Abstract—The localization experience for the Patient Summary, based on the Health Level Seven Version 3 (HL7v3) Clinical Document Architecture, Release 2 (CDA Rel.2), is presented. An overview of the Chronic Care Model (CCM) is introduced with particular attention to the clinical information systems, in order to organize patient and population clinical data by sharing information among healthcare providers in management of chronic diseases. We propose, as case study, a project for the integration of various services for General Practitioners (GP) and Hospital Specialists (HS), accessing the Electronic Health Record (EHR), implementing the Patient Summary and managing the exchange of Chronic Care medical records. This project is in line with the state of the art in the normative referring context for the Italian healthcare, both at national and regional level (Tuscany Region).

Index Terms—e-Health, HL7, Interoperability, Chronic Care Model, Patient Summary, EHR

I. INTRODUCTION

New challenges in healthcare should be based [1], [2] on a rationalization of administrative and managerial processes; an improvement of the clinical and healthcare processes; a reduction of clinical risks; and an expanded Chronic Care Model (CCM) [3] in order to overcome the deficiencies in current management of chronic disease. The Italian healthcare situation is characterized by an huge diffusion of heterogeneous ad hoc applications and legacy systems in all the administrative and clinical domains; a very low presence of advanced solutions (Service Oriented Architecture and Business Process Management); deficiency of guidelines both at regional and national level; and, finally, lack of applications based on technological standards. One of the solution is the use of innovative standards for the integration of the information systems and the implementation of application solutions based on modern technological standards. The use of standard enables the interoperability. Interoperability is the ability of two or more systems or components to exchange information and to use the information that has been exchanged. We will refer to HL7v3 [4] as the most widely used standard for healthcare interoperability. The Patient Summary (in Italian Profilo Sanitario Sintetico (PSS)), an electronic clinical document summarizing the most relevant clinical information facts about a patient’s healthcare, represents one of the main elements of the Electronic Health Record (EHR) systems.

The integration of the Clinical Information Systems, between hospital and primary care is one of the essential aspects of the Chronic Care Model, as reported in [5] for Tuscany Region, for the development of diagnostic and therapeutic paths Percorsi Diagnostico Terapeutici Assistenziali (PDTA).

In a recent FIASO (Federazione Italiana Aziende Sanitarie e Ospedaliere) report [6] an optimistic picture of the Italian situation is overviewed with regards to the knowledge of the EHR (71% of GPs and 67% of HSs) and a spread use of EHR and Patient Summary reported as 7 regions among 20.

The paper is organized as follows: in the following we present the referring normative and technological context with a brief overview of the standard HL7v3 for the Clinical Document Architecture (CDA) Rel.2, and the Chronic Care Model for the Clinical Information Systems; in section II we describe the experience with the CDA Rel.2 localization for Patient Summary and in section III the experience in implementing the CCM medical record; in section IV we describe a project of Integration for General Practitioners (GP) and Hospital Specialists (HS), accessing the EHR, implementing the Patient Summary and managing the exchange of Chronic Care medical records; and, finally, in section V we draw some final remarks.

A. Referring normative and technological context

The referring context for Italian e-health is primarily described in the project of the Health objective for the Italian plan e-Gov 2012 [7], including the project Medici in Rete for the connection of the General Practitioners and the Pediatricians with the regional infrastructures; and the project Fascicolo Sanitario Elettronico (FSE) for the implementation of a distributed solution for patient’s EHR (in Italian FSE), at regional, national and European level. The technological references have been published by the Tavolo permanente di Sanità Elettronica (TSE) composed by the regional representatives, and coordinated by the Department Digitalizzazione e Innovazione Tecnologica of the Innovation and Public Administration Ministry (Ministero della Pubblica Amministrazione e Innovazione), with the participation of the Health Ministry.
CDA Rel. 2, for the exchange of clinical data at national level [10], [11].

According to these projects, and also to Progetto Mattoni SSN (Servizio Sanitario Nazionale) Realizzazione del Patient File [12], HL7 Version 3 has been indicated as the messaging standard in healthcare information exchange, and HL7-CDA Rel. 2 as the standard for clinical documents exchange. The IHE-XDS profile (Cross-Enterprise Document Sharing) is also suggested as one of the reference framework for registering and sharing electronic health record documents between healthcare enterprises [13].

