

AN HL7/CDA FRAMEWORK FOR THE DESIGN AND DEPLOYMENT OF TELEMEDICINE SERVICES

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Abstract- The advance of regional healthcare networks has created increasing demand for telemedicine services tailored to particular medical specialties and healthcare settings. At the same time, emerging telemedicine protocols and guidelines combined with various medical standards provide specifications not only for the exchanged clinical content but also for the physical setting and technology in use.

This paper presents a framework for the design and deployment of telemedicine services based on open standards: HL7/ CDA for clinical documents, DICOM 3 for imaging, and SCP-ECG for ECGs. The originality of the approach lays on: (a) the creation, maintenance, and reuse of clinical document templates adhering to the HL7 Clinical Document Architecture (CDA) - a recent ISO standard and (b) interoperability with middleware services of the health information infrastructure (HII). This work adds value to the WebOnCOLL collaboration infrastructure, which has been deployed successfully for provision of remote consultation services in cardiology.

Keywords - Telemedicine, medical standards, Clinical Document Architecture, middleware, regional healthcare networks

I. INTRODUCTION - BACKGROUND

Telemedicine as the use of telecommunication technologies to facilitate healthcare delivery dates back to the 1920s when radio was used to link physicians at shore stations with ships in case of medical emergencies [1]. With traditional telemedicine consultation, relevant health information is communicated verbally among the participants. In some cases, video-conferencing equipment, post or fax services are also used to enhance communication. It is only recently with the convergence of information and telecommunication technologies that clinical documents including objective medical data and diagnostic reports, can be exchanged electronically in the context of a telemedicine session.

However, as telemedicine is gradually accepted as a typical healthcare procedure, there is increasing demand for accessible, accountable, secure, efficient, and effective services. Accessibility refers to making available specialized medical expertise at the point of need in a timely manner. That entails availability of the networking infrastructure and provision of up-to-date resource information - a real challenge for the health information infrastructure (HII) of the regional network [2,3].

Accountable telemedicine services require detailed records for the telemedicine sessions. Telemedicine records should include besides the management data necessary for assessment and reimbursement, clinical data including the consultation request, diagnostic examinations (x-rays, ECGs, etc.), and diagnostic reports. Since telemedicine records outlive the session in which they were created, clinical documents and other objective medical data need to be in a standard format to facilitate portability and accessibility. They

should also be digitally signed to meet integrity and non-repudiation requirements. Digital signing and verification requires access to the services of the public key infrastructure (PKI) of the regional network. Finally, as telemedicine sessions are medical contacts, telemedicine records should be part of the patient's life-long health record.

Efficient and effective telemedicine requires taking into account technology guidelines for the physical environment and technology used. Emerging technology guidelines contribute to effective telemedicine by ensuring the compatibility, interoperability, scalability, and reliability of equipment and systems used in telemedicine [4]. However, setting up the physical environment for remote consultation is not enough. Effective telemedicine also involves making available relevant clinical data to accurately depict the patient's clinical condition and select the most appropriate treatment in a timely manner. Clinical protocols and guidelines for diagnosis and treatment published regularly by professional organizations provide relevant information [5]. They are the result of continuous medical research and are shaping current medical practice including telemedicine.

In retrospect, designing and deploying telemedicine services that meet these requirements requires a framework that supports the iterative design and flexible deployment of telemedicine services taking advantage of the regional HII and supporting open standards. The Clinical Document Architecture of HL7 [6,7,8] is an important standardization effort in that respect because it uses XML (<http://www.w3c.org/XML>) to model the structure of clinical documents and is compatible with the HL7 v3. HL7 (<http://www.hl7.org>) is a widely used standard for the electronic interchange of clinical, financial, and administrative information among heterogeneous computer systems. Structured clinical document templates conforming to the CDA and incorporating information from clinical protocols, may be tailored to specific medical disciplines and suspected problems. These templates may also incorporate information from other regional information sources such as coding schemes and prescription databases. Furthermore, interoperability with the Electronic Health Record (EHR) facilitates automatic retrieval of relevant health data from the health record to be included as part of the clinical document. In this way, not only the submission of a consultation request or a diagnostic report may be accelerated but also requests for additional medical data may be reduced.

