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

CEN/TC 251/N04-012
2004-03-09

CEN/TC 251
Health Informatics
Secretariat: SIS

TITLE/ SUBJECT:	**EHRCOM prEN 13606-1 - 2nd working draft**
SOURCE:	***Task Force EHRCOM***
ACTION REQUIRED:	***For information***

CEN/TC 251 Secretariat: SIS - Swedish Standards Institute

Mail address:	SE-118 80 Stockholm	*TC Secretary:*	Mats Söderlund
	Sweden	*Visiting and Courier mail:*	S:t Paulsgatan 6
Fax:	+46(0)8 555 520 04	*e-mail:*	mats.soderlund@sis.se
Tel:	+46(0)8 555 520 54	*Web site:*	www.centc251.org

CEN /TC 251

Date: 2004-02

prEN 13606-1.2

CEN /TC 251

Secretariat: SIS

Health informatics — Electronic health record communication — Part 1: Reference model

ICS:

Descriptors:

Document type: European Standard
Document subtype:
Document stage: Working Document
Document language: E

C:\David\Projects\EHRCOM\2ndWD-prEN13606-1_(E)-0.9DLDKDL.doc STD Version 2.0

Contents

Page

Foreword

This document prEN 13606-1 has been prepared by Technical Committee CEN/TC 251 “Health Informatics”, the secretariat of which is held by SIS.

The original 1995 CEN European pre-standard: ENV 12265 Electronic Healthcare Record Architecture was a foundation standard defining the basic principles upon which electronic healthcare records should be based. A successor pre-standard ENV 13606 Electronic Healthcare Record Communication was published in 1999 as a four-part standard:

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

This new standard has five parts:

Part 1: Reference Model: a generic information model for communicating the electronic health record of any one patient, as a refinement of ENV13606 Part 1.

Part 2: Archetype Interchange Specification: a generic information model and language for representing and communicating the definition of individual instances of Archetypes.

Part 3: Reference Archetypes and Term Lists: a range of Archetypes reflecting a diversity of clinical requirements and settings, as a "starter set" for adopters and to illustrate how other clinical domains might similarly be represented (for example by health professional groups), plus relevant enumerated lists (normative or informative) in support of the other parts of this standard. This will draw on ENV13606 Part 2.

Part 4: Security Features: the information model concepts that need to be reflected within individual EHR instances to enable suitable interaction with the security components that are anticipated to be required in any future EHR deployment. This will draw on ENV13606 Part 3.

Part 5: Exchange Models: a set of models that build on the above parts and can form the basis of message-based or service based communication, fulfilling the same role as ENV13606 Part 4.

This document is the Second Working Document of Part 1.

It is recognised that the complete interpretation of this part standard is difficult without sight of the other parts, which are still being prepared. However, it has been considered appropriate to provide early sight of each part as it becomes available, in order to obtain those feedback comments that can be made on this part alone.

Introduction

[Text in red font will be removed from the final draft; it is included to assist readers in understanding the process and approach of the Task Force, or drafting notes]

The EHRcom Task Force

The EHRcom Task Force was set up to review and revise the 1999 four-part pre-standard ENV 13606 relating to Electronic Healthcare Record Communications, and to produce a formal standard (EN).

The overall goal of this standard is to define a rigorous and durable information architecture for representing the EHR, in order to support the interoperability of systems and components that need to interact with EHR services:

- as discrete systems or as middleware components;
- to access, transfer, add or modify health record entries;
- via electronic messages or distributed objects;
- preserving the original clinical meaning intended by the author;
- reflecting the confidentiality of that data as intended by the author and patient.

In tackling this challenge, the goal has been to specify the information architecture required for interoperable communications between systems and services that might request or provide EHR data. This standard is not intended to specify the internal architecture or database design of such systems. Nor is it intended to prescribe the kinds of clinical applications that might request 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.

Since the announcement of the Task Force some parties have expressed wish for this revision not to present a radically new information architecture for the EHR, but that it should build on the existing ENV. Other views have been expressed that some aspects of ENV 13606 were not easy to implement, were ambiguous, or considered unnecessarily complex. It is certainly the case that hardly any independent implementations of ENV13606 are mutually interoperable – rather defeating the purpose of standardisation.

This standard 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 health care 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. this standard 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. The general principle of the Task Force has been to rely upon the existence of such services and not arbitrarily to extend its scope to subsume these other significant areas of health informatics.

The Task Force has had to balance the need for improvements and advances in the field to be taken into account with the need for changes to the existing ENV to be justified and of benefit for future interoperability. This standard 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. It has also to be recognised that the majority of deployed clinical systems will not be complete EHR systems for some years, and that the current levels of health ICT spending in most Member States is low in comparison with other industry sectors, offering only a modest opportunity for radical systems redesign.

The scope of the revision

This revision has drawn on the practical experience that has been gained in implementing ENV13606 and other EHR-related standards and specifications through commercial systems and demonstrator pilots in the communication of whole or part of patients' EHRs, and on contemporary research findings in the field. This standard builds on ENV 13606, updating it in order to make it more rigorous and complete, to accommodate new requirements identified, to interoperate with new specifications such as HL7 version 3, and to incorporate a robust means of applying the generic models to individual clinical domains. A mapping from the existing pre-standard is also provided to support implementers of existing conformant systems.

The scope of the revision takes into account several new 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 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 CEN work, and valuable experience from beyond Europe has contributed to the revision.

d. Harmonisation with HL7 has been considered an important goal, to facilitate interoperability between these sets of standards.

e. The 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 openEHR Foundation, integrating threads of R&D in Europe and Australia, is one such example.

A combination of good working relationships between representatives from CEN, openEHR and HL7 has led to efforts to harmonise this standard with HL7 (the RIM, the Clinical Document Architecture and Templates) and with openEHR (reference model and archetype approach). The three groups are developing cross-mappings to enable the exchange of EHR data between implementations of each approach. Part 5 of this part standard includes an HL7 Domain Message Information Model (D-MIM) corresponding to this EN 13606 Reference Model. [NOTE: In view of this new D-MIM work the CDA mapping table provided in the first Working Draft of this part standard has been removed].

Other relevant contemporary work in CEN includes the definition of standard data types that can be adopted by other future CEN standards as an aid to their interoperability. These data types are being harmonised with those specified in the HL7 v3 RIM, by adapting a sub-set of these HL7 data types and refining them by incorporating features from other healthcare domain models such as the EHR specification of openEHR. This standard utilises the CEN data types standard TS 14796 for the representation of Data Values and attribute values.

CEN standard ENV 13940 defines a set of concepts for health care parties, threads of care and mandates (responsibilities) that are needed to ensure the complete documentation of continuing shared care. These concepts need to be represented consistently and communicated between clinical information systems to support safe and high-quality care. That standard is presently being updated, and forthcoming drafts of this standard may indicate some minor adaptations to the draft part-standard presented in this document to facilitate interoperability between these standards.

Another important European interface to HL7 is the definition of General Purpose Information Components (GPICs), which are re-usable information model fragments (such as a demographic or address component), which are derived from the HL7 v3 RIM. These models will be used within future CEN standards to ensure a

consistency between standards on certain basic classes of information and also ensure that cross-mapping such standards to future HL7 v 3 messages will be easier. This standard utilises the CEN GPICs standard TS 14822 for the representation demographic entities. Other clinical and non-clinical GPICs may be represented through *archetypes* (see below).

The Dual Model approach

The challenge addressed by the dual-model approach to the design of the EHR communications information architecture has been to devise a scalable model for representing any conceivable health record information. 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 health care domains will be diverse, complex and will change frequently as clinical practice and medical knowledge advance. The dual model approach distinguishes a Reference Model, used to represent the generic properties of health record information, and Archetypes (conforming to an Archetype Model), which are meta-data used to represent the specific characteristics of the various kinds of clinical data that might need to be represented to meet the requirements of each particular profession, speciality or service.

The Reference Model is presented as an ODP Information Viewpoint Model, representing the global characteristics of health record entries, how they are aggregated, and the context information required to meet ethical, legal and provenance requirements. This model corresponds conceptually to the EHCR architecture of GEHR , the Synapses SynOM , the information model of ENV 13606-1 and the openEHR Reference Model. 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 (e.g. federated) EHR environment as specific messages or interfaces.

Such a generic information model for the EHR needs to be complemented in the knowledge domain by a formal method of communicating and sharing the named hierarchical structures within EHRs, the data types and value ranges that actual record entries may take, and other constraints, in order to ensure interoperability, data consistency and data quality.

Archetypes each define (and effectively constrain) legal combinations of the building-block classes defined in the Reference Model for particular clinical domains, organisations, and operational contexts by specifying particular record component names, data-types and prescribed value ranges, and values. Archetype instances themselves conform to an archetype description language (ADL) (and hence an equivalent formal model, known as an Archetype Model), which is formally related to the Reference Model. Although the ADL and Archetype Model are stable, individual archetype instances can be revised or succeeded by others as clinical practice evolves. Version control ensures that new revisions do not invalidate data created with previous revisions. The ADL is the syntactic equivalent of the Synapses Object Dictionary, and the archetype models (AMs) of the Good Electronic Health Record project and openEHR. A sharable ADL formalism is being developed for use with openEHR, HL7 and CEN. Archetypes expressed in this language will also be convertible to HL7 RMIMs and CMETs.

Archetype Repositories. In each enterprise or region there is a diversity of health information stored on paper and in legacy feeder systems. These may give rise to a wide range of possible archetypes that could be required within a shared EHR community. The potential sources for such archetype definitions will include:

a. the clinical data schemata (models) of existing feeder systems;

b. the lay-out of computer screen forms used by these systems for data entry and for the display of analyses performed;

c. data entry templates, pop-up lists and look-up tables used by these systems;

d. shared care data sets, messages and reports used locally and nationally;

e. the structure of templates and guidelines used for the documentation of clinical consultations or summaries within paper records.

However, in order to realise the full benefits of a local or national federation of EHR repositories, enterprises ideally should progressively agree on common definitions that they could use to exchange clinical information. By conforming to a common Reference Model and Archetype Description Language the individual libraries of archetype definitions held in each repository (however implemented) can be exchanged (e.g. via XML) in order to facilitate this progressive convergence across sites or regions.

In the longer term, it is anticipated that the involvement of national health services, academic organisations and professional bodies in the development of such definitions will enable this approach to contribute to the pursuit of quality evidence-based clinical practice. In the future regional or national public domain libraries of archetype definitions might be accessed via the Internet, and downloaded for local use within EHR systems and local or regional federations.

The archetype approach, including the specification of an interchange format, forms the basis of Part 2 of this standard.

1 Scope

This work item consists of the revision of the four part standard ENV 13606 to a full European standard (EN).

This standard specifies the information architecture required for interoperable communications between systems and services that might request or provide EHR data. This standard is not intended to specify the internal architecture or database design of such systems.

The subject of the record or record extract to be communicated is an individual person, and the scope of the communication is predominantly with respect to that person's care.

Uses of healthcare records for other purposes such as administration, management, research and epidemiology, which require aggregations of individual people's records, are not the focus of this standard but such secondary uses could also find the standard useful.

2 Normative References

This document incorporates by dated or undated references, provisions from other publications. These normative references are cited in the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments and revisions of any of these publications apply to this European standard only when they are incorporated in it by amendment and revision. For undated references the latest edition of the publication referred to, applies.

CEN/ENV 13606: 1999 Health Informatics – Electronic Healthcare Record Communication

CEN/TS 14822: 2003 Health Informatics – General Purpose Information Components (Parts 1-3)

CEN/TS 14796: 2004 Health Informatics - CEN Data Types

ISO/TS 18308: 2002 Requirements for an Electronic Health Record Reference Architecture

Informative references are included in a bibliography in Annex 6.

3 Terms and Definitions

For the purposes of this European standard, the following definitions apply.

Abstract class

In UML, a “virtual” common parent to two or more classes; the abstract class will never be instantiated. Its value in modelling terms is to provide a container for attributes and associations that might apply to several other classes (its sub-classes).

Access control

A means of ensuring that the resources of a data processing system can be accessed only by authorized entities in authorized ways. [ISO/IEC 2382-8, 1998]

Accountability

The property that ensures that the actions of an entity may be traced uniquely to that entity. [ISO/IEC 2382-8, 1998]

Archetype

An individual metadata class instance of an Archetype Model, specifying the clinical concept and the value constraints that apply to one class of Record Component instances in an EHR extract.

Archetype Model

The information model of the metadata to represent the domain-specific characteristics of EHR entries, by specifying values or value constraints for classes and attributes in the EHR Reference Model

Archetype Repository

Persistent repository of archetype definitions, accessed by a client authoring tool or by a run-time component within an EHR service

Attester

A party (person) who certifies and records legal responsibility for a particular unit of information.

Attestation

The process of certifying and recording legal responsibility for a particular unit of information

Audit trail

A chronological record of activities of information system users which enables prior states of the information to be faithfully reconstructed.

Authentication

The act of verifying the claimed identity of an entity. [ISO/IEC 2382-8, 1998]

Authorisation

The granting of rights, which includes the granting of access based on access rights. [ISO/IEC 2382-8, 1998]

Client application

Any healthcare application which is behaving at that moment as a requester of health record data from a shareable EHR

Clinical information

Information about a person, relevant to his or her health or health care

CLUSTER

This concrete sub-class of RECORD_COMPONENT in the EN 13606 Reference Model is used to aggregate sets of ELEMENTS within an ENTRY in order to permit the representation of complex data structures, such as tables, lists of lists and interval time series.

Committed

Information that has been persisted within an EHR system and which constitutes part of the EHR of a subject of care.

Committer

Agent (party, device or software) that whose direct actions have resulted in data being committed to an EHR.

Composer

Agent (party, device or software) responsible for creating, synthesising or organising 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.

COMPOSITION

This concrete sub-class of RECORD_COMPONENT in the EN 13606 Reference Model contains the set of RECORD_COMPONENTS composed (authored) during one user's clinical session or record interaction, for committal within one EHR.

Concept

Unit of thought constituted through abstraction on the basis of properties common to a set of objects [ISO 1087]

Confidentiality

The property of data that indicates the extent to which these data have not been made available or disclosed to unauthorized individuals, processes, or other entities. [ISO/IEC 2382-8, 1998]

Contribution

The set of RECORD_COMPONENTS committed by one user at one point in time in the EHR of one subject of care.

Digital signature

Data appended to, or a cryptographic transformation of, a data unit that allows a recipient of the data unit to prove the source and integrity of the unit and protect against forgery e.g. by the recipient. [ISO 7498-2]

Distributed processing

Information processing in which discrete components may be located in different places, or where communication between components may suffer delay or may fail.

EHR extract

The unit of communication of the EHR from an EHR provider to an EHR recipient.

EHR_EXTRACT

This is the root class of the EN 13606 Reference Model, representing the health record information extracted from an EHR provider system for the purposes of communication to an EHR recipient process.

EHR information architecture

ODP Information Viewpoint specification of an electronic health record.

EHR provider

The EHR system providing the EHR extract which is to be represented and communicated using this standard.

EHR provider

The EHR system providing the EHR extract which is to be represented and communicated using this standard.

EHR recipient

The computational process to which an EHR extract is communicated. This might not always be the same process as the EHR requestor.

EHR requestor

The computational process specifying and communicating a request for an EHR extract to an EHR provider.

EHR system

System for recording, retrieving and manipulating information in electronic health records

ELEMENT

This concrete sub-class of RECORD_COMPONENT in the EN 13606 Reference Model represents the leaf node in the EHR_EXTRACT hierarchy and contains one DATA_VALUE.

entries

This term is used within this standard to refer to health record data in general (clinical observations, statements, reasoning, intentions, plans etc) without particular specification of their formal representation, hierarchical organisation or of the particular Record Component class(es) that might be used to represent them.

ENTRY

This concrete sub-class of RECORD_COMPONENT in the EN 13606 Reference Model contains the data structure needed to represent a single observation or observation-set, a clinical statement or a healthcare act specification. The ENTRY class associates this data structure with a set of context attributes to facilitate safe interpretation.

Federated Health Record

The virtual view of a patient’s health record data that would be obtained from the global set of EHR entries about that patient.

Feeder system

A repository (for health record data) that may be queried within a federation of such systems in order to contribute to a Federated Health Record.

FOLDER

This concrete sub-class of RECORD_COMPONENT in the EN 13606 Reference Model is used to represent the highest-level organisations of the EHR_EXTRACT e.g. to group parts of the record by episode, care team,

clinical speciality or clinical condition.

Generic

This term has been used when describing requirements or information models that are applicable across healthcare professions, domains and countries

Healthcare agent

Health care person, organisation, device or software component that performs a role in a health care activity

Healthcare device

Device or equipment involved in the direct or indirect provision of health care services to an individual or to a population

Healthcare organization

Organisation involved in the direct or indirect provision of health care services to an individual or to a population; groupings or subdivisions of an organisation, such as departments, may also be considered as organisations where there is a need to identify them

Healthcare party

Organisation or person involved in the direct or indirect provision of health care services to an individual or to a population

Healthcare service

Service provided with the intention of directly or indirectly improving the health of the person or populations to whom it is provided

Legacy data

Data that were collected and maintained using a “previous” system, but are now preserved on a “current” system

Metadata

“Data about data”, a schema to define a data set or to provide knowledge about the contents of a data set

Non-repudiation

The capacity for any actor to obtain proof that confirms the integrity and origin of a data item and cannot be forged. [Revise to use ISO/TS 17090-1]

Patient

An individual person that is a subject of care.

Persistent data

Data which are stored on a permanent basis

Privacy

Freedom from intrusion into the private life or affairs of an individual when that intrusion results from undue or illegal gathering and use of data about that individual. [ISO/IEC 2382-8, 1998]

RECORD_COMPONENT

This abstract class is the super-class of all of the concrete nodes in the EN 13606 Reference Model EHR_EXTRACT hierarchy: FOLDER, COMPOSITION, SECTION, ENTRY, CLUSTER, ELEMENT, and for

two abstract class nodes: CONTENT and ITEM.

Role

The name of a set of behaviours that is associated with a task. [ISO/TS 17090, 2001, modified]

SECTION

This concrete sub-class of RECORD_COMPONENT in the EN 13606 Reference Model is used to represent a containment hierarchy of clinical headings that group and organise entries within a COMPOSITION.

Semantic interoperability

The ability for data shared by systems to be understood at the level of formally defined domain concepts.

Shareable EHR

An EHR with a standardised information model which is independent of EHR systems and accessible by multiple authorised users [ISO draft Technical Report: Electronic Health Record Definition, Scope, and Context, August 2003]

Standard

A standard is a document, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. (ISO 1992)

Standardised specification

A specification that is intended to be used consistently as if it were a standard

State (of a process)

A condition or situation during the life of an object during which it satisfies some condition, performs some activity, or waits for some event.

Subject of care

Person scheduled to receive, receiving, or having received health care

View

Alternate presentation of data for a different user or purpose.

4 Abbreviations

CEN

Comité Européen de Normalisation, responsible for European legislative standards

CEN TC/251

CEN Technical Committee 251 (develops standards within health informatics)

EHCR

Electronic Healthcare Record

EHR

Electronic Health Record

EU
European Union

GP
General Practitioner

HISA
Healthcare Information Systems Architecture

HL7
Health Level Seven

ISO
International Standardization Organization

ODP
ISO Open Distributed Processing specification, used for describing distributed systems

R&D
Research and development

UML
Unified Modelling Language

XML
Extensible Mark-up Language

5 Requirements

From the early 1990's it was recognised that a suitable 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 one. 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 standardised way that can rigorously and generically represent the data values and contextual organisation 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 extensive 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 must 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, EHCR-SupA, Synapses, I4C and Nora projects and work by SPRI. These key requirements publications are listed in the bibliography in Annex 6. These requirements have recently been consolidated on the international stage within an ISO Technical Specification, ISO TS 18308.

ISO TS 18308 has been adopted as the reference set of requirements to underpin the features within this EHR communications Reference Model.

A mapping of these requirements statements to the constructs proposed here is given in Annex 5 of this document.

6 Reference Model

This section defines the information model for representing the EHR extract. Readers unfamiliar with this model are first recommended to read Annex B, which provides an explanation of the main classes representing the EHR hierarchy and of some specific issues.

The information model comprises a set of classes and attributes: the Reference Model. It is presented as a set of diagrams drawn using the Unified Modelling Language (UML) together with formal documentation which explains each construct, and defines any associated cardinalities, data types, invariants and constraints, and any relevant term sets. Readers unfamiliar with UML are recommended first to read Annex A, which provides a brief outline of these modelling conventions.

The Reference Model is divided, for convenience, into several class packages.

- The Extract package, which defines the EHR_EXTRACT root class and the EHR data that it contains.
- The Demographics package, which provides a minimal data set to define the various persons, software agents, devices and organisations that are referenced within the EHR_EXTRACT.
- The Access Control package; which defines the representation for access policies (such as consents for disclosure) that pertain to and are to be communicated within the EHR_EXTRACT.
- The Message package; this class is a placeholder for the attributes that will be required to communicate the EHR_EXTRACT to a requesting process via a message or other serialised form.

The diagrams follow the conventions prescribed by UML. This includes the use of *UML qualifiers* to specify the associations between classes using pointers (i.e. reference attributes) instead of aggregations. Abstract classes are shown with italicised class names.

Background colours have been used for classes to aid readability. The EHR_EXTRACT is the root of the EHR extract, and is shown with a green background. RECORD_COMPONENT and all of its sub-classes are shown with a purple background. All other classes are shown with a cream background. The colours carry no formal modelling significance.

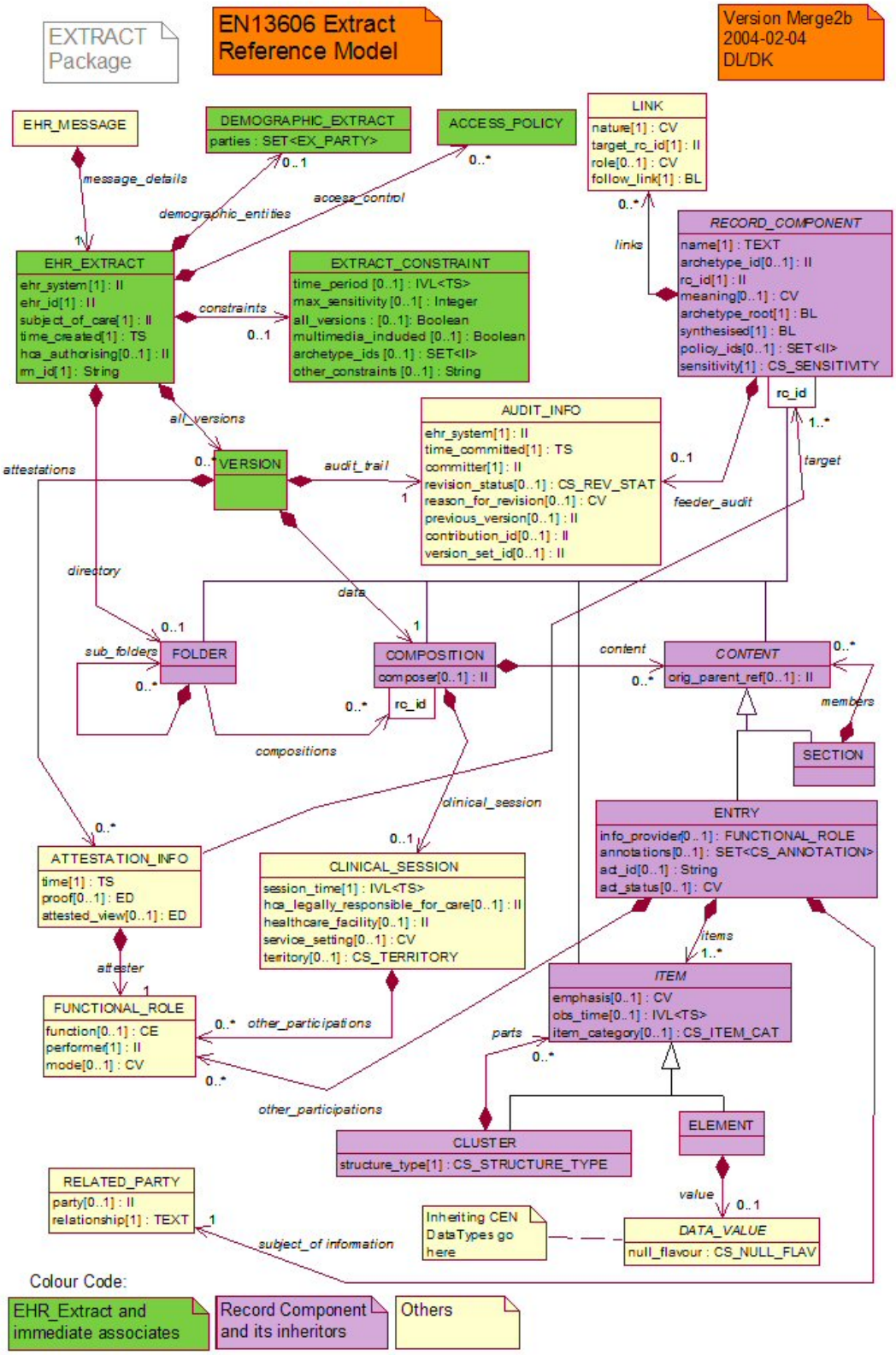
To avoid redundant repetition within the documentation, inherited attributes are not repeated within each inheriting class. This applies to the attributes of RECORD_COMPONENT, CONTENT and ITEM. The reader should, therefore, read the textual descriptions of the model in conjunction with the diagrams.

The table of contents below is included to facilitate navigation to the classes and attributes within each package. The order of the classes corresponds to the principal diagram of the EHR_EXTRACT in Section 0, reading from left to right, top to bottom of the diagram.

Several attributes in this model require controlled vocabularies. Each such attribute has been assigned a data type name of the type CS_XXX where XXX is the name of the attribute. These controlled vocabularies are (to be) defined in Part 3 of this standard. It is assumed that they will be represented as sub-types of the CS data type as defined in TS 14796.

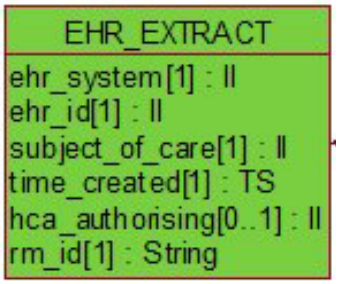
6.1 Class, Attribute, and Association Documentation table of contents

6.2 EHR_Extract model diagram



6.3 Package: Extract

6.4 Class: EHR_EXTRACT



This class represents the root node of an Extract of part or all of the health record information taken from a providing system for the purposes of communication to a receiving process (which might be another repository, a client application or a middleware service such as an electronic guideline engine), and supporting the faithful inclusion of the communicated data in the receiving system.

In all cases where the EHR (from which these data are extracted) makes reference to services outside the EHR itself, the values used from these services are included in the extract. This is to ensure that the extract is self-contained and thus comprehensible by the receiver of the extract even though the receiving system might not have access to all of the same external services.

6.4.1 attribute: ehr_system[1]: II

The identity of the EHR provider system from which this Extract is being taken.

6.4.2 attribute: ehr_id[1]: II

The identity of the EHR from which this extract is taken. It must be unique for that EHR system for a single subject_of_care.

6.4.3 attribute: subject_of_care[1]: II

Unique identifier of the subject of care from whose EHR this extract is taken.

6.4.4 attribute: time_created[1]: TS

Date/Time of creation of this Extract

6.4.5 attribute: hca_authorising[0..1]: II

Health care agent authorising the extract to be created and sent. This attribute is optional since some extracts might be created automatically between (authorised) interacting computing services.

6.4.6 attribute: rm_id[1]: String

The identity and version of the reference model under which this EHR_EXTRACT was made. e.g. EN 13606:rev1.0

6.4.7 association: directory

from: EXTRACT Package::EHR_EXTRACT to: EXTRACT Package::FOLDER [0..1] By Value

The FOLDER hierarchy contained within the EHR_EXTRACT; each of these FOLDERs will contain a set of rc_ids that reference COMPOSITIONs

6.4.8 association: all_versions

from: EXTRACT Package::EHR_EXTRACT to: EXTRACT Package::VERSION [0..*] By Value

All Composition versions included in this extract are included by value (via the VERSION class) through this attribute.

6.4.9 association: demographic_entities

from: EXTRACT Package::EHR_EXTRACT to: EXTRACT Package::DEMOGRAPHIC_EXTRACT [0..1] By Value

Included with the Extract will be sufficient identifying information, derived from a demographics service, to allow confirmation of subject_of_care matching at the receiver to be performed as well as identification of all health care actors mentioned in the extract.

6.4.10 association: constraints

from: EXTRACT Package::EHR_EXTRACT to: EXTRACT Package::EXTRACT_CONSTRAINT [0..1] By Value

Each EHR_EXTRACT may include a summary of the selection criteria that were used to extract the information, if this is not the whole EHR for that subject_of_care held by the EHR provider. It acts partially as a surrogate for carrying the details of the request in satisfaction of which this Extract was created.

6.4.11 association: access_control

from: EXTRACT Package::EHR_EXTRACT to: ACCESS Package::ACCESS_POLICY [0..*] By Value

This association enables the EHR_EXTRACT to include the set of access control policies that pertain to individual RECORD_COMPONENTS or to the EHR_EXTRACT as a whole, and which are intended to be incorporated into the access control framework of the EHR recipient. (The information model for policies will be defined in Part 4 of this standard.)

6.4.11.1 Invariant:

ehr_node != null

ehr_id != null

subject_of_care is a member of the set demographic_entities.parties.eid

subject_of_care !=null

time_created != null

hca_authorising is a member of the set demographic_entities.parties.eid

included_multimedia != null

rm_id != null

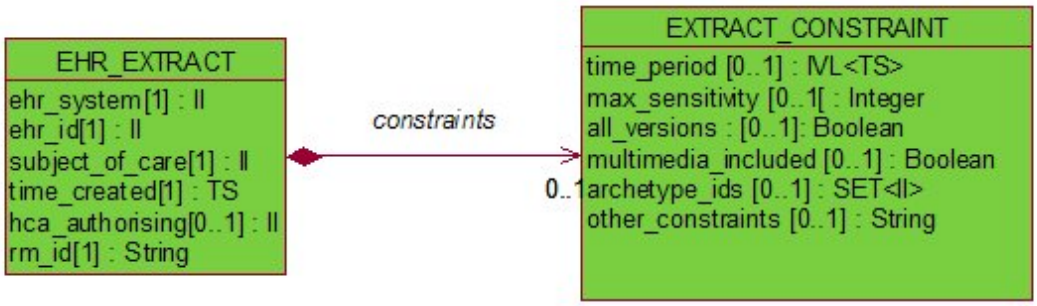
6.5 Class: DEMOGRAPHIC_EXTRACT

The association to this Class enables the EHR_EXTRACT to include the set of demographic entities that are referenced from within the main EHR hierarchy. 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 identifiers used by the Extract provider.