In the present work, we mainly focus on the Patient Summary that is an important aspect in the GP systems integration with the EHR. In the past, TSE started various regional projects for the General Practitioners [14] Sanità Elettronica - Rete dei Medici di Medicina Generale, including the Patient Summary, the electronic clinical document summarizing the most relevant clinical information facts about a patient’s healthcare, to support the continuity of care. Patient Summary is a document of the EHR that must be created, updated and digital signed by the GPs providing a snapshot in time containing the pertinent clinical data, as the emergency data set. Patient Summary is developed according to the standard CDA Rel. 2 and is based on the HL7 Continuity Care Document (CCD), a CDA implementation of ASTM Continuity of Care Record (CCR) [15]; the IHE Patient Care Coordination (PCC) [16]; and [17],[18],[19],[20].

The need to identify synthetic and effective tools to facilitate the sharing of information between the various actors involved in the process of care and assistance of a patient has been recently increased at international level (see Belgium (SUMEHR), England (Summary Health Record), Sweden, Finland (Patient Core Data Set), U.S. (Continuity of Care Record), Canada). In Italy, up to now, the standard for the Patient Summary CDA Rel.2 has not been yet delivered. The TSE is working on a draft document for the definition of the Patient Summary, based on the indications resulting from the various regional projects Medici in Rete, among which the CR SISS Regione Lombardia [21] LUMIR Regione Basilicata [22], RMMG Regione Abruzzo [23]. In Tuscany Region, Patient Summary is defined in the RFC 133 [24], according to [25].

The exchange and sharing of clinical information in chronic illness is an other important aspect of the GP Integration Project with the Hospital Specialist. The integration of the Clinical Information Systems, with particular attention to the GP Medical Records with the Hospital Specialist Medical Records represents one of the essential elements in implementing the Chronic Care Model (CCM). This aspect is in line with the development of a proactive healthcare that is based on an integrated management of the diagnostic and therapeutic paths (PDTA) between hospitals and primary care with the community-based facilities and services. The normative referring context at Tuscany Region level is the Piano Sanitario Regionale (PSR) 2008-2010 [5], specifically the objectives of proactive healthcare and the Chronic Care Model; the various bylaws of Regional Health Department [26], [27],[28]; and the opinions of the Regional Council Health Committee [29], [30], [31].

B. HL7 Version 3 CDA Rel.2

Health Level Seven International (HL7) is 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" [4], HL7 Version 3 (HL7v3) is a reference paradigm for the syntactic-semantic interoperability. The HL7 V3 methodology uses the Reference Information Model (RIM), the Data Types Specification, and the HL7 Vocabulary as its starting point. It then establishes a message development process for refining and constrain the Reference Information Model to arrive at the Hierarchical Message Descriptor (HMD) that specifies a number of messages called Message Types.

The following Figure 1 shows the refinement process specified in the methodology. As diagrammed, the processes are used to derive one or more Domain Message Information Models (D-MIM) from the RIM. Each such model represents the set of concepts embodied in the individual Refined Message Information Model (R-MIM) needed to represents the requirements of a particular HL7 domain.

Fig. 1. Refinement Process for defining messages based on the HL7 RIM (Source: Health Level Seven, Inc.)

The HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA documents are encoded in Extensible Markup Language (XML). A CDA document is wrapped by the <ClinicalDocument> element, and contains a header and a body. The header lies between the <ClinicalDocument> and the <structuredBody> elements, and identifies and classifies the document and provides information on authentication, the encounter, the patient, and
the involved providers. The body contains the clinical report, and can be either an unstructured blob, or can be comprised of structured markup. A CDA document section is wrapped by the `<section>` element. Each section can contain a single narrative block, and any number of CDA entries and external references. The CDA narrative block is wrapped by the `<text>` element within the `<section>` element, and must contain the human readable content to be rendered.

C. Chronic Care Model

The Chronic Care Model summarizes the basic elements for improving chronic illness care in health systems at the community, organization, practice and patient levels. This model, elaborated by Prof. Wagner of the Mac- Coll Institute for Healthcare Innovation [3], [32], identifies the essential elements of a healthcare system that help high-quality chronic disease care, such as diabetes, heart disease, hypertension, chronic obstructive pulmonary disease. These elements are

- Community resources
- Organization of Health Systems
- Self-management support
- Delivery system design
- Decision support
- Clinical information systems

In Figure 2, the model is depicted with reference to the six main elements and their interactions. The improved outcomes of this model are productive interactions between an informed and activated patient and a prepared and proactive multi-professional health care team. Informed patients have sufficient information to become a wise decision-maker related to their illness and they also need to be activated by understanding the importance of their role in managing the illness. A prepared team is a practice team that is organized, trained, and equipped to conduct productive interaction. A productive interaction is one that assures that patient needs for evidence-based clinical and behavioral care information and support to become better self-managers, and monitoring over time are met, as reported in [3].

