A HIERACHICAL MODEL FOR MEDICAL REGISTRATIONS

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Abstract

The aim of this paper is to improve solutions for developing and improving medical and pharmaceutical services. We made a SWOT analyze of SIUI in order to build a document management system and create medical registration papers, based on collaborative editing and international medical standard. This model was focused on hierarchical decomposition of PHR and EHR records, using modular solution, which stores all data in XML files. It requires a system that is simple to use and allows users to focus their efforts on the content rather that on the technology used to create it. This approach allows a great flexibility in handling document and user interaction.

Keywords: medical registrations, HME standards, PHR, SIUI, hierarchical decomposition

Introduction

Medical registrations are longitudinal electronic registrations of information about a patients' health, generated by one or more meetings between the patient and their doctors from any medical assistance point. This information includes demographical data about the patient, progress notifications, prescriptions, medical history, immunizations, laboratory data and H.I.M.S.S. reports. Medical registrations automate and rationalize workflow and have the capacity to generate a complete report about a patient. Furthermore, medical registrations have the ability to support many other direct or indirect related activities in health care business, for example, the proof based decision support, quality management support and results report support [1].

In Europe, CEN/TC 251 is the official authority in medical informatics standardization field. This authority has the competence and responsibility to organize, coordinate, and monitories activities to develop standards in medical informatics field, as well as in promulgating them [2]. CEN/TC 251 principles are [3]:

1. medical informatics has a global meaning of informatics for health insurance;
2. one should not over-standardize;

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3. one should use bottom-up (users needs) or top-down complementary models and both of them should be applied at all levels of development to ensure work sharing, which strongly influences effort and determines success or failure;
4. work duplication must be avoided;
5. international collaboration must occur to avoid conflicts;
6. make standards more compatible;
7. work will begin only when a standard is necessary and needed by users.

This article presents the design of a solution, implemented by family doctors, beginning from formalizing xml. In the first section, we will present medical standardization aspects, the second section treats security issues in medical software and in the third section, we present an HME design, based on a SWOT analysis, solving all the weaknesses pointed in HME.

Standards in Medical Field

Globally, the main authority concerning standardization is ISO (International Standards Organization). Technical committee TC 251 is the authority that is responsible for the medical field. In Europe, the activity of standardization is a part of CEN (Comité Européen de Normalisation). In 1991, inside CEN, technical commitee for medical informatics TC 251 was founded. The work program of CEN/TC 215 called „Directory of the European Standardisation Requirements for Healthcare Informatics and Telematics. Programme for the Development of Standard" was approved in december 1995 [4].
The main organizations involved in standardizing medical field are: **ISO** – International Organization for Standardization, **ISO/TC 251 -** Health Informatics, **CEN** – European Comittee for Standardization, TC 251, **ASTM** – American Society for Testing and Materials, **OpenEHR** – Open Electronic Health Record Fundation, **HL7** – Health Level 7, **EHTO** – European Health Telematics Observatory, **ETSI –** European Telecomunication Standards Institute, **IEC** – International Electrotechnical Comission, **IMIA –** International Medical Informatics Association and **UN/EDIFACT** – United Nations directories for Electronic Data Interchange for Administration, Commerce and Transport. ISO/TC251 has a few working groups: **ISO/TC 251/WG1 –** Health Records and Information Modeling Coordination, **ISO/TC 251/WG2** – Messaging and Communication, **ISO/TC 251/WG3** – Health Concept Representation, **ISO/TC 251/WG4 –** Security, **ISO/TC 251/WG5** – Health Cards, **ISO/TC 251/WG6** – Pharmacy and Medication Business [5], [6].

Nowadays, specific IME Standards are being developed. They refer to the definition and the purpose of IME systems, types of data and data codification, detailed specification of software systems that save data and documents, and the modalities of exchanging medical information. Main standards are: **ISO DTR 20514** – EHR definition and scope, **ISO TS 18308** – EHR Requirements, **CEN TS 14796** – Data Types, **CEN/TC 215 EN 13606** – EHR Communication, **HL7** – EHR Functional Specification, **HL7** – Template Specification, **HL7** – Clinical Document Architecture, **DICOM** – Digital Imaging and Communication in Medicine, **EDIFACT, XML** – Messaging standards [6].

Health Level 7 (HL7) has been developed in a public-private framework. The standard has been highly accepted by users and companies, and has been imposed as the main

standard for exchanging electronic information in medical field. The standards major objective was to facilitate message exchange between applications that manage medical data. HL7 Methodology is based on the acceptance that an occurred event in the medical act determines a message exchange between two or more applications. For example, a patients' hospitalization determines the need of collecting information about him and the need to transmit them to other systems [7].

