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Health informatics — Requirements for an electronic health record architecture

Informatique de santé — Exigences relatives à une architecture de l'enregistrement électronique en matière de santé

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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

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

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

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 18308 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

This first edition cancels and replaces ISO/TS 18308:2004, of which it constitutes a technical revision.

Introduction

Context

This International Standard defines the set of requirements that shall be met by the architecture of systems and services processing, managing and communicating electronic health record (EHR) information. This is in order to ensure that these EHRs are faithful to the needs of healthcare delivery, are clinically valid and reliable, are ethically sound, meet prevailing legal requirements, support good clinical practice and facilitate data analysis for a multitude of purposes.

For the purposes of this International Standard, the EHR is defined as:

> "one or more repositories, physically or virtually integrated, of information in computer processable form, relevant to the wellness, health and healthcare of an individual, capable of being stored and communicated securely and of being accessible by multiple authorized users, represented according to a standardized or commonly agreed logical information model. Its primary purpose is the support of life-long, effective, high quality and safe integrated healthcare."

To complement this definition, the ideal vision of health (and consequently health information) is reflected in the WHO definition from 1946[1)]:

> "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."

The scope of the EHR is recognized as being broader than the documentation of illnesses and their prevention and treatment. The systems and services that are deemed potential contributors to an EHR will increasingly include systems capturing complementary therapy, wellness, and home care information in addition to the conventional clinical systems within healthcare provider organizations.

The notion of the personal health record (PHR)[2)] is also maturing internationally and, while this International Standard does not specifically focus on the PHR, its requirements have been deliberately worded to be inclusive of the PHR in general terms, i.e. most of these EHR requirements will also apply to the PHR.

It is recognized, as a limitation, that no authoritative source of requirements has been found for the records of any of the complementary or traditional forms of healthcare practised internationally. Indeed, a recent literature review has suggested that there is a real lack of published work on the use of electronic health records within complementary healthcare or on the sharing of these health records (paper or electronic) with allopathic medicine[23]. It is equally the case that there is a lack of consensus requirements for systems to support wellness, social, and home care, but these systems will increasingly play an interactive role with EHRs, and information in them might become part of the EHR.

This International Standard is intended to be used when designing the architecture of health information services that incorporate or interact with electronic health record systems (EHR-Ss) or repositories.

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1) WHO. Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June 1946, and entered into force on 7 April 1948. Available from: http://www.who.int/governance/eb/who_constitution_en.pdf

2) The personal health record is generally taken to mean a health record whose content is primarily managed by an individual, while the EHR is generally taken to mean a health record that is controlled and managed by a healthcare provider (organization or person), but to which the subject of care normally has certain rights. It is recognized that a clear distinction does not always exist between these kinds of records.

EHR architectures

The requirements in this International Standard relate to shared EHR information [sometimes referred to as the “shared health record” (SHR), “shared care record” (SCR), or “health information exchange” (HIE)] and those aspects of governance within and between EHR systems that may be used to support and coordinate patient-centred continuity of care. The EHR for a subject of care might be scattered physically across multiple (discrete or interconnected) clinical systems and repositories, each of which will hold and manage a partial EHR for each of its subjects of care, scoped according to the service or community settings, clinical domains and time periods of use of that system in the life of each person.

The use of distributed computing mechanisms could permit a more holistic EHR to be realized, subject to relevant permissions. This holistic EHR will sometimes be stored and regularly updated in a centralized EHR repository (e.g. through a national e-health infrastructure), might be organized and accessed according to national indexing structures, or might only materialize just in time as a result of distributed querying across a distributed set of repositories. The formal (structural and functional) description of a system of components and services for recording, retrieving, and handling information in EHRs is known as an *EHR architecture*: this International Standard therefore defines the requirements for an EHR architecture (EHRA).

The Open Group Architecture Framework (TOGAF)[3)] explains an architecture as:

> “a formal description of a system, organized in a way that supports reasoning about the structural properties of the system. It defines the system components or building blocks…and provides a plan from which products can be procured, and systems developed, that will work together to implement the overall system.”

This International Standard is not concerned with the specific requirements that individual (localized) applications and EHR repositories and services need to meet, but with the common set of requirements that ALL shall meet in order to permit their EHR data to be safely communicated and combined to form richer and more complete EHRs. It is therefore primarily concerned with the EHR from the perspective of a user or purchaser, and corresponds to the RM-ODP enterprise viewpoint perspective (reference model of Open Distributed Processing ISO/IEC 10746-1) rather than its technical specification.

It should be noted that the progressive adoption of electronic health records and systems globally will often be complemented by other changes to the business processes of healthcare and health services, some of which might be mediated through the functions and workflows of EHR systems, and other changes effected through training and the development of new staff roles and new healthcare resources. The business objectives defined in Clause 5 are likely to require a holistic approach to their realization rather than to arise as a direct result of the EHR in isolation.

EHR architecture and EHR system requirements

An EHR system will comprise one or more data repositories, directory services listing human and other resource entities, knowledge services containing terminological systems, care pathways and workflows, end user applications, reporting modules, security services, etc. The requirements for an EHR system relate closely to the functionality that end users will experience directly, and will reflect the business processes to be supported at the care setting in which the system is deployed. In contrast, an EHRA focuses on the infrastructure (the structure and functional relationships of components) managing the health information assets, which might include multiple EHR systems and repositories, and other systems that are beyond the scope of a single care setting (such as national registries of healthcare professionals). Inevitably, though, some requirements for EHR systems and EHR architectures will be common.

