EMR Standards in Cardiological Outpatient Management

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Abstract

From 1997 a Hospital Informative System (HIS) has been established in our Institute for clinical data management and proprietary protocols have been adopted for data exchange. In the outpatient setting standardization for direct integration with other subsystems is mandatory due to huge clinical and administrative data amounts. Aim of this study was to standardize a common informative system using HL7-CDA rel.2 protocol as data interface exchange among different outpatient specialties.

An interaction model was produced and compared with a draft version of HL7 CDA version 2; structured data were superimposed to the basic CDA skeleton. The structured body was extended with clinical information coded with LOINC and SNOMED dictionary. This system was able to set a CDA packet containing visit reports and relevant clinical information, sharing data with other specialties through a Central repository.

1. Introduction

Electronic Medical Records (EMR) in the outpatient setting have characteristics different from inpatient EMR; this is due to the huge amount of information - both administrative and clinical - collected and analyzed in a short period of time. Moreover, in this setting a variety of different data may come from all sorts of laboratories (either instrumental or biochemical) which may have different data exchange protocols that require a complex work for integration deployments. Standardization of informative systems are therefore mandatory and digital imaging and communication protocols (DICOM) and Health-Level (HL) 7 standard must be adopted in order to use pre existing infrastructures and to reduce the technological negative aspect of new or proprietary communication protocols. Aim of this study was to standardize a clinical informative system using HL7-CDA (Clinical Document Architecture) release 2 protocol as data interface exchange among different specialities in the outpatient setting, starting from the cardiology outpatient laboratory and comprehending lung, metabolism and endocrine disorders, as well as the Administrative (ADT) system.

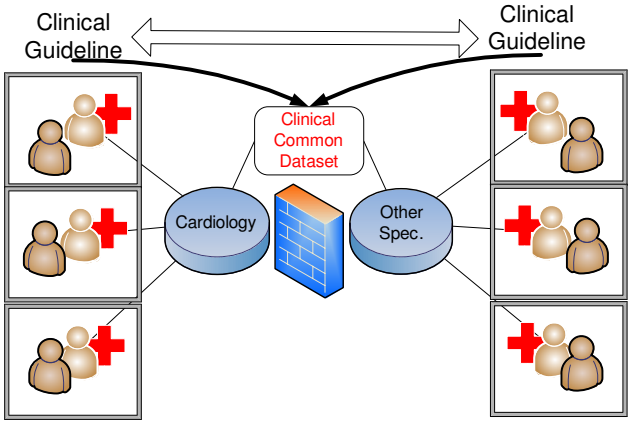

Figure 1. Current outpatient clinical practice: activation of other specialistic laboratories is defined by shared clinical guidelines.

2. Methods

The increasing physicians request to filter the most meaningful information in a simple and effective way, led to development of technological innovations able to feed a database with multidisciplinary information. To reach a high level of data usability and effectiveness, already established communication protocols and data sharing methodologies - such as HL7, together with the emergent development of CDA in the field of structured clinical documents - were applied [1]. HL7 is a not-for-profit standards developing organization that provides standards for the exchange, management and integration of data for clinical patient care and management, delivery and evaluation of healthcare services.

The Clinical Document Architecture [2, 3] is a HL7 standard for the representation and machine processing of clinical documents in a way which makes the documents both human readable and machine processable and guarantees preservation of the content by using the eXtensible Markup Language (XML) standard. It is a useful an intuitive approach for the management of documents which make up a large part of the clinical information processing arena.

CDA offers an highly structured but modulable container. Its peculiar characteristics rely on the fact that

it is composed by two fundamental parts, an header and a body. The Header contains key descriptive information about the document (metadata) such as: who wrote it, who is it intended for, type of document, the necessary elements for the identification of the executed procedure, the affiliation of document destination, its version control fields, as well as other identification information to manage relations with other documents.

The body contains the text of the document which may be structured at least under key headings or sections. It is possible for the text to contain coded values. It is also possible to have non textual information in the body such as an image (using the DICOM standard representation).

The body can be classified in two main typologies: non- structured or structured, containing the clinical related information we want to exchange.

CDA with unstructured body can be used to include any type of objects such as a Binary file, an Acrobat document or a DICOM file to be transferred.

CDA with structured body allows a specific and complete exchange of structured clinical data.

Our choice of a structured body had the consequence of a CDA pattern adoption or definition, which represents an agreement between sender and receiver, so to map clinical data in a conventional mode.

It was then necessary to identify a dataset as a basis of a CDA pattern, which is extracted from clinical guidelines and basic evaluation of everyday clinical practice. A clinical data set is generically defined as a motivated set of entries that may be stored, shared or presented together with clinical applications, messages and electronic medical records.

