411

HEMIC Project: Design of a Clinical Information Modelling Tool Based on ISO13972 Technical Specification

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Abstract. The Andalusian Health Service is the public healthcare provider for 8.302.923 inhabitants in the South Spain. This organization coordinates primary and specialized care with an IT infrastructure composed by multiple Electronic Health Record Systems. According to the large volume of healthcare professionals involved, there is a need for providing a consistent management of information through multiple locations and systems. The HEMIC project aims to address this need developing and validating a methodology based on a software tool for standardizing information contained within EHR systems. The developed tool has been designed for supporting the participation of healthcare professionals the establishment of mechanisms for information governance. This research presents the requirements and designs for of a software tool focused on the adoption of recognized best practice in clinical information modeling. The designed tool has a Service Oriented Architecture that will be able to integrate terminology servers and repositories of clinical information models as part of the modeling process. Moreover, the defined tool organizes clinicians, IT developers and terminology experts involved in the modeling process in three levels to promote their coordination in the definition, specialization and validation of clinical information models. In order to ensure the quality of the developed clinical information models, the defined tool is based on the requirements defined in the ISO13972 Technical Specification.

Keywords. Quality Management System, Tool, Software, Semantic Interoperability, Electronic Health Record.

1. Introduction

Nowadays there are multiple specifications that aim to define how clinical information is structured in order to be transferred between EHR systems. Some of the most relevant specifications are: Detailed Clinical Model, HL7 CDA templates, HL7 FHIR

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resources, CIMI models, ISO 13606 and openEHR archetypes. As part of this research we use the term Clinical Information Model to be able to describe any of the above presented specifications applicable to define how clinical information is structured in order to be transferred between EHR systems.

1.1. Clinical Information Modeling Processes, Quality Standards and Tools

The Clinical Information Modeling Process (CIMP) is an iterative process that includes the analysis of the domain and requirements, designing, implementing, validating and maintaining CIMs. The analysis of how the CIMs are developed in the published literature shows that it is possible to define a unified process to guide CIM definition, including the description of best practices to increase the quality of the CIMs because there are not particular differences on the process adopted associated with the applied EHR specification [1].

In the clinical information modeling field, ISO 13972 Technical Specification: Detailed Clinical Models Definition and Processes [2] describes how to implement quality processes that lead to the recommended definition of CIMs. Moreover, this specification details a set of testable quality attributes of these resulting models and how to implement a Quality Management System for the CIMP. The implementation of a Quality Management System allows establishing a continuous improvement cycle through the continuous adaptation of processes and measurements within each of the steps to obtain improved quality in the final product. Given that this specification has been recently approved, most of the existing modeling tools don't comply with the full list defined CIMP requirements.

Clinical information modeling tools are software platforms designed to support the processes associated with the definition of CIMs, as well as, establishing governance for the multiple CIMs applicable within an infrastructure or domain. Currently there are multiple tools such as the openEHR suite [3], DCM suite [4] and LinkEHR [5] that provide the mechanisms for defining and management CIMs in the form of archetypes or DCMs. A recent evaluation study shows that existing modeling tools have a good adoption of functionalities related with the management EHR specifications, data types, terminology binding and CIM metadata. As well, this study identified the need for increasing the support of the CIMP [6].

1.2. Andalusian Health Service

The Andalusian Health Service (AHS) is a public healthcare provider responsible for providing care for more than 8 million people. AHS has developed an IT infrastructure composed by multiple EHR systems covering primary and specialized care. The development of this infrastructure began in 2000, with the deployment of a centralized EHR system called Diraya in all the primary care centers of the region. Diraya contains modules that manage unique identification, ePrescription, Diagnostic orders, appointments, professional access for the region. In the subsequent years, additional EHR systems for hospital care and emergency department were developed. As a result, the AHS IT infrastructure has been deployed through the full network of 29 hospitals and 1,500 Primary care centers distributed throughout the region. The deployed infrastructure is currently used by approximately 85,000 health professionals and it contains more than 70 million ePrescriptions and 40 million primary care encounters.

The AHS has defined a central strategy for improving the quality of integrated care through the definition of a set of Integrated Healthcare Processes (IHP) for the 70 most relevant diseases. IHPs are based on the development of flexible organizational models and an appropriate management of the processes according to the integration of scientific knowledge and evaluation of their performance in healthcare environment. Each IHP describes how multiple actors are involved in each of the steps of the patient care through the multiple healthcare centres of the region.

Based on the existing infrastructure and the need for providing integrated care, AHS has strong need for establishing a consistent management of information mechanisms to ensure that information collected is adequately exploited and analyzed. The HEMIC project aims to develop and validate a methodology based on a software tool for standardizing information contained within EHR systems.

2. Methodology

This research aims to define the requirements for an online tool that support the CIMP through functionalities that ensure the application of the previously defined methodology for defining forms and information models. The definition of requirements was based on: (i) CIMP identified as part of the systematic literature review about papers talking about semantic interoperability in EHR systems [1]; (ii) metrics defined as part of the ISO13972 standard for implementing a Quality Management System [2]; and (iii) essential requirements for modeling tools [7].

