SLOVENSKI STANDARD
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Zdravstvena informatika - Klinični informacijski modeli - Značilnosti, strukture in zahteve (ISO/DIS 13972:2020)

Health informatics - Clinical information models - Characteristics, structures and requirements (ISO/DIS 13972:2020)

Medizinische Informatik - Detaillierte klinische Modelle - Charakteristika und Prozesse (ISO/DIS 13972:2020)

Informatique de santé - Modèles d'informations cliniques - Caractéristiques, structures et exigences (ISO/DIS 13972:2020)

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Health informatics — Clinical information models — Characteristics, structures and requirements

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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).

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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 TS 13972: 2015) which has been technically revised.

The main changes compared to the previous edition are as follows:

- reduction of content that is not directly aiming at the clinical information models, such as clinician involvement, governance, and patient safety matters.
- updates on modelling practices, e.g. the strict relationship to a RIM or RM has been loosened to reflect ongoing practices, such as with HL7 FHIR.

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

In current health care the exchange of information from one healthcare professional to another, and hence, the exchange of data from one application to the other, has become a necessity. Of course, sender and receiver want to understand the exchanged information or data properly. To achieve mutual understanding 'semantic interoperability' is of utmost importance. Semantic interoperability represents the core need for electronic health records (EHR) and other health ICT systems and for communication between these systems. Semantic interoperability is defined as "ensuring that the precise meaning of exchanged information is understandable by any other system or application not initially developed for this purpose" [EC Recommendation, COM (2008) 3282 final]. This standard provides an approach to achieve semantic interoperability through Clinical Information Models (CIMs). There are five reasons for this standard. These include:

1. CIMs describe the **clinical world** of patients and health professionals, representing the clinical knowledge in ICT.

2. CIMs function as **building blocks** from which many different useful solutions can be created, keeping the underlying data standardized.

3. CIMs are specific instances of representations of clinical concepts, contexts, and relations. CIMs function as specific instances of health ICT architectures. CIMs bridge between real world clinical processes and IT solutions supporting them. For example, when using the ISO/DIS 23903 Interoperability and Integration Reference Architecture, CIMs can be represented in IT models using IT ontologies.

4. CIMs are **independent from technology choices** and can be used in any health information technology.

5. CIMs define **representations** of clinical concepts independent of implementation, enabling safe translation from one technological implementation of a CIM into another technology based on the same CIM.

Each reason for CIMs is described further below.

Firstly, CIMs are models that describe the clinical world, the world of patients and health professionals, in all kinds of fashions. CIMs provide views on the healthcare business at the most detailed level. CIMs allow providers to represent and capture the meaning of specific types of clinical information consistently and precisely. This to exchange that information without concerns about misinterpretation and to re-use, re-purpose and re-position that information in multiple contexts. Consistent clinical documentation in electronic health record systems (EHRs) and personal health record systems (PHRs) is at the core of CIM's benefit to assure and ascertain continuity of care across time, provider, and location. This is a prerequisite for data use, data reuse and data exchange. In addition, semantic interoperability addresses issues of how to enable health professionals and ICT professionals to establish and maintain this meaning, coding and transmission of data across time and health services, and to perform meaningful and cooperative care, based on shared knowledge. CIMs support exchanging meaning between health care professionals, providers, patients, and citizens, with a focus on the end user independent of the actual ICT system(s) used.

In addition, they facilitate mutual understanding between authorities, researchers, managers, policy makers, educators and more (modified from Semantic Health, 2009). A key requirement to achieve meaningful data use and exchange is the standardization of clinical concept representation within health data, including its content, structure, context, and transmission processes. The ability to use and exchange information between clinical information systems without loss of clinical meaning is also essential to enable safe and effective implementation of automated decision support. Interoperability and system integration are challenges which CIMs can help overcome to meet business objectives.

