COMPUTER METHODS AND PROGRAMS IN BIOMEDICINE 130 (2016) 198–204

journal homepage: www.intl.elsevierhealth.com/journals/cmpb

Proposed model for a Romanian register of chronic diseases in children

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ARTICLE INFO

Article history:
Received 19 July 2015
Received in revised form
6 January 2016
Accepted 28 January 2016

Keywords:
Disease register
Chronic disease
Children
Electronic health record
OpenEHR
Interoperability

ABSTRACT

Background and Objectives: The prevalence of chronic diseases at children is increasing due to the progress made in medicine, which radically changed the evolution and the prognostics. Disease registers became important tools to register and monitor the chronic patients in order to asses their needs and improve their care. Disease registers are also very important for adjusting to population needs the actions in the public health field.

The main objective for this research is to develop a model for a chronic disease register of children in Romania, taking into account the current situation of chronic diseases' registration and reporting, the specific requirements for such medical database and the particularities of the information systems in the Romanian healthcare system.

Methods: Our study was based on interviews with specialists and Health Ministry representatives, field observations, and analysis of published and unpublished data).

Results: We developed a platform for a chronic diseases register of children based on open EHR specifications and architecture, which respects the requirements for data security and the particularities of Romania's healthcare system. The model created is functioning on two levels. The first one is local and corresponds to a medical unit, while the second one represents the connection and the communication method within the entire national medical system. In order to achieve the highest level of interoperability at the semantic level, we used, for the communication module of a National Disease Register system, only EN 13606 or HL7 v3 and / or HL7 v3 CDA.

Conclusions: This model is functional and can be applied initially at a clinical level for medical and administrative purposes. Its design allows a future development, integrated with the current informational systems and implemented at regional and national level. This will significantly improve the knowledge that may support good medical practice in this field, will enhance the coherence of data collection and, as a consequence, will impact positevely on the health of children diagnosed with chronic diseases.

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http://dx.doi.org/10.1016/j.cmpb.2016.01.022
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1. Introduction

A disease register represent a database which contains information about the people diagnosed with specific diseases in a defined population [1–3]. Based on the information documented in this register, it is possible to achieve important objectives such as: monitor the disease's evolution and the active measures addressed to patients, improve the activity in the public health sector, and increase the level of medical knowledge which may support good medical practice in this field [1,4]. Beyond their importance in achieving these objectives, disease registers could be expensive and could demand a great deal of attention from the ethical point of view because of the concerns related to data protection [1,5,6].

Children represent 17% of the population in Romania [7,8]. The health and quality of their life depend very much on how the preventive and curative services are being planned and organized, on how and to what extent they collaborate, if they are designed from an interdisciplinary perspective and if they achieve qualitative standards [9].

According to the latest morbidity reports from school doctors (2012–2013 school year), the prevalence of chronic diseases in school children communities is 24.96%, increasing compare to the previous years, and varies by region between 3.14% and 45.68% [8,10].

The increasing prevalence of chronic pathology at children is the result of several factors: the progress made in medicine which radically changed the evolution and the prognostics, increasing concern for managing the complications and disabilities, and multiple reports of the same case [11–13].

The problem of children chronic diseases cannot be studied thoroughly due to the lack of a standardized national register aimed to facilitate real knowledge of the number, gravity and particularities in evolution of the cases. Without a national register it is also impossible to follow up and compare in dynamics, between different countries, the evolution of chronic pathology of children [9,14].

It is a known fact that the European Union (EU) current health information system does not always provide consistently high-quality and fully comparable information. Recognizing this challenge facing the health information system, the European Commission (DG Health and Consumers together with Eurostat) is actively working to improve the mechanisms for health reporting and to develop operational systems for collection of data on the state of health of populations [15]. The possibilities for developing national registers vary between countries, depending on priorities and factors such as population size and data protection considerations. The development of European registers will depend on national developments [16,17].

The Romanian National Public Health Strategy sets as specific objective [18], in accordance with WHO recommendations, the development of an operative system to monitor chronic diseases of children (cardiovascular, respiratory, digestive, renal, hepatitis, diabetes). However, this is yet to be achieved [19].

