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Health informatics — Electronic health record — Definition, scope and context

Informatique de santé — Dossier de santé informatisé — Définitions, domaine et contexte

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

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ISO/TR 20514 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

This Technical Report was prepared in order to establish a set of categories of, and definitions for, electronic health records in order to describe the scope of application of the family of EHR standards currently programmed for development by ISO.

The primary purpose of ISO's family of EHR standards is to maximize interoperability between electronic records and systems that are specifically intended to be shareable, irrespective of the technologies they use and the platforms on which they reside.

However, a variety of health information systems may include features and functionality that could be characterized as belonging to an EHR system. Similarly, many health information systems may produce output in the form of EHR extracts or entries, as described in ISO/TS 18308, irrespective of whether their primary purpose or application is as a shareable EHR.

Health informatics — Electronic health record — Definition, scope and context

1 Scope

This Technical Report describes a pragmatic classification of electronic health records, provides simple definitions for the main categories of EHR and provides supporting descriptions of the characteristics of electronic health records and record systems.

2 Terms and definitions

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

2.1
archetype
⟨descriptive⟩ model of a clinical or other domain-specific concept which defines the structure and business rules of the concept

NOTE Archetypes may define simple compound concepts such as "blood pressure" or "address", or more complex compound concepts such as "family history" or "microbiology result". They are not used to define atomic concepts such as anatomical terms. Archetypes use terms which may be derived from external terminologies to identify archetype components.

[Beale:2003[11]]

2.2
archetype
⟨technical⟩ computable expression of a domain-level concept in the form of structured constraint statements, based on some reference information model

NOTE 1 Archetypes are one-to-one with domain concepts, which can themselves have interior complexity.

NOTE 2 Archetypes all have the same formalism but can be either part of a standardized/shared ontology (i.e. definitional) or only used locally or regionally (i.e. not considered definitional).

[Beale:2003[11]]

2.3
architecture
that set of design artefacts or descriptive representations that are relevant for describing an object such that it can be produced to requirements (quality) as well as maintained over the period of its useful life (change)

[Zachman:1996[24]]

2.4
client
individual who is a subject of care

NOTE The terms "client" and "patient" are synonymous but the usage of one or other of these terms tends to differ between different groups of health professionals. Clinicians working in a hospital setting and medical practitioners in most settings tend to use the term "patient" whereas allied health professionals tend to use the term "client".

2.5
clinical data repository
CDR
data store that holds and manages clinical data collected from service encounters at point of service locations (e.g. hospitals, clinics)

NOTE 1 Adapted from Infoway:2003[13].

NOTE 2 Data from a CDR can be fed to the EHR for that subject of care; in that sense the CDR is recognized as a source system for the EHR.

NOTE 3 A CDR complies with the definition of a basic-generic EHR but not with the more specialized definition of an Integrated Care EHR (ICEHR).

2.6
clinician
health professional who delivers health services directly to a patient/client

NOTE Adapted from ISO/TS 18308[3].

2.7
COMPOSITION
sub-class of RECORD_COMPONENT in the EN13606 Reference Model that contains the set of RECORD_COMPONENTS composed (authored) during one user's clinical session or record interaction, for committal within one HER

[ENV 13606-1[6]]

2.8
computer processable information
information which can be programmatically created, stored, manipulated, and retrieved in an electronic computer

2.9
consumer
individual who may become a subject of care

2.10
electronic health record for integrated care
ICEHR
repository of information regarding the health status of a subject of care, in computer processable form, stored and transmitted securely and accessible by multiple authorized users, having a standardized or commonly agreed logical information model that is independent of EHR systems and whose primary purpose is the support of continuing, efficient and quality integrated health care

NOTE It contains information which is retrospective, concurrent and prospective.

2.11
electronic health record
EHR
⟨basic generic form⟩ repository of information regarding the health status of a subject of care, in computer processable form

NOTE The definition of the EHR for integrated care in 2.10 is considered to be the primary definition of an electronic health record. The definition of a basic-generic EHR is given only for completeness and to acknowledge that there are still currently many variants of the EHR in health information systems which do not comply with the main (ICEHR) EHR definition (e.g. a CDR complies with the basic-generic EHR definition but not with the ICEHR definition).