A separate and complementary International Standard, ISO/HL7 10781:2009, the HL7 EHR-S functional model, defines the requirements that shall be met by individual EHR systems. The authors of this International Standard and ISO/HL7 10781:2009 have reviewed both standards and verified that there are no conflicting requirements between them. It has not been possible to produce a detailed mapping of common themes, because the requirements statements are expressed at different levels of granularity between the two

3) See http://www.opengroup.org/togaf/ for more information.

International Standards. However, it is recognized that a more precise indication of overlap is a desirable future strategy for both International Standards, when they are next due for revision.

ISO has two complementary documents that specify the requirements of good practice for a clinical data warehouse: ISO/TR 22221 and ISO/TS 29585. These publications clarify good practice in information governance, the protection of privacy, the handling of metadata, management of data quality and general architectural principles. It is anticipated that many clinical data warehouses, used for health system quality monitoring, research and data mining, will be derived from EHR repositories, and many of the information provenance and governance requirements overlap. It is also possible for data flows to work in the opposite direction: for a clinical data warehouse to feed an EHR. There is growing interest internationally in exploring how best to unify these two functions within a single implemented repository; in this case, the requirements and principles for both an EHR architecture and a clinical data warehouse will need to be met.

Approach to defining these requirements

This International Standard updates and replaces ISO/TS 18308:2004, the first normative set of comprehensive requirements for an EHR architecture. Much has been learned since 2004, and several other complementary standards relating to the EHR have been published or are in development. Whereas ISO/TS 18308:2004 drew on and synthesized a significant body of requirements published by research and national projects, this International Standard has been able additionally to draw on a now more mature experience base in the design and use of EHR systems and early experience of large scale e-health infrastructures. Further, it has been possible to build on work done to develop other EHR quality and interoperability standards such as ISO 13606, HL7 v3 Clinical Document Architecture, HL7 v3 Care Provision Message for Record Exchange, the HL7 EHR System Functional Model, and the work of the *open*EHR Foundation. The inputs to this International Standard have therefore included expertise from many standards developers, as well as member bodies who now have experience using ISO/TS 18308:2004.

Requirements statements for computer systems and software should ideally comply with IEEE 830-1998, and should be verifiable, traceable, unambiguous, correct, and relevant. Many of the requirements in this International Standard, particularly those in the ethico-legal category, come under the SRS (software requirements specification) heading of constraints for which the IEEE specification is less precise. Nevertheless, this International Standard follows these IEEE principles as closely as possible.

Ideally each statement below should reference the original published sources of the requirement (as part of its traceability). However, the formal attribution of individual requirements to sources on this scale is neither practical nor faithful. In the 15 year period since some of the earliest publications used by this International Standard, there has been much cross-fertilization of ideas and cross-inclusion of requirements in newer publications, with some improvement and updating as the scope of electronic health records has evolved. Individual publications often cover similar requirement themes to a different level of granularity or stress different perspectives. Although many of the original source publications targeted the specific needs of a country, professional group or implementation scenario, the collated statements attempt to express these requirements in the most generic way possible. This International Standard therefore does not provide citations for the individual requirements statements. The bibliography lists the more substantive publications of generic EHR requirements that have been reviewed during the drafting of this International Standard and ISO/TS 18308:2004.

As for any International Standard and as per ISO/IEC Directives, Part 2, 2004, an EHRA conforms to this International Standard if it can demonstrate conformance to all of the mandatory requirements in Clause 6: those specified using the word “shall”. A small number of requirements in Clause 6 use the word “should”; these are not considered mandatory at the time of publication either because they are as yet too ambitious or might only be of importance in some care settings or countries. It is recognized that this demonstration of conformance will require the development of test plans that are derived from these requirements, and which may also need to reflect any additional local business requirements and anticipated context of use of the EHR architecture.

The EHR business objectives specified in Clause 5 are all optional, but are included as a perspective on the goals to which an EHR and its architecture should contribute, and which have informed the requirements of Clause 6.

Health informatics — Requirements for an electronic health record architecture

1 Scope

This International Standard defines the set of requirements for the architecture of a system that processes, manages and communicates electronic health record (EHR) information: an EHR architecture. The requirements are formulated to ensure that these EHRs are faithful to the needs of healthcare delivery, are clinically valid and reliable, are ethically sound, meet prevailing legal requirements, support good clinical practice and facilitate data analysis for a multitude of purposes.

This International Standard does not specify the full set of requirements that need to be met by an EHR system for direct patient care or for other use cases, but the requirements defined by this International Standard do contribute to the governance of EHR information within such systems.

2 Notation

Each business objective statement in Clause 5 and each requirement statement in Clause 6 is prefixed by a short code. These codes are internal unique identifiers for the statements, to assist in referring to them in other resources such as test plans. These are non-semantic identifiers; they convey no specific meaning in themselves and do not serve to alter the interpretation of the statements they identify. They bear no relation to identifiers used in any other publication.

3 Terms and definitions

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

3.1
architecture
system
structure of components, their functions, their inter-relationships, and the principles and guidelines governing their design and evolution over time

NOTE Adapted from the Open Group Architecture Framework (TOGAF), 2009.

Source: http://www.opengroup.org/architecture/togaf8-doc/arch/chap01.html#tag_02_03.

3.2
attestation
process of certifying and recording legal responsibility for a particular unit of information

[ISO 13606-1:2008, 3.8]

3.3
audit trail
chronological record of activities of information system users which enables prior states of the information to be faithfully reconstructed

[ISO 13606-1:2008, 3.9]

3.4
authentication
process of reliably identifying security subjects by securely associating an identifier and its authenticator

NOTE Adapted from ISO 7498-2:1989, 3.3.22 and 3.3.40.