2. Materials and methods

The authors of this paper performed a study that had as main objective the creation of an electronic model for a register of children chronic diseases.

The specific objectives of this study were: (1) to establish the most relevant and useful data to be included in the register; (2) to develop the electronic model for registering and monitoring the cases of chronic disease of children based on the data previously identified, while respecting the standard's requirements; and (3) to test the feasibility of the model in order to identify the problems that may occur and to put in place the procedures for registering and processing the data.

We observed and analyzed the current practice existing regarding the recording, following-up and reporting the cases diagnosed with a chronic disease, in both general and children population. For determining the relevant data to be introduced in a register of chronic diseases of children, we performed interviews with pediatricians from university pediatric clinics, representatives of county public health authorities (which are the representatives of Ministry of Health in the territory), public health specialists, family doctors and school doctors.

In order to accomplish the proposed model, we have studied the practice existing in other countries and analyzed the technical possibilities in order to choose the most stringent need: to develop and extend this model in the future. Also we took in account ensuring the compatibility with the existing systems used to report medical data.

3. Results and discussions

3.1. *Current practice regarding morbidity reporting in Romania*

The healthcare reform law no. 95/2006 regulates the public health activities, the funding process of the health services, storing and transferring data within the system, the communication method and using of the medical records [20].

The current rules provide that the data regarding chronic diseases at children are gathered from three sources: family doctors, school doctors and hospitals. Their reports are recorded on different report sheets configuration, with different frequencies of reporting.

From 2007, the National Health Insurance House introduced a software product in order to obtain and to feed data from family doctors and hospitals [21].

Family doctors are using the single integrated information system (SIUI) to report the prevalence of chronic diseases quarterly, by group ages (from five to five years) and by International Codes of Diseases 10th edition. Until 2014, the family doctors reported the morbidity on different age groups, situation that makes it difficult to follow up in time the prevalence of chronic diseases, especially at children.

The school doctors report annually the prevalence of chronic diseases at pupils they are assisting, at the end of the school year, by specific required disease groups (different from those from the family physicians' report sheets) and by age

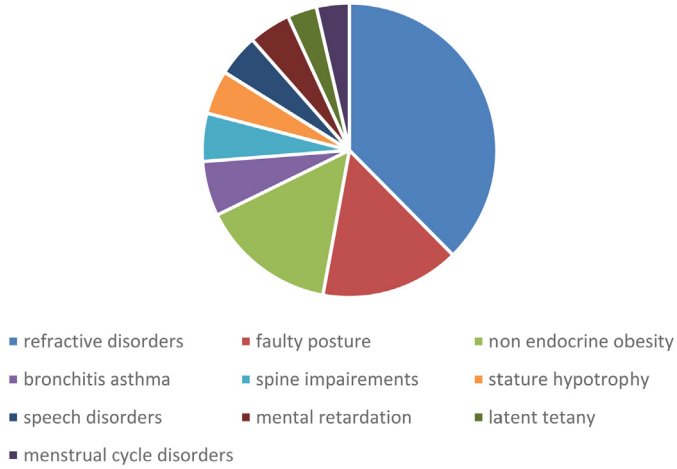

Fig. 1 – Children chronic disease in Romania.

groups according to the children's study levels (1st, 4th, 8th and 12th grades).

The hospitals are reporting a minimal set of data for each patient admitted in the hospital monthly, through the Diagnostic Related Group system (DRG).

The County Public Health Authorities are gathering the morbidity data from all the sources mentioned before, and send it to the National Institute of Public Health, which is in charge with their centralization and review.

We have identified the following problems that are influencing the knowledge of chronic morbidity in children population:

1. The data are not collected in a unitary, integrated system; we have three parallel ways of reporting medical data: SIUI, DRG and MS-Office Excel files;
2. Not all the schools (particularly those from rural areas) have school doctors to register, monitor and report annually the chronic diseases. This responsibility is assumed by the family doctor who has to report chronic morbidity in two different forms;
3. Children with chronic diseases access and use different medical services, and each service has to register the case and report it further to County Public Health Authorities. Therefore it is not unusual for one case to be reported multiple times – for example a child with asthma may be in the evidence of the family doctor, school doctor, allergist and pneumologist [10];
4. The current register for chronic diseases is only on paper format; therefore only the doctor who administers it can access the information noted on it.