A. WebOnCOLL Collaboration Infrastructure

The collaboration infrastructure of WebOnCOLL supports accountable, accessible, and secure telemedicine services. The basic concept of WebOnCOLL is the teleconsultation folder (TCF), an actively shared persistent folder, which in-

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cludes multimedia clinical documents shared in the course of a telemedicine session and management data regarding the events that occurred (i.e. log, status, timestamps, digital signatures, etc). All the objects in the TCF are in standard format: clinical documents adhere to CDA, diagnostic images to DICOM 3, and ECGs to the SCP-ECG standard. Furthermore, users interacting with a TCF are aware of other users connected to the same folder.

Each TCF corresponds to a shared workspace managed by the workspace manager of WebOnCOLL. The workspace manager, mediates collaborative access to workspaces keeping track of all user actions and sending update messages when the contents or the users on-line change. Authorized users may retrieve archived TCFs as well as search the TCF archive, to get information relevant to specific types of episodes. The medical specialists that provide telemedicine services are considered mobile, that is, available on-call but not bound to a specific location. Specialized notification agents alert a specialist on-call when a new telemedicine request has arrived or a scheduled telemedicine session is about to start. Interoperability with middleware services of the HII provides for authentication, certification, and resource location. Fig. 1 presents these basic components of the collaboration infrastructure: an application server (i.e. the workspace manager) and software agents, which manage activities related to handling telemedicine sessions and notification of mobile experts.

A single TCF may be reached from the local EHR system or the integrated electronic health record (I-EHR) [9], which indexes all medical contacts of a patient in the regional network. Thus, the overall architecture promotes continuity of care and supports evolution of the life-long electronic health record.

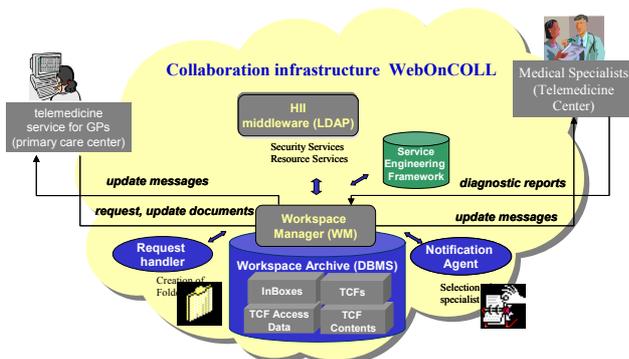


Fig. 1: WebOnCOLL collaboration infrastructure

II. METHODOLOGY

The objective of this framework is to support the iterative design and development of efficient and effective telemedicine services. Furthermore, it should enable rapid prototyping through reuse of software components and fragments of clinical document templates. A telemedicine service can be described by a teleconsultation protocol and a set of clinical document templates that conform to the CDA. The teleconsultation protocol specifies the flow of data in the course of a

session, while clinical document templates facilitate structured data entry.

A. Clinical Document Templates

Each telemedicine service uses a set of clinical document templates, which are submitted before or during a telemedicine session. Clinical document templates correspond to structured forms that are filled out by healthcare professionals in the context of a telemedicine session e.g. request for consultation, diagnostic report, progress note, etc.

Clinical document templates validate against the “CDA Level One” specification [8]. They are comprised of a header, referred to as the “CDA Header” and a body, which at CDA Level One is referred to as the “CDA Level One Body.” The CDA Header identifies and classifies the document and provides information on the document authenticator, the patient, the encounter, provider, and other service actors. Document-related information includes the *id*, *set id*, *version*, *type*, and various *timestamps*. The *id* element uniquely identifies the specific clinical document, while the *set id* identifies the TCF. The *type* and *version* elements identify the clinical document template. Encounter data include the *id*, *code*, *timestamps*, *service location*, and *local header*. The *id* and *code* elements uniquely identify the relevant encounter and its type in the regional network, while attribute-value pairs in the *local header* facilitate interoperability with the local EHR system. The body of the clinical document consists of *section* elements. Sections correspond to reusable XML fragments. Each CDA *section* may contain CDA structures such as *paragraph*, *list*, and *table* elements, nested CDA sections, or *coded_entry* elements. CDA structures contain CDA “entries” such as *content*, *link*, *coded_entry* and *local_markup*. *Sections* including only a *link* are used to refer to external multimedia objects such as an ECG. A *coded_entry* element is used to refer to terminology. These attribute-value pairs encode information relevant to locating and connecting to middleware services (i.e. service name, communication protocol, etc) through appropriate filters.