6.5.1 attribute: parties: SET<EX_PARTY>

Each unique party identified within any class in the EXTRACT package will have a corresponding instance of the class EX_PARTY within the extract whose eid attribute will have the same instance identifier value. Other attributes of EX_PARTY, through its associations, will provide other descriptive information about each party, as defined in the Demographics Package. The parties attribute thus brings together the identification of all parties occurring in the EHR_Extract.

6.6 Class: EXTRACT_CONSTRAINT



The attributes of this class list the constraints or restrictions that were placed on the process that created this EHR_EXTRACT. This information will enable the EHR recipient (who might not be the EHR requestor) to be aware of the way in which this EHR_EXTRACT might include a subset of the whole EHR held by the EHR provider.

6.6.1 attribute: time_period [0..1]: IVL<TS>

This attribute specifies a date or time interval to which this EHR_EXTRACT is limited

6.6.2 attribute: max_sensitivity [0..1[:Integer

This attribute specifies the maximum permitted sensitivity level (extent of authorisation) that was used to extract the data from the EHR provider system.

6.6.3 attribute: all_versions: [0..1]: Boolean

This attribute indicates 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).

6.6.4 attribute: multimedia_included [0..1]: Boolean

This attribute indicates if multimedia data have deliberately been excluded from this EHR_EXTRACT (for example, to limit its size).

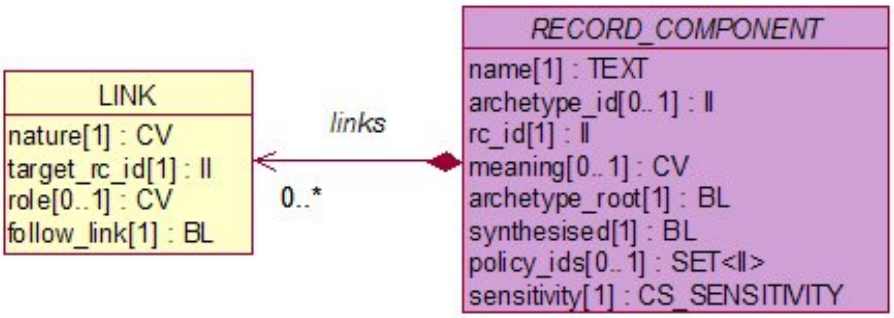
6.6.5 attribute: archetype_ids [0..1]: SET<II>

This attribute specifies a set of archetypes that were selected for inclusion in this EHR_EXTRACT.

6.6.6 attribute: other_constraints [0..1]: String

This attribute is a placeholder for additional criteria that might be specified locally.

6.7 Class: RECORD_COMPONENT

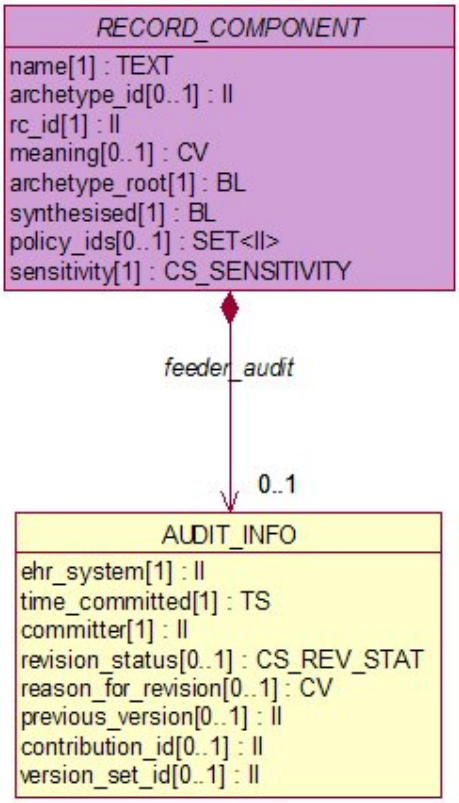


This abstract class is the super-class of all of the concrete nodes in the EHR hierarchy: FOLDER, COMPOSITION, SECTION, ENTRY, CLUSTER, ELEMENT, and for two abstract class nodes: CONTENT and ITEM.

RECORD_COMPONENT has a set of attributes that could apply to any node in the hierarchy, including:

- component identification
- component name used in the underlying EHR provider system
- archetype ID and (standardised) archetype name
- sensitivity code and references to access control policies

Since some clinical systems may permit committal and revision at various levels of the record hierarchy, from FOLDER down to ELEMENT, a set of AUDIT_INFO attributes is associated with this class to permit the faithful representation of these fine-grained committal/revision meta-data. Attestations pertaining only to the data contained by a specific level in the record hierarchy may reference that node using the ATTESTATION_INFO.target association.



6.7.1 attribute: name[1]: TEXT

All instances of RECORD_COMPONENT have a name, expressed as a coded value or as plain text. This will be the name by which the component is labelled in the EHR system from which this Extract is derived.

6.7.2 attribute: archetype_id[0..1]: II

This attribute contains the identity of the creating archetype. The identity of the archetype is globally unique. If additionally this node is the root node of an archetyped structure, then archetype_root must also be true.

6.7.3 attribute: rc_id[1]: II

The identity of the instance of a RECORD_COMPONENT. This identifier must be that which is uniquely and consistently applied to this RECORD_COMPONENT by the originating EHR provider at which this RECORD_COMPONENT was originally created (as identified by the EHR_system attribute). Other holders of this RECORD_COMPONENT must retain this attribute value to ensure that any subsequent extracts are always consistently identified. The use of this attribute and its value makes no assumptions about local identifiers that might be used within EHR systems for repository management and indexing.

6.7.4 attribute: meaning[0..1]: CV

In contrast to the name attribute, this attribute value will be a standardised concept to which the name attribute has been mapped. In archetyped systems it will correspond to the archetype name. This attribute will better support the systematic processing of data that has originated from diverse EHR systems.

6.7.5 attribute: archetype_root[1]: BL

Indicates whether this component is a root-node of an Archetyped structure.

6.7.6 attribute: synthesised[1]: BL

When generating an EHR_EXTRACT conformant to this standard 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.

6.7.7 attribute: policy_ids[0..1]: SET<II>

This attribute identifies one or more access control policies that specifically pertain to this RECORD_COMPONENT and which need to be communicated to the EHR recipient to govern future access to this data. The policies are themselves defined within the ACCESS_POLICY package.

6.7.8 attribute: sensitivity[1]: CS_SENSITIVITY

This attribute provides a simple mechanism to indicate the sensitivity of the RECORD_COMPONENT. The code set for this attribute will be defined in Part 4 of this standard.

6.7.9 association: links

from: EXTRACT Package::RECORD_COMPONENT to: EXTRACT Package::LINK [0..*] By Value

Any RECORD_COMPONENT may have zero or more links to another RECORD_COMPONENT.

6.7.10 association: feeder_audit

from: EXTRACT Package::RECORD_COMPONENT to: EXTRACT Package::AUDIT_INFO [0..1] By Value

This association represents any committal and revision information specifically related to this RECORD_COMPONENT within the EHR provider's system.

6.7.10.1 Invariant:

name != null

ac_id != null

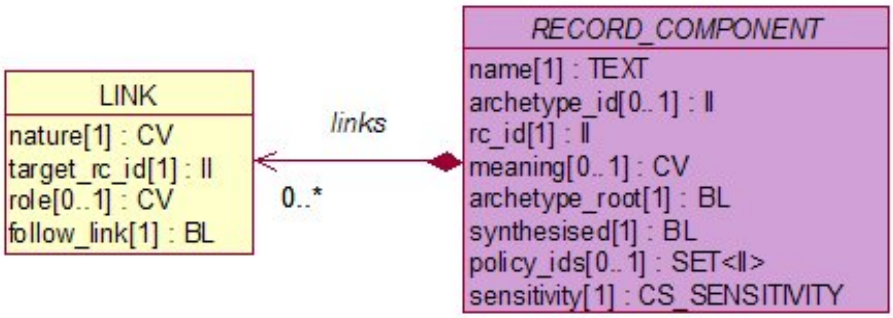
sensitivity != null

meaning != null

is_archetype_root implies archetype_id !=null

synthesised != null

6.8 Class: LINK



Links one RECORD_COMPONENT to another. Links may be required between any two RECORD_COMPONENTs

- e.g. to indicate cause and effect
- e.g. to track the evolution of orders from request to completion

These might need to form linkage networks

- e.g. for clinical problems
- e.g. for clinical or service episodes

6.8.1 attribute: nature[1]: CV

The general category of the link that is being declared between two components, e.g. cause and effect, problem, request/result. This code set is (to be) defined in Part 3 of this standard, and is based on the table of link categories defined in ENV13606-2.

6.8.2 attribute: target_rc_id[1]: II

The identity of the record component to which the link is made.

6.8.3 attribute: role[0..1]: CV

This attribute describes the role fulfilled by the target of the link. For example, cause, test result, problem. In a problem link the role might be a symptom, a diagnostic test, the actual diagnosis, a treatment, a complication etc. It has yet to be decided if this code set will be defined in this standard or left to terminologies to populate.

6.8.4 attribute: follow_link[1]: BL

Indicates whether the Target of the Link must (in the opinion of the originator) be included in the extract. Part 5 of this standard will require the target RECORD_COMPONENT of a Link to be included in the EHR_EXTRACT if the source RECORD_COMPONENT has been included, and vice versa.

Note that if this is False, this does not prevent the Link being 'followed' if the requester requires it.

6.8.4.1 Invariant:

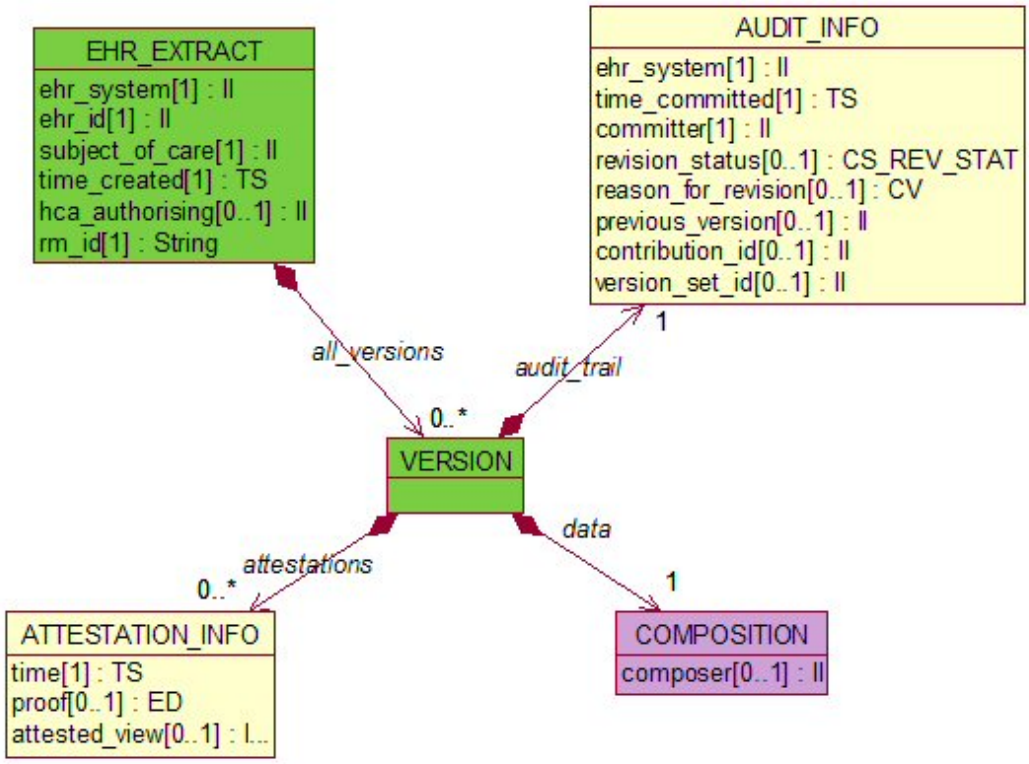
nature != null

target_rc_id != null

role != null

follow_link != null

6.9 Class: VERSION



This class associates a given version of a COMPOSITION with its committal audit information (describing creation or modifications) and with any attestations of it. The EHR_EXTRACT contains a set of VERSION instances, which in turn contain the actual EHR data and the medico-legal metadata.

6.9.1 association: audit_trail

from: EXTRACT Package::VERSION to: EXTRACT Package::AUDIT_INFO [1] By Value

This association represents the committal and revision meta-data for each version of a COMPOSITION.

6.9.2 association: data

from: EXTRACT Package::VERSION to: EXTRACT Package::COMPOSITION [1] By Value

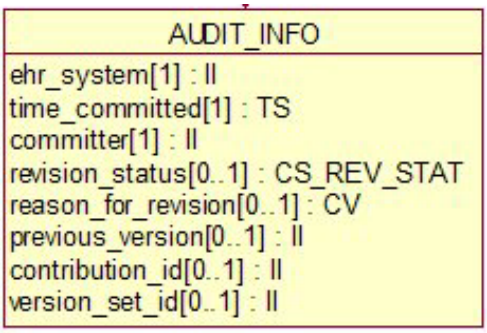
The EHR data of any version are contained in a Composition.

6.9.3 association: attestations

from: EXTRACT Package::VERSION to: EXTRACT Package::ATTESTATION_INFO [0..*] By Value

Any VERSION may be associated with zero or more attestations. Attestation(s) are added without causing new formal revisions of the RECORD_COMPONENT.

6.10 Class: AUDIT_INFO



This class, which subsumes the function of the ENV13606 Revision Information class, is used to represent the committal and revision meta-data about any RECORD_COMPONENT, through the feeder_audit association. This association can be made at any point in the EHR hierarchy, to cater for possible diversity in the granularity at which such meta-data is held within EHR provider systems.

An additional association to this class from VERSION represents the committal and revision information specifically for COMPOSITIONs to provide a means of managing version control within the EHR_EXTRACT.

Notes

The COMPOSITION class represents the committal wrapper class in the EHR_EXTRACT to ensure that a consistent containment hierarchy is used within all Extracts. A COMPOSITION is always used to communicate version updates, and additional attestations, between EHR systems, even if the actual updates or attestations refer to parts of that COMPOSITION.

However, since some clinical systems may permit committal and revision at the level of individual fine-grained entries and observations (or at a higher level, for FOLDERs), the same set of AUDIT_INFO attributes is also associated with RECORD_COMPONENT, to permit the faithful representation of these finer-grained committal/revision meta-data.

Attestations might also reference only parts of a COMPOSITION, for which a particular clinician is responsible. This is supported by the ATTESTATION_INFO.target_rc-id attribute. However, for consistency, all attestations relating to parts or all of a COMPOSITION are associated with the instance of VERSION containing that COMPOSITION.

6.10.1 attribute: ehr_system[1]: II

This is the EHR system to which this RECORD_COMPONENT was originally committed.

6.10.2 attribute: time_committed[1]: TS

Date time at which this RECORD_COMPONENT was persisted within an EHR system and therefore became part of the EHR of the subject of care.

6.10.3 attribute: committer[1]: II

The party responsible for including this RECORD_COMPONENT within the patient's EHR. He/she will usually but might not always have been responsible for the data entry, and might or might not have the authority to attest the information.

6.10.4 attribute: revision_status[0..1]: CS_REV_STAT

This optional attribute is primarily to categorise why a component has been created or revised. It will not be used for first versions of EHR data that have been extracted from their original EHR system. The values of this attribute are (to be) defined in Part 3 of this standard. Example values might include: Import, Update, Correction, Deletion. Import implies that these data were previously acquired from another feeder or EHR system. Deletion implies these data have been logically, not physically, removed from the EHR.

6.10.5 attribute: reason_for_revision[0..1]: CV

A code for the reason for the revision e.g. "to correct a data error".

6.10.6 attribute: previous_version[0..1]: II

This attribute uniquely identifies the RECORD_COMPONENT of which the current RECORD_COMPONENT is a revision (null for the first ever version).

6.10.7 attribute: contribution_id[0..1]: II

The Contribution is the set of RECORD_COMPONENTS 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 an update to a repeat medication list stored elsewhere in the EHR). The Contribution refers to all of the changes and updates committed to that EHR during that committer's session.

6.10.8 attribute: version_set_id[0..1]: II

This attribute value is held in common across all versions of a RECORD_COMPONENT. This will permit the recipient of a multiply-revised RECORD_COMPONENT within an EHR_EXTRACT to match a late version with a much earlier version already stored in the EHR recipient system, particularly if the recipient does not have access to all of the intermediate versions.

6.10.8.1 Invariant:

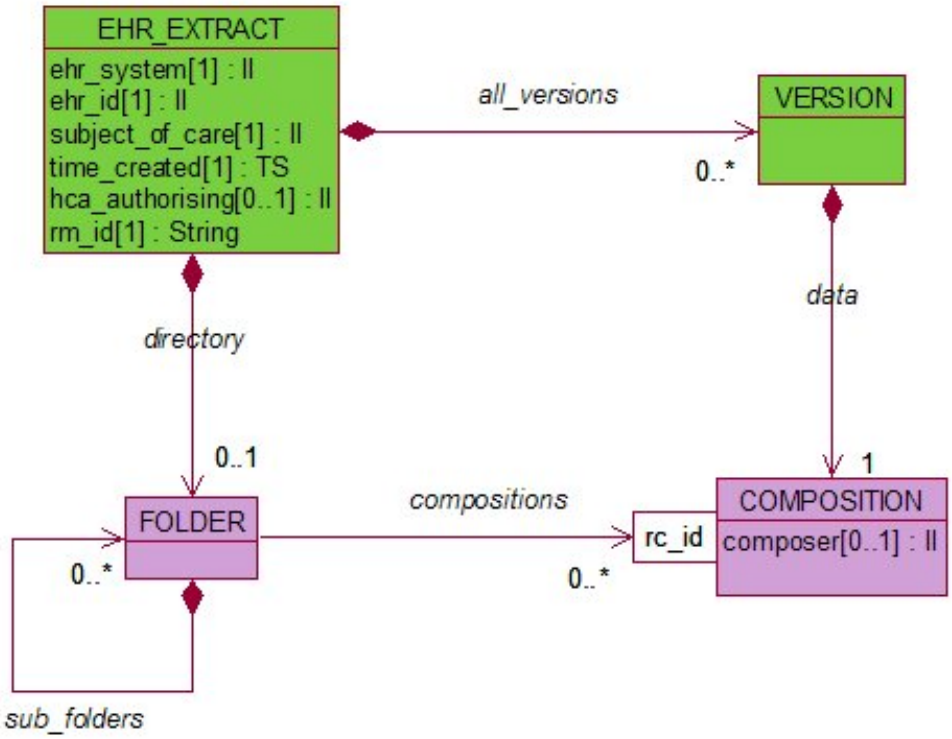
ehr_node != null

time_committed != null

committer != null

committer is a member of the set demographic_entities.parties.eid

6.11 Class: FOLDER



This class is used to represent the high-level organisation of the EHR_EXTRACT e.g. to group parts of the record in any way required, e.g. by episode, care team, clinical speciality or clinical condition. Internationally, this kind of organising structure is used variably: in some centres and systems the Folder is treated as an informal compartmentalisation of the overall health record; in others it might represent a significant legal portion of the EHR relating to the originating enterprise or team. The FOLDER is a means of providing organisation of COMPOSITIONs (and optionally other FOLDERs)

Folders may contain:

- FOLDERs;

- COMPOSITIONs.

Different FOLDERs may also reference the same COMPOSITION.

The anticipated use of the FOLDER class is varied, and the evolution of Folders and their contents over time might be managed differently in different EHR systems. It is most likely that an EHR_EXTRACT will reflect the latest version and contents of the Folder hierarchy within an EHR, or may include Folders that have been expressly created for the EHR_EXTRACT.

FOLDER may optionally be associated with committal, attestation and revision information derived from the underlying contributing system(s). The set of AUDIT_INFO attributes is associated with this class (inherited from RECORD_COMPONENT) to permit the faithful representation of committal/revision meta-data.

Attestations pertaining to the data contained at this level in the hierarchy may reference this component using the ATTESTATION_INFO.target association.

This therefore permits the medico-legal tracking of the evolution of FOLDERs and their contents in those situations where particular EHRs or FOLDERs need this, perhaps for legal purposes.

FOLDER inherits attributes and associations from RECORD_COMPONENT.

6.11.1 association: sub_folders

from: EXTRACT Package::FOLDER to: EXTRACT Package::FOLDER [0..*] By Value

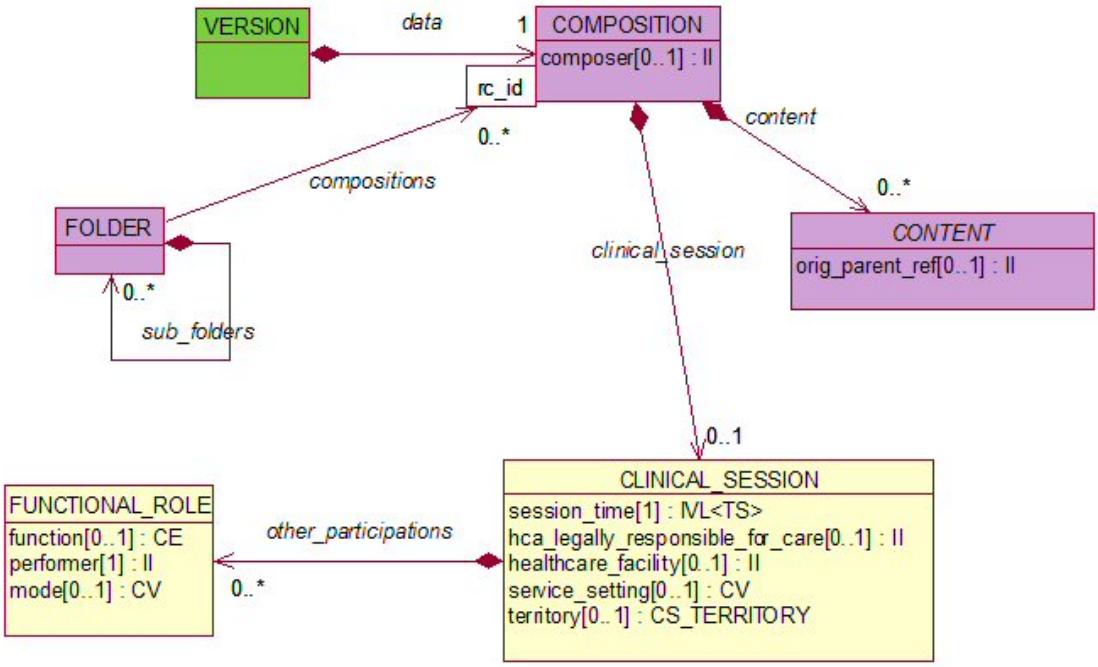
This association permits the representation of a Folder hierarchy.

6.11.2 association: compositions

from: EXTRACT Package::FOLDER to: EXTRACT Package::COMPOSITION [0..*] By Value

FOLDERs reference COMPOSITIONs by containing the values of the rc_id attributes of those COMPOSITIONs, logically permitting many-to-many containment by reference. This is shown in the model as a UML association qualifier (i.e. a key). A COMPOSITION may thus appear in more than one FOLDER (or in none).

6.12 Class: COMPOSITION



The COMPOSITION represents the set of RECORD_COMPONENTS composed (authored) during one user's clinical session or record interaction 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.

At times a COMPOSITION might include information originating from or generated by other participants in the care process (for example, on an intensive care unit where several parties might collectively acquire a set of observations on a patient at the same time). Those parties will each need to be separately associated with their own entries and optionally to be able to attest only their own entries within that COMPOSITION.

The COMPOSITION is the main container class for EHR data within the extract itself: the EHR_EXTRACT contains a set of COMPOSITIONs together with audit trail meta-data about the committal of each. Any updates in the form of revisions of EHR data will be represented as one or more successor COMPOSITIONs, each referencing the preceding version (via the VERSION class containing it). Attestations are also associated with each COMPOSITION (via VERSION), even if individual attestations only pertain to some of the data within the COMPOSITION. This approach has been taken to ensure that recipient systems can rely upon a consistent class for version management within the EHR_EXTRACT itself. No assumption or prescription is made about the level of granularity at which committal, revision or attestation are performed in the underlying systems that provide the EHR_EXTRACT. Provision is made for original committal and revision meta-data to be represented for any node in the EHR hierarchy via an association from RECORD_COMPONENT.

6.12.1 attribute: composer[0..1]: II

Agent (party, device or software) responsible for creating, synthesising or organising 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.

6.12.2 association: clinical_session

from: EXTRACT Package::COMPOSITION to: EXTRACT Package::CLINICAL_SESSION [0..1] By Value

This optional association permits a COMPOSITION that was composed as a result of a clinical care activity to include core (medico-legal) data about that activity: when and where it took place, and under whose ultimate clinical authority.

6.12.3 association: content

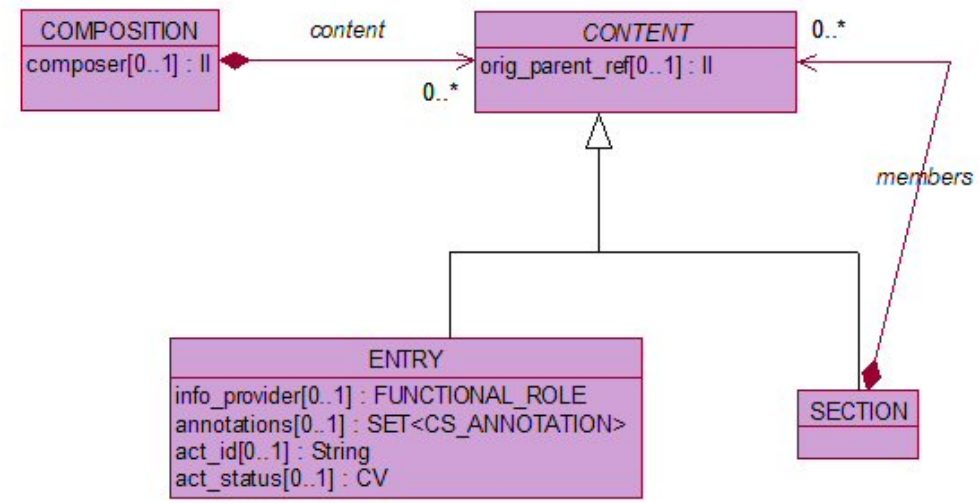
from: EXTRACT Package::COMPOSITION to: EXTRACT Package::CONTENT [0..*] By Value

Compositions contain Sections and ENTRYs, but a Composition is also able to be empty to cope with the case where its contents were removed by formal revision (for example if the original version was saved in the wrong patient's record).

6.12.3.1 Invariant:

composer is a member of the set demographic_entities.parties.eid

6.13 Class: CONTENT



This class is the abstract parent for SECTION and ENTRY, which constitute the "content" of a COMPOSITION.

6.13.1 attribute: orig_parent_ref[0..1]: II

The identity of the COMPOSITION or SECTION that provides the original context for this SECTION or ENTRY.

Health record entries often refer to other pre-existing entries, and include them as "copies". In most cases the EHR_EXTRACT does need to contain these referenced RECORD_COMPONENTS as data, to support reliable communication. However, it is important medico-legally also to communicate that these entries are copies, and that they originate from a different part of that patient's EHR. Both SECTION and ENTRY have the optional attribute original_parent_ref that may be used to represent the rc-id of the original parent RECORD_COMPONENT if the data is a copy. If this attribute is null, the data is in its original context and is not a copy.

6.14 Class: SECTION

The record entries relating to a single clinical session are usually grouped under headings that represent phases of the encounter, or assist with layout and navigation. Clinical headings usually reflect the clinical workflow during a care session or sub-topics within a clinical care process, 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 generally not used consistently enough to support safe automatic processing of the EHR.

A SECTION may contain:

- other SECTIONs

- ENTRYs

The actual structure of section trees is defined by section archetypes.

Since some clinical systems may permit committal and revision at this level of the record hierarchy, the set of AUDIT_INFO attributes is associated with this class (inherited from RECORD_COMPONENT) to permit the

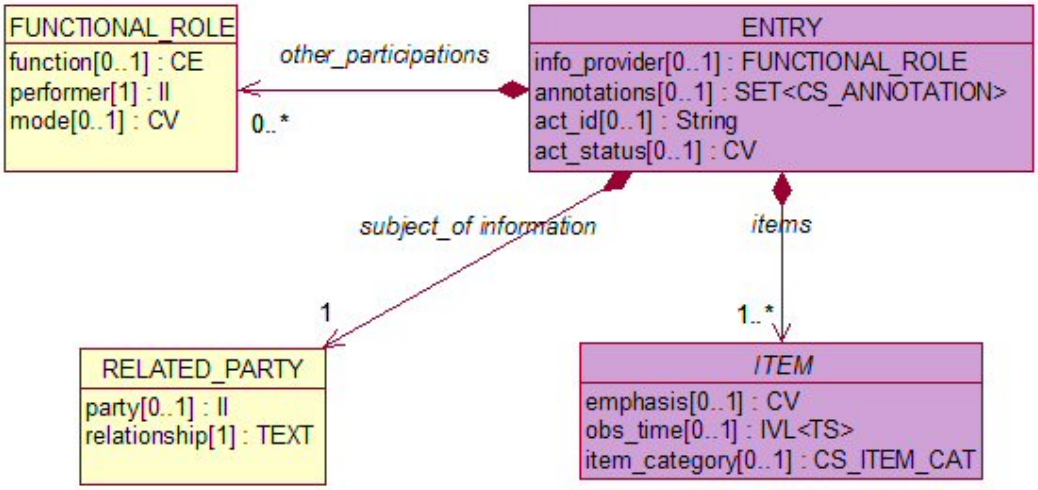
faithful representation of these fine-grained committal/revision meta-data. Attestations pertaining only to the data contained at this level in the hierarchy may reference this component using the ATTESTATION_INFO.target association.

SECTION inherits attributes and associations from RECORD_COMPONENT.

6.14.1 association: members

from: EXTRACT Package::SECTION to: EXTRACT Package::CONTENT [0..*] By Value Permits any SECTION to contain other SECTIONs and/or ENTRYs."

6.15 Class: ENTRY



The ENTRY class contains (as ITEMs) 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).

- information in an ENTRY may have been provided by someone other than the patient/clinician.

- other participants might need to be identified with the ENTRY.

- the ENTRY may represent the evolving status of a clinical Act (e.g. requested, performed, reported, cancelled).

- the ENTRY can include safety Component Annotations (a sub-set of those originally in ENV13606-2, (to be) published in Part 3 of this standard).

Since some clinical systems may permit committal and revision at this level of the record hierarchy, the set of AUDIT_INFO attributes is associated with this class (inherited from RECORD_COMPONENT) to permit the faithful representation of these fine-grained committal/revision meta-data. Attestations pertaining only to the data contained at this level in the hierarchy may reference this component using the ATTESTATION_INFO.target association.

ENTRY inherits attributes and associations from RECORD_COMPONENT.

6.15.1 attribute: info_provider[0..1]: FUNCTIONAL_ROLE

The Party who provided the information, in particular if it is neither the patient nor the clinician e.g. relative, other healthcare party. By using the class FUNCTIONAL_ROLE to represent this attribute, the relevant party can be described by their status or functional role, or can be specified as an identifiable party if appropriate.

