



ISO 18308:2011 Health Informatics - Requirements for an Electronic Health Record Architecture

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- 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.
- 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.”

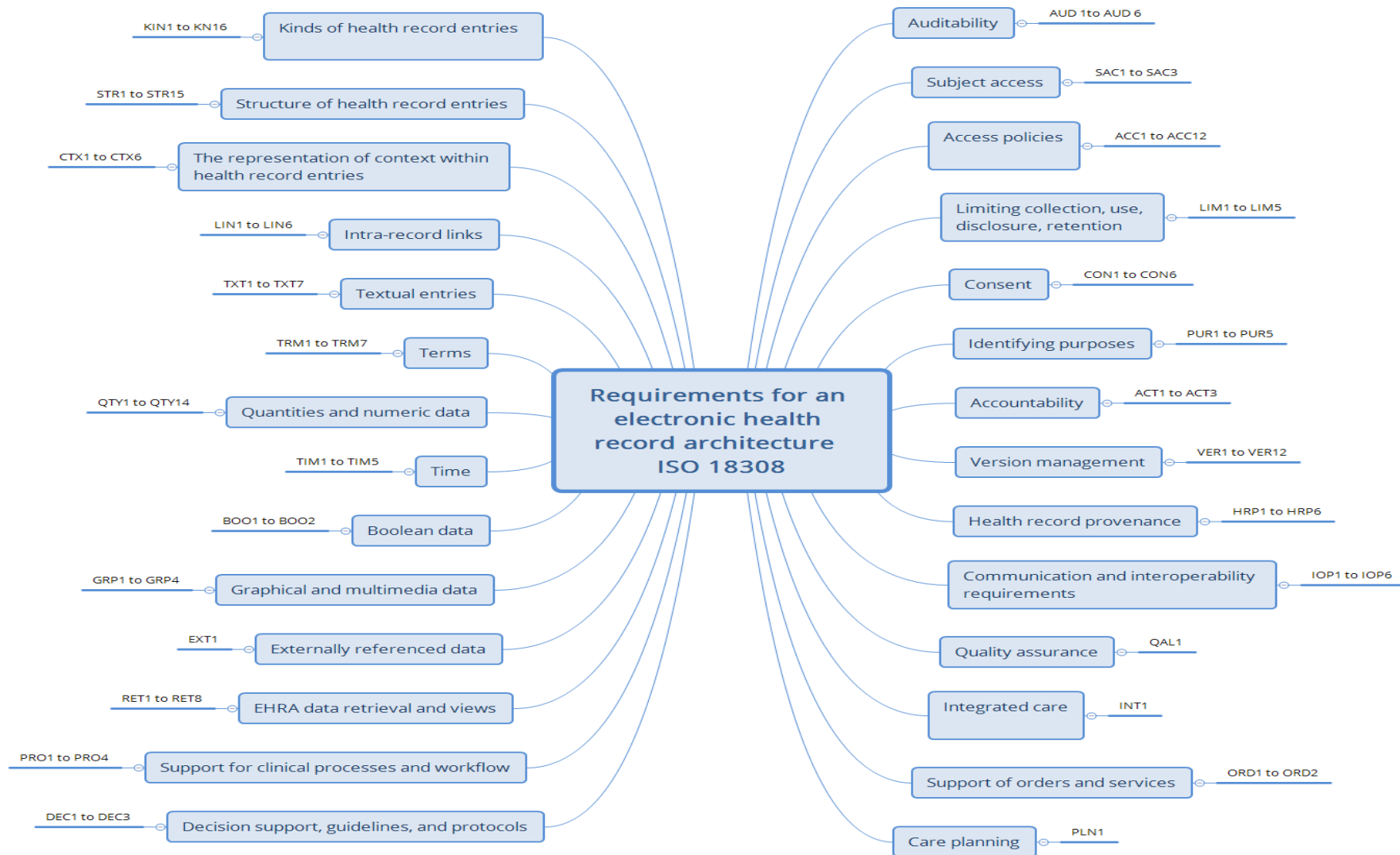
Requirements for an electronic health record architecture

Requirements for the representation of clinical information

Communication and interoperability requirements

Ethical and legal requirements

Fair information principles



Requirements for an Electronic Health Record Architecture

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Representation of Clinical Information



REQUIREMENTS FOR THE REPRESENTATION OF CLINICAL INFORMATION

I. Kinds of health record entries



This section explains the different types of data values and data entries that are needed to be allowed by an EHR.

