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Health informatics — Electronic health record communication —

Part 1: Reference model

Informatique de santé — Communication du dossier de santé informatisé —

Partie 1: Modèle de référence

Reference number
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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 13606-1 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*

0 Introduction

0.1 Preface

The overall goal of ISO 13606 is to define a rigorous and stable information architecture for communicating part or all of the Electronic Health Record (EHR) of a single subject of care (patient). This is to support the interoperability of systems and components that need to communicate (access, transfer, add or modify) EHR data via electronic messages or as distributed objects:

— preserving the original clinical meaning intended by the author;

— reflecting the confidentiality of that data as intended by the author and patient.

ISO 13606 is not intended to specify the internal architecture or database design of EHR systems or components. Nor is it intended to prescribe the kinds of clinical application that might require or contribute EHR data in particular settings, domains or specialities. For this reason, the information model proposed here is called the EHR Extract, and might be used to define a message, an XML document or schema, or an object interface. The information model in this part of ISO 13606 is an ISO Reference Model for Open Distributed Processing (RM-ODP) RM-ODP Information Viewpoint of the EHR Extract.

ISO 13606 considers the EHR to be the persistent longitudinal and potentially multi-enterprise or multi-national record of health and care provision relating to a single subject of care (the patient), created and stored in one or more physical systems in order to inform the subject's future healthcare and to provide a medico-legal record of care that has been provided. Whilst an EHR service or system will need to interact with many other services or systems providing terminology, medical knowledge, guidelines, workflow, security, persons registries, billing etc., ISO 13606 has only touched on those areas if some persistent trace of such interactions is required in the EHR itself, and requires specific features in the reference model to allow their communication.

ISO 13606 may offer a practical and useful contribution to the design of EHR systems but will primarily be realised as a common set of external interfaces or messages built on otherwise heterogeneous clinical systems.

This part of ISO 13606 is the first part to be published of a five-part series. In this part of ISO 13606 dependency upon one of the other parts of this series is explicitly stated where it applies.

0.2 Technical approach

ISO 13606 has drawn on the practical experience that has been gained in implementing a European precursor prestandard, ENV 13606, other EHR-related standards and specifications, commercial systems and demonstrator pilots in the communication of whole or part of patients' EHRs, and on fifteen years of research findings in the field. ISO 13606 builds on ENV 13606, in order to provide a more rigorous and complete specification, to accommodate new requirements identified, to incorporate a robust means of applying the generic models to individual clinical domains, and to enable communication using HL7 version 3 messages. A mapping from the European prestandard is also provided to support implementers of systems that conformed to it. The technical approach to producing ISO 13606 has taken into account several contemporary areas of requirement.

a) In addition to a traditional message-based communication between isolated clinical systems, the Electronic Health Record will in some cases be implemented as a middleware component (a record server) using distributed object technology and/or web services.

b) “Customers” of such record services will be not only other electronic health record systems but also other middleware services such as security components, workflow systems, alerting and decision support services and other medical knowledge agents.

c) There is wide international interest in this work, and this part of ISO 13606 has been drafted jointly through CEN and ISO with significant input from many member countries.

d) Mapping to HL7 version 3 has been considered an important goal, to enable conformance to this part of ISO 13606 within an HL7 version 3 environment.

e) The research and development (R & D) inputs on which ENV 13606 was based have moved forward since 1999 and important new contributions to the field have been taken into account. The *open* EHR foundation, integrating threads of R & D in Europe and Australia, is one such example.

Given the diversity of deployed EHR systems, ISO 13606 has made most features of EHR communication optional rather than mandatory. However, some degree of prescription is required to make EHR Extracts safely processable by an EHR recipient system, which is reflected through mandatory properties within the models in Parts 1, 2, and 4, and through normative term lists (defined in Part 3).

ISO 13606 will, in practice, usually be adopted alongside other health informatics standards that define particular aspects of health data representation. Annex B explains how ISO 13606 can be used alongside key complementary standards, including the HL7 Version 3 Reference Information Model (RIM), EN 14822-1, EN 14822-2, EN 14822-3, CEN/TS 14822-4 (GPIC), prEN 12967 (HISA) and prEN13940 (CONTSYS).

0.3 The Dual Model approach

The challenge for EHR interoperability is to devise a generalized approach to representing every conceivable kind of health record data structure *in a consistent way*. This needs to cater for records arising from any profession, speciality or service, whilst recognising that the clinical data sets, value sets, templates, etc. required by different healthcare domains will be diverse, complex and will change frequently as clinical practice and medical knowledge advance. This requirement is part of the widely acknowledged health informatics challenge of *semantic interoperability*.

