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Health informatics - Electronic health record communication - Part 1: Reference model (ISO/DIS 13606-1:2026)

Medizinische Informatik - Kommunikation von Patientendaten in elektronischer Form - Teil 1: Referenzmodell (ISO/DIS 13606-1:2026)

Informatique de santé - Communication du dossier de santé informatisé - Partie 1: Modèle de référence (ISO/DIS 13606-1:2026)

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Health informatics — Electronic health record communication —

Part 1: Reference model

Informatique de santé — Communication du dossier de santé informatisé —

Partie 1: Modèle de référence

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Foreword

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

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

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

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

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

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

This third edition cancels and replaces previous editions, which have been technically revised

— The scope of all parts remains the same.

— The alignment with HL7 FHIR and with the openEHR Reference Model has been improved, utilising the guide published in ISO/PAS 24305 [1].

— The name attribute has been reinstated in this revision against circumstances to cater better for vendors and providers who do not intend to use archetypes.

— The structural alignment with the openEHR Reference Model and archetype-based semantics has been improved. However, the explicitly separate template layer that openEHR uses has not been introduced, and is an area of consideration for future harmonisation guidance.

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

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

Introduction

0.1 Preface

The overall goal of this document is to define a rigorous and stable information architecture for exchanging or archiving part or all of the electronic health record (EHR) of a single subject of care (patient), or for a group of patients whose information might need to be communicated together (for example, a family). This is to support the interoperability of systems (see Annex C). and components that need to communicate (access, transfer, add or modify) EHR data. The information architecture defined in this document is intended to support safe processing of exchanged EHR data by ensuring that the exchange can:

— preserve the original clinical meaning intended by the author;

— incorporate the necessary provenance metadata to inform the recipient or receiving system about the context in which the EHR data were obtained and composed;

— observe and communicate the confidentiality of that data as intended by the author and subject of care .

This document considers the EHR to be the persistent longitudinal and potentially multi-organisation or multi-national record of health and care provision, most often relating to a single subject of care (the patient), created and stored in one or more physical systems. Its primary purpose is to support future healthcare for the subject of care and to provide a medico-legal record of care delivered. This corresponds to the definition provided in ISO 18308 [2].

This document is not intended to specify the internal architecture or database design of EHR systems or components, nor is it intended to prescribe the kinds of clinical 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. These might be used to communicate EHR data between two repositories, to update a centralised regional or national EHR repository, or within a distributed network of EHR components, systems and services. 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 document has only touched on those areas if some persistent trace of such interactions is required in the EHR itself, and therefore requires specific features in the reference model to communicate that trace.

This document 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. The components that might support an interface conforming to this document will be not only electronic health record systems but also other middleware services such as security components, guideline and workflow systems, alerting and decision support services, personal health systems and applications, sensors and wearable devices, and medical knowledge management services. This document might also prove useful for communicating data about individuals between electronic health record systems and population registries, and also for conducting (approved) research using electronic health records.

This document is part of a five-part standard series, published jointly by CEN and ISO through the Vienna Agreement.

In this document dependency upon any of the other parts of this series is explicitly stated where it applies.

0.2 Technical approach

This document is the third version of an original standard which was published in 2007 by CEN, and in 2008 by ISO. It meets the relevant requirements in ISO 18308 [2].

The revision has taken into account, and aligns as far as possible, with other CEN and ISO Standards and Technical Specifications with which this document might also be used, with international terminology standards and with emerging standards from HL7: Fast Healthcare Interoperability Resources (FHIR). The specifications in this document have drawn from, and align as far as possible with, the reference model specifications published by the openEHR Foundation, and with the archetype models published by the openEHR Foundation.

The information model in this document is an Information Viewpoint of the ISO Reference Model for Open Distributed Processing (ISO/IEC 10746-1 [3] **)**. In practical terms, this document defines the structure and semantics of EHR information to be exchanged, rather than prescribing technologies, storage architectures, or deployment patterns.

Given the diversity of deployed EHR systems, this document permits optionality for many features of EHR communication. However, a minimum level of prescription is required to ensure that EHR extracts can be processed safely and consistently by EHR recipient systems. This is reflected in mandatory properties within the models in Parts 1, 2 and 4 of this series, and through normative term lists (defined in Part 3).

0.3 The Dual Model approach

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

The approach adopted by this standard series distinguishes a Reference Model, defined in this document and used to represent the generic properties of health record information , and Archetypes (conforming to an archetype model , defined in ISO 13606-2:2019 [4]), which are meta-data used to define patterns for the specific characteristics of the healthcare data that represents the requirements of each particular profession, speciality or service.

This document adopts a dual model approach based on a stable Reference Model and archetype constraints. However, readers should note that openEHR operationalises a more explicit multi-level modelling pattern in which archetypes define reusable domain concepts and templates apply context-specific constraints for particular use cases, workflows and deployment settings. In this document, such template-level concerns are not separated with the same degree of formality, and this has implications for granularity, semantic governance and implementation guidance.

