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Interopérabilité entre hôpitaux et acteurs médicaux

Deliverable D2.1 – Part A:
Technical State-of-the-art of Medical Interoperability
(Etat de l'art technique de l'interopérabilité médicale)

Bruno Alves et Michael Schumacher
Institute of Business Information Systems

Abstract:

The goal of this document is to give a general overview of existing standards for exchanging *Electronic Health Records* (EHR) documents. A Patient *EHR* document refers to the medical record of a patient stored in a digital format. The information stored in an EHR might include patient information such as demographics, medical history, medication, allergy list, lab results, or radiology. After reviewing EHR standards, this document also discusses interoperability capabilities of existing HER standards.

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1 Introduction

The goal of this document is to give a general overview of existing standards for exchanging *Electronic Health Records* (EHR) documents. A Patient *EHR* document refers to the medical record of a patient stored in a digital format. The information stored in an EHR might include patient information such as demographics, medical history, medication, allergy list, lab results, or radiology. After reviewing EHR standards, this document discusses interoperability issues between systems that run different EHR.

Actually, nowadays, a great number of care centres still store patient data in their own proprietary format. However, the problem arises when a patient needs to have medication in another location. When there is no means to exchange this health record, the patient needs to give his medical history again. However, to allow a seamless integration of the patient EHR with the medical assistance systems, the patient EHR data format must be readable. This is achieved by techniques for the exchange and interoperability of *Electronic Health Records*.

The direction of the research tends towards the harmonization of formats in order to achieve at least a partial interoperability. Interoperability implies that:

- A data channel should be established between care centres, which would be understandable by both. For example, a first-aid worker would ask for patient data on a mobile phone terminal and should be able to get the allergy list of the patient before administrating medication;
- The Patient EHR should be universally understood by the machines requesting it. It is necessary, to achieve this level of integration, that exchanged documents contain meaning in some ontological language. Having a common data channel and message format does not ensure that medical systems can understand and interpret correctly each other.

Interoperability in this document is voluntarily employed for designing both semantic and technical interoperability. No further care will be given for cultural, ethical, political, legal or international interoperability issues.

2 Electronic Health Records

There exists a plethora of different formats for storage, retrieval and data exchange of EHR. Although a large variety exists, they are all based on the same principles:

1. A reference model, which specifies the basic data structures and types;
2. An extension model proposing additional constraint rules under the form of archetypes, templates, etc.

Note that it is an abuse of language to speak of standards, since most of the formats presented in next sections are not truly validated EHR standards. However, most of them are standardized by other organizations and they partially implement the required points to become a full EHR standard.

2.1 Electronic Healthcare Record Communication

The "Electronic Healthcare Record Communication" (EHRcom (1)), also known as ENV/EN 13606 European Standards was created by the *Technical Committee on Health Informatics of the European Committee for Standardization* (CEN/TC 251) EHRcom Task Force as a revision of the ENV 13606 four-part pre-standard. It is intended to "define rigorous and stable information architecture for communicating part of all of the Electronic Health Record (EHR) of a single subject of care (patient)"[1]. EHRcom is based on the openEHR framework (2) and is still in development at the technical committee on Health Informatics of the European Committee for Standardization (CEN/TC 251),

EHRcom is composed of logical building blocks describing the EHR content (see Figure 1). The top-level is a folder, which can possibly nest other *Folders*. This structure allows describing a hierarchical organization of the EHR, and is stored per episode or per clinical speciality. Folders contain zero or more "compositions". A composition (which roughly corresponds to one clinical document) contains a list of sections with section headers and entries, which consist of elements or clusters of elements. Each element has a single value of a single data type. Content in the EHR extract is always added or replaced as a complete composition.

EHR	The electronic healthcare record for one person
Folders	High-level organization of the EHR, e. g. per episode, per clinical specialty
Compositions	A clinical care session, encounter or document e. g. test result, letter
Sections	Clinical heading reflecting the workflow and consultation process
Entries	Clinical "statement" about Observations, Evaluations and Instructions
Clusters	Nested multi-part data structures (tables and interval time series) e.g. audiogram
Elements	Leaf nodes with single data values, e. g. reason for encounter, body weight
Data Values	Data types for instance values, e.g. coded terms, measurement with units

Figure 1. Building blocks of the Reference Model

EHRcom is composed, in its current state of five substandards:

1. The Reference Model
2. Archetype Interchange Specification
3. Reference Archetypes and Term Lists
4. Security Features

[1] Wikipedia definition for European Standard EN 13606 available at http://en.wikipedia.org/wiki/EN_13606

5. Exchange Models

Currently, only the Reference Model is stable. Documents 2 to 5 are still working drafts. Since this standard does not define an internal architecture design nor defines the kind of applications, which may request EHR data, EHRcom is simply designated as “EHR extract”.

2.1.1 EN13606-1: Reference Model

The *Reference Model* (RM), known as CEN EN13606-1, defines the entities used in the EHR extract, whose structure is given in one of the following four RM parts also known as packages:

- *Extract*
- *Demographics*
- *Access Control*
- *Message*

2.1.1.1 Extract

The *Extract* package defines the main classes of the reference model along with the data structures describing the EHR content. It defines the root class of the RM also named as “EHR_EXTRACT”.

2.1.1.2 Demographics

The *Demographics* package allows defining persons, software agents, devices and organizations. These roles are typically defined in the EHR extract. For example, they allow describing the patient and the doctor in charge of the patient. The structures included in the package are described in the CEN prEN 14822-1 2003 document.

2.1.1.3 Access control

The *Access Control* package defines a representation for access policies and is described under the name CEN EN13606-4.

2.1.1.4 Message package

The *Message* package, developed as CEN EN13606-5, defines the necessary attributes for communicating the EHR extract to a remote process via a message or any other serialized form. The last revision in development includes the HL7 Domain Message Information Model (D-MIM). This new addition will allow using HL7 version 3 messages for communication (3 p. 9).

2.1.2 prEN 13606-2: Archetype Interchange Specification

Even if the generic *Reference Model* is specific to the healthcare domain, it is still very general and contains only relatively few classes. There is however a clear need to describe specific clinical concepts. This is done with archetypes, which model *healthcare* and *application specific concepts* such as blood pressure, lab results, etc. *Archetypes* are thus constraint rules, which specialize the generic data structures that can be implemented using the reference model.