Features of Security in HME Systems

Security is a process, a way of thinking linked to systems, networks, users and applications built upon a specific set of technologies. The minimal set of requirements that a secure application has to meet includes: **Confidentiality –** maintaining the private character of the information, **Integrity** – proofing that a specific information was not modified, **Authenticity –** proofing the senders' identity, **Non-Repudiation** – security measures that make sure that the sender will not denigrate the massage after sending it [8]. In the first part of 2010, two ISO documents were created. The objective of these documents was to secure medical recordings. The documents impose international harmonized directives for archiving information about patients: **ISO/TS 21547:2010** and **ISO/TR 21548:20101**. **ISO/TS 21547:2010** standard – Informatics in medical Field, includes security requirements for archiving electronic registrations about a patients' health. It sets forth the indispensable, fundamental principles for long-term protection of the medical data, regardless data's format. Archiving is seen as a holistic process that includes information management, keeping, sharing and destroying registrations. **ISO/TR 21548:2010** – Complementary directives referring to ISO/TS 21547, is a standard that sets forth the main directives about how the first standard should be applied. Nevertheless, it includes security requirements regarding medical archives. This informative report sets up a method and the required practical tools for creating and managing electronic archive [9].

A New Approach for HME

1. SIUI Features

The National Health Insurance House (CNAS) administration is doing its best to improve substantially the health insurance system and the quality of medical and pharmaceutical services in Romania. Thereby, CNAS has implemented a unique, integrated, computer system, called SIUI. SIUI is essential for developing and improving medical and pharmaceutical services. Nevertheless, SIUI is a solution for improving the unique, national insurance fund management and for offering improved medical services for insures. SIUI is extremely important for achieving health virtualization, for standardizing the national and zonal reporting and medical data management system. It can be easily aligned to the international standards so it could exchange information with other foreign authorities as well [10].

A consortium formed by Hewlett-Packard (HP) – system integrator and computer infrastructure provider; STS (Special Transmissions Service) – specialist in telecommunications; and SIVECO Romania – specialist in designing, developing and installing applications; is working to create SIUI [11]. **DOCS MF** is the user's guide for

DOCS application. It was conceived, especially, to help doctors use the application [12]. DOCS MF was designed to be used in family medical cabinets, to improve the consultation process, introducing patients' information in databases, completing the predefined documents and for managing and reporting information to CNAS, SIUI and ASP (Public Health Administration) as well. The application was created by SC SEFAS Data System SRL [13]. Main functionalities of DOCS are [14]:

- Imports information from SIUI and PNESS (National Program for Health Evaluation);
- Manages the patients from the doctors' list;
- Manages consultations – symptoms, alerts, diagnostics, medication, sending tickets;
- Manages all chronicle patients;
- Manages appointments;
- Prescribes milk powder for infants;
- Prints the register;
- Prints the consultation sheet;
- Prints predefined documents – receipts, sending tickets, medical dismissal, reporting documents;
- Creates synthesis reports for SIUI and ASP;
- Calculates the money amount gained from the services;
- Automates reporting;
- Ensures e-mail feedback and intelligent search;
- Works in networks; users can work on more than one document if proper access rights are set.

Heaving into consideration the family doctors' activities, the central point of the application is the consultation. Thus, the application allows the user to add new patients or update information about an existent one. At the patients' level, users can complete their antecedents, their medical alerts and their illness history. The application allows inserting information about pregnant women in the database, as well. At this same level, users manage deceases and removed patients. In the *Persons* module, users can search patients in database using the following criteria: CNP (Personal Numeric Code), patients' name, insurance category or locality. Beside these criteria, one can search patients by: **insured quality** (all those who are or are not insured) or using the **Personal doctors' list** (all patients who are in the doctors' current list).

Because all medical information (symptoms, diagnoses, medication, sending tickets and medical dismissals) has a direct common link with consultations, one can say that consultation is the central part of the application. Introducing consultation data, a user has to fulfill, in order, all of the following fields: Patients' name, Year and registers' number, Location, Consultations' type, Doctors' name. In DOCS application, there are two ways a user can generate new consultations. For chronicle patients, a user can generate the consultation sheet, using the predefined prescripts model. For non-chronicle patients they have to create a new sheet. In both cases, the fields that need to be completed are obligatory and identical.

