1. Introduction

Goal

The goal of this document os to provide input to ANTILOPE project and address the serious criticism put forward by the EN13606 Association.

It is the opinion of the EN13606 Association that in the present ANTILOPE deliverables not enough attention has been paid to artefacts that result from the ANTILOPE Use Cases but expressed using the CEN ISO EN 13606 EHR-communication standard

We submit this text for the WP leaders of Wp2, Wp3 and Wp4 to consider.

EN13606 Back ground information

The EN 13606:2008 is a CEN and ISO standard that is being revised at this moment.

The standard is based on the Two Level Modeling Paradigm.

The Two Level Modeling Paradigm is different from the HL7 Message Paradigm.

The EN13606 consists of 5 parts:

1. Reference Model defining classes and attributes needed for documenting and archiving any structured document. A formal ISO Standard provided the requirements (ISO 18303 Requirements for EHR system Architecture.
2. Archetype Object Model that allows the expression of cli nical and non-clinical document content by means of the specification of constraints on the UML classes and attributes of the Reference Model of part 1.
3. A set of vocabularies used by the standard.
4. Expression of the Patient Mandate stating who has access to what information
5. A simple set of supporting messages that can be used to exchange data between IT-system.

Although the EN13606 is seen as a messaging standard actually it is a standard defining the data in various IT-system Interfaces.

Because of the (at least) two models that are the basis for En13606 artefacts (Archetypes and Templates) it is called to be based on the Two Level Modeling Paradigm.

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In the EN13606 community data needs expressed as data sets are transformed into Templates. Templates express the temporal local data needs. Templates are composed of reusable Archetypes that are constrained to fit the local needs. Templates can be considered to be the En13606 profiles.

Archetypes define what is documented in general about a specific topic. With archetypes from the Archetype Library all possible Templates can be constructed. Archetypes carry (pre-bound) codes from coding systems.

For Semantic Interoperability it is needed that all systems involved use Archetypes from the shared Archetype Library.

The standard is used in: Ireland, Spain, Japan, Singapore, England, Brasil, Iran. Profiles of the standard are used in: Australia, Norway, Slovenia, and by the Clinical Information Modeling Initiative (CIMI: e.g. InterMountain, Mayo Clinics, Kaiser Peranente, VA, National projects of Australia, Canada, England, EN13606 Association of implementors.

Implementation of the EN13606 standard

When IT-systems know how to deal with XML data defined according the standard part 1, 2, 3 and 4 the IT-system is technically conformant.

The standard is used to express data requireents for procurement and can be used to exchange data between IT-system interfaces including external third party systems.

Because of the Two Models fully model driven tools (Editor, Viewer, Mapping tool and testing tools) are used. Because of the Model driven nature very agile deployment of Templates is possible of any clinical and non-clinical data in any document.

In the 13606 Archetype (Template) editors it is possible to generate various human and machine readable exports such as:

- ADL
- HTML Mock-up screen
- Excel
- MindMaps
- HTML reporting format
- XML-schema’s and XML Schematron files

In addition it is possible to design integration archetypes that reflect proprietary format. With existing mapping tools it is possible to gene

2. Interoperability Stack

The scope of the CEN/ISO EN13606 standard is restricted to the Information Viewpoint of the ISO RM/ODP standard. This RM/ODP standard consists of a stack of 5 layers:

1. Enterprise Viewpoint - defines legal, ethical and data requirements
2. Information Viewpoint - defines the data of the payload
3. Computational Viewpoint - defines ilT-system interfaces where the payload plays its role
4. Engineering Viewpoint - defines the engineering choices made in the system
5. Technology Viewpoint - defines the technical deployment

In contrast to HL7 messages and IHE profiles thereof CEN/ISO En13606 does not specify the technical layers of the RM/ODP stack. EN13606 is involved with the definition of the payload only. And subsequently only interested in quality assurance and testing problems of any the payload. EN 13606 is not in the business to define the clinical or non-clinical content of the payload but only in the expression of any payload.

3. Semantic Interoperability Stack

For En13606 based payload to be expressed several models are needed. These layers constitute the Semantic Interoperability Stack ideally consisting of:

1. Ontology (clinical and non-clinical concepts).
2. Reference Coding system based on an otology - e.g. SNOMED, ICD, LOINC, …
3. Standardised patterns to build archetypes (Semantic Interoperability Artefact Modelimng method: SIAMM).
4. An Archetype Library based on the CEN/ISO System of Concepts for Continuity of Care (ContSys) - that allows to model what is documented in clinical and non-clinical processes.
5. Archetype Object Model - allowing the specification of Archetypes allowing the documentation of payload as constraints on the Reference Model.
6. Reference Model - providing all the classes and attributes to document and archive any document.