6.15.2 attribute: annotations[0..1]: SET<CS_ANNOTATION>

This attribute represents the set of component annotations that pertain to this ENTRY. The annotations attribute of ENTRY is a placeholder for code sets that will be defined in Part 3 of this standard. This single attribute might then be replaced with specific attributes, one for each annotation concept.

6.15.3 attribute: act_id[0..1]: String

This attribute will permit the data in this ENTRY to be associated with a healthcare act. This ENTRY might be one state of an Act, or might be recording the fulfilment of a previously documented Act. This attribute value might be provided by a workflow system as a way of tagging successive ENTRYs as contributing to an Act or marking its evolution of state. A more rich data set about Act Management should be managed through archetypes.

6.15.4 attribute: act_status[0..1]: CV

This attribute represents the state of the ENTRY if it is an Act being managed by an Act Management system. It is an optional attribute since not all EHR systems will use act management functions. The values of this code set will be determined in collaboration with the CEN HISA Task Force, and will be defined in Part 3 of this standard.

6.15.5 association: other_participations

from: EXTRACT Package::ENTRY to: EXTRACT Package::FUNCTIONAL_ROLE [0..*] By Value

This association permits the representation of any other parties who have contributed to the health or healthcare processes involved in providing data for this ENTRY.

6.15.6 association: items

from: EXTRACT Package::ENTRY to: EXTRACT Package::ITEM [1..*] By Value

This association allows the data structure of an ENTRY to be represented to any level of complexity.

6.15.7 association: subject_of information

from: EXTRACT Package::ENTRY to: EXTRACT Package::RELATED_PARTY [1] By Value

Subject of this ENTRY, specified by his/her relationship to the subject_of_care and optionally, if appropriate, as a personally identified Party e.g.

- the subject of care (usual case)

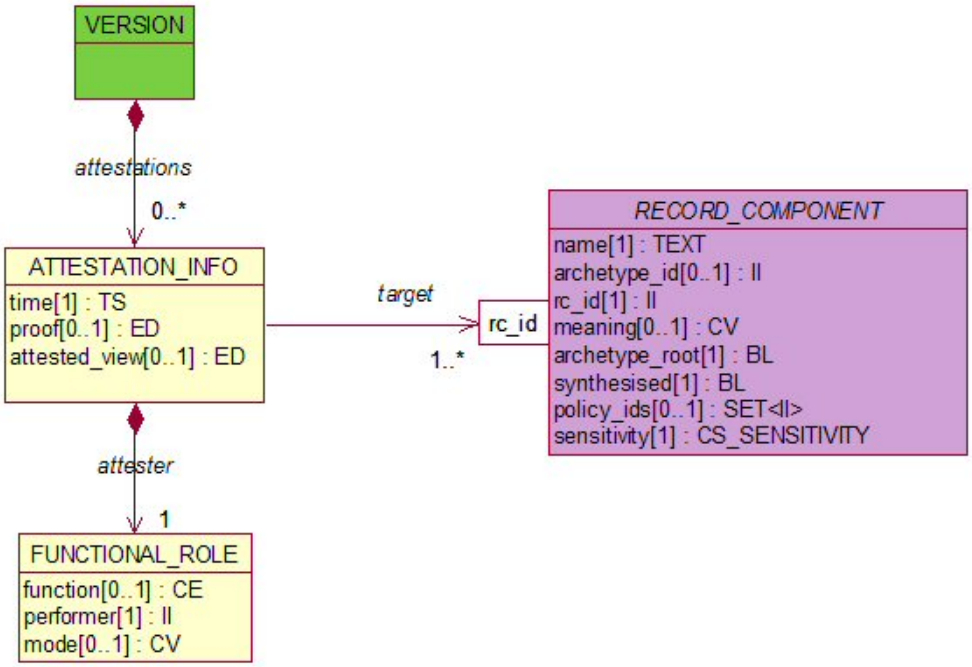
- organ donor

- foetus

- family member

- friend

6.16 Class: ATTESTATION_INFO



Attestation is the process of certifying and recording legal responsibility for a particular unit of information.

Attestation may be carried out by more than one person, at different times from the committal, and might not always be required in some health care services.

The attester will sometimes also be the committer, but might not always be (for example if a medical secretary is typing in the data).

The addition of an attestation after committal does not require a revision of the target RECORD_COMPONENT itself.

This class is a successor to the class Attestation Information in ENV13606.

6.16.1 attribute: time[1]: TS

The date and time at which this attestation has occurred.

6.16.2 attribute: proof[0..1]: ED

The electronic signature (as encapsulated data, or as reference to it) that verifies the attestation. This is optional as it may not be required when communicating EHR_EXTRACTS, particularly within a single health service.

6.16.3 attribute: attested_view[0..1]: ED

The encapsulated data, or a reference to it, that represents the screen image that was actually viewed by the attester. It is now required in some EU countries that this is retained within the EHR in addition to the data in its processable form.

6.16.4 association: attester

from: EXTRACT Package::ATTESTATION_INFO to: EXTRACT Package::FUNCTIONAL_ROLE [1] By Value

The person who made this attestation, including the role played by that person and the mechanism by which the attestation was made.

6.16.5 association: target

from: EXTRACT Package::ATTESTATION_INFO to: EXTRACT Package::RECORD_COMPONENT [1..*] By Value

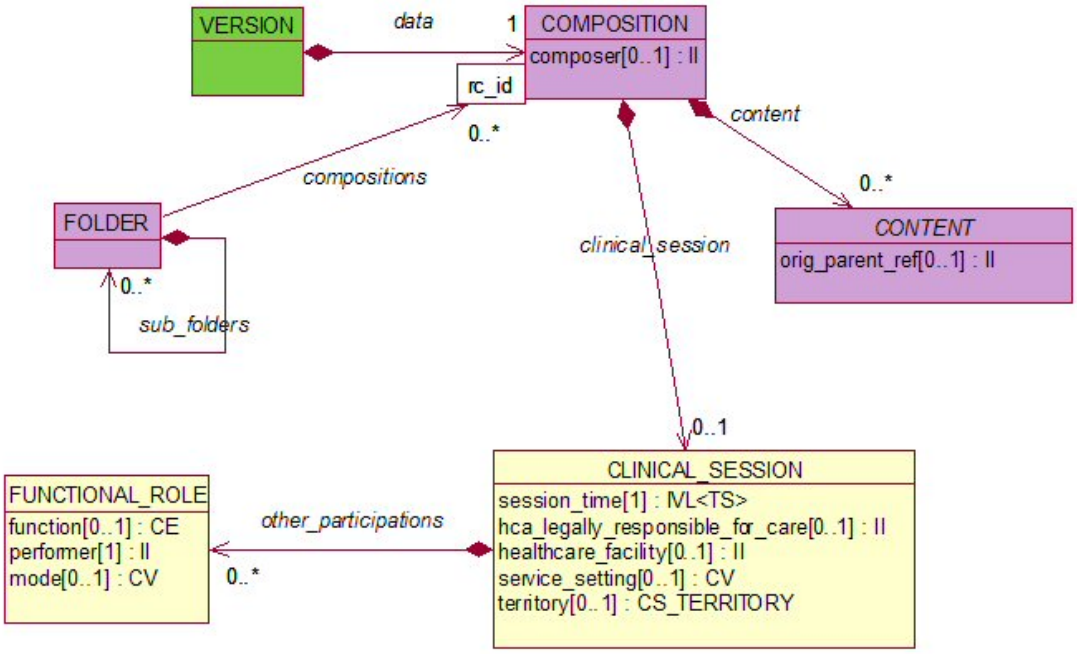
Attestations pertaining only to the data contained by a specific level in the record hierarchy will reference that node using this attribute, which is the rc_id identifier of that RECORD_COMPONENT.

6.16.5.1 Invariant:

date != null

proof != null

6.17 Class: CLINICAL_SESSION



This class provides the clinical context details for the clinical 'session' that led to the recording of the COMPOSITION associated with it. It contains the context information for this session (not to be confused with the context information for interaction with the EHR).

This whole class is optional and might not apply, for example if a patient is personally committing health information to the record.

6.17.1 attribute: session_time[1]: IVL<TS>

Timing of the session, which might be represented as a single date or time, or as an interval.

6.17.2 attribute: hca_legally_responsible_for_care[0..1]: II

The value of this attribute must be a healthcare professional. This is the professional who is legally responsible for the care of the patient at the time of this COMPOSITION being committed to the record. It is not necessarily the committer, composer or the attester of the COMPOSITION.

6.17.3 attribute: healthcare_facility[0..1]: II

The facility at which the healthcare activity recorded took place.

6.17.4 attribute: service_setting[0..1]: CV

The context, possibly service or location type (e.g. Outpatients clinic, patient's home etc), of the care provided.

6.17.5 attribute: territory[0..1]: CS_TERRITORY

Code for the territory in which this COMPOSITION was created, identified by ISO 3166. This will indicate the country under whose laws this COMPOSITION was created/modified. This might be relevant to determining the rights of the patient and/or the ownership and disclosure policies pertaining to the EHR data.

6.17.6 association: other_participations

from: EXTRACT Package::CLINICAL_SESSION to: EXTRACT Package::FUNCTIONAL_ROLE [0..*] By Value

This association permits the representation of any other parties who have contributed to this Clinical Session e.g. assisting surgeon, health advocate in attendance.

6.17.6.1 Invariant:

session_time != null

hca_legally_responsible_for_care is a member of the set demographic_entities.parties.eid

healthcare_facility != null

service_setting != null

6.18 Class: FUNCTIONAL_ROLE

This class is used to document the participation of a role in some activity recorded in the EHR. This approach resembles, but is simpler than, that adopted by HL7 for Participation and Role.

6.18.1 attribute: function[0..1]: CE

Function of the role in this particular participation. The set of possible values for this attribute will be defined in Part 4 of this Standard, in collaboration with an active work item in ISO TC/215.

6.18.2 attribute: performer[1]: II

Identity of the party performing that role.

6.18.3 attribute: mode[0..1]: CV

The mechanism by which that participation has been made e.g. by phone, by mail, in person. The code set for this attribute will be defined in Part 3 of this standard.

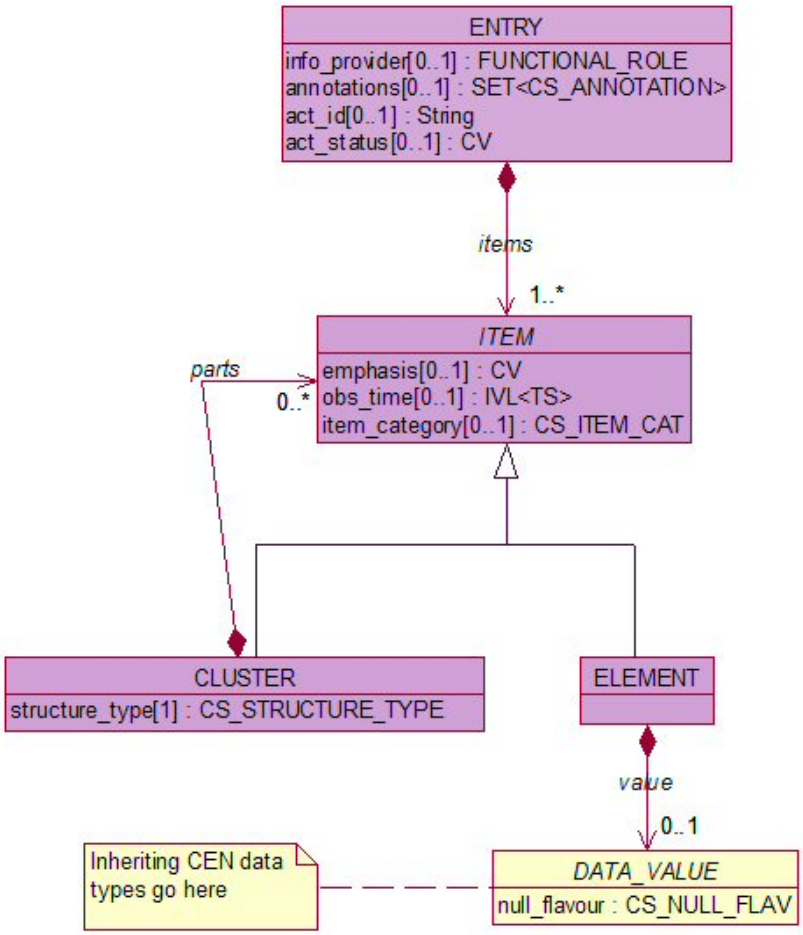
6.18.3.1 Invariant:

function != null

performer != null

performer is a member of the set demographic_entities.parties.eid

6.19 Class: ITEM



This class is the abstract parent of the hierarchy-building blocks CLUSTER and ELEMENT. This permits the data association of ENTRY to be a single ELEMENT, a list of ELEMENTs, a CLUSTER or a list of CLUSTERs. Combining this with the association of CLUSTERs (which may be further CLUSTERs or ELEMENTs or a combination of these) permits the representation of a wide range of data structures including trees, tables, matrices, lists, and time series.

The ITEM, CLUSTER and ELEMENT combination of classes supports a wide range of simple and complex data structures needed to represent the actual data values within one observation, battery, clinical statement, planned action or order.

ITEM may represent both the actual data describing the observation, inference, or action, and optionally the details supporting the clinical reasoning process such as a reference to an electronic guideline, decision support system, or other knowledge reference.

6.19.1 attribute: emphasis[0..1]: CV

A way of denoting that the composer wished to mark this ITEM as being of particular note to the reader e.g. an unusual measurement value, an unexpected outcome, anything that might be considered necessary to highlight to a future reader. This is a place-holder for a more specific indication of how this ITEM should be presented, as and when an interoperable specification for such EHR presentation guidance is defined.

6.19.2 attribute: obs_time[0..1]: IVL<TS>

The date-time or period pertaining to this ITEM. It may be in the past or future as required. This attribute is to be used to distinguish the ITEM time from the time at which the RECORD_COMPONENT and the COMPOSITION were committed, and from the time that the Clinical Session took place.

In a nested set of CLUSTERs and ELEMENTs the obs_time value propagates down to lower levels of the hierarchy unless a new value is specified in those CLUSTERs or ELEMENTs.

6.19.3 attribute: item_category[0..1]: CS_ITEM_CAT

ITEM might represent both the actual data describing an observation, inference, or action, and the 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 representing that distinction, which might be an aid to the automated analysis or filtering of the ITEMS in an ENTRY. The codeset for this attribute is (to be) defined in part 3 of this standard.

6.20 Class: ELEMENT

This class represents the leaf node within the EHR hierarchy. Examples of this include reason for encounter, body weight, pulse. Each instance of this class will have a single data value, which is one of a defined set of CEN data types.

Since some clinical systems may permit committal and revision at this level of the record hierarchy, the set of AUDIT_INFO attributes is associated with this class (inherited from RECORD_COMPONENT) to permit the faithful representation of these fine-grained committal/revision meta-data. Attestations pertaining only to the data contained at this level in the hierarchy may reference this component using the ATTESTATION_INFO.target association.

ELEMENT inherits attributes and associations from RECORD_COMPONENT.

6.20.1 association: value

from: EXTRACT Package::ELEMENT to: DATA_VALUE [0..1] By Value

An ELEMENT takes a single value unless indicated as absent by the null_flavour attribute of ELEMENT."

6.21 Class: CLUSTER

The representation of a single observation or action might itself be multi-part. Complex (nested) representations might for example be needed for measurements, test results or treatment instructions. These may need to be represented as a list, 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 data might need to be represented as a nested set of values, as a table, list, or as a time series. The CLUSTER class permits such aggregation within an ENTRY. This contrasts with SECTION whose role is to represent the navigational or workflow headings and sub-divisions of a COMPOSITION.

Since some clinical systems may permit committal and revision at this level of the record hierarchy, the set of AUDIT_INFO attributes is associated with this class (inherited from RECORD_COMPONENT) to permit the faithful representation of these fine-grained committal/revision meta-data. Attestations pertaining only to the data contained at this level in the hierarchy may reference this component using the ATTESTATION_INFO.target association.

CLUSTER inherits attributes and associations from RECORD_COMPONENT.

6.21.1 attribute: structure_type[1]: CS_STRUCTURE_TYPE

This will indicate the time and/or spatial organisation of the data within this CLUSTER e.g.

- Time Series

- Table

- List

- Tree

This attribute gives an indication to the EHR recipient of the original organisation of the data structure.

6.21.2 association: parts

from: EXTRACT Package::CLUSTER to: EXTRACT Package::ITEM [0..*] By Value

Permits any CLUSTER to contain other CLUSTERs and/or ELEMENTs."

6.21.2.1 Invariant:

structure_type != null

6.22 Class: RELATED_PARTY

This Class is provided, for ENTRY.subject_of_information, to identify a person in terms of his or her relationship to the subject_of_care when it is not necessarily relevant or permitted to identify the person absolutely. e.g. it might be necessary to record some data about the father of the subject_of_care without identifying the father personally. The party attribute is therefore optional whereas the relationship attribute is mandatory.

6.22.1 attribute: party[0..1]: II

The optional personal identification of the related party.

6.22.2 attribute: relationship[1]: TEXT

The relationship of the Related_Party to the subject of care e.g. father.

6.22.2.1 Invariant:

relationship !=null

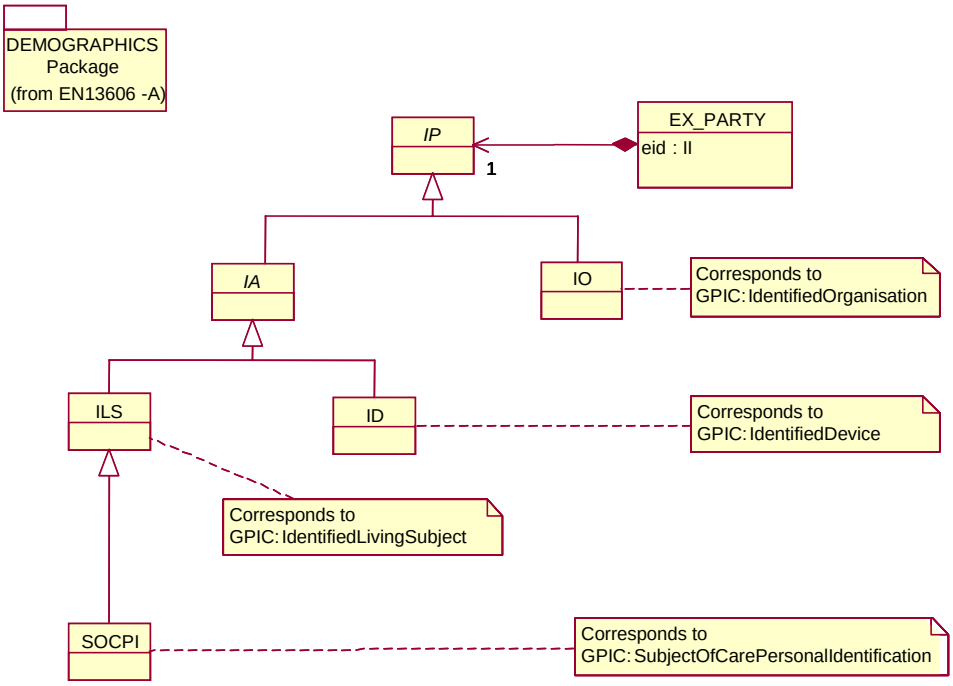
party is a member of the set demographic_entities.parties.eid

6.23 Package: Access

6.24 Class: ACCESS_POLICY

This class will contain the set of access control policies that pertain to part or all of the data contained in the EHR_EXTRACT. These are included with the EHR_EXTRACT to inform the EHR recipient of the access control measures that ought to apply to these data within the recipient's EHR system and be include with any onward communication of these data by the recipient. The details of this class will be defined in Part 4 of this standard.

6.25 Package: Demographics



6.26 Class: EX_PARTY

The demographic details necessary to accompany this party occurring in the Extract.

6.26.1 attribute: eid: II

The unique identification for this party used within the EHR data contained by this EHR_EXTRACT.

6.26.2 association: details

from: DEMOGRAPHICS Package::EX_PARTY to: DEMOGRAPHICS Package::IP [1] By Value

Association to the information used to define and describe this party, represented by the relevant GPIC."

6.27 Class: IP

(Abstract class.) Any Identified Party, which may be an Organisation, Person, or Device

6.28 Class: IA

(Abstract class.) Any Identified Agent, which may be a Person or Device

6.29 Class: IO

Identified Organisation. Corresponds to GPIC:IdentifiedOrganisation

6.30 Class: ILS

Identified Living Subject. Corresponds to GPIC:IdentifiedLivingSubject

6.31 Class: ID

Identified Device. Corresponds to GPIC:IdentifiedDevice

6.32 Class: SOCPI

Subject of Care person identification. Corresponds to GPIC:SubjectOfCarePersonalIdentification

Annex A
(informative)

Modelling Conventions

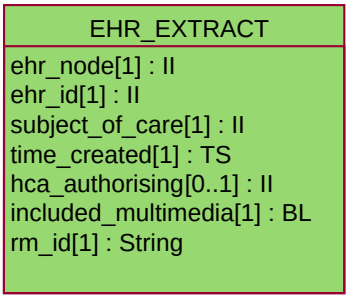
All model diagrams included in this part standard follow the conventions of the Unified Modelling Language (UML). The following example constructs are provided as a convenient reference to the reader.

A.1.1 Class

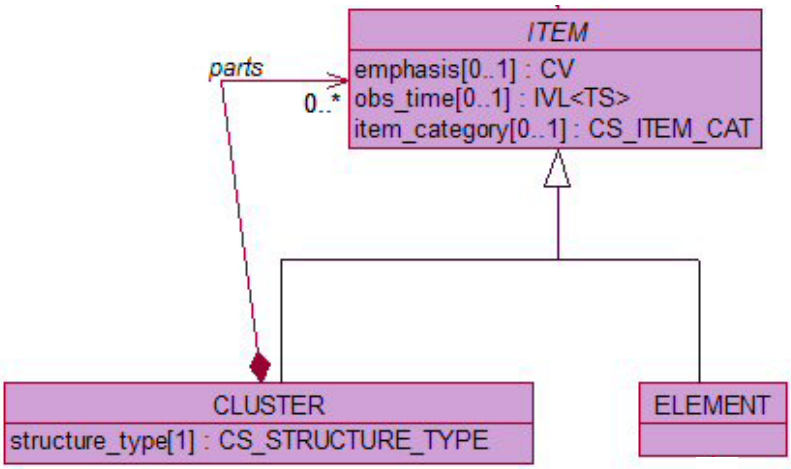
A class of information names a set of any real world objects or concepts, and describes the information properties common to all members of that set.

A.1.2 Attribute

An information property of a class. For example, the EHR_EXTRACT class defines a set of real world instances of extracts from EHR systems. One of its information properties is the date and time the information was extracted from the underlying clinical system to create this Extract (the time_created). This attribute will have a data type TS (a timestamp, which is defined elsewhere). Its cardinality is [1], meaning that every instance of an EHR_EXTRACT will have exactly one value of time_created. This means that time_created is a mandatory attribute. Other examples of cardinality include zero or one (the hca_authorising), and zero to many (used in several other parts of the Reference Model).



A.1.3 Inheritance

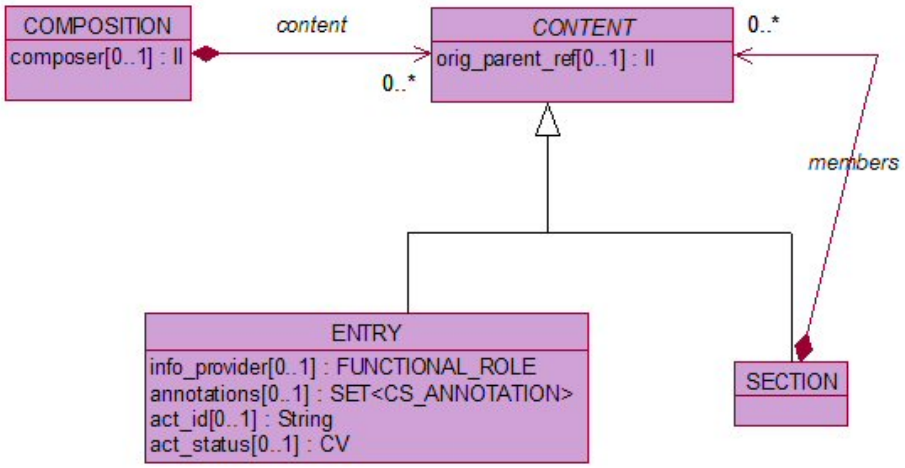


Inheritance implies that a child (sub-class) is a kind of its parent (super-class). It will have the same attributes as its parent in addition to any specified within its own definition. Inheritance provides a means of permitting more than one class to share a common set of features (attributes, associations, invariants, etc.). For example, CLUSTER and ELEMENT are both kinds of ITEM: each of the two concrete classes has the attributes emphasis and obs-time as well as structure_type (CLUSTER) or null_flavour (ELEMENT).

A.1.4 Abstract class

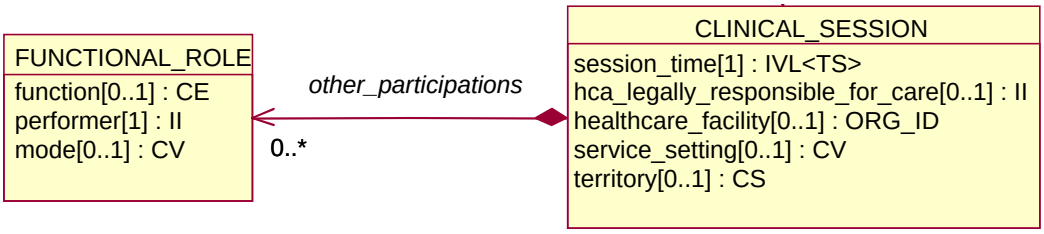
Most classes in this Reference Model are concrete. This means that instances of them will actually occur in real EHRs. An abstract class may be defined to provide a “virtual” common parent to two or more classes; the abstract class will never exist in a real EHR. Its value in modelling terms is to provide a container for attributes and associations that might apply to several other classes (its sub-classes).

The diagram below implies that a real instance of a COMPOSITION may contain (in concrete terms) SECTIONs and/or ENTRYs. A SECTION may contain other SECTIONs and/or ENTRYs. Both SECTION and ENTRY have the attribute orig_parent_ref. CONTENT will never exist in a real EHR.



A.1.5 Association by value

This permits an instance of a class to contain instances of another.



In this example, CLINICAL_SESSION may have zero or more other_participations, as an additional and potentially multiple attribute. This means that CLINICAL_SESSION might have the attributes function, performer and role repeated as a triplet any number of times. (In fact, since function and mode both have cardinality [0..1], the set of attributes might not always be a compete triplet, since some other_participations might only specify the performer and not their role or mode.) This kind of association is called containment by

value, because the attributes acquired through the association are actually considered a part of the associating class.

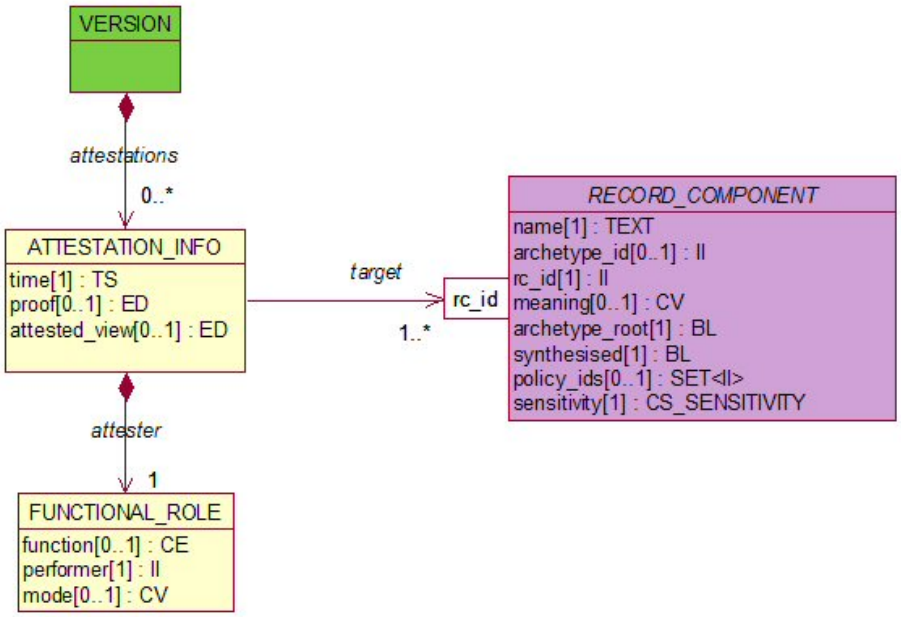
A.1.6 Associations

Roles at each end of associations are not shown. Rather, the name of the association is shown near the centre of the association line.

The navigation arrow shows the direction in which the association is to be read.

A.1.7 Association by Reference, using a UML qualifier attribute

In contrast to association by value, this is a kind of association that permits classes to reference others but not to physically contain them. In the example below, the class ATTESTATION_INFO references an instance of RECORD_COMPONENT as its target, but does not contain it. Furthermore, this diagram specifies that the RECORD_COMPONENT attribute rc_id is to be the key by which that reference is made i.e that ATTESTATION_INFO will physically contain a value for rc_id that corresponds to the RECORD_COMPONENT intended to be its target.



Note : there are no occurrences of containment by reference in the model (white diamonds).

Annex B
(informative)

Overview of the Reference Model

This Annex is intended to provide an explanatory description of the Reference Model, which might be read independently of the rest of this standard by those wishing to obtain a general overview of it. It does repeat some of the material from Section 6 of this document, but adds further explanatory material.

B.1 Introduction

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 organised 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 organisation, 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.

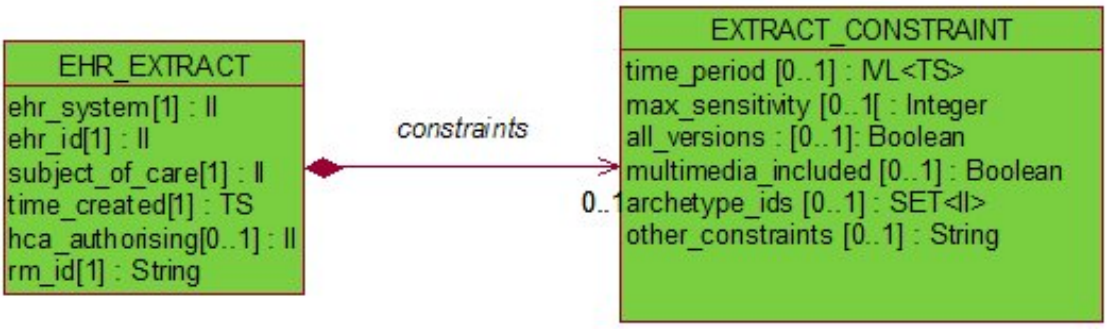
In this Reference Model the key EHR contextual requirements for such faithfulness are related to a set of logical building block classes, with suitable attributes proposed for each level in the EHR Extract hierarchy.

