ISO TC 215/SC

Date: 2009-07-23

ISO/DIS 18308

ISO TC 215/SC /WG 8

Secretariat: ANSI

Health Informatics — Requirements for an electronic health record reference architecture

Élément introductif — Élément central — Élément complémentaire

Warning

This document is not an ISO International Standard. It is distributed for review and comment. It is subject to change without notice and may not be referred to as an International Standard.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Document type: International Standard
Document subtype:
Document stage: (40) Enquiry
Document language: E

ISO_18308_(E)_Draft_FDIS 08 July 2010.doc STD Version 2.1c2

Contents

Page

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*, Subcommittee SC , .

This second/third/... edition cancels and replaces the first/second/... edition (), [clause(s) / subclause(s) / table(s) / figure(s) / annex(es)] of which [has / have] been technically revised.

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 health care 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 health care of an individual, capable of being stored and communicated securely and of being accessible by multiple authorised users, represented according to a standardised or commonly agreed logical information model. Its primary purpose is the support of life-long, effective, high quality and safe integrated health care"

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 recognised 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 health care provider organisations.

The notion of the Personal Health Record [2] is also maturing internationally and, whilst this standard does not specifically focus on the PHR, the requirements in this Standard 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 recognised, as a limitation, that no authoritative source of requirements was found for the records of any of the complementary or traditional forms of health care practiced 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 health care or on the sharing of these health records (paper or electronic) with allopathic medicine [Smith, Kalra 2008]. 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 standard is intended to be used when designing the architecture of health information services that incorporate or interact with electronic health record systems or repositories.

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 realised, subject to relevant permissions. This holistic EHR will sometimes be stored and regularly updated in a centralised EHR repository (e.g. through a national e-Health infrastructure), might be organised 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

---

[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] NOTE: 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 health care provider (organisation or person), but to which the subject of care normally has certain rights. It is recognised that a clear distinction does not always exist between these kinds of records.

and services for recording, retrieving and handling information in electronic health records is known as an *EHR architecture*: this 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 (localised) 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 10746-1:1998) 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 health care 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 health care resources. The business objectives defined in Section 5 of this International Standard are likely to require a holistic approach to their realisation rather than 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 EHR architecture 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 health care professionals). Inevitably, though, some requirements for EHR systems and EHR architectures will be common.

A separate and complementary International Standard, ISO 10781, the HL7 electronic health record system functional model, defines the requirements that shall be met by individual EHR systems. The authors of ISO 18308 and 10781 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 standards. However, it is recognised that a more precise indication of overlap is a desirable future strategy for both standards, when they are next due for review/revision.

ISO has two complementary documents that specify the requirements of good practice for a clinical data warehouse: ISO TR 22221 Good Principles and Practices for a Clinical Data Warehouse and ISO TS 29585 Deployment of a Clinical Data Warehouse. 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 Electronic Health Record Architecture and a Clinical Data Warehouse will need to be met.

Approach to defining these requirements

This International Standard updates and replaces the earlier Technical Specification ISO TS 18308, which was published in 2004 as the first normative set of comprehensive requirements for an EHR architecture. Much has been learned since then, and several other complementary standards relating to the EHR have been published or are in development. Whereas ISO TS 18308 drew on and synthesized a significant body of requirements published by research and national projects, this revision 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 eHealth infrastructures. Further, it has been possible to build on work done to develop other EHR quality and interoperability standards such as ISO/EN 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 revision have therefore included expertise from many standards developers, as well as Member Bodies who now have experience using ISO TS 18308:2004.

[3] Please see http://www.opengroup.org/togaf/ for more information.

Requirements statements for computer systems and software should ideally comply with the IEEE specification (IEEE 830-1998: Recommended Practice For Software Requirements Specifications), and should be verifiable, traceable, unambiguous, correct and relevant. Many of the requirements in ISO 18308, 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 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 fifteen year period since some of the earliest publications used by this International Standard there has been much cross-fertilisation 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 requirements 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. A bibliography at the end of this document lists the more substantive publications of generic EHR requirements that have been reviewed during the drafting of this standard and its predecessor.

