HL7v3 CDA Rel.2 Patient Summary and Chronic Care Model: Localization Experience and GP/HS Integration Project

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Overview

• Introduction
• HL7 Version 3 and CDA Rel.2 Localization for Patient Summary
• Chronic Care Model and Clinical Information Systems in chronic diseases (i.e. diabetes)
• Case study: Integration project of services for General Practitioners (GP) and Hospital Specialists (HS)
• Final remarks
Introduction
New challenges in Healthcare

- rationalization of administrative and managerial processes
- improvement of the clinical and healthcare processes
- reduction of clinical risks
- expanded Chronic Care Model (CCM) to overcome the deficiencies in current management of chronic disease
- standard for interoperability of health information technology
- Service-oriented Architecture (SOA) and BPM approach
Patient Summary (Profilo Sanitario Sintetico PSS) – GP’s clinical document is one of the main elements in Electronic Health Record (EHR) systems.

Integration of the Clinical Information Systems (between hospital and primary care) is essential in CCM for diagnostic and therapeutic paths (Percorsi Diagnostico Terapeutici Assistenziali (PDTA)).

Recent FIASO report (Fed. It. Aziende Sanitarie e Osp.): an optimistic picture of the Italian situation:
- knowledge of the EHR (71% of GPs and 67% of HSs)
- a spread use of EHR and Patient Summary: 7/20 regions
Standard HL7

• Health Level Seven, Inc. is one of the leading global authority for healthcare Information interoperability and standards with members in over 55 countries.

• HL7 is an ANSI accredited standard development organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services.

• HL7 Version 3 (HL7v3) methodology uses the Reference Information Model (RIM), the Data Types Specification, and the HL7 Vocabulary as its starting point.
HL7 Version 3

- Refinement Process for defining messages based on HL7 Reference Information Model (RIM)
Localization is the process of defining new HL7 Version 3 Message Types by a process including the constraint process and the extension process adding new concepts to the base Message Type.

We refer to the activity of the HL7 Italia Group: *Gruppo di Progetto HL7 Italia IG CDA2 Profilo Sanitario Sintetico*

Through the Patient Summary, the GP supplies a patient overview with a synthesis containing the only relevant data and let it available to the EHR.

Principal PSS aims:
- let the information be available for the emergency;
- help the chronic care processes;
- ensure the continuity of care.
The Patient Summary is a document satisfying some requirements, it must

- be synthetic and contain only the essential information;
- have a single author, the General Practitioners Pediatricians creating and updating it;
- be not clinically specialized to be used in different scenarios (Emergency, Chronic Care,..);
- not have a specific predefined recipient;
- be only one and there must be only one PSS for each patient inside the EHR.
• Patient Summary has been defined according to the CDA R–MIM.
• PSS is structured in a *Header* and a *CDA Body*, human readable (level 2) and machine readable (level 3).
• The CDA Body, structured in specific sections, contains the patient clinical data.
• The various elements `<section>` in the body may contain more than one element of type `<entry>` that could be narrative or partially–totally coded.
The compliance requirements of PSS are based on **CCD** (Continuity of Care Document), **IHE** (Integrating the Healthcare Enterprise) Patient Care Coordination and Italian (IT) realm templates.

The templates define constraints for document, section, clinical statement and entry levels.

The header is compliant with **CDA Rel.2 Header** (HL7 specifications localized by HL7 Italia).

PSS follows the coding specification defined in **Identificazione Object Identifiers (OID)**.
CCD Sections in PSS

- CCD sections required, optional, or not required in PSS localization

<table>
<thead>
<tr>
<th>CCD Section</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose</td>
<td>SHALL NOT</td>
</tr>
<tr>
<td>Payers</td>
<td>SHALL NOT</td>
</tr>
<tr>
<td>Medical Equipment</td>
<td>RECOMMENDED</td>
</tr>
<tr>
<td>Immunization</td>
<td>OPTIONAL</td>
</tr>
<tr>
<td>Vital Signs</td>
<td>OPTIONAL</td>
</tr>
<tr>
<td>Results</td>
<td>RECOMMENDED</td>
</tr>
<tr>
<td>Procedures</td>
<td>OPTIONAL</td>
</tr>
<tr>
<td>Encounters</td>
<td>OPTIONAL</td>
</tr>
<tr>
<td>Plan of Care</td>
<td>OPTIONAL</td>
</tr>
<tr>
<td>Advance Directives</td>
<td>SHALL NOT</td>
</tr>
<tr>
<td>Functional Status</td>
<td>OPTIONAL</td>
</tr>
<tr>
<td>Problems</td>
<td>REQUIRED</td>
</tr>
<tr>
<td>Family History</td>
<td>OPTIONAL</td>
</tr>
<tr>
<td>Social History</td>
<td>REQUIRED</td>
</tr>
<tr>
<td>Alerts</td>
<td>REQUIRED</td>
</tr>
<tr>
<td>Medications</td>
<td>OPTIONAL</td>
</tr>
<tr>
<td>History of Pregnancies</td>
<td>OPTIONAL</td>
</tr>
</tbody>
</table>