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

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

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

This document recognises that archetypes (or equivalent clinical models) are not always directly incorporated within the present-day architectures of electronic health record systems. This document therefore does not mandate that archetypes are used within such systems. It does, however, require that the clinical information models or equivalents (data items, data item aggregations, data value constraints, terminology bindings, units of measure etc.) that have been used to generate an EHR_EXTRACT are themselves created and communicated, or referenced, within each EHR_EXTRACT. These communicated or referenced archetypes have to conform to Part 2 of this standard series, and maybe communicated through an interface conforming to part 5 of this Standard series.

In this document, archetypes are the primary formal mechanism for expressing domain-level constraints over the reference model. Where implementers use templates or equivalent contextual artefacts, these are better understood as implementation-specific assemblies or refinements of archetypal content rather than as a separately formalised modelling layer.

0.4 Overview of the EHR_EXTRACT record hierarchy

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

The EHR Communications 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. To do this, the model formally sub-divides the EHR hierarchy into parts that have been found to provide a consistent mapping to the ways which individual EHRs are organised within heterogeneous EHR systems.

These parts are summarised in Table 1 below.

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

EHR HIERARCHY COMPONENT	DESCRIPTION	EXAMPLES
EHR_EXTRACT	The top-level container of part or all of the EHR of a single subject of care or for a group of subjects of care (such as a family), for communication between an EHR Provider system and an EHR Recipient.	(Not applicable)
FOLDER	The high level organisation within an EHR, dividing it into compartments relating to care provided to a single subject of care , for a single condition, by a clinical team or institution, or over a fixed time period such as an episode of care.	Diabetes care, Schizophrenia, Cholecystectomy, Paediatrics, St Mungo's Hospital, GP Folder, Episodes 2000-2001.
COMPOSITION	The set of information committed to one EHR by one agent, as a result of a single clinical encounter or record documentation session.	Progress note, Laboratory test result form, Radiology report, Referral letter, Clinic visit, Clinic letter, Discharge summary, Functional health assessment, Diabetes review.
SECTION	EHR data within a COMPOSITION that belongs under one clinical heading, usually reflecting the flow of information gathering during a clinical encounter, or structured for the benefit of future human readership.	Reason for encounter, Past history, Family history, Allergy information , Subjective symptoms, Objective findings, Analysis, Plan, Treatment, Diet, Posture, Abdominal examination, Retinal examination.
ENTRY	The information recorded in an EHR as a result of one clinical action, one observation, one clinical interpretation, or an intention. This is also known as a clinical statement.	A symptom, an observation, one test result, a prescribed drug, an allergy reaction, a diagnosis, a differential diagnosis, a differential white cell count, blood pressure measurement.
CLUSTER	The means of organising nested multi-part data structures such as time series, and to represent the columns of a table.	Audiogram results, electro-encephalogram interpretation, weighted differential diagnoses.
ELEMENT	The leaf node of the EHR hierarchy, containing a single data value.	Systolic blood pressure, heart rate, drug name, symptom, body weight.

An EHR_EXTRACT contains EHR data as COMPOSITIONs, organised in a FOLDER hierarchy.

COMPOSITIONs contain ENTRYs, optionally contained within a SECTION hierarchy.

ENTRYs contain ELEMENTS, optionally contained within a CLUSTER hierarchy.

Representing participation: The Reference Model in the previous version of this standard provided explicit classes at certain parts of the Record Component hierarchy through which it was possible to represent the identity and roles played by actors contributing to healthcare and to its documentation. In this version of the Reference Model the LINK class is intended to be used to reference demographic entities. The roles played by these entities can be labelled using extended term lists defined in Part 3 of this standard series. This updated mechanism offers greater flexibility than the previous version in where the references to such democratic entities may be represented within the Record Component hierarchy.

Representing context: Any EHR_EXTRACT references any other RECORD_COMPONENTS that are connected to the communicated content, for example via the RECORD_COMPONENT hierarchy and via LINK targets. If the EHR exchange service (e.g. as specified in Part 5) permits access to referenced components, any user would be able to access and review any additional areas of content that were not originally included. (Archetypes bring together the key elements of immediate documentation context.)

Representing authenticity: Every EHR_EXTRACT may contain attested views: these might be PDF or html or other renderings that are the authentic view of what was seen and persisted by the original author. The proof may also optionally be included, which is the evidence of a digital signature .

EHR_EXTRACTS are created for specific purposes, and will not automatically guarantee that these will be fit for other purposes.

0.5 Relationship of this standard to other relevant standards

— The data types used in this document are a profile of ISO 21090:2011 [5].

— Alignment has especially been undertaken with ISO 13940 [6]. All of the terms and definitions within the ISO 13606 series have been harmonised across the five parts, with most of the terms being in Part 1. All of them have been aligned with ISO 13940 [6].

