa Promeinfo, Universidad de Guayaquil, Guayaquil, Ecuador

## Abstract

Since September 2013 the Ministry of Public Health (MSP) in Ecuador has integrated a computerized solution for Integral Health Management called Sisalud. By 2014, the MSP and the National Institute for Standardization (INEN) adopted the ISO 13606 standard. In 2014 the Medical Informatics Research Program (PROMEINFO) was implemented at Universidad de Guayaquil. This article is the result of four years of research and development led by PROMEINFO at Universidad de Guayaquil in Ecuador.

**Objectives:** Several attempts have been made to develop a Standardized Ecuadorian Electronic Powered by Editorial Manager® and ProduXion Manager® from Aries Systems Corporation Health Record (EHR), to meet the Ministry of Health standard. These prior attempts failed mainly due to interoperability issues. This document presents a proposal for the development of compatible archetypes to interoperate EHR in Ecuador.

**Methods:** The project is based on the conventional engineering cycle for software development.

**Results:** PROMEINFO has developed a proposal for the new implementation of the Sisalud System, using a semantic interoperable system that complies with all of the Ecuadorian standards. The proposal operates through the use of archetypes based on ISO 13606 and SNOMED CT terminology for semantic interoperability.

**Conclusion:** It is expected that the present article will contribute to promote the interoperability of the medical records implemented in Ecuador, which will result in a timely and comprehensive attention of the patients and to improve their quality of health care.

**Keywords:** Electronic Health Records (EHRs); Interoperability; ISO 13606; SNOMED CT; Archetype design

## Introduction

In Europe and the United States, the biggest healthcare challenge is possibly the progressive demand for chronic patients; which is caused by the aging of the population. In Latin America and the Caribbean, it is necessary to optimize patient access to timely, efficient, fast, and superior quality healthcare; which is difficult due to social differences, geographical dispersion of the citizens, and economic factors.

An important aspect for healthcare is cross-platform medical care, because many citizens will receive care from multiple providers: Ministry of Health, Social Security, Private Providers, even Cross-Border information exchange. This goes far beyond medical care at the moment, since it transcends to the recovery period; so it is necessary to have cross-platform interoperability of patient information.

The Ecuadorian Ministry of Public Health developed in 2006 a Standardized Format for Written Health Records (WHR) [1]. Since September 2013, the Ministry of Public Health (MSP) has implemented a computerized solution for comprehensive health management called Sisalud. This project aims to systematize the administrative management of all health centres under its care. The plan is being implemented gradually and hopes to cover the entire national territory. With Sisalud, physicians will be able to obtain electronic health record information in real time and provide quality, effective care, and monitor national health outcomes. Through this system, all patient data is entered, consulted, updated; physical forms are eliminated and the appointment process is speeded up.

One of the objectives of the MSP is to make the information clearer, more organized, more effective, and reliable; helping to reduce the number of forms that the doctor has to fill. The MSP has had to invest in the implementation and adaptation of the system in the different health

centres which initiates interoperability in the Ministry of Public Health. But there is also another group of hospitals that are not yet accounted for the interoperability of electronic health records, which are isolated and private centres that should be gradually integrated to the system. They have followed an approach similar to that of Netherlands, where the drivers for semantic interoperability, have not primarily been monetary incentives, but rather stakeholder awareness, education, and involvement [2].

We can define interoperability as “the ability to communicate, run applications or transfer data between multiple units”. Interoperability is born from the evolution of information technologies in the boom of information systems, in which it seeks to differentiate and go beyond the database managed concept. It can be managed in the following environments: technical, semantic, political, human, inter-community and international [3]. Technical interoperability is the basis on which the connection between systems is supported and allows sending bytes from one system to another. Syntactic interoperability allows the transfer of documents, ensuring that in the documents or messages exchanged, each piece is in place. Semantic interoperability is the state that exists between two applications-entities regarding a specific task; an application can accept data from another and perform that task

**\*Corresponding author:** Ricardo Silva, Ph.D., Programa Promeinfo, Universidad de Guayaquil, Campus Universidad de Guayaquil, Guayaquil, Ecuador, Tel: 593999340108; E-mail: [rjsilvab@gmail.com](mailto:rjsilvab@gmail.com)

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satisfactorily, without the need for external intervention of an operator. Organizational interoperability implies that two organizations that relate to each other must share a common context in their procedures and workflow. There could be no interoperability if the process definitions, welfare, or assistance plan is different or incompatible [4].

