1 Scope

This European Standard specifies the communication of part or all of the electronic health record (EHR) of a single identified subject of care between EHR systems, or between EHR systems and a centralised EHR data repository.

It may also be used for EHR communication between an EHR system or repository and clinical applications or middleware components (such as decision support components) that need to access or provide EHR data.

This European Standard will predominantly be used to support the direct care given to identifiable individuals, or to support population monitoring systems such as disease registries and public health surveillance. Uses of health records for other purposes such as teaching, clinical audit, administration and reporting, service management, research and epidemiology, which often require anonymisation or aggregation of individual records, are not the focus of this European Standard but such secondary uses might also find the standard useful.

This Part 1 of the multipart series is an Information Viewpoint specification as defined by the Open Distributed Processing – Reference model: Overview (ISO/IEC 10746-1). This European Standard is not intended to specify the internal architecture or database design of EHR systems.

2 Normative references

Not applicable.

3 Terms and definitions

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

3.1
abstract class
in Unified Modelling Language, a “virtual” common parent to two or more classes; the abstract class will never be instantiated.

NOTE Its value in modelling terms is to provide a container for attributes and associations that might apply to several other classes (its sub-classes)

3.2
access control
means of ensuring that the resources of a data processing system can be accessed only by authorised entities in authorised ways

[ISO/IEC 2382-8:1998]

3.3
accountability
property that ensures that the actions of an entity may be traced uniquely to that entity

[ISO/IEC 2382-8:1998]

3.4
archetype instance
individual metadata class instance of an Archetype Model, specifying the clinical concept and the value constraints that apply to one class of Record Component instances in an electronic health record extract

3.5
archetype model
information model of the metadata to represent the domain-specific characteristics of electronic health record entries, by specifying values or value constraints for classes and attributes in the electronic health record Reference Model

3.6
archetype repository
persistent repository of archetype definitions, accessed by a client authoring tool or by a run-time component within an electronic health record service

3.7
attester
party (person) who certifies and records legal responsibility for a particular unit of information

3.8
attestation
process of certifying and recording legal responsibility for a particular unit of information

3.9
audit trail
chronological record of activities of information system users which enables prior states of the information to be faithfully reconstructed

3.10
authentication
process of reliably identifying security subjects by securely associating an identifier and its authenticator

[ISO 7498-2:1989]

3.11
authorisation
granting of rights

3.12
client application
healthcare application which is behaving at that moment as a requester of health record data from a shareable electronic health record

3.13
clinical information
information about a person, relevant to his or her health or health care

3.14
committed
information that has been persisted within an electronic health record system and which constitutes part of the electronic health record of a subject of care

3.15
committer
agent (party, device or software) whose direct actions have resulted in data being committed to an electronic health record

3.16
composer
agent (party, device or software) responsible for creating, synthesising or organising information that is committed to an electronic health record.

NOTE This agent takes responsibility for its inclusion in that electronic health record, even if not the originator of it and even if not the committer of it

3.17
confidentiality
property that information is not made available or disclosed to unauthorised individuals, entities, or processes

[ISO 7498-2:1989]

3.18
contribution
set of Record Components committed by one user at one point in time in the electronic health record of one subject of care

3.19
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 7498-2:1989]

3.20
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

3.21
electronic health record extract
part or all of the electronic health record of a subject of care, communicated in compliance with EN 13606

3.22
electronic health record information architecture
ODP Information Viewpoint specification of an electronic health record

3.23
electronic health record provider
entity in legitimate possession of electronic health record data and in a position to communicate it to another appropriate entity

3.24
electronic health record recipient
entity to whom electronic health record data is communicated by an electronic health record provider

3.25
electronic health record requester
entity initiating a request for electronic health record communication to take place between an electronic health record provider and an electronic health record recipient

3.26
electronic health record system
system for recording, retrieving and manipulating information in electronic health records

3.27
entries
health record data in general (clinical observations, statements, reasoning, intentions, plans or actions) without particular specification of their formal representation, hierarchical organisation or of the particular Record Component class(es) that might be used to represent them

3.28
federated health record
virtual view of a patient's health record that can be obtained from all electronic health record entries about that patient that are held by different systems in communication using standard electronic health record extracts

3.29
feeder system
repository (for health record data) that may be queried within a federation of electronic health record systems in order to contribute to a federated health record

3.30
generic
applicable to requirements or information models across healthcare professions, domains and countries

3.31
health care agent
person, device, or software that performs a role in a health care activity

[prEN 13940:2005]

3.32
health care device
device or equipment involved in the direct or indirect provision of health care services to an individual or to a population

3.33
health care organization
organisation involved in the direct or indirect provision of health care services to an individual or to a population

NOTE Groupings or subdivisions of an organisation, such as departments, may also be considered as organisations where there is a need to identify them.

