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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health Informatics*.

This second edition cancels and replaces the first edition (ISO 13606-1:2008), which has been technically revised. The main changes compared to the previous edition are summarised in the Introduction.

A list of all parts in the ISO 13606 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

0.1 Preface

The overall goal of this document is to define a rigorous and stable information architecture for communicating part or all of the Electronic Health Record (EHR) of a single subject of care (patient), or for a group of patients whose information might need to be communicated together (for example, a family). This is to support the interoperability of systems (see Annex C). and components that need to communicate (access, transfer, add or modify) EHR data:

— preserving the original clinical meaning intended by the author;

— incorporating the necessary provenance metadata to inform the recipient or receiving system about the context in which the EHR data were obtained and composed;

— observing and communicating the confidentiality of that data as intended by the author and subject of care.

This document considers the EHR to be the persistent longitudinal and potentially multi-organisation or multi-national record of health and care provision, most often relating to a single subject of care (the patient), created and stored in one or more physical systems in order to inform each subject's future healthcare and to provide a medico-legal record of care that has been provided. This corresponds to the definition provided in ISO 18308:2011 (Requirements for an Electronic Health Record Architecture).

This document is not intended to specify the internal architecture or database design of EHR systems or components, nor is it intended to prescribe the kinds of clinical applications that might request or contribute EHR data in particular settings, domains or specialities. For this reason, the information model proposed here is called the EHR Extract, and might be used to define a message, an XML document or schema, or an object interface. These might be used to communicate EHR data between two repositories, to update a centralised regional or national EHR repository, or within a distributed network of EHR components, systems and services. Whilst an EHR service or system will need to interact with many other services or systems providing terminology, medical knowledge, guidelines, workflow, security, persons registries, billing etc. this document has only touched on those areas if some persistent trace of such interactions is required in the EHR itself, and requires specific features in the reference model to allow their communication.

This document may offer a practical and useful contribution to the design of EHR systems but will primarily be realised as a common set of external interfaces or messages built on otherwise heterogeneous clinical systems. The components that might support an interface conforming to this document will be not only electronic health record systems but also other middleware services such as security components, guideline and workflow systems, alerting and decision support services, personal health systems and applications, sensors and wearable devices, and medical knowledge management services. This document might also prove useful for communicating data about individuals between electronic health record systems and population registries, and also for conducting (approved) research using electronic health records.

This document is part of a five-part standard series, published jointly by CEN and ISO through the Vienna Agreement.

In this document dependency upon any of the other parts of this series is explicitly stated where it applies.

0.2 Technical approach

This document is the second version of an original standard which was published in 2007 by CEN, and in 2008 by ISO. This revision has taken into account the experiences gained by EHR system developers and by large scale eHealth programmes from using the original standard. These were ascertained through an international survey, a wide range of 1:1 interviews, a review of the academic literature, and interactions with many experts active in R&D relating to the EHR. It also meets the relevant requirements in ISO 18308:2011 (Requirements for an Electronic Health Record Architecture). The

revision has taken into account, and aligns as far as possible, with other CEN and ISO Standards and Technical Specifications with which this document might also be used, with international terminology standards and with emerging standards from HL7: Fast Healthcare Interoperability Resources (FHIR). The specifications in this document have drawn from, and align as far as possible with, the reference model specifications published by the openEHR Foundation, and with the archetype models published by the openEHR Foundation and by the Clinical Information Modeling Initiative (CIMI).

The information model in this document is an Information Viewpoint of the ISO Reference Model for Open Distributed Processing (ISO/IEC 10746-1:1998**)**.

Given the diversity of deployed EHR systems, this document has made most features of EHR communication optional rather than mandatory. However, some degree of prescription is required to make EHR Extracts safely processable by an EHR recipient system, which is reflected through mandatory properties within the models in Parts 1, 2, and 4 of this series, and through normative term lists (defined in Part 3 of this series).

0.3 The Dual Model approach

The challenge for EHR interoperability is to devise a generalised approach to representing every conceivable kind of health record data structure in a consistent way. This needs to cater for records arising from any profession, speciality or service, whilst recognising that the healthcare data sets, value sets, templates etc. required by different healthcare domains will be diverse, complex and will change frequently as clinical practice and medical knowledge advance. This requirement is part of the widely acknowledged health informatics challenge of semantic interoperability.

The approach adopted by this standard series distinguishes a Reference Model, defined in this document and used to represent the generic properties of health record information, and Archetypes (conforming to an Archetype Model, defined in Part 2 of this series), which are meta-data used to define patterns for the specific characteristics of the healthcare data that represents the requirements of each particular profession, speciality or service.

The Reference Model represents the global characteristics of health record components, how they are aggregated, and the context information required to meet ethical, legal and provenance requirements. This model defines the set of classes that form the generic building blocks of the EHR. It reflects the stable characteristics of an electronic health record, and would be embedded in a distributed (federated) EHR environment as specific messages or interfaces (as specified in Part 5 of this series).

This generic information model needs to be complemented by a formal method of communicating and sharing the organisational structure of predefined classes of EHR fragment corresponding to sets of record components made in particular clinical situations. These are effectively pre-coordinated combinations of named RECORD_COMPONENT hierarchies that are agreed within a community in order to ensure interoperability, data consistency and data quality.

An Archetype is the formal definition of prescribed combinations of the building-block classes defined in the Reference Model for particular clinical domains or organisations. An archetype is a formal expression of a distinct, domain-level concept, expressed in the form of constraints on data whose instances conform to the reference model. For an EHR_EXTRACT, as defined in this document, an archetype instance specifies (and effectively constrains) a particular hierarchy of RECORD_COMPONENT sub-classes, defining or constraining their names and other relevant attribute values, optionality and multiplicity at any point in the hierarchy, the data types and value ranges that ELEMENT data values may take, and other constraints.

This document recognises that archetypes (or equivalent clinical models) are not always directly incorporated within the present-day architectures of electronic health record systems. This document therefore does not mandate that archetypes are used within such systems. It does, however, require that the clinical information models or equivalents (data items, data item aggregations, data value constraints, terminology bindings, units of measure etc.) that have been used to generate an EHR_EXTRACT are themselves created and communicated, or referenced, within each EHR_EXTRACT. These communicated or referenced archetypes have to conform to Part 2 of this standard series, and maybe communicated through an interface conforming to part 5 of this Standard series.