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Zdravstvena informatika ï Informacijske komponente za splo÷no uporabo ï 3. del: Klini¸ni podatki

Health informatics - General purpose information components - Part 3: Clinical

Medizinische Informatik - Allgemein verwendbare Informationskomponenten - Teil 3: Klinische Informationen

Informatique de santé - Unité d'information dans les messages - Partie 3: Clinique

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Health informatics - General purpose information components - Part 3: Clinical

Informatique de santé - Unité d'information dans les messages - Partie 3: Clinique

Medizinische Informatik - Allgemein verwendbare Informationskomenten - Teil 3: Klinische Informationen

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Foreword

This European Standard (EN 14822-3:2005) has been prepared by Technical Committee CEN/TC 251 “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of an identical text or by endorsement, at the latest by April 2006, and conflicting national standards shall be withdrawn at the latest by April 2006.

This is part three of a multipart standard under the heading:

Health informatics - General purpose information components:

— Part 1: Overview

— Part 2: Non-clinical

— Part 3: Clinical

This European Standard is definition of a set of clinical general purpose information components.

IMPORTANT — Within this draft document each of the General Purpose Information Components and various sub-components are provided with identifiers, which are unique only internally within this European Standard.

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

Introduction

Many previous messaging and information structure standards for health have overlapping parts with a number of objects being defined in separate documents, sometimes with small variations making implementation of conformant applications more difficult. It therefore makes sense to define a set of general purpose components that can be used for definition of message structures for different purposes[1]. This approach was suggested and approved as a strategy for CEN/TC 251 in the Short Strategic Study on message standards alignment in 1999 examining a set of five European prestandards for messages. This document is aiming to provide such a set of components and has been developed jointly with a new European standard for Service Request and Report messages that is using the components defined herein.

Another important background to the development of this European Standard has been the wish for a harmonisation of information models for health developed in Europe and the USA expressed in the collaboration agreement entered March 2000 between CEN/TC 251 and HL7 (Health Level Seven, Ann Arbor. Michigan). The goal was set for a maximum degree of alignment while maintaining their independence and need to serve the business requirements of the respective markets but also to make the results available to ISO for possible international standardization.

HL7 have adapted a general strategy similar to CEN/TC 251 using information modelling[2] expressed in UML (Unified Modeling Language) for their new standards and a lot of interaction and information sharing has occurred between CEN experts and HL7 in an open spirit of collaboration.

This European Standard includes a large number of objects which are technically identical to descriptions in draft documents of HL7, although partly described differently due to the fact that CEN is following the ISO rules for drafting and presentation of standards which HL7 is not. CEN wishes to express its gratitude towards HL7 experts for generously sharing their models with the European expert team.

This European Standard contains definition of a set of clinical general purpose information components.

Many aspects of this document require explanation which is provided in EN 14822-1.

[1] See Annex A: Rationale for this document on General Purpose Information Components.

[2] Modelling is British English spelling whereas Modeling is US English spelling.

1 Scope

This European Standard specifies the definition and structuring of information relating to entities that are commonly encountered in communications with and between clinical information computer systems.

Within the scope of this European Standard is a description of components and their use. In particular, these components relate to the following sub-domains:

— Analysable objects: including samples, body parts, x-rays and other study products, together with their collection and properties.

— Clinical information: including observations, patient conditions, procedures, medication treatment, investigations, counselling plus how these items are organised within a record.

— Medicinal products: including appliances, dosage regimes,etc.

— Routing aspects of medication treatment or other procedures.

Care Service information: including referrals for care services, care encounter information and scheduling.

2 Normative references

Not applicable.

3 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply.

3.1
analysable object
something derived from or to be derived from a patient as part of a diagnostic or laboratory investigation
[ENV 12539:1997 - revised]

NOTE 1 Analysed object is a generalisation that includes samples taken from a patient and physical or digital records of information derived from a patient as part of a diagnostic service. An analysed object that is not a sample is referred to as a study product.

NOTE 2 An analysed object need not exist in a tangible form but may represent something observed briefly by a diagnostic service provider.

EXAMPLE 1 An x-ray image, a series of x-ray images, part of an x-ray image. The image may exist in a digitised form or as a film.

EXAMPLE 2 An electrocardiograph (ECG) monitor tracing or a twelve lead ECG.

EXAMPLE 3 An organ removed during surgery or post-mortem, a biopsy, a particular slide containing a section taken from a biopsy.

EXAMPLE 4 A view observed through an endoscope, an observation during an echocardiographic examination.

3.2
analysable object in use
information about an analysable object and the part it plays in an activity

EXAMPLE 1 Blood collected for a biochemical or hematological analysis during exploratory surgery.

EXAMPLE 2 Urine sample taken by the patient to a routine examination.

3.3
body system
demarcated system that is related to a subject of care or component of a subject of care

EXAMPLE 1 Systems: a man, an organ or anatomical structure.

EXAMPLE 2 Components: pathological cells in a biopsy from an organ.