The approach adopted by ISO 13606 distinguishes a reference model, defined in this part of ISO 13606 and used to represent the generic properties of health record information, and archetypes (conforming to an archetype model, defined in Part 2), which are meta-data used to define patterns for the specific characteristics of the clinical data that represent the requirements of each particular profession, speciality or service.

The Reference Model represents the global characteristics of health record components, how they are aggregated, and the context information required to meet ethical, legal and provenance requirements. This model defines the set of classes that form the generic building blocks of the EHR. It reflects the stable characteristics of an electronic health record, and would be embedded in a distributed (federated) EHR environment as specific messages or interfaces (as specified in Part 5).

This generic information model needs to be complemented by a formal method of communicating and sharing the organizational structure of predefined classes of EHR fragment corresponding to sets of record components made in particular clinical situations. These are effectively precoordinated combinations of named RECORD_COMPONENT hierarchies that are agreed within a community in order to ensure interoperability, data consistency and data quality.

An Archetype is the formal definition of prescribed combinations of the building-block classes defined in the Reference Model for particular clinical domains or organizations. An archetype is a formal expression of a distinct, *domain-level concept*, expressed in the form of constraints on data whose instances conform to the *reference model.* For an EHR_Extract, as defined in this part of ISO 13606, an archetype instance specifies (and effectively constrains) a particular hierarchy of RECORD_COMPONENT sub-classes, defining or constraining their names and other relevant attribute values, optionality and multiplicity at any point in the hierarchy, the data types and value ranges that ELEMENT data values may take, and other constraints.

This part of ISO 13606 recognises that archetypes might be used to support communication between some EHR systems in the future, or might be used as a knowledge specification by some EHR system external interfaces when mapping parts of an EHR to an EHR_EXTRACT, or might not be used at all between some EHR systems. The use of archetypes is therefore supported, but not made mandatory, by this part of ISO 13606. A specification for communicating archetypes is defined by Part 2.

0.4 Requirements basis for this part of ISO 13606

From the early 1990s it was recognised that a generic representation is required for the communication of arbitrary health record information between systems, and in Europe this has resulted in a succession of EU sponsored R & D projects and two generations of CEN health informatics standards prior to this International Standard. These projects and standards have sought to define the generic characteristics of EHR information and to embody these in information models and message models that could provide a standard interface between clinical systems. The vision of such work has been to enable diverse and specialist clinical systems to exchange whole or parts of a person's EHR in a standardized way that can rigorously and generically represent the data values and contextual organization of the information in any originating system. A complementary goal has been to accommodate the evolving nature of medical knowledge and the inherent diversity of clinical practice.

Many investigations of user and enterprise requirements for the EHR have taken place over this period, which have sought to span the information needs of diverse specialties across primary, secondary and tertiary care, between professions and across countries. These requirements have been distilled and analysed by expert groups, mainly within Europe, in order to identify the basic information that needs to be accommodated within an EHR information architecture to:

- capture faithfully the original meaning intended by the author of a record entry or set of entries;
- provide a framework appropriate to the needs of professionals and enterprises to analyse and interpret EHRs on an individual or population basis;

- incorporate the necessary medico-legal constructs to support the safe and relevant communication of EHR entries between professionals working on the same or different sites.

This work includes the GEHR [41, 48, 57], EHCR-SupA [36-38], Synapses [42, 43], I4C and Nora projects and work by the Swedish Institute for Health Services Development (SPRI). These key requirement publications are listed in the Bibliography [51]. These requirements have recently been consolidated on the international stage within an ISO Technical Specification, ISO/TS 18308[9].

In this reference model the key EHR contextual requirements for such faithfulness are related to a set of logical building block classes, with suitable attributes proposed for each level in the EHR extract hierarchy. ISO/TS 18308 has been adopted as the reference set of requirements to underpin the features within this EHR communications reference model, and a mapping of these requirements statements to the constructs in the reference model is given in Annex D.

0.5 Overview of the EHR extract record hierarchy

The information in a health record is inherently hierarchical. Clinical observations, reasoning and intentions can have a simple or a more complex structure. They are generally organized under headings, and contained in "documents" such as consultation notes, letters and reports. These documents are usually filed in folders, and a patient may have more than one folder within a healthcare enterprise (e.g. medical, nursing, obstetric).