Clinical information systems are the crucial factor in improving chronic illness care with their clinical database containing the critical information necessary to get productive interactions. The fundamental functions to be guaranteed are: providing reminders and alerts for providers and patients; identifying relevant patient subpopulations according to their chronic illness for proactive care; facilitating individual patient care planning; sharing information with providers and patients; and, finally, monitoring performance of team with respect to the chronic care illness indicators.

The Chronic Care Model will require a transformation of health care, from a system that is essentially reactive - responding mainly when a person is sick - to one that is proactive and focused on keeping a person as healthy as possible. This model has been promoted by the World Health Organization [33] and exploited in many countries such as Canada, Holland, Germany, United Kingdom, Denmark. In Tuscany Region this model has been used as the basis for the Expanded Chronic Care Model [34],[35] where the single patient takes a more informed role inside the community and where the General Practitioner clinical aspects are integrated with those of the public health.

II. An experience in localizing the CDA Rel.2 for Patient Summary

Localization is the process of defining new HL7 Version 3 Message Types by a process that includes both the constraint process and an extension process that adds new concepts to the base Message Type. Any local HL7 affiliated organization needs to adapt the standard to the national or regional requirements. We report hereafter a brief summary of the experience of localization carried out with HL7 Italia, in the V3 Domain Working Group - Gruppo di Progetto HL7 Italia IG CDA2 Profilo Sanitario Sintetico. Within this experience, the document Implementation Guide Clinical Document Architecture (CDA) Rel. 2 Profilo Sanitario Sintetico (IT Real) is actually under discussion [25],[15],[16], [36].

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. The principal aims of the PSS will then be the following: let the information be available for the emergency; help the chronic care processes; ensure the continuity of care. The PSS is a document satisfying some requirements:

- it must be synthetic and contain only the essential information;
- it must have a single author, the General Practitioners/Pediatricians creating and updating it;
- it is not clinically specialized to be used in different scenarios (Emergency, Chronic Care...);
- it does not have a specific predefined recipient;
- it must be only one and there must be only one PSS for each patient inside the EHR.

The compliance requirements of Patient Summary are based on the CCD, the IHE Patient Care Coordination and the Italian (IT) realm templates. The templates define the constraints for document, section, clinical statement and entry levels. Moreover the header must be compliant with the CDA Rel. 2 Header as defined by HL7 specifications and localized by HL7 Italia.
### Table I

<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>SHALL NOT</td>
</tr>
<tr>
<td>Advance Directives</td>
<td>OPTIONAL</td>
</tr>
<tr>
<td>Functional Status</td>
<td>REQUIRED</td>
</tr>
<tr>
<td>Problems</td>
<td>OPTIONAL</td>
</tr>
<tr>
<td>Family History</td>
<td>REQUIRED</td>
</tr>
<tr>
<td>Social History</td>
<td>REQUIRED</td>
</tr>
<tr>
<td>Alerts</td>
<td>OPTIONAL</td>
</tr>
<tr>
<td>Medications</td>
<td>RECOMMENDED</td>
</tr>
<tr>
<td>History of Pregnancies</td>
<td>OPTIONAL</td>
</tr>
</tbody>
</table>

**List of requirements for the inclusion of the CCD sections**  
(Source: HL7 Italia)

[36]. Patient Summary also follows the coding specification defined in the HL7 Italia document *Identificazione Object Identifiers (OID)* [37].

Patient Summary has been defined according to the CDA R-MIM. It 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. Hereafter, we assume that the information contents of the coded entry will always be reported also as text in the narrative block. Not all the CCD sections have been implemented in the CDA Body. Table I reports which section is required, optional or not required, up to now.

We report the CCD sections that are now under discussion in the Patient Summary localization.

- **Allocations**: 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. At a minimum, the currently active medications should be listed, with an entire medication history as an option, particularly when the summary document is used for comprehensive data export.
- **Immunizations**: section defining a patient’s current immunization status and pertinent immunization history. The section should include current immunization status, and may contain the entire immunization history that is relevant to the period of time being summarized.
- **Problems**: section deputed to summarize the relevant clinical problems, including the main pathologies. At a minimum, all pertinent current and historical problems should be listed. CDA Rel.2 represents problems as Observations.
- **Family History**: section collecting the family medical history, relevant for the patient risks. This section contains data defining the patient’s genetic relatives that have a potential impact on the patient’s healthcare risk profile.
- **Social History**: section containing the patient’s occupational, personal (e.g. lifestyle), social and environmental history. Social history can have significant influence on a patient’s physical, psychological and emotional health and wellbeing.