3.5
authorization
granting permissions

NOTE Adapted from ISO/TS 22600-1:2006, 2.6.

3.6
availability
property of being accessible and useable upon demand by an authorized entity

[ISO 7498-2:1989, 3.3.11]

3.7
care plan
personalized statement of planned healthcare activities relating to one or more specified health issues

NOTE Adapted from EN 13940-1:2007.

3.8
clinical information
information about a person, relevant to his or her health or healthcare

[ISO 13606-1:2008, 3.13]

3.9
clinical process
set of interrelated or interacting healthcare activities performed by one or more healthcare professionals

3.10
code meaning
element within a coded set

[EN 1068:2005]

EXAMPLE "Paris Charles-De-Gaulle" which is mapped on to the three-letter abbreviation "CDG"" by the coding scheme for three-letter abbreviations of airport names.

3.11
code value
result of applying a coding scheme to a code meaning

[EN 1068:2005]

EXAMPLE "CDG" as the representation of "Paris Charles-De-Gaulle" in the coding scheme for three-letter representations of airport names.

3.12
coded set
set of elements that is mapped on to another set according to a code

[ISO/IEC 2382-4:1999, 04.02.02]

3.13
code
coding scheme
collection of rules that maps the elements of a first set on to the elements of a second set

[ISO/IEC 2382-4:1999, 04.02.01]

NOTE The two sets considered here are

— a set of “code meanings” (or “coded set”), and

— a set of “code values” (or “code set”).

Those sets are not *per se* part of the coding scheme.

3.14
coding system
combination of a set of code meanings and a set of code values, based on a coding scheme

[EN 1068:2005]

NOTE Code meanings are typically represented by terms or rubrics, but they can have other representations. Code values are typically numeric or alphanumeric.

3.15
concept
unit of knowledge created by a unique combination of characteristics

[ISO 1087-1:2000, 3.2.1]

3.16
confidentiality
property that information is not made available or disclosed to unauthorized individuals, entities, or processes

[ISO 7498-2:1989, 3.3.16]

3.17
consent
agreement, approval, or permission as to some act or purpose given voluntarily by a competent person

[*Black's law dictionary*, 2009]

3.18
de-identification
process of removing the association between a set of identifying data and the data subject

[ISO/TS 25237:2008, 3.18]

3.19
directive
instruction how to proceed or act

[*Concise Oxford English dictionary*. Oxford: Oxford University Press, 2008]

3.20
electronic health record
EHR
information relevant to the wellness, health and healthcare of an individual, in computer-processable form and represented according to a standardized information model

3.21
electronic health record architecture
EHRA
formal description of a system of components and services for recording, retrieving and handling information in electronic health records

3.22
electronic health record system
EHR-S
system for recording, retrieving and manipulating information in electronic health records

[ISO 13606-1:2008, 3.26]

3.23
entity
concrete or abstract thing of interest, including associations among things

NOTE Adapted from ISO/IEC 2382-17:1999, 17.02.05.

3.24
entry
documentation of a discrete item of health information

NOTE An entry can, for example, represent the documentation of a clinical observation, an inference, an intention, a plan or an action.

3.25
explicit consent
agreement, approval or permission that is freely and directly given, expressed either *viva voce* or in writing or other legally authorized signature, e.g. electronic

3.26
healthcare
activities, services, or supplies related to the health of an individual

[EN 13940-1:2007]

3.27
healthcare activity
activity performed for a subject of care with the intention of directly or indirectly improving or maintaining the health of that subject of care

[EN 13940-1:2007]

3.28
health information
information about a person relevant to his or her health

3.29
health issue
issue related to the health of a subject of care, as identified or stated by a specific healthcare party

[EN 13940-1:2007]

3.30
healthcare party
organization or person involved in the process of healthcare

[EN 13940-1:2007]

3.31
healthcare professional
person authorized to be involved in the direct provision of certain healthcare provider activities in a jurisdiction according to a mechanism recognized in that jurisdiction

NOTE Adapted from EN 13940-1:2007.

3.32
healthcare provider
healthcare organization or healthcare professional involved in the direct provision of healthcare

[EN 13940-1:2007]

3.33
health mandate
statement authorized by the subject of care, an authorized representative of the subject of care, or by the authority of law, defining the scope and limits of the specific role assigned to one healthcare party, and delineating its responsibilities towards that subject of care with regard to this role

[EN 13940-1:2007]

3.34
identifier
unambiguous name, in a given naming context

[ISO/IEC 10746-2:2009, 12.2]

3.35
implied consent
consent inferred from signs, actions, or facts, or by inaction or silence

3.36
information model
structured specification, expressed graphically and/or in narrative, of the information requirements of a domain

3.37
integrity
state of an artefact that has not been altered, deliberately or accidentally

3.38
knowledge model
structured specification of facts that are true for a given domain

3.39
organization
unique framework of authority within which a person or persons act, or are designated to act towards some purpose

NOTE Adapted from ISO/IEC 6523-1:1998, 3.1.

3.40
persisted
stored on a permanent basis

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

3.42
policy
privilege management and access control
set of legal, political, organizational, functional and technical rules which can be expressed as obligations, permissions or prohibitions

NOTE Adapted from ISO/TS 22600-1:2006, 2.13.

3.43
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, 08.01.23]

3.44
role
set of competences and/or performances which is associated with a task

[ISO/TS 22600-1:2006, 2.19]

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

3.46
services
set of related software functionality

3.47
subject of care
person seeking to receive, receiving, or having received healthcare

[EN 13940-1:2007]

3.48
syntactic interoperability
capability of two or more systems to communicate and exchange data through specified data formats and communication protocols

3.49
term
verbal designation of a general concept in a specific subject field

NOTE A term may contain symbols and can have variants, e.g. different forms of spelling.