The EHR extract reference model needs to reflect this hierarchical structure and organization, meeting published requirements in order to be faithful to the original clinical context and to ensure meaning is preserved when records are communicated between heterogeneous clinical systems. To do this, the model formally sub-divides the EHR hierarchy into parts that have been found to provide a consistent mapping to the ways which individual EHRs are organized within heterogeneous EHR systems.

These parts are summarised in Table 1.

Table 1 — Main hierarchy components of the EHR Extract Reference Model

EHR hierarchy component	Description	Examples
EHR_EXTRACT	The top-level container of part or all of the EHR of a single subject of care, for communication between an EHR provider system and an EHR recipient.	Not applicable
FOLDER	The high level organization within an EHR, dividing it into compartments relating to care provided for a single condition, by a clinical team or institution, or over a fixed time period such as an episode of care.	Diabetes care, schizophrenia, cholecystectomy, paediatrics, St Mungo's Hospital, GP folder, Episodes 2000-2001, Italy
COMPOSITION	The set of information committed to one EHR by one agent, as a result of a single clinical encounter or record documentation session.	Progress note, laboratory test result form, radiology report, referral letter, clinic visit, clinic letter, discharge summary, functional health assessment, diabetes review
SECTION	EHR data within a COMPOSITION that belongs under one clinical heading, usually reflecting the flow of information gathering during a clinical encounter, or structured for the benefit of future human readership.	Reason for encounter, past history, family history, allergy information, subjective symptoms, objective findings, analysis, plan, treatment, diet, posture, abdominal examination, retinal examination
ENTRY	The information recorded in an EHR as a result of one clinical action, one observation, one clinical interpretation, or an intention. This is also known as a clinical statement.	A symptom, an observation, one test result, a prescribed drug, an allergy reaction, a diagnosis, a differential diagnosis, a differential white cell count, blood pressure measurement
CLUSTER	The means of organizing nested multi-part data structures such as time series, and to represent the columns of a table.	Audiogram results, electro-encephalogram interpretation, weighted differential diagnoses
ELEMENT	The leaf node of the EHR hierarchy, containing a single data value.	Systolic blood pressure, heart rate, drug name, symptom, body weight

An EHR_EXTRACT contains EHR data as COMPOSITIONs, optionally organized by a FOLDER hierarchy.

COMPOSITIONs contain ENTRYs, optionally contained within a SECTION hierarchy.

ENTRYs contain ELEMENTS, optionally contained within a CLUSTER hierarchy.

