Journal of Medical Systems (2019) 43: 57
https://doi.org/10.1007/s10916-019-1179-7

TRANSACTIONAL PROCESSING SYSTEMS

Archetype Development Process: A Case Study of Support Interoperability among Electronic Health Record in the State of Minas Gerais, Brazil

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Received: 24 June 2018 / Accepted: 22 January 2019 / Published online: 31 January 2019

Abstract

The interoperability among electronic medical records requires a standard that guarantees the semantic persistency of information. The study proposes an archetypes development process to support the Electronic Health Record (EHR) in the State of Minas Gerais, Brazil. It was case study with a qualitative analysis of applied nature with methodological exploratory purposes. For this, there was a literature review on archetypes development processes. The selected studies had their processes compared. Then, an own archetypes development process was proposed, also considering the legislation of Unified Health System in Brazil. The process was tested in a proof of concept, a practical test on a theoretical proposal. The proposed governance model was considered adequate for the organization of EHR at such scenario. It is expected that with its effective implementation, the proposed process supports the interoperability among clinical data arising from different levels of health care services.

Keywords Electronic health record · Archetype · Unified health system · Archetype governance process · Archetype development process

Introduction

The Brazilian Unified Health System, created by the Constitution of 1988, involves a network of regionalized and hierarchical services responsible for health promotion, prevention, recovery and rehabilitation in Brazil [1–4].

This national system is available in Brazil that is the fifth biggest country in the world with 8.51 million of km^2 and more than 207.7 million of the habitants. The state of Minas Gerais, the scenario of this study, has 586,520.732 km^2, a population of 21,119,536 and 853 cities. Territorially this state is bigger than countries like Spain, Germany, Italy, Equator, New Zeeland, Greece, Portugal, Denmark, and Switzerland.

Reducing chronic disease burden involves the adoption of a health care model, such as the Health Care Networks, which are a form of organization of health services to ensure comprehensive and continued health care [5]. People receive care at various institutions and therefore the data and information from clinical encounters are either recorded on paper or distributed in different Electronic Patient Records (EPR), which are often not interoperable, that is, they do not enable information exchange with other systems [6–10]. In such scenario it is not different; each city may have its own EPR developed using different technology.

However, to enable the sharing of information among the various EPRs, the use of Electronic Health Record (EHR) is supposed to allow interoperability of one or more repositories of information from computers, physically or virtually

This article is part of the Topical Collection on *Transactional Processing Systems*

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integrated, enabling a longitudinal record of clinical information centered on the citizen, regardless of the institution that has originated the record [11–13]. Therefore, EHR is a logistical support system to Health Care Networks that enables the interoperability of data and information, promoting the comprehensive health care of the individual throughout life, with high quality, efficiency and safety [8].

The interoperability of the EHR based on two-level modeling is divided

- Functional or syntactic interoperability, understood as the ability of two or more systems to exchange information, which is called Reference Model [14].
- Semantic interoperability, which is the ability of two or more systems to apprehend the information shared at a conceptual level, allowing automatic processing by the computer, which is termed archetype or clinical knowledge artifact [15].

Worldwide, countries at different stages of development and socioeconomic situations use information technology applied to health care, also known as e-Health, for the planning and investment in this sector maintains the proper and efficient use of information for the improvement of health care [16, 17].

However, although Brazil has investments in health information systems, they have usually been constructed to meet demands of records, programs or even specific institution's records and, therefore, are disjointed and generate fragmented information [18]. To reduce health information fragmentation, subsidize the activities of health professionals and managers [19] the State Health Secretariat has organized the National Health System in its territory at Health Care Networks and has created the Information Technology Project for Health Care to provide an interoperable EHR. The proposal responds to the premise set by the Ministry of Health: "By 2020, e-Health will be incorporated into SUS as a fundamental dimension, being recognized as consistent improvement strategy of health services through the availability and use of comprehensive, accurate and safe information to improve the quality of care and health processes, on the three levels of government and in the private sector, benefiting patients, citizens, professionals, managers and health organizations" [18]. Such Project, has chosen the ISO/CEN 13606 Standard, based on a two-level modeling, to develop and to make available EHR Base (B-EHR), that contained the core set of health data, and the EHR System, which can be understood as an EPR [20].

