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Health informatics — Electronic health record communication —

Part 3: Reference archetypes and term lists

Informatique de santé — Communication du dossier de santé informatisé —

Partie 3: Archétypes de référence et listes de termes

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Contents

Page

Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health Informatics*.

This second edition cancels and replaces the first edition (ISO 13606-3:2009), which has been technically revised. The main changes compared to the previous edition are summarised in the Introduction.

A list of all parts in the ISO 13606 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

0.1 General

This document is part of a five-part series of standards, published jointly by CEN and ISO through the Vienna Agreement. In this document, dependency upon any of the other parts of this series of standards is explicitly stated where it applies.

0.2 Preface

ISO 13606-3 defines two kinds of specifications.

1) A normative set of (coded) term lists that each defines a controlled vocabulary for a Reference Model attribute that is defined in ISO 13606-1;

2) A set of Reference Archetypes that specify how the ISO 13606-1 Reference Model should be applied for communicating information for:

   — null_flavor;

   — access policies;

   — demographic entities;

   — example clinical reference archetypes, conforming to ISO 13940 (Contsys).

0.3 Term Lists

Each term list is referenced by its corresponding attribute as an invariant constraint in ISO 13606-1, by referring to its term list name. For each term list, every code value is accompanied by a phrase and description; however, in each case it is the code that is used as the Reference Model attribute value. Language translations of the phrase and description will therefore not affect the instances of RECORD_COMPONENT that are communicated using this document.

Should any revision prove necessary in the future to these term lists, a technical revision to this document will be required. Such a revised document should specify an updated Reference Model identifier that should then be used as the value of the rm_id of an EHR_EXTRACT, to inform the recipient of the version of this document that was used in its creation.

0.4 Reference archetypes

An archetype, sometimes known as a clinical model, specifies a pattern for representing an aspect of clinical documentation within an electronic health record. An archetype defines the structural and semantic relationships between fine-grained data items, including the domains of content each data item may contain in order to be a valid component of that archetype. The concept of archetypes is outlined in the introduction of ISO 13606-1, and the formal representation of archetypes is specified in ISO 13606-2. Archetypes are used in this document to shape parts of an EHR extract, in order to provide predictability of the way in which clinical information is represented within it.

Given the vast domain of health and healthcare, there might eventually be hundreds of archetypes covering its many different documentation and communication needs. Because archetypes might be created by different communities in different countries and settings, there is a risk that archetypes for similar areas of documentation will be made differently by different groups, and therefore hamper interoperability. *Reference archetypes* are archetypes that represent very fundamental areas of clinical documentation, which might be used as they are or may serve as a kind of *base pattern* for more specialised archetypes. By acting as the base pattern for a set of specialised archetypes, the members of the set are likely to be better structurally and semantically aligned with each other. Their use will facilitate semantic interoperability by making it easier for EHR extracts that have used different members of that set to be interpreted collectively.

A reference archetype is a starting point for archetype specialisation (using a sub-set of properties and/or constraints on the ELEMENT value domains), or localised by adding natural language or local terminology mappings, or may be extended with additional properties. In all such cases the reference archetype should be specified as the underlying "specialisation parent", in accordance with ISO 13606-2. Some reference archetypes may be implemented directly. A reference archetype is therefore a conventional archetype that has been designated as a recommended (informative) or mandated (normative) basis for developing commonly required archetypes.

This document defines several categories of reference archetypes, some of which have been designated as normative and others informative. The decision of which to make normative is based on the information source used to create each reference archetype: if the underlying source is itself part of this document or is required to implement it then it has been designated as normative. If it is an external source such as another standard, which might be revised at a different time point to this document, then the reference archetype has been made informative.

In this document, a normative null_flavor reference archetype is defined to be used for the corresponding property in ISO 13606-1. A normative access policy rule reference archetype is specified in accordance with the corresponding information model for an access policy rule specified in ISO 13606-4. Informative reference archetypes are defined for the most frequently needed demographic entities. An informative archetype is specified for medicinal product, which has been defined in accordance with the ISO IDMP standard series.

The examples of clinical reference archetypes presented in Clause 11 are based on the clinical reference information structures in Clause 12. The clinical reference information structures in Clause 12 are developed out from the clinical concepts as they are defined in ISO 13940:2015 (Contsys).