The technical and semantic dimensions constitute the bases of interoperability. Technical interoperability refers to relationship between computer systems and services. It is the set of characteristics and technological elements that physically allow the information systems of the participating entities to interact with each other. Currently in Ecuador there is no integrated system that interconnects regional, provincial and inter-institutional subsystems.

In Ecuador there is a lack of information systems' interoperability, since they have been created to automate processes in order to fulfil an institutional mission, and are not prepared to exchange information with other entities that perform the same function. At this point in time, it is essential to achieve interoperability between health information systems, in order to obtain efficient procedures with effective results. As an example, we analysed the database from Guayaquil University Hospital and found that it does not count with data filing standardization. As seen in Figure 1, all infections registered at the emergency room are classified under the same category; whereas urinary infections are written in various formats, so they would not be catalogued together in an automatic report. We have found incorrect or misspelled entries in almost all the fields, there are no clear relationship entity models; there are tables that are no longer in use and other diagnosed problems. Similar results can be found throughout the rest of the Ecuadorian Health System (Figure 1).

This study was carried out from July 2015 to February 2017 through a University Supported Research project. The project is named PROMEINFO and is a continuous research program that employs students from Computer Systems Engineering (CSE), with supervision from CSE faculty and the School of Medicine. We have proposed systems' architecture and developed a software platform, assuming that such a system was in place.

## Objectives

The ISO 13606 standard was adopted by the Ecuadorian National Institute for Standardization (INEN) in 2014 [5]. It was adopted by

Ministerial Order No. 00001190 from the Ecuadorian Ministry of Health [6], which states the use of the ISO 13606 and ISO TC 215 supplementary standards and their implementation in all institutions of the National Health System, must follow the existing INEN regulations. The ISO 13606 standard allows semantic interoperability between platforms. To date, the Ministry of Health is promoting the use of this standard, which is divided into 5 parts: Reference model, specification for the exchange of archetypes, list of reference terms and archetypes, security, and interface specification.

We have incorporated the Systematized Nomenclature of Medicine-Clinical Terms (SNOMED CT) terminology for semantic interoperability, and would like to deepen the analysis as to how the archetypes are filled from the health information systems databases. The objective of this work is to present the Ecuadorian Ministry of Public Health with a proposal for the implementation of compatible archetypes to interoperate EHR in Ecuador, based on the implementation of ISO 13606 standard and SNOMED CT, for lexical and syntactic interoperability.

## Methods

Information is identified, by the World Health Organization (WHO), as one of the six building blocks of a health system [7]. However, Low and Middle-income Countries (LMICs) have generally been found to have inadequate health information systems; in order to solve this problem, various developers suggest that an evolutionary, middle-out approach should be utilized to enable effective sharing of information [8,9]. We used this approach, by associating technical development with process and organizational changes with local development teams i.e., University of Guayaquil PROMEINFO research group, which combines faculty and students from Medicine, CSE, and Guayaquil University Hospital (Figure 2).

The PROMEINFO Development Platform was based on the conventional engineering cycle for software development. Each stage has a set of well-defined activities, which contribute to the satisfaction of these goals. The life cycle archetype encompasses the following activities:

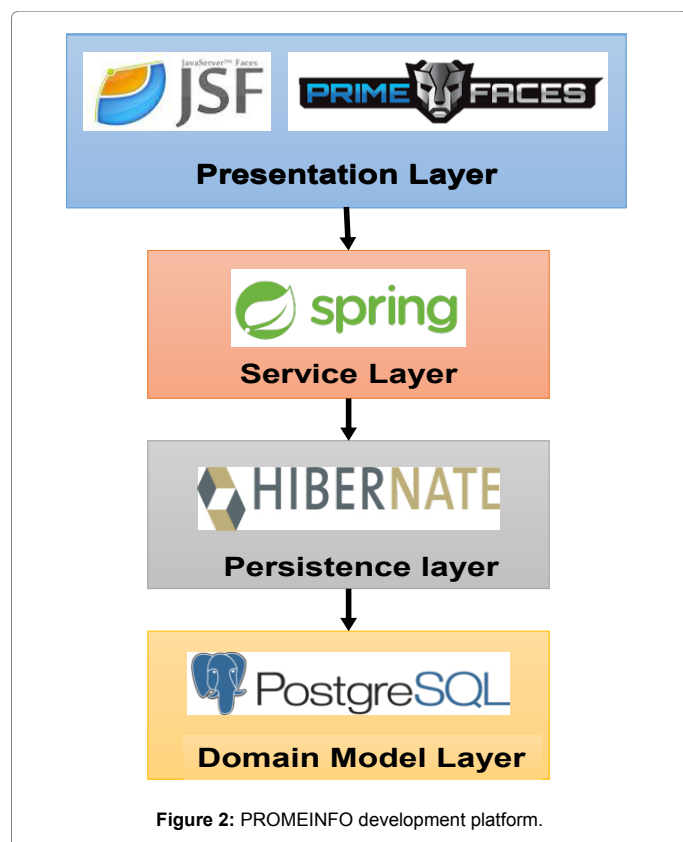
1. Engineering and System Analysis: Meetings were held with the medical staff, to determine Ministry of Public Health forms that would be converted through the use of ISO 13606 standards.
2. Software Requirements: The software requirements were established in meetings held throughout the development of the project with M.D.'s working in Public Institutions. It was determined that there is a high volume of data that needs to be stored in the EHR, this requires Software with good performance and high levels of transactionality to improve the quality of patient care and improve current systems.
3. Design: In order to choose the project design framework, research was carried out to evaluate architectural approaches for the application of ISO 13606 [10,11]. According to the study, four-layer architecture was chosen (Figure 2):
  - Presentation Layer: Interacts with the end user, is in charge of displaying and collecting the information.
  - Service Layer: Encloses business rules or the way data acquired from the presentation layer is validated.
  - Persistence Layer: Responsible for abstracting and connecting to a relational database engine.
  - Domain Model Layer: Contains all the classes that model the domain: its entities, and its primary and foreign keys.

<div> <div>Resulta</div> <div>Messages</div> </div>						
EDAD	MotivoConsulta	MES	AÑO	ENFERMEDAD	PROCEDENCIA	
1	26	INFECCION DE VAS URINARIAS	5	2013	INFECCION	EMERGENCIA
2	58	INFECCION DE VAS URINARIAS	9	2010	INFECCION	EMERGENCIA
3	62	INFECCION DE VAS URINARIAS	3	2011	INFECCION	EMERGENCIA
4	28	INFECCION DE LAS VAS RESP	8	2013	INFECCION	EMERGENCIA
5	4	IESS ANEXO 2 NIVEL 2 LITERAL 49 NIÑOS CON SINTOM...	10	2012	INFECCION	EMERGENCIA
6	33	INFECCION VAS URINARIAS	7	2011	INFECCION	EMERGENCIA
7	38	INFECCION DE VAS URINARIAS	8	2013	INFECCION	EMERGENCIA
8	35	INFECCION EN VAS URINARIA	2	2011	INFECCION	EMERGENCIA
9	14	INFECCION DE VAS URINARIAS	8	2013	INFECCION	EMERGENCIA
10	54	INFECCION DE VAS URINARIAS	5	2012	INFECCION	EMERGENCIA
11	36	INFECCION DE VAS URINARIAS	8	2012	INFECCION	EMERGENCIA
12	31	INFECCION VAS URINARIAS	8	2008	INFECCION	EMERGENCIA
13	27	INFECCION DE VAS URINARIAS	8	2008	INFECCION	EMERGENCIA
14	63	INFECCION DE VAS URINARIAS	9	2012	INFECCION	EMERGENCIA
15	26	INFECCION DE VAS URINARIAS	7	2012	INFECCION	EMERGENCIA
16	61	INFECCION DE VAS URINARIAS	7	2012	INFECCION	EMERGENCIA
17	38	INFECCION DE VAS URINARIAS	10	2012	INFECCION	EMERGENCIA
18	30	INFECCION DE VAS URINARIAS	6	2013	INFECCION	EMERGENCIA
19	4	INFECCION DE VAS URINARIAS	4	2013	INFECCION	EMERGENCIA
20	39	INFECCION DE VAS URINARIAS	7	2013	INFECCION	EMERGENCIA
21	22	INFECCION DE VAS URINARIAS	8	2013	INFECCION	EMERGENCIA
22	60	INFECCION DE VAS RESPIRATORIAS	4	2010	INFECCION	EMERGENCIA
23	74	INFECCION EN VAS RESPIRATORIAS	1	2011	INFECCION	EMERGENCIA
24	59	INFECCION DE VAS URINARIAS	5	2012	INFECCION	EMERGENCIA