Standardization of clinical concept representation is a desirable and cost-effective way to aggregate data from EHR systems for multiple data use and reuse, for example for decision support, clinical quality, epidemiology, management, policy making, and research. These are the main information

processing activities in healthcare. With respect to the processes relevant to CIMs governance, a Quality Management system (QMS) based on a framework such as ISO 9001 can be used. Defined processes for development, application, and governance ensure the quality of CIM artefacts and its use.

A second important aspect of CIMs is that in any given implementation context, they will need to be combined into larger interlinked structures or compositions. CIMs facilitate use as building blocks from which meaningful and useful integrated information solutions can be composed. An individual CIM does usually not actually facilitate anything. CIMs must be grouped together to create a working solution. CIMs are not specific for a particular use case but can be created and combined for specific use cases to meet the clinical needs. CIMs facilitate a bottom up approach. A consequence of such requirements is that mechanisms such as composition and decomposition are needed to enable CIMs to be safely represented at different levels of detail. For example, a hospital discharge summary will consist of many data elements, many of which might be CIMs. However, the data specification of a discharge summary is a separate artefact making use of several CIMs and is **not** a CIM in itself. How these combinations of CIMs can be achieved using ISO/DIS 23903 is not part of this standard. For example, a quality indicator or quality report will usually consist of several CIMs (as a composition): one CIM to identify the patient (even if anonymous, but with a respondent number), the health organization CIM, the clinical problem CIM, the clinical activities CIM, and so on. Similarly, for quality care, the same and other CIMs will be used along a patient journey or clinical pathway.

The third reason for this standard is the transformation of health care towards personalized ubiquitous care. This requires the advancement of data exchange between computer systems to knowledge sharing among the stakeholders involved, including patients, or even citizens. For that reason, CIMs facilitate the representation of any clinical business processes' clinical concepts, contexts, and relations into finally implementable IT models, using IT ontologies. For correctly and consistently performing this challenge, ISO/DIS 23903 *Interoperability and Integration Reference Architecture* can be deployed to formally represent the clinical business system based on the knowledge space of the involved domains' experts represented by those domains' terminologies and ontologies. In some policies this level is referred to as the information layer, representing the detailed semantic level of the healthcare business. As part of a standardized software development process, this formalized system is then transformed into specific instances for specific enterprise and information models to specify platform-specific models and implement them.

Another standard conceptualizing health care processes is ISO 13940 *Health informatics — System of concepts to support continuity of care*. The need to evidence the quality of the CIMs is inevitable. Therefore, the standard specifies clinical model quality requirements, principles, development methodology, and governance. This standard refers to standardized terminologies, relationships, standardized datatypes, and the need to reference term or value sets, and units of measure. CIMs model clinical concepts that are defined precisely at the logical level. CIMs are **logical** constructs, specifying modular data for clinical information. This standard reflects a pragmatic consensus based on experience, regarding the level of detail in the breakdown and representation of a CIM. Similarly, pragmatic views present examples of CIM, and support how instance data based on CIMs can be used within Healthcare Information Architectures. The development and management of CIMs requires common and more generic definitions/descriptions of clinical concepts, such as health care processes and the constructs health professionals use within these processes, as generally depicted in ISO 13940. Contsys is suitable (but not required) as a common base for development of CIMs.

A fourth reason is that CIMs do not force into taking one direction with respect to technologies. CIMs are independent from technology choices, and are therefore core assets describing the healthcare domains, which are crucial in the negotiations with health IT professionals. There is widespread acceptance that CIMs need to be developed and standardized by stakeholders including health professionals, patients, managers, and (clinical) researchers on one hand while being technology 'neutral' yet usable in real systems. CIMs address the conceptual content for the logical levels of modelling, but do not intervene in the physical implementation of IT systems in healthcare. Hence, each CIM can be used in various use cases, IT architectures, and IT technologies.

