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Relevance of health level 7 clinical document architecture and integrating the healthcare enterprise cross-enterprise document sharing profile for managing chronic wounds in a telemedicine context

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Abstract — The number of patients with complications associated with chronic diseases increases with the aging population. In particular, complex chronic wounds raise the re-admission rate in hospitals. In this context, the implementation of a telemedicine application in Basse Normandie, France, contributes to reduce hospital stays and transport. This application requires a new collaboration among general practitioners, private duty nurses and the hospital staff. However, the main constraint mentioned by the users of this system is the lack of interoperability between the information system of this application and various partners' information systems. In order to improve medical data exchanges, we propose a new implementation based on the introduction of interoperable clinical documents and a digital document repository for managing the sharing of the documents between the telemedicine application users. We then show that this technical solution is suitable for any telemedicine application and any document sharing system in a healthcare facility or network.

1. Introduction: The number of patients suffering from one or more non-communicable diseases increases with the aging of the population [1]. Non-communicable chronic diseases were responsible for 36 of the 57 million deaths worldwide in 2008 [2]. There are several complications associated with chronic diseases. For example, diabetes slows wound healing and increases the risk of infection [3]. In Basse Normandie, France, there are around 20,000 patients with complex wounds [4]. Complex chronic wounds increase re-admission rate in hospitals (15 days per patient per year at the Caen University Hospital between 2008 and 2012) [5] and require repeated transportations for people with low independence. In this context, telemedicine can contribute to reduce hospital consultations and transport [6]. Telemedicine facilitates patient follow-up outside hospital [7]. Telemedicine applications can help reducing healthcare costs while maintaining healthcare quality [7].

This situation has led the Basse-Normandie and Languedoc-Roussillon regions to implement the Domoplaie telemedicine project [4]. Its goal was to develop a wound care system with tele-expertise, teleconsultation and tele-assistance for home care patients in order to reduce both transportations and hospital stays. This application supports collaboration between the general practitioner, the private duty nurse and the hospital staff.

In the current implementation, a specific Electronic Healthcare Record supports medical data exchange between the healthcare professionals. However, interoperability between this system and the various partners' information systems remains limited. This study focuses on the Domoplaie implementation in Basse-Normandie in the context of TELAP [telemedicine network applied to wound care].

We propose a new implementation of medical data exchange based on Health Level 7 (HL7) Clinical Document Architecture (CDA) and on implementation guidelines from the Integrating the Healthcare Enterprise (IHE) Cross-Enterprise Document Sharing (XDS) profile facilitating interoperation between the various information systems.

In this contribution, we first describe the Domoplaie telemedicine application and analyse its current constraints and limitations, with a particular focus on interoperability. In a second step, we propose a solution which makes it possible to obtain interoperability of clinical data when including a patient in the TELAP network.

2. Description of Domoplaie:

2.1. Steps of the coordinated healthcare circuit: Domoplaie covers all the stages of the coordinated healthcare circuit [4]. The main Domoplaie users are then general practitioners, private duty nurses, hospital staff and specialists [4]. The first stage is to conduct an initial complete medical examination of the patient chronic wound. It can be performed either by a general practitioner or a specialist. Then, an inclusion request is completed with the patient's data as well as the result of medical examinations. Currently, this inclusion request has to be faxed or sent by e-mail to the TELAP coordination.

The patient's data contained in this document need to be manually recorded in the Electronic Healthcare Record by the TELAP staff. Next, a first teleconsultation session between the hospital staff, the private duty nurse and the patient must be planned by the TELAP coordination. The aim of the teleconsultation is to obtain a second opinion from a remote specialist (dermatologist or diabetologist) so that patient transport is not required. During the videoconference, the specialist can examine pictures sent by the nurse.

At the end of the teleconsultation session, a report is sent to Domoplaie partners (e.g. general practitioner) through secure messaging. Additional teleconsultation sessions can be planned if needed until the patient's recovery.

2.2. System components: The various system components incorporate three technology types (see Fig. 1): Patient's data are stored in a specific Electronic Healthcare Record. Teleconsultation sessions are supported by a videoconferencing system available at three expert sites in Basse-Normandie (Alençon Hospital diabetes department, Caen University Hospital dermatology department and Cherbourg Hospital dermatology department). The private duty nurse is equipped with a smartphone or a tablet [4] to take pictures or videos of wounds at the patient's home.

