Hälso- och sjukvårdsinformatik – Kommunikation av elektronisk patientjournal – Del 1: Referensmodell

Health informatics – Electronic health record communication – Part 1: Reference model

Denna standard ersätter SS-ENV 13606-1, utgåva 1.

The European Standard EN 13606-1:2007 has the status of a Swedish Standard. This document contains the official English version of EN 13606-1:2007.

This standard supersedes the Swedish Standard SS-ENV 13606-1, edition 1.
Health informatics - Electronic health record communication - Part 1: Reference model

This European Standard was approved by CEN on 15 December 2006.

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Foreword

This document (EN 13606-1:2007) has been prepared by Technical Committee CEN/TC251 “Health informatics”, the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2007, and conflicting national standards shall be withdrawn at the latest by August 2007.

This document supersedes ENV 13606-1:2000.

This multipart standard under the general heading Health informatics – Electronic health record communication consists of the following parts:

Part 1: Reference model

Part 2: Archetypes interchange specification

Part 3: Reference archetypes and term lists

Part 4: Security

Part 5: Messages for exchange

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.
Introduction

The overall goal of this European Standard is to define a rigorous and stable information architecture for communicating part or all of the Electronic Health Record (EHR) of a single subject of care (patient). This is to support the interoperability of systems and components that need to communicate (access, transfer, add or modify) EHR data via electronic messages or as distributed objects:

- preserving the original clinical meaning intended by the author;
- reflecting the confidentiality of that data as intended by the author and patient.

This European Standard is not intended to specify the internal architecture or database design of EHR systems or components. Nor is it intended to prescribe the kinds of clinical applications that might request or contribute EHR data in particular settings, domains or specialities. For this reason, the information model proposed here is called the EHR Extract, and might be used to define a message, an XML document or schema, or an object interface. The information model in this European Standard is an ISO RM-ODP Information Viewpoint of the EHR Extract.

This European Standard considers the EHR to be the persistent longitudinal and potentially multi-enterprise or multi-national record of health and care provision relating to a single subject of care (the patient), created and stored in one or more physical systems in order to inform the subject’s future health care and to provide a medico-legal record of care that has been provided. Whilst an EHR service or system will need to interact with many other services or systems providing terminology, medical knowledge, guidelines, workflow, security, persons registries, billing etc. this European Standard has only touched on those areas if some persistent trace of such interactions is required in the EHR itself, and requires specific features in the reference model to allow their communication.

This European Standard may offer a practical and useful contribution to the design of EHR systems but will primarily be realised as a common set of external interfaces or messages built on otherwise heterogeneous clinical systems.

Technical approach

This European Standard has drawn on the practical experience that has been gained in implementing its European predecessor, ENV 13606, other EHR-related standards and specifications, commercial systems and demonstrator pilots in the communication of whole or part of patients’ EHRs, and on fifteen years of research findings in the field. This European Standard builds on ENV 13606, updating it in order to make it more rigorous and complete, to accommodate new requirements identified, to incorporate a robust means of applying the generic models to individual clinical domains, and to enable communication using HL7 version 3 messages. A mapping from the existing prestandard is also provided to support implementers of existing conformant systems. The technical approach to producing this European Standard has taken into account several contemporary areas of requirement.

a. In addition to a traditional message-based communication between isolated clinical systems, the Electronic Health Record will in some cases be implemented as a middleware component (a record server) using distributed object technology and/or web services.

b. “Customers” of such record services will be not only other electronic health record systems but also other middleware services such as security components, workflow systems, alerting and decision support services and other medical knowledge agents.

c. There is wide international interest in this work, and this European Standard has been drafted jointly through CEN and ISO with significant input from many member countries.
d. Mapping to HL7 version 3 has been considered an important goal, to enable conformance to this European Standard within an HL7 version 3 environment.

e. The R&D inputs on which ENV 13606 was based have moved forward since 1999 and important new contributions to the field have been taken into account. The openEHR foundation, integrating threads of R&D in Europe and Australia, is one such example.

Given the diversity of deployed EHR systems, this European Standard has made most features of EHR communication optional rather than mandatory. However, some degree of prescription is required to make EHR Extracts safely processable by an EHR recipient system, which is reflected through mandatory properties within the models in Parts 1, 2, and 4 of this series, and through normative term lists (defined in Part 3 of this series).