In our research we discovered that the only available national data regarding chronic morbidity in children population is the one based on the reports from school doctors. After analyzing these reports, we concluded that from a total of 63 chronic conditions included in the report form, as few as 10 represent 70% of total prevalence. These are: refractive disorders (26.40%), faulty posture (10.75%) non endocrine obesity (10.44%), bronchitis asthma (4.23%), spine impairments (3.72%), stature hypotrophy (3.39%), speech disorders (3.25%), mental retardation (3.24%), latent tetany (2.28%) and menstrual cycle disorders (2.54%) [8,10] (Fig. 1).

3.2. *Proposed model of chronic disease register*

We designed the register following the pattern of the current used medical chart, with general data (demographical) and medical data that is required to be completed.

The general data refers to: location (county, town, medical unit), name, gender, date of birth, residence, nationality, weight at birth, weight (for children under 1 year), log date, date of current admission, reason for the current presentation, mother and father's name (or of legal tutors), mother's occupation, mother's level of instruction, data from mother's identity card and from the child's birth certificate. The medical data fields include: medical history, symptoms, clinical examination, laboratory examinations, other investigations and treatment.

Based on our discussions with pediatricians and other countries' practices [1,3,5,22–29], we concluded that a register for chronic diseases in children should include those diseases which, due to their gravity, have the potential to develop serious complications, may affect the children's evolution and their future adult life and whether or not there is the need for care from a multidisciplinary perspective. Therefore we developed fields for laboratory examinations, other preclinical investigations and treatment for only 20 groups of chronic diseases. The included groups of diseases are congenital heart diseases, hypertension, diabetes mellitus, obesity, celiac disease, inflammatory bowel diseases, hepatopathies, malformations of urinary tract, chronic renal diseases, bronchial asthma, cystic fibrosis, rachitis, juvenile idiopathic arthritis, systemic lupus erythematosus, anemia, Kawasaky disease, Henoch-Schonlein purple, hemostasis disorders, acute lymphoblastic leukemia, and non-Hodgkin lymphoma.

For all these diseases we set the mandatory investigations essential for the diagnostics, which further were developed in fields mandatory to be filled in (otherwise the case cannot be registered in the system).

3.2.1. *openEHR specifications*

In order to accomplish the proposed model, we have studied the existing practice in other countries and analyzed the technical possibilities in order to choose the appropriate one for our need to develop and extend it in the future. We concluded that openEHR is a solution to create a versioned and distributed EHR infrastructure. The openEHR specifications [30] are developed by an independent nonprofit community and try to offer a solution for a lifelong electronic health record, for the confidentiality of the medical information, for supporting the clinical decision and for the necessary semantic interoperability [31].

The key innovation of the openEHR architecture is the two-level modeling structures obtained by separating record keeping concerns from the clinical data collection using archetypes [32,33].

The first level, i.e. the reference model, is used to represent the generic properties of the health record information. It represents the global characteristics of the health record components, the way they are aggregated and the context information required to meet ethical, legal and provenance requirements. This model defines the set of classes forming the generic building blocks of the EHR. It reflects the stable characteristics of an electronic health record [30,34].

The second level, i.e. Archetypes and Templates, is the meta-data used to define patterns for the specific characteristics of the clinical data representing the requirements of each particular profession, specialty or service. This level creates a semantic link to the terminologies, clinical guidelines and classifications in the EHRs. The Archetypes are developed by medical staff and, basically, represent a set of constraints on the openEHR Reference Model. Archetypes are all expressed in the same way. In general, they are defined for wide re-use; however, they can be specialized to include local particularities. They can accommodate any number of natural languages and terminologies [32].

3.2.2. *Communication standards*

Before designing the Disease National Register that would communicate with the existing medical solution, we studied what medical interoperability standards currently exist [35].