In general, each clinical document template consists of XML fragments, which are the units of reuse among document templates. Thus, XML fragments are used to assemble clinical document templates. XML fragments may be linked to middleware services of the HII for terminology, resources, profiles, security, and certification, to allow retrieval of up-to-date information. Additionally, XML fragments may be linked to EHR data sources using methods like OMG COAS (<http://www.omg.org>) and JDBC, to facilitate the automatic retrieval of objective medical data based on the suspected medical problem. Interoperability with middleware services of the HII and other data sources such as the local EHR system affects *local header* and *local_markup* elements of the clinical documents templates.

Once the clinical documents reach their final form, the local markup is removed by applying an appropriate XSL style sheet. Multimedia documents such as ECGs or x-rays are linked into the clinical document. The author is authenti-

cated, the clinical document is digitally signed, and both the clinical document and the digital signature are stored in the shared TCF. This process of creating a CDA document appears in Fig. 2.

B. Design and Deployment of Telemedicine Services

In the process of engineering a telemedicine service a working group of healthcare specialists, GPs, and IT experts is formed. In a series of meetings, they create a telemedicine protocol that models the information exchange in the course of the telemedicine session taking into account best practice guidelines and related clinical protocols. The objective is to maximize the amount of relevant information that is extracted from the EHR and transmitted at the time of the request, so that requests for additional data are rare. The group identifies clinical documents, specifies their structural and logical components, and structures their contents as much as possible. Based on these specifications, clinical document templates are designed reusing existing or creating new XML fragments and associating them with middleware services through appropriate filters.

Then, the telemedicine service enters a pilot phase, during which the clinical documents templates go through major revisions regarding their clinical content. It is only through iterative design and continuous assessment in clinical practice that data entry is reduced sufficiently and the service effectively meets the needs of the users.

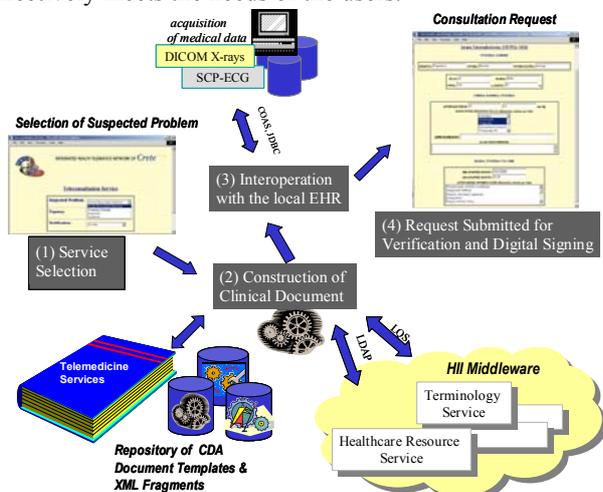


Fig. 2: Process of creating a CDA document

Deployment of a telemedicine service involves configuring the clinical document templates at the remote side to enable interoperability with local EHR systems and middleware services of the HII. Additionally, styles sheets for clinical documents are adapted to reflect the originating healthcare organization. Clinical document templates at the remote site are also configured to interface a number of medical devices such as a 12 lead digital Echocardiograph, and a 12-bit medical scanner for x-rays. Software components embedded in clinical document templates are responsible for searching or acquiring medical data and, if necessary, translate it into a standard format such as SCP for ECGs and DICOM 3.0 for

images. These software components (typically ActiveX technology) are removed at the transformation of the clinical document template to the CDA document that will be included in the TCF.

III. RESULTS

This framework is currently been applied in the design and deployment of remote consultation services to primary healthcare centers in the context of HYGEIANet (<http://www.hygeianet.gr>), the regional health telematics network of Crete. Primary healthcare centers frequently lack the expertise necessary for the timely treatment of difficult cases. Remote consultation in cardiology involves requesting a second opinion on the digital ECG of a patient. In the typical scenario shown in Fig 3, the General Practitioner (GP) at the remote healthcare center conducts a clinical examination of the patient, records a digital 12-lead ECG, and possibly orders some relevant laboratory exams. All this information is stored in the local EHR system. In case of a suspicious ECG recording, instead of transferring the patient to a central hospital, the GP may request a second opinion from a telemedicine center. Fig. 2 shows the process of constructing a CDA document in the context of filling a remote consultation request. Based on the suspected medical problem, the GP selects the most appropriate teleconsultation service option. Special filters may be used to retrieve and structure terminology, resource, or prescription data in the clinical document template. Then, transparently, the explicitly or implicitly known patient and encounter identification and the *local markup* in the clinical document template, are used to retrieve and auto-complete as many fields of the request as possible. Next, XSL templates personalize the presentation of the clinical document template according to the preferences of the GP. The GP reviews the clinical document template, selects one of the available telemedicine centers and/ or experts retrieved from the regional resource service, and adds further information or comments. A CDA document is constructed, digitally signed by the GP, and submitted to the selected telemedicine center as part of a teleconsultation request.