2.12
electronic health record architecture
EHRA
generic structural components from which all EHRs are built, defined in terms of an information model

[ISO/TS 18308[3]]

NOTE A more descriptive informal definition of an EHRA is that of a model of the generic features necessary in any electronic healthcare record in order that the record may be communicable, complete, a useful and effective ethico-legal record of care and may retain integrity across systems, countries and time. The architecture does not prescribe or dictate what anyone stores in their healthcare records. Nor does it prescribe or dictate how any electronic healthcare record system is implemented. It places no restrictions on the types of data which can appear in the record, including those that have no counterpart in paper records. Details like “field sizes”, coming from the world of physical databases, are not relevant to the electronic healthcare record architecture.

[EU-CEN:1997[12]]

2.13
EHR extract
unit of communication of all or part of the EHR which is itself attestable and which consists of one or more EHR compositions

NOTE Adapted from ISO/TS 18308[3].

2.14
EHR node
physical location where EHRs are stored and maintained

2.15
EHR system
⟨components⟩ set of components that form the mechanism by which electronic health records are created, used, stored and retrieved including people, data, rules and procedures, processing and storage devices, and communication and support facilities

NOTE 1 Adapted from IOM:1991[14].

NOTE 2 The original IOM definition referred to a “CPR System” (Computer-based Patient Record System) and used the term “patient records” rather than “electronic health records”.

2.16
EHR system
⟨system⟩ system for recording, retrieving and manipulating information in electronic health records

NOTE 1 Adapted from ENV 13606-1[6].

NOTE 2 This definition is identical to the original CEN definition except that the original term “electronic health care record” has been abbreviated to “electronic health record” to be consistent with the terminology used throughout this Technical Report.

2.17
encounter
contact in the course of which health activities are delivered to a subject of care in her or his presence, and her or his health record is accessed or managed

NOTE 1 Adapted from EN 13940-1[8].

NOTE 2 This definition is identical to the original CEN definition except that the original term “health care” has been abbreviated to “health” to be consistent with the terminology used throughout this Technical Report.

2.18
functional interoperability
ability of two or more systems to exchange information

2.19
health
state of complete physical, mental and social well-being and not merely the absence of disease or infirmity

[WHO:1948[23]]

2.20
health condition
alterations or attributes of the health status of an individual which may lead to distress, interference with daily activities, or contact with health services; it may be a disease (acute or chronic), disorder, injury or trauma, or reflect other health-related states such as pregnancy, aging, stress, congenital anomaly or genetic disposition

[WHO:1948[23]]

2.21
health organization
organisation involved in the direct provision of health activities

NOTE 1 Adapted from ENV 13940-1[8].

NOTE 2 This definition is identical to the original CEN definition except that the original term “health care” has been abbreviated to “health” to be consistent with the terminology used throughout this Technical Report.

2.22
health problem
health condition that results in some disability, pain and/or activity limitation

2.23
health professional
person who is authorized by a recognized body to be qualified to perform certain health duties

NOTE 1 Adapted from ISO/TS 17090-1[2].

NOTE 2 The defined term is often named “healthcare professional”. A convention has been adopted in this Technical Report whereby the term “healthcare” is abbreviated to “health” when used in an adjectival form. When used in a noun form, the word “care” is retained but as a separate word (e.g. delivery of health care).

2.24
health provider
health professional or health organization involved in the direct provision of health activities

NOTE 1 Adapted from ENV 13940-1[8].

NOTE 2 This definition is identical to the original CEN definition except that the original term “health care” has been abbreviated to “health” to be consistent with the terminology used throughout this Technical Report.

2.25
health record
repository of information regarding the health of a subject of care

NOTE Adapted from ENV 13940-1[8].