Query executed successfully.

Figure 1: Query from the current database at Guayaquil University Hospital.

Figure 1: Query from the current database at Guayaquil University Hospital.



4. Coding: The lines of code are written with comments that guide the functionality of each method, the layer classes that belong to the domain model were generated directly with a connection to the database.
5. Proof: Internal software testing was conducted in conjunction with the project manager and medical users.
6. Maintenance: Changes were made at the end of each phase, whenever the user requested additional software requirements.

## Ethical Considerations

The current project proposes a new standardized methodology for EHR implementation. It does not directly involve the human subject as part of the research. Ethical constraints have been built into the system to ensure confidentiality of patient information, safety and security of the data, as required by international accreditation bodies. The work has been performed under the supervision of the Ecuadorian Ministry of Public Health and the Secretariat for Higher Education, Science and Technology (Senescyt). Up to this point no ethical compels have been raised by either institution.

## Results

A proper metadata structure is necessary to enable efficient query processing, especially when sharing data among heterogeneous data sources [12]. Extensible Mark-up Language (XML) was chosen as the programming language. XML is composed of descriptive elements (Meta-language) with its corresponding values (Name, Last Name, City, etc.) this facilitates transfer of this file to other computer systems or companies. Once the information is in XML format, it can be transferred to a program in Java, Perl, or other server applications, through a DOM, SAX or JDOM parser.

JDOM stands for Java Document Object Model, it generates a hierarchical tree in the XML document, based on each element <housing and service>, <socioeconomic status>, <family group structure>, etc. This hierarchical tree allows information manipulation through the “parser” (Xerces or some other); the advantages are the following:

- A node (Information) can be added anywhere in the tree.
- You can delete information from a node anywhere in the tree.

JDOM is only a specification Application Programming Interface (API) and therefore there are several implementations.

1. A.java class that contains Public Methods allowing the generation of a Web Services Description Language (WSDL) file to invoke the service from any application by using Simple Object Access Protocol (SOAP).
2. .java class that contains the interaction with the database by executing Stored Procedures.
3. .java class that contains the entity and attributes for the correct communication of the Data Access Object (DAO) class with the database, these entities were generated by Java Persistence API (JPA) for conversion of database tables in class .java.
4. .java class that contains the connection and configuration with the database using properties for handling in case of changes of the database server.
5. .jar library “sqljdbc4.jar” that allows communication between the PostgreSQL database and any application developed in JAVA.

All User Interface screens designed and programmed in Java JSF, follow the design pattern shown in Figure 3

An archetype viewer has been developed using JDOM technology to read XML files processing schemas, Document Type Definition (DTD) embedded web services and Service Oriented Architecture (SOA) services. LinkEHR ED<sup>®</sup> and the FreeMind<sup>®</sup> tool for mental mapping were used to design the archetypes. As stated before, SNOMED CT terminology was used for the semantic interoperability, which unified medical concepts between the M.D.'s and the developers. In dual model approaches, archetypes constitute a tool for building clinical consensus and this enables interoperability between different health information systems. An archetype constrains entities for the reference model, which are applied to attributes defined for each entity: range, cardinality, etc. Ongoing work is helping to provide ways of improving this semantics by aligning archetypes and health records with ICD-10 and SNOMED-CT [13].