In case a person was selected, the user can see patients' medical alerts and chronicle illnesses. To be able to move to the second step, the user has to complete the following fields: Register number, location and consultation type. To add services users have to choose the person, the diagnosis, and a date. The services are filtered by: the pack of services (no category or expired category, facultative, European card, any other category), patients' age and gender and time range between last service was provided and current date – because no service can be provided two times in the same day. The filtered services can be filtered again by General Services, Immunizations, Pregnant Women, and Permanents. A service can be deleted from a report sheet only if it has not been already reported.

Data import from CAS is an extremely important process for populating the application database with each doctors' patient list and for updating these data using the information received from CAS. Furthermore, it is an important process for calculating capitation.

Reporting to CAS (using module 6: Reports) can be made using operations like *reports adding*, *correcting reports* and *old version or new version report*. **Report update** is realized if no report has been made for the current month. In case of an existing report for the current month, the following reports become *Correcting reports*. **Managing capital reports** is a process that occurs before capitation reporting. All updates on person information made by the doctor must be visualized and reported. The application allows users to follow and print all updates (inputs, outputs, modifications) using the *Centralized Printing* module. **Managing service reports** is a process that allows users to print services' annexes, including the CNP sorted list. Transmitting reports to CAS using the **Reports Transmission** module is possible using a magnetic support (floppy disk, CD, memory stick). Another way of transmitting reports is e-mailing it directly to CAS. Files have a predefined format – month, year, doctors' signature and a delimiter *Misc* for updates and *Serv* for services.

2. SWOT Analysis

For defining the strong and weak points of the application, we have created a SWOT analysis.

Strengths:

- Reporting is an easier process;
- Statistics can be easily made;
- Reporting to CNAS is a fast process;
- Patients' information security is high because of the login module for doctors;
- Financial process is easy.

Weaknesses:

- Drugs' database is incomplete. Many of Drugs' classes are missing, especially the Drugs' classes that do not appear on the compensated medication lists.
- In case doctors do not remember the diagnosis' code, they cannot use the application unless they access the codes specified in OMS. This will have a big impact on the speed of introducing the diagnosis.

- Diagnoses are defined using the old terminology. With the medicine evolution, a new terminology appeared. This new terminology was not updated in the application.
- There are some diagnoses that cannot be found in the application, for example Onychomycosis (nails fungal infection), Chronicle Mumps (chronicle inflammation of mumps), and Lingual Mycosis (fungal infection of the tongue).
- The application supplies inexact definitions for diseases, for example, the Congenital Pancreatic Cyst appears as the patient has a pancreatic cyst since his birth. There are other known forms of the pancreatic cysts that do not appear in the application, for example the pancreatic cysts that appear during the patients' life (Mutinous Pancreatic Cyst, Multiple Pancreatic Cyst).
- Erroneous information appear in the application: a patient can appear as not having a health insurance even though he has one. CASS sends the database that includes such mistakes.
- Some patients appear as excluded from doctors' list. If the list is updated when a doctor is working with a patients' file, the application will mark exclude the patient from the list as if he moved to another doctor.
- CASS sends database to all doctors every end of month. The database includes the deceased patients as well. More than that, they appear as insured patients. This is a major error because the application will erroneous calculate the income of a cabinet. If the doctor does not perceive the mistake, CASS will fine him.
- The doctor spends a lot of time with data update. Thus, the administrative process is not improved.
- Reporting to ASP (Public Health Administration) is a difficult process because the diseases' codes have to be introduced in the system depending on age category, all year long.
- Home consultations services will be interpreted by the system as normal consultations even though they were provided outside doctors' schedule. Consultations made outside the program should be marked whit 10 points, meaning that they bring more money to the cabinet. Normal consultations have no value, meaning that they do not bring any money. Thereby, this is a big error as well.
- The "Consultations" and "Diagnosis and medication" modules include some irrelevant fields that must be filled in. Thus, the working process on these modules is quite a waste of time.

Opportunities (if errors were corrected):
- The application would support patients' medical care services; more than that, it could improve the services' qualities.
- The application would increase doctors' productivity and would decrease the administrative cost.
- The application can be easily adapted with future technology, politics, management and the medical care services financing.

Threats (if errors were not corrected):
- Medical cabinets could go bankrupt.

- Bureaucracy will increase. This mean decreasing medical service quality, concerning consultations, hygienic-sanitary advises and treatments.
- The errors would generate an enormous waste of supplies.