B.2 Overview of the main classes in the record hierarchy

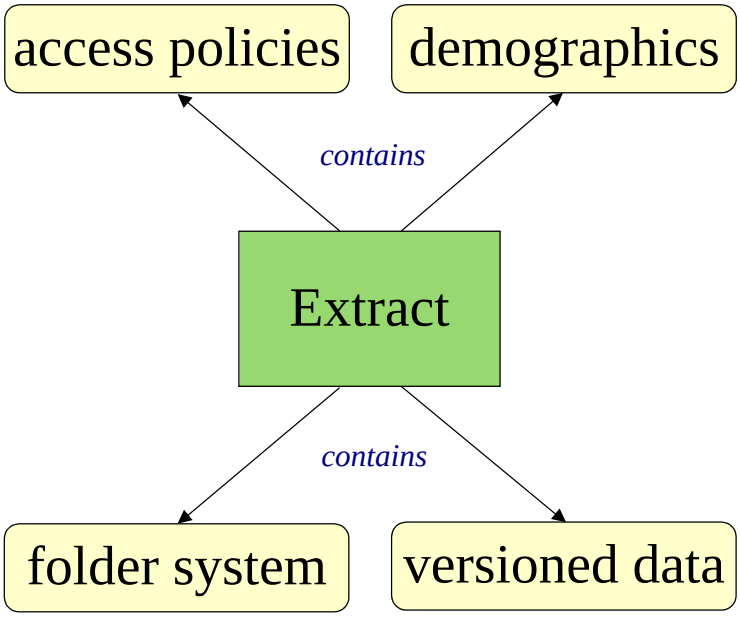
B.2.1 EHR_EXTRACT

This is the root class of the Reference Model (corresponding to the Root Architectural Component in ENV13606). Logically it represents the virtual electronic health record for one person, the subject of care (usually a patient). In practice, this model will be 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 process (which might be another repository, a client application or a middleware service such as an electronic guideline engine), 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 party responsible for creating it.



The EHR_EXTRACT contains a set of constraint descriptions in the class EXTRACT_CONSTRAINTS. This describes the filter or selection criteria by which this EHR_EXTRACT has been created. This may or may not correspond directly to the criteria in the EHR_Request, and provides a persistent record of the kind of subset this EHR_EXTRACT is of the overall EHR held by the EHR_Provider.



The EHR_EXTRACT contains the EHR data, in four parts:

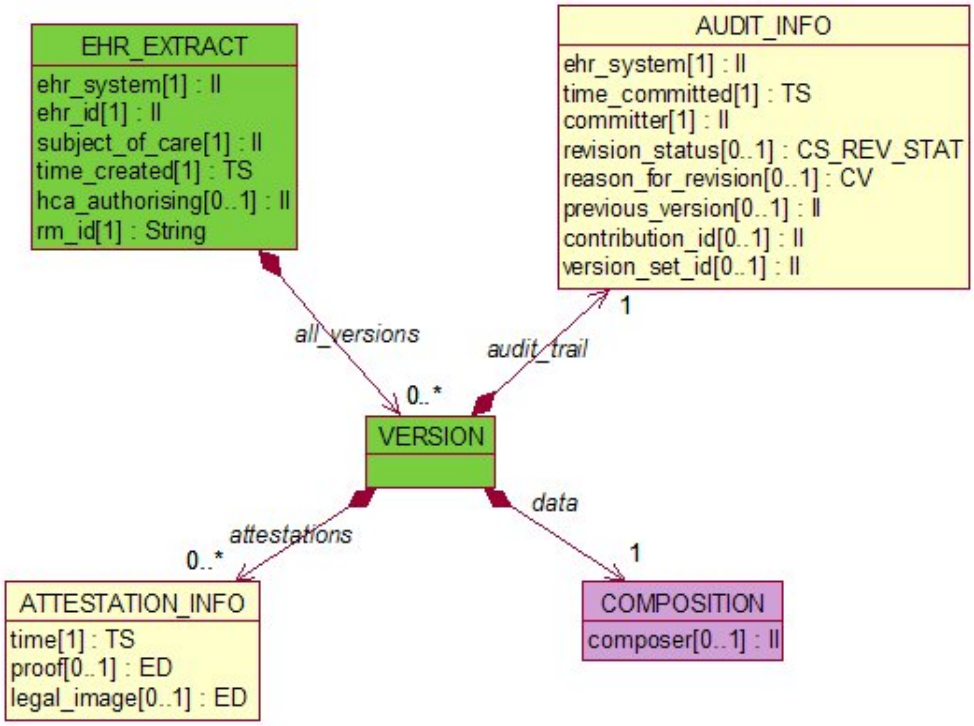
1) a directory of FOLDERs

2) a set of Versioned objects each of which includes a COMPOSITION

3) a set of demographic entities that are referenced from within the main EHR hierarchy; 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 identifiers used by the Extract provider.

4) a set of access control policies that pertain to individual RECORD_COMPONENTS or to the EHR_EXTRACT as a whole, and which are intended to be incorporated into the access control framework of the EHR recipient. The information model for representing these access policies is (to be) defined in Part 4 of this standard.

B.2.2 Version



The core EHR data within an extract is encapsulated in COMPOSITIONs. This standard treats the COMPOSITION as the unit for the communication of revision history for the EHR_EXTRACT. This does not limit the freedom of EHR systems to internally represent revision using any classes of the RECORD_COMPONENT hierarchy. Each set of changes made at any level of the EHR (except Folder) are incorporated into a new COMPOSITION within the EHR_EXTRACT and stamped with change management meta-data using the audit_trail association from VERSION, so that the receiving system can reconcile this data more consistently with any previous version it holds.

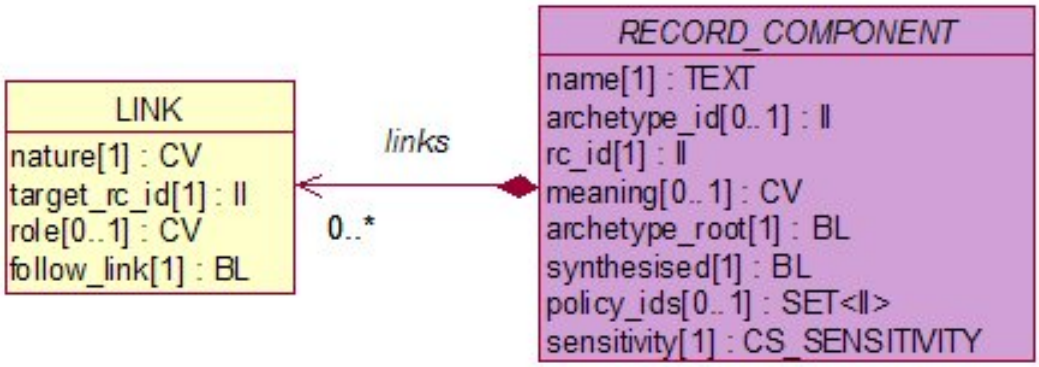
This class therefore provides a means of managing version control of EHR data communicated within the EHR_EXTRACT. (as opposed to representing the way in which the revision of individual RECORD_COMPONENTs might be represented in the underlying EHR provider system).

The audit_trail association from VERSION relates each COMPOSITION to information about its committal and optionally its previous version. Revisions to any RECORD_COMPONENTs within a COMPOSITION will give rise to a new version of it in the extract, and therefore also to a new instance of VERSION.

The VERSION class also binds together each COMPOSITION version with a set of attestations that pertain to it or to some of its contents. This is required because some enterprises and EHR systems enable clinical documents and other EHR data to be attested some time after their committal (as well as at the time of committal). These attestations would not normally constitute a revision of the data being attested. (A revised COMPOSITION does not automatically acquire the attestations of its predecessor, for legal reasons.)

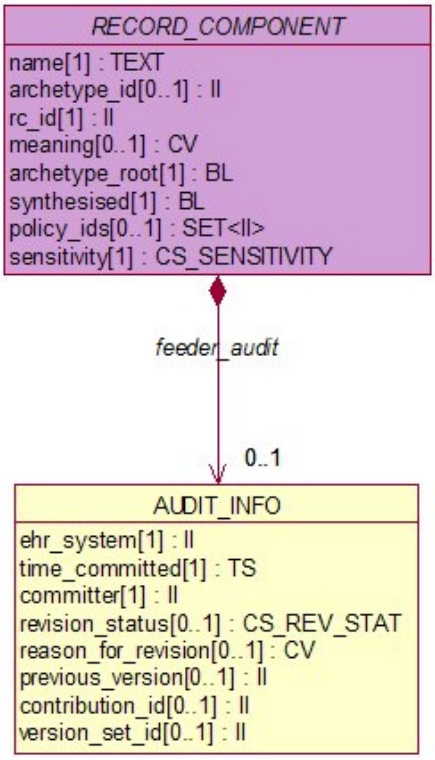
B.2.3 Record Component

This abstract class is the super-class of all of the concrete nodes in the EHR hierarchy: FOLDER, COMPOSITION, SECTION, ENTRY, CLUSTER, ELEMENT, and for two abstract class nodes: CONTENT and ITEM.



RECORD_COMPONENT has a set of attributes that could apply to any node in the hierarchy, including:

- component identification
- component name used in the underlying EHR provider system
- archetype ID and (standardised) archetype name
- sensitivity code and references to access control policies
- support for Links between any Record Components (discussed later).

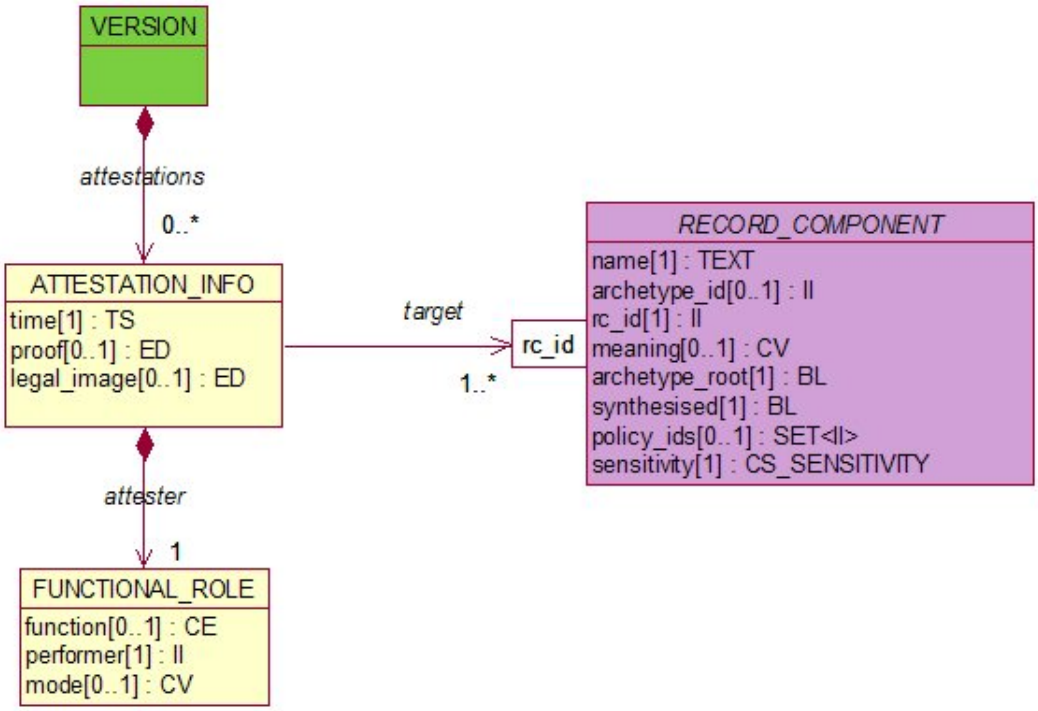


Any RECORD_COMPONENT may include audit trail meta-data about committal, revision or attestations that might exist at any hierarchical level in the EHR provider system(s) contributing to the Extract.

Each revised version of a RECORD_COMPONENT may include the revision status, the reason for the revision and the ID of the preceding version. However, for Data Protection reasons it is advised that previous (erroneous) versions of components are not communicated as part of normal clinical shared care, but only in circumstances where an EHR transfer is being made for legal reasons.

Attestations include: a reference to the attesting party, their functional role, optional digital ‘proof”, optional “image view” of what was seen and signed. Any number of attestations may be added at or after committal.

When generating an EHR_EXTRACT conformant to this standard 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. Examples of this include: the creation of FOLDERs to organise a set of requested COMPOSITIONS, or the introduction of a COMPOSITION or ENTRY to contain lower-level data that did not have a corresponding container class 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.



Contribution

The Contribution is the set of RECORD_COMPONENTS 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 an update to a repeat medication list 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 RECORD_COMPONENTs comprising one Contribution can be collectively identified by providing a common value for the contribution_id attribute in each AUDIT_INFO for each RECORD_COMPONENT instance, irrespective of the COMPOSITIONs they are contained in.

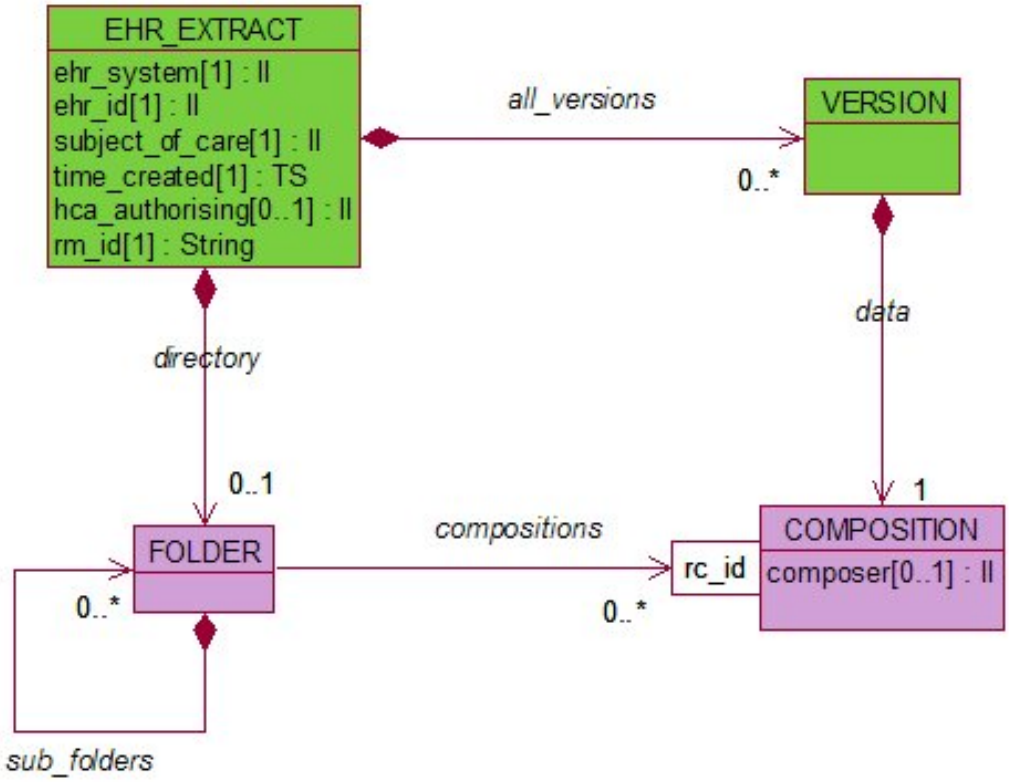
B.2.4 Folder

This class is used to represent the highest-level organisations of the EHR_EXTRACT e.g. to group parts of the record by episode, care team, clinical speciality or clinical condition. Internationally, this kind of organising structure is used variably: in some centres and systems the Folder is treated as an informal compartmentalisation of the overall health record; in others it might represent a significant legal portion of the EHR relating to the originating enterprise or team.

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 from the underlying feeder system. FOLDERs may be attested.

In some situations FOLDERs might be created specifically to organise 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 any direct correspondence with those in the contributing EHR provider system, and a medico-legal approach to representing FOLDERs would not really be appropriate; all of the AUDIT_INFO attributes may be omitted in these cases. In such situations it is suggested that an EHR recipient system might reasonably ignore the FOLDERS within the EHR_EXTRACT on import, and optionally to re-associate the COMPOSITIONS within its own local folder or directory system.

FOLDERs reference COMPOSITIONs by physically containing the values of their rc_id attributes, logically permitting many to many containment by reference (e.g. a COMPOSITION might be contained by more than one FOLDER).

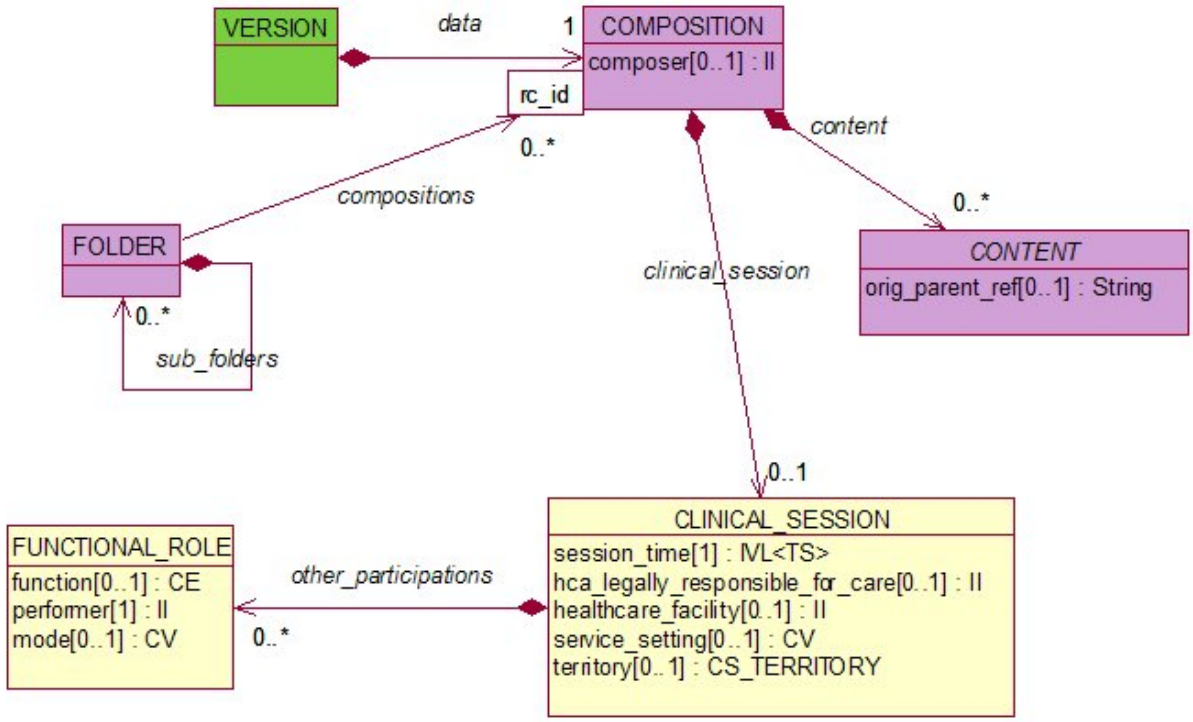


B.2.5 Composition

The COMPOSITION represents the set of RECORD_COMPONENTS composed (authored) during one user's clinical session or record interaction 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.

At times a COMPOSITION might include information originating from or generated by other participants in the care process (for example, on an intensive care unit where several parties might collectively acquire a set of observations on a patient at the same time). Those parties will each need to be separately associated with their own entries and optionally to be able to attest only their own entries within that COMPOSITION.

The COMPOSITION is the main container class for EHR data within the extract itself: the EHR_EXTRACT contains a set of COMPOSITIONs together with audit trail meta-data about the committal of each. Any updates in the form of revisions of EHR data will be represented as one or more successor COMPOSITIONs, each referencing the preceding version (via the VERSION class containing it). Attestations are also associated with each COMPOSITION (via VERSION), even if individual attestations only pertain to some of the data within the COMPOSITION. This approach has been taken to ensure that recipient systems can rely upon a consistent class for version management within the EHR_EXTRACT itself. No assumption or prescription is made about the level of granularity at which committal, revision or attestation are performed in the underlying systems that provide the EHR_EXTRACT. Provision is made for original committal and revision meta-data to be represented for any node in the EHR hierarchy via an association from RECORD_COMPONENT.



(NOTE: the attributes and the associations (LINK and feeder_audit) inherited from RECORD_COMPONENT are not shown in this diagram)

The CLINICAL_SESSION class represents the generic (medico-legal) context pertaining to that session or healthcare process:

- when and when the care activity took place;
- at which care facility, as part of what service and at which location;
- under what legal jurisdiction (territory);
- which clinician was in charge of the care;
- references to any other participants in the care process.

This class might be revised in order to harmonise with the CONTSYS standard, which is presently being drafted.

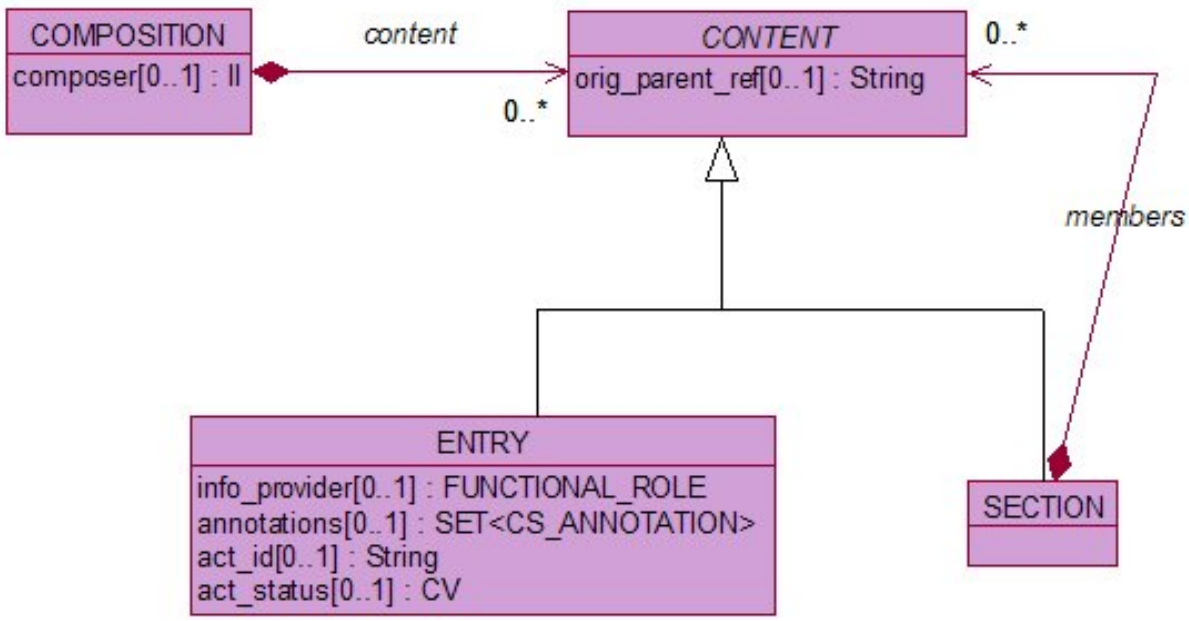
Re-used RECORD_COMPONENTS

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. There are many different ways in which this might be represented within an EHR system, which might avoid having to actually duplicate the actual data within the database. However, it is assumed that in most cases the EHR_EXTRACT does need to contain these referenced RECORD_COMPONENTS as data, to support reliable communication, even if they are duplicated. However, it is important medico-legally also to communicate that these entries are copies, and that they originate from a different part of that patient's EHR. Both SECTION and ENTRY have an optional attribute original_parent_ref that may be used to represent the rc-id of the original parent RECORD_COMPONENT if the data is a copy.

B.2.6 Section

The record entries relating to a single clinical session are usually grouped under headings that represent phases or sub-topics within the 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 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 organise entries within a COMPOSITION. SECTIONs may contain data that originates from another part of the patient's EHR.

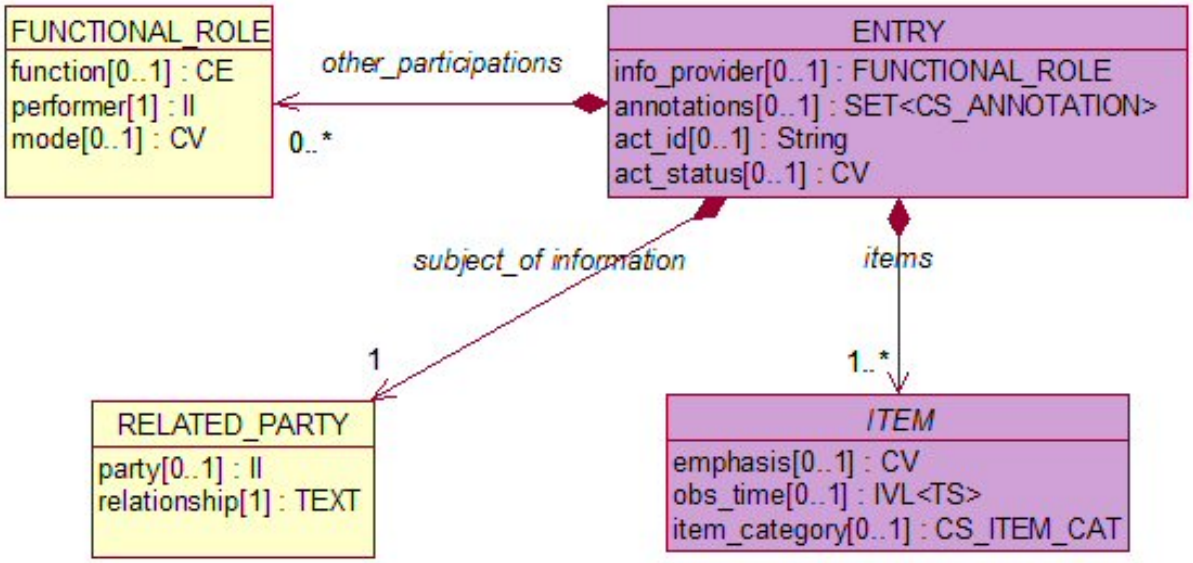


B.2.7 Entry

The ENTRY class contains (as ITEMs) 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).
- information in an ENTRY may have been provided by someone other than the patient/clinician.
- other participants might need to be identified with the ENTRY.
- the ENTRY may represent the evolving status of a clinical Act (e.g. requested, performed, reported, cancelled).
- the ENTRY can include safety Component Annotations (a sub-set of those originally in ENV13606-2, to be published in Part 3 of this standard). These might indicate:
    - if an observation or conclusion is uncertain;
    - if an observation or conclusion is unusual, abnormal or unexpected;
    - if an observation or conclusion is not the actual state of the patient;
      e.g. at risk of, goal, prognosis, excluded.

The annotations attribute of ENTRY is a placeholder for code sets that will be defined in Part 3 of this standard. This single attribute might then be replaced with specific attributes, one for each annotation concept.



ENTRY is the lowest level in the EHR hierarchy at which Functional Roles and Related Parties can be can be associated in a generic way. (Specific archetypes can always be defined that include ELEMENTs whose values identify specific parties as might be required, for example, in an archetype for a medico-legal tribuneral.)

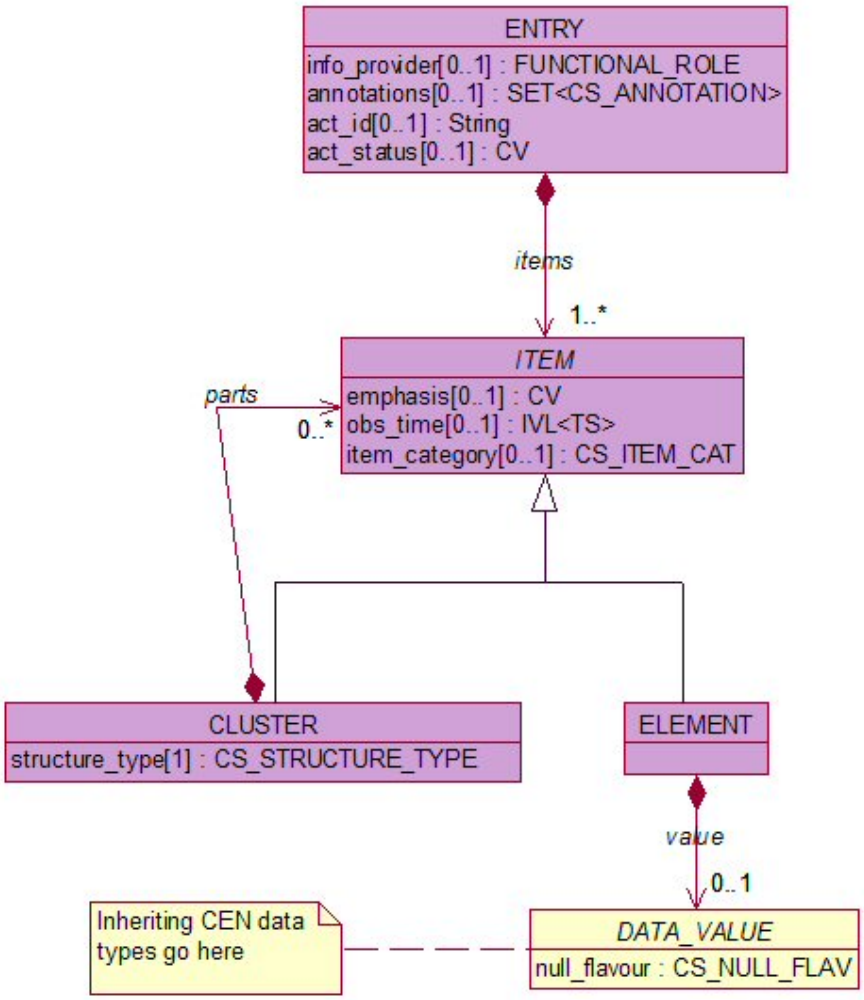
B.2.8 Item, Cluster, Element

The ITEM, CLUSTER and ELEMENT combination of classes supports a wide range of simple and complex data structures needed to represent the actual data values within one observation, battery, clinical statement, planned action or order. Complex (nested) representations might for example be needed for measurements, test results or treatment instructions. These may need to be represented as a list, 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.

ITEM may represent both the actual data describing the observation, inference, or action, and optionally the 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 representing that distinction, which might be an aid to the automated analysis or filtering of the ITEMS in an ENTRY. The codeset for this attribute is (to be) defined in part 3 of this standard.

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 organised as a time series of images.

Information in an ITEM might be emphasised by the author as being exceptional or noteworthy. The code set for this attribute is (to be) defined later in Part 3 of this standard.



B.2.9 Element, Data Value

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.

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

- text and coded terms;
- quantities including ratios, intervals and durations;
- dates and time;
- primitive and basic data types;
- graphical and other MIME type (e.g. image, signal).

