Abstract. The comparison of the patient's current medication list with the medication being ordered when admitted to Hospital, identifying omissions, duplications, dosing errors, and potential interactions, constitutes the core process of medicines reconciliation. Access to the medication the patient is taking at home could be unfeasible as this information is frequently stored in various locations and in diverse proprietary formats. The lack of interoperability between those information systems, namely the Primary Care and the Specialized Electronic Health Records (EHRs), facilitates medication errors and endangers patient safety. Thus, the development of a Patient Summary that includes clinical data from different electronic systems will allow doctors access to relevant information enabling a safer and more efficient assistance. Such a collection of data from heterogeneous and distributed systems has been achieved in this Project through the construction of a federated view based on the ISO/CEN EN13606 Standard for architecture and communication of EHRs.

Keywords. Medicines reconciliation, patient safety, semantic interoperability, patient summary, archetypes.

Introduction

Medicines reconciliation, or in other words, assuring medication accuracy at the transitions in care, is considered a vital tool to improve patient safety. In fact, it is one of the "Nine Patient Safety Solutions" [1] described by the World Health Organization to help reduce the toll of healthcare-related harm affecting millions of patients worldwide.

Medication errors have a significant impact; it has been estimated that only in the United States medication errors harm 1, 5 people and kill several thousand each year [2]. Medication was found to be the leading cause of injury during medical care, followed by healthcare associated infections and surgical errors [3].

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Some studies report discrepancies varying from 30-70% between the medications patients were taking before admission and the prescriptions ordered in hospitals [4] [5] [6]. Omissions were repeatedly found the most frequent of these discrepancies [7]. In a recent retrospective cohort study [8] medication discrepancies were analyzed to describe their incidence, drug classes, and probable importance. A random sample of adult patients admitted to the general medicine, cardiology or general surgery was examined. Potentially high-risk discrepancies and differences were identified by determining if the medications were included on either the Institute for Safe Medication Practice high-alert list or the North Carolina Narrow Therapeutics Index list. The authors found that of the 178 patients who did have medication listed on admission, 41 had at least 1 discrepancy identified by the reconciliation process on admission (23%; 95% CI, 17-29), 19% (95% CI, 11-31) of these medications were considered to be potentially high risk. Cardiovascular drugs were the most frequent class involved at both admissions (31%) and discharge (27%) in medication discrepancies or differences.

The medicines reconciliation process is therefore designed to prevent those medication errors that take place at patient transitions by identifying the most accurate list of all medication a patient is taking and using this list to provide correct medications for patients anywhere within the health care system [9] [10].

Many factors may contribute to medicines reconciliation errors [9] [10]:

- Lack of access to the patient’s prescriptions list from Primary Care: as information is not usually collected in a standardized way, the systems fail to transfer information from Primary Care to Hospital.
- Difficulties in obtaining an accurate account of a patient’s medication due to an acute condition, sensory or cognitive impairment, lack of access to family or caregiver, or due to language barriers.
- Errors in transcribing medication details to the hospital clinical record: in the case of hand-written prescriptions, that may contribute to errors if they are illegible, incomplete, or use inappropriate abbreviations.

1. Medicines Reconciliation Program implemented at Hospital Universitario de Fuenlabrada: use case of the Patient Summary Project

The Hospital Universitario de Fuenlabrada is a public general hospital located in the Madrid region which started its activity in 2004. It provides assistance to a population of 217,000 inhabitants. The Hospital implemented at its inception a global EHR system that integrates all the specific software applications from different providers installed in the Pharmacy and other Departments (Diagnostic Imaging, Critical Care Unit, Surgery, Pathology and Laboratory).

The Patient Summary Project was developed to provide doctors at both settings, the Hospital and the Primary Care, access to the most complete and updated clinical information about patients collected from all the systems where this information was stored.

The final aim of the Project was in fact, patient safety as we seek to ensure that the medicines prescribed on admission to hospital correspond to those that the patient was taking at home, unless they need to be modified due to clinical conditions.
The practical implementation of the overall Project was then structured in two main objectives:

- The development of a **Patient Summary** that includes clinical data from three different and distributed systems: the Primary Care Electronic Health Record (EHR), the Hospital EHR, and the Hospital Pharmacy software application.

- The establishment of a clinical **Standard Operating Protocol (SOP)** to prevent medication errors through a medicines reconciliation program.

The SOP for medicines reconciliation contains the complete set of instructions for implementing the process by multiple users, the healthcare professionals, in a consistent and measurable manner. This SOP includes as a first step collecting information on medication history, using the most recent and accurate sources of information to create a full and current list of medicines. This list is completed with the information from the patient or his family or caregiver. Then, the information collected about current medication is checked against the hospital prescriptions, ensuring any discrepancies are accounted for and communicated, if necessary, to the doctor. Such discrepancies are defined as unexplained differences among documented regimens across different sites of care; in our project, prescriptions prior to admission compared with hospital orders.

The information contained in the home medication list should include:

- Prescription medications
- Sample medications
- Vitamins
- Nutraceuticals
- Other OTC medicines
- Herbal medicines

And the specific data to be collected should consider: drug name, strength, pharmaceutical form and route of administration, frequency, indication, timing of last dose, and source of the patient's medications.