To improve maintenance and reuse, several linked primary archetypes integrate an Archetype Organization, instead of a single Archetype. In order to structure the data according to the standard, the COMPOSITION class was integrated by seven SECTIONS:

- ENTRY. Vivienda\_y\_servicios (Home and Services).
- ENTRY.condicion\_socio\_economica (Socio Economic Status).
- ENTRY.Riesgo\_Familiar (Family Risk).
- CLUSTER.Framework\_of\_family\_group (Family Group).
- ENTRY.Riesgo\_Social (Social Risk).
- ENTRY.Evolucion\_del\_caso (Case Evolution).

ENTRY. Prescription (Prescription).

A LinkEHR view of the family risk archetype in Algorithm Definition Language (ADL) format can be seen above in Figure 4. Figure 5 shows a mental map with the architecture of part of the system (anamnesis formulary) and a SONOMED CT table for semantic interoperability. For the semantic interoperability of the EHR the nomenclature hierarchies of SNOMED CT ENVIRONMENT where applied, the GEOGRAPHICAL LOCATION mainly the subhierarchies; SOCIAL CONTEXT for the form 038 SOCIAL WORK; And for the forms 002 EXTERNAL CONSULTATION, 003 ANAMNESIS, 008 EMERGENCY the CLINICAL FIND hierarchy is used in the sub-hierarchy clinical finding in disorder (disease) and all subhierarchies of clinical finding.

Discussion

The WHR includes over 40 formularies for multiple health disciplines; for this study, the most common forms were selected: Outpatients (002), Anamnesis (003), Second Opinion (007), Emergency (008) and Social Work Form (038). To explain the process flow, Form 038 is used as an example. The interface is divided into processes which are sequential, i.e. a procedure begins after the completion of the previous procedure, as shown in Table 1.

The Social Risk module is unique in many ways, since it allows

the social worker to evaluate: Housing and Services, Socio-Economic Condition, Family Risk, and Family Structure. For each of the conditions, clicking the “Save” button stores the information in the database and generates an archetype file in XML format within the repository that can be transmitted between hospitals. The final generated and interoperable archetype is shown below in Figure 6.

The implementation strategy works this way: A SOA web service reads information from the databases and fills the archetypes. Models and Model Groups Exports’ from database (ADL files) are retrieved using XML format. Extracts from archetypes of CS1, CS2, CSn Health Centers, are sent to the “R” Receiver in XML. The ADL is used by the LinkEHR to define and validate the consistency of archetypes generated in the context of the Reference Model.

The archetype data instances must also be validated because there cannot be a person measuring 10 meters or weighting 2000 kilos. From a practical perspective, the whole theory of ADL is transparent, because it uses the XML file for sending and receiving information. The question is: “Where does the data validation occur, in each of the CS1, CS2, CSn, or in R?” In our design, the receiver R is a central node (NC) queried as part of the process. The Viewer operates as an application in each CS machine that accesses the Interoperability System.

JDOM is a source code library for XML data manipulations optimized for Java. Despite its similarity to the World Wide Web