In this context, the development of archetypes and the proposition of a governance model has become a priority for facilitating an EHR system that meets the health professional needs, the continued care of citizens, service time reduction, clinical safety of citizens, health care cost reduction. The archetypes governance process, or archetypes development process, is a type of knowledge management. In this management there is a systematic and consensual process that ensures consistency and coordinated evolution of the version, the lifecycle, the meta-data associated, and the resources of the archetypes used in the EHR, though there is still systematization in the literature on how it should be performed [12, 21, 22].

Given this scenario, what should be the steps, roles and artifacts of the archetypes development process used in the clinical record of EHR in Brazilian Unified Health System? In response, this study had the general objective of setting the steps, roles and artifacts of the archetype's governance process used in the local EHR. It also has the following specific objectives: identify the archetype development processes in literature, the steps, roles and common artifacts in the identified archetypes development processes to propose a model for the archetypes governance process for the Unified Health System, as a pilot project in the State of Minas Gerais in and validate the proposed model.

Methods

According to Moresi [23], the approach of this study:

- is a qualitative type since it seeks to deepen the understanding of the subject in question;
- is an applied nature since it aims at the solution of a local question since, in this case, the study is directed to the reality of the clinical record of care in the Brazilian Unified Health System;
- had methodological exploratory purposes, since there is a review about the subject and, in the end, will describe a process for governance of archetypes and will use as a procedure the case study whose universe is the clinical record of care in the Brazilian Unified Health System in the State of Minas Gerais [23].

For this, the study was divided into four steps:

1. Identify archetype development process;
2. Identify common steps, roles and artifacts in the identified archetype development process;
3. Propose a model for an archetype development process for the clinical record in the Unified Health System in Minas Gerais;
4. Validate the proposed model.

Results

The review developed in the Step 1 allowed the selection of three reports [22, 25, 26]. These reports were joined to academic reports, dissertation [21] and a thesis [12], both about health knowledge management, previously obtained for analysis in this study.

The extraction of steps, roles and artifacts identified in the literature is organized in Table 1 [24]. This outcome is the result of the Step 2 according to the methodology.

In step 3, the proposal of the archetypes development process of EHR clinical information was carried out (Fig. 1). The flow of a new archetype starts in Plan Phase, following the ISO 13606 standard, terminologies and Brazilian public health scenario were represented in this Figure.

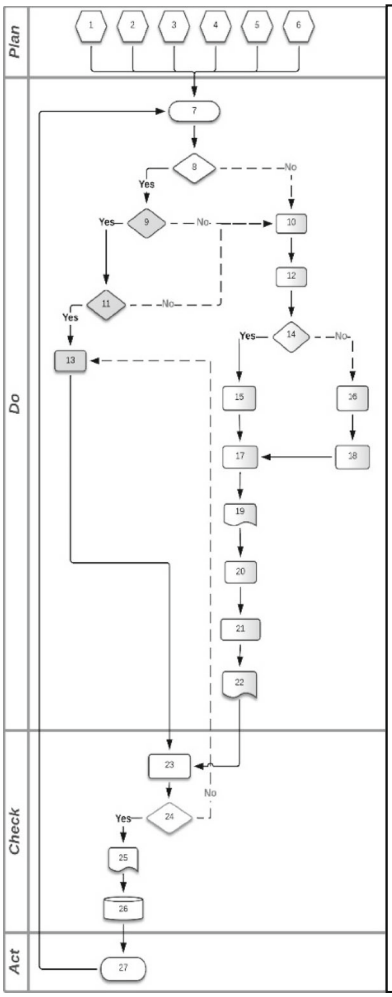
During the Do Phase, the archetype management team nominates the archetype editor that will accompany the process as lead developer. The next phase was Check, when the archetype reviewer verifies if the proposal meets the quality requirements (Table 2). The final phase, Act, the archetype is publicized, and the archetype management team monitors it for continuous improvement. However, there is more than one way to manage an archetype by alternative flow, highlighted in gray gradient (Fig. 1) That allows adaptations in an existing artifact.