An *Archetype Description Language* (ADL) (4) and a library of archetypes are still in development (CEN EN13606-2 and CEN EN13606-3). ADL-described *Archetypes* are fully convertible to *HL7 Refined Message Information Models* (R-MIMs) (5). R-MIM is an information structure, which represents the necessary classes, attributes, associations, and data types for a set of messages. This behaviour is intended to “harmonize the EHRcom archetype concept with the HL7 Clinical Document Architecture (CDA) and HL7 Templates” (3 p. 10).

The figure below presents the description of an archetype "Complete Blood Picture" using ADL:

```
OBSERVATION[at0000] matches { -- Complete blood picture
 data matches {
  HISTORY[at0001] matches { -- history
```

```
    events cardinality matches {1..*; unordered} matches {
      EVENT[at0002] occurrences matches {0..*} matches { -- any event
        data matches {
          ITEM_TREE[at0003] matches { -- structure
            items cardinality matches {1..*; ordered} matches {
              ELEMENT[at0004] occurrences matches {0..1} matches {-            - Hemoglobin
                value matches {
                  C_QUANTITY <
                    property = <[openehr::119]>
                    list = <
                      ["1"] = <
                        units = <"gm/L">
                        magnitude = <|>= 0.0|>
                > > >
              } }
              ELEMENT[at0012] occurrences matches {0..1} matches {-- Platelet count
                value matches {
                  C_QUANTITY <
                   property = <[openehr::119]>
                   list = <
                     ["1"] = <
                       units = <"10*9/L">
                       magnitude = <|>= 0.0|>
                 > > >
} } } } } } } } } }
```

Figure 2. Part of an ADL definition of "Complete Blood Picture" (source (6))

2.1.3 prEN 13606-3: Reference Archetypes and Term Lists

CEN EN13606-3 is intended to describe a library of archetypes for a large palette of purposes. It also defines the vocabulary associated to archetype attributes.

2.1.4 EN 13606-4: Security Features

Security features of EHRcom are intended to define measures to help in supporting access control and auditability of the EHR communications.

2.1.5 EN 13606-5: Exchange Models

Defined as standard CEN 13606-5, the exchange models of the EHRcom describe messages and service interfaces to enable EHR and archetype communication.

2.1.6 Example

In the following example, we define a new archetype for blood pressure. This example will show the existing relationship between archetypes and their instantiation in a composition (in a EHR_EXTRACT).

The concept of blood pressure is modelled with three values: systolic and diastolic pressures both given in millimeters of mercury (mmHg) and the time at which the pressure was measured. Pressures are limited to values between 10mmHg and 500mmHg.

This example, which is taken from (7) spans over three primary steps:

1. *Conceptualisation* of the archetype
2. *Definition* of the archetype in ADL
3. *Instantiation or implementation* of the archetype for a particular case

2.1.6.1 Archetype schematization

When creating a new archetype, the first step, is to schematize in order to simplify its development. In this example, the complete blood pressure picture is composed of the systolic and diastolic pressures and of the date and time. ENTRY and ELEMENT are part of CEN EN13606-1 (R*eference Model*), see also Figure 3.

Figure 3. Block representation of the archetype

2.1.6.2 ADL description

The next step involves the formalization of the archetype in a description langage. The ADL language, which is used for CEN EN13606 archetype definition, is XML-based.

```
archetype
 CEN-EHR-ENTRY.BloodPressure.v1
concept
 [at0000] --Blood pressure
definition
 ENTRY[at0000] matches {      -- Blood Pressure
  items cardinality matches {0..1; unordered} matches {
   ELEMENT[at0001] matches { -- Systolic
    value matches {
     PHYSICAL_QUANTITY matches {
      value matches {|10.0..500.0|}
```

```
          property matches {"pressure"}
          units matches {"mm[Hg]"}
        }
      }
    }
    ELEMENT[at0002] matches { -- Dyastolic
      value matches {
        PHYSICAL_QUANTITY matches {
          value matches {|10.0..500.0|}
          property matches {"pressure"}
          units matches {"mm[Hg]"}
        }
      }
    }
    ELEMENT[at0003] matches { -- DateTime
      value matches {yyyy-mm-dd HH:MM:SS}
    }
  }
}
ontology
  primary_language = <"en">
  langages_available = <"en","es">
  term_definitions = <
    ["en"] = <
      items = <
        ["at0000"] = <
          description = <"Blood Pressure measurement">
          text = <"Blood Pressure">
        >
        ["at0001"] = <
          description = <"Systolic Pressure">
          text = <"Systolic">
        >
        ["at0002"] = <
          description = <"Dystolic Pressure">
          text = <"Dyastolic">
        >
        ["at0003"] = <
          description = <"Time of measurement">
```

```
    text = <"DateTime">
  >
```

Figure 4. ADL archetype

The identifier of the archetype has a special syntax and identifies archetypes in a global space. Its syntax is given in (8 p. 13) and its goal is to allow the creation of new archetypes, which relate to each other but does not invalidate the previous one. Archetypes can relate to each other in the following ways:

- *Revision*: the new archetype contains changes that do not invalidate any of the data created with the previous archetype;
- *Specialisation*: acts like specialisation for object-oriented langages. The new archetypes extends the nodes and entries of its parent;
- *Version*: allows news versions of the archetype, which a small number of changes, which are incompatible with previous version;
- *Composition*: allows having several archetypes as nodes of a single archetype.