3.2.2.1. HL7 v2. HL7 v2 is the health's clinical and administrative data exchange standard. It's developing process started way back in 1989 and is based on external events. This standard uses a human-readable encoding ASCII. Even though it is the most used and implemented standard in the world, it is still a "non-standard standard" [36], due to several aspects: the built interface can interpret the same message differently; it uses a large number of optional segments and sub-segments; and the property's segments can be used without respecting the standard. The main idea behind the creation process of this standard – the flexibility – led to its large adoption, but now represents its biggest problem. HL7 v2 does not ensure semantic interoperability.

3.2.2.2. HL7 v3 and HL7 v3 clinical document architecture. Between 1994 and 1997, HL7 started to design a completely new version of the above standard, called HL7 v3. It had the same goal, to create a method that facilitates the exchange of medical information. This new standard was built from scratch, because the HL7 developing board decided not to be constrained by the predecessor. They started to use another human-readable standard (XML) for data encoding, but they encountered another problem: HL7v3 is not backward compatible with HL7v2. This led to a low ratio of the adoption by the software designers and did not reach the success that the HL7 had hoped.

The next step of the Health Level Seven Organization was to develop another standard used for document mark-up. This one also uses the XML encoding standard and tries to specify the semantics and the structure of the clinical documents in order to prepare them for the exchange process between different healthcare providers and patients [37].

3.2.2.3. EN/ISO 13606. EN/ISO-13606 is a European Communication Standard and the first part of it is an ISO Communication Standard. It derives from the Electronic Health Record Communication Standard ENV13606. This new Electronic Health Record Communication Standard is an extract of openEHR and, according to a report of the European Union, complies with the highest level of interoperability [38,39].

Taking into consideration that EN/ISO 13606 represents a subset of the full openEHR specifications, a system based on openEHR information model can easily comply with EN/ISO 13606 communication standard and can solve the semantic gap between health professionals and IT professionals (Fig. 2) [40–42]. The dual model architecture of openEHR and EN/ISO 13606 also influenced the Clinical Document Architecture of HL7.

3.2.2.4. Preliminary conclusions. To achieve the highest level of interoperability at semantic level we took into consideration only using EN 13606 or HL7 v3 and/or HL7 v3 CDA for the communication module of a National Disease Register system.

Most of HL7 v3 and HL7 v3 CDA primary shortcomings are coming from the usage of HL7 RIM [43]. One of the main problems is that the usage of coded text (that can be interpreted by computers) is not required; also the constraints are not well supported by HL7 v3.

The primary shortcoming of the EN/ISO 13606 standard is that it is new, even if a lot of enthusiasm is shown in the community due to the dual model approach.

The starting point in developing the platform was the mapping process of every concept from these results to a specific openEHR archetype or element. Even though most of them could be found in the international repository of the openEHR Foundation, in the interviews and surveys results there were a lot of particular elements only for the Romanian healthcare systems. For those elements the team had to develop or extend some archetypes. All the archetypes created or extended follow the openEHR specification.

Fig. 3 (left side) presents an excerpt from the definition part of the created archetype for personal details and in the right side the interface can be found.

3.2.3. *Platform architecture*

In terms of functional and technical architecture, the proposed solution can be considered from two separate perspectives.