Each selected clinical concept in Contsys has been elaborated based on the definition, relations and explanations in notes given in ISO 13940. The attributes of the clinical reference information structures are thus mainly based on ISO 13940. Some further attributes are added to harmonize the structures with e.g. FHIR resources or openEHR.

The result is information structures representing basic clinical concepts including a gross list of attributes for each concept. The gross list is intended to be comprehensive and cover all needs for clinical information in different specializations and applications. This approach reflects the general idea to include all needed types of characteristics/attributes and constrain the number applied when specializing clinical archetypes for instantiation.

The level of granularity/abstraction of the classes/selected concepts in the clinical reference information structures in Clause 12 and in the examples of clinical reference archetypes in Clause 11 is explained by the purpose of being general at the conceptual level for all clinical situations where information about this type of concept is relevant (content as well as context) but still specific for that clinical concept.

One example of the chosen level of abstraction is healthcare activity element as the concretized specialization of healthcare activity with a specific purpose (e.g. investigation or treatment). Another example could be that the method of performing activity elements are specified at a general level common for surgical treatments, pharmacological treatments (including administration routes) and laboratory tests as investigations.

Clause 12 includes clinical reference information models, conformant to ISO 13940(Contsys), to be used as bases for specifying clinical reference archetypes. These are aimed for further specializations as clinical archetypes in an EHR. The clinical reference information models are also aimed for further use as a basis for harmonizing between coexisting standards for specifying clinical content. A future possibility could be to develop FHIR resources based on these reference models. Another possibility for future development is that CIMI archetypes could accept the same bases as a "middle layer" between their reference model and specific archetypes. Altogether such approaches could result in harmonization of the different information specification standards/approaches to the common conceptual basis of Contsys. These resources are offered in an informative Clause to indicate the direction of ongoing work to develop a portfolio of Reference Archetypes that align with Contsys and with corresponding FHIR resources, but which are not yet mature enough to include here as normative specifications.

Health informatics — Electronic health record communication —

Part 3: Reference archetypes and term lists

1 Scope

This document specifies a means for communicating part or all of the electronic health record (EHR) of one or more identified subjects of care between EHR systems, or between EHR systems and a centralised EHR data repository.

It can also be used for EHR communication between an EHR system or repository and clinical applications or middleware components (such as decision support components), or personal health applications and devices, that need to access or provide EHR data, or as the representation of EHR data within a distributed (federated) record system.

This document defines term lists that each specify the set of values for the particular attributes of the Reference Model defined in ISO 13606-1. It also defines normative and informative Reference Archetypes that enable frequently-occurring instances of EHR data to be represented within a consistent structure when communicated using this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13606-1, *Health informatics — Electronic health record communication — Part 1: Reference model*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 13606-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
healthcare activity
activity intended directly or indirectly to improve or maintain a health state

Note 1 to entry: Each specialization of this concept represents *healthcare activities* performed by a specialization of *healthcare actor*.

Note 2 to entry: Different types of *healthcare activity elements* (e.g. *healthcare investigation* or *healthcare treatment)* may be performed during a *healthcare activity*.

Note 3 to entry: See the *concepts healthcare provider activity*, *self-care activity*, *healthcare third party activity* and *automated healthcare* when it comes to the recording of *information* that are the result of *healthcare activities* (e.g. ratified observations).

EXAMPLE A blood pressure measurement completed by a qualified nurse including the *healthcare activity elements* of taking, documenting and evaluation.

[SOURCE: ISO 13940:2015]

3.2
reference archetype
archetype serving as a base pattern for archetype specialisations

4 Abbreviations

For the purposes of this document, the following abbreviations apply.

EHR	Electronic Health Record
EU	European Union
GP	General Practitioner
HL7	Health Level Seven
ISO	International Organization for Standardization
OID	Object Identifier
UML	Unified Modelling Language

5 Conformance

When electronic health record information is to be communicated using ISO 13606 (all parts) and where an attribute of the Reference Model defined in ISO 13606-1 requires a value to be taken from a bounded set of codes from a named term list, the code shall be one of those defined in Clause 6 for the correspondingly-named term list.

An archetype that is used to organize the structure and semantics of part of an electronic health record that is communicated using this standard series shall be a logical transformation or specialization of a normative reference archetype defined in Clauses 7 or 8, if the archetype is intended to communicate information corresponding to the scope of one of those reference archetypes. This document does not prescribe the structure or semantics of any other archetypes used to communicate electronic health record information.

