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

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Foreword

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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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This document was prepared by Technical Committee ISO/TC 215, *Health informatics,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This first edition of ISO 13972 cancels and replaces ISO/TS 13972:2015, which has been technically revised.

The main changes 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.

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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. As sender and receiver want to understand the exchanged information or data properly, it is of utmost importance to achieve mutual understanding through 'semantic interoperability'. Semantic interoperability represents the core need for electronic health records (EHR) and other health ICT systems, and for communication between these systems. This document provides an approach to achieve semantic interoperability through Clinical Information Models (CIMs).

There are five reasons for this document:

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

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

c) 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 ISO 23903, CIMs can be represented in IT models using IT ontologies.

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

e) 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 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[2]. 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 that 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.

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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 can best 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 23903 is not part of this document. 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 document 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. To perform this challenge correctly and consistently, ISO 23903 can be deployed to formally represent the clinical business system based on the knowledge space of the experts of the domains involved 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 International Standard conceptualizing health care processes is ISO 13940. The need to evidence the quality of the CIMs is inevitable. This document 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 document reflects a pragmatic consensus based on experience, regarding the level of detail in the breakdown and representation of a CIM representing medical knowledge. 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 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 should be chosen and the CIMs should be translated to this document 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 ISO/IEC 21778 JSON, or 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

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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 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. 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®[1] FHIR®[2] to a SQL based EHR. Data specifications similar to the CIMs described in this document 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 (see References [6][7][8][9][10][11][12][13][14][15][16]).

CIMs also offer a migration path in perspective of ISO 23903, 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), for instance ISO 18308, where data needs to be accepted from multiple sources and stored in a consistent and predetermined format. In addition, for a functional EHR system (ISO/HL7 10781), queries need to 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 document 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.

In this document, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "can" indicates a possibility or a capability;

— "may" indicates a permission.

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

1 Scope

This document:

— 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** for the transformation and application of clinical information models through the wide variation of health information technology.

This document excludes:

— Requirements on the content or application of any particular clinical information model or clinical information modelling methodology;

— 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 does 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

There are no normative references in this document.

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

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

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

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

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

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3.1.1
concept
unit of thought

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

[SOURCE: Reference [19]]

3.1.3
concept definition
description of the attributes of a concept to delineate its 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
abstract description of reality in any form (including concepts, data elements, terms, and their relationships, statistical, theoretical, mathematical, physical, symbolic, graphical or descriptive form of a domain) that presents a certain aspect of that reality

Note 1 to entry: It is often further specified to distinguish between conceptual, logical and computational models.

[SOURCE: ISO/TR 23087:2018, 3.5, modified —"concepts, data elements, terms and their relationships, added statistical, theoretical" and Note 1 to entry have added.]

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: Reference [21]]

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

Note 1 to entry: This pertains in particular to concepts representing clinical information in conceptual models.

[SOURCE: ISO/TS 18864:2017, 3.6, modified —"description" changed to "model that describes", Note 1 to entry added.]

3.1.8
logical information model
logical 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 with "data elements", note removed.]

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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: This document focuses on the flow from business concepts in any domain via clinical (logical) information models to their technical implementation in a specific application or system.

[SOURCE: ISO/IEC 20944-1:2013, 3.14.3.6, modified — Note 1 to entry added.]

3.1.10
information
knowledge concerning objects, such as facts, events, things, processes, or ideas, including concepts, that within a certain context has a particular meaning

Note 1 to entry: Information is something that is meaningful. Data might be regarded as information once its meaning is revealed.

[SOURCE: ISO/IEC 2382:2015, 2121271, modified — Notes to entry removed, new Note 1 to entry added.]

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

Note 1 to entry: This does include activities in which a patient and care professional interact directly or indirectly.

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

[SOURCE: ISO 13940:2015, 3.9.4, modified — "clinical information" added as a term, "health" added, Notes to entry added.]

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]

3.1.13
clinical information model
CIM
health and care information model
HCIM
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

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.

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[SOURCE: ISO 13119:2012, 2.1, modified — Note 1 to entry modified, Note 2 to entry added.]

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

Note 1 to entry: EC Recommendation, COM (2008) 3282 final, stresses that this implies to work for any other system or application the defined domain concepts were not initially developed for.

[SOURCE: ISO 18308:2011, 3.45, modified — Note 1 to entry added.]

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 to entry removed.]

3.1.17
data element
variable, clinical elements are considered synonyms in a clinical information model unit of data that is considered, in context, to be indivisible

[SOURCE: ISO/IEC 14957:2010, 3.1, modified — "variable, clinical elements are considered synonyms in a clinical information model" added.]

3.1.18
attribute
characteristic of an object or set of objects

Note 1 to entry: In the context of this document it can be a specific characteristic of a data element.