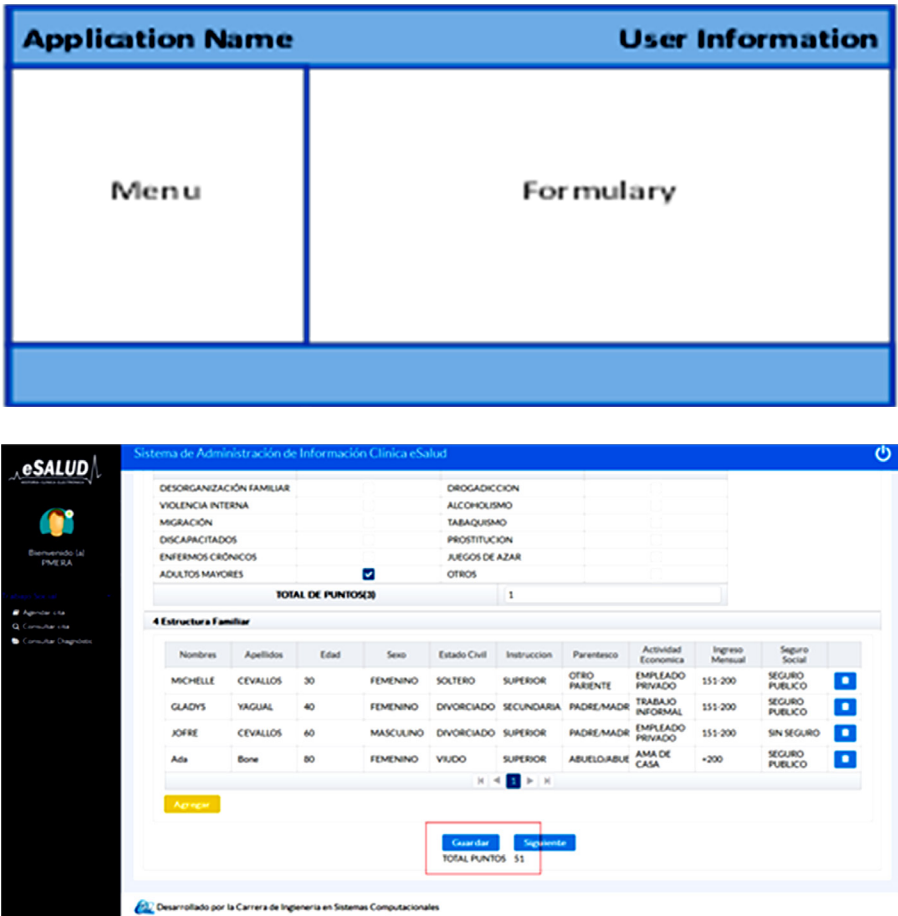


Figure 3: Screen pattern for application and sample screen.



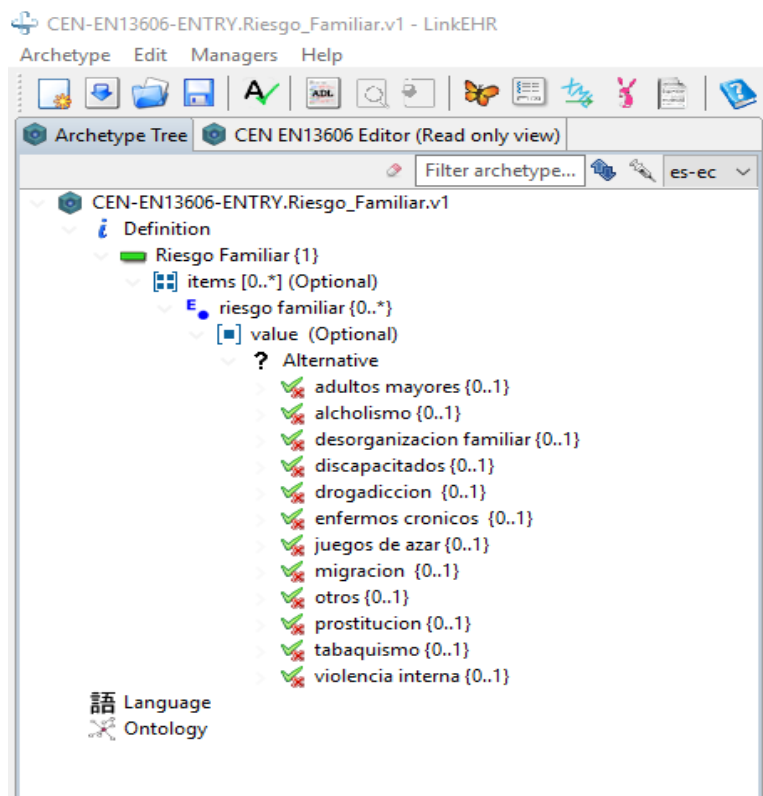


Figure 4: View on LinkEHR of the organizational archetype.