For example:

- Free text
- Time and duration
- Drawings
- Diagrams
- Charts and Tables etc..

II. Structure of health record entries



In this section, the standard explains about the different aspects of records that are either mandatory or optional in an EHR.

For example:

- Longitudinal partitions of a health record
- Multiple values of the same measurement
- Data that were originally represented as a table such that the logical relationships of the data to row and column headings are preserved

III. The representation of context within health record entries



- The EHR may enable the representation of all types of entries according to the context of clinical care.
- For example:
 - Clinician's comment
 - Rationale for clinical decisions
 - Enable an author to explain or justify his or her reasoning or assertions
 - Optionally to reference external sources as the basis for a conclusion or strategy

IV. Intra-record links



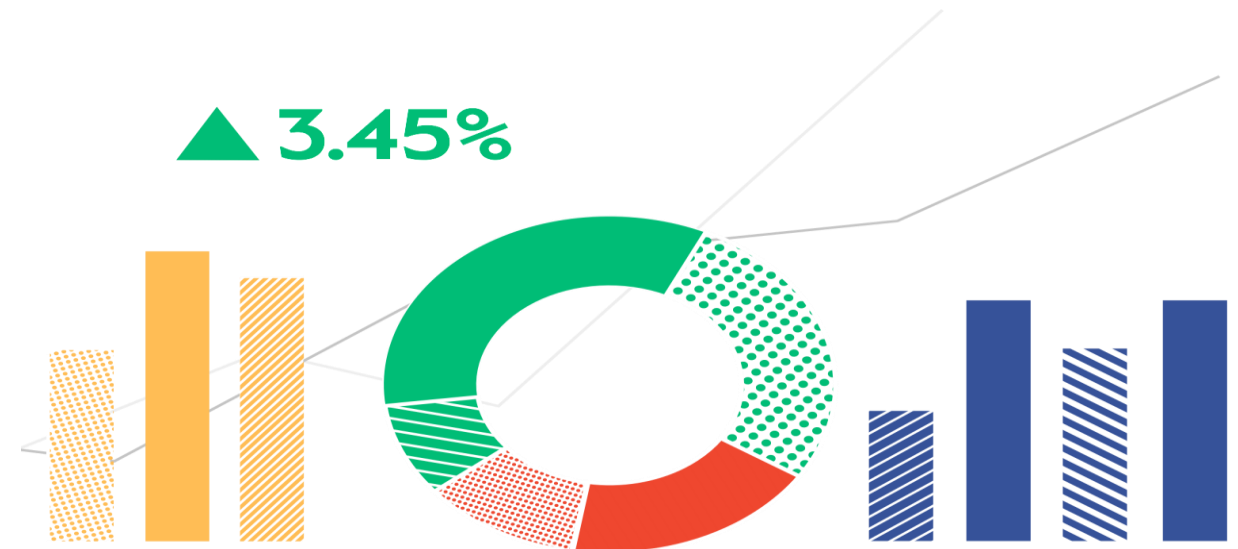
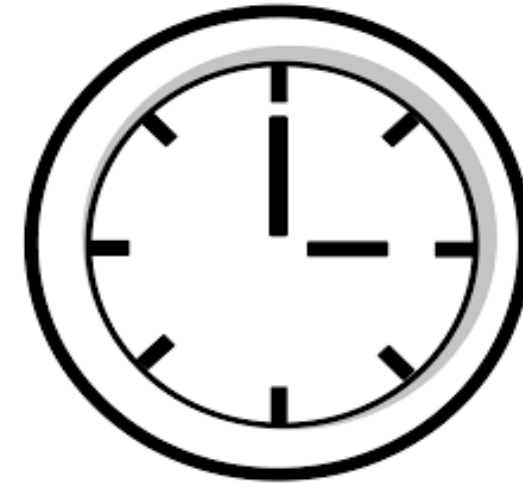
- The EHR must be able to connect different sections of health records through links so that a whole longitudinal health record is formed.
- For Example:
 - Defined and labelled relationships (links) between individual or groups of health record entries
 - Relationship between one or more health record entries connected through changes in the life-cycle status of an activity or plan
 - Pre-existing health record entry to a newer entry