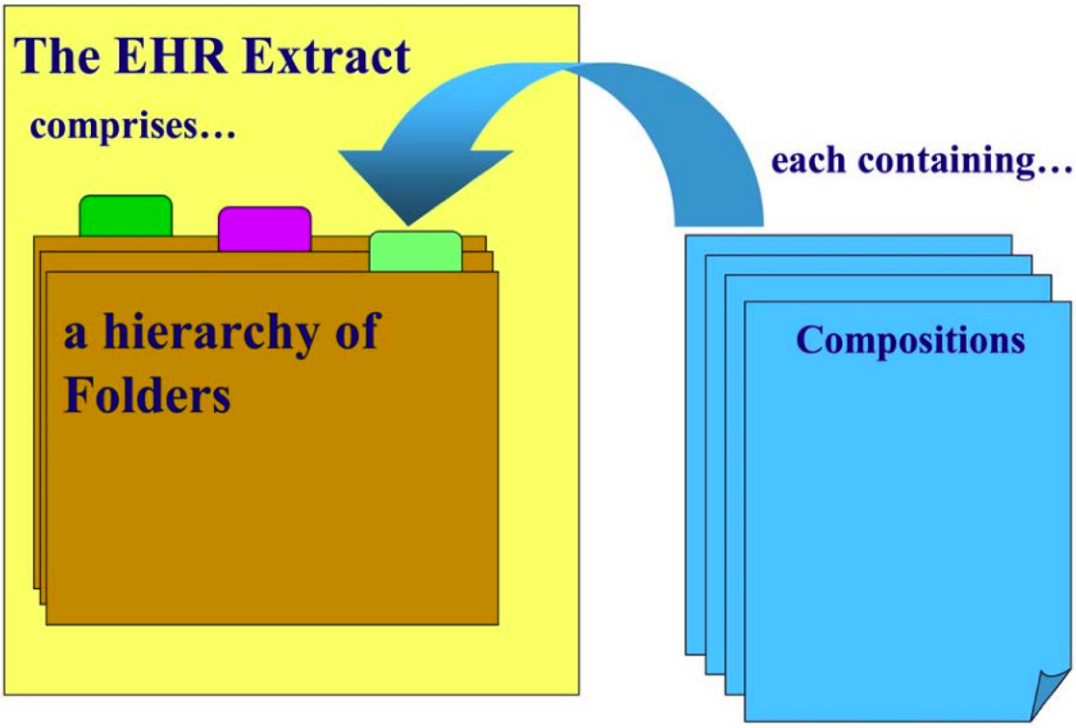

Figure 1 — Diagram of the EHR Extract hierarchy (Part 1)

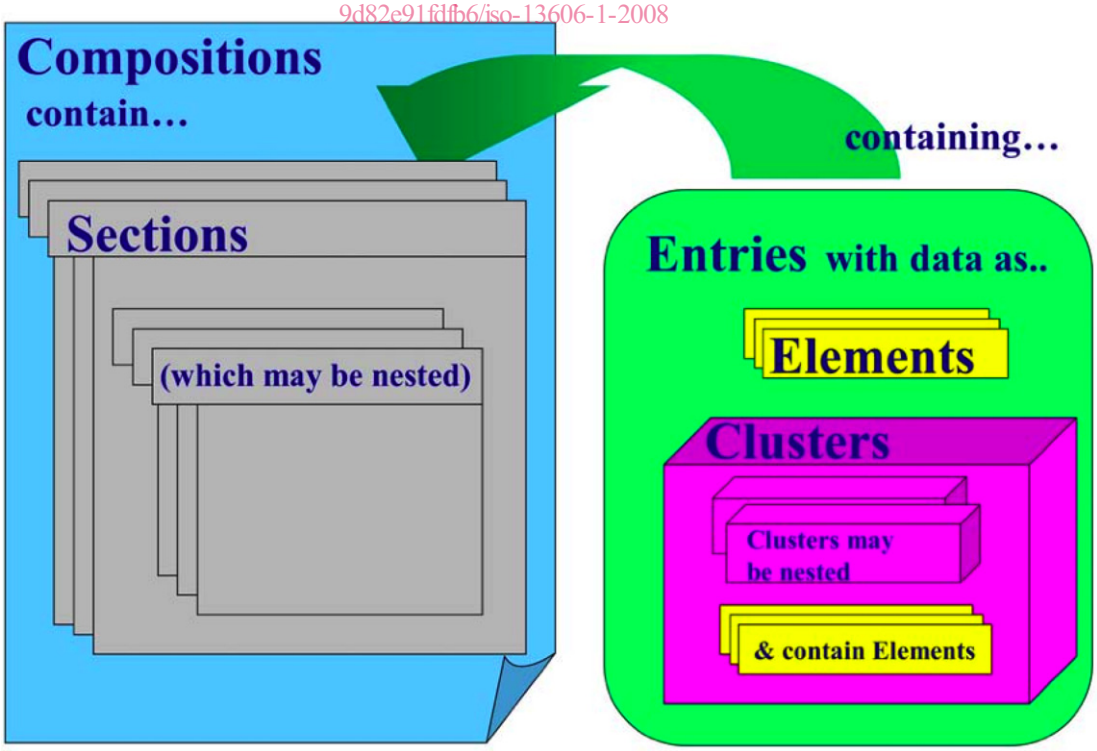

Figure 2 — Diagram of the EHR Extract hierarchy (Part 2)

0.6 Description of the main Reference Model classes

EHR_EXTRACT

The EHR_EXTRACT is used to represent part or all of the health record information extracted from an EHR provider system for the purposes of communication to an EHR recipient (which might be another EHR system, a clinical data repository, a client application or a middleware service such as an electronic guideline component) and supporting the faithful inclusion of the communicated data in the receiving system.

The EHR_EXTRACT class contains attributes to identify the subject of care whose record this is, the EHR Provider system from which it has been derived and the identifier of that subject's EHR in that system, and optionally the agent responsible for creating it.