— An important 13606 FHIR profile project is in progress within HL7 (see Annex B). No challenges have been identified with being able to create such a profile.

— Parts 1 and 4 align with ISO 27789 [7]. Alignment in Part 4 has been maintained with ISO 22600 series .

Health informatics — Electronic health record communication —

Part 1: Reference model

1 Scope

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

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

This document will predominantly be used to support the direct care given to identifiable individuals or self-care by individuals themselves, or to support population monitoring systems such as disease registries and public health surveillance, animals, and events such as pollution, poisons, etc. . Uses of health records for other purposes such as teaching, clinical audit, administration and reporting, service management, research and epidemiology, which often require anonymization or aggregation of individual records, are not the focus of this document but such secondary uses might also find the document useful.

This document is an Information Viewpoint specification as defined ISO/IEC 10746-1 [3]. This document is not intended to specify the internal architecture or database design of EHR systems.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

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

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

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

3.1 Actors

3.1.1
attester
actor (person) who certifies and records legal responsibility for a particular unit of *information* (3.3.9)

3.1.2
committer
agent (party, device or software) whose direct actions have resulted in *information* (3.3.9) being committed

3.1.3
composer
healthcare actor responsible for creating, synthesising or organising information that is committed to an electronic health record

Note 1 to entry: This agent takes responsibility for its inclusion in that *electronic health record* (3.3.13) , even if not the originator of it and even if not the *committer* (3.1.2) of it.

3.1.4
electronic health record provider
healthcare actor in legitimate possession of *electronic health record* (3.3.13) *data* (3.3.5) and in a position to communicate it to another appropriate entity

3.1.5
healthcare provider
care provider
health provider
health service provider
healthcare service provider
healthcare actor that is able to be assigned one or more care period mandates

Note 1 to entry: The personnel of a healthcare organization that is a *healthcare provider* (3.1.5) may include both healthcare professionals and others which participate in the provision of healthcare.

Note 2 to entry: This document includes only two specializations of *healthcare provider* (3.1.5). This is not meant to exclude the possibility of other specializations. In jurisdictions where other kinds of healthcare actors are included in the concept of *healthcare provider* (3.1.5), the necessary specializations may be added.

Note 3 to entry: According to this definition, organizations solely responsible for the funding, payment, or reimbursement of healthcare provision are not healthcare providers; for the purpose of this document they are considered as healthcare third parties.

[SOURCE: ISO/FDIS 13940 [8]]

3.1.6
role
function or position

3.1.7
subject of care
patient
client
service user
consumer
person seeking to receive, receiving, or having received care

EXAMPLE 1 A treated patient.

EXAMPLE 2 A client of a physiotherapist.

EXAMPLE 3 Each member of a target population for screening.

EXAMPLE 4 Each member of a group of diabetic people attending a session of medical education.

EXAMPLE 5 A person seeking health advice.

Note 1 to entry: A foetus may be considered as a subject of care when receiving care.

[SOURCE: ISO/FDIS 13940 [8] 3.3.2, modified Note 2 removed]

3.2 Concepts and terms

3.2.1
generic
applicable to requirements or information models across healthcare professions, domains and countries

3.3 Information management

3.3.1
abstract class
class that cannot be instantiated independently

[SOURCE: ISO/IEC/IEEE 24765:2017 [9] , 3.24]

3.3.2
archetype
instance of an *archetype model* (3.3.3) , specifying the clinical concept and the value constraints that apply to one class of Record Component instances in an *electronic health record* (3.3.13) extract

3.3.3
archetype model
information model of the *metadata* (3.3.18) to represent the domain-specific characteristics of *electronic health record* (3.3.13) entries, by specifying values or value constraints for classes and attributes in the *electronic health record* (3.3.13) reference model

3.3.4
client application
healthcare application (3.3.16) which is behaving at that moment as a requester of *health record* (3.3.11) *data* (3.3.5) from a shareable *electronic health record* (3.3.13)

3.3.5
data
reinterpretable representation of *information* (3.3.9) in a formalized manner suitable for communication, interpretation or processing

Note 1 to entry: *data* (3.3.5) defined without any context in such a way that by itself one cannot tell its correct meaning, where it has meaning this is *information* (3.3.9) .

[SOURCE: ISO/IEC 2382:2015 [10], 2121272]

3.3.6
data repository
identifiable *data* (3.3.5) storage facility

Note 1 to entry: In ISO 10303-22:1998 [11] this is the definition of repository.

[SOURCE: ISO/FDIS 13940 [8] 3.1.17]

3.3.7
healthcare data
data (3.3.5) produced during healthcare activities

3.3.8
healthcare information
information (3.3.9) about a person, relevant to his or her healthcare

3.3.9
information
knowledge concerning objects that within a certain context has a particular meaning

Note 1 to entry: Facts, events, things, processes, and ideas, including concepts, are examples of objects.