3. Modeling Solution for Personal Health Record

The proposed system will use Internet technologies; it will be accessible to patient itself from any location that is available for an internet connection that can be accessed by any authorized medical system membership. According to described standards, we implement a DMS that uses two kinds of records: PHR and EHR, both structured in Xml formalization approach, in order to obtain several links with laboratory, doctor, surgeon, dentist and patient.

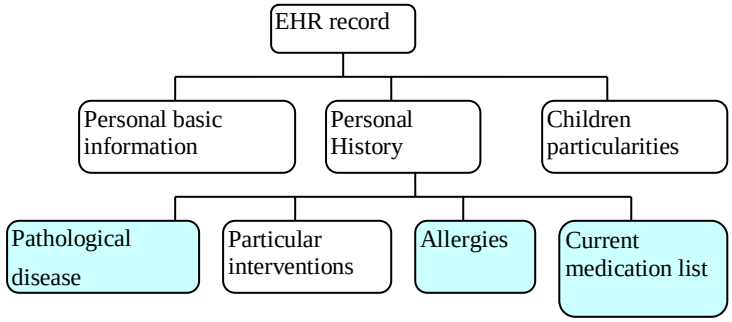

Figure1. EHR hierachical decomposition

The structure of EHR health record has three parts: *Personal basic information*, *personal history* and *children particularities*. Personal basic information consists in birth date, name, age, sex, address, Profession /Job, Birthday Prescriber, personal doctor (name, unique national code and email) and family history. This last field contains details about both parents and it is required only for children (Figure 1).

Personal history has been hierarchies in *Pathological disease*, *Particular intervention*, *Allergies* and *Current medication list*. If patient has one or more of listed *pathological disease* (diabetes, anemia, heart disease, rheumatism, CA, ASO) *current medication list* contain more than one medicine. In addition, if the patient has *allergies*, he/she will point which one it is and he will fill *current medication list.* Workflow will check *Pathological disease* and *Allergies*, and follow special branch for treatment. For orthodontics treatments, children (or their parents) will fill the section children particularities and family history [16].

Based on Role Based Access Control, we define several factors involved in this project: doctor, patient, dentist, specialist and surgeon. Patients can add/remove/change information from several categories: *Personal basic information*, *personal history* and *children particularities*. In addition, he/she can see the EHR file or children's EHR file. Doctor or dentist can manage *Personal history* with all hierarchies (*Pathological disease*, *Particular intervention*, *Allergies* and *Current medication list)*and Specialist will give the *Pathological disease* and *Current medication list*, at the moment or some specific analyses on demand (special treatment or clinical intervention). Surgeon can view the

patient health record and fill the statement and details about clinical intervention and *Current medication list* [17].

In addition, every treatment or clinical intervention will be recorded in EHR by using appropriate form, filled by dentist or surgeon, which contains several treatment information: date, tooth number, type of intervention, medicine and costs.

Thereby, to correct the SIUI weakness, we propose a conceptual model for *Simptoms* and *Diagnosis and Medication*, based on hierarchical decomposition, using three level.

Symptoms (Figure 2):
A1. – Symptoms classification (text box)
A2. – Observation (list box)
- B1. Initial
- B2. For control

A3. – Personal data
- B3. Arterial tension (text box)
- B4. Ventricular allure (text box)
- B5. Heart rhythm (list box)
    - Rhythm
    - Arrhythmic
- B6. Height (text box)
- B7. Weight

Diagnosis (Figure 3):
A1. Diagnosis (smart search field)
A2. Diagnoses type (list box)
- B1. Acute
- B2. Sub acute
- B3. Chronic
- B4. Prophylactic

Medication:
A3. Adding historical data (for chronicle patients)
A4. Adding from the list
- B5. Drugs (smart search field)
- B6. Quantity (text box)
- B7. Administration mode (list box + text box)
- B8. Treatment schema (list box + text box)