2.3. Lack of interoperability in Domoplaie: The first difficulty concerns the inclusion request. This document is initially recorded by the general practitioner who can either fax it or send it as a PDF file. In both cases, the TELAP staff is then required to enter data manually for patient data registration into the Domoplaie Electronic Healthcare Record. The second difficulty is the lack of interoperability between Domoplaie and the information systems of the healthcare facilities

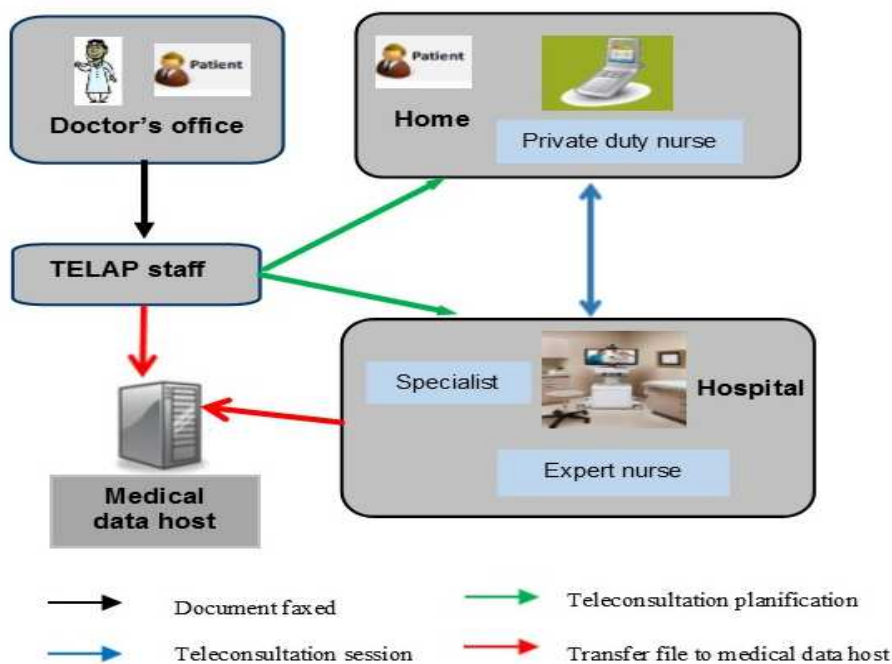


Fig1 : Domoplaie application

(clinical care centres, hospitals, etc.). The only way for TELAP to communicate with healthcare facilities is to send PDF files by secure messaging. At the receiver end, these documents cannot be easily integrated into the information system.

3. Proposed new implementation: Improved data exchange should allow, on the one hand, a single data entry during inclusion request, and, on the other hand, interoperable representation of clinical documents. For Domoplaie, the coordinated healthcare circuit requires two types of interoperable clinical documents (the first one for the inclusion request, the second one for the teleconsultation session reports). This new implementation must also take into account an architecture supporting the sharing of these documents between the heterogeneous information systems of the various partners.

3.1. Functional and technical requirements: Clinical documents named "inclusion request" are required to initiate the process. The header of these documents must include the patient's identification, the contact details of medical practitioners and nurses, and the addresses of the facilities involved in the coordinated healthcare circuit. The document bodies must contain results from laboratory analysis, ultrasound and imaging examinations. They should provide the results of the wound initial assessment. These documents must be interoperable with software from healthcare facilities. They must contain coded and structured data, which can be integrated in the healthcare facilities' databases. They must also be easily read by humans. These documents should be accessible by Domoplaie users and TELAP staff. They can be archived on the same server as electronic health records.

Inclusion Request: A computerised data entry form for the patient inclusion request is a technical solution for removing redundant manual data entry. It must be a simple form which can be on a website, that is easily accessible to all Domoplaie users (like with a regional web portal). For each field in the form, data entered by general practitioners or private duty nurses are added to the inclusion request created for

each patient's first medical examination.

Teleconsultation session reports: To share the teleconsultation reports, the development of a second model of interoperable clinical documents is proposed. There is no structured model of the teleconsultation session report yet. The content of these documents varies depending on the medical examination performed during the teleconsultation session. Patients and health professionals' identification and teleconsultation dates are currently the only structured information fields. However, the reports may contain pictures, values in the form of trends or tables and other results of medical examinations as plain text.

Digital document repository: To share the inclusion requests and the teleconsultation reports with the entire Domoplaie community, a digital document repository is needed. This system must facilitate clinical documents archiving and reading. This document repository can be located at a healthcare data host.

3.2. Standard data exchange procedures and formats: To share clinical documents between Domoplaie users, the use of international standards such as HL7 CDA [8] is an interesting option. A CDA document is a complete information object, which can include text, pictures, sound and other contents. It can either be sent within a message or exist independently [8]. As for the implementation of a digital document repository, we propose to use the IHE XDS profile [9] which facilitates the registration, distribution and access to medical documents across healthcare facilities.