V. The representation of data values within health record entries



The following types of data values are to be included in the EHR architecture:

- Textual entries
- Terms
- Quantities and Numeric data
- Time
- Boolean Data
- Graphical and multimedia data
- Externally Referenced data



VI. EHRA data retrieval and views



- The EHR may enable the representation of different ways of data retrieval for multiple views of the same data.
- For Example:
 - Filtering or selective retrieval for entries
 - Authorized analysis within an individual subject of care's record and on a population of records
 - Chronological overview of the entire EHR for a subject of care, including prospective, concurrent and retrospective data

VII. Representation and support of clinical processes and workflow



- The EHR may be able to represent the progression of care in clinical practice under the following headers:
 - Support for clinical processes and workflow
 - Decision support, guidelines, and protocols
 - Care planning
 - Support of orders and services
 - Integrated care
 - Quality assurance

Communication and interoperability requirements



- The EHR may allow the communication between different departments of one organization and between different organizations also.

For Example:

- 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.
- Support the keeping of an audit trail of EHR communications.



An EHR may be able to present following details in its architecture so that a longitudinal record can be maintained:

- Health record provenance
- Subject of care
- Identification, authorization and attestation for EHR data entry
- Healthcare locations
- Dates and times
- Version management



I. Health record provenance



- The EHR may:
 - Represent and persist all information relevant to supporting and improving the wellness, health and healthcare of the subject of care
 - Represent all the information included by an authorized clinician/professional

II. Subject of care



- The EHR may involve the details of one subject of care (Unambiguously), along with the details of his /her care takers (family members announced by subject of care)
- EHR may be able to consider one or more than one identifiers for a subject of care.

III. Identification, authorization and attestation for EHR data entry



- The EHRA may 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).
- It may identify the parties who enter data into the EHR.

IV. Healthcare locations

- The EHR may record the location of the hospital where the data was recorded regarding the clinical care of the subject.



V. Dates and times



- The EHR may record :
 - The date and time at which each health record entry was originally committed to an EHR repository
 - The date and time when the event documented occurred
 - The date and when the documented information was submitted to EHR repository

VI. Version management



The EHR:

- May identify each and every entry in the data as the new version and save the previous data as the previous version.
- Identify the prior version that was the source of a revision of an EHR entry.
- Represent the rationale for revising an EHR entry or set of entries.

Fair information principles



- Accountability
- Identifying purposes
- Consent
- Limiting collection, use, disclosure, retention
- Access policies
- Subject access
- Auditability

Fair information principles



I. Accountability

The EHR may be able to recognize the organization which is either the source of information or is involved in the communication of the information to other organization and EHRA may be able to represent it

II. Identifying purposes

It may identify various purposes for which the data versioning happened, or the data was collected by any person.

III. Consent

EHRA may be able to represent consent for new data entry, disclosure of data, transfer of data and its tracking details.

IV. Limiting collection, use, disclosure, retention

EHRA may enable the implementation of policies that control access for use and access for onward disclosure of EHR information to authorized individuals and computer systems

V. Access policies

The EHRA may be able to represent the access of the user to his/her data and should allow the user to specify policies for the access of the concerned data. It should be able to update the policies when and where ever required.

VI. Subject access

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

VII. Auditability

EHRA may enable the maintenance of an audit trail of the creation of, amendment of, and access to health record entries. EHRA audit trail may be protected from modification.

- ISO 18308:2011 Health Informatics - Requirements for an Electronic Health Record Architecture <https://www.iso.org/obp/ui/#iso:std:iso:18308:ed-1:v1:en>

Thank You

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