2.1.6.3 Archetype instantiation

Instantiating an archetype implies creating a section with custom data that matches the template given by the archetype. Archetype definitions are thus similar to data schemas. The figure below shows an instance of the blood pressure archetype:


```
<ENTRY>
 <name><originalText>Blood Pressure</originalText></name>
 <rc_id>
  <assigingAuthorityName>HUPH</assigingAuthorityName><extension>0041</extension>
 </rc_id>
 <meaning>
  <displayName>Blood Pressure</displayName>
  <codeValue>CENarch-xvbnh</codeValue>
  <codingSchemeName>CEN</codingSchemeName>
  <codingSchemeVersion>1.1</codingSchemeVersion>
  <codingScheme><oldValue>123456790</oldValue></codingScheme>
 </meaning>
 <uncertainty_expressed>true</uncertainty_expressed>
 <synthesised><value>false</value></synthesised>
 <items>
  <ELEMENT>
   <name><originalText>Systolic</originalText></name>
   <rc_id>
    <assigningAuthorityName>HUPH</assigningAuthorityName><extension>0045</extension>
   </rc_id>
   <synthesised><value>false</value></synthesised>
   <meaning>
```

```xml
    <displayName>Measurement of systolic blood pressure</displayName>
    <codeValue>CENarch-xvbnhS</codeValue>
    <codingSchemeName>CEN</codingSchemeName>
    <codingSchemeVersion>1.1</codingSchemeVersion>
    <codingScheme><oldValue>123456790</oldValue></codingScheme>
   </meaning>
   <value>
    <PHYSICAL_QUANTITY>
     <value>120</value>
     <property><codeValue>pressure</codeValue></property>
     <unit><codeValue>mmHg</codeValue></unit>
    </PHYSICAL_QUANTITY>
   </value>
  </ELEMENT>
  <ELEMENT>
   <name><originalText>Dyastolic</originalText></name>
   <rc_id>
    <assigningAuthorityName>HUPH</assigningAuthorityName><extension>0046</extension>
   </rc_id>
   <synthesised><value>false</value></synthesised>
   <meaning>
    <displayName>Measurement of dyastolic blood pressure</displayName>
    <codeValue>CENarch-xvbnhD</codeValue>
    <codingSchemeName>CEN</codingSchemeName>
    <codingSchemeVersion>1.1</codingSchemeVersion>
    <codingScheme><oldValue>123456790</oldValue></codingScheme>
   </meaning>
   <value>
    <PHYSICAL_QUANTITY>
     <value>70</value>
     <property><codeValue>pressure</codeValue></property>
     <unit><codeValue>mmHg</codeValue></unit>
    </PHYSICAL_QUANTITY>
   </value>
  </ELEMENT>
  <ELEMENT>
   <name><originalText>DateTime</originalText></name>
   <rc_id>
    <assigningAuthorityName>HUPH</assigningAuthorityName><extension>0048</extension>
```

```xml
    </rc_id>
    <synthesised><value>false</value></synthesised>
    <meaning>
      <displayName>Date and Time of the measurement</displayName>
      <codeValue>CENarch-xvbnhD</codeValue>
      <codingSchemeName>CEN</codingSchemeName>
      <codingSchemeVersion>1.1</codingSchemeVersion>
      <codingScheme><oldValue>123456790</oldValue></codingScheme>
    </meaning>
    <value><time>2004/07/16 17:32:00</time></value>
  </ELEMENT>
 </items>
</ENTRY>
```

Figure 5. XML fragment containing and instance of the archetype

CEN/TC 251, the European body mandated to develop standards for Health Informations, is planning to make CEN EN13606 a basis for an international EHR standard.

One great advantage of XML-based exchange formats is that they can be visually represented by *Extensible Stylesheet Language* (XSLT) (9) style sheets.

2.2 Health Level Seven

Health Level Seven (HL7) (10) is a non-profit ANSI recognized Standards Developing Organization. Its role is the development of clinical messaging standards and management and integration of clinical patient care data. HL7 developed two messaging standards: HL7 Version 2 and Version 3.

2.2.1 HL7 Version 2

HL7 v2 is the world most widespread Clinical Messaging Standard (CMS). Version 2 presents a great flexibility since it does not reference any information model. Instead, it describes large amounts of optional fields and defines only a small amount of mandatory ones. Thus, being HL7 v2 compliant doesn't mean that two systems are necessarily interoperable; because both ends cannot necessary interpret the data contained in the message.

2.2.2 HL7 Version 3

HL7 Version 3 (HL7 v3) (11) was created and approved as a replacement for Version 2. It is fully object-oriented and its content is described by an information model: The *Reference Information Model* (HL7 RIM) (12). This information model is an abstract and formal representation of entities including their properties, relationships and operations, which can be performed on them.

Version 2.5 only allowed exchanging messages between two medical information systems (inside the same domain; care center, hospital, etc). This is not the case anymore in version 3, which allows exchanging messages between institutes (care centers, hospitals, etc.).

HL7 v3 message specification is derived from the RIM and is called *Message Information Model* (MIM). This model is detailed under the *Refined Message Information Model* (R-MIM) specification. This subset of the HL7 RIM is thus used for the creation of HL7 v3 messages and uses HL7 data types.

HL7 also specifies the *Hierarchical Message Definition* (HMD), which allows defining different types of messages from the same RIM. Each HMD acts as a recipe or template for instancing new messages. HL7 also introduced the possibility of sharing common elements between HMD's (which are often unnecessarily repeated). These elements are called *Common Message Element Types* (CMET) and allow gaining time and avoid rewriting common message elements (13).

The figure below presents an example of an HL7 v3 message in XML format (source (14 p. 159)). A detailled explanation is given in the same source and does not enter in the scope of this document.


```
<?xml version="1.0"?>
<!DOCTYPE Pt SYSTEM "admitexamp1.dtd" [ ]>
<Pt>     <!-- 1 -->
 <id V="12345" AA="100.12.92.81.5.7" APN="MRN"/>    <!-- 2, 3 -->
 <status V="L" S="HL7003" R="3.0"/>    <!-- 2 -->
 <isAroleOfPersnAsPt>             <!-- 4, 5 -->
  <adminvGendr V="M" S="HL7001" R="3.0" PN="Male"/>         <!-- 4 -->
  <brthDttm V="19790924162403-0800"/>         <!-- 4, 6 -->
  <phon>         <!-- 4 -->
   <_TEL ADR="tel:(358)555-1234" USE="PRN EMR"/>            <!-7, 9 -->
  </phon>         <!-- 4 -->
  <hasSetPrsnNameForPt> <!-4, 8 -->
   <_PrsnNameForPt>
    <nm>
     <G V="Irma" CLAS="R"/>
     <G V="Corine" CLAS="R"/>
     <F V="Jongeneel" CLAS="R M"/>
     <D V="-"/>
     <F V="de Haas" CLAS="R B"/>
    </nm>
    <purpse V="L" S="HL7005" R="3.0"/>
   </_PrsnNameForPt>
  </PtPrsnName>         <!-- 4 -->
 </isAroleOfPersnAsPt>           <!-- 2 -->
 <hasAprimryProvdrIHCP>        <!-- 2 -->
  <phon>
   <_TEL ADR="tel:(358)555-1234" USE="PRN EMR"/>            <!-- 8 -->
   <_TEL ADR="tel:(358)555-4321" USE="FAX"/>         <!-- 8 -->
  </phon>
  <isRoleOfPersnAsIHCP>
   <hasPrsnNameForIHCP>
    <nm>
     <G V="Bubba" CLAS="R"/>
     <G V="Corine" CLAS="R"/>
```

```
        <F V="Jongeneel" CLAS="R M"/>
        <D V="-"/>
        <F V="de Haas" CLAS="R B"/>
      </nm>
    </hasPrsnNameForIHCP>
  </isRoleOfPersnAsIHCP>
</hasAprimryProvdrIHCP>
<isInvlvdInPtEncntr T="PtEncntr">        <!-- 2 -->
  <id V="12345A23" AA="100.12.92.81.5.7" APN="EID"/>
  <startDttm V="19990924162403-0800"/>
  <status V="L"/>
  <hasAsPartcpntSetEncntrPractnr>
    <_EncntrPractnr>
      <partcptnTyp V="ATT"/>
      <isPartcpntForIHCP>
        <phon>
        <_TEL ADR="tel:(358)555-1234" USE="PRN EMR"/>
        </phon>
        <hasPrsnNameForIHCP>
          <nm>
            <G V="Bubba" CLAS="R"/>
            <G V="Corine" CLAS="R"/>
            <F V="Jongeneel" CLAS="R M"/>
            <D V="-"/>
            <F V="de Haas" CLAS="R B"/>
          </nm>
        </hasPrsnNameForIHCP>
      </isPartcpntForIHCP>
      </_EncntrPractnr>
      <_EncntrPractnr>
      <partcptnType V="CONS"/>
        <isPartcpntForIHCP>
          <phon>
            <_TEL ADR="tel:(358)555-1234" USE="PRN EMR"/>     <!-- 8 -->
          </phon>
          <hasPrsnNameForIHCP>
            <nm>
              <G V="Billy-Bob<" CLAS="R"/>
              <F V="de Haas" CLAS="R B"/>
```

```
          </nm>
        </hasPrsnNameForIHCP>
      </isPartcpntForIHCP>
    </_EncntrPractnr>
  </hasAsPartcpntSetEncntrPractnr>
 </isInvlvdInPtEncntr>  <!-- 2 -->
</Pt>   <!-- 1 -->
```