Conformance

As for any ISO requirements standard and as per ISO/IEC Directives Part 2, 2004, an electronic health record architecture 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 Section 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 Section 5 are all optional, but are included as a perspective on the goals that an EHR and its architecture should contribute to, and which have informed the requirements of Section 6.

Health Informatics — Requirements for an electronic health record reference architecture

1. Scope

This International Standard defines the set of requirements that shall be met by the architecture of a system that processes, manages and communicates Electronic Health Record information: an EHR Architecture (EHRA). This is in order to ensure that these EHRs are faithful to the needs of health care 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 Standard does not specify the full set of requirements that need to be met by an electronic health record system for direct patient care or for other use cases, but the requirements defined by this standard do contribute to the governance of EHR information within such systems.

2. Notation

Each business objective statement in Section 5 and each requirement statement in Section 6 of this International Standard 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

[Open Group Architecture Framework (TOGAF), 2009 [modified]

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/EN 13606-1:2008]

3.3.
audit trail

chronological record of activities of information system users which enables prior states of the information to be faithfully reconstructed [ISO/EN 13606-1:2008]

3.4.
authentication

process of reliably identifying security subjects by securely associating an identifier and its authenticator [ISO 7498-2:1989]

3.5.
authorization

granting permissions
NOTE this is a modification of the definition in ISO/TS 22600-1:2007 of “granting rights”

3.6.
availability

property of being accessible and useable upon demand by an authorised entity [ISO/IEC 7498-2, 1989]

3.7.

care plan

personalised statement of planned health care activities relating to one or more specified health issues [EN 13940-1:2007, modified]

3.8.

clinical information

information about a person, relevant to his or her health or health care [ISO/EN 13606-1:2008]

3.9.

clinical process

set of interrelated or interacting health care activities performed by one or more health care 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 which is mapped on to another set according to a coding scheme
[ISO/IEC 2382-4:1999] [EN 1068:2005]

3.13.

coding scheme

collection of rules that maps the elements of one set on to the elements of a second set
[ISO/IEC 2382-4:1999] [EN 1068:2005]
NOTE The two sets considered here are (1) a set of 'code meanings' (or 'coded set'), and (2) 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]

3.16.

confidentiality

property that information is not made available or disclosed to unauthorised individuals, entities, or processes [ISO 7498-2:1989]

3.17.

consent

agreement, approval, or permission as to some act or purpose given voluntarily by a competent person [Black's Law Dictionary, 2008]

3.18.

de-identification

process of removing the association between a set of identifying data and the data subject [ISO/TS 25237:2008]

3.19.

directive

instruction how to proceed or act [Oxford English Dictionary, 2008]

3.20.

electronic health record

information relevant to the wellness, health and health care of an individual, in computer processable form and represented according to a standardised information model

3.21.

electronic health record architecture

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

system for recording, retrieving and handling information in electronic health records [ISO/EN 13606-1:2008]

3.23.

entity

concrete or abstract thing of interest, including associations among things [ISO/IEC 2382]

3.24.

entry

documentation of a discrete item of health information
NOTE: an entry may 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.

health care

activities, services, or supplies related to the health of an individual
[EN 13940-1:2007]

3.27.

health care 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 health care party
[EN 13940-1:2007]

3.30.

health care party

organisation or person involved in the process of health care
[EN 13940-1:2007]

3.31.

health care professional

person authorised to be involved in the direct provision of certain health care provider activities in a jurisdiction according to a mechanism recognised in that jurisdiction
[EN 13940-1:2007, modified]

3.32.

health care provider

health care organisation or health care professional involved in the direct provision of health care
[EN 13940-1:2007]

3.33.