An implementation technology standard has to be chosen and the CIMs have to be translated to this technical standard within the limits and the constraints of that standard before technical artefacts for that specific implementation technology can be derived. These resources, artefacts, or archetypes

themselves can be transformed into various computational representations and programming languages such as JSON, XML, OWL, Java, C# among many others. In such developments, CIMs are the core source material and their main function is to offer all technologies the same core clinical information model, so that the consistency and logic of data can remain in various systems, offering a key benefit to stakeholders to retain knowledge when replacing old technologies with new. In the world of ubiquitous personalized health, this applies for the new technologies used by patients themselves which offer highly dynamic interoperability services provided in real time.

Note Of course, for specific implementations the use of a reference (information) model can be required or recommended, but that is only in the stage where technology decisions are or have been made. Any constraints that technology choices impose on the clinical world do not apply at the CIMs level, hence the CIMs remain the "pure" unconstrained descriptions of the healthcare business.

Fifth, CIMs define representations of clinical concepts independent of implementation, enabling safe translation from one technological implementation of a CIM into another technology based on the same CIM. CIMs facilitate various products from standards and technology developers to seamlessly work together, hence, CIMs build bridges between different technologies, e.g. exchange data from an archetype based EHR via HL7 FHIR to a SQL based EHR. Data specifications similar to the CIMs described in this standard have been found to be useful in a wide range of health care information and communication technologies, including but not limited to EHR systems, telehealth applications, messaging integration, medical devices, computer algorithms, and deductive reasoning for decision support (e.g. Huff et al., 2004, Hoy et al., 2007, 2009, Kalra et al., 2008, Rector, Qamar, Marley, 2008, Goossen et al., 2010, Shafarman and Gilliam, 2010, Moreno - Conde et al, 2015, González-Ferrer et al, 2016, among others).

CIMs also offer a migration path in perspective of the ISO 23903 *Interoperability and Integration Reference Architecture*, facilitating an approach in which old systems or applications can be replaced by new ones, without affecting other layers or views in the architecture, if of course the standards in the various layers are applied.

Standardized CIMs further underpin the coherence of Electronic Health Records (EHR, ISO 18308), where data needs to be accepted from multiple sources and stored in consistent and predetermined format. In addition, for a functional EHR system (EHR System Functional Model, ISO/HL7 10781), queries must be constructed based on clinical knowledge and tied to clinical context, content, semantics and workflow; services need to be automated based on known values of patient data linked to agreed protocols and terminologies; data display and data entry needs to reference clinical guidelines; and safety and quality issues for clinicians moving from system to system can be minimized through consistent information representation. In this way, standardized CIMs form the lingua franca of use, reuse and reusability within and across various health, clinical and care related systems.

In summary, CIMs can be used as a set of accurate clinical building blocks representing clinical concepts that together meet the requirements for specific healthcare related use cases for which a mixed set of information and communication technological solutions are developed and/or deployed.

The target audience for this standard includes health informaticians in general but it does have a particular relevance for Chief Medical Information Officers, Chief Nursing Information Officers, Chief Patient Information Officers, Healthcare Information Analysts, Healthcare Information Modelers, and Healthcare Information Architects.

Health informatics — Clinical information models — Characteristics, structures and requirements

1 Scope

This Standard:

— Specifies **clinical information models** (CIMs) as health and care concepts that can be used to define and to structure information for various purposes in health care, also enabling information reuse.

— Describes **requirements** for CIMs content, **structure** and context and specification of their data elements, data element relationships, meta-data and versioning, and provides guidance and examples.

— Specifies key **characteristics** of CIMs used in conceptual and logical analysis for use cases such as (reference) architectures, information layers, EHR and PHR systems, interoperability, systems integration in the health domain, and secondary use of data including for public health reporting.

— Defines a **Quality Management System (QMS)** for a systematic and effective governance, quality management, and measurement of CIMs through their lifecycle of development, testing, distribution, application and maintenance.

— Provides **principles** to be followed in the transformation and application of clinical information models through the wide variation of health information technology.

This Standard excludes:

— Normative specification of the content or application of any particular clinical information model or clinical information modelling methodology. However, informative examples are presented.

— Specific applications of clinical information models such as for dynamic modelling of workflow.