Figure 6. Example of an HL7 v3 message

2.2.3 Clinical Document Architecture

Clinical Document Architecture (CDA) (15), previously known as “Patient Record Architecture (PRA)” is a document markup standard created by HL7 (Health Level Seven) and approved as an ANSI standard.

Two releases exist:

- CDA R1 is the first specification derived from the HL7 Reference Information Model (RIM) and uses HL7 V3 data types.
- CDA R2 is essentially the same as R1, but is more expressive, enabling the representation of clinical statements such as observations, medication instructions, etc.

CDA consists in a mark-up document (typically XML) with a header and a body. CDA R2 specifies the structure and semantics of a clinical document containing text, images, sounds and other multimedia content. It can be transferred within a message as a multimedia "Multipurpose Internet Mail Extensions" (16) (MIME) object and can exist independently of the container.

CDA content meaning is derived from the Reference Model (RIM) and HL7 V3 Data Types, which are described in the HL7 RIM. Concept representation is derived from standard coding systems such as ***S**ystematized **N**omenclature of **MED**icine **C**linical **T**erms* (SNOMED CT®) (17) and ***L**ogical **O**bservation **I**dentifiers **N**ames and **C**odes* (LOINC®) (18).

CDA documents have three different levels of granularity, which are summarised in the next table:

CDA Release One	*CDA Release Two*
CDA Level One	Unconstrained CDA Specification
CDA Level Two	CDA specification with section-level templates applied
CDA Level Three	CDA specification with entry-level templates applied.

“*Level One*” (L1) is used for narrative documents. L1 documents are organised in two parts: a *Header* and a *Body*. The header is derived from the RIM and defines the semantics of each entry of the document using HL7 data types. The body consists of unconstrained text or can be a nested assembly of section, paragraphs, lists and table elements in structured XML. L1 body does not carry semantics and cannot be understood by anything else than human readers.

“*Level Two*” (L2) allows constraining both the structure and content of a document with a template. Since the template is known by the two parties, the interoperability is ensured because the receiver knows what to expect from the receiver.

“*Level Three*” (L3) allows specifying the semantics of each content entry making it *machine-processable* and fully interoperable.

CDA Release 2 does not use the term “Level” anymore. However, the different levels or granularity remain the same.

The CDA transport does not specify any transport mechanism, thus it cannot be considered as a true EHR standard. However it becomes widely and rapidly adopted.

Figure 7 presents an example of an extremely simple CDA document:

```
<ClinicalDocument>
 ... CDA Header ...
 <structuredBody>
  <section>
   <code code="8716" codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC" />
   <title>Vital Signs</title>
   <text>Temperature is 36.9°</text>
   <entry>
    <observation classCode="OBS" moodCode="EVN">
     <code code="386725007" codeSystem="2.16.840.1.113883.6.96"
      codeSystemName="SNOMED CT" displayName="Body temperature" />
     <statusCode code="completed"/>
     <effectiveTime value="200004071430" />
     <value xsi:type="PQ" value="36.9" unit="Cel" />
    </observation>
   </entry>
  </section>
 </structuredBody>
</ClinicalDocument>
```

Figure 7. Example of a CDA R2 document defining a single observation

This example shows how to define a single observation. In this example, the physician noted that the body temperature of patient X was of 36.9°. Of course, if the document is intended to be machine-processable, the computer must know what the concept temperature means. These concepts are defined by vocabularies such as the SNOMED CT®.

There is an excellent example online (19) showing an example CDA report, which also shows the advantage of XML-based formats by using a style sheet for displaying the contents of the file.

2.3 Medical Markup Language

The Medical Markup Language (MML) (20 p. 9) was developed in Japan as an effort to propose a standardized way to exchange medical documents and other clinical data. The current version 3.0 uses HL7 CDA R1 documents with a local header extension to store MML specific header fields and local markup to store the MML specific content.

The illustration below shows the MML schema:

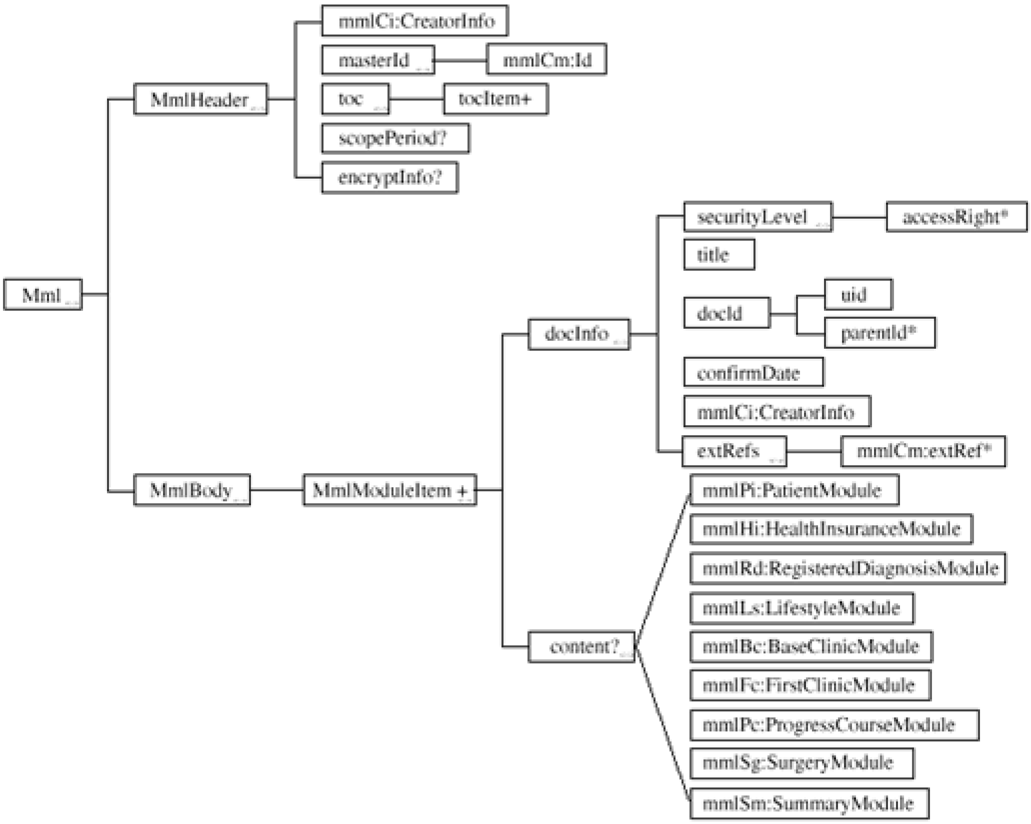

Figure 8. Basic structure of MML 2.2.1(source (21))

The body of a MML document is composed much like simple HTML. XML tags have a special meaning that make the document machine-processable. For example, to assign a diagnostic to a patient, we would then write:

<name>Albert Wille**</name>**

<diagnosis>Sclerose en plaques**</diagnosis>**

MML exchange does not ask complex architectures since it relies on the XML standard. Each institution receiving the MML messages maps the content to a local database, which schema can differ from care center to care center. This topology has the advantage that only one interface is necessary to communicate between systems (one interface, different schemas). But it has the disadvantage that the system is not really interoperable.

2.4 Digital Imaging and Communication in Medicine

Digital Imaging and Communication in Medicine, known as DICOM (22), is a communication and medical imaging archive standard. It is currently considered as the medical imaging reference format. DICOM is one of the only EHR standards using a binary encoding. Two DICOM-based standards exist: DICOM Structured Reporting and Web Access to DICOM Persistent Objects (WADO).

2.4.1 DICOM Structured Reporting

The DICOM Structured Reporting (SR) (23) is an extension of the original standard covering medical reports and other clinical data. It consists in a general model for encoding medical reports in the tag-based format used by the original DICOM standard. SR can rely on existing DICOM network infrastructure for archiving, communicating, encrypting and digitally signing SR documents with minimal changes to the infrastructure.

The content of a SR document is represented by a tree given by its own Document Object Model (DOM) (Figure 9). The semantics of most nodes are given by a machine-processable code and, therefore, automatic evaluation and processing by computers is made possible. Codes are taken from controlled vocabularies like SNOMED or LOINC. DICOM SR can store efficiently any kind of data. It is able to store and exchange various document types ranging from free text reports to structured documents with numeric measurement values and codes.

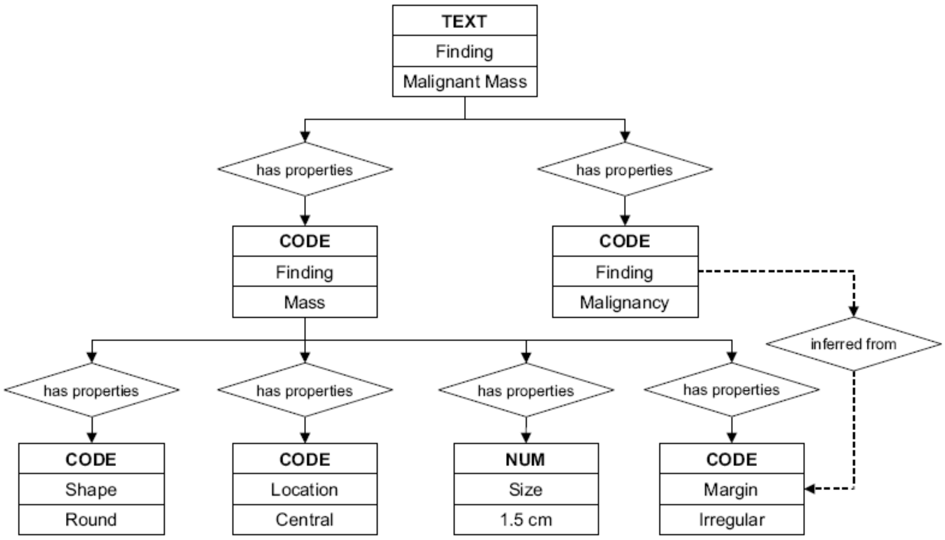

Figure 9. Excerpt from a DICOM SR Document Tree (source [13])

DICOM also defines templates and groups of codes to enhance interoperability between systems. The standard collection of templates supported by the standard is called the DICOM Content Mapping Resource.

DICOM SR only specifies the structure of the document, not how to render it. It is the responsibility of the reader application to correctly represent the semantics of the document content.

DICOM SR is not really used outside the medical imaging field and for this reason it is very unlikely to become an EHR standard (or at least a comprehensive EHR standard). Only recently, the medical industry started to make commercial products supporting the DICOM SR format.

The structure of DICOM SR files is too complex to be described here in this summary. A detailed overview is given in the source for DICOM SR (23).

2.4.2 Web Access to DICOM Persistent Objects

Wweb Access to DICOM Persistent Objects (WADO) defines a Web Service, which is used to retrieve DICOM objects (images, waveforms and reports) via HTTP or HTTPS. WADO has no support for queries. All objects must be accessed by its *Unique Identifier* for the study, series and instance level or the hierarchical DICOM information model. WADO supports a number of options, which can be passed through the request URL. DICOM objects can be converted and returned and presentation formats (JPEG for images and HTML for reports).

```
https://192.168.1.2/RetrieveDocument?requestType=WADO
    &studyUID=1.2.250.1.59.40211.12345678.678910
    &seriesUID=1.2.250.1.59.40211.789001276.14556172.67789
    &objectUID=1.2.250.1.59.40211.2678810.87991027.899772.2
    &contentType=text%2Fhtml
    &charset=UTF-8
```

Figure 10. Example WADO URL for retrieves a DICOM Structured Report (3)

The figure above shows a request to retrieve a DICOM structured report in HTML. WADO does not specify how the document should be visualized. Different server implementations will render the report differently.