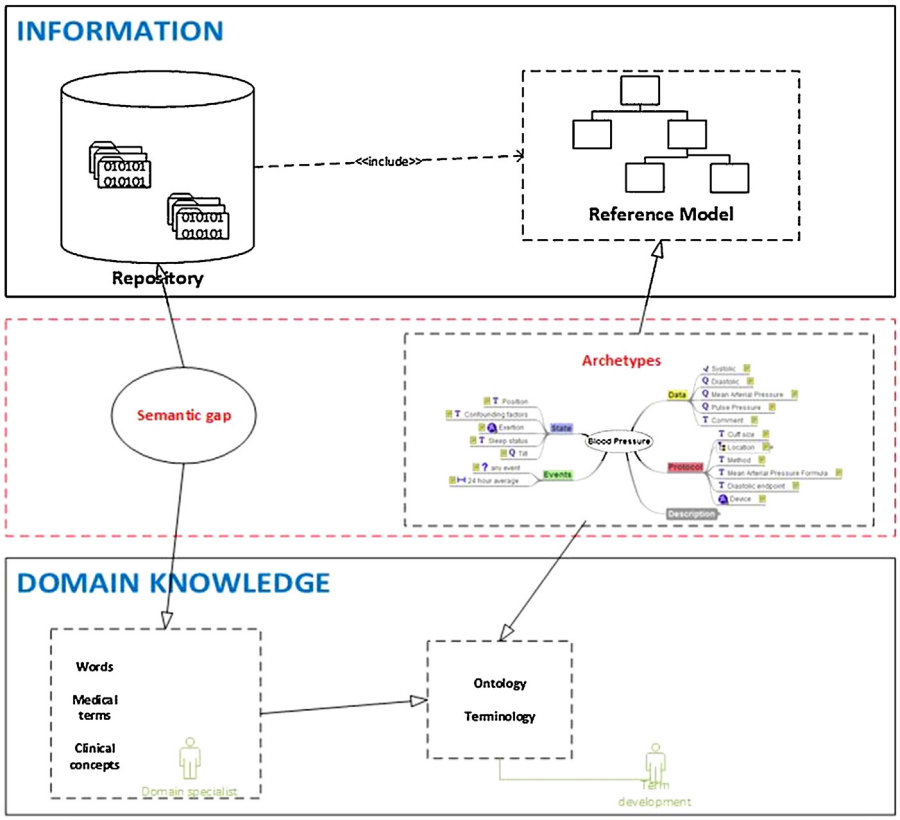

Fig. 2 – Solving the semantic gap.

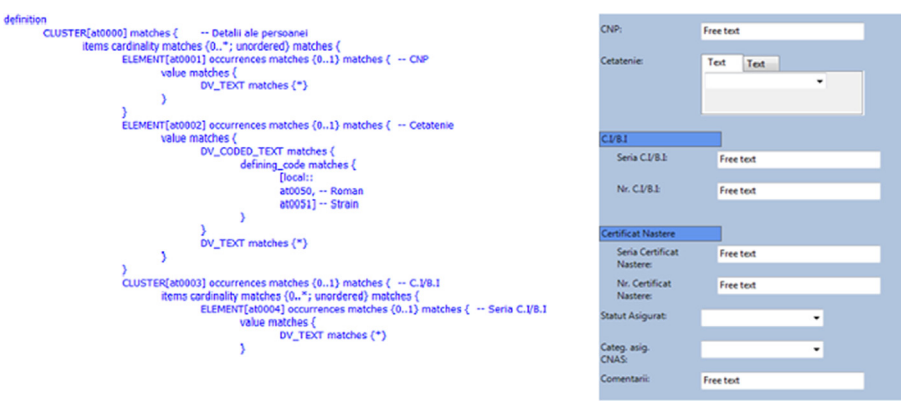

Fig. 3 – Person details archetype.

The first one is the local level and corresponds to a medical unit, while the second represents the connection and the communication method of the entire medical system in Romania.

At local level, the software architecture refers to the component to be used in order to obtain an EHR at a medical clinic. The software was designed on three levels: the data level, the control level and the presentation level.

The data level is used in order to store the system's information in a secure environment. To increase the system's security, the medical information is stored separately from the demographic information. As such, there are three databases: *Med* (managing the medical information), *Dem* (managing the demographical data) and *Index* (which is encrypted and correlates Med and *Dem*).

The presentation level basically presents and acquires data from and to the user. It represents the proposed solution's user interface.

The middle level, the control, includes the methods, processes and mechanisms used to create and store the operational templates according to openEHR Specifications, to create and save the data in composition and then in the database, to validate them and to display and search the patient's file.

The National Level (Fig. 4) details how to interconnect different local unit systems in order to create a national network. Our platform is based on a National Reference Registry and a National Archetype Repository. For communication we used the EN/ISO 13606 standard.