The need of compatibility with other medical standards determines the choice of body type, but the structured body seems preferable when this mechanism of communication has to be fully exploited. Moreover, the structured body offers the possibility to link to external documents, like those present on a file-system, or provided by a web service.

The eventual overlapped information present in the linked file and the CDA header has to be coincident, in order to avoid ambiguity; a congruity information control is therefore mandatory, to reject erroneous CDA documents to data source.

To obtain a friendly and flexible system and to follow an evolving environment like in the outpatient care, a new development approach was adopted.

Extreme Programming (XP) [4] is a software development approach that represents an effective method for building smaller systems in an environment where requirements are continuously changing. XP methodology was originally applied to develop in-house information systems projects with a small developers team, like in our Institution .

XP is based on long standing industry best practices, including evolutionary prototyping, short release cycle and active end-user involvement in requirements definition. XP contributes to bundle and package specific practices to form a methodology: planning game, pair programming, small releases, collective code ownership, metaphor, continuous integration, simple design, regression testing, on-site customer, continuous code refactoring, coding standard.

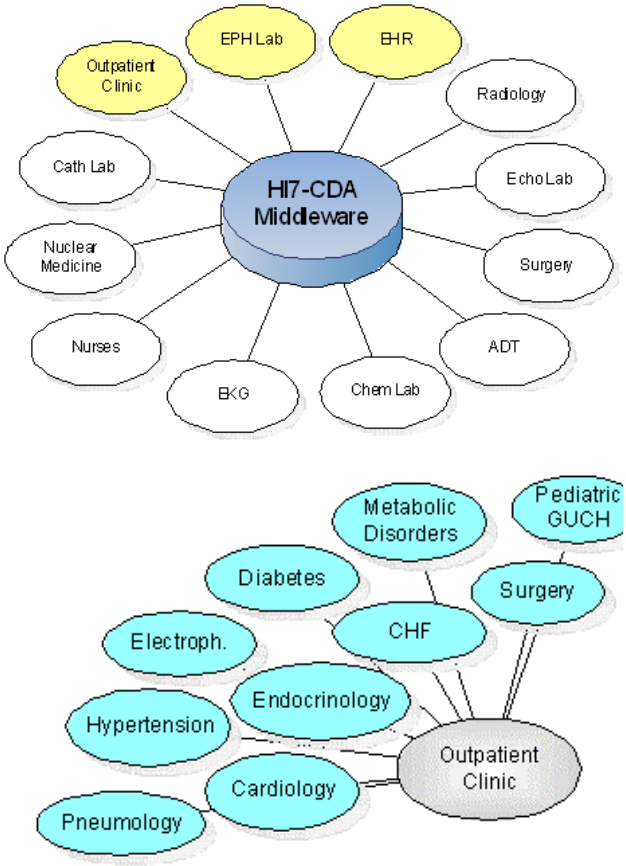

Figure 2. Extension of HIS with connected instrumental laboratories and current CDA-Middleware use.

The core element of this system, partially inherited from the one developed for in-patients [5, 6, 7], is the clinical information system (SIC), which consists of many sub-systems for laboratories and clinical environments, as depicted in Figure 2

3. Results

The defined clinical dataset is made of the diverse

clinical aspects used in outpatient visit and collected in the outpatient EMR: ID, clinical history, Physical examination reports, baseline ECG and other instrumental data (like 2D echo or nuclear medicine data, magnetic resonance imaging, when available), conclusions, therapy and programmed follow up, when needed.

After that, a CDA pattern was generated containing dataset definitions, detailing items value as mandatory or optional. Some of the coded entries were mapped with LOINC representation, others with internal codes.

A sample of CDA pattern filled with clinical data is shown in Figure 4.

```
<ClinicalDocument>
...
  <bodyChoice>
   <StructuredBody>
        ...
    <component>
      <section>
       <entry>
        <entryChoice>
          <CodedEntry>
            <id>Pathology</id>
            <code>DB-61000</code>
          </CodedEntry>
        </entryChoice>
       </entry>
      </section>
    </component>
...
    <component>
      <section>
       <entry>
        <entryChoice>
          <Observation>
            <id>Pre_Implant_Symptoms</id>
            <code>B1</code>
          </Observation>
        </entryChoice>
       </entry>
      </section>
    </component>
...
   </StructuredBody>
  </bodyChoice>
    ...
</ClinicalDocument>
```

Figure 4. CDA pattern example

To manage CDA communication we developed a message broker based on Servlet technology [8, 9], using HTTP POST as interface vs. clinical workstations, in order to allow message exchange using different applications (Java, FileMaker, C++, .NET).