3 Integrating the Healthcare Enterprise

Integrating the Healthcare Enterprise (IHE) (24) is an open (non-profit) initiative founded by the RSNA (Radiological Society of North America) and the HIMSS (Healthcare Information and Management Systems Society). Its goal is to “stimulate the integration of healthcare information resources” (3).

IHE primarily recommends standards for specific scenarios and also tries to drive the development towards an ever easier and seamless integration of systems. IHE brings together healthcare information technology stakeholders to implement standards for communicating patient information efficiently throughout and among healthcare enterprises by developing a framework for interoperability. As such, IHE does not develop standards but rather ***drives the adoption of standards to address specific clinical needs.***

They do so by creating documents on how to use standards and how to use them in conjunction to others. Their name is *Integration Profiles* (technical specification enhancing the integration of healthcare systems). The IHE.net website provides an exhaustive list of currently available integration profiles.

3.1 IHE Integration Profiles

Integration profiles are organized by *domains*: cardiology, eye care, IT infrastructure, laboratory, pathology, patient care coordination, patient care devices, quality, radiation oncology and radiology.

For IT infrastructures, our domain of interest, the recommended profiles (taken from (25)) are:

Profile Name	Abrev.	Description
Consistent Time	**(CT)**	ensures that system clocks and time stamps of computers in a network are well synchronized (median error less than 1 second).
Audit Trail and Node Authentication	**(ATNA)**	describes authenticating systems using certificates and transmitting PHI-related audit events to a repository. This helps sites implementing confidentiality policies.
Request Information for Display	**(RID)**	provides simple (browser-based) read-only access to clinical information (e.g. allergies or lab results) located outside the user’s current application.
Enterprise User Authentication	**(EUA)**	enables single sign-on by facilitating one name per user for participating devices and software.
Patient Identifier Cross Referencing	**(PIX)**	cross-references patient identifiers between hospitals, care sites, health information exchanges, etc.
Patient Synchronized Application	**(PSA)**	allows selection of a patient in one application to cause other applications on a workstation to tune

		to that same patient.
Patient Demographics Query	**(PDQ)**	lets applications query a central patient information server and retrieve a patient's demographic and visit information.
Cross Enterprise Document Sharing	**(XDS)**	registers and shares electronic health record documents between healthcare enterprises, ranging from physician offices to clinics to acute care in-patient facilities.
Personnel White Pages	**(PWP)**	provides basic directory information on human workforce members to other workforce members and applications
Cross-Enterprise Document Media Interchange	**(XDM)**	transfers XDS documents and metadata over CD-R and USB memory devices, and over email using a ZIP attachment
Cross-Enterprise Document Reliable Interchange	**(XDR)**	provides a standards-based specification for managing the interchange of documents that healthcare enterprises have decided to explicitly exchange using a reliable point-to-point network communication
Cross-Enterprise Sharing of Scanned Documents	**(XDS-SD)**	defines how to couple legacy paper, film, electronic and scanner outputted formats, represented within a structured HL7 CDA R2 header, with a PDF or plaintext formatted document containing clinical information
Patient Identifier Cross-Reference and Patient Demographics Query for HL7v3	**(PIX/PDQ/v3)**	extends the Patient Identifier Cross-Reference and Patient Demographics Query profiles leveraging HL7 version 3
Registry Stored Query Transaction for Cross-Enterprise Document Sharing Profile		adds a single transaction, Stored Query, to the XDS Profile
Stored Query		is a large improvement over the existing Query Registry transaction since it removes the use of SQL
Retrieve Form for Data Capture	**(RFD)**	enables EHR applications to directly request forms from clinical trial sponsors and public health reporting

These integration profiles can be combined in order to achieve a solid and efficient integration based on the implementation of communication standards such as DICOM or HL7. They provide precise definitions of how standards can be implemented to meet specific clinical needs.

3.2 IHE Retrieve Information for Display

Request Information for Display (RID) (26 p. 19) , is a technical specification for providing simple and read-only access to patient-centric clinical data. It is one of the IHE *Integration Profiles* and provides access to persistent documents in well-known presentation formats, as well as access to specific patient-centric information such as allergies, current medications or summary or reports.

Technically speaking RID is nothing more than a web service front-end. The integration level of RID is rather focused on the visual presentation. It does not try to define the complete integration of the internal databases (serving for RID requests). Documents are exchanged in well-known formats such as HL7 CDA L1, PDF or JPEG.

RID specification distinguishes between: information source and display: the "*information source*" is the system, which provides an RID web service; the "*display*" is the system that accesses the information source.

It is of the responsibility of the "*information source*" to convert the healthcare semantics into a suitable presentation format. The "display" may render this document with minimal knowledge but will not typically be able to process it beyond document display.

RID can be combined with other specifications making RID both fast and very flexible. It provides two types of services (27):

- *Retrieve Specific Information* to get the necessary information without retrieving the complete document;
- *Retrieve a Document* to get the persistent document in one of the following presentation formats: XHTML, PDF, JPEG or CDA.

RID can also be combined with security and authentication integrations profiles, for instance:

- *Entreprise User Authentication* (EUA) establishes on name per user, which facilitates the centralized user management through *Kerberos* (28) or *HL7 Clinical Context Object Workgroup* (CCOW) (29);
- *Audit Trail and Node Authentication* (ATNA).

The figure below illustrates sample integration between the RID, EUA, ATNA and PIX Integration Profiles.

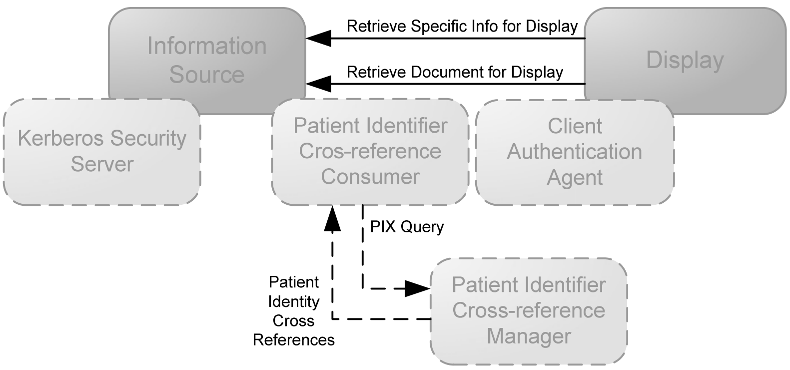

Figure 11. Interaction between RID, EUA, ATNA and PIX Integration Profiles (source [2])

In this scenario, the information source can serve requests to patient IDs from a different patient ID domain. This is done by looking for a cross-reference in the PIX "Patient Identifier Cross-Reference Manager".