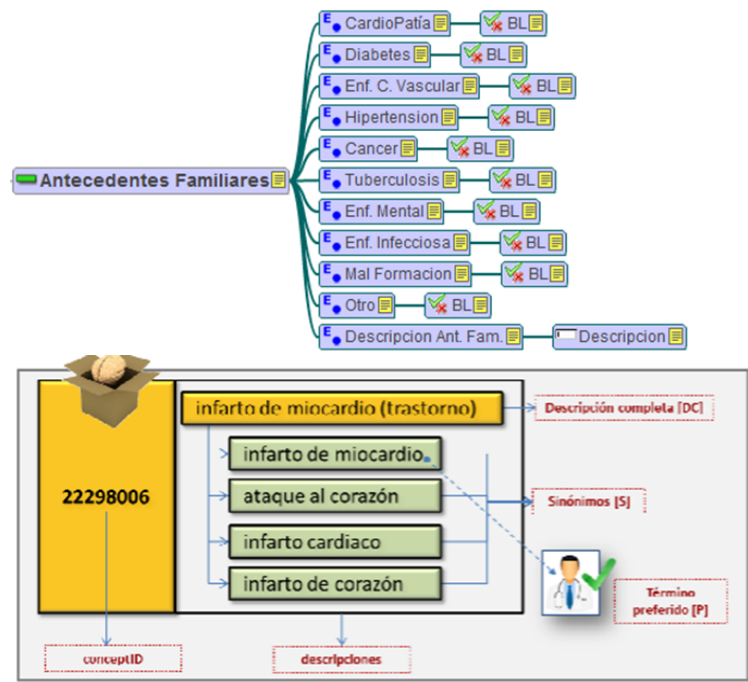


Figure 5: Left: Mental map of the family history formulary. Right: SNOMED CT semantic interoperability table for heart attack.

The screenshot displays the 'eSALUD' web application interface. The top navigation bar includes 'Inicio', 'Agregar datos', 'Consultar datos', and 'Consultar Diagnóstico'. The main content area is titled 'VISOR ARQUETIPO' and contains two sections: 'Datos Unidad Médica' and 'Datos del Paciente'. Below these is a table for 'Vivienda y Servicios'. At the bottom, an XML snippet represents the patient's data in an archetype format.

Sistema de Administración de Información Clínica eSalud			
VISOR ARQUETIPO			
Datos Unidad Médica			
Institución del Sistema:	HG Abel Gilbert Pontón	Nombre Unidad Médica:	FRANCISCO ICAZA BUSTAMANTE
Código Localización:	001-26-2	Código Unidad:	010901013
Datos del Paciente			
Nombres y Apellidos del Paciente:	CEVALLOS YAGUAL JENNIFER INES	Doc. Identidad:	0802590257
Historia Clínica:	2238811	Provincia:	GUAYAS
Dirección:	URBANOR MZ 123 V4	Cantón:	GUAYAS
Teléfono:	0982426218	Trabajador(a) Social:	CEVALLOS BONE GISELLA MARGARETH
Fecha Cita:	06/11/2016	Hora:	09:30:00
Vivienda y Servicios			
Código Principal	Descripción	Puntuación	
15	Tenencia	2	
15	Personas por Dormitorio	2	
15	Agua para consumo	2	
15	Luz Eléctrica	2	
15	Servicio Higiénico	2	

```

<diagnosticoSocial>Problemas relacionados con la educación y la alfabetización</diagnosticoSocial>
<direccion>URBANOR MZ 123 V4</direccion>
<estructuraFamiliar>
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    <nombre>GLADYS </nombre>
    <apellidos>YAGUAL MORA</apellidos>
    <edad>50</edad>
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    <instruccion>SECUNDARIA</instruccion>
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<telefonoRepresentante></telefonoRepresentante>
<unidadeOperativa>KENDRY NORTO</unidadeOperativa>
</archetype>
  
```

Figure 6: Final archetype produced by the software.