B.3 Approach taken to specific areas of representation

B.3.1 Links within the EHR

A cumulative longitudinal EHR comprises incremental additions reflecting a patient's ongoing health story and health care interactions. Much research and empirical evidence points to a hierarchically-organised internal structure to this data, as reflected by the “original” component class hierarchy in two previous generations of CEN standard, and many published EHR architectures from research and industry.

However, much of this work has also drawn attention to the clinical requirement for various organisations and associations of data other than hierarchical containment. These other perspectives can be summarised into four broad use cases.

1. Ad hoc queries

Users frequently require views of certain types of entry or of higher level groupings, which can be derived computationally by filtering the longitudinal EHR for certain classes of information (in future this could be by archetype). Certain attribute or data values might be used to sort the resulting filtrate into a suitable user view, for example by date, alphabetically or by descending size of the value.

There are no specific features required of the underlying longitudinal entries to support this, and the logic for deriving each view will usually reside within a clinical application, not within each individual EHR. The most important point is that the result of performing the query is not itself stored in the EHR or communicated, so the Reference Model does not need to represent it. Examples might be a graph of blood pressures over time or a list of medication prescribed within the past 30 days.

2. Stored queries

Some views or filtrations might be derived by a "custom" query that has been specifically composed for use within a particular EHR. In such cases it may be desirable to store the query parameters within the patient's EHR for the benefit of future clinicians. The extent to which this is useful to share between enterprises and systems depends on how interoperable that query specification is. Given that active work within the archetype community is formalising the language for specifying archetype definitions and constraints, and the guidelines community is also progressing towards interoperable specifications, it seems likely that a generic EHR query specification will emerge, no doubt building on industry standard query formalisms or constraint languages such as OCL.

This standard, as with ENV13606, aims to support the communication of query specifications, although not through a single dedicated class like the SCC class of ENV 13606.

3. Customised queries

There are occasions when a user wishes to include by value particular pre-existing record instances in a new COMPOSITION or SECTION. This might arise either as a result of running a query and customising the result set to produce a hand-crafted filtrate that the user wishes to preserve in the EHR, or by carrying out some kind of drag and drop function that permits him to create a hand-crafted summary of an episode or problem that he wishes to keep. Perhaps the commonest example of this is a discharge summary. An EHR_EXTRACT must be able to communicate if data that has been included “as a copy” from its original location.

4. Linked queries

A user may wish to create *ad hoc* connections between any arbitrary points in an EHR, for example to indicate the evolution of a condition, the likely historic cause of a problem, or a response to a previous request. In these situations a mechanism is required for a composer to point from any node in the current COMPOSITION, SECTION, ENTRY etc. to a previous component in the EHR at any hierarchical level, and optionally to label the link.

An extension of this would be to use one location in the EHR as a kind of linkage hub, for example the formal statement of a clinical condition might be used as an anchor point for all historic and subsequent entries relating to that condition.

A wide range of end user interfaces can be envisaged for such functionality, but the task of this standard is to provide a generic and safe means for communicating the existence of such links to diverse EHR systems. This might at times require the communication of the actual COMPOSITION containing the link target as well at the link source, because a composer felt that any future recipient must be aware of the content of both COMPOSITIONs, for example if a procedure had catastrophic complications.

One variation on this scenario is if a user wishes to create a new link between two pre-existing components, for example to reflect a new insight. This presents both a real requirement and a real risk. The addition of a link between two components can alter the safe interpretation of either. It is therefore suggested that the subsequent addition of a link from a source component to a target should be performed by a revision of the source to add the link i.e. that the source RECORD_COMPONENT is formally revised, and the link is a formal part of that component. This makes it clear that the Link did not exist when the component was originally composed.

It is also important that a safe and simple-to-execute mechanism exists to ensure that critical clinical interpretations embodied within a link are not omitted when parts of a record are communicated to a requesting process.

Mechanisms to meet these use cases

Ad hoc queries

As mentioned above, this use case relies upon selection criteria based on the class names, attribute values and archetypes used within EHR instances. No particular features are required within the Reference Model to support this in the communications context, although selection criteria will be important part of a request for EHR data from an EHR requestor (to be defined in Part 5 of this standard).

2. Stored queries

This use case deals with the requirement to communicated locally-stored EHR queries in an EHR_EXTRACT. There is as yet no standardised convention for specifying an EHR-related query, but it is likely that these specifications will be a data set of string values or name value pairs. Such a specification can be represented within the proposed ITEM sub-classes CLUSTER and ELEMENT, with data values of type STRING. It is therefore proposed that ENTRY archetypes are used to define the representation of EHR queries which need to be communicated. This has the advantage that more than one such query specification can be defined for use within healthcare systems, and refined over time, without requiring any modification to this standard. An illustrative example is given below.

Entry **Blood Pressure Graph Query**

cluster: **Query Specification**

element: **Query Syntax:** <EHR_OQLv1>

element: **Query String:** “Select….

where Cluster.meaning = <Blood Pressure>

and containing.Entry.subject_of_information = <Patient>

and containing.Composition.Clinical_Session.session_time.start

> (now>-365days)”

element: **Datetime first authored:** 20 February 2003

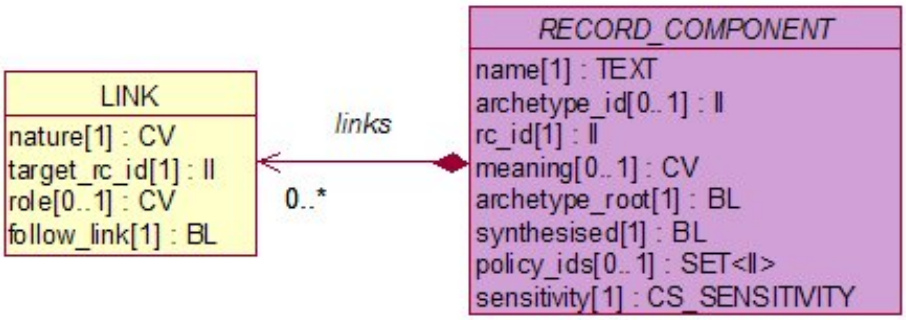
Note: the actual syntax of the query string in the example above is for illustration only, and it does not conform to any known syntax. In the case of such a real query stored in the record the syntax would have to follow whatever scheme is identified in the Query Syntax ELEMENT.

3. Customised queries

This use case requires that re-used RECORD_COMPONENTs are copied by value into the relevant parts of an EHR_EXTRACT. The original_parent_ref attribute of SECTION and ENTRY permits such copied data to be identified as originating elsewhere. A fuller description of re-use is given in Sections B.2.6 and B.2.7.

4. Linked queries

This use case exploits the LINK class that is associated with RECORD_COMPONENT. Through this class any concrete instance of RECORD_COMPONENT (i.e. FOLDER, COMPOSITION, SECTION, ENTRY, CLUSTER, ELEMENT) can act as the source of one or more LINKs. Each Link specifies one target component, which itself might be any RECORD_COMPONENT, and optionally permits the composer to label the Link to indicate its clinical role.



A further and important feature is the follow_link attribute, which indicates how the LINK should be managed during EHR_EXTRACT generation. If follow_link true, the composer intended that any EHR extract that includes the COMPOSITION containing the source must also include the COMPOSITION containing the target. This is a safety feature, but is not likely to be the commoner scenario. It is more likely that follow_link will be false, in which case the recipient of a source component will know that a Link exists, what label it has, and the identifier of the target. It will then be for local policy or user choice whether additionally to request this target or not.

One casualty of the indelibility of EHR entries within an EHR system is that a target component will not normally contain any information that it is the target of a Link. This might not matter, except in the case where follow_link is set to true on the source of the Link. This implies that the composer intended that the Extract generated in response to a request for the source should automatically also include the target COMPOSITION. However, the reciprocal should also occur i.e. any extract containing the target should automatically include the COMPOSITION containing the source. It will be a matter for individual EHR system vendors to identify appropriate means to ensure that EHR_EXTRACTs conforming to this standard always contain both source and target RECORD_COMPONENTS when a LINK instance has the follow_link attribute with a value of true.

What about the SCC?

ENV12265 defined two classes of View Record Item Complex, one dealing with query specifications (use case 2 above) and one dealing with absolute references (Use Case 3 above). ENV13606 combined these into a single class, the Selected Component Complex, but did not elaborate formalisms to be used to populate instances of these. The requirements underpinning the SCC are important, and this standard separates out the two use cases (2 and 3 above) and proposes different and more appropriate mechanisms for handling each.

What about the Link Item?

The research work on the Link Item arose late in Synapses, was fed into PT26 and adopted in ENV13606, and implemented at UCL as one of a set of approaches for handling linkage. UCL found that the strength of the Link Item was its ability to be authored, attributed and revised independently of the components that were the source and target of that link. However, a corresponding disadvantage was that a link had to be specifically created as an independent entity and, importantly, that it was a part of neither source nor target, requiring great care when either source or target were extracted. The use case for being able to create links "with the benefit of hindsight" between a pre-existing source and a pre-existing target is recognised. However, for safety, it has now been proposed that the Link is formally a part of the source component, not a separate class within an independent Composition. This does require revision of the source, permitting the attribution of the Link to the reviser and documenting the date and time of its addition.

Example A. Simple Link

The example below (Figure 1) shows two consecutive COMPOSITIONs. The first (C1) being a record of an excision biopsy of a lump in the patient's left forearm. The second (C2) is an urgent attendance with infection which the doctor regards as a complication from the surgery.

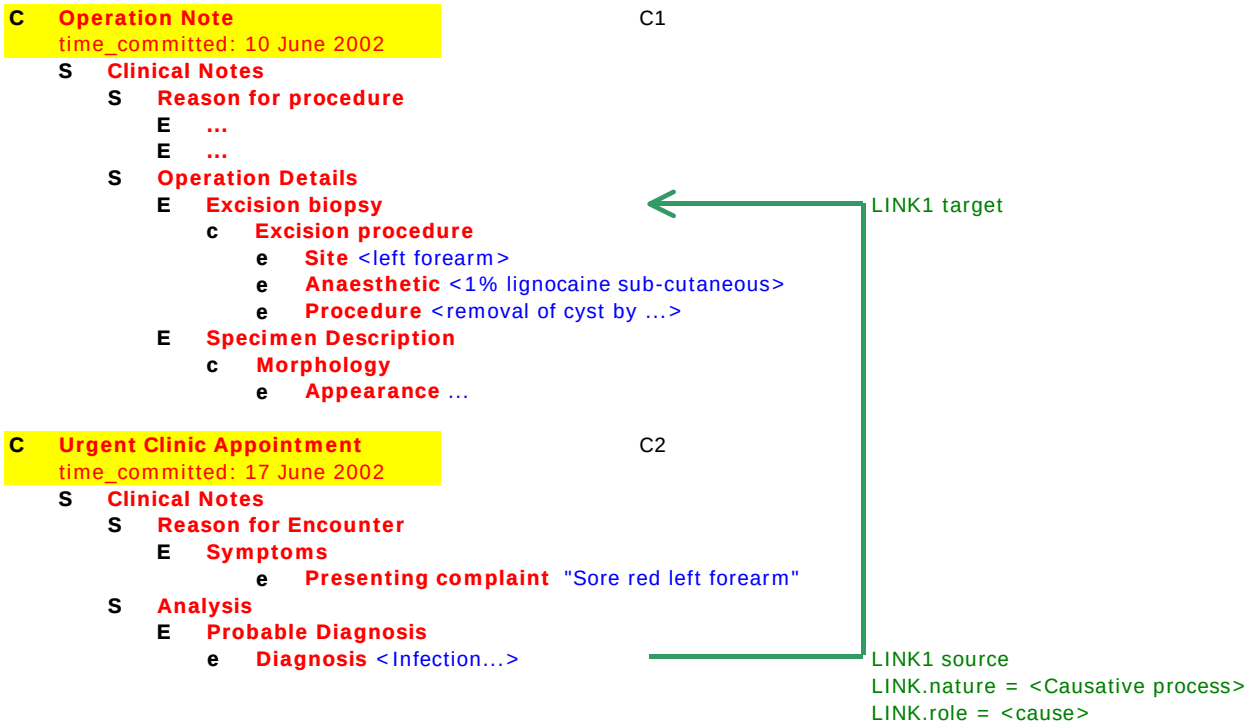


Figure 1

While authoring COMPOSITION 2, the doctor has inserted a Link (LINK1) from the ELEMENT recording his Diagnosis to the ENTRY documenting the Excision Biopsy to indicate the causative process underlying the infection.

Example B. Linkage Hub

Figure 2 below shows two GP consultation COMPOSITIONs. In the first (C3), the patient presents to the GP with a history of wheezing, which the doctor considers might be due to asthma or to a viral infection. He prescribes Ventolin (an inhaler often used to treat asthma attacks), perhaps on a whim to see if the patient improves on this (no debates please on the clinical judgement shown here). In the second consultation (C4) the GP notes that the patient has improved, and now documents that the patient does indeed have asthma as a clinical problem.

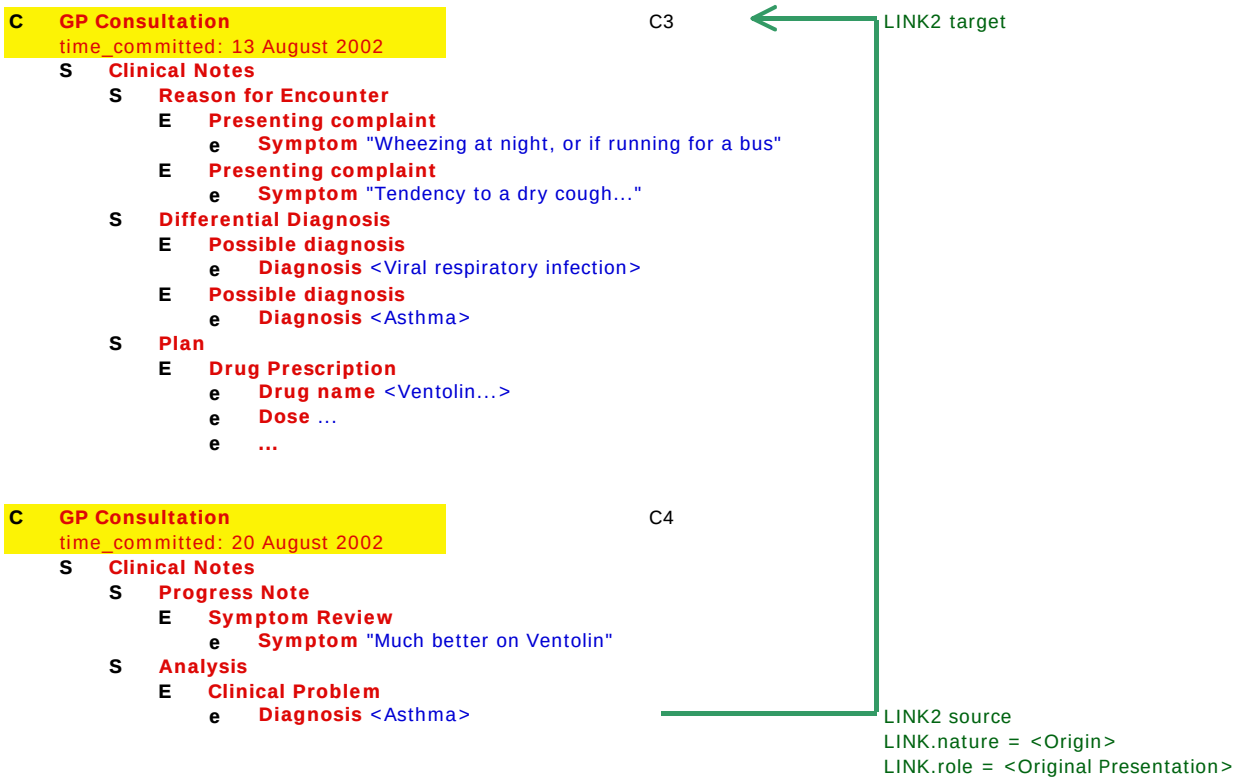


Figure 2

The GP records a link (LINK2) between his documentation of this new clinical problem and the original consultation when the patient presented, since this contained the history etc. that originally led to this diagnosis.

In Figure 3 below a third COMPOSITION (C5) has been added, and the second one (C4) has been revised. The third COMPOSITION (C5) is an asthma review, at which the patient's regular asthma treatment is defined (the patient is put on an inhaler that is considered more suitable for regular treatment, as opposed to Ventolin that is more commonly used for acute situations).

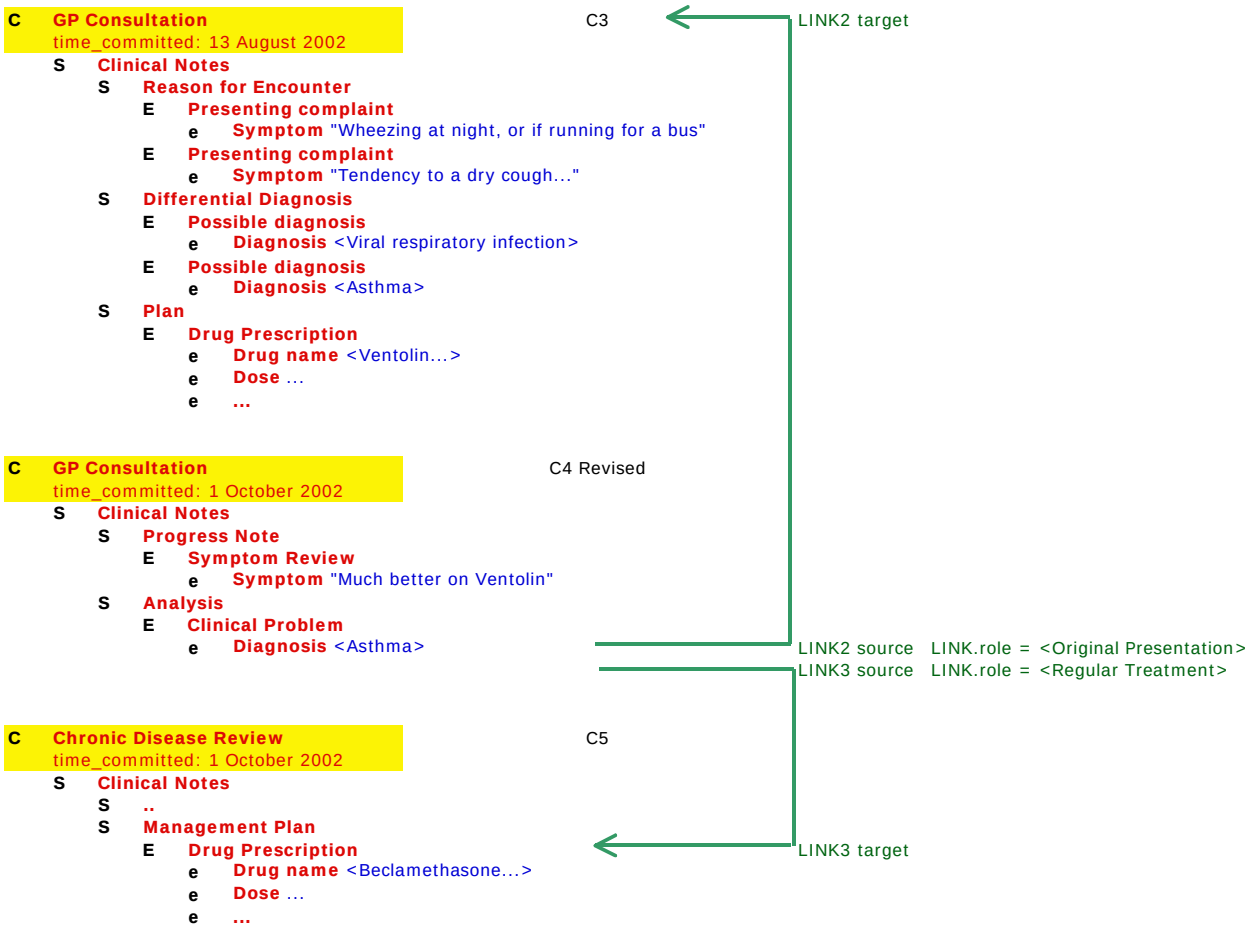


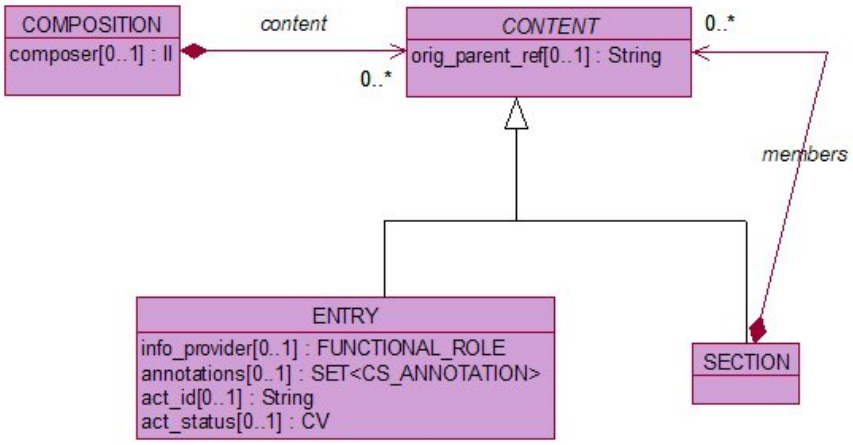
Figure 3

Having established the Clinical Problem of asthma in the record, the doctor wishes to use this as a linkage hub. He therefore revises that second consultation (C4) to add a new Link (LINK3) from the clinical problem to his new regular treatment.

In this example the doctor has chosen to regard the entry defining the patient's asthma as a clinical problem as a kind of hub or anchor point in the record. In the future he may wish to add further links from this clinical problem hub to successive asthma related consultations, so that it is possible always to extract all entries relating to asthma by following the links from the this anchor point. He would do this by further revising C4.

B.3.2 Re-use of components

This Section illustrates the ability to re-use Components. The critical feature is the orig_parent_ref attribute in CONTENT (inherited by both SECTION and ENTRY).



Clinical scenario

1 week ago, as part of the recording of a Health Check COMPOSITION, a SECTION on “CV Exam” under “Physical Exam” recorded some observations as ENTRYs for BP, Heart Sounds, and Weight, conforming to an established Section Archetype CV1.

Today, as part of a Diabetic Review, recorded in a new COMPOSITION, the Clinician wants to include a SECTION for today’s CV Exam, using the same Archetype CV1. However, whilst the BP and Heart sounds are taken afresh today, he wants to re-use the weight as measured 1 week ago. This situation would be satisfied in the model as follows.

	rc_id	orig_parent_ref
(1 week ago)		
C Health check	01	
S Physical exam	10	
S CV Exam	20	
E Blood pressure	21	
E Heart sounds	22	
E Weight	23	
(today)		
C Diabetic Review	50	
S CV Exam	60	
E Blood pressure	61	
E Heart sounds	62	
E Weight	23	20

Key:

- C Composition
- S Section
- E Entry
- c Cluster
- e Element

(indentation implies Containment)

Archetype CV1 specifies

S	meaning = "CV Exam"		
E	meaning = "Blood Pressure"	as	c
E	meaning = "Heart Sounds"	as	c
E	meaning = "Weight"	as	e

Each component has been given a numeric identity as the value of the attribute rc_id inherited from RECORD_COMPONENT. The orig_parent_ref attribute of the CONTENT class is also shown; all except the weight in today's COMPOSITION are null.

Effectively last week's Weight (with all its inherited attributes) will be logically copied as today's Weight ENTRY within today's SECTION "CV Exam".

An application could, if necessary, find the original context attributes of the Weight Entry by looking up the Component whose identity is given by its orig_parent_ref attribute.

This mechanism applies equally to SECTIONs and ENTRYs.

The ENTRY is the lowest level of granularity supporting re-use, since CLUSTERSs and ELEMENTs are intended to represent only parts of the ENTRY's data structure.

B.3.3 EHR roles and responsibilities

Performing a care act in a modern health service can involve a large number of actors, with different roles and responsibilities, each of whom might need to be represented in a patient's EHR. The approach taken in most generic EHR architectures, including this standard, is to differentiate these into three broad categories.

A. Actors playing a role in the actual health care process.

This set will usually include a core party who is the key person relating to the patient during that act (e.g. during a forceps delivery in an industrialised country it will normally be an obstetrician), and a series of related parties who may be providing or supporting parts of the care (e.g. midwives), are involved in making decisions (e.g. an anaesthetist), are observers (e.g. medical students), or are present to support or co-represent the patient (e.g. the patient's husband). These actors might not all be present: for example, the policies of a consultant in charge of care may be followed because the patient is under his team, even if he is himself not with the patient on that occasion. Sometimes an EHR Composition might be documenting a case review or a care planning negotiation involving one or more professionals but where the patient is not present.

B. Actors contributing to the process of generating the EHR Composition documenting the care act.

This will usually be a subset of those involved in care (and most commonly, the key actor), but might include people who were not part of delivering the care (e.g. a secretary or a transcriptionist) and may (more so in the future) include the person who is the subject of their care. It is important to recognise that the different actors will often complete different records of events and attest them independently.

C. Actors confirming the validity of the documenting Composition.

The paper analogy of this is the signing of a letter or report. Most commonly the act of signing a document combines two intentions: to confirm that the document is correct (e.g. free of typos and omissions) and for the signer to confirm that he agrees to the content (e.g. to validate a prescription). In most of these situations the status or seniority of the signer is important. Some of the actors described in a care act will not themselves sign the COMPOSITION or the ENTRYs describing their contribution to care: much of healthcare works through delegation. For example, the medical record documentation made by a junior doctor on a ward round is rarely reviewed by the consultant and almost never countersigned. Most observations on a monitoring chart are not individually signed. With electronic systems this practice might change, but some level of delegation and trust will probably always exist within care teams.

Clearly there is a wide range of potential roles and responsibilities that might need to be represented in an EHR, and as patterns of health service evolve these might change in the future. The goal of the EHR_EXTRACT architecture is to permit any number of "participations" to be defined within a COMPOSITION: either for the whole COMPOSITION or more narrowly for individual ENTRYs.

The approach taken in this standard (as in other EHR architectures such as ENV13606 and HL7 CDA), is:

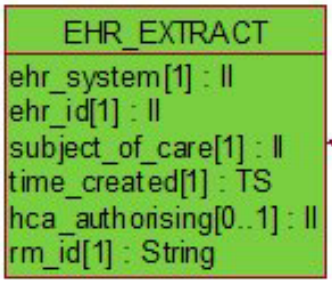
- to specify a small number of roles that need to be unambiguously communicated to ensure safe interpretation of EHR_EXTRACTs by a receiving system, and which are likely to arise frequently;
- to permit other *ad hoc* participations to be defined by health services, systems or in individual EHR instances at the COMPOSITION or ENTRY level;
- to permit any number of attestations to be added to the EHR, to sign COMPOSITIONs or to permit attestation only of parts of COMPOSITIONs. Attestation may take place during, or any time after, the committal of the RECORD_COMPONENTS, but the act of attestation does not cause a formal revision of this EHR data (no new version is created).

The specific roles that have been defined in this Reference Model are discussed below in three sub-sections.

A. Defined roles relating to the health care process

1. Subject of care

It is assumed that each EHR, and therefore any EHR_EXTRACT, will be about the health and health care of one person, who is also in data protection terms the data subject. This does have important implications for data contained in that EHR that might relate to a different data subject (as in the case of family history); this is discussed below under Subject of Information.



Several “special case” exceptions are often cited to the norm that each EHR is about one data subject.

Pregnancy: here it is usual practice for the mother’s record to contain the full pregnancy care record including that of her baby or babies until after birth, when any relevant information is copied into the new records of those babies.

In utero interventions: in some situations a new record is created well before a baby is born, perhaps if significant health care is required. In such situations the new record is being created for the foetus as a convenience to permit a separation of data from the mother’s record, and in anticipation of a new legal record for the baby. Depending upon the age of the foetus, and the laws pertaining to each country, either the baby or the mother will be the legal data subject, but in any case there is still a single identifiable subject of care for each record.

Multiple pregnancy with each foetus having its own record: this is often cited as a situation in which health actions might really “belong” to two or more subjects of care. In these situations it would seem logical that each baby's Extract contains a copy of the relevant COMPOSITIONs, rather than attempting a complex join between two or more records to reference a single COMPOSITION held in one of these records. (Of course, more complex cross-linkage arrangements might be made within local EHR systems, permitting users to enter the data once and have it logically added to both records).

Siamese twins: yes, there has been discussion on such rare cases! Again in this case it seems logical and safe for each twin to have a copy of the relevant COMPOSITIONs, whenever separate EHRs are created, rather than inter-linked record extracts that might not be safely managed by receiving systems.

Donated organs: Some test results relating to the donor of an organ may be appropriate to store in the EHR of the person receiving the donated organ – such as the viral status of the donor and in future the genetic record of the donor – as the person will from this time on be a genetic mosaic. For this reason, the subject of the information of some information in the EHR may be "donor".

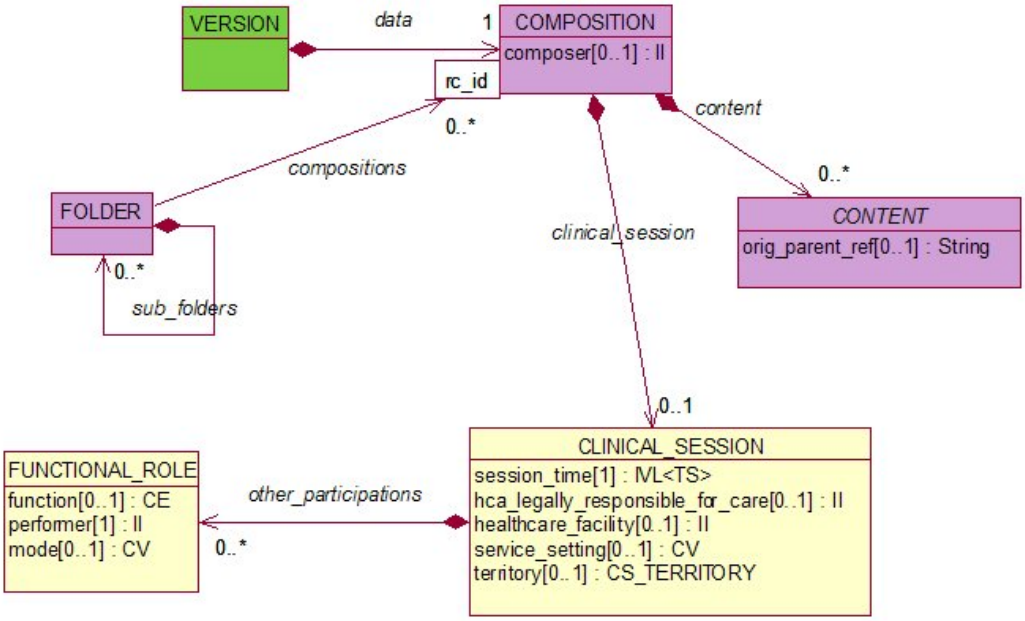
The proposal for the subject_of_care attribute is that it will contain a snapshot of patient demographic information of the subject of care from whose EHR the extract is taken. This snapshot is based on the relevant GPIC: SubjectOfCarePersonIdentification.