health mandate

statement authorised by the subject of care, an authorised representative of the subject of care, or by the authority of law, defining the scope and limits of the specific role assigned to one health care 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 name context
ISO/IEC 10746-2:1996

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
[ISO 6523-1:1998]

3.40.

persisted

stored on a permanent basis

3.41.

personal health record

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
[ISO/TS 22600-1: 2005, modified]

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]

3.44.

role

set of competences and/or performances associated with a task [ISO/TS 22600-1:2007]

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 health care [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 [ISO 1087-1: 2000]

3.50.

terminological system

set of concepts structured according to the relations among them, each concept being represented by a sign which denotes it
[merging ISO/IEC 11179-1:2004 and ISO 1087-1:2000 definitions]
NOTE In terminology work three types of such signs (designations) are distinguished: symbols, appellations and terms.

3.51.

view

alternative presentation of data for a different user or purpose [ISO/EN 13606-1:2008]

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 10781]
EHRA electronic health record architecture
PHR personal health record
PHR-S personal health record system

5. EHR business objectives (Informative)

5.1.Introduction

This informative section 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 anonymised information for health system management.

HSO2 The EHR should enable authorised 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 authorised users to access health information seamlessly and as originally organised, 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, discharge letters etc.;
- 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 & research activities within health care organisations, by:

- providing a framework for standardised representation of information, and the consistent use of coding systems within that representation, that improves data quality at source and enhances re-use 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 health care systems, by jurisdictions and by authorised 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 health care 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 personalised or individualised medicine.

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

HSO12 The EHR should embody and enable the science of health care 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 health care 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 health care 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 health care of subjects of care and providing evidence of health care.

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

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

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

CPO5 The EHR should enable information in a record to be organised 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 health care.

CPO8 The EHR and EHRA should be flexible enough to allow for future evolution in the understanding of health and for innovations in health care, 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 health care. 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 (Normative)

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 authorised user, including health professionals of any specialty from primary, secondary, tertiary, community or complementary health care organisations, 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 health care.

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 authorised 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 fetus 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 utilisation.

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 organise, 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 recognised 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 was 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, for example 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 health care 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 emphasise 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 health care activity, which might be specified as a value from a standardised term list or terminology system, for example 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 (such as 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 (for example, 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 or 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 contains 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 (for example 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 (for example 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 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 (AM, PM, 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, four hours post-operative, two days post discharge, one week after last dose;
- alternating and patterned dates/times: e.g. alternate every 8 hours, 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 synchronisation 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 authorised 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 health care 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 organisation 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 health care 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 authorised 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.

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 or 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 authorise 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 organisations that have originally provided information within an EHR even if the data now forms part of the EHR of a different organisation.

IAA9 The EHRA shall be able to represent the profession, status and role of any parties identified or described as health care providers within the EHR, and identify an organisation 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 health care 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, organisation 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 authorised parties to access health information for the purpose of aggregation, analysis and reporting to inform the jurisdictional healthcare system and health care 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 authorisations exist.

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

6.3.4. Health care locations

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

LOC2 The EHRA shall represent the care setting, organisation 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, for example 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, for example 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 may be necessary to modify the access policies for data that has been replaced with a corrected version to prevent further unintended access to the incorrect version. NOTE 2: This requirement may be over-ridden 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.

VER9 The EHRA shall not automatically propagate attestations covering previous versions of an EHR entry to the new revised version.

VER10 The EHRA shall be able to represent a chronological and sequenced version change history for any set of EHR entries, even if multiple changes have taken place across multiple EHR repositories in a disjointed way.

VER11 The EHRA shall be able to represent a version status (e.g. "draft") to health record entries that were known to be incomplete at the time that they were committed to the health record (e.g. interim test results).

VER12 The EHRA shall represent evidence of the merger of one or more records as versioned changes to a level of detail that would support this merger being reversed at any future date.

6.4. Fair information principles

6.4.1. Accountability

ACT1 The EHRA shall identify the organisation with legal data controller responsibility for each EHR.