In the Quality Assurance process of Archetypes and Templates several items play a crucial role.

At the technical level all data must conform to the RM, the Archetype Object Model, the model behind the ContSys standard, SIAMM and the way bindings to coding systems and code- and value-sets are defined.

The coding systems and ontologies ideally need to be quality assured separately.

Each of the Models in layers 3, 4, 5, and 6 can be expressed as XML-schema;s and Schematrons that can be used to parse XML data files and test conformance against.

Testing conformance of the data requirements to the Template is a manual inspection process.

4. Semantic Interoperability Artefacts

In the context of EN13606 implementations a set of interoperability semantic artefacts are needed to be quality assured:

1. Archetype/Template Library
2. Code sets and value sets
3. Coding Systems and their codes (SNOMED-CT, LOINC, ICD, …
4. Ontology supporting the Coding System
5. Parsers that parse XML data files and test conformance to the 13606 RM, AOM, internal code and value sets
6. En13606 XML Schema of the RM and Data types, And EN13606 XML Schematron for detailed rules based testing.
7. Supporting documentation

Several of these artefacts (1, 5, 6 and 7) are used, generated by an EN13606 conformant Archetype editor. All these artefacts need to be maintained and published in a conherent way in a Document Management Service. The Coding System related artefacts (2, 3 and 4) rely on Terminology related Services for the maintenance and publishing.

5. Testing Semantic Interoperability Artefacts

CEN ISO EN13606 standard focusses on the Information Viewpoint of the ISO RM/ODP standard. This implies that it uses data requirements from the RM/ODP Enterprise Viewpoint and specifies the data part inside Interfaces at the RM/ODP Computational Viewpoint.

As a service the standard provides (for those that need to exchange data and do not want to resort to IHE profiles) a simple scenario to generate message when IT-systems exchange clinical and non-clinical data. In many cases IHE profiles will be used to transport the payload defined by an CEN ISO EN13606 EHR-Extract or Composition.

Securing of the conformance of the EHR-Extracts and Compositions, the payload, to the standard and data requirements are secured at archetype design time. The Archetype editor expresses all data points as constraints on the Reference Information Model (EN13606 part 1) and with constraints expressed conforming the Archetype Object Model (EN13606 part 2).

Data exchanged using these archetypes collected in a Template that expresses the temporal and local data needs is constructed in the Archetype Editor. The Archetype editor can publish a XML-Schema and XML Schematron file that can be used to generate data instantiations that conform. Equally these XML Schema and Schematron files can be used to parse new XML data against and test for conformance.

The XML schema in particular tests against the Reference Model and Archetype Object Model specifications. The XML Schematron additionally is capable to test in much more detail against the Template expressing constraints placed on data points and data types.

Systems that claim conformance to the CEN ISO EN13606 standard at level 1 must be tested using a set of archetypes (in a test Template) and associated test data. The archetype test set must use all classes and attributes of the Reference Model and allowed data types. The conformance claiming system must be able to use all archetypes of the test set and parse on accepting the data and parse on producing data in EHR-Extracts or Compositions.

Systems that claim conformance to the CEN ISO EN13606 standard at level 2 will be tested by sending the test data set,the test archetypes and test Template and respond to a set of archetypes produced that act as query specification.

EHR-Extracts and Compositions that claim conformance to a set of archetypes (template) are tested using the parsers in the archetype editor or via existing validated parsers.

All conformance claims are (will be) available for software developers to use in their software developments.

Observe that additional testing of the lower levels of the RM/ODP stack is necessary. IHE profiles can play an important role. But that alternative solutions that are not part if the IHE profiles, can be used. For example: According to the EN13606 Association, in extremo, exchange must be possible using attachments to e-mail messages.

It is the opinion of the EN13606 Association that based on the standard one to one communicating parties can and will agree on a temporal and local Template at the level of the Information Viewpoint. These local implementations must be able to test themselves the semantic conformance to the agreed data set, code sets, and value sets.

For the exchange we expect that for the exchange of payloads already tested and validated need to be executed in an equally flexible and self-testing fashion.