This European Standard will, in practice, usually be adopted alongside other health informatics standards that define particular aspects of health data representation. Annex B explains how this European Standard can be used alongside key complementary standards, including the HL7 Version 3 Reference Information Model (RIM), EN 14822-1, EN 14822-2, EN 14822-3, CEN/TS 14822-4 (GPIC), prEN 12967 (HISA) and prEN13940 (CONTSYS).

The Dual Model approach

The challenge for EHR interoperability is to devise a generalised approach to representing every conceivable kind of health record data structure in a consistent way. This needs to cater for records arising from any profession, speciality or service, whilst recognising that the clinical data sets, value sets, templates etc. required by different health care domains will be diverse, complex and will change frequently as clinical practice and medical knowledge advance. This requirement is part of the widely acknowledged health informatics challenge of semantic interoperability.

The approach adopted by this European Standard distinguishes a Reference Model, defined in this European Standard and used to represent the generic properties of health record information, and Archetypes (conforming to an Archetype Model, defined in Part 2 of this series), which are meta-data used to define patterns for the specific characteristics of the clinical data that represents the requirements of each particular profession, speciality or service.

The Reference Model represents the global characteristics of health record components, how they are aggregated, and the context information required to meet ethical, legal and provenance requirements. This model defines the set of classes that form the generic building blocks of the EHR. It reflects the stable characteristics of an electronic health record, and would be embedded in a distributed (federated) EHR environment as specific messages or interfaces (as specified in Part 5 of this series).

This generic information model needs to be complemented by a formal method of communicating and sharing the organisational structure of predefined classes of EHR fragment corresponding to sets of record components made in particular clinical situations. These are effectively pre-coordinated combinations of named RECORD_COMPONENT hierarchies that are agreed within a community in order to ensure interoperability, data consistency and data quality.

An Archetype is the formal definition of prescribed combinations of the building-block classes defined in the Reference Model for particular clinical domains or organisations. An archetype is a formal expression of a distinct, domain-level concept, expressed in the form of constraints on data whose instances conform to the reference model. For an EHR_Extract as defined in this European Standard, an archetype instance specifies (and effectively constrains) a particular hierarchy of RECORD_COMPONENT sub-classes, defining or constraining their names and other relevant attribute values, optionality and multiplicity at any point in the hierarchy, the data types and value ranges that ELEMENT data values may take, and other constraints.

This European Standard recognises that archetypes might be used to support communication between some EHR systems in the future, or might be used as a knowledge specification by some EHR system external interfaces when mapping parts of an EHR to an EHR_EXTRACT, or might not be used at all between some
EHR systems. The use of archetypes is therefore supported, but not made mandatory, by this European Standard. A specification for communicating archetypes is defined by Part 2 of this series.

Requirements basis for this European Standard

From the early 1990's it was recognised that a generic representation is required for the communication of arbitrary health record information between systems, and in Europe this has resulted in a succession of EU sponsored R&D projects and two generations of CEN health informatics standards prior to this one. These projects and standards have sought to define the generic characteristics of EHR information and to embody these in information models and message models that could provide a standard interface between clinical systems. The vision of such work has been to enable diverse and specialist clinical systems to exchange whole or parts of a person's EHR in a standardised way that can rigorously and generically represent the data values and contextual organisation of the information in any originating system. A complementary goal has been to accommodate the evolving nature of medical knowledge and the inherent diversity of clinical practice.

Many investigations of user and enterprise requirements for the EHR have taken place over this period, which have sought to span the information needs of diverse specialties across primary, secondary and tertiary care, between professions and across countries. These requirements have been distilled and analysed by expert groups, mainly within Europe, in order to identify the basic information that needs to be accommodated within an EHR information architecture to:

- capture faithfully the original meaning intended by the author of a record entry or set of entries;
- provide a framework appropriate to the needs of professionals and enterprises to analyse and interpret EHRs on an individual or population basis;
- incorporate the necessary medico-legal constructs to support the safe and relevant communication of EHR entries between professionals working on the same or different sites.

This work includes the GEHR, EHCR-SupA, Synapses, I4C and Nora projects and work by SPRI. These key requirements publications are listed in the Bibliography. These requirements have recently been consolidated on the international stage within an ISO Technical Specification, ISO/TS 18308.