[ISO 1087-1:2000, 3.4.3]

3.50
terminological system
set of concepts structured according to the relations among them, each concept being represented by a sign which denotes it

NOTE 1 Adapted from ISO 1087-1:2000, 3.2.11.

NOTE 2 In terminology work, three types of such signs (designations) are distinguished: symbols, appellations and terms.

3.51
view
alternate presentation of data for a different user or purpose

[ISO 13606-1:2008, 3.50]

3.52
workflow
depiction of the actual sequence of the operations or actions taken in a process

NOTE A workflow reflects the successive decisions and activities in the performance of a process.

4 Abbreviations

EHR electronic health record

EHR-S electronic health record system [ISO/HL7 10781]

EHRA electronic health record architecture

PHR personal health record

PHR-S personal health record system

5 EHR business objectives

5.1 Introduction

This informative clause lists the high-level business objectives for electronic health records, which should be supported by relevant information and knowledge models and services provided by an EHR architecture.

5.2 Health system objectives

HSO1 The EHR should enable the consistent capture, processing, retention, protection and communication of health information such that interoperability is achieved in support of shared care, improved quality of care, effective resource management, providing evidence of actions taken in health(care), and in support of the uses of anonymized information for health system management.

HSO2 The EHR should enable authorized users to access health information that is relevant, intact, appropriate to their permissions and within a timeframe that is appropriate to the context.

HSO3 The EHR should enable authorized users to access health information seamlessly and as originally organized, independently of the EHR systems and of the physical formats in which it was originally stored.

HSO4 The EHR should enable the communication of all health information between care settings, subject to appropriate consent and access rights, to a sufficient quality to support safe shared clinical care.

HSO5 The EHR should help ensure that subjects of care receive the most appropriate care as quickly and safely as possible by:

— enabling the documentation and sharing of information about the care and progress of care within and between clinical teams, and to other care providers;

— acting as an information source for decision support applications;

— enabling more informed care through more rapid diagnoses and more appropriate treatments;

— avoiding unnecessary duplication of examinations, tests and other procedures;

— identifying and avoiding risks;

— supporting consistent clinical documentation to improve quality and safety monitoring;

— assisting with tasks such as producing referrals, order forms, and discharge letters;

— supporting individuals with self-management of health and health issues;

— supporting evaluation of care to improve outcomes and evolve best practices;

— facilitating best practices to achieve effective care;

— helping to meet societal expectations of confidentiality, integrity and continuity of care across providers.

HSO6 The EHR should enrich audit and research activities within healthcare organizations by:

— providing a framework for standardized representation of information, and the consistent use of coding systems within that representation, that improves data quality at source and enhances reuse of data;

— providing information for audit of individual clinical cases, and for quality assurance relating to services and outcomes;

— providing information for research into best clinical practice and the design of clinical guidelines;

— acting as a source of information to support knowledge discovery, although without prejudicing the protection of privacy;

— acting as a source of information for decisions about the management of healthcare systems, by jurisdictions and by authorized bodies.

HSO7 The EHR should support strategic planning decisions by:

— enabling the monitoring and improvement of the quality of care provided, including the achievement of standards of care specified in contracts and guidelines;

— enabling the monitoring of costs, e.g. by providing tools for evaluating cost-per-pathology or diagnosis related groups, or similar cost and resource calculating methods;

— acting as a source of information to support the management of the cost of healthcare provision and of litigation.

HSO8 The EHR should support continuing health professional learning by:

— supporting the review of personal care provision to enable case-based learning;

— supporting clinical decision making and clinical outcomes management through information analysis, including adherence to best practice and to guidelines;

— offering better facilities for learning through the generation and export of de-identified records and audit data, to relevant systems.

HSO9 The EHR should support the workflow of clinical teams and care settings by:

— exchanging information with workflow systems and services to facilitate efficient practice;

— avoiding unnecessary changes to clinical practice to adopt the EHR.

HSO10 The EHR should help society move toward the practice of personalized or individualized medicine.

HSO11 The EHR should encourage and facilitate a programme of wellness.

HSO12 The EHR should embody and enable the science of healthcare delivery.

HSO13 The EHR should facilitate and document evidence-based clinical decision-making.

HSO14 The EHR should provide value by encouraging innovation and teamwork.

HSO15 The EHR should be woven (integrated well) into the fabric of healthcare provision.

HSO16 The EHR should portray the involvement and collaboration of multiple stakeholders in the provision of care.

HSO17 The EHR should facilitate citizen mobility by supporting the informed provision of healthcare to them at any location.

5.3 Clinical practice objectives

CPO1 The EHR should fulfil the primary roles of the health record: supporting the ongoing healthcare of subjects of care and providing evidence of healthcare.

CPO2 The EHR should be able to represent and persist or reference any information relevant to the health and healthcare of a subject of care.

CPO3 The EHR should represent information in a manner that facilitates the safe and effective delivery of healthcare.

CPO4 The EHR should enable the inclusion of health record entries about a subject of care, preserving the way in which they are originally organized as well as enabling re-organization and retrieval of information in a manner that is specific to different types of healthcare providers and care contexts.

CPO5 The EHR should enable information in a record to be organized and retrieved in a manner that additionally facilitates permitted uses other than direct care.

CPO6 The EHR should be flexible enough to allow for individual and professional variations in the interpretation of health and illness.

CPO7 The EHR should be flexible enough to allow for regional, national and cultural variations in health expectations and healthcare.

