Development and Implementation of CDA R2 documents using CCD templates in the Homecare Service Electronic Health Record

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Abstract
This paper describes the experience of the patient continuous care program at the Hospital Italiano of Buenos Aires during the development of the new solution for the Home Care Service Electronic Health Record (HCS EHR).

The integrated workflow implemented in this project gives doctors, nurses and other healthcare providers the secure access via the Internet to their patients’ medical records either from home using own computers or on the road using mobile devices. The application not only registers their actions and observations, but also allows ordering studies and referrals to other services or professionals. The HCS EHR information is stored and exchanged using the constraints set on the HL7 Clinical Document Architecture, Release Two (CDA R2) standard described in the Continuity of Care Document (CCD) specification.

This implementation allowed combining the physicians' narrative text with the structured information that uses controlled vocabularies. Generated CDA R2 Documents are digitally signed by the health care professionals and stored as part of the inalterable patient clinical data repository. They are perfect for communication with third parties involved in the patient care.

Keywords
HL7, CDA R2, CCD, Hospital Information Systems, Homecare Services, Electronic Health Record, Patient Summary, Digital Signature.

Introduction – Business Case

Patient care outside of the hospital in the home environment is a complex task. There are ongoing and complicated interactions between patients, medical and administrative staff. Physicians or health care professionals working in ancillary services can be challenged in giving the prompt care without access to the real time clinical data or if they are unable to share knowledge effectively. Errors may occur in case of communication failure or poor information coordination.[1].

The objective of this initiative was to enable the efficient recording of agents' activities and make the patient summary information available and shared between all authorized parties to improve the patient care, reduce the number of errors and enhance the patient safety. It was decided to use a standard format for clinical documents to increase the chance of achieving the EHR Interoperability. HL7 CDA R2 standard was chosen for this implementation. The structure of CDA R2 documents allows transferring the detailed clinical information using the standard format and avoiding ambiguity. Adding the CCD implementation is increasing the likelihood of the EHR Interoperability.[2]

As part of the medical record informatization, the Hospital Italiano of Buenos Aires has implemented this standard to generate clinical documents supporting different health events and then added a digital signature process to give the legal validity and authentication to the documents. Various documents can be accessed in different formats; it enables their full readability and allows the processing and subsequent inclusions of the information from/to other related healthcare systems or applications. These documents can be navigated through any medical record application supporting CDA/CCD standards and/or viewed using any Internet browser.

Materials and Methods

The Hospital Italiano of Buenos Aires (HIBA) is a non-profit health care academic center founded in 1853, with over 1,500 physicians and 3,500 employees. HIBA has a network of two hospitals with 750 beds (200 for intensive care), 500 "Homecare" patients under care, and 23 clinics. It has an insurance plan that covers approximately 150,000 people and also coordinates insurance for another 1,500,000 people covered by affiliated insurers. Each year over 38,000 inpatients (pediatric and adult) are admitted to hospitals that are located in Buenos Aires and its suburban area. HIBA has more than 2,200,000 outpatient visits annually from patients from across the country and Latin America.

HIBA, a well-developed teaching hospital, offers both graduate medical education and residency training for 35 medical subspecialities and 34 fellowships programs. There are currently 400 residents and fellows in training.

In 1998 HIBA began the implementation of a Healthcare Information System (HIS) by integrating clinical information with administrative applications that were already in use. This in-house project currently handles all clinical and
administrative health care information from data capture through to analysis. It is now a fully implemented web-based, problem-oriented and patient centered EHR system. The system includes computerized provider order entry (CPOE) which is available to physicians throughout the HIBA network.

In 1999 this EHR was integrated using HL7 v2.3 messages to the different administrative and service systems [3]. In early 2008, it was decided to start the design of the HCS EHR, and its implementation was completed in 2009.

Implementation, Methodology and Tools

This information system was developed using Java technology, J2EE Enterprise Architecture with 24x7 availability supported by the clustered application servers IAS Oracle® 10g Red Hat Linux platform.

The database layer is implemented using Oracle® 11g Database on the cluster of Sun servers to support high application availability and system redundancy.

The application development process can be phased into two major parts: the HCS EHR solution and the CDA R2 Generation module.