Table 2 presents the quality requirements that address clinical, public health management, technical and governance information of the archetype development process. Quality requirements presented in Table 2. They were established based on the review phase and according to Brazilians healthy public policies and legislation [1–4, 12, 21, 22, 25–27].

In step 4, the proof of concept followed the flow of archetype development process (Fig. 1). Plan Phase was performed as described in items 1, 2, 3, 4, 5 and 6 of the flow. Do Phase was performed as described in items 7, 8, 9, 11 and 13 of the flow. In the Check Phase, the process was performed what is described in items 23, 24, 25 and 26 of the flow. In the Act Phase, tasks were performed what is described in item 27 of the flow. As a result, it was necessary to adjust the list (terminology) of routine and special vaccine, create some elements, update the

Table 1 Study steps, adapted from [23]

Step	Specific objective	Methodology	Source of data	Information treatment
1	Identify archetype development process	Bibliographic procedure with exploratory nature	To carry out literature review used the keywords “archetype development process” and “archetype governance” in the index bases “IEEExplore”, “Science Direct” and “Springer Link”, only in English, without restriction of publication date	Present the archetype development process identified [12, 20, 21, 24, 25]
2	Identify common steps, roles and artifacts in the identified archetype development process	Descriptive procedure in documentary research by comparison technique	Articles identified in the literature review, a master dissertation and a thesis [12, 20, 21, 24, 25]	Compare, in a table, the archetype development process in terms of steps, roles, and artifacts identified in the documents in step 1
3	Propose a model for archetype development process for the clinical record in Unified Health System in Minas Gerais	Descriptive procedure of case study of applied nature	[4, 12–14, 20, 21, 24, 25]	Propose a model for archetype development process of the clinical knowledge artifacts for Unified Health System in the State of Minas Gerais considering the results of step 2, existing legislation on Unified Health System, the reference model and the ISO 13606 archetype model and the ages of the documents defined by requirement model for computerized archival document management systems [4, 12–14, 20, 21, 24–26]
4	Validate the proposed model	Qualitative approach for descriptive purposes	Document prepared in step 3	Perform proof of concept, that is a practical test on a theoretical proposal, of the process proposed in step 3 that used the archetype CEN-EN13606-COMPOSITION.Res_Imunobiologicos.v7 of the EHR system, because the national vaccination schedule [19]



1 Reference Model: ISO 13606
2 Archetype development tool: LinkEHR
3 Health model: Unified Health System
4 Roles played in the archetype development process
5 Valid measurement units: National Institute of Metrology, Quality and Technology – INMETRO
6 Terminology: Unified Health System, ICD and ICPC2
7 Archetype management team identifies changes in literature or receives archetype change demand
8 Definition of the Unified Health System Manager
9 There is archetype published on the subject or is impacted by the definition
10 Archetype management team nominates the archetype editor (AE) that will accompany the process as lead developer
11 Published archetypes may be used or adapted without changing the meaning
12 Top Developer invites team of experts from Unified Health System and from partner institutions to participate. Team identifies publications and archetypes related to the topic
13 AE performs adjustments
14 Published archetypes may be used or adapted without changing the meaning
15 Team turns into concepts the documents found in the previous step
16 Archetype lost its meaning and is obsolete. Keep it available only for historical reference.
17 Team models the necessary archetypes.
18 AE starts the development of new archetype: survey of documents and transformation in concepts
19 Archetype draft
20 Archetype management team publishes the draft for unprivileged users who are interested to contribute to the process
21 Main developer and team of experts make the necessary adjustments
22 Archetypal draft
23 Archetype reviewer checks if the proposal meets the quality requirements
24 Quality requirements were followed
25 Archetype ready for publication
26 Updated archetypes are published on the site
27 After published, it is set into production and is monitoring for continuous improvement.