In this Reference Model the key EHR contextual requirements for such faithfulness are related to a set of logical building block classes, with suitable attributes proposed for each level in the EHR Extract hierarchy. ISO/TS 18308 has been adopted as the reference set of requirements to underpin the features within this EHR communications Reference Model, and a mapping of these requirements statements to the constructs in the Reference Model is given in Annex D.

Overview of the EHR Extract record hierarchy

The information in a health record is inherently hierarchical. Clinical observations, reasoning and intentions can have a simple or a more complex structure. They are generally organised under headings, and contained in “documents” such as consultation notes, letters and reports. These documents are usually filed in folders, and a patient may have more than one folder within a healthcare enterprise (e.g. medical, nursing, obstetric).

The EHR Extract Reference Model needs to reflect this hierarchical structure and organisation, meeting published requirements in order to be faithful to the original clinical context and to ensure meaning is preserved when records are communicated between heterogeneous clinical systems. To do this, the model formally sub-divides the EHR hierarchy into parts that have been found to provide a consistent mapping to the ways in which individual EHRs are organised within heterogeneous EHR systems.

These parts are summarised in Table 1 below.
<table>
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<th>EHR HIERARCHY COMPONENT</th>
<th>DESCRIPTION</th>
<th>EXAMPLES</th>
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<tr>
<td>EHR_EXTRACT</td>
<td>The top-level container of part or all of the EHR of a single subject of care, for communication between an EHR Provider system and an EHR Recipient.</td>
<td>(Not applicable)</td>
</tr>
<tr>
<td>FOLDER</td>
<td>The high level organisation within an EHR, dividing it into compartments relating to care provided for a single condition, by a clinical team or institution, or over a fixed time period such as an episode of care.</td>
<td>Diabetes care, Schizophrenia, Cholecystectomy, Paediatrics, St Mungo’s Hospital, GP Folder, Episodes 2000-2001, Italy.</td>
</tr>
<tr>
<td>COMPOSITION</td>
<td>The set of information committed to one EHR by one agent, as a result of a single clinical encounter or record documentation session.</td>
<td>Progress note, Laboratory test result form, Radiology report, Referral letter, Clinic visit, Clinic letter, Discharge summary, Functional health assessment, Diabetes review.</td>
</tr>
<tr>
<td>SECTION</td>
<td>EHR data within a COMPOSITION that belongs under one clinical heading, usually reflecting the flow of information gathering during a clinical encounter, or structured for the benefit of future human readership.</td>
<td>Reason for encounter, Past history, Family history, Allergy information, Subjective symptoms, Objective findings, Analysis, Plan, Treatment, Diet, Posture, Abdominal examination, Retinal examination.</td>
</tr>
<tr>
<td>ENTRY</td>
<td>The information recorded in an EHR as a result of one clinical action, one observation, one clinical interpretation, or an intention. This is also known as a clinical statement.</td>
<td>A symptom, an observation, one test result, a prescribed drug, an allergy reaction, a diagnosis, a differential diagnosis, a differential white cell count, blood pressure measurement.</td>
</tr>
<tr>
<td>CLUSTER</td>
<td>The means of organising nested multi-part data structures such as time series, and to represent the columns of a table.</td>
<td>Audiogram results, electro-encephalogram interpretation, weighted differential diagnoses.</td>
</tr>
<tr>
<td>ELEMENT</td>
<td>The leaf node of the EHR hierarchy, containing a single data value.</td>
<td>Systolic blood pressure, heart rate, drug name, symptom, body weight.</td>
</tr>
</tbody>
</table>

An EHR_EXTRACT contains EHR data as COMPOSITIONs, optionally organised by a FOLDER hierarchy. COMPOSITIONs contain ENTRYs, optionally contained within a SECTION hierarchy. ENTRYs contain ELEMENTs, optionally contained within a CLUSTER hierarchy.
The EHR Extract comprises…

a hierarchy of Folders

Each containing…

Compositions

Compositions contain…

Sections

(Which may be nested)

Containing…

Entries with data as…

Elements

Clusters

Clusters may be nested & contain Elements

Figure 1 — Diagram of the EHR Extract hierarchy (part 1)

Figure 2 — Diagram of the EHR Extract hierarchy (part 2)