**TABLE 1**
List of requirements for the inclusion of the CCD sections
(Source: HL7 Italia)
Patient Summary
Sections

- **Alerts**: section collecting alarms relative to any allergies, adverse reactions, and alerts that are pertinent to the patient's current or past medical history.
- **Medications**: section collecting all the actual prescribed pharmacological therapies.
- **Immunizations**: section defining a patient's current immunization status and pertinent immunization history.
- **Problems**: section deputed to summarize the relevant clinical problems, including the main pathologies.
- **Family History**: section collecting the family medical history, relevant for the patient risks.
- **Social History**: section containing the patient's occupational, personal (e.g. lifestyle), social and environmental history.
• The information related to allergies and pharmacological reaction are listed in the **section** named with the LOINC code 48765–2 (Allergies, adverse reactions, alerts)
The information regarding an alarm is represented through an act derived from the template “Allergy and Intollerance Concern”.
• The information related to prescriptions and substance administration are listed in the section named with the LOINC code 10160–0 (Medications)
The information regarding a medication activity is represented through a `substanceAdministration` derived from the template “Medication Activity”.
Chronic Care Model

- CCM identifies the essentials elements of an health care systems helping high-quality chronic care disease, such as diabetes, heart disease, hypertension, chronic obstructive pulmonary disease.
• **Continuity of Care for chronic illnesses** (diabetes, heart disease, hypertension and chronic obstructive pulmonary disease):
  – providing reminders and alerts for providers and patients
  – identifying relevant patient subpopulations according to their chronic illness
  – sharing information with providers and patients
  – monitoring performance of team with respect to the chronic care illness indicators

• Crucial: in the Clinical Information Systems, the clinical aspects summarized in the **medical records** need to be integrated among the GP and the Public Health organizations

• According also to regional guidelines to implement the exchange and sharing of medical records for the **management of the diagnostic and therapeutic paths (PDTA)**, it is essential to specify
  – clinical data set
  – technological interfaces and messaging
Clinical Data sets

CMM

- Clinical Data sets are used in the horizontal integration among the different GP Medical Records systems (Management of diagnostics and therapeutics care plans)

<table>
<thead>
<tr>
<th>Fields</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>trxIdentificazione</td>
<td>Patient identification</td>
</tr>
<tr>
<td>trxAnagrafica</td>
<td>Patient registry</td>
</tr>
<tr>
<td>trxAnamnesiFamiliare</td>
<td>Family History</td>
</tr>
<tr>
<td>trxEsenzione</td>
<td>Patient exemption</td>
</tr>
<tr>
<td>trxIntollFarmaco</td>
<td>Alerts, adverse reaction</td>
</tr>
<tr>
<td>trxMalattiaRilevante</td>
<td>Pathology, Chronic Disease</td>
</tr>
<tr>
<td>trxMonitoraggio</td>
<td>Vital Signs</td>
</tr>
<tr>
<td>trxPrescrizione</td>
<td>Prescription (laboratory)</td>
</tr>
<tr>
<td>trxRisultato</td>
<td>Results</td>
</tr>
<tr>
<td>trxPrescrizioneEsStru</td>
<td>Prescription (instrumental exams)</td>
</tr>
<tr>
<td>trxPrescrizioneFarmaco</td>
<td>Prescription (medications)</td>
</tr>
<tr>
<td>trxPrescrizioneVisitaSpecialistica</td>
<td>Prescription (specialist visit)</td>
</tr>
<tr>
<td>trxRicoveroOspedaliero</td>
<td>Hospitalization</td>
</tr>
<tr>
<td>trxStileVita</td>
<td>Social History</td>
</tr>
<tr>
<td>trxVaccinazione</td>
<td>Immunizations</td>
</tr>
<tr>
<td>trxVisitaMMG</td>
<td>General Practitioner visit</td>
</tr>
<tr>
<td>trxXtraData</td>
<td>Specific application data</td>
</tr>
</tbody>
</table>