A5. Modification
A6. Deletion

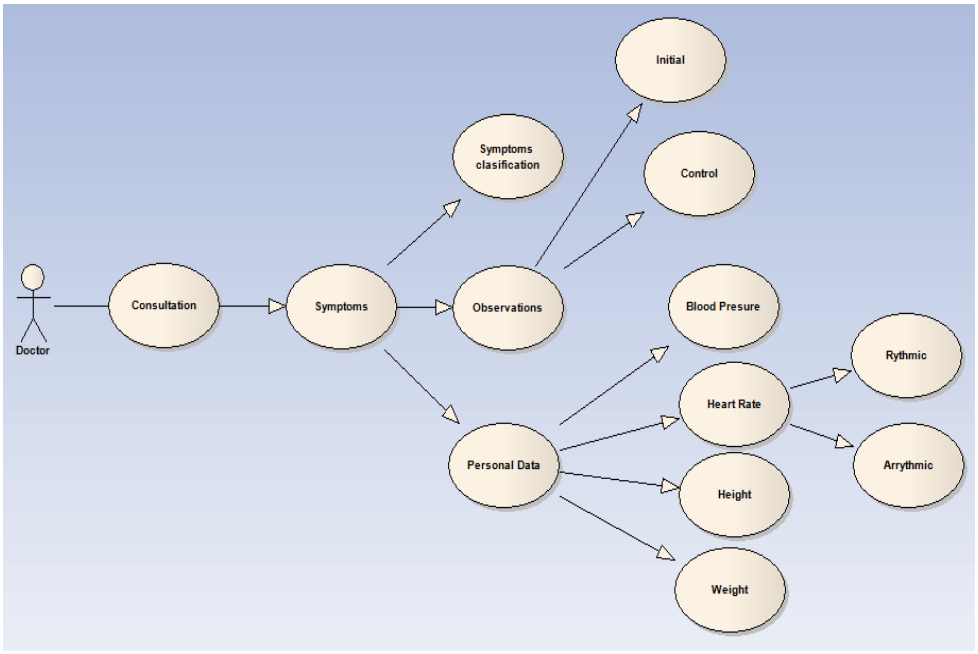

Figure 2. Symptoms

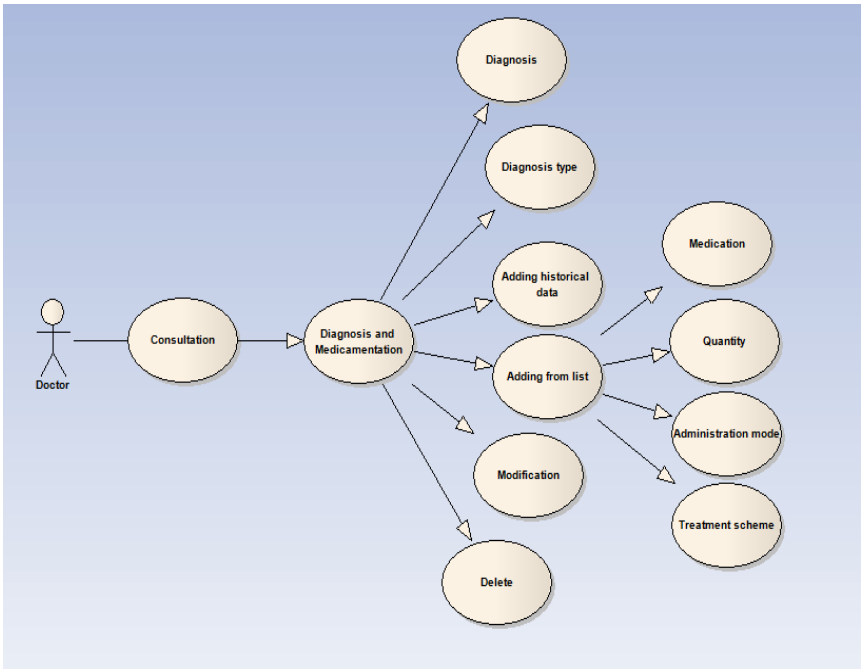

Figure 3. Diagnosis and medication

Conclusion

Based on EHR standards we analyzed SIUI, a national system for developing and improving medical and pharmaceutical services. SWOT analyses shows several strengths,

focused on reporting, financial situations and security, but also many weaknesses and threats.

We developed a document management system model to support the space independence of the doctors and integrate their collaborative effort in a common workplace in order to obtain greater team efficiency in medical act (diagnose and treatment). Our model was based on opportunities assuming that SIUI errors were corrected by implementing this model, in order to improve the services' qualities, increase doctors' productivity and decrease the administrative cost. This approach was implemented with a RBAC, according to EHR ISO recommendations, but also based on documents workflow from dental organizations and hospitals. The model design uses modular approach, and the document type definition files describe the structure of the documents and all metadata that can be added to them, according with international standards, and medical requirement. We show use-case for symptoms and for diagnosis and medication.

We have chosen this modular approach based on document types and user interfaces particularized on roles/rights and document types in order to facilitate further development of the system in such a manner that it could handle more.

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