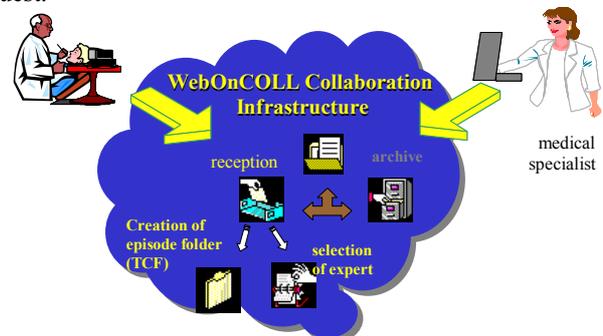


Fig. 3: Typical scenario of remote consultation in cardiology

The teleconsultation request including the CDA document and linked ECG in SCP-ECG format is forwarded to the selected telemedicine center using SOAP [10]. In response to the received message with the teleconsultation request, the

request handler (shown in Fig. 1) creates a shared TCF for the episode. During the teleconsultation, the healthcare professionals review the material in the shared TCF. Additional material is added to the TCF folder on demand. After the end of the telemedicine session, concluding reports are added, and the TCF is archived. At that point the TCF becomes part of the patient's I-EHR and authorized professionals may access its contents. Fig. 4 pictures a telemedicine session in time as supported by WebOnCOLL.

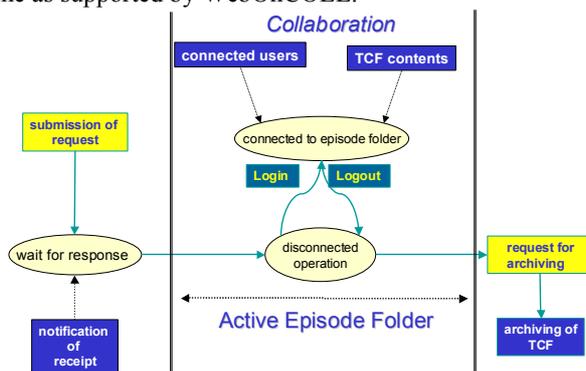


Fig. 4: Basic collaboration support provided by WebOnCOLL

IV. DISCUSSION

A number of researchers and standardization bodies around the world including CEN/TC251, ASTM E31.25, and HL7 SGML/XML SIG, are investigating the role of XML technology in sharing health records [11,12,13]. CEN/TC251 WG1 has accepted XML as a universal format to express data models for the various CEN specifications. The intent of the ASTM E31.25 committee is to develop standard electronic document representations of paper-based healthcare documents and forms (XML DTDs for Healthcare). In contrast to the CDA, the overall approach of ASTM E31.25 is bottom-up starting from the analysis of specific types of documents. The HL7 SGML/XML Special Interest Group is involved in the design of CDA (Clinical Document Architecture). Furthermore, recently, a committee was formed within HL7 to investigate the role of structured document templates in relation to the HL7 RIM [14].

Currently all XML-related efforts in the standardization of clinical documents for the exchange of medical records converge to the CDA. CDA, based on XML and the HL7 RIM, imposes minimal constraints on the document structure and content for exchange. CDA is envisioned as a hierarchically organized set of document schemas (or DTDs), which define the semantics and structural constraints necessary for the exchange of clinical documents. Each level of the architecture is derived from a more basic one, with higher levels to enable the automatic processing of rich semantics. Level 1, requires only conformance to a common header format, while Levels 2 & 3 proceed to more structured content.

Clinical document templates created using the methodology described in this paper may be made to conform to various levels of the CDA. Although, currently clinical document templates conform to CDA Level 1, we expect that as CDA Level 2 & 3 become available and teleconsultation ser-

vices evolve, they will become even structured and will conform to higher levels of the CDA.

V. CONCLUSION

XML technology emerging from the convergence of data processing, communication, and publishing technology, presents new opportunities for the representation, sharing, and automatic processing of health information. The presented framework assists the iterative design and deployment of telemedicine services that are efficient and effective, promoting reusability of clinical document templates. Based on our experience from the deployment of telemedicine services in HYGEIANet (<http://www.hygeianet.gr>), this framework is a valuable tool for working groups that are interested in the rapid prototyping and continuous evolution of telemedicine services.

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