6 Term lists

6.1 Introduction

The Reference Model defined in ISO 13606-1 defines several attributes whose values are to be selected from a fixed list of values. This clause defines those value lists (term lists) for each of those attributes. Attributes not included in this clause (or defined in ISO 13606-4) may take any value that conform to the data type and invariant specifications defined in ISO 13606-1.

There are no attributes in the Reference Model to specify the clinical content being communicated, except for the identifier of the archetypes that specify its overall structure and semantics and the term list defining semantic linkage between RECORD_COMPONENTs. Clinical concepts as they are defined in ISO 13940:2015, and a reference information structure as the informative basis for developing clinical reference archetypes, are presented in Clause 12.

6.2 Termlist SUBJECT_CATEGORY, Class ENTRY, attribute subject_of_information_category

This attribute provides a coarse-grained definition of the person who is the subject of an ENTRY. The default value is DS00 (the patient, or subject of care). A more fine-grained definition of the information subject (such as the precise relative with a family history) can be specified through the ENTRY.subject_of_information.relationship attribute.

Code	Meaning	Description
DS00	subject of care	*healthcare actor* with a *person role;* who seeks to receive, is receiving, or has received healthcare
DS01	relative of subject of care	*person role* being any human relative, without limitation to biological or adoptive relatives
DS02	next of kin	*person role* being either the closest living relative of *the subject of care* or identified as the one he has a close relationship with
DS03	foetus or neonate or infant	the baby or babies being described by an ENTRY in the EHR of the mother
DS04	mother	the mother of a foetus or neonate, if being described in the EHR of a baby (e.g. during pregnancy)
DS05	donor	*person role* being the donor of an organ or body specimen being described by an ENTRY in the EHR of the recipient
DS06	unrelated person	*person role* being any other person not related to the subject of care, such as an employer, friend, carer
DS07	healthcare third party	*healthcare actor* (organization or person) other than a *health-care provider* or the *subject of care*
DS08	subject of care proxy	*healthcare third party* having person role with the right to take decisions on behalf of the subject of care

NOTE If ENTRY.subject_of_information_category is null, the value DS00 is assumed.

The original list has been extended and revised to align with terms and concepts used in ISO 13940 (Contsys).

6.3 Termlist VERSION_STATUS, Class BASE_COMPONENT, attribute version_status

This attribute is used to indicate the status of a particular version of a RECORD_COMPONENT. This attribute is optional, and if no value is provided it is to be assumed that the RECORD_COMPONENT is the first definitive version corresponding to code value VER01. **In all cases, the new version of a RECORD_COMPONENT shall replace the former version, as specified in** ISO 13606-1**.**

Code	Meaning	Description
VER00	Draft	The version is known at the time of committal to be incomplete (because additional information is expected later) or if the necessary authorisations have not been made : VER00 implies that the EHR recipient might in future expect to receive a more definitive updated version of this RECORD_COMPONENT
VER01	Finished	The version is committed with the intention of being a final version, with no anticipated reason for revision
VER02	Updated	The version is an update of the previous version, usually by adding supplementary information that was not available at the time of committal. Revision is intended for additions usually to be made by the original author within a short time frame, and not for recoding an evolving clinical story

Code	Meaning	Description
VER03	Correction	The version corrects errors made in the recording of the previous version
VER04	Deletion (in error)	The version logically deletes the previous version to correct an error of documentation (e.g. if the RECORD_COMPONENT had been placed in the wrong patient's EHR)
VER05	Legal deletion	The version logically deletes the previous version because the removal is the outcome of a legal or policy matter (e.g. if the subject of care has exercised rights to have the information removed)
VER06	Encoded	The version updates the previous version through the addition of coded terms to which content in the previous version has been mapped, without replacing any of the original content of the previous version

NOTE If BASE_COMPONENT.version_status is null, the value VER01 is assumed.

6.4 Termlist MODE, Reference Archetype Healthcare activity participation

Code	Description
MODE01	Participation in person
MODE02	Participation using remote control to perform healthcare activity elements
MODE03	Participation via videoconference or similar electronics means (sound and video)
MODE04	Participation via telephone or similar electronics means (sound only)
MODE05	Participation using on-line communication of text and possibly also pictures
MODE05	Contributing by providing text and/or pictures ahead of the healthcare activity

NOTE If MODE is null, the value MODE01 is assumed.