3.4
care encounter
situation on the uninterrupted course of which one or more health care professionals delivers health care services to a subject of care
[ENV 13940:2001 - modified]

3.5
care service
activity performed for a subject of care by a health care provider with the intention of directly or indirectly improving or maintaining the health of that subject of care
[ENV 13940:2001 - modified]

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

[ENV 13606:2000]

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

3.7
clinical information complex
healthcare record component representing an aggregation of other healthcare record components
[ENV 13606:2000]

3.8
clinical observation
clinical information excluding information about treatment and intervention
NOTE The observer may be the patient or related person (information about symptoms, family history, occupation or life style), or a healthcare professional (information about physical signs, measurements, properties observed or diagnoses). While information about the nature of a planned or performed treatment is excluded by the definition, clinical observations may be recorded as the results of a treatment or during the course of a treatment or as its result.

3.9
clinical procedure
clinical intervention or treatment of a subject of care or group of subjects of care excluding counselling, investigation or medication

3.10
General Purpose Information Component
GPIC
commonly useful information component that is a specialisation of classes in an international reference information model which is intended to be used in the specification of an information service for health or of a communication between health information systems

3.11
healthcare
provision of health related services
[ENV 13940:2001 - modified]

NOTE 1 This includes more than performing procedures on subjects of care. It also includes, for example, the management of the information about patients, their health status and their relations within the health care framework.

NOTE2 In the present European pre-standard, the term 'care' may be used as a synonym for 'health care'.

3.12
healthcare agent
healthcare person, healthcare organisation, healthcare device or that performs a role in a healthcare activity

3.13
healthcare device
device or equipment involved in the direct or indirect provision of healthcare services to an individual or to a population
[ENV 13606:2000]

EXAMPLES ECG machine, auto-analyser, syringe pump.

3.14
healthcare organisation
organisation involved in the direct provision of health care services
[ENV 13606-4:2000 - modified] [ENV 1613:1995, modified]

3.15
healthcare party
organisation or person involved in the direct or indirect provision of healthcare services to an individual or to a population
[ENV 13606:2000]

3.16
healthcare professional
person involved in the direct or indirect provision of healthcare services to an individual or to a population
[ENV 13606:2000 –revised]

NOTE A carer or the patient may be a healthcare person.

3.17
medicinal appliance
device or piece of equipment which may be used by human beings or administered to animals for treating or preventing disease, with the view to making medical diagnosis, to restore, correct or modify physiological functions or to alleviate handicap

EXAMPLES Syringes, spacers for inhalation, diagnostic kits for pregnancy, bandages, catheters, diapers for incontinence, orthopaedic shoes, colostomy bags, wheel chairs, pneumatic mattresses.

3.18
medicinal product
any substance or combination of substances, which may be administered to human beings or animals for treating or preventing disease, with the view to making medical diagnosis or to restore, correct or modify physiological functions

NOTE Some medicinal products are prescribed as a combination of a medicinal product and a medicinal appliance. Such combinations are regarded in this document as medicinal products. [Directive 65/65/EEC, modified]

3.19
medicinal product package
delivery unit of a medicinal product in an outer container
[ENV 12610:1997]

3.20
medication supply
provision of one or more medicinal products for administration to a subject of care

3.21
medication treatment
administration of one or more medicinal products to a subject of care at one or more administration events

3.22
object characteristics
measurement made upon, or a measurement parameter of a specimen or study product

3.23
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 6523:1998]

3.24
preservation material
material or substance that is used in order to preserve a specimen or body part

3.25
specimen
one or more parts taken or to be taken from a system and intended to provide information on that system or on a subsystem, or to provide a basis for decision on either of these

[ENV 12359:1997 - modified]

NOTE The system from which a sample is taken may be a patient or may itself be a specimen. The specimen is assumed to be representative of the system. The term sample is sometimes used with the same meaning.

3.26
study product
identifiable record of information derived from a patient as part of a diagnostic service. It may take the form of a physical object or may consist of digital information in an electronic information system
[ENV 12539:1997]

NOTE A study product differs from a sample in that a sample is something taken from a patient whereas a study product is a recording of information derived from a patient. A consequence of this distinction is that a study product can be copied. Furthermore, if the study product is represented in a digital form it can be held within or transferred between computer systems.

EXAMPLE 1 An x-ray image, a series of x-ray images, part of an x-ray image.

EXAMPLE 2 The image(s) may exist in a digitised form or as a film.

EXAMPLE 3 An electrocardiograph (ECG) monitor tracing or a twelve lead ECG.

EXAMPLE 4 The tracing may exist on paper or as a digitised signal.

3.27
subject of care
person or other living subject, or group of persons or other living subjects, scheduled to receive or receiving healthcare services

4 Abbreviations

NOTE All those marked by ‡ as defined in the CEN/TS 14796:2003 “Health Informatics - Data Types”.