Home Care Service Electronic Health Record

The Home Care Service department is different from all other clinical departments at HIBA. Geographically HCS provides services covering the area of approximately 350 square km (City of Buenos Aires). The average number of admitted patients ranges from 350 to 400 daily and is divided into two categories according to the patient care level:

- "Follow-Up Care": 25% of patients without acute symptoms requiring one physician or nurse visit per month, e.g. the follow up for the medication refill to treat deep venous thrombosis.
- "Home Care": 75% of patients requiring at least one physician or nurse visit at their home per week, e.g. surgical wound infection.

HCS is provided by 61 physicians: 49 internal medicine physicians, 12 physicians from others specialties (Cardiology, Psychiatry, Trauma, General Surgery, Infectology, Neurology, Palliative Care and Urology) and 4 auditing physicians (service coordination). 32 nurses are administering medications, drawing blood samples, monitoring and providing daily physical care, and 6 administrative clerks assessing the patient/physician ratio by location. [4]

The successful design of the HCS EHR solution was achieved due to active collaboration between the hospital information department and HCS staff.

The existing EHR applications implemented for Outpatient Care, Hospital Inpatient Care and Emergency Departments served as a good starting point for the new solution, enabling the re-use of already developed valuable components and reducing the application development, testing and staff training time. [5]

The main application screen (Figure 1) provides a healthcare professional with access to the list of assigned patients, allows searching the drug database; review and sign outstanding CDA R2 documents, etc.

![Figure 1 – HCS EHR Main screen](image1)

The patient summary screen has convenient navigation, viewing and generation of CDA R2 documents functions.

![Figure 2 – HCS EHR Patient Summary screen](image2)
The Evolution (Progress/Visit Report) screen displays all registered clinical events as a timeline. Upon selection of any of these items the system will show the generated CDA R2 document for the visit. The Figure 3 shows the sample of the CDA R2 summary for a consultation with registered events, vital signs and ordered studies shown.

Digital Signature

The digital signature implementation was the most important and major change in the solution. By the end of each visit the physician signs the generated document after registering all his/her actions and observations. The card and the card reader were assigned to each doctor and nurse to support this process.

When the CDA R2 document is signed, the XML code containing the digital signature information is added, and a new document is generated replacing the unsigned version. However, the document repository system stores both instances. [6]

CDA in Use

The CDA R2 document can be generated not only by healthcare professional’s request. HCS EHR application uses automatic CDA R2 document generation to log user’s activity.

The automatic CDA R2 generation service is started when the user finishes registering clinical observations, medication requests, lab and other orders, etc.

If more than one document needed, i.e. for a final consultation and discharge reporting, the doctor may mark a problem as solved, request subsequent control studies, and the application will generate the discharge summary reports using all corresponding CDA R2 documents.

HCS EHR CDA R2 Document Generation Events

Currently, the following actions generate CDA R2 documents:

Problems
- New
- Delete
- Change status
- Request Second Opinion
- Associate
- Detach

Discharge Summary
- New
- Delete
- Update

Referrals
- New
- Complete
- Delete

Orders
- New
- Cancel

Medication
- New
- Suspend
- Update

Evolution
- New

Vital Signs
- New

For ancillary services, each reporting procedure is considered to be a health event, so it generates a document.
The full CDA R2 generation cycle includes:

1. The user selects the patient by searching the demographic data or selecting the assigned patient from the list. All patients must be enrolled in the master patient index of the hospital information system (HIS).

2. The user enters the relevant data. The new and updated information is saved to generate the CDA R2 document.

3. The application generates a new event and the web service is called to send the medical information to the clinical data repository.

4. The user identity must be verified and the digital signature of the document is included. Digital certificates and required key pairs are provided through a cryptographic USB token given to each physician with an USB card reader installed on their PC or Notebook.

5. The signed document and control parameters are stored in a data file system.

**Major Components of a CDA R2 Document**

The header, body and each section of the CDA R2 document are generated by combining the relevant information from the relational database and XSL templates into an XML document. This process is similar to the "Green CDA" prototype.

Example 1: XSL Use for the document processing.

```
<xml-stylesheet type="text/xsl" href="http://www.hospital...

<ClinicalDocument>
  <xsl:apply-templates select="ClinicalDocument">
    <xsl:choose>
      <xsl:when test="Patient">
        <xsl:apply-templates select="Patient"/>
      </xsl:when>
      <xsl:when test="Document">
        <xsl:apply-templates select="Document"/>
      </xsl:when>
      <xsl:when test="Message">
        <xsl:apply-templates select="Message"/>
      </xsl:when>
    </xsl:choose>
  </xsl:apply-templates>
</ClinicalDocument>
```

Figure 5 shows components used in the CDA document.