6.5 Class LINK, attribute link_description

Six separate term lists are defined for this Reference Model property, reflecting the main purposes for which links may need to be communicated between EHR systems. The main advantage of sub-dividing the set of link terms into these six categories is to enable archetypes or other constraints and profiles of the Reference Model to specify if only a particular category of link terms is relevant to a given situation.

The six categories are:

— **Related to**: a generic category for linking parts of the EHR.

— **Authorised by or confirmed by**: links that connect the documentation of the legal or authoritative basis for an activity documented in another part of the EHR, including mandates for care and attestations of EHR content.

— **Related to the same health condition or health problem**: links that connect two health or health care situations, events or activities that pertain to the same healthcare matter, such as defining a health problem for which the linked component is a manifestation (as an inclusion criteria), specifying the health condition being the motivation/indication for a healthcare activity, asserting a cause and effect relationship, relates to specified phases of a clinical process, linking stages in an evolving clinical history, or connecting different interpretations of an observation.

— **Related to the same clinical process, care plan, healthcare activity or episode of care**: linking parts of the same health condition (as criteria for a health condition and/or as a motivation for healthcare activities), clinical process (as a clinical process concern), care plan, healthcare activity or episode of care.

— **Related documentation:** linking alternative documentary forms, such as re-use of pre-existing EHR content in another part of the EHR, the re-expression of the same clinical information, additional supplementary explanatory information or a summary.

— **Plays a role**: linking EHR content to a demographic entity that has played a (structural) role in the information that is documented.

The list from the previous version of this document has now been divided into subgroups for easier specification in archetypes and for easier maintenance. It has been extended by adding terms identified in previous implementer feedback, terms to align with changes to ISO 13606-1, terms to link a RECORD_COMPONENT to an attestation or to link two attestations, and terms corresponding to Contsys associations that were not covered in the original term list.

6.5.1 Termlist RELATED_TO, Class LINK, attribute link_description

Code	Meaning	Description
LINK-A1	concerns, or unspecified link	The term is used when no semantic information is available for the Link in the EHR system from which the EXTRACT has been created.
LINK-A2	suggests/considered (tentatively related to)	The interpretation expressed in the target component is assessed to be a possible (considered) cause or outcome of the findings documented in the source component.
LINK-A2i	is considered/suggested by	The inverse relationship of LINK-A2.
LINK-A3	re-occurrence or repeat of	The source component documents a clinical situation which, in the opinion of the composer, is a repeat occurrence of the clinical situation documented in the target. This is intended for re-occurrences of real-world situations, not repeated documentation of the same real-world event.

6.5.2 Termlist AUTHORISED_BY, Class LINK, attribute link_description

Code	Meaning	Description
LINK-B1	endorses/concluded (agrees with, confirms, verifies)	The interpretation expressed in the source component provides confirmatory evidence or a confirmatory opinion of the interpretation expressed in the target component. An example of this is where specified observed conditions documented in source component are considered being inclusion criteria for a health condition expressed in the target component.
LINK-B2	disagrees with (e.g. another opinion)	The interpretation expressed in the source component disproves or disagrees with or excludes the interpretation expressed in the target component. An example of this is where specified observed conditions in the source component are considered being exclusion criteria for a health condition in the target component.
LINK-B3	permits (sanctions, authorises)	The source component documents a permission or an authorization of an action documented in the target component. A permission can include an informed consent from a subject of care or an authorization by law.
LINK-B3i	permitted by	The inverse relationship of LINK-B3.
LINK-B4	assumes responsibility for	The participant (e.g. composer) identified in the source component is taking responsibility for the care acts documented in the target component (accepting a healthcare mandate). A mandate includes a commitment to perform an activity and a permission to perform it.
LINK-B5	declines (refuses, cancels)	The participant (e.g. composer) identified in the source component is declining or withdrawing consent to take responsibility for the care acts documented in the target component. Refusal to accept a healthcare mandate.

