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Health informatics - Electronic healthcare record communication - Part 1: Extended architecture

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Health informatics - Electronic healthcare record communication - Part 1: Extended architecture

This European Prestandard (ENV) was approved by CEN on 29 July 1999 as a prospective standard for provisional application.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

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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 multipart standard consists of the following parts, under the general title *Electronic Healthcare Record Communication*:

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

This standard builds on the foundations of the previous prENV 12265 Electronic Healthcare Record Architecture but extends it and modifies that standard which is withdrawn.

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

All Annexes are Informative.

Introduction

Healthcare records have become an established and intrinsic part of clinical practice. These record will contain information that is deemed to be important for the care of an individual. Such records are used in many different ways for diverse purposes, and are subject to government policies, as well as social, ethical and legal norms that vary from institution to institution, and from country to country.

The trend is towards representing these records in an electronic medium so that they are processable by computer systems. The Electronic Healthcare Record is then a technological means of documenting the care process for an individual person. A high standard of quality is necessary and as such the record requires appropriate representations of structure and content to both capture clinical information and to permit its communication.

The prime purpose of this multipart Prestandard is Electronic Healthcare Record communication; communication being defined as the act of imparting information. Each part of the Prestandard has a specific role to play and combined with the other parts, provides the principles, structures, terms, rules, and formats for open and safe communication of the electronic healthcare record (EHCR).

This part of the Prestandard, i.e. Part 1 the Extended Architecture, is a Reference Architecture. It describes a conceptual model of structure and content suitable for communicating the EHCR. It is a high level template which provides a set of design decisions which can be used by system vendors to develop specific implementations for their customers. To the healthcare organisation and the clinicians this architecture offers protection for their investment in clinical information against the vagaries of incompatible systems and from the changes arising from evolving business requirements, both in the computer industry and in the healthcare sector. To the individual person, insofar as their health and care depends upon the safe communication of clinical information, the architecture offers a more direct benefit. It does this by providing sound principles to ensure that the important original information context regarding the individual person is preserved and not lost nor degraded in the act of communication.

The Prestandard prENV12265 was the first version of an Electronic Healthcare Record Architecture (EHCRA) intended to provide a foundation for the safe communication of part or whole of the record in diverse and

legitimate circumstances. The Extended Architecture is an 'updated version' of EHCRA. The new version clarifies the organisation of the architecture and the relationships between its components. The intention is that it 'will enable healthcare record information of any sort to be recognisable and understandable when displaced from its origin, through faithful preservation of its content and context'. In particular, the Extended Architecture emphasises the importance of 'context' as an architectural principle, as many of the other principles necessary for effective communication are reliant to some extent upon this one principle.

'context' has been defined as: 'a text preceding and following any particular passage, giving it a meaning fuller or more identifiable than if it were read in isolation'. With respect to the electronic communication of person based clinical information, the standards being developed are not so much concerned with enriching the context as primarily with safeguarding or preserving the context so that data is not lost or wrongfully interpreted, thereby causing unintentional harm to a person. Furthermore, in the EHCR Architecture, context is represented not just by 'text' but by architectural components that singularly or collectively surround, contain, link, constrain, and/or qualify the content so as to make the communication safe and unambiguous. The content may be multi-media as well as simple text strings.

The CEN Report of the Domain Model, which accompanies this multipart Prestandard, describes how the individual parts of the Prestandard interact and provides more detail on the role and importance of context for the Prestandard as a whole.

Electronic Healthcare Communication – Part 1: Extended Architecture

1 Scope

The Extended Architecture is a Reference Architecture for communicating part or whole of an electronic healthcare record (EHCR). The subject of the record to be communicated is an individual person, and the communication is solely with respect to that person's care. Other uses of healthcare records for purposes such as administration, management, research and epidemiology, which require aggregations of individual people's records, are not directly within the scope of this Prestandard.

The Extended Architecture is Part 1 of a four part Prestandard. Together with Part 2, the Domain Term List, and Part 3, the Distribution Rules, it enables open, safe and secure communication of part or whole of an EHCR. Part 4, the EHCR message, is one example of an enabled communicative act, which exchanges EHCR information in a linear format.

Part 1 is a Reference Architecture; it is a conceptual model providing structures and content schema, and is made concrete with terms from the Term Lists presented in Part 2. The Extended Architecture places no restrictions on the communication of the EHCR with respect to the place, the type of communication used, and the timing of the communication. Communication is defined as the act of imparting information, and this Prestandard does not restrict how that should be done, permitting, for example the interchange mechanism to take the form of a message or a system view.