Subject_of_care is defined at the top of the model in the EHR_EXTRACT class.

2. HCA_legally_responsible_for_care

Much of daily health care is delivered by junior team members (in-training grades, particularly in hospital) working with delegated responsibility. Many requirements sources refer to the need to be clear about the person with senior clinical (and therefore legal) responsibility for the provision of a service. This person might not be personally involved in delivering the care that is described in a COMPOSITION.

This attribute of CLINICAL_SESSION is therefore to represent the healthcare agent with senior clinical responsibility for the patient at the point of care documented by the COMPOSITION. It is optional, and might not apply, for example, to patient-authored COMPOSITIONs.



The CEN CONTSYS standard is presently being revised, and the class containing this attribute might be updated to harmonise with that work.

3. Composer

This attribute is described in section B below. The composer will almost always be the key actor in the delivery of a health care act being documented. If not, the key actor or actors will need to be identified through the COMPOSITION.CLINICAL_SESSION.other_participations and ENTRY.other_participations attributes.

B. Defined roles relating to the EHR information

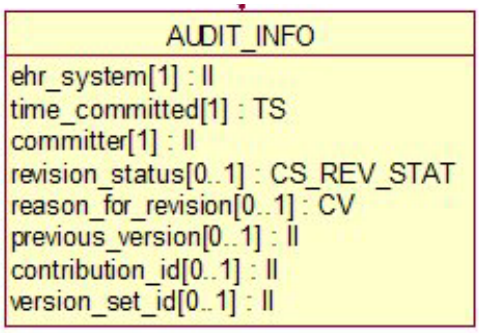
1. Composer

This actor is the person who has actually composed the words, terms, figures, values etc that are represented in the COMPOSITION. The composer will almost always have played a key role in the information gathering, thinking or actioning aspects of the health care being documented. Sometimes, though, he or she might be a junior team member writing up the notes on behalf of a team. Even so, it will be the composer's words or phrases that shape the documentation. The role of team members other than the composer can be added as other_participations (in the CLINICAL_SESSION). Individual ENTRYs can also be separately attributed via an other_participations association.

The Composer attribute therefore represents the party who composed the data in a COMPOSITION, irrespective of who committed it or who attested it. The COMPOSITION will be seen as being 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 for display purposes.

2. Committer

In many situations the person who composes the words is not the one who keys them in. A common example is dictated letters and reports, which may be typed up by a secretary or transcriptionist. A junior clinical team member might also describe himself as the committer if he is really only acting as the scribe for another (composing) senior team colleague. In some transcription scenarios the typed text is checked by the composer who then commits it to the patient's EHR himself. In some scenarios several clinical team members are working in collaboration to deliver a care service; each of these might be able to document (and attest) their own portions of this care in the patient’s record.



Other situations might arise in which the committer is not responsible for data entry, for example when a measurement device is directly feeding a clinical application. In these situations the information_provider or other_participations attributes can be used to supplement the set of defined actors.

3. Authoriser

The (optional) hca_authorising attribute of EHR_EXTRACT identifies the party who authorized this Extract to be taken from the record, if this is specified. This authorisation implies that the party has checked not only the content of the Extract but also that any necessary checks on suitable regulatory frameworks at the receiving end have been carried out.

4. Subject of information

This attribute is needed to identify the person about whom the information in an ENTRY relates if not the subject of care e.g. if the information is about a family member, such as the patient's father or mother. This is regarded as an important "safety" attribute to supplement any meaning implied by a component name or archetype, particularly if records are communicated across countries and languages.

In some contexts parties might only be specified precisely if they are registered within the local demographics service AND they have given their consent to be identified in this patient's EHR. This will increasingly arise in clinical fields like cancer genetics that manage patients within their family context. The commoner situation is where the patient is describing the health of others.

The subject_of_information association from ENTRY refers to the class RELATED_PARTY, permitting the relationship of that subject to the patient to be defined as a coded term, and optionally also through a party identifier (probably linking to the demographics service within the EHR system).

This approach will allow archetypes to be reused with different subjects of care, and the processing of EHR ENTRYs unambiguously to distinguish data about the patient from data about other parties.

5. Information provider

Most of the information documented in an EHR will originate from the patient or one of the participants in the care act. However at times ENTRYs may be added whose data values have originated from some other party, for example a relative or carer who might be with the patient or seeing the patient's doctor on their own, perhaps confidentially. Other clinical parties might provide information indirectly (e.g. by phone, to the composer).

The info_provider association from ENTRY refers to the class FUNCTIONAL_ROLE, permitting their function and mode of contribution (by phone, in person etc.) to be represented. As with Subject of information, the party might or might not be formally identified, depending on consent and if they are registered in the local demographic service. The formal identification of information providers provides one way for a composer to attribute some ENTRYs in that COMPOSITION to other clinicians or to devices (other_participations is another way).

C. Attesting the data

Attestations to parts of or whole COMPOSITIONs may be added by any of the party roles mentioned above, or by any other third party, at the same time as the data are committed or at any subsequent point in time. The class ATTESTATION_INFO is anchored (as an association from the class VERSION) to a single version of a COMPOSITION, but the target of the attestation might be any finer grained parts of that COMPOSITION, or indeed to the FOLDER which contains that COMPOSITION and others. Attestation is discussed in more detail below

B.3.4 Attestation

The attestation of a RECORD_COMPONENT is a mechanism whereby the attester can provide his authority that the contents of that RECORD_COMPONENT are, in his opinion, correct. This means that he is satisfied that the contents are a fair and faithful reflection of the processes they document, and do not to his knowledge deliberately misrepresent the truth.

Attesting a RECORD_COMPONENT will not have modified its content or interpretation, other than by adding weight to its authenticity. (Anything which added an opinion, a new viewpoint or perspective would have been either a revision or a new RECORD_COMPONENT with a link to this one.)

Clearly any modification to a RECORD_COMPONENT through revision cannot automatically carry forward any previous attestations - if necessary the original attester would have been invited to re-attest that he remains happy now it has been modified or the reviser attested the new version, or both, or neither.

There has been much debate over many years about what information needs to be retained within electronic systems:

a) to verify the authorisation of the attester (ranging from a simple flag to indicate that he had been authenticated in that system's normal way, to a complex hash of the user's digital key, date and time, and part or all of the document being signed, and optionally sent to a trusted third party notary service)

b) as a permanent legal record of what was attested (ranging from no specific addition to the raw database record that is being signed, to XML output files WITH stylesheet as a proxy to show how it was presented, to bitmaps of each screen as it was actually presented for signature).

Clearly a wide range of options exists now and an even wider set will exist in the future, and it is difficult to predict how far society and lawyers will require health informatics to go in establishing the proof of what was signed. Fortunately, this standard does not need at this moment to standardise the approach that must be taken across every European health service to this evolving challenge.

When communicating a RECORD_COMPONENT, it would normally be appropriate to communicate the set of attestations that pertain to it, specifying the parties who have attested it and when they were each added. There may be a need to include a ‘purpose’ for the attestation, although the purpose is normally to verify its faithfulness.

A simple attestation data set will normally be accepted for communication between accredited systems within a health service, without the routine need to transfer proof. It may be appropriate in some circumstances, however, to include the "proof" in some form, but it is far more likely that the proof will reside at the institution that committed and attested the RECORD_COMPONENTs, and be available on request for those occasions when deliberate falsification is suspected. The transfer of proof is probably going to be to a lawyer, and not as part of routine clinical shared care, except perhaps for a few specific medico-legal documents.

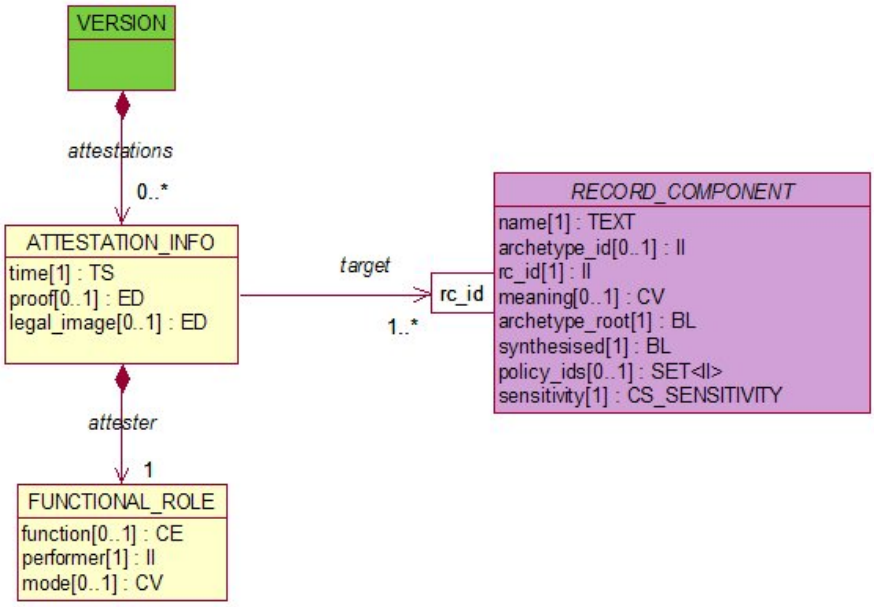
In the EHR_EXTRACT:

1. Attestations are associated with the class VERSION, which is itself associated with a specific COMPOSITION version.

2. Attestation details may apply to any RECORD_COMPONENT, including data within a COMPOSITION, or to specific FOLDERS.

3. Attestations may optionally include some form of proof (as encapsulated data), and a copy of or reference to a screen image or other legal artefact to indicate exactly what was “signed”.

4. Each new attestation applies to a particular version of a COMPOSITION, and attestation is not automatically carried forward from one version to the next. However, attestations referencing unchanged parts of a COMPOSITION may be included within a revised version if appropriate, and can be distinguished from newly added ones by the attestation time.



B.3.5 Revision

Revision is an important and potentially complicated area. In addition to the well-known medico-legal requirements for tracking and attributing revisions, the following functional requirements have underpinned the approach taken.

1. The vast majority of requests for parts of or whole EHRs will warrant the generation of an extract that contains the most up-to-date versions of the contained RECORD_COMPONENTs.

2. Even in such situations, it may be helpful to know that the communicated RECORD_COMPONENTs have been the subject of a correction.

3. There will be an infrequent need to transfer serial versions of RECORD_COMPONENTs for clinical care purposes, for example to explain an error.

4. There is a need to be able to transfer a whole EHR, including all versions of revised components, for example when care is legally being transferred between enterprises.

5. The COMPOSITION should anchor the communication of committal and revision within the EHR_EXTRACT, even though the changes made through a revision might only affect a few of its contained components.

6. The evolution of FOLDERs over time may also need to be similarly revision-managed, although this will usually be within EHR systems and a FOLDER feeder audit will probably only occasionally be included within an EHR_EXTRACT.

7. In many cases it might not be legal to communicate errors that have been corrected: revised components should therefore not “contain” the original data that has been corrected, even if marked as logically deleted. For example, erroneous data corrected at the request of a patient must not be communicated according to EU Directives and most national data protection legislation.

A variety of techniques exists for version-tracking of modifications within databases, any of which might be used within individual EHR systems. The approach taken for this standard is to specify a structured way in which the necessary clinical and medico-legal requirements can be met within an EHR_EXTRACT, without prescribing any particular versioning methodology to be used inside these EHR systems.

Specifying the granularity for representing revision

It is important that the model for representing EHR communications is able to represent the data in the feeder systems contributing to it as faithfully as possible. Clinical systems vary in the level of granularity at which information is committed, attested and potentially revisable. For this reason the class RECORD_COMPONENT has a feeder_audit association permitting the representation of the committal of a revised version of any component, its revision status, the reason for revision and a reference to the previous version. It might be the case that a RECORD_COMPONENT is revised within an EHR system other than the originating one.

It is also important that systems in receipt of an EHR_EXTRACT are able to incorporate this information as faithfully as possible. This includes being able to reconcile serial versions of Extracts over time, some of which might contain revisions of RECORD_COMPONENTs originally communicated in previous EHR_EXTRACTs.

In the EHR_EXTRACT, the COMPOSITION class functions as the container class for sets of RECORD_COMPONENTs that are to be communicated. Each such set has a second audit trail, indicating its committal to the EHR_EXTRACT and, if it is a revision, references to the previous version of this COMPOSITION.

How to tell what has been revised?

It is often not appropriate, nor even legal, to communicate errors and versions of EHR information that have been modified, perhaps at the request of the patient. For the majority of clinical purposes, a receiving system only needs to know about the latest version of the data. A revised version of a component therefore contains only a minimal set of information to indicate that it is a revision and why. An EHR system that is permitted to, and has, the successive versions is in a position to reconstruct the evolution of the data in support of a legal or clinical review.

In the following example, a differencing comparison between COMPOSITION 01 and 51 would reveal that the diastolic BP ELEMENT (22) had changed (to 52). Further investigation would show that the systolic blood pressure value had not been changed.

Example

Figure 4 shows the simplified representation of a COMPOSITION about a health check-up, committed by Dr Jones on 1st January 2002. Class names are shown at the beginning of each line

C = COMPOSITION
S = SECTION
E = ENTRY
e = ELEMENT

Containment is implied by paragraph indentation.

The name attribute of each RECORD_COMPONENT is shown in red, and its identifier as a green integer. If any component was a revision, the identifier of its previous version would be shown in red. Relevant committal or revision attributes of the COMPOSITION are shown on a yellow background. This first example shows an original version

					rc_id	previous_version	
C		Health Check-up			01		<<Original
	audit_trail	time_committed		2002-01-01			
	audit_trail	committer		Dr Jones			
	S	Physical Exam			02		
		E	Height		03		
		E	Weight		10		
		E	Blood Pressure		20		
			e	Systolic BP 120	21		
			e	Diastolic BP 80	22		

Figure 4

On 1st March 2002 Dr Jones corrected an error in the recording of the diastolic blood pressure, as shown in Figure 5 below.

					rc_id	previous_version	
C		Health Check-up			51	01	<<First Revision (Diastolic BP)
	audit_trail	time_committed		2002-01-03			
	audit_trail	committer		Dr Jones			
	feeder_audit	time_committed		2002-01-01			
	feeder_audit	committer		Dr Jones			
	S	Physical Exam			02		
		E	Height		03		
		E	Weight		10		
		E	Blood Pressure		20		
			e	Systolic BP 120	21		
			e	Diastolic BP 90	52	22	

Figure 5

The new ELEMENT for the corrected Diastolic BP has a (new) rc_id of 52. Note, however, that the whole COMPOSITION has been revised and has a new rc_id of 51 (its orig_parent_ref is 01). This latter revision would be required in the EHR_EXTRACT, if both versions of the data were to be communicated.

The recipients of this COMPOSITION would know that the details in it include a revision, which component was revised and why.

Note that all the content values of the data within the COMPOSITION are directly available, so there would be no immediate need to access earlier versions, unless some kind of ethico-legal enquiry were needed.

Some months later Dr Smith realises that the patient's weight had also been incorrectly recorded, and makes a further revision as shown in Figure 6 below. This time, perhaps, it is an aspect of the ENTRY that has been changed (e.g. to alter the information_provider attribute value).

							rc_id	previous_version	
C			Health Check-up				71	51	<< Second Revision (Weight)
	audit_trail		time_committed			2002-12-25			
	audit_trail		committer			Dr Smith			
	feeder_audit		time_committed			2002-01-01			
	feeder_audit		committer			Dr Jones			
		S	Physical Exam				02		
			E	Height			03		
			E	Weight			72	10	
			E	Blood Pressure			20		
				e	Systolic BP	120	21		
				e	Diastolic BP	90	52	22	

Figure 6

This version introduces a new COMPOSITION version with rc_id 71, which now references previous_version = 51. The majority of its components are still re-used originals, but this COMPOSITION now contains two components that have been revised, each referencing their previous versions.

B.3.6 Presentation

Three scenarios that involve presentation information are envisaged.

The ITEM.emphasis attribute may be used for interoperable communication of user-indicated emphasis (e.g. to mark exceptional results) - and it would be up to receiving systems to determine how its local users would wish this emphasis to be presented.

There will be times when more complex presentation features need to be included alongside the data, to prescribe the rendering that should be used (e.g. for some images). These should be managed through archetypes for those classes of data that need a presentation specification.

Some countries (e.g. Germany) now require that a visual snapshot is retained of anything that is digitally signed - so each attestation is associated with a “legal” view of the data and its form/presentation. An attested_view attribute is included within the ATTESTATION_INFO class (data type ED) to permit the representation of this.

Annex C
(informative)

Comparison with ENV13606

C.1 Technical approach to the revision

In defining this model, as a forward evolution from the 1999 pre-standard, a balance needs to be struck between loose and tight specifications.

Advantages of optionality (flexibility):

- the same attributes are available at each point in the hierarchy
- all points in the ENV13606 hierarchy have nearly-identical characteristics (Composition, Headed Section, Cluster etc.)
- there are many loosely-defined attributes ("Related..." attributes, presentation, SCC selection criteria etc.)
- a permissive model is an ideal "universal recipient": almost any system can map easily into it with minimal effort
- there is considerable flexibility in how each class and attribute may be used.

However, this very flexibility also counts against its value for true interoperability, which requires that systems can import data that was originally created through a different vendor's conformant system. Classes and attributes can be used quite differently, resulting in many different ways to represent the same kind of clinical information, thus creating a significant challenge to being able to import any kind of conformant record components. This requires an import interface that can cope with every combinatorial possibility of uses for each class and attribute. It is generally accepted that the EN13606 model needs to be more constrained than ENV13606 to make interoperability more reliable and rigorous.

Consistent class and attribute use is also important in helping to build up consistently-structured longitudinal EHRs for patients and across populations.

In developing the Reference Model for this standard, several matters of technical approach were defined. Firstly that the focus of this standard is EHR communication and distributed access, not the internal model of an EHR system. The main areas of change in comparison with ENV13606 are summarised below.

1. Revised the reference model to make it more rigorous

- retained the main ENV classes: Folder, Composition, Headed Section, Cluster
- provided more focused containment rules, making the role of each class more explicit
- formalised the lower-level (ITEM) class structure, taking advantage of archetypes and of the new CEN data types
- reduced excessive inheritance of attributes
- put “context” attributes at the right hierarchical level
- provided more explicit attributes, fewer “related” classes

2. Incorporated archetypes

- an archetype model (in Part 2 of this standard)
- specific normalised archeypes (in Part 3 of this standard)

3. Simplified the distribution rules

- focus is on representing access control information, and re-using other (existing and new) security standards (in Part 4 of this standard)

4. Avoided the repetition that exists in the previous Part 1 and Part 4 - to be reflected in part 5 of this standard

It is recognised that implementers and EHR demonstrators have made use of ENV13606, either as a basis from which to specify messages for clinical communications, or as a basis for the internal database schema within EHR-like systems. However, the deployment and use of these systems is still somewhat limited. The experience gathered in drafting this new standard suggests that these implementations have all built on ENV13606, rather than used it precisely. This has the drawback that most of these implementations are not mutually interoperable with a consequence that, whatever constructs are included in the new standard, some amount of interface adaptation and/or systems redesign will be necessary to conform to it.

The main constructs of the ENV 13606 Extended Architecture are listed in the following sections. The additional or corrective goals/requirements for each class or attribute are given first, and then rationale for the modification adopted in the new model is summarised.

This Annex does not describe the complete set of requirements underpinning the old or the new model. A mapping of the new model to the ISO EHR architecture requirements is given in Annex E of RFC 13606-1.

C.2 Strategic influences on the 13606 revision

- Desire for more robust interoperability

In particular, IMPORT interoperability

- revising the attributes that are imprecisely specified

- reducing the degrees of freedom for containment (to reduce the number of alternative ways that might be used to represent the same record structures)

- Utilise the CEN data types and GPICs

Removing the need for most of ENV13606-1 Section 8 (Attribute data types, common classes and sub-classes)

- Incorporate archetypes

Resulting in changes to the component name structure and removing the need for component name categories in the old Part 2

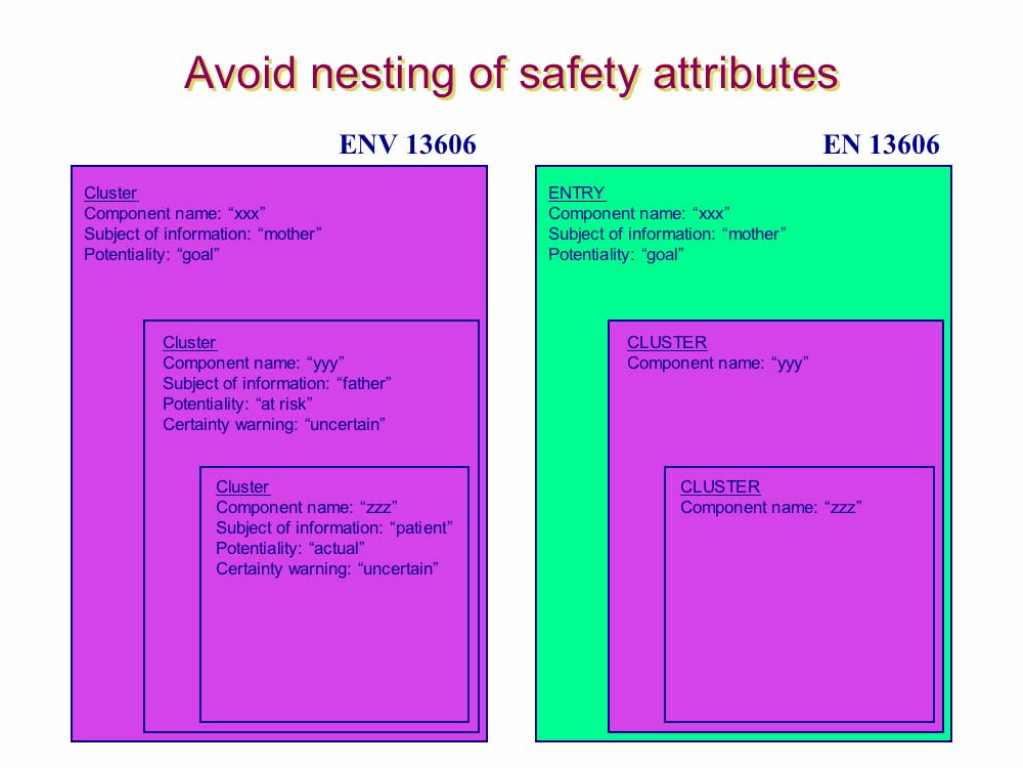
- Optimise interoperability with HL7

C.3 General aspects of the approach

- Adopt the GPICs for demographics
- Adopt the CEN data types
- Harmonise with HISA and Contsys in relevant areas
- Interface with ISO Privilege Management and Access Control Task Force on access policy representation
- Build on the assumption that Europe will progressively be using a mixture of CEN and HL7 messages for communicating clinical data: map the new model to the RIM and produce a D-MIM from it
- Rename attributes to make their meaning and use clearer and/or more compatible with GPICs and HL7
- Avoid inheriting attributes down the Record Component hierarchy if they do not pertain to all levels

- Avoid the possibility of confusing containment of attributes (e.g. negation, subject of information), by using non-recursing classes to represent specific areas of medico-legal or safe-interpretation context (e.g. Composition and Entry rather than Section and Cluster).

  [For example, the ENV Cluster OCC contains a set of annotation identifiers including negation. Since a Cluster OCC may contain additional Clusters it is possible for a Cluster that is negated through an annotation to contain others that are also negated, and so on. The meaning of negated information containing negated information is ambiguous and may be completely uninterpretable. In the new model the Entry class is used for such annotations. Since an Entry cannot contain a further Entry, it is no longer possible for the negation annotation to be recursively contained.]



The diagram above shows a potentially ambiguous (uninterpretable) set of nested Clusters that would be conformant to ENV13606, and how the model of EN13606 seeks to avoid the risk of such a representation.

C.4 Specific aspects of the approach

C.4.1 Attestation

- To represent the addition of attestations after committal
- Optionally to include a copy of the image or view that was legally signed

ENV 13606 included the attributes agent, date-time, reason and signature

EN13606 has added an attested_view attribute, to meet new legal requirements (e.g. Germany) and to harmonise with HL7 (CDA)

The main change is that Record Components do not now contain their attestations A container class Version relates one version of a Composition to any attestations of that Composition or of Record Components contained in it. This permits subsequent as well as contemporaneous attestations without having caused a revision of the component (e.g. the addition of a co-attestation). As in the original ENV, revised versions do not automatically acquire the attestations of former versions (for legal reasons).

ENV 13606: Attestation Information class	**EN 13606: ATTESTATION class**
Attesting agent	FUNCTIONAL_ROLE.performer
Date and time	time
Reason for attestation	FUNCTIONAL_ROLE.function
Proof	proof
	attested_view

C.4.2 Revision

- To ensure compliance with data protection legislation (no new requirements)

Following much debate last year the consensus has been to leave the approach to representing revision information largely unchanged from the approach taken in ENV13606 Revision Information. Any Record Component can therefore carry with it the information that it is a revision of a previous Record Component, the reason for the revision, and a reference to that preceding version but, as in the ENV, the EHR_Extract does not automatically include that previous version for medico-legal reasons. (These revision attributes are now

ENV 13606: Revision Information class	**EN 13606: AUDIT_INFO class**
Revised version reference	previous_version
	version_set_id
Reason for revision	revision_status
Reason for revision comments	reason_for_revision

combined with committal information in the Audit_info class).

C.4.3 Distributed version management

- To facilitate (during import) the reconciliation of multiple or serial changes within a Record Component hierarchy

The new model treats the Composition as the unit for the communication of revision history for the Extract. This does not limit the freedom of EHR systems to internally represent revision using any classes of the Record Component hierarchy. Each set of changes made at any level of the EHR (except Folder) are incorporated into a new Composition within the Extract and stamped with change management meta-data using the audit_trail association from Version, so that the receiving system can reconcile this data more consistently with any previous version it holds.

(Note that all Record Components, including Composition and Folder, have a feeder_audit association to Audit_info to represent faithfully the actual committal and revision information in the EHR-provider system.)

C.4.4 Links

- To enable a direct and labelled link between any two Record Components at any hierarchical level
- To permit any class of Record Component to act as the hub of a linkage network
- To ensure that recipients of any two critically-related parts of an EHR receive both parts in an Extract (even if only one was part of the original request)

The new model extends the functionality of the Link Item to any Record Component:

- additional Targets can be added and separately labelled
- one component can act as the hub of a linkage network
- links can be established directly between any two components e.g. between two SECTIONs
- links can be “required” to be followed when creating an EHR_EXTRACT, for clinical safety purposes (using the follow_link attribute)

An ELEMENT with two Link associations (one for Source, one for Target) will behave exactly as the ENV Link Item. It has:

- known committal, revision, attestation information
- is separate from either Source or Target of the link
- references one Source and one Target Record Component

The Link class also has a follow_link attribute to indicate if the target must be included with the Record Component in an Extract. (This corresponds to ActRelationship.separatableInd in the HL7 RIM). Attribution and version management of Record Components that have Links is handled in the same way as any other Record Component.

C.4.5 SCC

- To be specific enough to support interoperability

This class has been overhauled as its original specification was a placeholder and it did not *per se* contribute to interoperability. (The original specification of the contents of an SCC were to be “enterprise or community defined”). The requirement for an SCC is in any case more appropriate for an EHR system than for EHR communications: in most cases an Extract will contain original Record Components (which might have been pulled out of an EHR system using locally-stored queries or a list of references).

1. Interoperable EHR query specifications that need to be communicated can be represented through the existing classes and attributes, probably as an ENTRY comprising several ELEMENTS with String values

2. References between Record Components can be represented through Links

3. COMPOSITIONs can be contained by reference in multiple FOLDERs

4. COMPOSITIONs might contain data that has been copied from an existing component (e.g. for a discharge summary or report). Recipients should be aware that it is a “copy” whether or not they are allowed to access the original location. SECTION and ENTRY both have an original_parent_ref attribute to indicate the original parent if it is a “copy location”

C.4.6 Originating and Related Health Care Agents

- To be specific enough to support interoperability

The originating health care agent is now called the committer - it might not be a health care agent (e.g. the patient). The “related” attribute is too imprecise to ensure interoperability, at least for key parties that need to be unambiguously communicated in the EHR Extract.

In the new model:

- any Record Component can have any number of attesters

- Composition can have a composer, hca_legally_responsible_for_care, and any number of other participants (not just health care agents)

- Entry can have a subject of information, information provider, and any number of other participants

This set has been deliberately constrained in comparison to the ENV

- to ensure interoperability for the main parties that need to be distinguished medico-legally or for safe interpretation

- placing these in non-recursive classes to reduce ambiguity

C.4.7 Originating and Related times

- To be specific enough to support interoperability

Originating time is now called committal_time, for all Record Components (corresponds to HL7 RIM availabilityTime). The “related” attribute is too imprecise to ensure interoperability, at least for key date-times that need to be unambiguously communicated in the EHR Extract. Specific attributes have instead been added:

- obs_time, in Cluster and Element (corresponds to HL7 RIM effectiveTime)

- session_time, in Composition (corresponds to HL7 RIM activityTime)

It is generally agreed that these three date-times require unambiguous differentiation. Other times can be added as data values, optionally via archetypes.

C.4.8 Presentation

- To be specific enough to support interoperability
- To provide a minimal level of safe interoperability whilst supporting appropriate diversity of detailed requirements

There was much discussion about this last year. There is no generic interoperable specification for presentation. Requirements are very diverse for different kinds of clinical information (from underlining, bold, colour etc for text, to formal rendering specifications for images, overlays and annotations, and time-sequenced video and narration). This specification has largely been left to be included within the archetypes for each kind of clinical information. An emphasis attribute has been included at the lowest levels of the hierarchy as a minimal basis for interoperability.

C.4.9 Root Architectural Component

- To re-scope this class as the formal container of EHR data that has been extracted from an EHR system for the purposes of communication, and to ensure that it can represent the key medico-legal attributes of the extraction process

Now called the EHR_Extract class to reflect that scope. There is now no recommendation that there be one per patient (this was implied in ENV13606-1), and no prescription about how or if these data are held within an EHR system. This class is not intended to represent part of the EHR, but is a container for the EHR data being communicated. Hence it does not include presentation or revision information, component name structure etc. Instead, it contains information about the selection/filtering and time span of the extract. It does specify which EHR system (and optionally which person) was responsible for providing this EHR_Extract. (The EHR_Extract is not itself attestable, although the message carrying it might be digitally signed). The root Folder contained by the EHR_Extract has the necessary Record Component attributes for those other functions of Root Architectural Component, if needed, including attestation.

