INTERNATIONAL STANDARD

ISO 13606-3

First edition
2009-02-01

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

Reference number
ISO 13606-3:2009(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 13606-3 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

ISO 13606 consists of the following parts, under the general title *Health informatics — Electronic health record communication*:

— *Part 1: Reference model*

— *Part 2: Archetype interchange specification*

— *Part 3: Reference archetypes and term lists*

— *Part 5: Interface specification*

The following part is in preparation:

— *Part 4: Security*

Introduction

0.1 Summary

This part of ISO 13606 contains two kinds of specification:

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

2) an informative set of reference archetypes, expressed as mappings that each specify how the Reference Model in ISO 13606-1 should be used to represent information originating from

   — the set of HL7 Version 3 Acts that form part of the Clinical Statement Pattern (Draft Standard for Trial Use), and

   — the specializations of ENTRY that are defined in the *open*EHR Reference Model.

0.2 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 to be 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 part of ISO 13606.

Should any revision to these term lists prove necessary in the future, a technical revision to this part of ISO 13606 will be required. Such a revised version must specify an updated Reference Model identifier that shall then be used as the value of the rm_id of an EHR_EXTRACT, to inform the recipient of the version of this part of ISO 13606 that was used in its creation.

A cross-mapping of the term list for LINK.role to HL7 actRelationship typecodes is also provided, for the convenience of those wishing to adopt or interface this part of ISO 13606 with HL7 Version 3. This is part of a longer-term vocabulary harmonization project between the health informatics standards development organizations (SDOs), and might therefore be extended in the future via other publications, such as the planned HL7-13606 Implementation Guide (see below). It is therefore informative in this document.

0.3 Reference archetypes

Each reference archetype is represented in this part of ISO 13606 as a mapping correspondence table to indicate the way in which the ITEM structure within an ISO 13606-1 ENTRY is to be used to represent the classes and attributes of relevant HL7 v3 and *open*EHR classes. These two external models have been chosen for inclusion as these are the most likely internationally used source models from which fine-grained clinical data may need to be transformed into this document for communication.

These reference archetypes are included as an aid to those adopting this part of ISO 13606 and wishing to transform Electronic Health Record (EHR) data from existing HL7 v3 or *open*EHR instances or messages. It is recognised that full two-way interoperability between these various representations requires more detail, including rich vocabulary and data type harmonization, and a corresponding set of technical artefacts such as eXtensible Markup Language (XML) Schemata and Extensible Stylesheet Language Transformation (XSLT) scripts. Such interoperability is very much the goal of current SDO harmonization efforts, and will be published as an HL7-13606 Implementation Guide, possibly as an open-access and regularly updated resource. However, the outstanding work required to achieve this level of interoperability might take up to another year after publication of this part of ISO 13606. It has therefore been decided to offer what does exist towards harmonization in an informative form within this part of ISO 13606, as an aid to those already needing to make such data transformations. A worked example of the HL7 v3 to ISO 13606 mapping is given in Annex B.

Health informatics — Electronic health record communication —

Part 3: Reference archetypes and term lists

1 Scope

This part of ISO 13606 is for the communication of part or all of the electronic health record (EHR) of a single identified subject of care between EHR systems, or between EHR systems and a centralized EHR data repository. It may also be used for EHR communication between an EHR system or repository and clinical applications or middleware components (such as decision support components) that need to access or provide EHR data, or as the representation of EHR data within a distributed (federated) record system.

This part of ISO 13606 (EHR Communications Standard Series), defines term lists that each specify the set of values that particular attributes of the Reference Model defined in ISO 13606-1 may take. It also defines informative reference archetypes that correspond to ENTRY-level compound data structures within the Reference Models of *open*EHR and HL7 Version 3, to enable those instances to be represented within a consistent structure when communicated using this part of ISO 13606.

2 Terms and definitions

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

2.1
archetype instance
individual metadata class instance of an Archetype Model, specifying the clinical concept and the value constraints that apply to one class of Record Component instance in an electronic health record extract

2.2
clinical information
information about a person, relevant to his or her health or health care

2.3
committed
information that has been persisted within an electronic health record system and which constitutes part of the electronic health record for a subject of care

2.4
committer
agent (party, device or software) whose direct actions have resulted in data being committed to an electronic health record

2.5
composer
agent (party, device or software) responsible for creating, synthesising or organizing information that is committed to an electronic health record

2.6
electronic health record extract
part or all of the electronic health record for a subject of care, communicated in compliance with the ISO 13606 series of International Standards

2.7
electronic health record system
system for recording, retrieving and manipulating information in electronic health records

2.8
entries
health record data in general (clinical observations, statements, reasoning, intentions, plans or actions) without particular specification of their formal representation, hierarchical organization or of the particular Record Component class(es) that might be used to represent them

2.9
Record Component
part of the electronic health record extract of a single subject of care, represented as a node within a hierarchical data structure conforming to the ISO 13606 series of International Standards

2.10
state (of a process)
condition or situation during the lifecycle of an object during which it satisfies some condition, performs some activity or waits for some event

[ISO/TS 18308:2004, definition 3.39]

2.11
subject of care
patient
person scheduled to receive, receiving, or having received health care

3 Abbreviations

CEN	Comité Européen de Normalisation (European Committee for Standardization)
CEN/TC 251	CEN Technical Committee 251, *Health informatics*
EHR	electronic health record
EU	European Union
HISA	Health Information Systems Architecture
HL7	Health Level Seven
ISO	International Organization for Standardization
UML	Unified Modeling Language
XML	Extensible Mark-up Language

4 Conformance

When electronic health record information is to be communicated using the ISO 13606 series of International Standards 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 5 of this part of ISO 13606 for the correspondingly named term list.