Code	Meaning	Description
LINK-B6	consents to	The participant identified in the source component is proving consent to care actions documented in the target component. A subject of care gives an informed consent to a commitment for provision of healthcare given by a healthcare provider.
LINK-B6i	consented by	The inverse relationship of LINK-B6.
LINK-B7	countersigns	The source component is a countersignature of the information contained in the target component
LINK-B8	revokes attestation	The source component contains information or an attestation that effectively revokes the validity of the target attestation, or the source attestation that revokes the validity of the target attestation
LINK-B9	removes attestation	The source component contains information or an attestation that logically deletes the target attestation because the original attestation had been added in error, or the source attestation logically deletes the target attestation because the original attestation had been added in error.
LINK-B10	unspecified reference to an attestation	The target of the LINK is an attestation, but its relationship to the source component is not otherwise specified
LINK-B11	regulates	The source component specifies a regulation or policy or procedure or rule that governs activities or decisions documented within the target component
LINK-B11i	is regulated by	The activities or decisions documented within the source component are governed by a regulation or policy or procedure or rule specified in the target component
LINK-B12	commissions	The source component specifies the commissioning basis for care documented within the target component
Link-B12i	is commissioned by	The care documented in the target commitment has been commissioned as specified in the target component

6.5.3 Termlist SAME_HEALTH_ISSUE, Class LINK, attribute link_description

Code	Meaning	Description
LINK-C1	cause (interpretation)	The clinical situation documented in the source component is considered by the author to be the cause of the clinical situation documented in the target component. This is commonly an association between health conditions (e.g. an observed condition in the source component is assessed to be the cause of a professionally assessed condition in the target component), but could also be an association between an activity or an event and a health condition.
LINK-C1i	caused by	The inverse relationship of LINK-C1.
LINK-C2	revised interpretation	The interpretation documented in the source component is a revision of or difference in clinical thinking compared to that documented in the target component.
LINK-C3	evidence for	The observation or interpretation documented in the source component provides confirmatory evidence of the interpretation expressed in the target component. This is an association between health conditions where one observed condition by knowledge is an inclusion criterion for a more composite health condition.
LINK-C3i	justified by	The inverse relationship of LINK-C3.

Code	Meaning	Description
LINK-C4	evidence against	The observation or interpretation documented in the source component provides evidence against the interpretation expressed in the target component. This is an association between health conditions where one observed condition by knowledge is an exclusion criteria for a more composite health condition.
LINK-C4i	countered by	The inverse relationship of LINK-C4.
LINK-C5	Indicated/motivated by	The target component documents a clinical indication for the care action documented in the source component. This is an association between a health condition being the motivation for a healthcare activity element.
LINK-C5i	Indication/motivation for	The inverse relationship of LINK-C5.
LINK-C6	contraindicated by	The target component documents an observation or interpretation that is a contraindication for a care action documented in the source component. This is commonly an association between a health condition and a healthcare activity but could also be an association between two healthcare activities.
LINK-C6i	contraindication for	The inverse relationship of LINK-C6.
LINK-C7	trigger for	The source component is the trigger event or situation for the clinical situation documented in the target component. This is e.g. a component of a clinical risk describing the trigger for an event that could have consequences for the health state of a subject of care (a risk condition).
LINK-C7i	triggered by	The inverse relationship of LINK-C7.
LINK-C8	manifestation of	The source component documents a clinical manifestation of the phenomenon documented in the target component.
LINK-C8i	manifested by	The inverse relationship of LINK-C8.
LINK-C9	sequel (consequence, progression)	The source component documents a clinical situation that is a temporal successor to the target component (expected or unexpected, intended or unintended). Health condition evolution is an example of a sequel.
LINK-C10	intended (aim, goal, target, hoped for, desired)	The clinical situation documented in the target component is an intended consequence, sequel or outcome of the situation documented in the source component. A target condition is an example of “intended”.
LINK-C11	anticipated (predicted)	The clinical situation documented in the target component is an anticipated consequence, sequel or outcome of the situation documented in the source component (desirable or undesirable). A prognostic condition is an example of “anticipated”.
LINK-C12	to be avoided (at risk of, fear of, prophylaxis against)	The clinical situation documented in the target component is an undesirable but possible consequence, sequel or outcome of the situation documented in the source component. A risk condition is an example of “to be avoided”.

Recognising that it is desirable to represent uncertainty and negation for ‘clinical links’ (‘possibly caused by’, ‘is not a contraindication for’), such advanced expressivity is not supported by the current vocabulary and class. Work continues to explore this topic.