ACT2 The EHRA shall be able to represent the source legal data controller responsible for the original contribution of all EHR data persisted within it.

ACT3 The EHRA shall include the identity of the legal data controller of any EHR information communicated to another system.

6.4.2. Identifying purposes

PUR1 The EHRA shall be able to represent the purpose for which EHR information was collected and may be used; particular purposes may apply to an EHR as a whole or only to specific parts of the information in it.

PUR2 The EHRA shall be able to represent the purpose of collection and use using jurisdictionally or internationally defined standard terminologies.

PUR3 The EHRA shall enable access to EHR information to be filtered to match the purpose(s) of each request or for each user session or user role.

PUR4 The EHRA audit trail shall be able to represent the declared purpose of use for each disclosure.

PUR5 The EHRA audit trail shall be able to represent the declared purpose for each access request, regardless of whether that request was granted or denied.

6.4.3. Consent

CON1 The EHRA shall be able to represent consent for the creation of a health record, and for the collection, use and disclosure of EHR data.

CON2 The EHRA shall support obtaining, recording and tracking the status of consent to access the whole or specified sections of the EHR, for defined purposes.

CON3 The EHRA shall not require the presence or provision of explicit consent information in order to provide access to, use or disclosure of EHRA data, for example if policies permit the use of an implied consent approach.

CON4 The EHRA shall be able to represent the purposes for which consent is obtained.

CON5 The EHRA shall be able to represent the approvals and authorisations for particular uses of health record information for which such approvals are required.

CON6 References to EHR data that reside in the EHR of another subject of care shall only exist whilst both subjects of care (or their representatives) consent to their existence.

6.4.4. Limiting collection, use, disclosure, retention

LIM1 The EHRA shall enable the implementation of policies that control access for use and access for onward disclosure of EHR information to authorised individuals and computer systems.

LIM2 The EHRA shall enable access to EHR information to be filtered to match the access permissions of the individual or computer system in accordance with their role, context and purpose of use.

LIM3 The EHRA shall enable the implementation of policies that control the disclosure of EHR information to other systems.

LIM4 The EHRA should enable the implementation of policies that dictate specific periods for data retention if explicit or implied consent or health system policies or jurisdictional regulations do not allow EHR data to be held indefinitely.

LIM5 The EHRA should enable the implementation of policies that specify the circumstances under which record linkage to other databases is authorised as well as those under which it is expressly prohibited.

6.4.5. Access policies

ACC1 The EHRA shall be able to represent the consent and policies specified by a subject of care or a representative for the disclosure of his or her EHR information.

ACC2 The EHRA shall be able to represent or reference access policies, defined by authorised users or organisations, which apply to information within an EHR.

ACC3 The EHRA shall be able to represent if an access policy has been updated or revoked, when and on what authority, and at what time.

ACC4 The EHRA shall be able to associate an EHR entry, or group of entries (such as a section or document), with information properties and specific access policies that apply to it.

ACC5 The communication of EHR extracts shall comply with the access policies pertaining to the information being communicated.

ACC6 EHR extracts shall be able to include or reference any policies that specifically apply to the information being communicated.

ACC7 EHR access policies shall permit authorised users to grant or to restrict access to nominated EHR information to identified individuals, to specific structural or functional role groups, to specified organisations and to classes of care setting, for specific data uses as required.

ACC8 EHR access policies shall permit health care professionals to mark health record information as not for disclosure to the subject of care, if this is permitted in law.

ACC9 A set of entries made by one author at one date and time should only contain information associated with different levels of access rights if the author is fully confident that any incomplete access to that set of entries does not seriously distort its meaning.

ACC10 EHR access policies shall specify a time interval over which their stipulations apply. EHR access policies shall identify their author and may be attested.

ACC11 The EHRA shall be able to represent policies that nominate authorised individuals who may act on behalf of the subject of care in relation to care decisions and in relation to processing the subject's EHR information.