BL ‡	Boolean
CD ‡	Concept Descriptor
CS ‡	Coded Simple value
CV ‡	Coded Value
ED ‡	Encapsulated Data
GP	General Practitioner
GPIC	General Purpose Information Component
II ‡	Instance Identifier
IVL ‡	Interval
IVL<PQ> ‡	Interval of Physical Quantity
IVL<TS> ‡	Interval of Time
INT ‡	Integer
PQ ‡	Physical Quantity
ST ‡	String
TS ‡	Time stamp (point in time)
UML	Unified Modelling Language

5 Rules governing the use of general purpose information components

5.1

When using a GPIC, a system or communication protocol which conforms to this document shall implement all of the features (classes, associations, attributes) that are described within the GPIC core[3]. In particular, a conformant system that utilises a GPIC shall be able to receive and process information present in all classes and attributes, even where these classes and attributes are specified as being optional.

A conformant system that utilises a GPIC to send information shall not be obliged to populate optional classes or attributes.

5.2

Each of the classes and embedded GPICs that constitute a GPIC description has a class type. These are shown as follows[4]:

3 See Annex B: How to read the models.

4 See Annex C: Health Level 7 (HL7) Reference Information Model.

A	**Act**	Describe actions, plans etc. Examples include observations, tests, referrals, transportation etc.
AR	**Act Relationship**	Relationships between acts. Often used to group Acts together, for example, a test result with a clinical observation.
P	**Participation**	Used to links an Act to Entities. May include information about the type of participation of the Entity.
R	**Role**	Used to provide information about the roles entities play.
RL	**Role link**	Used to link two Entity/Role pairs together, for example person/employee ←> organisation/employer.
E	**Entity**	Describe physical things. Examples include people, animals, organisations, places, materials, devices etc.

For each GPIC there is a definition of the type(s) of objects to which the GPIC may be attached within any external models or implementations. A conformant system will restrict GPIC use accordingly[5].

5.3

GPICs may be associated with other GPICs in ways which extend their functionality. These extensions are informative in nature and will not subject to conformance testing.

5.4

A user community, e.g. a national body or a message development agency, may wish to 'localise' a GPIC for use in a particular circumstance. The rules which underpin such localisation are[6]:

— All mandatory attributes and associations shall be present in any design using the GPIC, i.e. it is not permitted to omit these features.

— A user community may in any part of a communication or system design:

  — specify that certain specialisations of a general class are not allowed;

  — specify that certain optional attributes or associations are omitted;

  — restrict (constrain) a data type: For example, the data type ST (string) being defined in place of ED (multimedia data);

  — define constraints on the allowable values of an attribute;

5 See Annex D: Common features of the General Purpose Information Components.

6 See Annex E: Localisation of the general purpose information components.

— define constraints on the vocabulary sets that may be associated with a coded attribute.

— A user community shall **not**:

— omit mandatory attributes and associations but may restrict values and vocabulary sets as outlined above;

— add attributes;

— add associations except to other GPICs as formal extensions.

5.5

User communities may create new GPICs.

6 General Purpose Information Components – an overview

GPIC Name	Description/Use
AnalysableObject **R**	Information about something derived from, or to be derived from, a living subject of care, or a physical location, as part of a diagnostic or laboratory investigation. This GPIC shall be used only where the application or communication about this entity is concerned with a: — Specimen, i.e. substances or samples that are analysed in laboratory investigations or; — Study products such as ECG tracings, x-rays, digital representation of an x-ray etc. NOTE Where it can be identified that only one of these options is required, and where the Role interface and/or the associations to the external GPICs are required, the user should utilise this GPIC but specify a restriction to either the Specimen GPIC or StudyProduct GPIC specialisation.
AnalysableObjectInUse **P**	An AnalysableObject GPIC with a Participation interface allowing it to be associated with an action or activity. EXAMPLES 1) Blood for a biochemical or hematological analysis collected during exploratory surgery. 2) Urine sample taken by the patient to a routine examination.

GPIC Name	Description/Use
Specimen E	Information about one or more parts taken or to be taken from a system and intended to provide information on that system or on a subsystem, or to provide a basis for decision on either of these. This GPIC may be used in the following situations: 1) In its own right when it is used to specify information concerning a non-manufactured substance without the explicit use of the AnalysableObject class 2) As a specialisation of the AnalysableObject class within the AnalysableObject GPIC where the user or application needs to: — leave open the possibility of referring to a specimen or study product; — provide a role interface as in the AnalysablObject GPIC (Note that it is possible to restrict the AnalysableObject GPIC so as to only include the possibility of describing a specimen); — provide links to external GPICs such as ObjectCharacteristic, BodySystem or acquisition details. NOTE If there is a requirement to relate this specimen to other specimen use the RelatedAnalysableObject facility within the AnalysableObject GPIC.
RelatedAnalysableObject RL	Provides a means of linking a specimen or study product to a related specimen or study product.
ManufacturedSpecimen R	Information about a sample of material that is a representative part of a manufactured substance. EXAMPLES A sample of vaccine, blood products.
SpecimenTreatment A	Information about any physical or chemical treatment of a specimen. EXAMPLES Freezing, centrifuging, treatment with a preservation material.
RelatedSpecimenTreatment P	SpecimenTreatment GPIC with a Participation interface. This permits the treatment to be associated with a specimen through RelatedAnalysableObject GPIC.