Fig. 1 Archetype development process of EHR for Unified Health System, adapted from [23]

clinical summary and verify the quality requirements to follow the determination of the Ministry of Health.

Discussion

The proposed archetype development model demonstrated that the recommendations arising out of public legislation have a potential for implementation in real scenarios. This statement contrasts with the actual scenario in Brazil, one of the pioneers in the regulation related to the interoperability among health information systems, but with a few real applications. This experience may contribute to enhance the coherence between the EHR system and public policies.

An important contribution for archetype governance is the Clinical Knowledge Management (CKM) Platform initiated in Australia [28]. The collaborative development of knowledge artifacts in this platform is supposed to be generally applied to a clinical proposal. The governance model in the present study intends to allow clinical and public management of health. Customized to attend the scene of the clinical record at the public health system, the model has the potential to meet the legal requirements, accelerating the process of the archetype development (steps highlighted in gray in Fig. 1). Besides, the introduction of management requirements to archetypal quality requirements seem to contribute to the reduction of rework of health professionals and was an innovation in relation to the works identified in Step 1.

This exploratory study had limitations. The number of studies identified in the review phase was restrained in the consulted databases. In fact, there are only a few reports focused on the health context of archetype management. Another limitation is regarding the generality of the results since the background reflected a local demand. However, this experience is important to support the organization of public health information in a scenario with initial EHR implementation.

Besides, the proof of concept did not test all the proposed flow (steps highlighted in gray gradient in Fig. 1). This made it impossible to assess the need to set the time for process

Table 2 Quality requirements, adapted from [23]

Requirement Type	Requirement
Clinical Requirements	Does the archetype meet the clinical guidelines proposed by the Unified Health System? In the absence of specific clinical guidelines, is the supporting literature specified? Was the material made available in the library for consultation of all the people involved?
	Is the archetype scope detailed and referenced?
	Should the proposed archetype compose the clinical summary? If so, was the archetype of the clinical summary updated?
SUS - Public Health Management Requirements	Does the archetype deal with any item monitored by Organizational Contract of Public Health Action, as defined by the book of guidelines, goals, targets and indicators? If so, does the modeling allow the reuse for monitoring?
	Does the archetype deal with any item monitored by Structuring Programs and Projects? If so, does the modeling allow the reuse for monitoring?
	Does the archetype deal with any issue monitored monthly? If so, does the modeling allow the reuse for monitoring?
	Does the archetype deal with any item that makes up data of a information system? If so, does the modeling allow the reuse for automatic feeding of the Information System?
	Were the mandatory requirements that may influence the time of treatment approved by the Information Technology Commission and, in case of divergence, led to approval in Inter-Managers Commission of Unified Health System?
Technical Requirements	Does the archetype follow the ISO 13606 reference model?
	Are the types of data used described in ISO 13606?
	Was the proper terminology used?
	Is there any duplication or overlap with existing archetypes?
Information Governance Requirements	Does the ID for archetype identification follow ISO 13606 Standard?
	Is the concept that the archetype represents specified?
	Has the original language of the archetype been identified?
	Are the author and collaborators identified?
	Is the purpose of the archetype identified?
	Is the version of the archetype higher than the last publication?
	Is it possible to identify the status of the archetype (Draft, Published, and Obsolete)?

participants to manifest about the archetypes that are being created or edited to avoid that the process is time-consuming and does not meet the dynamics of the evolution of knowledge in healthcare.