[SOURCE: ISO/IEC 11179-1:2015, 3.1.1, modified — Note 1 to entry added.]

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

Note 1 to entry: In the context of this document, the metadata that describe clinical information models are meant to govern the clinical information model (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.

[SOURCE: ISO/IEC 11179-1:2015, 3.2.16, modified — Notes to entry added.]

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3.1.22
term
designation that represents a general concept by linguistic means

EXAMPLE "Patient", "Doctor", "Body temperature", "Pacemaker", "Covid-19 virus".

[SOURCE: ISO 1087:2019, 3.4.2, modified — EXAMPLE, modified, Note to entry, removed.]

3.1.23
terminological system
set of concepts structured according to the relations among them, each concept being represented by a sign which denotes it

Note 1 to entry: In terminology work, and in this document, three types of such signs (designations) are distinguished: symbols, appellations and terms.

[SOURCE: ISO 18308:2011, 3.50, modified — Note 1 to entry removed, Note 2 to entry has become new Note 1 to entry.]

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

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, for example because they have coding schemes included.

[SOURCE: ISO/TR 12300:2014, 2.2.5, modified — Notes to entry added.]

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

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

[SOURCE: EN 1068:2005, 3.6, modified — Example added.]

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

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.

[SOURCE: ISO/TS 18864:2017, 3.32, modified — "of the value set" removed.]

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, Reference [36]]

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

Note 1 to entry: It specifies interactions between external actors and the system to attain particular goals or a particular methodology.

Note 2 to entry: Use cases can be used in system analysis to identify, clarify, and organize system requirements or process steps.

[SOURCE: ISO/TR 19669:2017, 3.17, modified — Note to entry removed, new Notes to entry added.]

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]

3.1.30
archetype model
information model of the metadata to represent the domain-specific characteristics of electronic health record entries, by specifying values or value constraints for classes and attributes in the electronic health record reference model

[SOURCE: ISO 13606-1:2019, 3.3.3]

3.1.31
clinical template
clinical information model that structures information around discrete clinical concepts in a way that supports reuse of components across different clinical communication and record keeping activities and promotes common approaches to clinical information system development and interoperability

3.1.32
electronic health record
EHR
information relevant to the wellness, health and healthcare of an individual, in computer-processable form and represented according to a standardized information model

Note 1 to entry: It is the logical representation of information regarding or relevant to the health of a subject of care.

[SOURCE: ISO 18308:2011, 3.20, modified — Note to entry added.]

3.1.33
electronic health record architecture
formal description of a system of components and services for recording, retrieving and handling information in electronic health records

Note 1 to entry: It is about the logical components defined in terms of information models, and the computational services.

Note 2 to entry: The two-level modelling principle can be applied in electronic health record architectures using one generic information model for the whole system and specifying the details in clinical information models.

[SOURCE: ISO 18308:2011, 3.21, modified — Notes to entry added.]

3.1.34
association
relationship in which classes in a model relate to each other via a connector or link

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3.1.35
aggregation
special type of association in which child classes are configured together to create a more complex parent class

3.1.36
composition
special type of association in which a child class cannot exist independent of the parent class

3.1.37
generalization
mechanism to combine similar classes into one single, more generic class

3.1.38
specialization
mechanism to create new sub-classes from one existing class

3.1.39
information governance
processes by which an organization obtains assurance that the risks to its information and thereby the operational capabilities and integrity of the organization are effectively identified and managed

[SOURCE: ISO/TS 14441:2013, 3.25]

3.1.40
lifecycle
sequence of events that mark the development and use of an information resource

Note 1 to entry: Clinical information models are seen as information resources that undergo governance, for which a lifecycle is a key part.

EXAMPLE Conception of an invention, creation of a draft, revision of an article, publication of a book, acquisition by a library, transcription to magnetic disk, migration to optical storage, translation into English and derivation of a new work (e.g. a movie).

[SOURCE: ISO 15836-1:2017, 3.1.2, modified — "of a resource" removed from term and "information" added to definition, Note 1 to entry added.]

3.1.41
quality
degree to which a set of inherent characteristics of an object fulfils requirements

Note 1 to entry: This defines the degree to which all the properties and characteristics of a product, process, or service satisfy the requirements that ensue from the purpose for which that product, process, or service is to be used.

Note 2 to entry: In the context of clinical information models this is about the quality of the models, the quality of the developmental process and the services as to the governance of clinical information models.

[SOURCE: ISO 9000:2015, 3.6.2, modified — Notes to entry deleted, new notes to entry added.]

3.1.42
quality management system
QMS
part of a management system with regard to qualityNote 1 to entry: It is presented here as a framework described by ISO 9000 and ISO 9001 and it comprises of the three core elements: quality control, quality assurance and quality improvement.

[SOURCE: ISO 9000:2015, 3.5.4, modified — Note to entry added.]

3.2 Abbreviated terms

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