In the following, the CDA body for Alarms and Medications sections are reported as an example of localization.

**Alarms**

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 general structure of the Alarms section is reported in Figure 3.

**Fig. 3. Alarms: general structure of the section (Source: HL7 Italia)**

The information regarding an alarm is represented through an `act` derived from the template "Allergy and Intolerance Concern". The general structure of the entry Alarm is reported in Figure 4.

**Fig. 4. Alarms: general structure of the clinical statements (Source: HL7 Italia)**

The detailed information for a generic alarm or an allergy or some intolerance, are listed as an `Observation` element. Further information, as for example the allergy status or the alert severity, can be included as specific classes referred through `entryRelationship`.

**Medications**

All the information related to prescriptions and substance administration are listed in the section named with LOINC...
Health organization. In order to implement the exchange and sharing of medical records between hospital and primary care for the management of the diagnostic and therapeutic paths (PDTA), it is important to specify both the clinical data set and the technological interfaces and messaging, according also to the regional guidelines.

### Clinical data set

Up to now, there are no national/regional standard specifications for the definition of the clinical data set in PDTA for the various chronic pathologies. Here, we consider the TRX-PDTA, a possible solution based on TRX-CiCoM specifications.

### Interface and messaging

Both in the Hospital Specialist area and in the Primary Care area the integration allows the operators to use its own medical record systems in order to manage and archive the information related to the specific clinical dataset. As an example, the...
The horizontal integration of the different Electronic Medical Record systems for General Practitioners has been taken into account by the MITO.SI project. We extend it, with a vertical integration to the EHR, both at local and regional public health organization level. Both the e-Prescription and the Patient Summary are implemented according to the CDA Rel.2 standard.

Collecting and comparing data for self-audits and clinical governance is also considered for General Practitioners, as required by the CCM. TRX-ANR is the XML dataset shared in the GP ANR (National Research Area), based on the TRX-CICoM specifications, used in the clinical audit process and for epidemiological studies on chronic diseases.

Moreover, according to CCM, in order to develop the exchange of medical records between Hospital Specialists and General Practitioners, we consider a vertical integration through an interface (HL7-based) of the Clinical Information Systems, and an integration (CDA Rel. 2) with the EHR for the Hospital Specialists. The TRX-PDTA is the XML dataset common to all PDTA used for the exchange and the sharing of the medical record information.

The interface to access the Person/Patient Registry is implemented according to the HL7v3-based regional specifications [48], [49]. We need also to implement the integration with the Public Health/Regional Code systems and Identification schema, according to the HL7 OIDs (Object Identifiers) [37].

The module Hospital Specialist (HS) Medical Record, depicted in Figure 8, is detailed with all its connections and HL7 interfaces in Figure 9. Notice that we are considering the main Chronic illness such as Diabetes, Heart disease, Hypertension, Chronic Obstructive Pulmonary disease and Brain stroke.

In Figure 10 the scheme of the Person/Patient Registry HL7v3 Integration is drawn. It refers to WP1 and WP2 workpackages. As shown, an integration is needed between the person/patient registry of the GP/HS Medical Record systems and the Public Health person/patient registry. This integration is implemented through two services: an HL7 patient registry interface using the regional Common Terminology (OID); a
consumer of the Public Health person/patient registry service through the Local Application Node to the CART infrastructure.

In Figure 11 the integration scheme of the CDA Rel.2 Patient Summary is shown, referring to WP4, WP5, WP6 and WP2 workpackages. This scheme shows how the various services interact to provide (and retrieve) Patient Summary documents to (from) the EHR, at regional and local level.

V. Final Remarks

The proposed GP/HS project represents, at regional level, an example of integration/interoperability for the Patient Summary documents, the Prescription documents and the PDTA medical records within the Electronic Health Record. This in line with the Italian IPSE [50] and European epSOS (European Patients Smart Open Services [51]) projects, with their initial focus on both patient summary/emergency data sets and medication record/ePrescribing solutions. Tuscany Region and various other Italian regions are involved in the [50] project; and Italy with Lombardia Region and many European member
states are involved in [51]. The analysis carried out in 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. It also highlights that 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 activity [10]. An ongoing HL7 international project on definition of minimum data set and data standards in EHR systems for diabetes assessment in outpatient clinic settings is documented in [52].

The development and localization of the Patient Summary has been started with the involvement of the GP. The work of the HL7 Italia Group [25] is actually in progress and TSE has recently released a draft of technical specifications for the creation of the Profilo Sanitario Sintetico according to the standard CDA Rel.2 [53].

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