The information source is combined with the EUA profile and acts as a “kerberized server”. It validates the kerberos ticket provided as part of the HTTP requests. The display actor is grouped with the “Client Authentication Agent” in order to provide Kerberos tickets together with the requests. Finally, the communication channel can be protected using the Transport Layer Security (TLS) protocol encapsulating the HTTP traffic.

3.3 IHE Cross-Enterprise Document Sharing

Cross-Enterprise Document Sharing (XDS) (26 p. 72) is another IHE specification (Integration Profile), which aims at providing a document archive for healthcare records from diverse institutional sources. XDS is content agnostic which makes it perfect for storing all sorts of media. However, the user must provide metadata (defined by the XDS spec) for a particular document.

XDS uses an ebXML registry and one or more attached repository systems. The figure below illustrates the actors and transactions of the XDS spec:

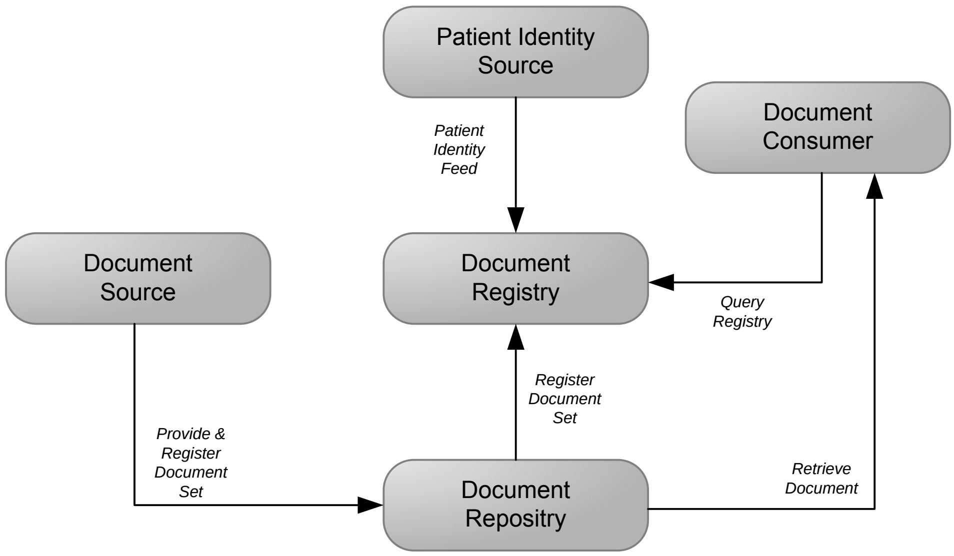

Figure 12. IHE Actors and transactions

The XDS specification defines:

- *Document source*, a healthcare point of service system where clinical data is collected;
- *Document repositories*, a system that stores documents and forwards the metadata to the document registry;
- *Document consumer*, a service application where care is given and information is requested;
- *Patient Identity Source*, a system that manages patients and identifiers for one XDS installation (affinity domain);
- *Affinity domain*, a group of healthcare enterprises that agree to work together and agree on sharing clinical documents.;
- *Document registry*, a system, which stores ebXML descriptions of the files to rapidly find them back.

Figure 13 presents a sample schema illustrating how to retrieve a document from an XDS domain:

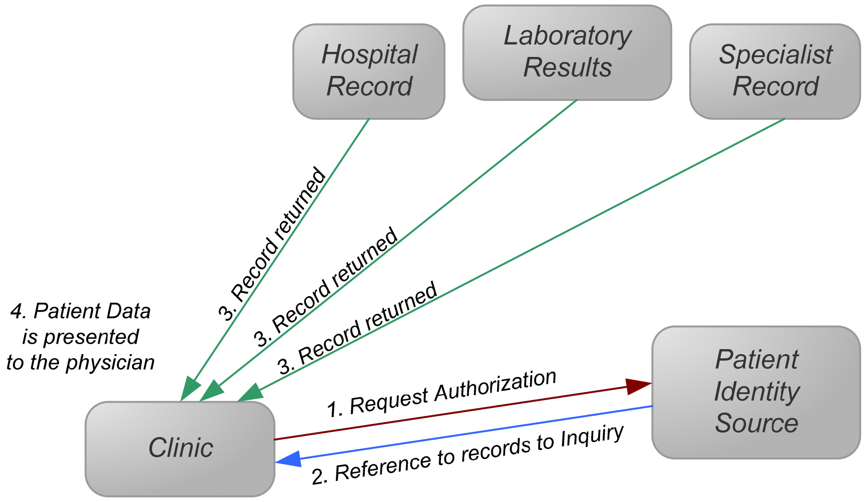

Figure 13. Retrieving a document

It is clearly intended that a document can only be shared on the same affinity domain. For two enterprises to be able to exchange EHR documents, they must belong to the same affinity domain. Furthermore, IHE XDS is truly distributed, since documents stay in the source EHR and accessed from the other computers of the domain. Only references are stored.

A information source about the IHE XDS transaction types can be found at (30).

4 Interoperability

4.1 EHR standards analysis

The EHRcom standard is intended to become a true EHR standard, which defines not only the document content structure, but also the display instructions, message exchange and security. CEN EN13606 Sand its ancestor, GEHR/openEHR are converging into a single harmonized EHR architecture making it a viable solution for interoperability at technical, syntactical and semantic levels. Work is currently been done in the harmonization of EHRcom with other formats such as CDA in the communications domain.

CDA only defines a content format. The format is based on the XML and supports any infrastructure for the exchange and display. Many infrastructures implement CDA documents in an IHE XDS network. The interoperability of the CDA is done on the document level through well known vocabularies and ontologies. The local database schema is irrelevant. HL7 v.2 is today the most implemented clinical messaging standard in the world. HL7 CDA is a sort of improvement, which relies on a relatively great user base.

MML is not worth further discussion, since it is used quasi-exclusively in Japan.