ACC12 The EHRA should support mechanisms to ensure the informed creation of policies and consents by identified and authorised individuals.

6.4.6. Subject access

SAC1 The EHRA shall support conformance to legislation, national and international mandates and directives on the protection of health information.

SAC2 The EHRA shall enable subjects of care and their representatives to access any or all of the personal health information that forms part of the EHR, including who created, viewed, used, changed, disclosed or destroyed it, as permitted by governance policies that apply to the information..

SAC3 The EHRA shall be able to represent changes to EHR information made by subjects of care or their legal representatives to correct errors, including amendments to the disclosure policy for entries.

6.4.7. Auditability

AUD1 The EHRA shall enable the maintenance of an audit trail of the creation of, amendment of, and access to health record entries.

AUD2 The EHRA audit trail shall specifically identify accesses that have over-ridden one or more policies (e.g. in a medical emergency situation) and include the rationale, user, date and time of the over-ride.

AUD3 The EHRA audit trail shall be protected from modification or erasure.

AUD4 The EHRA audit trail shall conform to relevant interoperability standards.

AUD5 The EHRA shall support the systems and services that enable data subjects to access the audit trail relating to their own EHRs.

AUD6 The EHRA shall support the systems and services that interrogate audit trail data to detect unlawful or unauthorised access or access attempts.

AUD7 The EHRA audit trail shall maintain a record of disclosures of the audit trail itself.

Bibliography

The following publications on EHR requirements have informed the development of this standard.

1. ASTM Standard Guide for Properties of Electronic Health Records and Record Systems. E1769-95, Feb 1996.

2. Commonwealth of Australia. A Health Information Network for Australia. National Electronic Health Record Taskforce. ISBN 0 642 44668 7. July 2000.

3. Computer-based Patient Record Institute. Description of the Computer-based Patient Record (CPR) and Computer-based Patient Record System. CPRI, May 1995.

4. Computer-based Patient Record Institute. Computer-based Patient Record Description of Content. CPRI, August 1996.

5. Dick R.S., Steen E.B., and Detmer D.E. The Computer-Based Patient Record, an Essential Technology for Healthcare (revised edition). National Academy Press, Washington DC; 1997.

6. Dixon R., Grubb P.A., Lloyd D., and Kalra D. Consolidated List of Requirements. EHCR Support Action Deliverable 1.4. European Commission DGXIII, Brussels; May 2001. 59pp. Available from http://www.chime.ucl.ac.uk/HealthI/EHCR-SupA/del1-4v1_3.PDF.

7. Frandji B. Healthcare record architecture information: relevant projects. Services, Architecture & Products for Health Information Systems (SAPHIS), Paris, 1996.

8. Goossen W.T.F, Epping P.J.M.M, Dassen T., 1997 Criteria for Nursing Information Systems as a Component of the Electronic Patient Record – an International Delphi Study, Computers in Nursing Vol.15 pp.307-315 and In: IMIA Yearbook 1999 of Medical Informatics, Jan van Bemmel, Alexa McCray (Eds), Schattauer Verlagsgesellschaft mbH, Stuttgart pp.383-391.

9. Grimson W. and Groth T., Editors. The Synapses User Requirements and Functional Specification (Part B). EU Telematics Application Programme, Brussels; 1996; The Synapses Project: Deliverable USER 1.1.1b.

10. Heard S., Grivel A., Schloeffel P., and Doust J. The benefits and difficulties of introducing a national approach to electronic health records in Australia in: National Electronic Health Records Taskforce. A Health Information Network for Australia. Department of Health and Aged Care, Commonwealth of Australia; Jul 2000.

11. Hurlen P., Editor, Project Team 1-011. ENV 12265: Electronic Healthcare Record Architecture - Supporting Documentation Annex. CEN TC/251, Brussels; 1995.

12. I4C (Integration and Communication for the Continuity of Cardiac Care). Project HC1024 of the EU 4th framework. Deliverable 1: User Requirements and Functional Specification/ORCA.