The EHR_EXTRACT contains the EHR data, in three parts:

1) a set of COMPOSITIONs;

2) optionally, a directory of FOLDERs that provide a high-level grouping and organizing of the COMPOSITIONs;

3) optionally, a set of demographic descriptors for each of the persons, organizations, devices or software components that are identified within (1) and (2) above. This approach allows such entities to be referenced uniquely via an identifier within the body of the EHR, without repetition of the descriptive details each time, and also ensures that any EHR_EXTRACT can be interpreted in isolation if the recipient system does not have access to the services needed to decode the entity identifiers used by the EHR Provider.

A formal mechanism is defined in Part 4 of ISO 13606 for including access policy information within the EHR_EXTRACT. This is intended to inform the EHR recipient about the wishes of the subject of care and of healthcare providers for how future access requests for the data should be managed.

The EHR_EXTRACT also contains a summary of the filter or selection criteria by which this EHR_EXTRACT was created. This may or may not correspond directly to the criteria in the EHR request, and provides a record of the kind of subset this EHR_EXTRACT is of the overall EHR held by the EHR provider. This might be of importance if the EHR_EXTRACT is retained intact by the EHR provider or EHR recipient, and subsequently accessed by agents who do not have access to the original EHR request. For example, this class can specify if this EHR_EXTRACT is limited to the most recent version of each COMPOSITION (as required for most clinical care purposes) or if it includes all historic versions (which might be required for legal purposes). It might specify the maximum level of sensitivity of the data (implying that data that is more sensitive than this level may exist and have been filtered out), or that multi-media objects have been excluded to limit its total size. If the EHR_EXTRACT was created by selecting particular categories of clinical data (e.g., only laboratory data) then this may be indicated through a list of the archetypes that were included in the selection criteria. An option exists to include additional criteria (expressed as strings); this may be used to provide additional human readable information about this EHR_EXTRACT or may be used for locally-agreed computer-interpretable constraint information.

RECORD_COMPONENT

The main building block classes that are used to construct the EHR data hierarchy within an EHR_EXTRACT are kinds of RECORD_COMPONENT. This is an abstract class, the super-class of all of the concrete nodes in the EHR hierarchy: FOLDER, COMPOSITION, SECTION, ENTRY, CLUSTER, ELEMENT, and also the super-class for two other abstract class nodes: CONTENT and ITEM.

RECORD_COMPONENT defines the information properties that are common to all of these building blocks, including:

— the unique identifier that was issued to this EHR node by the EHR system in which it was first committed (its originating EHR system); other holders of this RECORD_COMPONENT need to retain this attribute value to ensure that any subsequent extracts are always consistently identified;

- the clinical name, used in its originating EHR system to label this part of the EHR data;
- optionally, a standardized coded concept to which the name has been mapped to support the semantic interoperability of equivalent EHR instances even if these have been given different clinical names by different EHR systems;
- the identifier of the archetype node to which this RECORD_COMPONENT conforms, to be used by archetype enabled-EHR systems or if archetypes have been used when mapping the data into the EHR_EXTRACT format;
- a sensitivity code and references to access control policies that should be used by the EHR recipient to govern future access to the data;
- support for links between any record components.

When generating an EHR_EXTRACT conformant to this part of ISO 13606 the EHR provider system might, in some situations, need to introduce a RECORD_COMPONENT into the hierarchy that does not have a direct correspondence with any original data in the EHR system. The synthesised attribute of RECORD_COMPONENT permits the exporting EHR provider system to indicate that a RECORD_COMPONENT has been created within the EHR_EXTRACT for this purpose.

Health record entries often refer to other pre-existing entries, and include them as “copies”. A common example of this is a discharge summary, which might include copies of several parts of an inpatient stay record such as the admission circumstances, the main diagnoses, principal interventions and treatments. In most cases the EHR_EXTRACT needs to contain these referenced RECORD_COMPONENTS explicitly by value, so that each COMPOSITION can be interpreted by the EHR Recipient. However, it is also important, medico-legally, to communicate that these entries are copies, and that they originate from a different part of that subject’s EHR. The optional attribute original_parent_ref may be used to represent the rc_id of the original parent RECORD_COMPONENT if the data are a copy.

Any RECORD_COMPONENT may include audit data about when and by whom it was committed in its originating EHR system. Each revised version of a RECORD_COMPONENT may document the version status, the reason for the revision and the identifier of the preceding version. However, for data protection reasons it is usually advised that previous (erroneous) versions of an EHR are not communicated as part of normal clinical shared care, but only in circumstances where an EHR transfer is being made for legal reasons.