CPO8 The EHR and EHRA should be flexible enough to allow for future evolution in the understanding of health and for innovations in healthcare, such as new forms of clinical knowledge, new clinical disciplines, and new clinical practices and processes.

5.4 Citizen inclusion objectives

CIO1 Subjects of care and their representatives should be able to contribute to and view their own health record, as active participants in their own healthcare. The EHR should enable systems to:

— support individuals to understand the subject of care's health status, health issues, plans and goals;

— support individuals in choosing appropriate treatments, in the self-management of health issues and the assessment of outcomes;

— underpin good communication and continuity of care between all parties involved in the delivery of care as well as with subjects of care and their care-givers;

— support individuals in the specification of access control rules to their EHR information;

— improve clinical outcomes through improved personal access to health information.

6 Requirements for an electronic health record architecture

6.1 Requirements for the representation of clinical information

6.1.1 Kinds of health record entries

KIN1 The EHRA shall be able to represent health record information authored by any authorized user, including health professionals of any specialty from primary, secondary, tertiary, community or complementary healthcare organizations, subjects of care and their representatives.

KIN2 An EHR entry shall be able to represent data values that are:

— free text;

— terms that originate from at least one terminology system, as required in the deployment context;

— codes and classifications;

— identifiers;

— physiological measurements, quantities, units of measure;

— biological signals;

— time and duration;

— drawings, diagrams, charts and tables;

— images, including radiological images, photographs and scanned documents or references to such images;

— sound;

— video.

KIN3 The EHRA shall be able to represent reported, assessed and measured observations, including scales, measures and scores.

KIN4 The EHRA shall be able to represent opinions, suggestions and hypotheses.

KIN5 The EHRA shall be able to represent intentions, goals and care plans.

KIN6 The EHRA shall be able to represent actions considered, planned or performed.

KIN7 The EHRA shall be able to represent concerns, risks, alerts, precautions or warnings about situations to be avoided or activities not to be performed in the future.

KIN8 The EHRA shall be able to represent preventative and wellness information such as health assessments, prophylaxis measures and lifestyle.

KIN9 The EHRA shall be able to represent psychological, social, environmental, family, and other life circumstance information.

KIN10 The EHRA shall be able to represent consents, directives, contracts and health mandates, donor permissions and other legal documents relating to health status and to healthcare.

KIN11 The EHRA shall be able to represent self-care information, points of view on personal health issues, levels of satisfaction, expectations and comments authored by the subject of care and authorized representatives and carers.

KIN12 The EHRA shall be able to distinguish information about subjects of care from information about other persons documented within an EHR, e.g. family history, the heart rate of a foetus in the mother's record.

KIN13 The EHRA shall be able to represent subject of care identifiers and demographic traits, location(s), employment and other administrative data.

KIN14 The EHRA shall be able to interface with standardized code sets and terminologies to represent structured and coded information about a subject of care to facilitate analysis and reporting for health system management.

KIN15 The EHRA shall be able to represent financial and other care management information, such as health plan enrolment, eligibility and coverage information, guarantor, costs, charges, and resource utilization.

KIN16 The EHRA should be able to represent pre-birth and post-death entries.

6.1.2 Structure of health record entries

STR1 The EHRA shall be able to preserve and recreate the original presentation of EHR data and enable alternative views of the data to be created without losing the semantic intent of the data.

STR2 The EHRA shall preserve the original headings and sub-headings used to organize, group or order individual record entries, including the names and terms used to label them.

STR3 The EHRA shall be able to present clinical data according to various recognized conventions, including source oriented, time oriented, problem oriented, overview of health issues, care plan, and supporting the generation of tabular and graphical trends as dictated by jurisdictional policies and mandates.

STR4 The EHRA shall persist any explicitly defined relationships between different parts of the record, such as links between treatments and subsequent complications and outcomes.

STR5 The EHRA shall persist the original data values within an EHR entry, including code systems and measurement units used at the time the data were originally committed to an EHR system.

STR6 The EHRA shall represent lists of data items and data values within a health record entry such that their original intended order is preserved.

STR7 The EHRA shall represent data that were originally represented as a table such that the logical relationships of the data to row and column headings are preserved.

STR8 The EHRA shall be able to represent multiple values of the same measurement(s) taken at closely proximate times, e.g. as a time series.

STR9 The EHRA shall be able to represent any original longitudinal partitions of a health record, e.g. periods of care, which might be defined retrospectively.

STR10 The EHRA shall preserve text in the original language used for composing a health record entry, and identify the language used.

STR11 The EHRA shall be able to include the values of reference ranges used to interpret particular data values.

STR12 An EHR entry shall be able to represent links between requested, planned, performed and reported healthcare activities (e.g. linking a test request to a performed test and to its result).

STR13 The EHRA shall enable one or more comments or annotations to be linked to an original health record entry, possibly composed by different authors at different points in time, without changing the content of the original entry.

STR14 An EHR entry shall be able to represent health status, functional status, health issues, and environmental circumstances.

STR15 An EHR entry should be able to represent references to externally held data such as images (if these are not included in the EHR itself) or knowledge artefacts (e.g. educational materials, published papers, care pathways).

6.1.3 The representation of context within health record entries

CTX1 An EHRA shall be able to represent entries that include a free-text author's comment.

CTX2 The EHRA shall enable an author to explain or justify his or her reasoning or assertions, and optionally to reference external sources as the basis for a conclusion or strategy, such as a guideline, care plan or published paper.

CTX3 An EHR entry shall be able to represent the rationale for clinical decisions, including attribution to care plans, knowledge databases, bibliographic references or decision support systems.