13. IEEE Recommended Practice For Software Requirements Specifications. IEEE Computer Society; 1998; Std 830.

14. Ingram D., Hap B., Lloyd D., Grubb P. and others. The GEHR Requirements for Portability. European Commission, Brussels; 1992; The Good European Health Record Project: Deliverable 5.

15. Ingram D., Lloyd D., Baille O., Grubb P. and others. The GEHR Requirements for Communication Capacity. European Commission, Brussels; 1992; The Good European Health Record Project: Deliverable 6.

16. Ingram D., Murphy J., Griffith S., Machado H. and others. GEHR Educational Requirements. European Commission, Brussels; 1993; The Good European Health Record Project: Deliverable 9.

17. Ingram D, Southgate L, Heard S, Doyle L., Kalra D. and others. The GEHR Requirements for Ethical and Legal Acceptability. European Commission, Brussels; 1993; The Good European Health Record Project: Deliverable 8. 9 Chapters, 68 pages.

18. Ingram D., Southgate L., Kalra D., Griffith S., Heard S. and others. The GEHR Requirements for Clinical Comprehensiveness. European Commission, Brussels; 1992; The Good European Health Record Project: Deliverable 4. 19 chapters, 144 pages.

19. Kalra D., Editor. The Synapses User Requirements and Functional Specification (Part A). EU Telematics Application Programme, Brussels; 1996b; The Synapses Project: Deliverable USER 1.1.1a. 6 chapters, 176 pages.

20. Kalra, D. Clinical foundations and information architecture for the implementation of a federated health record service. Doctoral thesis, University of London, 2002. Available from: http://eprints.ucl.ac.uk/1584/

21. Lloyd D., Kalra D., Beale T., Maskens A., Dixon R., Ellis J., Camplin D., Grubb P., and Ingram D., Editors. The GEHR Final Architecture Description. European Commission, Brussels; 1995; The Good European Health Record Project: Deliverable 19. 11 chapters; 250 pages. available from http://www.chime.ucl.ac.uk/HealthI/GEHR/EUCEN/del19.pdf.

22. Skifjeld K., Harket G., Hurlen P., Piene J., and Skjervold S. A Document Architecture For Health Care Records - Integrating Structural And Semantic Aspects. National Institute of Public Health. Department of Medical Informatics, N 0462, Oslo Norway. 1988.

23. Smith,K., Kalra,D. (2008). Electronic Health Records In Complementary and Alternative Medicine. International Journal of Medical Informatics 77(9), 576-588. ISSN: 1386-5056.

24. Swedish Institute for Health Services Development (SPRI). RAM – A Reference Architecture for Information Systems in the Health Care Domain. SPRI, Sweden; 1998; Report number 316.

25. Swedish Institute for Health Services Development (SPRI). Introducing computer based patient records: prerequisites and requirements. SPRI, Sweden; 1998; Report number 477; ISSN 0586-1691.

26. The New Zealand Electronic Medical Record Standard. Electronic Medical Records Standards Subcommittee. SC606, WG3 Draft v1.06, 25 February 1998.

27. Electronic Health Record (EHR) Privacy and Security Requirements. Canada Health Infoway. Version 1.1, February 7, 2005.

Relevant International Standards

28. ISO/TR 20514:2005 Health informatics - Electronic health record - Definition, scope and context

29. ISO 10781 Health informatics - HL7 Electronic health record system functional model

30. ISO 13606:2008 Health informatics - Electronic health record communication - Part 1: Reference Model

31. ISO TS 13606:2009 Health informatics - Electronic health record communication - Part 4: Security

32. ISO 21090 Health informatics – Harmonized data types for information interchange

33. ISO/TR 22221:2006 Health informatics - Good principles and practices for a clinical data warehouse

34. ISO/IEC 10746:1998 Information Processing Systems - Open Systems Interconnection - Basic Reference Model of Open Distributed Processing