It is important that each RECORD_COMPONENT be uniquely and consistently identified across multiple EHR_EXTRACTS, so that references to or between them remain valid. Examples of such references are semantic links, revision and attestation. The rc_id attribute is of data type *Instance Identifier (II)*, which incorporates an ISO OID; II is currently considered internationally to be the most appropriate data type for persistent identifiers that are required to be globally unique. It is unlikely that contemporary EHR systems will have existing primary keys or internal identifiers that correspond directly to globally-unique II instances. However, an EHR provider system that has been issued with an organizational OID might use its internal references to construct unique *local extensions* to that OID and thereby construct globally-unique rc_id values. Alternatively, it might create completely new rc_ids and retain a record of the mapping of these to each internal identifier, so that any future EHR_EXTRACTS it generates will use consistent rc_id values. It is also unlikely that an EHR recipient system will be able to use received rc_id values as its internal primary keys for the data, since every database uses a slightly different approach to generating and using such keys. The EHR recipient might therefore also need to keep a record of the mapping of imported rc_id values to its primary keys, so that future references to those RECORD_COMPONENTS can be appropriately matched, and it can create EHR_EXTRACTs that reapply those rc_id values to the exported data. An alternative approach is for EHR systems to explicitly store the rc_id values along with the clinical data, and treat this as part of the “payload” data and not attempt to use these also as primary keys. It should also be noted that the rc_id does not function as a primary key equivalent within an EHR_EXTRACT i.e. duplicate values of rc_id are permitted if each instance does indeed refer to the same piece of clinical data within the EHR provider system.

FOLDER

This class is used to represent the highest-level organizations of EHR data within the EHR_EXTRACT, e.g., to group COMPOSITIONs by episode, care team, clinical speciality, clinical condition or time interval. Internationally, this kind of organizing structure is used variably: in some enterprises and systems the folder concept is treated as an informal compartmentalization of the overall health record; in others it might represent a significant legal portion of the EHR relating to the services provided by an enterprise or team.

In the EHR_EXTRACT, FOLDERs are an optional hierarchy. FOLDERs may contain other FOLDERs to form a complete directory system, and may include any pertinent information about their committal or revision within the EHR Provider system. FOLDERs reference COMPOSITIONs via a list of unique identifiers, rather than by physically containing them. This permits any COMPOSITION to appear within more than one FOLDER, which is a requirement that some vendors and jurisdictions have indicated.

In some situations FOLDERs might be created specifically to organize the EHR_EXTRACT, or contain only a selected subset of the data in the corresponding folder in the EHR provider system. In such circumstances the FOLDERs within the EHR_EXTRACT will not have a direct correspondence with those in the contributing EHR provider system, i.e. they will have been synthesised.

A FOLDER may be used to group a set of COMPOSITIONS comprising the individual records made of members of a multi-professional team during a single clinical encounter. In situations like this where a FOLDER represents a finite interval of care, it may be attested. This approach should be used to communicate that the FOLDER's contents are a complete record of that interval of care. This also provides an indication to the EHR recipient that additional COMPOSITIONS ought not to be added to this FOLDER.

Since folder systems are used variably within EHR systems, this International Standard cannot prescribe how they should be handled within the EHR recipient's system: i.e. it does not require that the EHR recipient explicitly use these within its EHR system. However, if a FOLDER has been attested, an intact copy of this information shall be retained for future reference and possible onward communication.

COMPOSITION

The COMPOSITION represents the set of RECORD_COMPONENTS composed (authored) during one user's clinical session or record documentation session, for committal within one EHR. Common examples of this include a consultation note, a progress note, a report or a letter, an investigation report, a prescription form and a set of bedside nursing observations. The COMPOSITION documents the date and time or interval of the clinical encounter, and the legal jurisdiction in which the records were composed.

The composer is the agent (party, device or software) responsible for creating, synthesising or organizing information that is committed to an EHR. This agent takes responsibility for its inclusion in that EHR, even if not the originator of it and even if not the committer of it. The content of the COMPOSITION is primarily attributed to this person. Whether or not the composer is changed when a revision is made is optional. Applications will generally use the composer's name to label COMPOSITION data when used for clinical care. There may be occasions when there is no single main composer (e.g. a multi-professional tele-consultation, or a case conference); in such cases the composer role might not be formally specified even though each participant and clinical role is declared. The composer is therefore optional.

Provision is made for a COMPOSITION to include the details and locations of any other participants involved in the clinical encounter or record documentation session. Some of these might have participated from different locations (for example on the telephone, or via a video-consultation).

