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Health informatics - Electronic healthcare record communication - Part 2: Domain term list

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Health informatics - Electronic healthcare record communication - Part 2: Domain term list

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Contents

Foreword

This European Prestandard has been prepared by Technical Committee CEN/TC 251 "Health informatics", the secretariat of which is held by SIS.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this European Prestandard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

This is Part 3 of a multipart standard on *Electronic Healthcare Record Communication*. The multipart standard consists of the following parts:

- Part 1: Extended architecture
- Part 2: Domain term list
- Part 3: Distribution rules
- Part 4: Messages for the exchange of information

This Prestandard was drafted using the conventions of the ISO/IEC directive part 3.

Annexes A, B, C, E, F are normative.
Annexes D and G are informative.

Introduction

For the convenience of the reader, the following conventions have been used within this document:

- architecture constructs generic to the overall standard are shown with initial capitalisation: class names are shown in normal font and attributes are shown in **bold** font;
- constructs and formalisms specific to this part of ENV 13606 are shown in *italics*.

The definitions of terms used within the document are given in Clause 3 of this part of ENV 13606.

The principal normative provisions are given in Clause 4 of this part of ENV 13606. These make reference to normative tables that are given in Annexes A, B, C, E and F and to the informative tables given in Annex D.

Requirements for conformance to this part of ENV 13606 are given in Clause 5.

A fuller description of the measures defined here is provided in Annex G (Informative). Readers unfamiliar with this part of ENV 13606 are strongly recommended to read this first.

Health informatics - Electronic healthcare record communication - Part 2: Domain term list

1 Scope

1.1 General

The Domain Termlist part of ENV 13606 provides a set of measures to support various degrees of interoperability of the EHCRs created on different systems or by different teams on the same system. These measures aim to enhance the likelihood that EHCR entries can be accessed or communicated in a way that:

- supports the visual interpretation of original entries by the end-user of a recipient system;
- facilitates record navigation;
- enables a limited level of amalgamation of received data sufficient to permit the generation of longitudinal views; and
- allows for a limited degree of automated processing, e.g. information retrieval.

These are intended to complement the communication of structural organisation within record entries provided by the architecture (Part 1) and message (Part 4) provisions of ENV 13606.

The real world of health and health care is made up of individual *clinical situations* (see Clause 3), which are described by an EHCR author as *clinical statements*. Within an EHCR system each *clinical statement* will be expressed as an *elementary healthcare record entry*. This will usually combine a set of clinical concepts (perhaps a core concept with some qualification e.g. site, laterality) with a set of contextual information (much of which may also be represented through qualification e.g. certainty, negation). Significant meaning may be conveyed through these qualifiers, but there is no consistent means of assuring that such detailed meaning will be reproducibly communicated between dissimilar systems.

The measures in this part of ENV 13606 are intended to provide a high-level and coarse-grained "shadow" representation of intended meaning that can be applied in a consistent manner even though a wide diversity will (quite properly) continue to exist in the way clinical details are actually recorded within EHCR entries. The coarse-grained annotations on Clusters and Data Items attempts to summarise the most important aspects of this detail, primarily to reduce the risk of serious misinterpretation.

It is not appropriate for this work to attempt a complete and rigorous "mirror" of the detailed clinical entries themselves. It is therefore important to appreciate that these measures are not considered sufficient to assure the safe automatic processing of EHCR data from heterogeneous sources for clinical decision making. Nevertheless, a measure is provided as a framework to build fine-grained coding systems supporting more advanced levels of interoperability in particular communities of users. The common framework will assist to avoid unnecessary diversity and will facilitate a future convergence of the local coding systems.

These proposals are presented as a set of seven measures. The measures are complementary, applied to different classes or parts of a Record Component hierarchy, and offer different degrees of interoperability. Each of these measures is defined within Clause 4 (Provisions) and Annexes A (Normative), B (Normative), C (Normative), D (Informative), E (Normative) and F (Normative) of this part of ENV 13606, and is explained in more detail in Annex G (Informative).

1.2 Target groups of this document

This document is applicable to:

a) developers of standards on interchange formats for messages involving clinical information;
b) developers of EHCR architecture standards,
c) developers of categorial structures and terminological systems on sub-domains where clinical information need to be covered,
d) information modellers and knowledge engineers building models for record systems,
e) developers of information systems which need to handle an explicit system of clinical concepts for internal organisation, data warehouse management and middleware services,
f) developers of mark-up standards for the representation of healthcare documents.

1.3 Topics considered outside the scope of this document

This document is not intended to:

a) provide value sets to replace original values of either names or content of record components;
b) represent administrative and organisational context i.e. data about the patient, the professional, and the healthcare organisation, such as names, addresses, identifiers, locations, attestation data: these topics are addressed by other parts of ENV 13606;
c) regulate how details shall be used either within names or within content of record items: in particular, it is not overlapping with categorial structures defined by CEN ENV 12264;
d) define precise names for or the content of Record Components;
e) propose large or exhaustive lists of acceptable names for low-level Record Components (as, for example, provided by LOINC [18]).