3.34
health care party
person involved in the direct or indirect provision of health care services to an individual or to a population

3.35
health care service
service provided with the intention of directly or indirectly improving the health of the person or populations to whom it is provided

3.36
legacy data
data that were collected and maintained using a "previous" system, but are now preserved on a "current" system

3.37
metadata
data that defines object class and property for the information collected

[ISO/IEC 11179-3:2003]

3.38
non-repudiation
service providing proof of the integrity and origin of data (both in an un-forgeable relationship), which can be verified by any party

[ISO/TS 17090-1:2002]

3.39
patient
synonym for a subject of care

3.40
persistent data
data which are stored on a permanent basis

3.41
personal health record
health record for which the subject of care or a legal representative of the subject of care is the data controller

3.42
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]

3.43
Record Component
part of the electronic health record extract of a single subject of care, represented as a node within a hierarchical data structure conforming to EN 13606

3.44
role
name of a set of behaviours that is associated with a task

[ISO/TS 17090-1:2002]

3.45
semantic interoperability
ability for data shared by systems to be understood at the level of fully defined domain concepts

[ISO/TS 18308:2002]

3.46
shareable electronic health record
electronic health record with a standardised information model which is independent of electronic health record systems and accessible by multiple authorised users

[ISO/TR 20514:2005]

3.47
standard
document, established by consensus and approved by a recognized 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/IEC Guide 2:2004]

3.48
state (of a process)
condition or situation during the lifecycle of an object during which it satisfies some condition, performs some activity or waits for some event

[ISO/TS 18308:2002]

3.49
subject of care
person scheduled to receive, receiving, or having received health care

3.50
view
alternate presentation of data for a different user or purpose

4 Abbreviations

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

CEN
Comité Européen de Normalisation (European Committee for Standardization, a federation of 28 national standards bodies that are also ISO member bodies)

CEN/TC 251
CEN Technical Committee 251 (develops standards within health informatics)

CMET
Common Message Element Type (a formalism defined by HL7)

EHCR
Electronic Healthcare Record

EHR
Electronic Health Record

EU
European Union

GEHR
Good European Health Record (a research project, 1992-5)

GP
General Practitioner

HISA
Health Informatics Service Architecture (acronym used for prEN 12967)

HL7
Health Level Seven

IANA
Internet Assigned Numbers Authority

IETF
Internet Engineering Task Force

ISO
International Organization for Standardization

ODP
Open Distributed Processing (ISO/IEC 10746, used for describing distributed systems)

R&D
Research and Development

RFC
Request For Comments

SPRI
Swedish Institute for Health Services Development

UML
Unified Modelling Language

W3C
World Wide Web Consortium

XML
Extensible Mark-up Language

5 Conformance (normative)

5.1 EHR System conformance

5.1.1 A system for communication of EHR information is conformant with this European Standard if all information that is exchanged which is within the scope of this European Standard can be expressed in a form where there is a direct correspondence between the communicated data structure and the information model of an EHR_EXTRACT defined in Clause 6 herein using UML. Part 5 of this series specifies different exchange models.

5.1.2 Some conformant EHR systems will use only a subset of the many optional classes, attributes and data types defined in this European Standard, according to the intended uses. For a sending system this will be determined by the EHR data that can be stored in that system. An EHR receiving system that is fully conformant needs either to be able to handle all possible information that can be expressed using this European Standard or to declare its limitations of scope. Also, when all information classes and attributes are implemented, it is necessary to declare the limitations of the semantic interoperability of an EHR system conformant to this European Standard in relation to the use of terminology systems and e.g. various encapsulated objects.