5 Term lists

5.1 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 may take any value that conforms to the data type and invariant specifications defined in ISO 13606-1.

5.2 Term list 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	the subject of care
DS01	relative of subject of care	any human relative, without limitation to biological or adoptive relatives
DS02	foetus or neonate or infant	the baby or babies being described by an ENTRY in the EHR of the mother
DS03	mother	the mother of a foetus or neonate, if being described in the EHR of a baby (e.g. during pregnancy)
DS04	donor	The donor of an organ or body specimen being described by an ENTRY in the EHR of the recipient
DS05	unrelated person	any other person not related to the subject of care, such as an employer, friend, carer

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

5.3 Term list ITEM_CATEGORY, Class ITEM, attribute item_category

Some kinds of ENTRY might have a complex internal data structure, comprising the main values of interest and other kinds of context. This optional attribute in the Reference Model permits the communication of the category of information for each ELEMENT or CLUSTER. This may be of value to a receiving EHR system, to enable easier processing of the data.

Code	Meaning	Description
IC01	Principal or “core” value	The CLUSTERS or ELEMENTS that contain the main values that are the subject of the ENTRY
IC02	Supplementary/complementary details about the value	Contextual information that most users would regard as necessary to interpret the core values
IC03	Patient state/circumstances	Contextual information about the subject of care’s circumstances when an observation is made, e.g. fasting, standing
IC04	Method details	Contextual information about the method of an observation, such as the technique or device used
IC05	Clinical reasoning	Any explanatory information provided by the author to explain a clinical decision or interpretation, other than a specific reference to a protocol or guideline or knowledge source
IC06	Protocol/guideline	A description, reference or explanation of any protocol or guideline that informed the ENTRY (e.g. to perform an observation, or initiate a plan of care)
IC07	Knowledge source	A reference to any external knowledge source, such as a web site or medical text, that explains or amplifies a clinical decision
IC08	Presentation	Any information about how the values in the ENTRY should be presented; image rendering information is one example
IC09	Assertion status	To indicate that the ELEMENT contains a value that indicates the presence/absence, normality/ abnormality of the core values (e.g. if the core value is a questionnaire question, and the ELEMENT contains the yes/no answer)

5.4 Term list VERSION_STATUS, Class AUDIT_INFO, 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 the necessary authorizations 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	Update	The version is an update of the previous version, usually by adding supplementary information that was not available at the time of committal. NOTE 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.
VER03	Correction	The version corrects errors made in the recording of the previous version.
VER04	Deletion	The version logically deletes the previous version (e.g. if the RECORD_COMPONENT had been placed in the wrong patient's EHR).

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

5.5 Term list MODE, Class FUNCTIONAL_ROLE, attribute mode

This attribute is used to describe the physical or electronic means by which an entity has participated in the provision or documentation of health care. This term list is taken from the corresponding code set in EN 14822-2 except that codes have been added for use within an EHR extract.

Code	Meaning	Description	EN14822-2 term
MOD01	electronic data	Participation by non-human-language-based electronic signal.	ELECTRONIC
MOD02	verbal	Participation by voice communication.	VERBAL
MOD03	dictated	Participation by pre-recorded voice. Communication is limited to one direction (from the recorder to recipient).	DICTATED
MOD04	face-to-face	Participation by voice communication where parties speak to each other directly.	FACE
MOD05	telephone	Participation by voice communication where the voices of the communicating parties are transported over an electronic medium.	PHONE
MOD06	videoconferencing	Participation by voice and visual communication where the voices and images of the communicating parties are transported over an electronic medium.	VIDEOCONF
MOD07	written	Participation by human language recorded on a physical material.	WRITTEN
MOD08	e-mail	Participation by text or diagrams transmitted over an electronic mail system.	EMAIL
MOD09	telefax	Participation by text or diagrams printed on paper that have been transmitted over a fax device.	FAX
MOD10	handwritten	Participation by text or diagrams printed on paper or other recording medium.	HANDWRITTEN
MOD11	typewritten	Participation by text or diagrams printed on paper or other recording medium where the recording was performed using a typewriter, typesetter, computer or similar mechanism.	TYPEWRITTEN
MOD12	physical presence	Participation by direct action where subject and actor are in the same location. (The participation involves more than communication.)	PHYSICAL
MOD13	remote presence	Participation by direct action where subject and actor are in separate locations, and the actions of the actor are transmitted by electronic or mechanical means. (The participation involves more than communication.)	REMOTE

NOTE If FUNCTIONAL_ROLE.mode is null, the value MOD04 is assumed.