— Specifications for modelling entire domains or aggregates of many CIMs such as complete assessment documents or discharge summaries. It will not specify CIMs compositions.

— Specification of how to involve specific clinicians, how to carry out governance including information governance, or how to ensure patient safety.

2 Normative references

The following documents are referred to in the text in such a way that some or all their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/DIS 23903, *Interoperability and Integration Reference Architecture*

3 Terms, definitions, abbreviations and synonyms

3.1 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1.1
concept
a unit of thought

3.1.2
concept analysis
formal linguistic strategy that allows the defining attributes or characteristics of a concept to be examined

[SOURCE: Walker LO Avant KC (1988). Strategies for Theory Construction in Nursing. 2nd edition. Norwalk/ San Mateo, Appleton and Lange]

3.1.3
concept definition
description of the attributes of a concept to delineate the meaning

3.1.4
clinical concept
concept expressed by means of characteristics or attributes pertinent to its use in health or health care

3.1.5
model
something that represents another thing, either as a physical object that is usually smaller than the real object, or as a simple description that can be used in calculations; e.g. to construct a statistical/ theoretical/mathematical model

[SOURCE: https://dictionary.cambridge.org/dictionary/english/model]

Note 1 to entry: It can also be used to construct logical and computational models.

Note 2 to entry: Representation of a domain that uses abstraction to express the relevant concepts

Note 3 to entry: The model is a representation of reality with respect to concepts, data elements, terms, and their relationships.

3.1.6
modelling
construction of abstract representations in the course of design, for example to represent the logical structure of software applications before coding

[SOURCE: https://www.omg.org/gettingstarted/what_is_uml.htm]

3.1.7
conceptual model
describes common concepts and their relationships particularly in order to facilitate exchange of information between parties within a specific domain of healthcare

[SOURCE: ENV 1613 CR 12587]

Note 1 to entry: this pertains particularly to concepts representing clinical information in conceptual models

3.1.8
logical (information) model
information model that specifies the structures and relationships between data elements but is independent of any particular technology or implementation environment

[SOURCE: ISO/TR 20514:2005, 2.29 modified 'information' replaced by 'data elements', note removed]

3.1.9
physical level
level of consideration at which all aspects deal with the physical representation of data structures and with mapping them on corresponding storage organizations and their access operations in a data processing system

Note 1 to entry: physical level: term and definition standardized by ISO/IEC [ISO/IEC 2382-17:1999].

Note 2 to entry: instantiation of a logical (information) model that respects specific technological constraints, normally for use in building a specific system or product.

[SOURCE: ISO-IEC-2382-17 * 1999 * * *]

3.1.10
information
knowledge concerning objects that within a certain context has a particular meaning

[SOURCE: ISO/IEC 2382:2015, 2121271, modified, all examples as 'facts, events, things etc.' are removed]

Note 1 to entry: Facts, events, things, processes, and ideas, including concepts, are examples of objects.

Note 2 to entry: Information is something that is meaningful. Data might be regarded as information once its meaning is revealed.

3.1.11
healthcare information
information about a person, relevant to his or her health or health care

[SOURCE: ENV 13606:2000, ISO 13940:2015, 3.94]

Note 1 to entry: Healthcare information is pertaining to healthcare, to characterize activities in which a patient and care professional interact directly or indirectly.

Note 2 to entry: Healthcare information about a patient may include information about the patient's environment and/or about related people where this is relevant.

Note 3 to entry: Healthcare information is often referred to as clinical information.

Note 4 to entry: in ISO 18308 this description is also given for clinical information

3.1.12
context
related conditions and situations that provide a useful understanding and meaning of a subject

[SOURCE: ISO/TR 17119:2005, 2.4 ISO/DIS 17439, 3.4]

3.1.13
clinical information model
CIM
information model that expresses in a standardized and reusable manner one or more healthcare or clinical concepts and their context in a conceptual and logical model, specifying healthcare information as a discrete set of data elements, their characteristics and relationships, and appropriate terminology bindings

3.1.14
medical knowledge
field of knowledge pertaining to the structure, function or dysfunction of the human body and how these can be influenced by external or internal factors and interventions

[SOURCE: ISO 13119:2012]

Note 1 to entry: Medical does not imply "physician", all health professionals have medical knowledge according to this definition.