2 Normative references

This European Prestandard incorporates by dated or undated reference, provisions from other publications. These normative references are cited in the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments and revisions of any of these publications apply to this European Prestandard only when incorporated in it by amendment and revision. For undated references, the latest edition of the publication referred to applies.

ENV 12264:1997	Medical Informatics — Categorial structure of systems of concepts — Model for representation of semantics
ENV 12381:1996	Medical Informatics — Time standards for healthcare specific problems
ENV 13606-1:2000	Health informatics — Electronic healthcare record communication — part 1: Extended architecture
ENV 13606-4:2000	Health informatics — Electronic healthcare record communication — part 4: Messages for the exchange of information

3 Terms, definitions and abbreviations

For the purposes of this part of ENV 13606, the terms and definitions given in ENV 12264:1997, ENV 13606-1, ENV 13606-4 (some of which are repeated below for convenience) and the following apply.

3.1
situation
phenomenon occurring (or having the potential to occur) at or over a time in a given world context
[ENV 12381]

NOTE. It extends the normal English use of the term to any state or process, including activities.

3.2
clinical situation
situation applied specifically to clinical data and clinical care.

NOTE. *Clinical situations* include the health state of a patient, healthcare actions or any other type of event of healthcare relevance, whether in the past, present or projected for the future. A list of types of *clinical situations* is provided in this document as the "FOCUS *Annotation Type*" in Annex B, table B.1.

3.3
clinical statement
description of a single *clinical situation*, as intended for representation within a patient's record by an author.

NOTE. This is, in essence, a logical (virtual) concept; it provides the clinical information content of an *elementary healthcare record entry*. The information within a *clinical statement* is the minimum necessary, but sufficient, to describe the *clinical situation* precisely. It is not possible to define this concept unambiguously, but in practice it will usually reflect a single clinical observation, interpretation or action. This term is therefore not applicable to the whole of a longer clinical discourse, as might be represented by narrative entries, free-text letters etc.

3.4
healthcare record entry
data set, suitably attributed, which forms part of, or a whole, contribution to a healthcare record at one place and time.

3.5
elementary healthcare record entry
elementary entry
healthcare record entry which reflects a single *clinical situation*

NOTE. It is the representation of a single *clinical statement*. If subdivided, it will results in the loss or significant misrepresentation of its original meaning. Architecturally an elementary entry will usually be represented by a single Data Item or a *Cluster* (see Subclause 4.2), possibly with some additional qualifiers. The content type might, for example, be a coded term, a number, a Boolean or a date. Plain text, if a short phrase relating to a single *clinical situation*, might also be an appropriate content type but longer narrative entries would NOT be examples of an *elementary healthcare record entry*, even if they are represented by a single Data Item.

3.6
annotation type
feature of context pertaining to a *clinical statement*

EXAMPLES. Subject of information, life cycle, knowing mode, relevance.

3.7
annotation identifier
annotation
a means to summarise the key contextual information pertaining to a component complex or a *data item.*

NOTE. The *annotations* are added to the record component as a coded value. The Annotation Measure within this part of ENV 13606 provides a means to summarise in a standardised form the key contextual information pertaining to an elementary or compounded entry, primarily to assist in its safe interpretation. A secondary purpose is to facilitate the retrieval of relevant entries by computerised searches.

3.8
categorial structure
reduced system of concepts to describe the organisation of the semantic categories in a particular system of concepts for development, maintenance and application of terminological systems
[ENV 12264:1997, modified]

NOTE. Categorial structure, system of concept, semantic categories were introduced in ENV 12264:1997. Readers unfamiliar with these topics are strongly recommended to refer to that Prestandard before using the Archetype Measure in 4.6, 5.6 and Annex D (informative).

3.9
dissection
systematic representation of a phrase according to a predefined *categorial structure* and using predefined descriptors

3.10
archetype
semantic network to describe the typical relations among the semantic categories evoked by a particular entity

NOTE. Archetypes describe the typical structure of the involved entity. They are different from categorial structures defined in CEN ENV 12264 "Model of Semantics", that instead describes the mandatory structure of a semantic category for compliant terminological systems (i.e. the part of an archetype that can satisfy a specific purpose), with additional rules for well-formed expressions.

3.11
clinical information

information about a patient, relevant to the health or treatment of that patient, that is recorded by or on behalf of a healthcare professional.
[ENV1613]

NOTE Clinical information about a patient may include information about the patient's environment or about related people or animals where this is relevant.