S. No.	Process	Description
1	Login to the eHealth System	Authentication of the user in the system
2	Entry Options Menu	Contains the options for filling out or consulting the social work form
3	Patient Appointment	Allows to consult if the patient has an available appointment assigned to a social worker
4	Start Evaluation	Loads a page with the patient's data and allows the selection of the housing data, social conditions, risks and family structure of the patient
5	Point Category Calculation	Make a summation of the points obtained in the evaluation to assign a category
6	Generation of Archetype and Report	At the end of the evaluation the user is allowed to save the data in the database and within an archetype, or print it by generating the report
7	Patient Diagnostic Query	Allows to consult directly from a repository of archetypes the data of a diagnosis issued at a patient appointment
8	Archetype Loading on Web Page	Allows to view the data brought from the archetype file

Table 1: Process flow for social work form 038.

Consortium (W3C) DOM, is an alternative document for object modelling that is not included in DOM. The main difference is that while DOM was created to be a neutral language and initially used for manipulating HTML pages with JavaScript; JDOM was created specifically for use with Java and thus benefiting from Java features including overloading methods, collections, etc. The JDOM use of XML parsers to construct documents has proved to be a robust technique for e-Health business process [14]. For Java programmers, JDOM is a more natural and accurate extension.

SNOMED CT is an international clinical reference terminology, which provides quality to clinical and medical interoperability. SNOMED CT is reportedly used in over 50 countries; however, there are still few articles that describe how this nomenclature is being used in operational settings [15]. Countries such as the United States of

America, United Kingdom, Canada, Netherlands, New Zealand, and Australia have designated SNOMED CT as the recommended clinical reference terminology for clinical information systems [16]. The alternative to the use of equivalent nomenclature tables (synonyms) is the use of ontologies [17] which maintain data storage independent of content specification; but this approach is not yet standardized.

The proposal of PROMINFO is for Ecuador to have an electronic medical record that is interoperable lexical, syntactic, and semantically; so that the meanings of the diagnoses are understandable in all the country's hospital systems. Implementing ISO 13845 and SNOMED CT will improve data validations in order to avoid empty or repeated fields found in the existing databases. The implementation of SNOMED CT in Ecuador will allow work towards regional integration, since Chile and Uruguay already count with SNOMED CT implementations.

## Conclusion

Since September 2013 the MSP has integrated a computerized solution for Integral Health Management called SISALUD. By 2015, the system was already implemented in 116 establishments (109 primary care health centers and 7 hospitals), by the end of 2016, there were 151 state medical centers. The MSP has already been working with a competence center in the implementation of the process of 260 additional health units, such as the Military and Police Hospitals. The system is unique, but currently does not fully comply with the ISO 13606 Standard.

ISO 13606 has been implemented in a dual model, i.e., a reference model and an archetype model. The reference model provides the structures that model medical knowledge. The most outstanding feature of the dual model architecture is the separation between the information model that is implemented in the software and in the database (reference model), and domain concepts (archetypes) that are the responsibility of clinical experts. This feature allows systems to be developed without the need to define clinical concepts. These are independent of the software process and can be entered when the system is already in place. Thus, the adoption of dual architecture allows health experts to specify content models for clinical concepts, without the need for technical knowledge.

The semantic interoperable system that was developed complies with all of the Ecuadorian standards and is compatible with the WHR. The system has been presented to the Ecuadorian Ministry of Public Health and is being considered as a reference for the SISALUD; however, in order to become a national reference, a regulatory body needs to be created. To begin with the process of creating the ISO 13606 Foundation, Ecuador must meet the necessary legal requirements as established in Article 17.3 of Executive Decree No. 16 [18]: “After drafting the Internal Statute, a Constituent General Assembly must be convened in which the internal statute must be approved, to elect an Interim Directive.” The representative of the body will have to submit an application for approval of the statute and recognition of legal status to the State. Once this body has been established, it must be registered as a partner member to the ISO Organization, and therefore improve the quality of life for patients in the country. The same entity must accredit and take charge of adopting international templates and adapting them to the needs of our country.

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