Note 2 to entry: This would pertain to observations, findings, diagnoses, outcomes, therapy etc, to alleviate disease/dysfunction.

3.1.15
semantic interoperability
ability for data shared by systems to be understood at the level of fully defined domain concepts

[SOURCE: ISO/TS 18308:2011, 3.45]

3.1.16
data
reinterpretable representation of information in a formalized manner suitable for communication, interpretation or processing

[SOURCE: ISO/IEC 2382:2015, 2121272 modified notes removed]

3.1.17
data element
unit of data that is considered, in context, to be indivisible

[SOURCE: ISO/IEC 14957:2010, 3.1]

3.1.18
attribute
characteristic of an object or set of objects

[SOURCE: ISO/IEC 11179-1:2015]

Note 1 to entry: In the context of standard: a specific characteristic of a data element.

3.1.19
data model
description of the organization of data in a manner that reflects an information structure

[SOURCE: ISO 5127:2017, 3.1.13.33]

3.1.20
datatype
set of distinct values, characterized by properties of those values and by operations on those values

[SOURCE: ISO/IEC 11404:2007, 3.12]

3.1.21
metadata
data that defines and describes other data

[SOURCE: ISO/IEC 11179-1:22015, 3.2.16]

Note 1 to entry: in the context of this standard the metadata that describe clinical information models are meant to govern the CIM as objects, for instance to retrieve specific CIMs and to maintain CIM versions.

Note 2 to entry: it is possible to relate to persistent instance data using metadata that are based on the clinical information models in any storage or exchange format, for example to identify on which CIM specific data are based.

3.1.22
term
designation that represents a general concept by linguistic means

[SOURCE: ISO 1087-1:2019]

3.1.23
terminological system
ordered collection of concepts, in which each concept is expressed by terms, words or expressions

[SOURCE: NEN 7522, based on ISO/IEC 11179-1:2004, definition 3.2.25]

3.1.24
coding system
combination of a set of code meanings and a set of code values, based on a coding scheme

[SOURCE: EN 1068:2005]

Note 1 to entry: Code meanings are typically represented by terms or rubrics, but they can have other representations. Code values are typically numeric or alphanumeric.

Note 2 to entry: For clinical information models, the coding schemes are typically derived from terminological systems, e.g. because they have coding schemes included.

3.1.25
code value
result of applying a coding scheme to a code meaning

[SOURCE: EN 1068:2005]

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

3.1.26
value set
uniquely identifiable set of valid concept representations, where any concept representation can be tested to determine whether it is a member

[SOURCE: Adapted from TN903 HITSP specified metadata: element, description, HITSP Template Metadata and the HL7 Templates DSTU Property name, MIF mapping. Adapted from HL7 Version 3 Core Principals]

Note 1 to entry: A value set is intended to be a set in the formal sense, and so should contain only one code for each uniquely identifiable concept that it contains.

3.1.27
Reference Model for Open Distributed Processing (RM-ODP)
standardized approach to design and governance of information systems, in particular systems involving data communications between organizations that have different computing platforms.

[SOURCE: ITU-T Rec. X.901-X.904 | ISO/IEC 10746]

3.1.28
use case
set of scenarios which address a particular business/clinical domain or topic

[SOURCE: ISO/TR 19669:2017, 3.17]

Note 1 to entry: It can also be defined as a specification of interactions between external actors and the system to attain particular goals (technopedia.com) or methodology used in system analysis to identify, clarify, and organize system requirements (whatis.com).

3.1.29
archetype
instance of an archetype model, specifying the clinical concept and the value constraints that apply to one class of Record Component instances in an electronic health record extract

[SOURCE: ISO 13606-1:2019, 3.3.2]