HL7 CDA: CDA [10] is a new approach based on XML for structuring and exchanging medical data within and between healthcare facilities. CDA documents, which contain a header and a body, are defined with three levels of architecture corresponding to three different levels of interoperability [8]. For level 1, the clinical document body can be unstructured. It can contain something other than XML language (e.g. PDF file). With this level, the structured CDA headers allow to differentiate the types of documents. For level 2, The CDA document may include several different sections that contain human readable narrative

forms or codified structures for an automatic processing. Compared with level 2, CDA level 3 provides additional specified constraints at the entry level within a section. With this level, the body text sections include codified entries to recover external data. Today, the CDA exists in two main versions: the CDA release 1 (CDA R1) that mainly focuses on the structured header [11], and the CDA release 2 (CDA R2) [11] that includes structured elements in both the document header and the document body. The latter may contain health encoded data that can be easily integrated into data bases of healthcare facilities.

IHE XDS profile: For the creation of a digital document repository, IHE proposed the XDS profile [12], which comes from the IHE IT Infrastructure Technical Framework (ITI TF). This profile describes appropriate sharing of medical information It specifies the transactions supporting the registration, distribution and access to shared documents between healthcare facilities. These documents may contain any type of clinical information. They may include, for example, simple text, formatted text (e.g., HL7 CDA Release 1), images (e.g., DICOM) or structured and vocabulary coded clinical information (e.g., CDA Release 2). With the IHE XDS profile, sending and receiving clinical documents can be achieved with standard communication protocols as HTTP or HTTPS. This information flow is managed through one or more document repositories and one document registry which must be precisely defined.

3.3. CDA document implementation: The implementation of a CDA document requires to select an existing model that contains templates and rules sets [13]. The Implementation Guides for CDA [13] contain templates that address specific uses. They can represent professional recommendations, or national clinical practice guidelines.

Template definition: Templates are designed to create standardised clinical documents that are specifically intended to support clinical workflows in various use cases. A CDA template can be a document template that defines rules for an entire CDA document, or a header template, section template, or entry template covering a relevant portion of the overall CDA document.

Implementation of Domoplaie CDA documents: Our goal was to find CDA document templates suited to the inclusion request or the teleconsultation reports. Because of the national context of the Domoplaie project, the document templates were retrieved from the ASIP web site under the “Health Information Systems Interoperability Framework (HIS-IF)” heading [14]. As for the inclusion request document, a template matched our needs. The name and the Object Identifier (OID) of this document template were respectively “Volet de la Synthèse Médicale” and (1.2.250.1.213.1.1.1.3.1) [14]. The version of CDA used for this technical model document was CDA R2. As a result, Domoplaie CDA documents have potentially codified structures in the header and in the body of the document for an automatic processing. In contrast, there is no need for structured data for the teleconsultation report body. The use of the same model for both types of Domoplaie documents allows us to have a common codified header. This makes it easier to identify documents.

3.4. Creation of a data entry form and CDA documents: At first, it was necessary to create Domoplaie CDA documents. For this purpose, we chose a tool developed by the ART-DECOR expert group [15]. After creating the CDA documents, this tool also allows to check their structures and their XML contents (generation of schematrons) [16]. Creating CDA documents with ART-DECOR involves three steps [16]. The first step is the identification of the CDA document project team including the name of the author and the version of the document (required in HL7 CDA). In the second step, it is necessary, particularly for the document named “Inclusion request”, to describe the concepts which correspond to different analyzed items and datatypes in data set sections of these documents (according to the document template selected previously). For the inclusion request and the teleconsultation session reports, the document’s header must contain at least the

following concepts: patient information, contact details of primary physician, private duty nurse and other participants, document creation date and author identification. For the inclusion request, the concepts described in the document body are wound examination, associated pathology and past illness and wound healing factor.

In a third step, we have to define the considered scenarios which correspond to the use cases. At this level, we are able to determine two different transactions (the communication of the inclusion request and the communication of the teleconsultation session report). The terminology section of this tool includes the used nomenclatures (e.g. LOINC and SNOMED) and the related value set definitions. This section is also the place where the different templates are defined.

Finally, the combination of data sets, value sets and defined templates allows us to produce an XML file entitled “Retrieve Transaction”. We converted the XML file into an HTML data entry form using an XSLT stylesheet. This form can then be accessed by means of any Internet browser (see Fig. 2 for a simple example of a XLS transformation).