The COMPOSITION is the main container class for EHR data within the extract itself, to ensure that a consistent containment hierarchy is used within all Extracts: the EHR_EXTRACT contains a set of COMPOSITIONs together with audit data about the committal of each within the EHR Provider's system. A COMPOSITION is always used to communicate version updates between EHR systems, even if the actual updates refer to parts of that COMPOSITION. If multiple versions of EHR data are to be communicated within one EHR_EXTRACT, this will be as a set of distinct COMPOSITIONs, each referencing the preceding version and collectively referencing a version set identifier.

Each COMPOSITION also optionally documents any attestations (e.g. digital signatures) that pertain to it or to any of its contents.

Contribution The Contribution is the set of COMPOSITIONs committed by one user at one point in time in the EHR of one subject of care. Some clinical applications include complex screens capable of presenting multiple parts of an EHR simultaneously (for example through tabbed panes). On saving the screen, a user might actually be committing data to more than one part of the patient's EHR (e.g. the addition of a new consultation note and the revision of a medication entry stored elsewhere in the EHR). The Contribution refers to all of the changes and updates committed to that EHR during that committer's session. All of the COMPOSITIONs comprising one Contribution can be collectively identified by providing a common value for the contribution_id attribute.

SECTION

The record entries relating to a single clinical session are usually grouped under headings that represent phases or sub-topics within the clinical encounter, or assist with layout and navigation. Clinical headings usually reflect the clinical workflow during a care session, and might also reflect the main author's reasoning processes. Much research has demonstrated that headings are used differently by different professional groups and specialties, and that headings are not used consistently enough to support safe automatic processing of the EHR. They are therefore treated in this part of ISO 13606 as an optional (informal) containment for human navigation, filtering and readability.

SECTIONs may be used to represent the containment hierarchy of clinical headings used within the EHR provider system to group and organize entries within a COMPOSITION. Each SECTION may contain additional SECTIONs and/or ENTRYs.

ENTRY

The ENTRY is the container class for the ITEM data structure that represents the information acquired and recorded for a single observation or observation-set (battery or time series), a single clinical statement such as a portion of the patient's history or an inference or assertion, or a single action that might be intended or has actually been performed. The ENTRY class associates this ITEM structure with a set of context attributes to facilitate safe interpretation:

— information in an ENTRY may be about someone other than the patient (e.g. a relative): ENTRY defines the subject of the information;

— information in an ENTRY may have been provided by or is attributed to a particular individual: ENTRY defines the information provider;

— other participants might need to be associated with a particular ENTRY;

— the ENTRY may represent the evolving status of a clinical act (e.g. requested, performed, reported, cancelled) and may optionally carry an identifier that links it with a workflow system;

— the ENTRY may use a flag to advise the EHR recipient that the data structure includes some indication of uncertain findings or opinions, and that care needs to be taken when using the data for automated processing.

The ENTRY contains a data structure represented using CLUSTERS and ELEMENTS. It is important to note that ENTRY cannot contain further ENTRYs. The set of contexts defined at the ENTRY level (e.g. the subject of information) apply to the whole data structure and cannot be overridden.

ITEM, CLUSTER and ELEMENT

The ITEM may represent both the actual data describing the observation, inference, or action, and optionally the details describing the examination method, the patient's physical state or details supporting the clinical reasoning process such as a reference to an electronic guideline, decision support system or other knowledge reference. The item_category attribute provides an optional means of distinguishing these different parts of a

data structure, as an aid to the automated analysis or filtering of the ITEMS in an ENTRY. The codeset for this attribute is defined in ISO 13606-3.

Information in an ITEM (CLUSTER or ELEMENT) might have originated at a date/time different from the care activity or its recording. The obs_time attribute permits representation of a single date or time or an interval, to any level of granularity. This would permit, for example, an operation to be dated only by the year, the onset of a symptom to a month and year, a period of employment to be a precise date range or an interval in years, the precise time-stamping of an arrhythmia, or an angiogram to be organized as a time series of images.

Information in an ITEM might be emphasised by the author as being exceptional or noteworthy. This part of ISO 13606 does not define a code set for this attribute; any agreed terminology may be used to specify the degree of emphasis or to specify the kind of exception.

The CLUSTER supports the representation of complex data structures needed to represent the actual data values within a multi-part (nested) observation, clinical statement or instruction. These may need to be represented as a table, a tree or a time series. Specific examples include an ECG tracing, a full blood count, ankle reflex examination, the prescription of an intravenous drug infusion.