CTX4 An EHR entry shall represent features that emphasize particular health record entries (e.g. for unexpected findings or abnormal results).

CTX5 The EHRA shall be able to represent the life-cycle status of a healthcare activity, which might be specified as a value from a standardized term list or terminology system, e.g. to indicate if an activity is intended or scheduled or performed or cancelled.

CTX6 An EHR entry shall appropriately identify any third-party source of information documented in an EHR, such as information provided by a family member, another institution (e.g. providing a laboratory result) or a physical device (like a cardiac monitor).

6.1.4 Intra-record links

LIN1 The EHRA shall be able to represent defined and labelled relationships (links) between individual or groups of health record entries.

LIN2 The EHRA shall be able to represent lists of active health issues.

LIN3 The EHRA shall be able to represent the relationship between one or more health record entries connected through changes in the life-cycle status of an activity or plan (e.g. if a scheduled activity is later cancelled).

LIN4 The EHRA shall be able to link a pre-existing health record entry to a newer entry that amplifies or explains, challenges or endorses that health record entry (but does not replace the pre-existing entry).

LIN5 The EHRA shall be able to represent the modification or logical removal of links.

LIN6 The EHRA shall enable a user accessing data that contain one or more links to determine the presence of each link and be provided with sufficient information to determine the importance of specifically retrieving and reviewing the referenced health record entries.

6.1.5 The representation of data values within health record entries

6.1.5.1 Textual entries

TXT1 The EHRA shall be able to represent free text (narrative) comments and descriptions.

TXT2 The EHRA shall be able to represent and distinguish information recorded in different natural languages.

TXT3 The EHRA shall be able to represent proper nouns, synonyms and abbreviations in their original language.

TXT4 The EHRA shall indicate if textual information has been translated from its original language.

TXT5 The EHRA should be able to indicate if a term was an original value chosen by (and verified by) the author or has automatically been mapped from a different original value.

TXT6 The EHRA should indicate if textual information has been analysed and coded with text analysis software and, if so, by which software and version.

TXT7 The EHRA should indicate if a textual expression has been generated from a term or terms via natural language generation and, if so, by which software and version.

6.1.5.2 Terms

TRM1 The EHRA shall represent terms in a way that retains their meaning as set forth by the original author.

TRM2 The EHRA shall represent and persist (or reference) the original code meaning, as set forth by the original author, for each term used within the record.

TRM3 The EHRA shall represent a coded term through its code value together with the corresponding coding system identifier (name and version or OID).

TRM4 The EHRA shall be able to represent pre- and post-coordinated term combinations.

TRM5 An EHR entry shall represent any qualification of coded entries by negation, severity and confidence in it.

TRM6 The EHRA should be able to represent probability or confidence (e.g. as a scale, percentage or a term).

TRM7 The representation of the EHR should be able to accommodate future evolution in terminology systems, and the addition of new terms to existing systems.

6.1.5.3 Quantities and numeric data

QTY1 The EHRA shall be able to represent numeric and quantifiable data (e.g. integer, real).

QTY2 The EHRA shall be able to represent quantity ranges.

QTY3 The EHRA shall be able to represent units of measurement (including compound units).

QTY4 The EHRA shall be able to represent the precision and accuracy of a measured quantity.

QTY5 An EHRA entry shall be able to represent a confidence interval for a quantity (e.g. as an upper and lower limit, a coefficient of variation or a standard deviation).

QTY6 The EHRA shall be able to represent numeric values as percentages.

QTY7 The EHRA shall be able to represent an ordinal data value, in which a numeric value is combined with a term.

QTY8 The EHRA shall be able to represent quantity ratios, including independently specified units for the numerator and denominator.

QTY9 The EHRA shall be able to represent a reference range or normal physiological range, if these form an integral part of an observation's result.

QTY10 The EHRA shall be able to reference health record entries whose data values have been used as the raw data for a derived value; such references shall be specific to the version of each record entry that was used.

QTY11 The EHRA shall be able to represent derived data values that are based on pre-existing values in that EHR, and to reference the original entries on which that derived value is based (e.g. when calculating an Apgar score or Barthel index).

QTY12 The EHRA shall be able to represent or reference the calculations or formula(e) by which data have been derived.

QTY13 The EHRA shall be able to represent the description or identification of an instrument or device or system component from which clinical measurements have been obtained.

QTY14 The EHRA shall be able to indicate or represent the use of external decision support tools for calculation or derivations of values.

6.1.5.4 Time

TIM1 The EHRA shall be able to represent and distinguish multiple instances of the same observation, each with the absolute time of its recording or as an offset to an origin point in time.

TIM2 The EHRA shall be able to represent time in absolute terms, as a duration or as an expression relative to other times, events, or conditions.

TIM3 The EHRA shall represent absolute time together with a specified time zone.

TIM4 The EHRA shall be able to represent dates and times imprecisely (to different granularities, e.g. a date as a month and a year or only a year, time as an hour).

TIM5 The EHRA shall be able to represent time specifications expressed as

— periods of day or time: e.g. morning, afternoon, evening, shifts (a.m., p.m., at night);

— approximate points of date/time: e.g. upon awakening, at mealtime (breakfast, lunch, dinner), at bedtime;

— relative points of day or time: e.g. before breakfast, after lunch, before bedtime, 4 h post-operative, 2 days post-discharge, one week after last dose;

— alternating and patterned dates/times: e.g. alternate every 8 h, alternate every 3 days, every Monday/Wednesday/Friday, every Sunday, every third Tuesday.

6.1.5.5 Boolean data

BOO1 The EHRA shall be able to represent data that are of a Boolean type.