2.26
health status
individual's current state of physical, mental and social well-being

2.27
information service
ability of a system to provide a defined set of output information based on a defined set of input information

[EN 12967-1 to 3[7]]

2.28
integrated care EHR
ICEHR
See 2.10

2.29
logical information model
information model that specifies the structures and relationships between information but is independent of any particular technology or implementation environment

NOTE Information models are commonly classified from high-level abstract models through to concrete technology implementation models. The ISO Health Informatics Profiling Framework (ISO/TR 17119[1]) defines three levels of specificity for information models and other artefacts *viz* conceptual, logical and physical. Logical information models provide detailed specifications for components of the model (e.g. container, section and link classes in a UML object model of an EHR) and the relationships between the components, without any technological constraints. A logical information model is therefore independent of any particular implementation technology. A physical information model on the other hand, includes technological constraints to enable the building of a particular implementation of the logical model (e.g. an EHR system built for a particular hardware and software platform).

2.30
patient
client
individual who is a subject of care

NOTE 1 Adapted from ISO/TS 18308[3].

NOTE 2 The terms “patient” and “client” are synonymous but the usage of one or other of these terms tends to differ between different groups of health professionals. Clinicians working in a hospital setting and medical practitioners in most settings tend to use the term “patient” whereas allied health professionals tend to use the term “client”.

2.31
semantic interoperability
ability for information shared by systems to be understood at the level of formally defined domain concepts

NOTE Adapted from ISO/TS 18308[3].

2.32
service
number of processes, involving an organization in the provision of specific objectives

[EN 12967-1 to 3[7]]

NOTE See also 2.27.

2.33
shareable EHR
EHR with a commonly agreed logical information model

NOTE 1 The shareable EHR *per se* is an artefact between a basic-generic EHR and the Integrated Care EHR (ICEHR) which is a specialization of the shareable EHR. The shareable EHR is probably of little use without the additional clinical characteristics thath are necessary for its effective use in an integrated care setting.

NOTE 2 Whilst the ICEHR is the target for interoperability of patient health information and optimal patient care, it is of note that the large majority of EHRs in use at present are not even shareable let alone have the additional characteristics

required to comply with the definition of an Integrated Care EHR. A definition of a basic-generic EHR has therefore been included to acknowledge this current reality.

2.34
standard
document, established by consensus and approved by a recognized body, which 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[4]]

2.35
subject of care
one or more persons scheduled to receive, receiving or having received a health service

[ISO/TS 18308[3]]

NOTE 1 The terms “patient” and “client” are synonymous with subject of care in a health record context and are commonly used instead of the more formal term “subject of care”.

NOTE 2 The term “consumer” is also often used as a synonym in this context. However, it is of note that a consumer may not necessarily be a subject of care since it can be argued that it is possible for a consumer to have a health record without ever having received a health care service.

2.36
template
directly, locally usable data creation/validation artefact that is semantically a constraint/choice of archetypes and which will often correspond to a whole form or screen

[Beale:2003[11]]

NOTE Templates in general have a one-to-many relationship with underlying concepts, each of which is described by an archetype.

3 Definition of Electronic Health Record

3.1 Definitional approach

Previous attempts to develop a definition for the Electronic Health Record (EHR) have foundered due to the difficulty of encapsulating all of the many and varied facets of the EHR in a single comprehensive definition.

The approach taken in this Technical Report is to make a clear distinction between the content of the EHR and its form or structure. This is achieved by first defining the EHR in terms of its structure (i.e. as a container). This definition (called the “basic-generic EHR”) is intentionally concise and generic to ensure the broadest applicability to the widest range of existing and future users of EHRs and EHR systems. Such a definition shall also be able to support legislative and access control requirements that apply to all “forms” of EHR.

The basic-generic EHR definition is supplemented by a more detailed and specialized definition to cover two of the most essential characteristics of the EHR not covered by the basic-generic definition. These are the ability to share patient health information between authorized users of the EHR and the primary role of the EHR in supporting continuing, efficient and quality integrated health care. There are of course many other important characteristics of the EHR dependent on the scope and context of care, which will not be explicitly expressed in a single supplementary definition. It would be possible to develop a whole series of formal definitions to capture all of the nuances of different care contexts. However, the approach taken in this Technical Report is to keep the number of formal definitions of EHR types to an essential minimum and to demonstrate the inclusiveness of these definitions through explanatory text and examples.