### 2. The Patient Summary based on the ISO 13606 Standard

The electronic information about a person's health, his EHR, consists of data about observations, pathologies, laboratory tests, diagnostic imaging reports, treatments, patient identifying details, alerts, etc. Unfortunately, this information is frequently stored in various locations and in diverse proprietary formats, making access to it a real challenge. The consequently lack of interoperability between EHRs or ability "to talk to each other", causes problems while fully interoperable EHRs would make access to patient's information easier as well as enhance the quality and safety of healthcare by providing professionals with relevant and up-to-date information.

In this context, semantic interoperability designates that the precise meaning of exchanges information is understandable by another system or application not initially developed for this purpose.

The Patient Summary developed in this Project is constructed following the CEN EN13606 Standard for the Electronic Health Record Communication. This Standard
specifies the information architecture required for interoperable exchange between EHRs and a centralized repository.

The CEN EN13606 Standard was developed by the European Committee for Standardization (CEN) and applies the dual model approach based on the separation between information (the data) and knowledge (which may change over time). Knowledge is therefore represented in this project as archetypes or formal descriptions of the concepts of the specific domain. Obviously, there is a need for an expert's agreement on the specific data sets; this can be accomplished using archetypes developed by those experts, mainly doctors, pharmacists and nurses.

The core part of the Standard, the Reference Model, represents the global characteristics of healthcare record data, the way these data are aggregated, and the context information expected to addressing ethical, legal and provenance requirements. The model defines the set of classes that constitute the generic building blocks and stable characteristics of any EHR.

The other important feature of the Standard is the incorporation of archetypes for sharing semantic structures defined in the second part, the Archetype Model. Archetypes are formal definitions of domain-level concepts in the form of structured and constraint combinations of classes contained in the Reference Model. Their main purpose is to provide a powerful, reusable and interoperable mechanism for managing the creation, description, validation and query of EHRs. Archetypes provide semantics to data instances that conform to some reference model by assuring that the data obey a particular structure and satisfy a set of semantic constraints.

In this Project three archetypes were developed reusing ("specialized archetypes") the repository of archetypes of the openEHR organization:

- Alerts (including allergies)
- Problem list
- Medication

We "specialized" the current openEHR archetypes for those three sections of the Patient Summary in order to include local particularities. openEHR is an international not-for-profit Foundation, whose aim is making interoperable, life-long HER a reality, improving healthcare in the information society by creating specifications, open source software and tools. Specially, openEHR maintains a repository of archetypes.

The final federated view of the patient vital information was accomplished through a standardization platform which allows the edition of archetypes, the specification of mappings between archetypes and data sources and the semi-automated generation of data conversion scripts that translate not normalized data into XML documents conforming to the selected reference model and at the same time satisfy all the data constraints imposed by archetypes. Hence, the use of archetypes provides a means to standardization and semantic interoperability. In fact, archetypes convert existing information into standardized EHR extracts. Figure 1 shows an overview of the edition process of an integration archetype with four different stages.
After the integration archetype has been defined an XQuery program is automatically generated to extract and normalize data; the next step is building an infrastructure for the global EHR. The standardization platform creates the virtual or federated view of the patient HER whose data are among heterogeneous systems. Figure 2 shows the workflow that eventually creates the Patient Summary.
3. The Medicines Reconciliation Program

To implement the medicines reconciliation program a SOP was developed involving doctors, nurses and pharmacists. Each healthcare professional role and responsibilities were specified. Figure 3 shows the flowchart designed to diagram the process.

![Flowchart for the Medicines Reconciliation Program](image)

- **Patients who fulfilled the following criteria were eligible to enter the program:**
  - Admitted to Internal Medicinal Department
  - Age ≥ 65 years
  - Chronic treatment including more than 4-5 medicines

- Pharmacists play a central role in the program: after collecting information on the patient's home medications, problems and alerts, an interview with the patient or caregiver is conducted. We consider patient involvement of the greatest importance, as they are in the best position to be aware of all the medications they are prescribed by multiple healthcare professionals. Precisely, one valuable source of information is, in fact, the medication brought by patients to hospital. Asking patients about compliance can also clarify the possible lack of effect of a specific medicine.

- A template for collecting information prior the interview was used as a tool to guide the pharmacist when analyzing the information provided by the patient as well as when comparing the treatment prescribed at Hospital. Finally, a template collecting discrepancies between both list (current treatment and hospital orders) was designed to notify physicians the discrepancies encountered.
The Patient Summary was considered the first source of information to obtain the patient's current medication (Figure 4).

### Figure 4. Sections of the Patient Summary: alerts, problem list and medication.

4. Conclusions

The development of a Patient Summary that includes clinical data from different electronic systems (the Primary Care EHR, the Hospital EHR and the Pharmacy Department software application) was achieved through the construction of a virtual federated view of those systems using the ISO/CEN EN13606 standard. The first use case of this Project has been a Medicines Reconciliation Program at patient admission to Hospital that allows doctors access to the information about which medicines the patient is taking at home. Pharmacist participate in the program verifying that the orders prescribed at hospital correspond to the current treatment unless there are reasons for discontinuation, changes in dose, frequency or route.

Acknowledgement

This Project has been funded by the Spanish Health Ministry (Convenio de colaboración para el impulso de prácticas seguras en Centros Sanitarios 2008) and
has been awarded with one of the Quality within the Spanish National Health System Prizes 2009.

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