3.12
EHCR extract
EHCR message component representing the entirety of a patient's electronic healthcare record or that part of the record contained within a particular instance of an EHCR message.
[ENV13606-4]

3.13
record component
component
part of an electronic health care record that is identifiable for the purposes of referencing and revision.
[ENV13606-4]

3.14
original component complex
OCC
record component representing an aggregation of other *record components* that is determined by the time and situation in which they were originally added to the EHCR.
[ENV13606-4]

3.15
folder
original component complex used to group *record components* collected and/or recorded during several contacts with a patient.

NOTE. A folder may include information collected and recorded at different times and by different people.

3.16
composition
original component complex that contains a set of *record components* relating to one time and place of care delivery, a single session of recording or a single document included in the EHCR.

EXAMPLES. Consultation note, operation note, discharge summary, vital signs chart, laboratory report.

3.17
headed section
original component complex representing a sub-division within a *composition,* the contents of which have a common theme or are derived through the same healthcare process.

3.18
cluster
original component complex used to aggregate *data items* and/or other *clusters* to represent a compound concept.

EXAMPLES. A blood pressure measurement consisting of systolic and diastolic pressure, a collection or closely related clinical findings, results of a battery of laboratory investigations, a treatment schedule consisting of several individually specified preparations or dosages.

3.19
selected component complex
SCC
record component representing an aggregation of other *record components* that is not determined by the time or situation in which they were originally added to the EHCR.
[ENV13606-4]

NOTE. Selected component complexes are used to provide alternative view or groupings of records. They can represent the record as viewed at a particular time or they can represent groupings of clinically or logically associated record components.

3.20
data item
single unit of data that in a certain context is considered indivisible.
[ENV13606-4]

NOTE 1. The content of data is dependent upon the structure and type of the identified data type.
NOTE 2. The context may mean that this component's content may represent for example either a single clinical statement or a single complex type such as an X-ray report. Its granularity is determined by the context.

3.21
link set item
record component that provides a means of associating two or more other instances of EHCR message component, and specifying the relationship between them.
[ENV13606-4]

NOTE. The link set item is used to convey a collection of one or more link items (defined in accordance with part 1 of ENV 13606) for which both the link source component and relationship are identical.

3.22
component name category
attribute that provides a high level indication of the general nature of the content of a *record component*.
[ENV13606-4]

NOTE 1. These categories are assigned by or derived from the EHCR, depending upon the nature of the data or the process being carried out.
NOTE 2. See this part of ENV 13606 for permissible values, for the different types of record component.

3.23 Abbreviations

The following abbreviations are used in this European Prestandard.

DIM	Domain Information Model
DTD	Document Type Definition
EHCR	Electronic Healthcare Record
ENV	European Prestandard
GMD	General Message Description
GP	General Practitioner
HGMD	Hierarchical General Message Description
ICSI	International Coding Scheme Identifier
IMS	Implementable Message Specification
MIG	Message Implementation Guide
OCC	Original Component Complex
SCC	Selected Component Complex
UID	Unique Identifier
UML	Unified Modelling Language
XML	Extensible Markup Language

4 Provisions

4.1 General

The seven specific measures included within this Clause of the pre-standard are listed below.

1) A basic classification of Original Component Complexes.
2) A categorisation of names of Compositions and Headed Sections
3) A proposal for *Annotation Identifiers* to summarise the essential meaning contained within the lower-order parts of an EHCR hierarchy and the clinical detail within a Data Item.
4) A categorisation of the relationship names that may be represented by Link Set Items.
5) A framework for the semantic representation of the detail within *clinical statements*.
6) A set of tables to provide enumerated lists of terms and codes ("term list") to be used as value domains for a set of attributes described in part 4 of ENV 13606
7) As a support to the implementation of measures 1-3 above, a template for recording local cross-mapping information is also specified.

4.2 Specialisations of Original Component Complex

The abstract class Original Component Complex (OCC) is used within part 1 and part 4 of ENV 13606 to represent the principal aggregation and containment hierarchies within an EHCR for newly acquired clinical facts, interpretations and plans.
This part of ENV 13606 proposes a broad sub-categorisation of the OCC into four specialisations, as shown in Table 1 below.

Table 1: Specialisations of the Original Component Complex class

OCC specialisation	Description	Examples of Component Names
Folder	High-level subdivisions of the entire EHCR for a patient, usually grouping entries over long time-spans within one organisation or department, or for a particular health problem	GP Record Inpatient Stay Diabetes Care Record
Composition	A set of record entries relating to one time and place of care delivery; grouped contributions to an aspect of health care activity; composed reports and overviews of clinical progress	Consultation Operation Notes Discharge Summary Vital Signs Chart
Headed Section	Sub-divisions used to group entries with a common theme or derived through a common healthcare process	Past Medical History Presenting Symptoms Examination Findings Treatment Plan
Cluster	Low-level aggregations of elementary entries (Record Items) to represent a compound clinical concept	Heart Sounds Differential White Cell Count Insulin Schedule