3. Results

The HEMIC tool has been designed as a software instrument that will support the coordination of those healthcare professionals involved in the modeling process. This tool includes roles to classify users in three levels. The first level includes the coordinators that ensure the establishment of the information governance process. They coordinate and manage the definition of resources applicable for the multiple healthcare domains in the form generic CIMs. The second level includes a core team of multidisciplinary experts who work in depth on the detailed clinical and technical needs that the system and CIMs will need to satisfy. The third level comprises a larger group of domain experts responsible for validating the proposed clinical document or EHR form. A checklist has been designed to provide guidance about the recommended practices for the clinicians participating in the modelling process ensuring that models were based on relevant sources of information and followed appropriate validation mechanisms.

The HEMIC tool includes mechanisms for defining and managing the multiple clinical documents associated with each IHP. Moreover, associated with the evaluation of the implemented care process, the tool will support the definition of key performance indicators Most of these indicators are based on time associated with the healthcare delivery and healthcare outcomes in the patient population. Figure 1 details how multiple roles and tasks are assigned.
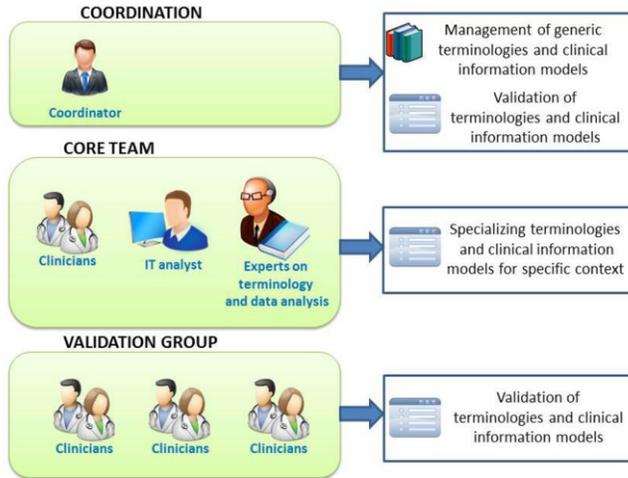
Figure 1. Coordination of participants in the definition process.

There were designed functionalities to allow clinicians designing clinical documents and the EHR forms based on the generic clinical information models approved by the coordination group. The tool specified mechanisms to access to a repository of generic CIMs and terminologies server. The Web Form Designer component accesses the list of approved semantic structures to allow clinicians define their required EHR form based on specialisation mechanisms. Specialisation mechanisms were based on the Archetype Design Principles [8] to ensure consistency of the specialised EHR form with a mechanism for detailing additional semantic context for the designed form. Associated with the definition of clinical documents, HEMIC tool generates validation tasks for modelling process coordinators ensure the satisfaction with the established information governance strategy.

The output of the modelling process will be initially in the form of CSS templates, and XML data storage structure. These outputs might be directly incorporated by the implemented AHS EHR systems as a new web form consistent with the established information governance. In addition, it will be provided an additional output according to the ISO13606 Extract structure. In the future, it is foreseen to be able to satisfy other specifications based on generic reference model such as CIMI models or openEHR. The HEMIC tool has been designed to provide the approved semantic structures to be incorporated in the EHR forms. Figure 2 shows a representation of the HEMIC tool architecture.
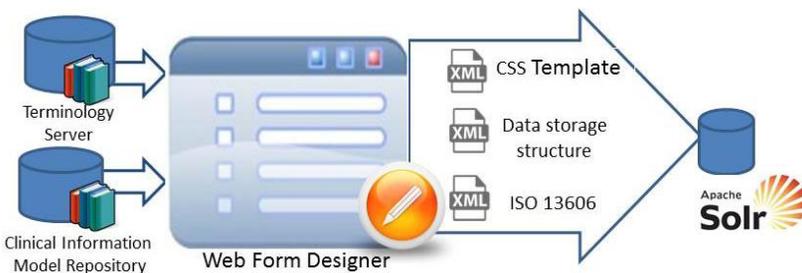
Figure 2. HEMIC tool architecture

4. Discussion

Traditional software development processes for defining and updating EHR systems require a large process with multiple meetings for obtaining clinical consensus and defining requirements. The traditional process has associated high cost and effort to coordinate meetings between multiple clinicians with limited availability. The HEMIC tool has been designed as an instrument focused on supporting the clinician involvement as part of the CIMP. Within the AHS there is a need for coordinating requests for modifying and generating new EHR forms, the defined functionalities are expected to allow clinicians to define clinical document and EHR forms with minimal supervision through consistent mechanisms for assigning semantics. As a consequence, clinicians would benefit from a web based tool that expects to accelerate the process of building consensus for defining the structure of EHR forms. The tool will be piloted with clinicians involved in the definition of new EHR forms as part of the AHS IT infrastructure in order to determine their acceptance and evaluate the benefits from adopting the HEMIC proposed methodology.

In order to ensure the quality of the developed CIMs, the defined CIMP has been designed to facilitate future quality labeling process based on the ISO 13972 Technical Specification.

5. Conclusion

The HEMIC tool has been designed as an instrument able to coordinate the participation of clinicians, terminology experts and IT developers as part of the CIMP based on the ISO13972 requirements. The tool includes functionalities for ensuring the establishment of information governance mechanisms through the management of generic CIMs able to be specialized to define EHR forms.

The HEMIC tool will be piloted with the definition of CIMs for one IHP in the coming months to evaluate the clinician perceived usability and acceptance. Moreover, this evaluation will assess the semantic consistency of the developed EHR forms and estimate the reduction of time in the CIMP.

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