BOO2 The EHRA shall be able to represent the particular language expression that was selected by an author when making a Boolean choice (such as “Yes”, “False”, “Positive”, “Agree”).

6.1.5.6 Graphical and multimedia data

GRP1 The EHRA shall be able to represent multimedia data types in standards-compliant formats, including diagrams, drawings, tables and graphs.

GRP2 The EHRA shall represent radiological images, bio-signals, video, sound and other multimedia data in a way that permits them to be rendered to a quality compatible with their source and intended use.

GRP3 The EHRA shall be able to represent the specification of rendering information for a multimedia data object.

GRP4 The EHRA shall be able to represent the annotation and narration of multimedia data in a way that preserves their spatial relationship and time synchronization to the original data.

6.1.5.7 Externally referenced data

EXT1 The EHRA should be able to represent references to data that are not part of the EHR, such as knowledge resources or multimedia data.

6.1.6 EHRA data retrieval and views

RET1 The EHRA shall support requests for one or more classes of health record information (e.g. for specific categories of clinical data).

RET2 The EHRA shall support a chronological overview of the entire EHR for a subject of care, including prospective, concurrent and retrospective data.

RET3 The EHRA shall support the generation, representation, persistence and maintenance of clinical summaries.

RET4 The EHRA shall support filtering or selective retrieval for entries:

— of a particular type;

— authored by a particular person or role;

— occurring in a particular department, institution or country;

— recorded at a particular point in time or within a time interval;

— containing a particular term or terms;

— relating to a particular health issue;

— contributing to a particular care plan;

— containing particular data types;

— with particular contextual values, such as a life-cycle status.

RET5 The EHRA shall support authorized analyses within an individual subject of care's record and on a population of records.

RET6 The EHRA shall clearly specify if a data set has been aggregated across a population or is about one subject of care.

RET7 The EHRA should facilitate the monitoring of the progress of a health issue or of a care plan.

RET8 The EHRA should enable users to:

— obtain extracts of the EHR;

— analyse EHR data for clinical audit, for continuing professional education, for case-mix and resource management;

— produce international, national and local data sets, and incorporate EHR data into standard reports;

— generate summaries of health issues or of periods of care, which are then accessible by other services, applications or databases.

6.1.7 Representation and support of clinical processes and workflow

6.1.7.1 Support for clinical processes and workflow

PRO1 The EHRA shall support the documentation and progression of clinical processes.

PRO2 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.

PRO3 The EHRA shall be able to represent partial completion of a clinical process.

PRO4 The EHRA shall support the representation, tracking and retrieval of health information that relates to a particular health issue or care plan.

6.1.7.2 Decision support, guidelines, and protocols

DEC1 The EHRA shall support the derivation of alert and trigger conditions from health record information.

DEC2 The EHRA shall be able to persist any user warnings, alerts and reminders that have been generated by EHRA components or EHR systems.

DEC3 The EHRA shall be able to represent or reference the use of decision support services or knowledge services for activities recorded within particular health record entries.

6.1.7.3 Care planning

PLN1 The EHRA shall be able to link one or more health record entries to a care plan that might be a part of the same EHR or held within an external knowledge service.

6.1.7.4 Support of orders and services

ORD1 The EHRA shall support the linking of orders with other health record entries (such as symptoms, observations, diagnoses or other clinical indications) that were the rationale for the order.

ORD2 The EHRA shall support the recording and temporal progress of orders and requests such as prescriptions, treatment orders, investigation requests, and referrals.

6.1.7.5 Integrated care

INT1 The EHRA shall support integrated care including collaborative multi-disciplinary care and case management across different healthcare sectors and settings (e.g. primary care, acute hospitals, allied health, home-based care).

6.1.7.6 Quality assurance

QAL1 The EHRA shall support the representation and retrieval of data to enable the measurement of operational and clinical performance, to ensure compliance with standards of care, to support assessments of the quality of care provided, and to measure outcomes.

6.2 Communication and interoperability requirements

IOP1 The EHRA shall support the retrieval of all of the information authored at any one date, time and context by one person within one EHR system for a subject of care, with its original structural organization and in its original language.

IOP2 The EHRA shall enable part or all of an EHR held in one EHR system to be communicated to another system in a way that conforms to EHR communications (interoperability) standards.

IOP3 The EHRA shall ensure that an EHR extract specifies the original authorship, time and place of creation and version history for all health record entries within it.

IOP4 The EHRA shall support the keeping of an audit trail of EHR communications, including any authorizations for the extraction and for the merger of EHR data.

IOP5 The EHRA shall support measures and formalisms to effect the computable syntactic and semantic interoperability of EHR data and of EHR extracts acquired from heterogeneous systems.

IOP6 The EHRA shall support interoperability standards pertaining to the data it contains, e.g. for:

— EHR reference models;

— clinical data structure definitions (e.g. archetypes, templates, detailed clinical models);

— domain specific data structures (e.g. for laboratory and medication);

— data type standards (e.g. for terminology and images);

— security and data protection standards;

— EHR interoperability interfaces and services.

6.3 Ethical and legal requirements

6.3.1 Health record provenance

HRP1 The EHRA shall be able to represent and persist all information relevant to supporting and improving the wellness, health and healthcare of the subject of care.

HRP2 The EHRA shall be able to represent and persist all information relevant to other purposes for which an EHR is maintained.

HRP3 The EHRA shall represent and persist all information committed by authorized sources to an EHR.

HRP4 The EHRA shall represent health record entries in a way that provides the accurate chronology of their authorship and availability within the EHR.

