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Formalize clinical processes into electronic health information systems: Modelling a screening service for diabetic retinopathy

Aitor Eguzkiza [a,*], Jesús Daniel Trigo [a,1], Miguel Martínez-Espronceda [a,1], Luis Serrano [a,c,1], José Andonegui [b]

[a] Department of Electrical and Electronic Engineering, Public University of Navarra, Campus de Arrosadia, 31006 Pamplona, Spain
[b] Department of Ophthalmology, Complejo Hospitalario de Navarra, 31008 Pamplona, Spain
[c] Institute of Smart Cities – ISC, Public University of Navarra, Campus de Arrosadia, 31006 Pamplona, Spain

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ABSTRACT

Most healthcare services use information and communication technologies to reduce and redistribute the workload associated with follow-up of chronic conditions. However, the lack of normalization of the information handled in and exchanged between such services hinders the scalability and extendibility. The use of medical standards for modelling and exchanging information, especially dual-model based approaches, can enhance the features of screening services. Hence, the approach of this paper is twofold. First, this article presents a generic methodology to model patient-centered clinical processes. Second, a proof of concept of the proposed methodology was conducted within the diabetic retinopathy (DR) screening service of the Health Service of Navarre (Spain) in compliance with a specific dual-model norm (openEHR). As a result, a set of elements required for deploying a model-driven DR screening service has been established, namely: clinical concepts, archetypes, termsets, templates, guideline definition rules, and user interface definitions. This model fosters reusability, because those elements are available to be downloaded and integrated in any healthcare service, and interoperability, since from then on such services can share information seamlessly.

1. Introduction

The development of telemedicine-based screening strategies in ophthalmology enables ubiquitous and instant medical information to clinicians. Given that traditional face-to-face consultation in ophthalmology is limited by the scarcity of specialists, this new scenario facilitates the redistribution of the workload toward more efficient clinical practices.

In this sense, previous experiences have proved that specifically trained general practitioners (GPs) can screen patients for diabetic retinopathy (DR) using non-mydriatic retinal photography [1,2]. Specifically trained nurses and imaging technicians also can perform the diagnostic tests required in this healthcare process [3]. Whereas traditional consultation considers that the expert ophthalmologist is responsible for handling the entire process, this new framework distinguishes different active roles in the process of detecting DR [4]:

- The "test acquisition" role involves the use of medical devices to obtain images and data of sufficient quality for diagnosis. Nurses or technicians can reliably perform this task.
- The "DR screening" role includes observation of diagnostic tests to identify signs of DR and determine if the patient being examined has treatable DR. GPs can reliably perform this task.
- The "medical care supervision" role is that in which retina specialists assume the ultimate responsibility in this process by interpreting the signs of DR to classify the disease and choose

Abbreviations: CDS, clinical decision support; CKM, clinical knowledge manager; DICOM, digital imaging and communications in medicine; DME, diabetic macular edema; DR, diabetic retinopathy; EHR, electronic health record; ETDRS, early treatment for diabetic retinopathy study; GDL, Guideline Definition Language; GP, general practitioners; ICD-10, international statistical classification of diseases and related health problems; IOP, intraocular pressure; PACS, Picture Archiving and Communication System; PC, personal computer; SNOMED-CT, systematized nomenclature of medicine, clinical terms; SNS-O, Health Service of Navarre (*Servicio Navarro de Salud – Osasunbidea*); UI, user interface.

* Corresponding author. Tel.: +34 948 169671.
E-mail addresses: aitor.eguzkiza@unavarra.es (A. Eguzkiza), jesusdaniel.trigo@unavarra.es (J.D. Trigo), miguel.martinezdeespronceda@unavarra.es (M. Martínez-Espronceda), lserrano@unavarra.es (L. Serrano), jose.andonegui.navarro@cfnavarra.es (J. Andonegui).
[1] Tel.: +34 948 169671.

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the appropriate treatment. Occasionally, they also supervise the work of other clinicians to verify correct functioning of the service.

A primary consequence of this new assignment of different tasks to specialized personnel based on fundus photography is that it is more cost effective compared to traditional methods of DR assessment [5–8].

However, the implementation of new healthcare proposals is hindered by the intense modelling efforts required to update the knowledge base, already registered into static and vendor-specific electronic health information systems [9]. This is due to several factors. First, there is an important interdisciplinary gap between clinicians and software developers when it comes to define the specific healthcare scenarios; and, second, the continuous evolution of medical knowledge. The consequent developmental costs resulting from this endless redesign become unaffordable for any healthcare service [9]. Further, specifically in ophthalmology, electronic health records (EHR) have special requirements regarding other clinical specialties that are not considered by traditional information systems [10].