The Extended Architecture is therefore independent of organisation, (e.g. institutional secondary or primary care records), and independent of temporal categories that are applied to records of care (e.g. episodic or longitudinal). The Extended Architecture also makes minimal assumptions regarding circumstances of its use. For example, it does not assume a particular decomposition of the healthcare domain nor does it assume that systems that might use this Prestandard will be of a particular implementation type or configuration. In particular, the fact that this Reference Architecture is represented conceptually by an object-oriented notation does not require conformant instances to be implemented using object technology.

The Extended Architecture does not say anything specifically about the security aspects of communication and supports integrity as a concept only in as far as the structures in this Prestandard enforce consistency to the original information context.

This Prestandard is a resource for both vendor and user, the first with respect to conformance and the second with respect to compliance. To the vendor it shall be used as a formal guide and pattern for the communication of electronic healthcare records conformant to the multipart Prestandard. Vendors, designers and developers are the intended audience for this document, and as such it is primarily and necessarily a technical document. The Prestandard, however, can also provide a resource for the user community to determine whether or not a specific communicative act involving whole or part of the EHCR, as defined in this Part 1, satisfies the clinical need and is fit for purpose. The user community may find that this document is helpful, although they are not the immediate audience. Examples are provided to help both vendor and user, but never the less, the document is intended primarily for a technical readership.

2 Normative References

This document incorporates by dated or undated references, 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 they are incorporated in it by amendment and revision. For undated references the latest edition of the publication referred to, applies.

ISO/IEC 7826-1	Information technology – General structure for the interchange of code values – Part 1: Identification of coding schemes
ISO/IEC 7826-2	Information technology – General structure for the interchange of code values – Part 2: Registration of coding schemes
ISO 2382-4:1987	Information processing - Vocabulary Part 4: Organisation of data
ISO 5281:1977	Information interchange - Representation of human sexes
ISO 639:1988	Symbols for languages, geographical areas and authorities
ISO 8601:1988	Data elements and interchange formats – Information interchange – Representation of dates and times
ISO 8859-1: 1987	Information Processing – Registration of graphics characters subrepertoires – Eight-bit single byte code graphic character sers - Part 1: Latin No 1.
prENV 12265	Medical Informatics - Electronic healthcare record architecture
ENV 12537-1 :1997	Medical Informatics - Registration of information objects used for EDI in healthcare - Part 1: The Register
ENV 12537-2 :1997	Medical Informatics - Registration of information objects used for EDI in healthcare - Part 2: Procedures for the registration of information objects used for electronic data interchange (EDI) in healthcare
ENV 12381 :1996	Medical informatics - Time standards for healthcare specific problems
ENV 12435 :1999	Medical informatics - Expression of the results of measurements in health sciences
ENV 12388 :1996	Medical informatics - Algorithm for digital signature services in healthcare
ENV 12443 :1999	Medical informatics - Medical Informatics healthcare information framework
ENV13606-2 :2000	Electronic healthcare record communication - Part 2: Domain term list
ENV13606-3 :2000	Electronic healthcare record communication - Part 3: Distribution rules
ENV13606-4 :2000	Electronic healthcare record communication - Part 4: Messages for the exchange of information

3 Terms and definitions

For the purpose of this European Prestandard, the following definitions apply:

3.1
annotation identifier
means to summarise the key contextual information pertaining to a Cluster OCC or a Data Item

NOTE The annotations are added to the record component as a coded value. The *component annotation* measure within Part 2 provides 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. See Part 2 for more details.

3.2
architectural component
fundamental constituent of the Electronic Healthcare Record Architecture (EHCRA)

NOTE This Prestandard specifies five types of EHCRA component, namely, EHCR Root Architectural Component, Original Component Complex (sub-typed as Folder OCC, Composition OCC, Headed Section OCC and Cluster OCC), Selected Component Complex, Data Item, and Link Item.

3.3
architectural sub-component
optional constituent of the Electronic Healthcare Record Architecture acting upon an architectural component

NOTE may relate to a higher level of conformance to EHCRA above the minimum level which requires presence of constituents to be mandatory.