The ELEMENT class represents the leaf node within the EHR hierarchy. Each instance of this class will have a single data value. (A ratio, an interval or a co-ordinated term are considered here to be examples of single data values). Examples of ELEMENT might include reason for encounter, body weight, pulse. An ELEMENT may have a null data value, for example if a value is not known.

Data values

Each ELEMENT contains one data value, to represent the actual instance values. This is one of the CEN Data Types (CEN/TS 14796) for:

— text and coded terms;

— quantities including ratios, intervals and durations;

— dates and time;

— graphical and other MIME type (e.g. image, signal).

It is recognised that, at the time of producing this part of ISO 13606, a new set of health informatic data types is being developed by ISO/TC 215. Once this is published, CEN is expected to deprecate CEN/TS 14796 in favour of this new standard. In doing so, it will need to provide a mapping correspondence to the new data type standard, and this mapping will also need to be used in order to adopt the new data types alongside this part of ISO 13606.

In order to support the adoption of this part of ISO 13606 more widely internationally than the jurisdiction of CEN/TS 14967, the set of attribute data types actually used within this reference model (other than the data value of ELEMENT) are explicitly included in this part of ISO 13606 in a support package. These should also be deprecated in favour of ISO data types once published.

NOTE Primitive data types such as Boolean, Integer are assumed to follow ISO/IEC 11404 and are not further defined here.

0.7 Description of the other principal classes of the reference model

AUDIT_INFO

It is a medico-legal requirement to document and to communicate when and by whom EHR data were entered into an EHR system. It is also important to track changes to EHR data if modifications are made, and to communicate this within an EHR_EXTRACT. The AUDIT_INFO class is used to represent these audit data:

a) for any RECORD_COMPONENT, as a permanent record of its commitment in its originating EHR system;

b) for any COMPOSITION, as a record of its commitment within the EHR provider system that has generated this EHR_EXTRACT.

A COMPOSITION might therefore have up to two audit data sets, one relating to its originating EHR system (called “feeder_audit”) and one to its subsequent commitment within the EHR provider’s system (called “committal”), if these are different. This part of ISO 13606 does not, however, require or support the communication of an indefinite accumulation of audit data sets for every system into which a COMPOSITION is committed. This is because a cumulative set of audit data sets without the actual clinical data to show the details of what was changed each time is not considered to be of clinical value. If a full change history is required to be communicated, each version of the COMPOSITION needs to be included in the EHR_EXTRACT.

For committal, the AUDIT_INFO class represents the timestamp of committal, it identifies the committer, and the EHR system into which the data were committed. The timestamp reflects when this RECORD_COMPONENT was persisted with in an EHR system and therefore became part of the EHR of the subject of care. The committer is responsible for including this RECORD_COMPONENT within the EHR, but might not be responsible for deciding upon the clinical content being committed.

The committer and time committed attributes are optional, to allow for the possibility that some data will have been imported from simple legacy systems in which the clinical data originated but for which these values are not known. However, for the committal AUDIT_INFO association these attributes are required to have non-null values, since they represent the time and party responsible for authorizing the clinical data to be included within an EHR system conforming to this part of ISO 13606.

For revision, the AUDIT_INFO class represents the version status, an optional reason for revision, the identity of the immediately previous version that was the basis of this revision, and an identifier that is common to all versions so that non-sequential versions made on different EHR systems can still be related to each other. An optional version status attribute indicates if the present version was, at the time of its committal, a draft (i.e. intended to be replaced in the near future), an update to a previous draft version, a correction of an erroneous former version, or an empty COMPOSITION or ENTRY that is the logical deletion of its predecessor (e.g. if the predecessor was saved in the wrong EHR). If no status is given, it is assumed that this is the definitive (first) version.

EHR systems vary in the granularity of EHR data at which committal and revision are permitted, and it is quite likely that all of the RECORD_COMPONENTs within a part of an EHR hierarchy (e.g. within one COMPOSITION) will share the same audit data. The standard therefore only requires the representation of this information if it is different from that of the parent RECORD_COMPONENT.

FUNCTIONAL_ROLE

This class is used to represent the details of who and where an individual agent has contributed to the healthcare or health record of a subject of care. This class identifies:

— the function that was performed in the situation being documented;

— the identity of the agent performing the function;

— the mode in which participation was made (e.g. in person, by telephone);