HRP5 The EHRA shall enable the retrieval of part or all of the information in an EHR that was present at any particular historic date and time.

HRP6 The EHRA shall enable unaltered persistence of an original data entry committed to the data repository while noting any subsequent change to or deletion of that data entry.

6.3.2 Subject of care

SBJ1 One EHR shall be the health record of one and only one subject of care (although information about other parties may be included if relevant to the subject of care).

SBJ2 An EHR may include health information about any other parties relevant to the subject of care, which may have been provided by the subject of care or another party (e.g. family history, observations of a witness).

SBJ3 The EHR shall unambiguously specify the person who is the subject of information for an entry if it is not the subject of care.

SBJ4 The EHR shall be able to include or reference information that supports the identification of the subject of care, including demographic descriptors, photographs and biometric properties.

SBJ5 The EHRA shall represent subject of care demographic information in a way that accommodates different and multiple person name formats and conventions.

SBJ6 The EHRA shall support the use of one or more unique identifiers for the subject of care in addition to demographic descriptors (in order to be durable in the case of a change of name, date of birth, etc.).

SBJ7 The EHRA shall be able to represent, retain and cross-reference a set of identifiers for the subject of care as used by different demographic services.

SBJ8 The EHRA shall enable the health record of a subject of care to be identified, located and retrieved through providing a variety of demographic descriptors, identifiers and biometric properties.

6.3.3 Identification, authorization and attestation for EHR data entry

IAA1 The EHRA shall uniquely and reliably identify users who author or authorize entries in a health record (i.e. who have determined the information to be entered into an EHR).

IAA2 The EHRA shall uniquely and reliably identify users who commit entries to a health record (i.e. who have actually entered the information into an EHR).

IAA3 The EHRA shall uniquely and reliably identify users who attest entries within a health record.

IAA4 The EHRA shall be able to represent if health record entries have been individually or collectively attested by more than one user, and on more than one occasion.

IAA5 The EHRA shall uniquely and reliably identify parties who provide information that is committed into a health record, if it is permitted and relevant to do so.

IAA6 The EHRA shall permit parties who provide information that is committed into a health record to be described, including the relationship they have to the subject of care if it is permitted or relevant to identify them.

IAA7 The EHRA shall distinguish parties who provide information from parties who commit it in an EHR or attest it.

IAA8 The EHRA shall identify the systems and organizations that have originally provided information within an EHR, even if the data now form part of the EHR of a different organization.

IAA9 The EHRA shall be able to represent the profession, status and role of any parties identified or described as healthcare providers within the EHR, and identify an organization responsible for sanctioning that role and/or status, if applicable.

IAA10 The EHRA shall be able to represent the mode by which any identified party contributed to healthcare or to the health record (e.g. in person, by phone, via video-conference).

IAA11 The EHRA shall enable the longitudinal ability to identify individual users, even if their name, status, profession, role, organization or other descriptors have changed between their various contributions to the record.

IAA12 The EHRA shall be able to represent an attestation status (e.g. “not signed”) to health record entries that have been committed to the health record (e.g. by a secretary or by a device) but still require attestation.

IAA13 The EHRA should allow for identification and authentication of jurisdictionally authorized parties to access health information for the purpose of aggregation, analysis and reporting to inform the jurisdictional healthcare system and healthcare parties about quality, effectiveness and safety of care and to inform other jurisdictionally and ethically authorized purposes of use.

IAA14 The EHRA should be able to support cross-jurisdictional EHR communications, if appropriate authorizations exist.

IAA15 The EHRA should identify users who have authorized the importing of data from another EHR source into their organization's EHR or into a shared EHR, or who have authorized a merger of EHRs.

6.3.4 Healthcare locations

LOC1 The EHRA shall represent the care setting, organization and physical location at which a recorded healthcare activity has occurred.

LOC2 The EHRA shall represent the care setting, organization and physical location at which a health record entry was composed, committed and attested.

6.3.5 Dates and times

DAT1 The EHRA shall represent the date and time at which each health record entry was originally committed to an EHR repository.

DAT2 The EHRA shall represent the date and time, or interval, when information was provided to or acquired by the composer of a health record entry, e.g. the date and time of a clinical encounter.

DAT3 The EHRA shall represent the date and time, or interval, when the details documented in a health record entry took place, e.g. when an event occurred, an observation was made, or a body sample was acquired.

DAT4 The EHRA shall represent the date and time when EHR extracts were contributed to a particular EHR repository.

DAT5 The EHRA shall represent the local time and time zone for which a date and time value is specified.

6.3.6 Version management

VER1 Each instance of a node within an EHR data hierarchy shall have a unique identifier that is retained for every persisted copy of that node by all EHR systems and repositories.

VER2 The EHRA shall represent any amendment to EHR entries as new versions of the original entries.

VER3 The EHRA shall represent any intended removal of an EHR entry as a new version of the original entry with a null content, and with an indication of the reason for the replacement (e.g. if the entry was originally placed in the wrong patient's record).

NOTE 1 It can prove necessary to modify the access policies for data that have been replaced with a corrected version to prevent further unintended access to the incorrect version.

NOTE 2 This requirement can be overridden if the EHR entry is required by law to be purged from the EHR, in which case no residual null entry will exist.

VER4 The EHRA shall identify a revised version of an EHR entry differently from its prior version.

VER5 The EHRA shall identify the prior version that was the source of a revision of an EHR entry.

VER6 The EHRA shall identify the party revising an EHR entry and the date and time of revision.

VER7 The EHRA shall be able to represent the rationale for revising an EHR entry or set of entries.

VER8 The EHRA shall only represent revision at a level of granularity at which the change could be attested.