Nevertheless, the advent of more adaptive health information standards based on dual-model layered architecture, such as the CEN/ISO 13606 or openEHR, has simplified all of those factors, i.e., agreement among clinicians and software developers, continuous need to adapt the information system, and system customization to ophthalmology. These new information standards have simplified the management of the clinical knowledge inside the EHR [11,12].

This architecture includes, on the one hand, a reference model that standardizes the way the information is handled inside the software, and, on the other hand, an archetype model that gathers knowledge about the clinical process to be managed [13]. In this way, experts in the clinical domain determine the components in the archetype model to customize the information in their own EHR systems, whereas software developers work in conformance with the reference model toward better tools to achieve interoperability among information systems [14]. Therefore, with regard to modelling clinical knowledge, the archetypes are the keystone of dual-model architecture, formally defined as computable expressions of the domain knowledge in the form of structured constraint statements. In other words, they are computer interpretable definitions of the semantics and structure of clinical concepts.

In principle, archetypes must be formulated toward wide re-use of clinical concepts validated by an international community of experts in the clinical domain. Thus, regarding local implementation, archetypes must be adapted according to the requirements of specific healthcare scenarios. Therefore, templates are modelled to constrain and group those archetypes into larger structures analogous to the paper medical records [15]. Then, the elements of knowledge that comprise both, i.e., archetypes and templates, can likewise be bound to equivalent concepts within standardized medical terminologies. Those connections provide semantic relationships and unambiguous identification for each data element when information is exchanged among different information systems [15].

In connection with this model-driven design strategy, the changes concerning the domain knowledge are included on the fly, in contrast to traditional information systems that require planning all causality before implementation [16]. In consequence, dual-model architecture has significantly improved the maintainability regarding time, cost, and simplicity of the software [17].

With consideration of all the above, the approach of this paper is twofold. First, this article presents a generic methodology to model clinical processes and, second, a proof of concept thereof in a specific scenario of DR screening in the SNS-O. Regarding the methodology, all information involved within clinical processes is modelled considering different levels of interoperability (technical, syntactic, semantic, process/organizational, and presentation) for a faithful data exchange among information systems. This methodology therefore goes one step further than computerize the domain knowledge in compliance with dual-model architectures, hence also proposes modelling the organizational management of the service and the specifications for the user interface (UI) (how that information is presented to users).

Therefore, the patient information must comprise not only the information gathered during an isolated clinical encounter, but also a whole system of organizational concepts to ensure a secure exchange toward ubiquitous and instant delivery of the information required by each healthcare provider involved in a particular clinical process.

Additionally, besides modelling the information handled during clinical encounters, clinicians must be involved in the definition of the UI specifications to guarantee a faithful representation of that information to the final users. In this way, there is no need of intermediaries to give a context and a purpose of use to the information modelled. Thus, the resulting UI models provide the flexibility required to reuse the same information depending on the specific purposes of clinicians at any given time (research, epidemiology, population health, health administration, best practice care testing, financing, healthcare procedure comparison, healthcare goal planning, etc.).

The consequent methodology would provide a framework to ensure the continuity of care within patient-centered complex clinical processes such as chronic disease management, which require tight coordination of resources. Therefore, this article will guide the readers in the definition of an entire set of knowledge artefacts that comprise a model with the aforementioned properties: clinical concepts, archetypes, termsets, templates, clinical decision support rules (CDS), and UI specifications.

Once the methodology is presented, the second step is to exemplify the application thereof. As a proof of concept, the DR screening service of the Health Service of Navarre (Servicio Navarro de Salud – Osasunbidea [SNS-O]) was analyzed. In fact, such service succeeded on using information and communication technologies to redistribute efficiently the workload resulting from DR screening [1]. However, the lack of normalization of the information inside the service made it difficult, if not impossible, extend this strategy to other healthcare facilities.

Therefore, the authors of this article work toward a methodology to formalize the aforementioned clinical process so as to extend this experience to other DR screening services.

This report is organized as follows: the methodology used to study an e-Ophthalmology-based clinical model and its implementation into the SNS-O is presented in Section 2; the results of the transcription of the clinical process into a standardized electronic model are described in Section 2.2.4; the discussion including the main challenges found during the modelling of this screening service is in Section 4; and the conclusions are presented in Section 4.3.

2. Materials and methods

The methodology described in this section is based on common patterns identified in similar clinical knowledge modelling experiences found in the literature. Most publications studied focused on the archetypes, since the point of departure for the model was the dual-model layered architecture. First, the development and maintenance of archetypes were studied at the theoretical level [18–22]. The research then focused on identification of the common patterns in real healthcare scenarios in which archetypes were modelled [23–25]. Some publications have gone one step