3.4
attestation
binding of the healthcare agent (with digital signature) to a unit of information content to confirm the acceptance of the content

3.5
attestation information
architectural sub-component used to supply information about the attestation of an Architectural Component

3.5.1
date and time of attestation
attribute of date and time related to the attestation of the architectural component

3.5.2
attesting agent
attribute providing a reference to a structure which holds information about a healthcare professional, organisation, software or device which provided the attestation including the role being played by this agent

3.5.3
reason for attestation
attribute permitting the reason for attesting to be given

3.6
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

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

3.7
cluster OCC
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.

3.8
code meaning
element within a coded set

EXAMPLE "Paris Charles-De-Gaulle" which is mapped on to the three-letter abbreviation "CDG" by the coding scheme for three-letter abbreviations of airport names.

3.9
code value
result of applying a coding scheme to a code meaning

EXAMPLE "CDG" as the representation of "Paris Charles-De-Gaulle" in the coding scheme for three-letter representations of airport names.

3.10
communicating community
geographically or organisationally defined grouping of healthcare parties that agree to communicate, subject to an agreed set of constraints or guidelines

3.11
component name
attribute that is used to provide a title or label to an instance of an architectural component

NOTE This is a general-purpose name that may be taken from a coding scheme of the terms used in a domain information model.

3.12
component name category
code values representing high level heading that may be attached to certain Record Components

NOTE 1. These headings may be pre-determined by the EHCR system depending upon the nature of the data or the process being carried out.

NOTE 2. See Part 2 for permissible values.

NOTE 3. The values which are relevant depends upon the Record Component type.

3.13
component name structure

attribute that provides a high level indication of the general nature of the content of a record component

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 Part 2 for permissible values, which may vary for different types of record component.

3.14
component status information
class representing a change in the state of an architectural component and the associated change details

NOTE This class includes details of 'revision status' as well as changes brought about by events other than creation, e.g. archiving.

3.15
component unique identifier
attribute used to identify an architectural component

NOTE This attribute just draws the attention to the fact that every architectural component needs to be identifiable, it does not necessarily mean that a conformant implementation will have an explicit identifier. This Prestandard does not restrict the implementation as to how this principle is achieved.

3.16
composition OCC
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
concept
unit of thought constituted through abstraction on the basis of properties common to a set of objects

[ISO 1087]

3.18
data item
DI
single unit of data that in a certain context is considered indivisible

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 (see Part 2) or a single complex type such as an X-ray report. Its granularity is determined by the context.

3.18.1
data item type reference
attribute identifying the type of information content carried by a Data Item

3.19
digital signature
data appended to, or a cryptographic transformation of, a data unit that allows a recipient of a data unit to prove the source and integrity of the unit and protect against forgery e.g. by the recipient

[ISO 7498-2]

3.20
distribution rule
DR
logical concept or rule intended to convey and govern distribution

NOTE The form of representation of EHCR distribution rules is the subject of Part 3 of this Prestandard.

3.21
distribution rule reference
class containing all the data necessary to apply specific distribution rules to an Architectural Component

NOTE Fully defined in Part 3 of this Prestandard.

3.22
domain information model
conceptual model describing common concepts and their relationships for communication parties required to facilitate exchange of information between these parties within a specific domain of healthcare

3.23
domain term list
specific vocabulary comprising a set of terms corresponding to a domain information model

NOTE Also the title of Part 2 of this Prestandard.

3.24
electronic healthcare record
EHCR
healthcare record in computer readable form

3.25
electronic healthcare record architecture
EHCRA
a set of principles governing the logical structure and behaviour of electronic healthcare records that enables communication of the whole or part of a healthcare record

3.26
EHCR communication view

re-use of stored EHCR data for purposes of communication

3.27
electronic healthcare record architecture context principle
EHCRA context principle
fundamental constituent EHCRA principle required for any safe communicative act

NOTE The architectural principle that ensures that the clinical information as entered into the electronic healthcare record by one or more healthcare agents remains safely intact and unambiguous (i.e. nothing is inadvertently or deliberately lost or added), irrespective of why, when, who, where, and how it is communicated.

3.28
electronic healthcare record architectural principle
EHCRA principle
healthcare domain specific concept held to be qualitatively important with respect to the communication of the healthcare record, irrespective of its form or substance

3.29
EHCRA_ref
data type used to reference an instance of architectural component within the scope of the subject of care's EHCR.

NOTE This Prestandard imposes no constraints as to how these references are organised, nor attempts to define their implementation nature.