**TABLE II**

TRX-PDTA principal fields and descriptions
Interface and Messaging

CCM

• The integration in Hospital Specialist and Primary Care area let the operators use their own medical record systems to manage and archive the information related to the specific clinical dataset.
• It is based on a PDTA services for the exchange and sharing of administrative and clinical data.
• The service operations comprise the
  – clinical data sending
  – query/response for the patient lists
  – query/response for the specialist visit lists
  – clinical data retrieving
• To guarantee interoperability, the PDTA service interactions are based on HL7 messaging.
An example: HL7 v2.3 R01—unsolicited transmission of observation message (ORU) for diabetes (Source: Progetto Sinapsis PDTA)
Case Study

HL7–based GP/HS integration services

- Integration services for GP (MMG, Medici di Medicina Generale and PLS, Pediatri di Libera Scelta) and HS (SO Specialisti Ospedalieri)
  - accessing the Electronic Health Record (EHR)
  - implementing the Patient Summary
  - managing the exchange of Chronic Care medical records

- In line with the normative referring context for the Italian healthcare and
  - the technical specifications of e.Toscana Compliance and the infrastructure CART Cooperazione Applicativa della Regione Toscana enabling the development of interoperable and cooperative software solutions
  - the Carta Sanitaria Elettronica Tuscany Region Project implementing the Electronic Health Record (EHR)
Case Study

HL7-based GP/HS integration services

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Case Study
HL7–based GP/HS integration services

• The **horizontal integration** of the different EMR systems for General Practitioners was developed by the MITO.SI project.

• We develop a **vertical integration** to the EHR, both at local and regional public health organization level. (e-Prescription and PSS implemented according to **CDA Rel.2 standard**)

• We collect and compare data for self-audits and clinical governance for GP as required by CCM. (TRX-ANR is the XML dataset based on TRX-CICoM specifications, used in the clinical audit process and for epidemiological studies on chronic diseases).
Case Study
HL7-based GP/HS integration services

• According to CCM, to develop the exchange of medical records between HS and GP, we consider an HL7-based interface of the Clinical Information Systems and a CDA Rel. 2 integration with the EHR for the HS. (TRX–PDTA is the XML dataset common to all PDTA for the exchange and the sharing of the medical record information)

• To access the Person/Patient Registry we implement an interface according to the HL7v3-based regional specifications RFC85, RFC86.

• The integration with the Public Health/Regional Code systems and Identification schema, according to the HL7 OID is also taken into account.
Case Study
HS Medical Record

- The module Hospital Specialist (HS) Medical Record is detailed with all its connections and HL7 interface.
Case Study
Person/Patient Registry HL7v3 Integration

- Integration scheme between the person/patient registry of the GP/HS Medical Record systems and the Public Health registry
Integration scheme of the CDA Rel.2 PSS shows how the services interact to provide (and retrieve) PSS documents to (from) the EHR.
• The proposed GP/HS project represents an example of integration/interoperability for the PSS documents, the Prescription documents and the PDTA medical records within the EHR.
• In line with the Italian IPSE and European epSOS projects, with their initial focus on both patient summary/emergency data sets and medication record/ePrescribing solutions.
• Tuscany and various other Italian regions are involved in the IPSE project; and Italy (Lombardia) and many European member states are involved in epSOS.
• These projects pointed out that the European situation is diversified with some regions and countries more advanced than others in terms of their capacity to implement EHR solutions. In Italy, the situation from region to region is also very dissimilar.
• Interoperability among different systems is the key to enhance the possibility of these services being provided across national or regional borders.
Future developments of the diagnostic and therapeutic paths (PDTA) need a standardization of the clinical data set with a strong interaction among Hospital Specialists and General Practitioners with the participation of the scientific and medical society for the different specialties related to the various chronic diseases.

It is also needed a standard definition of the PDTA document structure according to CDA Rel.2 to ensure interoperability within the EHR, in consideration also of the TSE (Tavolo di Sanità Elettronica) activity in Italian healthcare.

There is an ongoing HL7 international project on definition of minimum data set and data standards in EHR systems for diabetes assessment in outpatient clinic settings.

The work of the HL7 Italia Group is actually in progress and TSE has recently released a draft of technical specifications for the creation of the PSS according to the standard CDA Rel.2.
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