C.4.10 Record Component

- To retain this as the abstract parent class for Folder, Composition etc.
- To refine its attribute set to reduce ambiguity of use and enhance robust interoperability

C.4.10.1 Component unique identifier

- To avoid confusion with the UMLS CUI

Renamed to rc_id

C.4.10.2 Component name structure

- To revise representation of component names and semantic categories to take account of archetypes

Replaced by attributes: name, meaning, archetype_id, to cater for archetypes

C.4.10.3 Originating healthcare agent, Originating date and time

- To clarify that these refer to the committal process

Renamed “originating” attributes to committer and committal_date_time

C.4.10.4 Related healthcare agent, Related date and time

- To avoid ambiguity and diversity of names for those parties and date-times that are important for the safe or medico-legal interpretation of the Extract

The new model has removed these “related” attributes as they did not support interoperability as they were. Instead specific attributes have been added to the appropriate concrete classes for particular times and particular parties for which unambiguous communication is of greatest importance, and provision is made for additional *ad hoc* participants to be added at Composition and Entry.

C.4.10.5 Revision Information

(no functional change introduced)

Revision information is managed along with other change management metadata (e.g. committal) in the Audit_Info class.

C.4.10.6 Component status

(no functional change introduced)

Component_status has been renamed to revision_status and is represented in the Audit_Info class

C.4.10.7 Attestation

(see earlier in this section)

Attestation of any Record Component has been retained in principle, but the mechanism for this has been revised to cater for the ability to append new attestations without this constituting a revision of the Record Component being newly attested. Attestation relates to a particular version of a Record Component, and is not automatically applicable to a subsequently-revised version of it, for legal reasons.

C.4.10.8 Distribution Rule Reference

- To retain the approach in principle
- To provide an additional simple access control approach

Distribution Rule Reference is now represented through a set of policy_ids (references to policies which will be included in the Extract) and a sensitivity code. This approach is much the same as in the ENV. The sensitivity attribute enables a simpler way of managing access control for those situations where a sophisticated policy-based or role-based approach is not yet in place.

C.4.10.9 Language

- To conform to the relevant CEN data types
- To remove unnecessary attributes

Language is now part of the text data types (CD, CV etc), this applies to attribute names and values as well as Data Values. (This provides better flexibility for multi-lingual situations.)

C.4.10.10 OCC Type

- To remove unnecessary attributes

OCC type etc are not needed, since UML class names define the type of Record Component

C.4.11 Folder

- To permit Compositions to be represented in more than one Folder
- To permit Folders to be entirely optional

There is also a requirement to support the re-filing of Compositions in different Folders over time

Hence Folders contain Compositions by reference

Therefore EHR_Extract contains

- Folder hierarchy by value
- Versions (and therefore Compositions) by value

Folders are no longer open or closed (this is more an EHR system property than a communication one), but they can be attested. This is a recursive class, and it has no attributes other than those inherited from Record Component

C.4.12 Composition

- To support the representation of basic medico-legal attributes of a care session (to be aligned with Contsys)
- To represent certain specific care agents and cater for additional *ad hoc* participation

Added specific kinds of "related" agents: composer, hca_legally_responsible_for_care (and optionally any other participants)

Added session_time (corresponds to HL7 RIM Act.activityTime)

Clinical Session class carries the basic administrative data of a medico-legal nature about the care activity being documented. Any additional and locally-determined information would be added through archetypes.

C.4.13 Section

(no functional change introduced)

Recursive containment, as the ENV13606 Headed Section.

It has only one specific attribute, orig_parent_ref, in addition to those inherited from Record Component

C.4.14 Entry

- To provide a non-recursive containment class to represent specific parties, and concepts corresponding to ENV13606-2 Component Annotations
- To avoid the ambiguity and unsafe possibility of:

  e.g. a class with negation containing a class with negation

  e.g. a class containing uncertainty containing a class expressing uncertainty

  e.g. a class whose subject of information is a particular relative containing a class about a different relative

The Entry is a new non-recursive class, which could be thought of as the root Cluster. Its presence avoids having to place key medico-legal and safe interpretation attributes in a Cluster, which can recursively contain other Clusters.It contains the low-level context required for the safe interpretation of the data structures and data values it contains

e.g. subject of information

e.g. annotations such as negation and certainty

The previous standard permitted recursive containment of such values within the Cluster, which is now recognised as potentially dangerous by CEN, HL7 and SNOMED. Entry caters for a variety of "related" parties; some named directly, others may be added *ad hoc*.

C.4.15 Cluster

- To de-scope Cluster with respect to Component annotations (See Entry above)
- To enable a sufficient minimal representation of time series and tables to support communication
- To enable the minimal communication of emphasised or highlighted information as a safety measure to draw the attention of the recipient to the data

Recursive class, containing few unique attributes, to represent the data structures and/or time series organisation in the underlying system.

Has all of the attributes of Record Component plus:

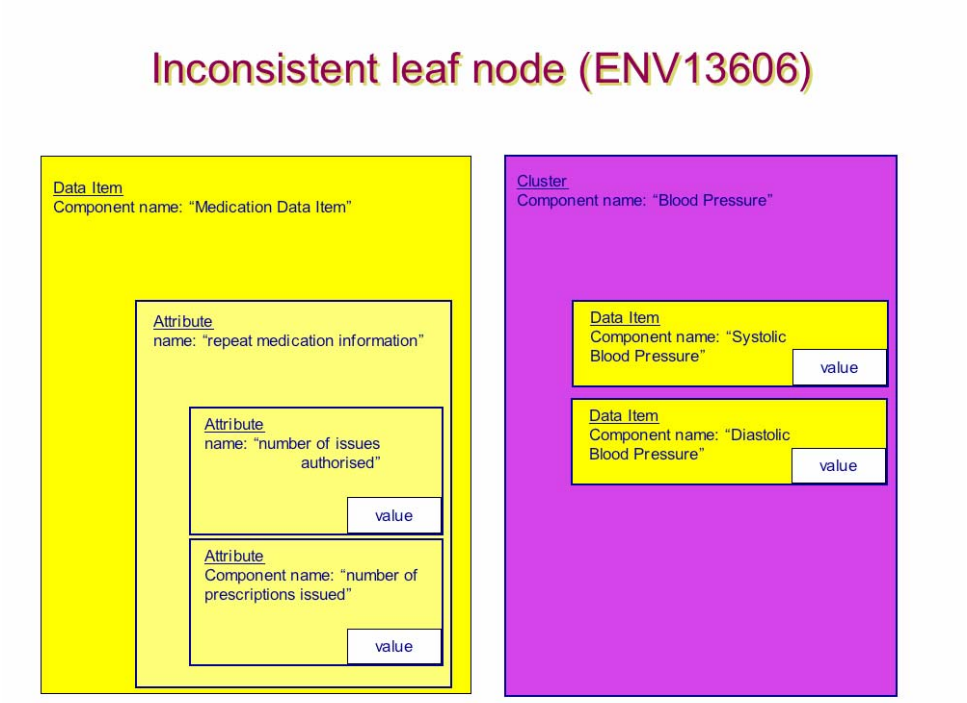
- emphasis (minimal presentation – code set to be defined in Part 3)
- obs_time (for time series)
- structure_type (to indicate if a table etc.)

C.4.16 Element

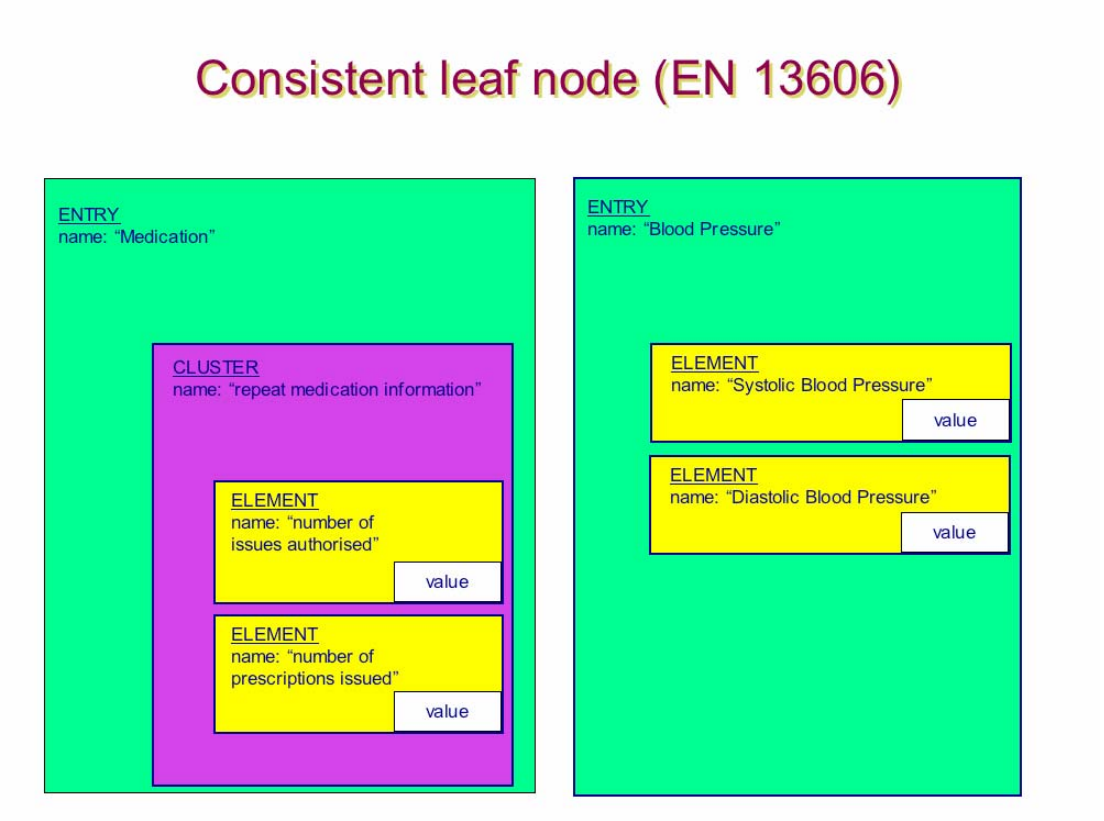
- To constrain the ENV Data Item to behave as a leaf node, with a single primary Data Value

Element is like the ENV Data Item, but it is more strictly a leaf node containing one data value association

Specialisations of Data Item defined in the previous standard (e.g. for medication) would now be handled by archetypes (and in some cases mirroring the appropriate clinical GPIC model). The diagram below shows the kind of inconsistency in leaf node that was possible in ENV13606, and which is now avoided in EN 13606.



The figure below shows the way in which the ELEMENT class is used always to contain a single data value.



This Annex offers a mapping guide between ENV13606-1 and EN 13606-1 to enable implementers familiar with the pre-standard to identify the areas of correspondence, and ease the process of designing migration interfaces. Successive versions of this mapping are likely to be refined as migration experience is built up following final publication of this standard, and it is proposed that a web resource is referenced from this standard and regularly updated as this experience grows.

ENV13606 Class	**ENV13606 attribute**	**Comment on the ENV13606 specification**	**EN 13606 Class**	**EN 13606 attribute**	**Mapping Comments**
Root Architectural Component			EHR_EXTRACT		
	Attestation Information			-	Attestation is considered to apply to particular components of the EHR, not to the EHR_EXTRACT as a whole. The root Folder of the EHR directory can be attested, as it is a kind of RECORD_COMPONENT
	Presentation Information			-	Presentation is considered to apply to particular components of the EHR, not to the EHR_EXTRACT as a whole
	component unique identifier			ehr_system AND ehr_id	
	originating healthcare agent			hca_authorising	
	originating date and time			time_created	
	related healthcare agent			-	Other parties can be specified for particular components in the EHR hierarchy, not for the EHR_EXTRACT as a whole. However, they can be defined in the root Folder of the EHR directory, as it is a kind of RECORD_COMPONENT
	related date and time			-	Other dates and times can be specified for particular components in the EHR hierarchy, not for the EHR_EXTRACT as a whole. However, they can be defined in the root Folder of the EHR directory, as it is a kind of RECORD_COMPONENT
	component name			-	The EHR_EXTRACT class does not include a name attribute, but the root

	structure				Folder of the EHR directory can, as it is a kind of RECORD_COMPONENT
	subject of care identifier			subject_of_care	
	component status information	Set to "Current" at the time of creation		-	For communication purposes, any EHR_EXTRACT is deemed current at the time of creation, given by the time_created attribute above
	Distribution Rule Reference			Not applicable	The approach to access control will be specified in Part 4 of this standard: some revision to this Reference Model may be required to accommodate its constructs
	language			-	Language is considered pertinent to individual terms or text values within the EHR, not to the EHR_EXTRACT as a whole
Record Component			RECORD_COMPONENT		
	Attestation Information			ATTESTATION_INFO	
	Presentation Information	ENV13606 only provided for a presentation reference, but did not otherwise formalise the representation of presentation information		-	Archetypes will be used to represent the specific presentation characteristics required for individual kinds of EHR data
	Revision Information			AUDIT_INFO	
	component unique identifier			rc_id	
	originating healthcare agent			AUDIT_INFO.committer	
	originating date and time			AUDIT_INFO.time_committed	
	related healthcare	No interoperable specification was provided for the		-	These are provided for as associations from Composition and Entry, but not from Folder, Section,

	agent	kinds of 'related" agents that might be represented			Cluster or Element
	related date and time	No interoperable specification was provided for the kinds of 'related" dates and times that might be represented			Provision is made through specific associations from Composition (session_time) and Item (obs_time)
	component name structure			name	This attribute may be represented as a code or plain text; in either case the language used may be included within the data type for string
	subject of care identifier				This attribute value is defined in the EHR_EXTRACT, and is not repeated at every node throughout the EHR hierarchy
	component status information			AUDIT_INFO.revision_status	
	Distribution Rule Reference			sensitivity policy_ids	The approach to access control will be specified in Part 4 of this standard: some revision to this Reference Model may be required to accommodate its constructs. The code set for sensitivity, and values for any other attributes required to represent access control constraints, will be defined in that part standard.
	language				Language can be defined for the individual terms or text values used for attribute values or for data values within the EHR
Folder OCC			FOLDER		
	Attestation Information			ATTESTATION_INFO	
	Presentation Information	ENV13606 only provided for a presentation reference, but did not otherwise formalise the representation of presentation information		-	Archetypes will be used to represent the specific presentation characteristics required for individual kinds of EHR data

	Revision Information			AUDIT_INFO	
	component unique identifier			rc_id	
	originating healthcare agent			AUDIT_INFO.committer	
	originating date and time			AUDIT_INFO.time_committed	
	related healthcare agent	No interoperable specification was provided for the kinds of 'related" agents that might be represented		-	No related healthcare agents are considered to pertain to Folders
	related date and time	No interoperable specification was provided for the kinds of 'related" dates and times that might be represented		-	No related dates and times are considered to pertain to Folders
	component name structure			name	This attribute may be represented as a code or plain text; in either case the language used may be included within the data type for string
	subject of care identifier			-	This attribute value is defined in the EHR_EXTRACT, and is not repeated at every node throughout the EHR hierarchy
	component status information			AUDIT_INFO.revision_status	
	Distribution Rule Reference			sensitivity policy_ids	The approach to access control will be specified in Part 4 of this standard: some revision to this Reference Model may be required to accommodate its constructs. The code set for sensitivity, and values for any other attributes required to represent access control constraints, will be defined in that part standard.
	language				Language can be defined for the individual terms or text values used for attribute values or for data values

					within the EHR
	OCC type	default value = "Folder OCC"		(class name)	This is given by the class name and need not be repeated as an attribute value
Composition OCC			COMPOSITION		
	Attestation Information			ATTESTATION_INFO	
	Presentation Information	ENV13606 only provided for a presentation reference, but did not otherwise formalise the representation of presentation information			Archetypes will be used to represent the specific presentation characteristics required for individual kinds of EHR data
	Revision Information			AUDIT_INFO	
	component unique identifier			rc_id	
	originating healthcare agent			AUDIT_INFO.committer	Since the Composition is the main container of EHR data within the Extract, provision is made to represent the committer of the underlying data in the feeder system AND the committer of the data to the EHR_Extract
	originating date and time			AUDIT_INFO.time_committed	Since the Composition is the main container of EHR data within the Extract, provision is made to represent the committal time of the underlying data in the feeder system AND the committal time of the data to the EHR_Extract
	related healthcare agent	No interoperable specification was provided for the kinds of 'related" agents that might be represented		composer	
	ditto		CLINICAL_SESSION	hca_legally_responsible_for_care AND other_participations	

	related date and time	No interoperable specification was provided for the kinds of 'related" dates and times that might be represented	CLINICAL_SESSION	session_time	
	component name structure			name	This attribute may be represented as a code or plain text; in either case the language used may be included within the data type for string
	subject of care identifier			-	This attribute value is defined in the EHR_EXTRACT, and is not repeated at every node throughout the EHR hierarchy
	component status information			AUDIT_INFO.revision_status	
	Distribution Rule Reference			sensitivity policy_ids	The approach to access control will be specified in Part 4 of this standard: some revision to this Reference Model may be required to accommodate its constructs. The code set for sensitivity, and values for any other attributes required to represent access control constraints, will be defined in that part standard.
	language			-	Language can be defined for the individual terms or text values used for attribute values or for data values within the EHR
	component name category			archetype_id AND meaning	
	OCC type	default value = "Composition OCC"			This is given by the class name and need not be repeated as an attribute value
Headed Section OCC			SECTION		
	Attestation Information			ATTESTATION_INFO	
	Presentation Information	ENV13606 only provided for a presentation reference, but did not otherwise formalise the			Archetypes will be used to represent the specific presentation characteristics required for individual kinds of EHR data

		representation of presentation information			
	Revision Information			AUDIT_INFO	
	component unique identifier			rc_id	
	originating healthcare agent			AUDIT_INFO.committer	
	originating date and time			AUDIT_INFO.time_committed	
	related healthcare agent	No interoperable specification was provided for the kinds of 'related" agents that might be represented		-	No related healthcare agents are considered to pertain to Headed Sections. These may be specified at the Entry level.
	related date and time	No interoperable specification was provided for the kinds of 'related" dates and times that might be represented		-	No related dates and times are considered to pertain to Headed Section. These may be specified at the Entry level.
	component name structure			name	This attribute may be represented as a code or plain text; in either case the language used may be included within the data type for string
	subject of care identifier			-	This attribute value is defined in the EHR_EXTRACT, and is not repeated at every node throughout the EHR hierarchy
	component status information			AUDIT_INFO.revision_status	
	Distribution Rule Reference			sensitivity policy_ids	The approach to access control will be specified in Part 4 of this standard: some revision to this Reference Model may be required to accommodate its constructs. The code set for sensitivity, and values for any other attributes required to represent access control constraints, will be defined in that part standard.

	language			-	Language can be defined for the individual terms or text values used for attribute values or for data values within the EHR
	component name category			archetype_id AND meaning	
	OCC type	default value = Headed Section OCC"			This is given by the class name and need not be repeated as an attribute value
Cluster OCC			ENTRY, CLUSTER		Please refer to the descriptions of these classes given in Annex 2 of this part standard
	Attestation Information			ATTESTATION_INFO	
	Presentation Information	ENV13606 only provided for a presentation reference, but did not otherwise formalise the representation of presentation information	CLUSTER	emphasis	1) The emphasis attribute offers a basic means of communicating the way in which a noteworthy value was highlighted within the originating system. This is intended primarily as a safety feature to draw the recipient's attention to this information. 2) Archetypes will be used to represent the specific presentation characteristics required for individual kinds of EHR data
	Revision Information			AUDIT_INFO	
	component unique identifier			rc_id	
	originating healthcare agent			AUDIT_INFO.committer	
	originating date and time			AUDIT_INFO.time_committed	
	related healthcare agent	No interoperable specification was provided for the kinds of 'related" agents that might be represented	ENTRY	info_provider AND other _participations	

	related date and time	No interoperable specification was provided for the kinds of 'related" dates and times that might be represented	CLUSTER	obs_time	The time or interval at which an actual event occurred, as opposed to when it was gathered within a healthcare activity (COMPOSITION.CLINCIAL_SESSION.session_time) or recorded in a clinical system (feeder_audit.AUDIT_INFO.time_committed) or included in the EHR_EXTRACT (audit_trail.AUDIT_INFO.time_committed)
	component name structure			name	This attribute may be represented as a code or plain text; in either case the language used may be included within the data type for string
	subject of care identifier			-	This attribute value is defined in the EHR_EXTRACT, and is not repeated at every node throughout the EHR hierarchy. NOTE: an ENTRY attribute subject_of_information is provided to indicate if the information contained in this ENTRY is about someone other than the subject_of_care (e.g. about a relative).
	component status information			AUDIT_INFO.revision_status	
	Distribution Rule Reference			sensitivity policy_ids	The approach to access control will be specified in Part 4 of this standard: some revision to this Reference Model may be required to accommodate its constructs. The code set for sensitivity, and values for any other attributes required to represent access control constraints, will be defined in that part standard.
	language			-	Language can be defined for the individual terms or text values used for attribute values or for data values within the EHR
	annotation identifier		ENTRY	annotations	It is intended that a subset of the Component Annotations originally defined in ENV13606-2 will be updated and retained in Part 3 of this standard, primarily those modifiers affecting the safety of interpretation
	OCC type	default value = "Cluster OCC"		-	

Data Item			CLUSTER, ELEMENT		Please refer to the descriptions of these classes given in Annex 2 of this part standard
	Attestation Information			ATTESTATION_INFO	
	Presentation Information	ENV13606 only provided for a presentation reference, but did not otherwise formalise the representation of presentation information	CLUSTER, ELEMENT	emphasis	1) The emphasis attribute offers a basic means of communicating the way in which a noteworthy value was highlighted within the originating system. This is intended primarily as a safety feature to draw the recipient's attention to this information. 2) Archetypes will be used to represent the specific presentation characteristics required for individual kinds of EHR data
	Revision Information			AUDIT_INFO	
	component unique identifier			rc_id	
	originating healthcare agent			AUDIT_INFO.committer	
	originating date and time			AUDIT_INFO.time_committed	
	related healthcare agent	No interoperable specification was provided for the kinds of 'related" agents that might be represented		-	
	related date and time	No interoperable specification was provided for the kinds of 'related" dates and times that might be represented	CLUSTER, ELEMENT	obs_time	The time or interval at which the actual event occurred, as opposed to when it was gathered within a healthcare activity (COMPOSITION.CLINCIAL_SESSION.session_time) or recorded in a clinical system (feeder_audit.AUDIT_INFO.time_committed) or included in the EHR_EXTRACT (audit_trail.AUDIT_INFO.time_committed)
	component name structure			name	This attribute may be represented as a code or plain text; in either case the language used may be included

					within the data type for string
	subject of care identifier			-	This attribute value is defined in the EHR_EXTRACT, and is not repeated at every node throughout the EHR hierarchy. NOTE: an ENTRY attribute subject_of_information is provided to indicate if the information contained in this ENTRY is about someone other than the subject_of_care (e.g. about a relative).
	component status information			AUDIT_INFO.revision_status	
	Distribution Rule Reference			sensitivity policy_ids	The approach to access control will be specified in Part 4 of this standard: some revision to this Reference Model may be required to accommodate its constructs. The code set for sensitivity, and values for any other attributes required to represent access control constraints, will be defined in that part standard.
	Language			-	Language can be defined for the individual terms or text values used for attribute values or for data values within the EHR
	annotation identifier		ENTRY	annotations	It is intended that a subset of the Component Annotations originally defined in ENV13606-2 will be updated and retained in Part 3 of this standard, primarily those modifiers affecting the safety of interpretation
	data item type reference	ENV1360-4 defined several types of data item, including a community-defined one. This meant that the Data Item might either behave as a leaf node or as a kind of Cluster		archetype_id AND meaning	In EN13606, the ELEMENT class is always a leaf node. Compound ENV 13606 data items will therefore map to CLUSTER, whilst single-values data items will map to ELEMENT.
	data item content			DATA_VALUE	The data types are now defined by the CEN Data Types standard and are not therefore defined in this standard
SCC			SECTION and ENTRY	orig_parent_ref	Please refer to Annex 2 of this part standard for a description of the ways

					in which views and selection criteria are now accommodated within this part standard
			LINK	target_rc_id	Please refer to Annex 2 of this part standard for a description of the ways in which views and selection criteria are now accommodated within this part standard
Link Item			LINK		Please refer to Annex 2 of this part standard for a description of the ways in which links are now accommodated within this part standard
Attestation Information			ATTESTATION_INFO		
	attesting agent			FUNCTIONAL_ROLE.performer	
	date and time of attestation			time	
	reason for attestation			FUNCTIONAL_ROLE.function	
	digital signature			proof	
Revision Information			AUDIT_INFO		
	revised version reference			previous_version	
	reason for revision			reason_for_revision	
	reason for revision comments			-	The reason_for_revision attribute (above) is of type CV (which includes a code, a display name for that code and an original text string), permitting organisations to adopt or define coding schemes to suit local or national policies on the justification that should be given for revising a RECORD_COMPONENT; reason for revision comments may be mapped to the original text attribute within the CV data type.
Data types					These are now represented using the CEN data types. Please refer to that

					standard for any required mapping information
Healthcare Agent subsystem					These are now represented using General Purpose Information Components (GPICs). Please refer to that standard for any required mapping information

Annex D
(informative)

Clinical example represented using the Reference Model

This annex shows how a simple part-record of an ante-natal check up can be represented using classes and attributes of the Reference Model. This has been shown below as a spreadsheet, showing each class in bold and the list of its attributes directly below it. Containment is shown through indentation to the right. For each attribute, a "dot" notation has been used to indicate which attribute of the relevant data type has been used for each actual value.

28-week check performed on 12/7/96 at 13:42 by Dr D Kalra
Gestation 27 weeks
Presenting Symptoms: “I feel lousy all the time”; heartburn
Abdomen:
Cephalic presentation
Foetal heart 140/min, regular (Using Sonicaid)
Blood Pressure: 100/60

EHR_EXTRACT					
ehr_system.extension = Whittington					
ehr_system.assigningAuthorityName = NHS					
ehr_id.extension = WH.1234					
ehr_id.assigningAuthorityName = NHS					
subject_of_care.extension = 9876543					
subject_of_care.assigningAuthorityName = NHS					
time_created.time = 16/07/2004 17:32					
rm_id = EN13606-1.0					
	VERSION				
	ehr_system.extension = Whittington				
	ehr_system.assigningAuthorityName = NHS				
	time_committed = 12.07.1996 13:42				
	committer.extension = KALRA194				
	committer.assigningAuthorityName = NHS				
		COMPOSITION			
		rc_id.extension = 0003			
		rc_id.assigningAuthorityName = NLONDON-NHS			
		name = 28-week check			
		meaning.codingScheme = 1234567890			
		meaning.codingSchemeName = CEN			
		meaning.codingSchemeVersion = 1.1			
		meaning.codeValue = CENarch-xvwyz			
		meaning.displayName = Antenatal review at 28 weeks gestation			
		archetype_root = TRUE			
		sensitivity = Clinical			
		composer.extension = KALRA194			
		composer.assigningAuthorityName = NHS			
			ENTRY		
			rc_id.extension = 0004		
			rc_id.assigningAuthorityName = NLONDON-NHS		
			name = Gestation		
			meaning.codingScheme = 1234567890		
			meaning.codingSchemeName = CEN		
			meaning.codingSchemeVersion = 1.1		
			meaning.codeValue = CENarch-xvwyzA		
			meaning.displayName = Gestation of pregnancy		
			archetype_root = TRUE		
			sensitivity = Clinical		
			subject_of_information = Patient		
				ELEMENT	
				rc_id.extension = 0005	
				rc_id.assigningAuthorityName = NLONDON-NHS	
				name = Gestational assessment	
				meaning.codingScheme = 1234567890	
				meaning.codingSchemeName = CEN	
				meaning.codingSchemeVersion = 1.1	
				meaning.codeValue = CENarch-xvwyzAA	
				meaning.displayName = Gestation assessment in weeks	
				archetype_root = FALSE	
				sensitivity = Clinical	
				value.PQ.value = 27	
				value.PQ.units = Weeks	
				value.PQ.property = time	

			ENTRY		
			rc_id.extension = 0006		
			rc_id.assigningAuthorityName = NLONDON-NHS		
			name = Presenting symptoms		
			meaning.codingScheme = 1234567890		
			meaning.codingSchemeName = CEN		
			meaning.codingSchemeVersion = 1.1		
			meaning.codeValue = CENarch-xvwyzB		
			meaning.displayName = Symptoms within pregnancy		
			archetype_root = TRUE		
			sensitivity = Clinical		
			subject_of_information = Patient		
				ELEMENT	
				rc_id.extension = 0007	
				rc_id.assigningAuthorityName = NLONDON-NHS	
				name = Symptom	
				meaning.codingScheme = 1234567890	
				meaning.codingSchemeName = CEN	
				meaning.codingSchemeVersion = 1.1	
				meaning.codeValue = CENarch-xvwabcA	
				meaning.displayName = Symptom description	
				archetype_root = FALSE	
				sensitivity = Clinical	
				value.TEXT.displayName = I feel lousy all the time	
				ELEMENT	
				rc_id.extension = 0008	
				rc_id.assigningAuthorityName = NLONDON-NHS	
				name = Symptom	
				meaning.codingScheme = 1234567890	
				meaning.codingSchemeNameRC_UID = 0012	
				meaning.codingSchemeVersion = 1.1	
				meaning.codeValue = CENarch-xvwabcA	
				meaning.displayName = Symptom description	
				archetype_root = FALSE	
				sensitivity = Clinical	
				value.CODED_TEXT.codingScheme = ICD-12	
				value.CODED_TEXT.codingSchemeName = Int. Class. Diseases	
				value.CODED_TEXT.codingSchemeVersion = 12	
				value.CODED_TEXT.codeValue = D1234	
				value.CODED_TEXT.displayName = Reflux oesophagitis	
				value.CODED_TEXT.originalText = Heartburn	
			SECTION		
			rc_id.extension = 0010		
			rc_id.assigningAuthorityName = NLONDON-NHS		
			name = Abdominal examination		
			archetype_root = FALSE		
			sensitivity = Clinical		
				ENTRY	
				rc_id.extension = 0011	
				rc_id.assigningAuthorityName = NLONDON-NHS	
				name = Presentation	
				meaning.codingScheme = 1234567890	
				meaning.codingSchemeName = CEN	
				meaning.codingSchemeVersion = 1.1	
				meaning.codeValue = CENarch-xvwyzF	
				meaning.displayName = Foetal position	
				archetype_root = TRUE	
				sensitivity = Clinical	
				subject_of_information = Foetus	
					ELEMENT
					rc_id.extension = 0012
					rc_id.assigningAuthorityName = NLONDON-NHS
					name = Lie
					meaning.codingScheme = 1234567890
					meaning.codingSchemeName = CEN
					meaning.codingSchemeVersion = 1.1
					meaning.codeValue = CENarch-xvwyzF1
					meaning.displayName = Foetal orientation
					archetype_root = FALSE
					sensitivity = Clinical
					value.CV.codingScheme = CTV3
					value.CV.codingSchemeName = NHS Clin. Terms
					value.CV.codingSchemeVersion = 1.0
					value.CV.codeValue = 635284
					value.CV.displayName = Longitudinal
					ELEMENT
					rc_id.extension = 0013
					rc_id.assigningAuthorityName = NLONDON-NHS
					name = Presentation
					meaning.codingScheme = 1234567890
					meaning.codingSchemeName = CEN
					meaning.codingSchemeVersion = 1.1
					meaning.codeValue = CENarch-xvwyzF2
					meaning.displayName = Foetal presentation
					archetype_root = FALSE
					sensitivity = Clinical
					value.CV.codingScheme = CTV3
					value.CV.codingSchemeName = NHS Clin. Terms
					value.CV.codingSchemeVersion = 1.0
					value.CV.codeValue = 635288
					value.CV.displayName = Cephalic