3.30
electronic healthcare record architecture root architectural component
EHCRA RAC
architectural component which has as its content the subject of care's electronic healthcare record

3.31
EHCR system
system for recording, retrieving and manipulating information in electronic healthcare records

3.32
folder OCC
original component complex used to group record components collected and/or recorded during several contacts with a subject of care

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

3.33
headed section OCC
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

3.34
healthcare agent
healthcare person, healthcare organisation, healthcare device or healthcare software component that performs a role in a healthcare activity

3.35
healthcare agent function
reference to a healthcare agent that identifies them *only* in terms of their function in relation to another healthcare agent and not by an individual name or identifier

NOTE The healthcare agent function allows a record component to refer to healthcare agents who are not individually identified at the time of recording.

EXAMPLES
- to indicate the contact details for a specialist's secretary,
- to distinguish between the parts of a pre-operative assessment applicable to the "anaesthetist".

3.36
healthcare agent in context
one or more healthcare agents related together in a specified manner for the purposes of performing a particular role in a healthcare activity.

3.37
healthcare agent relationship
relationship between two healthcare agents.

NOTE 1. A healthcare agent relationship may apply for a specified period of time.

EXAMPLE 1 Employee / employer

NOTE 2. A healthcare agent relationship may be specific to a particular healthcare agent role.

EXAMPLE 2 On behalf of / responsible for.

3.38
healthcare device
device or equipment involved in the direct or indirect provision of healthcare services to an individual or to a population.

EXAMPLE ECG machine, auto-analyser, syringe pump.

3.39
healthcare organisation
organisation involved in the direct or indirect provision of healthcare services to an individual or to a population.

NOTE Groupings or subdivisions of an organisation, such as departments or sub-departments, may also be considered as organisations where there is need to identify them.

3.40
healthcare party
organisation or person involved in the direct or indirect provision of healthcare services to an individual or to a population.

3.41
healthcare person
person involved in the direct or indirect provision of healthcare services to an individual or to a population.

NOTE A carer or the patient may be a healthcare person. This enables the role of the patient in providing his/her own care to be recorded.

EXAMPLE Primary care physician, dentist, nurse, social worker, pharmacist, medical secretary.

3.42
healthcare record
repository of information regarding the health of a subject of care.

3.43
healthcare reference architecture
reference architecture
specialisation of the conceptual architectural framework (i.e. collective term for healthcare domain, technology and user requirements) for a particular healthcare domain.

[prENV12443]

NOTE The particular domain for Part 1 is 'EHCR communication' on the application layer.

3.44
healthcare service
service provided with the intention of directly or indirectly improving the health of the person or populations to whom it is provided.

3.45
healthcare software
software component involved in the direct or indirect provision of healthcare services to an individual or to a population.

EXAMPLES EHCR system, decision support software, viewing tools.

3.46
ICSI
unique permanent identifier of a coding scheme as specified by ISO 7826-1.

[ISO7826]

3.47
link item
LI
record component that provides a means of associating two other instances of architectural component and specifying the relationship between them.

NOTE A link item may be used to link not only specialisations of record component but also instances of EHCRA RAC.

3.47.1
link item name
concept describing the nature of the link between a link source and link target.

NOTE An implementation would not need to duplicate name and type for this component. The name or type being represented as a coded concept is drawn from a list defined in Part 2 of this Prestandard.

EXAMPLES: reported in, caused by.

3.47.2
link source
attribute referencing the instance of architectural component which is acting in the role of 'link from'.

3.47.3
link target
attribute referencing the instance of architectural component which is acting in the role of 'link to'

3.48
member
record component instance that is referenced by an EHCR Root Architectural Component, original component complex or selected component complex and which may be considered to be a part of its content.

3.49
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.

3.49.1
original component complex type
OCC type
attribute identifying the type of OCC

NOTE An implementation is required to incorporate at least include Folder OCC, Composition OCC, Headed Section OCC, and Cluster OCC, drawn from a list of such concepts defined in Part 2 of this Prestandard.

3.50
original information context
topological placement and position of data in the EHCR precisely as entered by an authoring healthcare agent, be that person, software or device.

3.51
originating date and time
attribute for date and time associated with the creation of an instance of Architectural Component.

3.52
originating healthcare agent
attribute referencing the healthcare agent that originated the architectural component

NOTE The structure provided by healthcare agent in context includes the role in which the healthcare agent is acting.

3.53
organisation
unique framework of authority within which a person or persons act, or are designated to act towards some purpose.

NOTE Groupings or subdivisions of an organisation may also be considered as organisations where there is need to identify them for information interchange.

[ISO 6523-1984]