3.5. Creation of document repository: For the creation of this repository, the concept is to use Domoplaie’s current infrastructure. As shown in Fig. 3, this document sharing management system can be built with the XDS profile functional architecture. The Document Repository can be installed on the secure database server on the local host. A regional website can keep a register of CDA documents (patient identification is managed by the TELAP staff) [4]. In this case, (i) the general practitioners fill the Web form, (ii) the CDA document is automatically generated and (iii) it is made accessible by the Domoplaie users, on the regional Internet site. After their establishment, all CDA documents can be stored on the healthcare data host. Domoplaie users can retrieve them through the regional web-portal. For all transactions described in Fig. 3, the CDA documents can be exchanged over the HTTPS secure data transfer protocol [17].

4. Discussion: The key to success of this project relies in selecting an appropriate modeling tool for CDA document creation. This tool should consider both qualitative and quantitative data from Domoplaie documents. At the same time, it should be flexible enough to integrate essential non-structured data concerning the medical examination of the patient’s chronic wounds. Among the most commonly used CDA tools, MDHT, ART-DECOR and TRIFOLIA are the main candidates supporting the generation of various elements (e.g. creation of templates, documentation, XML instance, test tools, etc.) [18]. ART-DECOR is the most widely used in Europe. It is a web-based application that records HL7 and other reusable templates and value sets. The benefits of this tool are first to allow schematron validation, and, second, to enable integration of unstructured section in CDA document. This is important for the teleconsultation reports. With this tool, a document can combine unstructured and structured sections. Thus, this tool allows to easily create both types of Domoplaie information regarding patient identity, the document type and the document identification. With the XDS profile, to group together documents pertaining to the same patient, a unique patient identification is required [7]. The identifier is called the XDS Affinity Domain Patient Identifier (XAD-PID) linked to a local patient ID. The XAD-PID is assigned to all documents contained in a XDS Document Registry. It conveniently supports grouping the CDA documents pertaining to the same person. With the HL7 CDA R2 standard, it is possible to retrieve the patient identity and the document identification from the CDA document headers. With the XDS profile, the document repository registers this document information. So, the documents of interest for the care of one patient may be easily found by the Domoplaie users. The CDA documents are stored in the repository with an address allocated by the registry. This system allows telemedicine application users to retrieve any specific examination report from one

```

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Remplir le bilan plaie

Informations document

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Nom de l'auteur du document:	<input style="width: 90%;" type="text"/>
fonction:	<input style="width: 90%;" type="text"/>

Fig. 2: First sampleXML file entitled "Retrieve Transaction" with corresponding data entry form using an XLT stylesheet

patient from the repository.

We have now demonstrated that ART-DECOR is a suitable modeling tool for Domoplaie. It enables an implementation of a technical solution which allows the capture, the recording and the distribution of the CDA documents of telemedicine applications. This technical solution may be an interesting option for many telemedicine applications. The only parameter which varies according to telemedicine applications is the selection of document templates depending on the content of shared information.

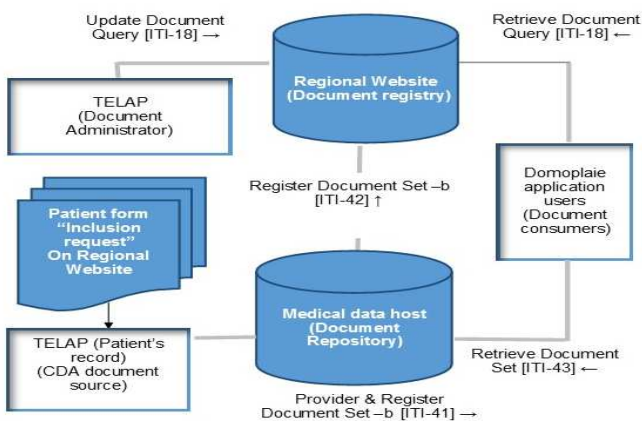


Fig3. CDA Domoplaie document repository

5. Conclusion: The lack of interoperability in Domoplaie has led us to propose a technical solution which facilitates communications between healthcare professionals of the coordinated healthcare circuit. The implementation of CDA documents avoids redundant data entries and simplifies the exchange of patient information. The ART-DECOR tool gives us the opportunity to implement a comprehensive system that will manage the creation, registration and distribution of clinical documents exchanged in telemedicine applications. With ART-DECOR, it is easy to integrate all structured and unstructured data which are contained in inclusion request documents.

The technical solution presented in this contribution is suitable for improving interoperability within any telemedicine application and any document sharing system in a healthcare facility or network.

The next steps will consist in deploying both CDA documents as well as the XDS-compliant actors within the Domoplaie infrastructure.

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