At the end of patient visit, after final report compilation, the collected clinical information were gathered and used to build a complete CDA packet, using pattern definition related to a generic specialistic evaluation.

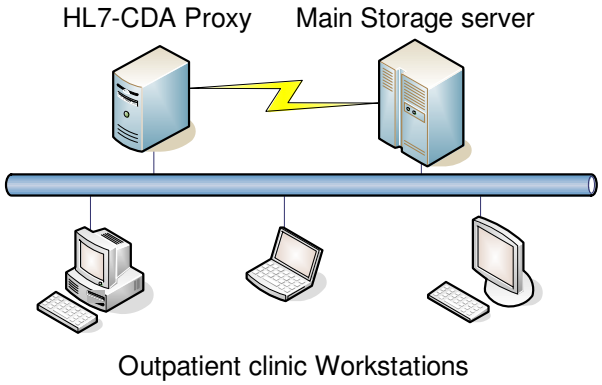

Figure 5. System network architecture.

The generated message was sent as a MIME multipart message to the CDA proxy, that contains an HTTPS receiving interface, internally redirected to a tomcat servlet implementing message reception.

A message parser analyzed the received messages, extracting single data from message structure, and stored clinical parameters in HIS database. This last action allows specialistic laboratories to collect all clinical information contained in CDA packet in order to complete clinical knowledge exchange.

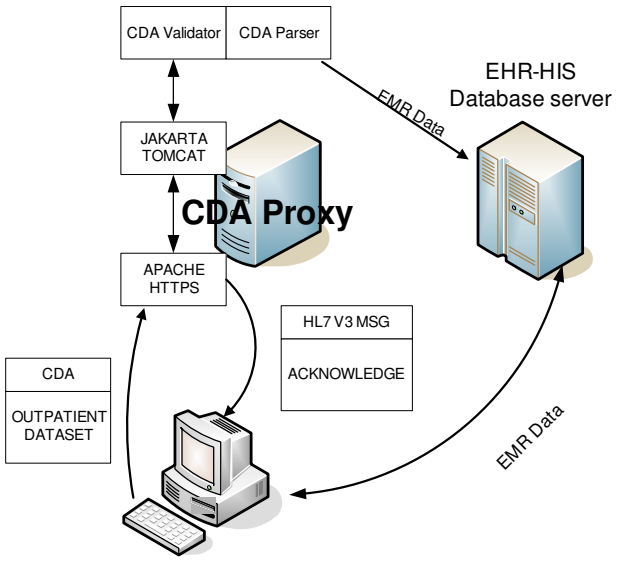

Figure 6. Life-cycle of CDA broker.

JAVA language was chosen for CDA proxy [10] to guarantee a free integration on many popular operating systems and platforms, and to allow an easy integration with many different database systems through the JDBC protocol.

EMR system was modified with a plug-in developed for a clinical data extraction, coming from patient visit, and subsequent transmission to CDA proxy.

A monitoring console was added to CDA proxy in order to track erroneous packet expedition or inconsistent clinical data values (e.g.: non existing patient, out-of-range parameters, etc). This console is used by the System administrator to correct system failure or EMR misuse.

In practical terms, this knowledge exchange allows the physician to activate a specific specialistic environment on the basis of the clinical hypothesis.

For example, if the cardiologist in charge of the generic cardiological outpatient lab, formulates the hypothesis of a specific arrhythmic disorder, additional data related to arrhythmias may be specifically collected and transmitted to the more specialistic electrophysiology laboratory.

4. Conclusions

The outpatient clinic represents a battlefield for informatization. Organization, on both administrative and clinical sides is of paramount importance in order to avoid ID mismatches, on one side, and unwanted waste of time, on the other. EMR developed in our Institute represents an important tool for personnel working in the outpatient settings, since it is able to simplify the relation between different clinical and instrumental Labs, starting from the true beginning: patient administrative ID. The correct patient ID allows proper retrieval of final reports of previous visits and examinations in the outpatient environment, as well as information from previous hospitalizations.

This system is able to set a CDA packet up, which contains visit report and relevant clinical information sharing acquired information with other specialties through a web-based central repository.

At present we rely on a generic approach for data vector, such as HL7-CDA. Use of a defined CDA pattern limit a wide use of clinical specialities interaction, due to the consensus at the basis of the defined pattern entries.

Our main goal is to build a more precise HL7-V3 characterization when consensus on specific approaches will be internationally defined, in order to allow more definite agreements on interdisciplinary clinical guidelines.

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