A positive experience came from the partnership with the Medicine Faculty of the Federal University of Minas Gerais. Through projects approved by the Research for the SUS Program, implemented the proposed archetype development process in an online system called Health Knowledge Manager. They tested the flow of interoperability between the EHR system and Clinical Hospital System through the obstetric discharge summary proposed by the ABNT Commission for Special Study on Health Informatics (ABNT/CEE-78 IS) [29–31].

The proposal follows what is internationally recommended (the adoption of a standard for the development of EHR, preferably with a two-level modeling, in this case, the ISO/CEN 13606 Standard). Therefore, it is expected that as the use of Health Knowledge Manager of many professionals occur a better semantic alignment of regional particularities and subtle differences pointed out by the authors about one same concept may occur, thus improving interoperability among EPR, continued care and supporting the achievement of the strategic vision of e-Health for Brazil [14, 15, 18].

However, to achieve a greater number of Health Knowledge Manager users it is necessary to engage researchers in this work, and there is still no proposal on how to ensure that participation in the archetypal governance process is considered co-authorship in technical work publication. These are important factors to ensure the participation of experts. Another challenge will be to mobilize the market for the adoption of standards since at MG does not have a financial program.

Conclusion

In recent decades, many countries have committed to achieve semantic interoperability in healthcare to provide clinical patient safety and hence the quality of supportive care [17, 32, 33].

From the results obtained and considering the proof of concept performed, the proposed archetype development process proved to be suitable for the EHR system and B-EHR to support the clinical record in the state network, also seeking both reduced rework and interoperability among information systems in healthcare.

The study is considered to have met the proposed objective. Also, the adaptation of the archetype's governance processes of SUS clinical record, with the inclusion of management requirements to quality requirements, added to the adaptation to Brazilian legislation on the storage of documents, have contributed to the development of knothe academyin academy and to the continued citizen care in Health Care Networks, thus benefiting society.

The study, however, was limited by addressing the clinical record in context of the public health system in the state of Minas Gerais, for the citizen has the right to choose where they want to consult (including the choice for supplementary health) and by the sample size used to perform the proof of concept.

Therefore, it highlights the importance of establishing confidentiality and privacy policies that allow data access and continuity of citizen care both at SUS and in supplementary health, ensuring a single record, to better support the assistance by health professionals to citizens.

In addition, as a contingency to limited sample and to improve the proposed process and the archetypes already developed, it is suggested, as a future study, the application of this model to other archetypes already developed using Health Knowledge Manager as a tool. In addition, a further study could be carried out to identify how easier the participation in this process is by health professionals who use the EHR system so that the EHR system and B-EHR are increasingly suited to the care needs of Brazilian Public Unified Health System.

Acknowledgements Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq), Fundação de Amparo à Pesquisa do Estado de Minas Gerais (FAPEMIG) and Secretaria de Estado de Saúde de Minas Gerais for the support to this research.

Author contributions Thais Maia – Data research, theoretical and final paper version.

Cristiana Fernandes De Muylder – Professor, researcher and advisor – Theoretical, data and final paper version.

Zilma S. Nogueria Reis – Theoretical and text analysis.

Funding This study was funded by:

• Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq) - CNPQ Productivity Grant - 308461/2017–7 – Cristiana Fernandes De Muylder.

• Fundação de Amparo à Pesquisa do Estado de Minas Gerais (FAPEMIG) - FAPEMIG Universal APQ-01938-15 – Cristiana Fernandes De Muylder.

• Fundação de Amparo à Pesquisa do Estado de Minas Gerais (FAPEMIG) - FAPEMIG Edital PPSUS, n° APQ-00879-12 – Zilma Nogueira Reis.

Compliance with ethical standards

Conflict of interest Thais Abreu Maia declares that she has no conflict of interest.

Cristiana Fernandes De Muylder declares that she has no conflict of interest.

Zilma Silveira Nogueira Reis declares that she has no conflict of interest.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

Publisher's Note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

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