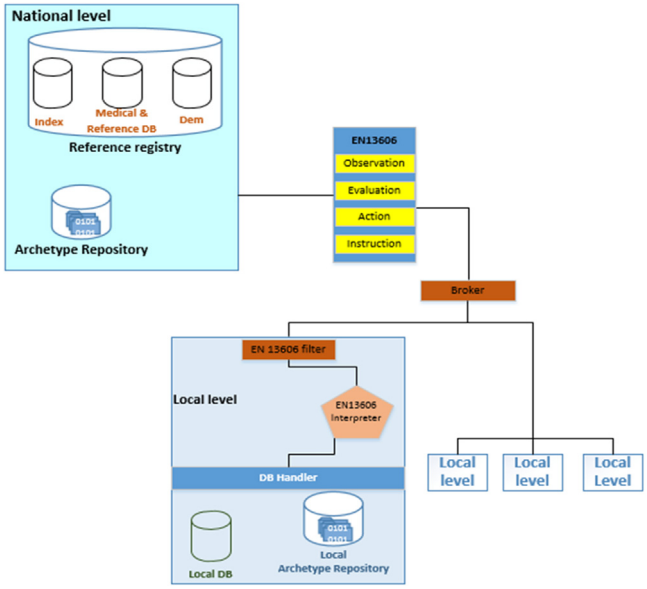

Fig. 4 – System at national level.

The National Archetypes Repository contains all necessary archetypes defined at national level in openEHR format. These are used to ensure the highest semantic interoperability level. For speed and stability reasons, each archetype is saved locally. When changes occur within an archetype, a new version is created; the previous one is not deleted and is used for compatible older records. All the medical units are notified about this change through a SOAP message, so they can download the new version.

The National Reference Registry is an index server storing links to the patients' data. This is the most important component and it contains demographic and certain medical data (ex: allergies, insurance type, and epicrisis). This approach has the advantage that it avoids overloading the system with data. However, a minimum of information must be doubled at national level because, in the worst-case scenario, there may be a time when a link to the medical facility that has the information cannot be determined.

3.2.4. *System testing*

System testing means checking that the system's components comply with the original specifications. This process occurs after integration testing and before acceptance testing. In fact, the entire testing process includes testing the sanity system, installation testing, functional testing, security testing, usability testing and accessibility testing, performance testing and regression testing. To ascertain these, we respected the functional specifications of the application, while we tested both manually and automatically. For the manual test we used the concept of "end-to-end".

After testing the experimental model at local level, we tested it at national level. This process basically involves examining the application for data transfer.

In order to accomplish the communication process, the application needs a Web service, which is a software system designed to support interoperable computer–computer interactions within a network. The communication system uses three components: SOAP (Simple Object Access Protocol), UDDI (Universal Description, Discovery and Integration) and WSDL (Web Services Description Language).

Communication between hospital units involves transfer of medical records, and the ability of the receiver unit to take the correct information and to process it for display. For this purpose, we designed and implemented the process transformation of data from openEHR format to EN/ISO 13606 format. As stated in Section 3.2.3, the medical information is stored in hospitals as dictated by the openEHR standard. Before the transfer they are converted to EN/ISO 13606, and then transmitted in this form. The receiver medical unit displays this information only to the authorized users. For this process we used two documents containing XSLT processing rules: one for data transformation openEHR in EN13606 and one for extracting necessary information received from the transfer.

4. Conclusion

We developed an electronic model for a children's chronic disease register, compatible with the current medical chart, respecting particularities of the Romanian healthcare system regarding the existing information systems and the requirements regarding data protection. Our platform is design based on openEHR architecture and specifications and for communication we use the EN/ISO 13606 standard.

It is our firm intention to develop this platform in the near future, in order to be implemented at regional and national level.

Authors' contribution

Florina Maria Gabor-Harosa: conception and design of the study, acquisition of data, analysis and interpretation of data, drafting the article, and final approval of the document.

Ovidiu Petru Stan: design of the study, analysis and interpretation of data, and drafting of the article.

Lucia Daina: critically revise the article for important intellectual content.

Floarea Mocean: critically revise the article for important intellectual content, and final approval of the document.

Acknowledgement

This paper was published under the frame of European Social Fund, Human Resources Development Operational Programme 2007–2013, project no. POSDRU/159/1.5/S/138776

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