				ENTRY	
				rc_id.extension = 0021	
				rc_id.assigningAuthorityName = NLONDON-NHS	
				name = Heart rate	
				meaning.codingScheme = 1234567890	
				meaning.codingSchemeName = CEN	
				meaning.codingSchemeVersion = 1.1	
				meaning.codeValue = CENarch-xvwyzH	
				meaning.displayName = Foetal cardiac assessment	
				archetype_root = TRUE	
				sensitivity = Clinical	
				subject_of_information = Foetus	
					ELEMENT
					rc_id.extension = 0023
					rc_id.assigningAuthorityName = NLONDON-NHS
					name = FH
					meaning.codingScheme = 1234567890
					meaning.codingSchemeName = CEN
					meaning.codingSchemeVersion = 1.1
					meaning.codeValue = CENarch-xvwyzHA
					meaning.displayName = Measurement of foetal cardiac rate per minute
					archetype_root = FALSE
					sensitivity = Clinical
					value.PQ.value = 140
					value.PQ.units = beats per minute
					value.PQ.property = frequency
					ELEMENT
					rc_id.extension = 0025
					rc_id.assigningAuthorityName = NLONDON-NHS
					name = Device
					meaning.codingScheme = 1234567890
					meaning.codingSchemeName = CEN
					meaning.codingSchemeVersion = 1.1
					meaning.codeValue = CENarch-xvwyzHD
					meaning.displayName = Measurement device for foetal cardiac rate
					archetype_root = FALSE
					sensitivity = Clinical
					value.CV.codingScheme = CEN DEV REG
					value.CV.codingSchemeName = CEN device registry
					value.CV.codingSchemeVersion = 6.8
					value.CV.codeValue = 5621
					value.CV.displayName = Sonicaid doppler deluxe
					ELEMENT
					rc_id.extension = 0026
					rc_id.assigningAuthorityName = NLONDON-NHS
					name = FH rhythm
					meaning.codingScheme = 1234567890
					meaning.codingSchemeName = CEN
					meaning.codingSchemeVersion = 1.1
					meaning.codeValue = CENarch-xvwyzHR
					meaning.displayName = Description of foetal cardiac rhythm
					archetype_root = FALSE
					sensitivity = Clinical
					value.CV.codingScheme = CTV3
					value.CV.codingSchemeName = NHS Clin. Terms
					value.CV.codingSchemeVersion = 1.0
					value.CV.codeValue = 635700
					value.CV.displayName = Regular
			ENTRY		
			rc_id.extension = 0041		
			rc_id.assigningAuthorityName = NLONDON-NHS		
			name = BP		
			meaning.codingScheme = 1234567890		
			meaning.codingSchemeName = CEN		
			meaning.codingSchemeVersion = 1.1		
			meaning.codeValue = CENarch-xvbnh		
			meaning.displayName = Blood Pressure		
			archetype_root = TRUE		
			sensitivity = Clinical		
			subject_of_information = Patient		
				ELEMENT	
				rc_id.extension = 0045	
				rc_id.assigningAuthorityName = NLONDON-NHS	
				name = Systolic	
				meaning.codingScheme = 1234567890	
				meaning.codingSchemeName = CEN	
				meaning.codingSchemeVersion = 1.1	
				meaning.codeValue = CENarch-xvbnhS	
				meaning.displayName = Measurement of systolic blood pressure	
				archetype_root = FALSE	
				sensitivity = Clinical	
				value.PQ.value = 100	
				value.PQ.units = mmHg	
				value.PQ.property = pressure	
				ELEMENT	
				rc_id.extension = 0048	
				rc_id.assigningAuthorityName = NLONDON-NHS	
				name = Diastolic	
				meaning.codingScheme = 1234567890	
				meaning.codingSchemeName = CEN	
				meaning.codingSchemeVersion = 1.1	
				meaning.codeValue = CENarch-xvbnhD	
				meaning.displayName = Measurement of diastolic blood pressure	
				archetype_root = FALSE	
				sensitivity = Clinical	
				value.PQ.value = 60	
				value.PQ.units = mmHg	
				value.PQ.property = pressure	

Annex E
(informative)

Mapping to statements of requirement

As indicated in the Introduction and in Section 5, ISO/TS 18308 has been adopted as the requirements basis for the new standard. A mapping of these statements to key constructs in the Reference Model is included here. Inevitably these mappings are not one-to-one, and the table includes some duplication of statements and of constructs. It is hoped that this table provides a further level of insight into the rationale behind elements of the approach taken in designing this Reference Model.

The ISO statements are shown in black font. Some additional requirements statements from the PhD thesis of the TF leader [Kalra, 2003] have also been included here. These are shown in blue font. The constructs in this standard, or comments about the requirement, are shown in purple font.

E.1 General EHR requirements

ISO code/ thesis code	**ISO statement or statement from PhD thesis**	**EN13606 class.attribute or feature**
	Long term goals of a logical interoperable health record approach	
STR1.3	The EHRA shall support an EHR which is moveable and mergeable between individuals and institutions independent of hardware, software (application programs, operating systems, programming languages), databases, networks, coding systems, and natural languages. (2.6)	(General objectives of the Reference Model)
STR2.13	The EHRA shall support the administration of healthcare processes and episodes of care as well as the organisation of visit and encounter data. (1.3.3)	(General objectives of the Reference Model)
COM2.6	The EHRA shall enable semantic interoperability of clinical concepts between EHR systems to support automatic processing of data at the receiving system. (3.3.4)	(General objectives of the Reference Model)
GOAL.3	The EHRA should enable the communication of healthcare information to support shared patient care, improved quality of care and effective resource management	
	Federating EHRs	
STR1.3	The EHRA shall support an EHR which is moveable and mergeable between individuals and institutions independent of hardware, software (application programs, operating systems, programming languages), databases, networks, coding systems, and natural languages. (2.6)	EHR_Extract
FHR.1	The EHRA must facilitate the creation of a single logical electronic health record for each patient within a healthcare enterprise or region, by enabling distributed and legitimate access to the set of EHRs and other clinical data held by or available to that healthcare enterprise	EHR_Extract
COM2.1	The EHRA shall allow for the exchange of a complete EHRA or a part of an EHR (an extract) between EHRA compliant systems. (4.4)	EHR_Extract
COM2.3	The EHRA shall define the semantics of merging data from an EHR extract with the EHR resident in the receiving system. (4.7)	EHR_Extract
STR3.16	The EHRA shall support the recording of contextual data associated with the subject	EHR_Extract.subject_of_care
MEL2.1	The EHRA shall cater for the subject of care of the EHR to be one or more persons (6.1.1)	This requirement is not properly met by EN13606. It needs further discussion before being considered appropriate for this EHR communications standard.
PRO1.16	The EHRA shall support integrated patient care including continuing collaborative multi-disciplinary care and case management across different healthcare sectors and settings (e.g. primary care, acute hospitals, allied health, home-based care) (3.2.3)	Composition.composer, Composition.Audit_Info.committer, Composition.Clinical_Session.hca_legally_responsible_for_care, Compostion.other_participations, Entry.information_provider, Entry.other_participations
FHR.9	It must be possible to identify the source feeder system for any entry in a patient's EHR	Composition.Audit_Info.ehr_system

E.2 EHR medico-legal and security requirements

ISO code/ thesis code	ISO statement or statement from PhD thesis	EN13606 class.attribute or feature
	Subject access rights	
COC1.1	The EHRA shall support the production of a consumer oriented view. (9.1)	Access control measures - to be included within Part 4 of this standard
PRS3.1	The EHRA shall support measures to define, attach, modify and remove access rights to the whole and/or sections of the EHR. (5.1.1)	Access control measures - to be included within Part 4 of this standard
PRS3.4	The EHRA shall support measures to separately control authorities to add to and/or modify the EHR from authorities to access the EHR (5.1.1)	Access control measures - to be included within Part 4 of this standard
COC1.2	The EHRA shall support consumers' right of access to all EHR information subject to jurisdictional constraints. (9.1)	Access control measures - to be included within Part 4 of this standard
COC1.3	The EHRA shall support consumers being able to incorporate self-care information, their point of view on personal healthcare issues, levels of satisfaction, expectations and comments they wish to record in EHRs. (9.1)	Access control measures - to be included within Part 4 of this standard
COM2.4	The EHRA shall provide an audit trail of exchange processes, including authentication, to enable identification of points of EHR extract transmittal and receipt. This needs to account for merging processes. (4.3)	Audit trail - to be included within Part 4 of this standard
	Confidentiality and access control	
STR2.10	The EHRA shall allow for comprehensive information storage and retrieval regarding patient care. The EHRA shall at a minimum allow for the recording of all structured and unstructured data on: - [others] - Disclosures and consent	Access control measures - to be included within Part 4 of this standard
PRS1.2	The EHRA shall support the labelling of the whole and/or sections of the EHR as restricted to authorised users and/or purposes. This should include restrictions at the level of reading, writing, amendment, verification, and transmission/disclosure of data and records (5.2)	Access control measures - to be included within Part 4 of this standard
PRS3.3	The EHRA shall support measures to enable and restrict access to the whole and/or sections of the EHR in accordance with prevailing consent and access rules. (5.1.1)	Access control measures - to be included within Part 4 of this standard
PRS1.2	The EHRA shall support the labelling of the whole and/or sections of the EHR as restricted to authorised users and/or purposes. This should include restrictions at the level of reading, writing, amendment, verification, and transmission/disclosure of data and records (5.2)	Access control measures - to be included within Part 4 of this standard
ACC.3a	The EHRA must support a multi-level access level framework, in which levels may be defined according to profession, position, speciality or role, and which may only be valid for individual patient records or parts of patient records and only for certain periods of time	
PRS2.2	The EHRA shall support obtaining, recording and tracking the status of informed consent to access the whole and/or sections of the EHR, for defined purposes. (5.3)	Access control measures - to be included within Part 4 of this standard
PRS2.4	The EHRA shall support recording of the time frames attached to each consent. (5.3)	Access control measures - to be included within Part 4 of this standard
PRS1.3	The EHRA shall support privacy and confidentiality restrictions at the level of both data sets and discrete data attributes.	Access control measures - to be included within Part 4 of this standard
ACC.13	A set of entries made by one author at one date and time should only contain data associated with more than one different level of access rights if the responsible healthcare professional is satisfied that the view derived through any one of those access levels does not seriously misrepresent the meaning of that whole set of entries	Access control measures - to be included within Part 4 of this standard. Will need constraints on the permitted values of Record_Component.sensitivity within one Composition
	Audit trails	
COM2.4	The EHRA shall provide an audit trail of exchange processes, including authentication, to enable identification of points of EHR extract transmittal and receipt. This needs to account for merging processes. (4.3)	Audit trail - to be included within Part 4 of this standard
PRS5.1	The EHRA shall support recording of an audit trail of access to and modifications of data within the whole or sections of the EHR. (5.5)	Audit trail - to be included within Part 4 of this standard
PRS5.2	The EHRA shall support recording of the nature of each access and/or modification. (5.5)	Audit trail - to be included within Part 4 of this standard
COM2.4	The EHRA shall provide an audit trail of exchange processes, including authentication, to enable identification of points of EHR extract transmittal and receipt. This needs to account for merging processes. (4.3)	Audit trail - to be included within Part 4 of this standard
	Unambiguous identification of patients	
STR2.11	The EHRA shall support the recording (and classifying for identification purposes) of patient identification, location, demographic, contact, employment and other administrative data. (1.3.3)	EHR_Extract.subject_of_care is of type Instance Identifier (II); this references a mini-demographic data set represented using the GPIC SubjectOfCarePersonalIdentification. Other demographic data may be archetyped.

STR3.16	The EHRA shall support the recording of contextual data associated with the subject	ditto
MEL2.2	The EHRA shall cater for the recording of appropriate patient identification attributes and clinically relevant patient attributes such as date of birth, sex, ethnicity etc. (6.1.2)	ditto
STR2.11	The EHRA shall support the recording (and classifying for identification purposes) of patient identification, location, demographic, contact, employment and other administrative data. (1.3.3)	ditto
	User Identification	
STR2.12	The EHRA shall support standards for information which enable the unambiguous identification of the subject of care, the clinicians involved in care (including their role and context of care), the location of care, the date/time and duration of care, and third parties such as next of kin and non-clinical contacts. (1.3.3)	Composition.composer, Entry.information_provider, and attestations which can reference any level of the record hierarchy
MEL2.3	The EHRA shall ensure that users who attest and commit any particular information to the record are uniquely and reliably identified (6.1.3)	Composition.composer, Entry.information_provider, and attestations which can reference any level of the record hierarchy

E.3 EHR clinical requirements

ISO code/ thesis code	ISO statement or statement from PhD thesis	EN13606 class.attribute or feature
	Fulfilling the role of the record	
STR2.10	The EHRA shall allow for comprehensive information storage and retrieval regarding patient care. The EHRA shall at a minimum allow for the recording of all structured and unstructured data on:	through archetypes
STR2.13	The EHRA shall support the administration of healthcare processes and episodes of care as well as the organisation of visit and encounter data. (1.3.3)	through archetypes
STR2.14	The EHRA shall support the recording of financial and other commercial information such as health plan enrolment, eligibility and coverage information, guarantor, costs, charges, and utilisation. (1.3.3)	through archetypes
STR2.15	The EHRA shall support the recording of legal status and consents relevant to the patient's healthcare (e.g. legal status of guardianship order, consents for operations and other procedures).	through archetypes
PRO1.1	The EHRA shall support the recording of any type of clinical event, encounter, or episode relevant to the care of a patient (3.1)	through archetypes
PRO1.5	The EHRA shall support the recording and presentation of holistic health status, functional status, problems, conditions, environmental circumstances and issues (3.2.1)	through archetypes
MEL3.1	The EHRA shall support the demonstration of clinical competence and accountability of clinicians (6.2)	through archetypes, and various medico-legal attributes of the Reference Model
	Authorship of health record entries	
MEL2.7	The EHRA shall support measures which ensure that every record entry is dated, and its author identified. (6.1.6)	Composition.composer, Composition.Clinical_Session.hca_legally_responsible_for_care, Version.attestations
MEL2.8	The EHRA shall support measures to ensure that there is an absolute requirement that each contribution to the record is attributed to a responsible healthcare party whether in the role of author or not. (6.1.5)	Composition.composer, Composition.Clinical_Session.hca_legally_responsible_for_care, Compostion.Audit_Info.ehr_system, Version.attestations
MEL2.4	The EHRA shall support the on-going ability to identify users, even if they change their name, profession, sex, or address. (6.1.3)	ditto
ATHR.4	There should be an agreed, ideally internationally, set of information recorded every time information is authored within the EHR. This might include the time and date, definition of time zone, identification of provider …, identification of language and coding system used, definition of ownership of the information and its level of sensitivity for disclosure.	Composition.Audit_Info.time_committed, Record_Component.Audit_Info.time_committed, Compostion.Audit_Info.ehr_system Composition.composer, Composition.Clinical_session.territory, Record_Component.sensitivity
ATHR.6	Test results or other information not yet seen by a responsible healthcare professional should be regarded as external to the EHR even if held on the same information system	Version.attestations
ATHR.8	The EHRA must be able to represent both the identify the laboratory or diagnostic department/institution that carried out a test and the party responsible for its incorporation into the EHR	Record_Component.Audit_Info.ehr_system, Entry.information_provider
MEL1.1	The EHRA shall support measures to ensure an accurate reflection of the chronology of clinical events and information availability in the EHR. (6.3)	Record_Component.Audit_Info.ehr_system, Composition.Audit_Info.committer
ATHR.9	Any extract incorporated into an EHR system (e.g. from a feeder system) should identify the HCP responsible for incorporating it into the EHR for that patient or confirm the patient's authorisation, and the date and time it was incorporated	Record_Component.Audit_Info.ehr_system, Composition.Audit_Info.ehr_system, Composition.Audit_Info.committer, Composition.Audit_Info.time_committed,
MEL1.2	The EHRA shall enable the viewing of an accurate representation of the EHR at any particular date and time since its creation (6.4)	using Composition.Audit_Info.time_committed and Record_Component.Audit_Info.time_commited
MEL2.9	The EHRA shall support measures which ensure that every contribution to the record is attested by a responsible person . (6.1.6)	Composition.composer, Composition.Clinical_Session.hca_legally_responsible_for_care, Entry.info_provider, Version.attestations Version.attestations may be added after original committal
	Identifying students	
STUD.3	The EHR should allow qualified professionals to validate a student's entry, document that they agree with the student's notes and change the status of the student's notes to that of qualified professional.	Composition.Clinical_Session.hca_legally_responsible_for_care, Subsequent authorisation through attestation, or by revision
	Identifying third parties	

MEL2.5	The EHRA shall support measures to ensure that all clinical parties referred to in the EHR are uniquely identified (6.1.4)	Composition.composer, Composition.Audit_Info.committer, Composition.Clinical_Session.hca_legally_responsible_for_care, Compostion.other_participations, Entry.information_provider, Entry.other_participations, Record_Component.Audit_Info.committer
THRD.1a	The EHRA must be able to represent information relevant to a patient about a third party without relying upon access to information held externally to that patient's record, for example information in the health record of the third party	Entry.information_provider
	Identifying healthcare and patient locations	
STR3.19	The EHRA shall support the recording of contextual data associated with the location where the event was recorded	Composition.Clinical_Session.healthcare_facility, Composition.Clinical_Session.service_setting, plus any detail specified within Composition-level archetypes
	Recording dates and times	
MEL1.1	The EHRA shall support measures to ensure an accurate reflection of the chronology of clinical events and information availability in the EHR. (6.3)	Composition.Audit_Info.time_committed, Composition.Audit_Info.contribution_id, Record_Component.Audit_Info.time_committed
MEL2.7	The EHRA shall support measures which ensure that every record entry is dated, and its author identified. (6.1.6)	Composition.Audit_Info.time_committed, Composition.Audit_Info.contribution_id, Record_Component.Audit_Info.time_committed
STR3.15	The EHRA shall support the recording of contextual data associated with the date/time the event was committed to the record	Composition.Audit_Info.time_committed, Record_Component.Audit_Info.time_committed
STR3.14	The EHRA shall support the recording of contextual data associated with the date/time the event occurred	Composition.Clinical_Session.session_time
	The Amendment of Health Record Entries	
PRO2.1	The EHRA shall support clear and consistent rules for entry, amendment, verification, transmittal, receipt, translation, and obsoleting/superceding of data. This requirement does not imply that it is necessary for a given implementation to allow deletion of EHR content. Local data retention rules will apply. (3.3.1)	each version is a new Composition instance, with Composition.Audit_Info attributes defining the new point of committal and referencing the previous version and including a reason for the revision
MEL7.1	The EHRA shall support versioning at the granularity at which information is attested (6.8)	Whole set of committed entries must be re-attested if parts of content are revised. Version.attestations point to data within a single Composition version, and are not automatically redirected to a revised one
AMND.6	If versions of an EHR or of some entries exist on more than one feeder system, modifications made on each must be capable of subsequent reconciliation to ensure that the overall EHR reflects the most recent modifications	revisions are each time stamped and reference the unique id of what they have replaced, NOT via version number (as in CDA) which is not robust if revisions occur on multiple sites
	Faithful representation of health record entries	
MEL2.1	The EHRA shall cater for the subject of care of the EHR to be one or more persons (6.1.1)	EHR_Extract.subject_of_care. This issue needs further discussion if it is to be incorporated into the standard.
STR2.15	The EHRA shall support the recording of legal status and consents relevant to the patient's healthcare (e.g. legal status of guardianship order, consents for operations and other procedures).	defined committal set (Composition) which may be attested
MEL1.1	The EHRA shall support measures to ensure an accurate reflection of the chronology of clinical events and information availability in the EHR. (6.3)	Composition.Audit_Info.time_committed, Composition.Audit_Info.contribution_id, Record_Component.Audit_Info.time_committed
	Faithful reflection of clinical practice	
STR2.8	The EHRA shall support the inclusion of comments within the data stored – enabling the clinician to qualify structured information appropriately. Comments shall be able to be linked to specific data attributes. (1.2.2.2)	Item.item_category permits the archetyping of clinical reasoning structures
PRAC.2.1	The EHRA Reference Model must permit an author to explain or justify their reasoning or assertions, and optionally to reference external sources as the basis for a conclusion or strategy	Item.item_category permits the archetyping of clinical reasoning structures
PRAC.1	The EHRA must be able to represent opinions, suggestions and hypotheses as well as firm factual knowledge about a patient	through archetypes
PRAC.2	The EHRA must permit an author to express a degree of uncertainty about a hypothesis; this may change as hypotheses are tested or as new information is acquired	This might be handled through Entry.annotations or via archetypes (safer)
	The structure of health record entries	
STR1.1	The EHRA shall enable information in the EHR to be organised in different sections allowing navigation by users and views of sections to be returned as the result of queries. (1.1)	Record_Component.name, the hierarchical containment of its sub-classes, Link
STR2.4	The EHRA shall enable storage of data such that simple name / value pairing is preserved. (1.2.1)	Record_Component.name, the hierarchical containment of its sub-classes, Link
STRC.2a	The EHRA must preserve original organisation and labels of compound clinical concepts and containment hierarchies, and any defined relationships between record components	Record_Component.name, the hierarchical containment of its sub-classes, Link

STR1.1	The EHRA shall enable information in the EHR to be organised in different sections allowing navigation by users and views of sections to be returned as the result of queries. (1.1)	Section and Entry, Item (Cluster and Element)
STRC.3.4	EHRA entries must preserve faithfully any longitudinal partitions of health records, for example episodes of care, which might be defined retrospectively	Folder (this is one option for doing this) or Link (this is more robust, but both methods are supported)
STR4.4	Where information is not represented uniquely in only one place and one way, the EHRA shall support explicit rules to avoid ambiguity (e.g. it must be clear what [not] [pedal pulses absent] means)	Precision is within PQ, Severity would be a qualifier within a CD, but negation and uncertainty are risky flags to include, and we need to discuss this issue further in Part 3 when defining the set of annotations
STR2.6	The EHRA shall support the inclusion of narrative free text. (1.2.2.1)	data type for TEXT
STR2.8	The EHRA shall support the inclusion of comments within the data stored – enabling the clinician to qualify structured information appropriately. Comments shall be able to be linked to specific data attributes. (1.2.2.2)	data type for TEXT
STR2.9	The EHRA shall provide a means for different levels of emphasis to be associated with comments and other entries – this may alter the way they are displayed or their returning in a query. (1.2.2.2)	Item.emphasis plus any additional presentation attributes included within specific archetypes
STR3.23	The EHRA shall support links to 'externally referenced data' which is not able to be stored within the EHR, providing patient safety is not compromised. (1.3.7)	data type ED
STRC.3.10	EHRA entries must preserve faithfully any information provided by a third party (such as a family member), another institution (e.g. providing a laboratory result) or a physical device (such as a cardiac monitor);	Entry.information_provider
PRO1.3	The EHRA shall support the continuity of a clinical process, the ability to query the status of a process, modify an existing process, and verify that a process has been completed (3.3.5)	Record_Component.Link
PRO1.14	The EHRA shall support the recording and tracking of clinical orders and requests such as prescriptions and other treatment orders, investigation requests, and referrals (3.3.6)	Record_Component.Link
PRO1.15	The EHRA shall support the linking of orders with the observations that arise as a result (e.g. the results of an investigation or administration of a medication with the order for these interventions).	Record_Component.Link
STRC.3.11	EHRA entries must preserve faithfully any links between activities and information generated by the activities (e.g., that a test result originates from a specific request); other linkage networks within a record such as problem links, disease progression or therapy programmes	Record_Component.Link
STR3.21	The EHRA shall support the recording of contextual data associated with the protocol associated with the information recorded	Item.item_category
STR3.20	The EHRA shall support the recording of contextual data associated with the reason for recording the information associated with the event	Item.item_category
PRO1.8	The EHRA shall support the recording of the clinical reasoning including by automated processes, for all diagnoses, conclusions, and actions regarding the care of a patient (3.2.2)	Item.item_category
STR4.6	The original textual representation as entered by the clinician shall be retained in the EHR when information is translated from one natural language to another or when terms are mapped from one coding/classification system to another.	Record_Component.name, and the CV/CD data types include a language attribute within the ST data type
STR3.23	The EHRA shall support links to 'externally referenced data' which is not able to be stored within the EHR, providing patient safety is not compromised. (1.3.7)	Record_Component.Link.follow_link
STR2.2	The EHRA shall enable storage of data in tables such that the relationships of the data with the row and column headings are preserved. (1.2.1)	Cluster.structure, Item hierarchy
STR2.3	The EHRA shall enable storage of data in hierarchies such that the relationship between the node parents and children are preserved. (1.2.1)	Cluster.structure, Item hierarchy and optionally an ED data type for diagrams
STR2.1	The EHRA shall enable storage of data as lists such that the order of the data is preserved when the data is displayed. (1.2.1)	Item.obs_time, Cluster/Element aggregations, plus Ordinal data type
PRO1.2	The EHRA shall support the creation, instantiation, and maintenance of clinical processes that support the activities of its users (3.3.5)	Entry.act_id and Entry.act_status to reference an act management system
PRO1.3	The EHRA shall support the continuity of a clinical process, the ability to query the status of a process, modify an existing process, and verify that a process has been completed (3.3.5)	Entry.act_id and Entry.act_status to reference an act management system
PRO1.4	The EHRA shall be able to accommodate partial completion of a clinical process. (3.3.5)	Entry.act_id and Entry.act_status to reference an act management system
PRO1.13	The EHRA shall support care planning, including the management of process states (eg planned, ordered, scheduled, in progress, on hold, pending, completed, amended, verified, cancelled), within the care planning process (3.2.4)	Entry.act_id and Entry.act_status to reference an act management system
STR3.21	The EHRA shall support the recording of contextual data associated with the protocol associated with the information recorded	Item.item_category offers an archetypable structure to represent this kind of information, which might vary in structure between sites and situations

PRO1.8	The EHRA shall support the recording of the clinical reasoning including by automated processes, for all diagnoses, conclusions, and actions regarding the care of a patient (3.2.2)	Item.item_category offers an archetypable structure to represent this kind of information, which might vary in structure between sites and situations
	Categories of clinical information	
STR2.10	The EHRA shall allow for comprehensive information storage and retrieval regarding patient care. The EHRA shall at a minimum allow for the recording of all structured and unstructured data on: - Patient history - Physical examination - Psychological, social, environmental, family, and self care information - Allergies and other therapeutic precautions - Preventative and wellness measures such as vaccinations and lifestyle interventions - Diagnostic tests and therapeutic interventions such as medications and procedures - Clinical observations, interpretations, decisions, and clinical reasoning - Requests/orders for further investigation, treatments, or discharge - Problems, diagnoses, issues, conditions, preferences and expectations - Healthcare plans, health and functional status, and health summaries - Disclosures and consents - Suppliers, model and manufacturer of devices (e.g. implants or prostheses)	through archetypes
PRO1.9	The EHRA shall support the automatic presentation of warnings, alerts and reminders such as patient infective status, allergies and other therapeutic precautions, outstanding interventions, and urgent results (3.2.1)	through archetypes
	Textual entries	
STR2.6	The EHRA shall support the inclusion of narrative free text. (1.2.2.1)	Data type TEXT
STR4.2	At the data attribute level, the EHRA shall support the capture of the code, the coding scheme (e.g., coding/classification system), version, original language, and original rubric.	Data type CD
STR4.3	The EHRA shall enable storage of data from terminologies and preserve the information about the terminology set from which it was chosen. (1.2.1)	Data type CD
STR4.4	Where information is not represented uniquely in only one place and one way, the EHRA shall support explicit rules to avoid ambiguity (e.g. it must be clear what [not] [pedal pulses absent] means)	Data Type CD, plus an outstanding issue on negation and certainty which might be handled through annotations or specific archetypes for reasoning
MEL5.1	Where plain text or coded terms in the EHR have been translated or mapped, the original text or rubric in the original language must be retained. (6.5.2)	Data type TEXT
	Quantities and numeric data	
STR3.2	The EHRA shall support the definition of the logical structure of numeric and quantifiable data, including the handling of units. (1.3.4.2)	Cluster.structure, Item hierarchy and optionally an PQ data type for quantities
STR3.2	Numeric and Quantifiable data	Data type PQ
STR3.5	Quantity ranges	Data type PQ
STR3.6	Quantity ratios	Data type PQ
QUAN.1-6	The EHRA must be able to represent complex numeric values including ratios with differing units, percentages, formulae and their results, precision, accuracy, reference ranges, instrument	Cluster.structure, Item hierarchy and optionally an PQ data type for quantities
	Time and other sequences	
STR2.1	The EHRA shall enable storage of data as lists such that the order of the data is preserved when the data is displayed. (1.2.1)	Item.obs_time, which is of type interval permitting date and time specifications to varying granularity, plus archetypable date/time Elements for time series in which time is part of the data
STR2.5	The EHRA shall enable the storage of multiple values of the same measurement taken at closely proximate times at the same contact, or at different contacts and at different locations. The context of these measurements shall be preserved – such as who took the measurement, what method was used etc. These values should be able to be returned in a query and ordered in different ways. (1.1)	Item.obs_time, which is of type interval permitting date and time specifications to varying granularity, plus archetypable date/time Elements for time series in which time is part of the data
TIME.1-4	The EHRA must be able to represent time series, imprecisely specified time, duration, relative times	Item.obs_time, which is of type interval permitting date and time specifications to varying granularity, plus archetypable date/time Elements for time series in which time is part of the data
	Graphical and multimedia data	
MULT.4-6	The EHRA must be able to represent drawings, symbolic diagrams and stylised symbols, multimedia, rendering information, annotations	Data type ED, possibly requiring additional presentation/rendering information through archetypes
	Intra-Record Links	

PRO1.15	The EHRA shall support the linking of orders with the observations that arise as a result (e.g. the results of an investigation or administration of a medication with the order for these interventions).	Handled by Record_Component.Link, zero to many, with nature and link_role attributes
STR3.22	The EHRA shall define the semantic representation of links between different information in the EHR. (1.3.7)	Handled by Record_Component.Link, zero to many, with nature and link_role attributes
	Linkage between patient EHRs	
MEL2.1	The EHRA shall cater for the subject of care of the EHR to be one or more persons (6.1.1)	Not yet handled by EN13606, although existing features would probably suffice since the Link.target_rc_id does not constrain the rc_id to be within the same EHR

Annex F
(informative)

Bibliography

[THIS SECTION WILL BE ADDED LATER]

END of DOCUMENT