DICOM resembles RID in the sense that it is primarily intended for display. The problem, which prevents making it a EHR standard is that it is “fine-tuned” for medical imaging. It can also be coupled to the IHE XDS profile.

RID was not constructed with the data exchange paradigm (send/receive) in mind. It is intended for presentation. The infrastructure defines a simple service, which a user can invoke to get the requested data in one of various presentation formats (CDA L1, PDF, JPG, etc.). Latest revisions of RID allow people to access some pieces of information and retrieve them as a CDA document. RID just like the other integration profiles can be mixed with other profiles. It is possible to couple it with an XDS infrastructure.

XDS is not an EHR standard since it does not define the structure of the exchanged documents. However it seems to be an infrastructure of choice, which allows grouping one or more care centers inside the same domain. Coupled to CDA, this solution can make a good replacement for a complete EHR standard just like EHRcom.

Source (3 p. 31) provides an excellent analysis of the different EHR standards.

4.2 Content structure

Contrary to other EHR standards, EHRcom “EHR_EXTRACT” represents a hierarchy of compositions, which roughly correspond to documents. It also contains structuring information in the form of folders as well. Single documents are also possible. While CDA represents a single document, CEN EN13606 can be compared to a folder with documents.

All standards are based on a two-level content modeling paradigm. All support a reference model along with additional constraint rules. These rules are expressed as “archetypes” in EHRcom/openEHR and as “templates” in HL7 CDA and DICOM. MML “content modules” are based on conventional *Document Type Definitions* (DTD) (31).

All standards specify at least a library of additional archetypes. However, only DICOM SR has an extensive set of *Templates*, while the other EHR standards are only at the beginning.

DICOM SR is the only format, which currently describes the possibility of attaching signatures to documents. However, since all the other formats (EHRcom, CDA and MML) can be represented as XML, the XML-Signature standard can be used as well to attach signatures. None of them specifies how the signature should be handled by the repository.

4.3 Access services

This section describes the various access services by EHR standard. CDA and MML are not detailed since they only define content formats.

EHRcom is intended to have support for querying, retrieving and submitting documents. The communication protocol is to be released as CEN EN13606-5 and will precisely define the exchange models of the standard.

DICOM SR refers to the DICOM Storage and Query/Retrieve Services. It also supports all base services like querying, retrieving and submitting documents in a traditional DICOM network architecture.

Contrary to the other communication protocols, RID does not support submitting documents. It is a HTTP/WSDL service uniquely defined for retrieval and viewing. RID does supports a document-centric storage.

XDS has the most complete set of access services, since it allows querying, retrieving and submitting documents. The standard describes an extensive architecture based on ebXML (32) (SOAP and HTTP) metadata and a document-centric storage/retrieval. Documents are fully described by metadata making possible to perform intelligent searches. Users can make complex queries based on the value of the metadata.

5 Conclusion

Figure 14 below indicates that contents “standards” are quite similar. RID and XDS are not shown since they do not define content on their own.

	EHRcom	*HL7 CDA*	*DICOM SR*	*MML*
EHR contains persistent documents	●	●	●	●
EHR can contain multimedia documents	●	●	●	●
References to multimedia data in documents	●	●	●	●
Structured content suitable for precessing	●	●	●	●
EHR supports archetypes / templates	●	●	●	●
Library of archetypes / templates	●	●	●	●
EHR specifies distribution rules	●			●
EHR standard covers visualization		●		
Digital signatures onto persistent documents			●	

Figure 14. Comparison of content standards (source [21])

There are some facts important to note:

- All standards use a two-layered approach consisting of a reference model and additional constraint rules (archetypes, templates or content modules);
- Some standards accept “distribution rules”, that is, statements specifying under, which circumstances the EHR content may be communicated. EEHR distribution rules are different from *Access Control;*
- DICOM SR is currently the only EHR standard, which supports attaching digital signatures. However, other markup-based standards could theoretically support XML signatures;
- Most EHR standards do not specify how to render documents (with the exception of CDA).

The next figure shows access capabilities of standards, which define transport mechanisms.

	EHRcom	*DICOM SR*	*RID*	*XDS*
Service for querying EHR content	●	●	●	●
Service for retrieving HER content	●	●	●	●
Service for submitting HER content	●	●		●
Document-centric storage / retrieval		●	●	●
Content format agnostic			●	●

Figure 15. Comparison of EHR standard sevices access (source [21])

Here are some facts, which result of previous chapters:

- EHRcom is not stable enough to make any prediction in the future, but seems promising as an “all-in-one” standard. When it will be ready, the CEN EN13606 standard has strong chances to become a recognized full EHR standard; it describes the content structure, access policies, exchange mechanisms and display
- HL7 CDA is more and more widely spread and accepted. Although, it does not define security nor transport mechanisms, it seems an important part of an EHR standard (when associated with HL7 messages for example).

- DICOM SR is widespread and seems mature enough for a EHR standard, since it has a workable and flexible structure and network infrastructure. However, DICOM SR is not really used outside medical imaging.
- RID provides a great infrastructure for retrieving data and displaying it, however it is ill-suited for an EHR standard, because it doesn’t allow submitting documents to the RID storage, nor transmitting complete EHRs.
- MML supposes a lot of markup duplication, and since HL7 CDA is being more and more widely adopted, it seems less probable that it will one day be used anywhere except in Japan.

In conclusion, HL7 CDA is missing a true messaging infrastructure. DICOM SR is currently the most mature and moreover, it presents true market relevance. Even if DICOM is originally an image-based format, it can be used to contain medical information, which can be semantically associated to external vocabularies. Furthermore, DICOM proposes a very large panel of templates, while the other formats are only at the beginning. CEN EN13606 is not yet full specified and as such, nobody can predict on adoption success or failure. It is however a rather complete proposal.. IHE XDS Integration Profile is definitely an acceptable choice for the transport of EHR documents. It should, however, first be evaluated in terms of ease of installation and maintenance.

In definitive, none of the other formats has a clear advantage over the others. Furthermore, exception for the DICOM format and EHRcom in the near future, none of the other formats present a complete EHR standard describing exchange models and content structure. However, we should not forget that HL7 CDA is currently widely widespread, and the future of EHR interoperability could seemingly be in the assembling of two standards.

In relation to the interoperability analysis, standards organisations have understood the necessity for interoperability accross different EHR solutions. Standards are advancing towards an harmonization of the EHR formats. CEN/TC251 and HL7 for instance are creating workshops, which study solutions for making EHRcom and HL7 more compatible (for exemple, compatibility or CEN EN13606 with HL7 v3 messages).

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