**Example 2: CDA R2 Header**

```
<xml-stylesheet type="text/xsl" href="http://www.hospital...

<ClinicalDocument>
  <xsl:apply-templates select="ClinicalDocument">
    <xsl:choose>
      <xsl:when test="Patient">
        <xsl:apply-templates select="Patient"/>
      </xsl:when>
      <xsl:when test="Document">
        <xsl:apply-templates select="Document"/>
      </xsl:when>
      <xsl:when test="Message">
        <xsl:apply-templates select="Message"/>
      </xsl:when>
    </xsl:choose>
  </xsl:apply-templates>
</ClinicalDocument>
```

Figure 5 – CDA R2 Implemented Components.

The object identifiers (OID), used in this solution are assigned by HL7 Argentina for the Hospital Italiano of Buenos Aires and by HIBA for local entities: patient and doctor numbers, service codes, orders and studies. The clinical entities are coded using the SNOMED CT vocabulary.
The following templates were used for CCD implementation:

### Problems
Problem section
2.16.840.1.113883.10.20.1.11

### Referrals
Plan of care section
2.16.840.1.113883.10.20.1.10

### Orders
Plan of care section
2.16.840.1.113883.10.20.1.10

Once the CDA document is digitally signed, the signature component is incorporated into the document.

### Example 4: Digital signature in CDA R2 document
Note: The Discharge Summary document does not follow the CCD implementation guide because it does not have a template designed for this purpose.

Evaluation/Assessment

The potential and the versatility of CDA R2 standard, based on a solid semantic structure and the use of standard medical vocabularies, gets fully demonstrated during and after the deployment: saving the project cost and time and simplifying the EHR Interoperability across the Healthcare Domain.

It is extremely complex to make it available to healthcare users of clinical notes in the free text format. However, the complexity of a standard is benefiting this solution, it allows transferring the detailed information between different software components that provide essential services to the hospital system (terminology services, master tables, etc.); it meets the project objective of achieving a better understanding of semantic information available.

23,653 documents were generated from the first day of implementation, at the rate of 2,148 documents per month.

The benefits of the implementation are:

- **Persistence**: document inalterability at any time is guaranteed by the digital signature.
- **Administration**: The document is managed by an organization; in this case the Hospital Italiano of Buenos Aires.
- **Authentication**: The XML structure of the document allows the use of a standard security system such as digital signatures and/or public/private key infrastructure (PKI).
- **Readability**: The document can be read by a person or can be processed by commonly used applications, such as Internet browsers, without installing additional software or components.
- **Platform Independence**: The document is encoded in a standard language (XML) and is not dependant on the operating system or programming languages, and both can be used under any system or platform and get a personalized view through use of style sheets (XSL).

Future Plans

The current solution will be extended to cover other health care events and departments, e.g. the nursing record or the manual loading of external non-HL7 healthcare reports, using the same approach and generating the CDA R2 documents from available or designed templates.

Discharge Summary report will be deployed using the Discharge Summary Specification from “Cross-Enterprise Sharing of Medical Summaries (XDS-MS) Integration Profile”: 1.3.6.1.4.1.19376.1.5.3.1.1.4. [7]

Conclusion

The implementation of this solution gives users the access to clinically important information: lab results, discharge summary reports, administrative data, evolution notes, diagnostics, procedures and prescriptions, in a format that can be read and understood, exchanged or included into other healthcare information systems or applications.

The CDA R2 template-based generation design allows the reusable, consistent, and timely deployment.

The document visualization can be easily customized using XSL style sheets. The styles, fonts and isotypes can be modified to be recognized and validated by the institution and suitable for inclusion in the EHRs maintaining their aesthetics.

The standard structure allows the implementation of XML digital signature of clinical documents under the public and private key infrastructure (PKI) giving the legal validity to documents in accordance to local regulations.

Lessons Learned

Not all healthcare events were represented accurately by the CCD implementation guide. It was required to represent the referrals as a care plan and it would not really distinguish except by an internal process, between an order for a study and a request for a referral.

Similarly, the discharge summary report can not be included in the same group of templates.

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