5.6 Term list ACT_STATUS, Class ENTRY, attribute act_status

This term list is identical to the act status values in EN 12967-3 except that codes have been added for use within an EHR extract.

Code	Meaning	Definition from EN 12967-3
ACT01	Foreseen	The activity to be done has been identified by the requestor, but a formal request or planning has not been issued yet.
ACT02	Requested	A formal request has been sent to the provider supposed to deliver the service(s).
ACT03	Accepted	The providing unit has formally accepted to provide the service.
ACT04	Booked	The actual activities to be executed have been identified and a date, shift and time for execution has been agreed between the involved agents (i.e. requestor, provider and other involved units).
ACT05	Planned	The act has been assigned to one (set of) Service Point, which will be in charge for its execution.
ACT06	Ready	All preliminary activities have been completed and the execution of the act may actually start.
ACT07	In progress	The execution of the act has actually started.
ACT08	Completed	The provider has completed the actual execution of the act.
ACT09	Reported	The provider has delivered the final report on the act.
ACT10	Terminated	The final report has been received and accepted by the original requester.
ACT11	Forwarded	The request of delivering the service has been transferred by the initially envisaged provider to a different provider.
ACT12	Suspended	The processing of the act (in any moment of its life-cycle) has been temporarily interrupted for various reasons.
ACT13	Annulled-Cancelled	The act has been annulled by the requestor (who cancels the request).
ACT14	Annulled-Rejected	The act has been annulled by the envisaged provider (who rejects the request received).
ACT15	Substituted	The act has been substituted with another one.

5.7 Term list LINK_NATURE, Class LINK, attribute nature

The LINK class contains two coded-value attributes to communicate the semantics of the relationship between the source and target RECORD_COMPONENTS. The nature attribute, which is mandatory in ISO 13606-1, is intended to be a coarse-grained category that can be used to enable interoperability between sender and receiver. The role attribute, which is optional in ISO 13606-1, provides for a more specific description of the actual role played by the target in relation to the source. This latter attribute may be populated from any suitable terminology, and therefore might support human readership better than interoperable automated processing. This part of ISO 13606 requires that the nature attribute be a value taken from the mandatory term list defined in this subclause. This part of ISO 13606 offers a term list for the role attribute, in 5.8, but it is not required that this be used.

Code	Meaning	Description
LINK-A0	is related to	A generic category for any link, the details of which will be given by the value of LINK.role.
LINK-B0	is confirmed by or authorized by	The target link contains a COMPOSITION, SECTION or ENTRY that acts as the legal or authoritative basis for the activity documented in the source RECORD_COMPONENT, or is a declaration of intent to provide (or not to provide) requested care. This Link shall be used to connect two RECORD_COMPONENTS, as opposed to the inclusion of a corroborating or authorizing participant as an identified party within a single COMPOSITION or ENTRY.
LINK-C0	is related to the same problem or health issue	The target RECORD_COMPONENT documents health or health care that pertains to the same clinical situation as the source component. One of the two might be defining a problem for which the other is a manifestation, or the relationship might, for example, be cause and effect, stages in an evolving clinical history, a different interpretation of an observation, a clinical indication or contra-indication.
LINK-D0	is related to the same plan of care, act or episode	The source and the target RECORD_COMPONENTs each document parts of the same plan of care, act or episode. One or the other might be defining the same plan of care, act or episode, or both might be related milestones.
LINK-E0	is a related documentation	The target RECORD_COMPONENT is an alternative documentary form of the source component, such as re-expression of the same clinical information or additional supplementary explanatory information.

NOTE A further understanding of each of these categories may be obtained by reviewing the detailed terms proposed for each, as values of LINK.role in 5.8.

5.8 Term list LINK_ROLE, Optional term list for LINK attribute role (informative)

5.8.1 Introduction

Each of the link terms in the list is a sub-category of a corresponding term in the table of 5.7, where that correspondence is indicated by the first letter after the code string “LINK-”, e.g. the term LINK-A1 is a subcategory of term LINK-A0. If a term in the list is used for the LINK.role attribute, the appropriate corresponding LINK.nature attribute value from 5.7 must be used.

5.8.2 Optional term list for LINK attribute role (informative)

Code	Meaning	Description
LINK-A1	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 (tentatively related to)	The interpretation expressed in the target component is a possible cause or outcome of the findings documented in the source component.
LINK-A2i	is 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.
LINK-B1	endorses (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.
LINK-B2	disagrees with (e.g. another opinion)	The interpretation expressed in the source component disproves or disagrees with the interpretation expressed in the target component.
LINK-B3	permits (sanctions, authorises)	The source component documents a permission or an authorisation of an action documented in the target component.
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.
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.
LINK-B6	consents to	The participant identified in the source component is proof of consent to care actions documented in the target component.
LINK-B6i	consented by	The inverse relationship of LINK-B6.
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.
LINK-C1i	caused by	The inverse relationship of LINK-C1.