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

Informatique de santé — Modèles d'informations cliniques — Caractéristiques, structures et exigences

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Contents

Page

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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®.

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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.

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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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ADL	Archetype Definition Language
CDA	Clinical Document Architecture
CEN	Comité Européen de Normalisation [Committee of European Norms]
CBB	Clinical Building Block
CIMI	Clinical Information Modeling Initiative
CMET	Common Message Element Type
DAM	Domain Analysis Model
DCM	Detailed Clinical Model
D-MIM	Domain Message Information Model
EHR-S FM	Electronic Health Record System Functional Model
EVM	Eye Verbal Motor
FHIR	Fast Healthcare Interoperability Resources
FM	Functional Model
GCM	Generic Component Model
GCS	Glasgow Coma Scale
HIT	Healthcare Information Technologies
HL7®	Health Level Seven
ICT	Information and Communication Technology
ID	Identifier
ITS	Information Technology Specification
IT	Information Technology
MDA	Model Driven Architecture
ReEIF	Refined eHealth European Interoperability Framework
RIM	Reference Information Model
RM	Reference Model
OCL	Object Constraint Language
PIM	Platform Independent Model
PSM	Platform Specific Model
QMS	Quality Management System
SFM	Specialized Functional Model
STU	Standard for Trial Use
UML	Unified Modelling Language
URI	Uniform Resource Identifier
URL	Uniform Resource Locator
VP	Viewpoint
zib	Zorg Informatie Bouwsteen [Care Information Building Block]

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4 Health care information models - Concept, purpose, contexts and position

4.1 The Concept of Clinical Information Models

CIMs are used to capture functional, semantic (non-technical) agreements for the standardization of information used in the care process.

They are models constructed to bridge/link the intersection between the business, enterprise, and information perspectives. Traceability from a health, clinical or care process (regarding the context)

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and/or a health, clinical or care concept (regarding the content) is recommended for the use of CIMs. That means that for example, a clinical guideline can express the required data elements for quality care in the form of a set of required CIMs. CIMs for implementation in health care information technology should be further expressed against one or more implementable standards to make them useful, however that process is not part of this document.

Structurally, CIMs provide the data elements and attributes of a concept, including the possible values and types of attributes and the relationships between data elements needed to convey the health, clinical or care requirements to domain experts, data users, modellers and implementers.

Contextually, CIMs can be positioned in various (reference) information models. In such context, CIMs shall be positioned in the Information Layer. See the European Interoperability Framework that has such an information layer in Reference [44]. An alternative representation of CIMs is in the information layer according to the ISO 12967 series (HISA), and specifically, the CIM placement in the Information Viewpoint of ISO 12967-2.

Ideally, all CIMs make use of a pragmatic and where possible, a purposeful defined maximal data set for universal use cases. For safety, "for purpose" CIMs should only use the required or optimal data elements from a potential maximal data set, as needed to suit their purpose in common use cases. "For purpose CIMs" means in this context that they are dedicated to specific and not broad clinical concepts. This constraint is also in accordance with ISO 23903, reducing the complexity of the modelled system to the necessary level. CIMs, which represent the clinical concepts at the logical model level, shall be implemented in applications or systems. Examples of use are described below:

— A widely accepted conceptual model of health care, such as ISO 13940 (Contsys) and/or similar authoritative clinical reference models can refer to CIMs.

— An agreed standard Electronic Health Record (EHR) reference (information) model, such as ISO 13606-1 and/or OpenEHR[48], or HL7® EHR-S FM can refer to CIMs to specify clinical content. The reference (information) model guarantees that the common attributes for information in health records (such as who, when and where) have already been identified and do not need to be addressed again in each CIM.

— An agreed standard information exchange reference information model such as the HL7® v3 RIM or ISO 13606-1, ISO 13606-3, or alternatively, the HL7® FHIR® resources, profiles and extensions can refer to CIMs for the clinical materials.

— Requirements for EHR architectures, such as ISO 18308 or HL7® EHR-S-FM, or health architectures such as ISO 12967-2 (HISA) can refer to CIMs.

CIMs can be developed at different levels of complexity, ranging from one single data element to the more common situation where most CIMs have multiple data elements. CIMs should best be of a size appropriate for the content and scope of the health, clinical or care concept they represent. The question about how big or how small a CIM is depends on different factors: if a data element has a role by itself, it is logical to have a single data element CIM. Specific health, clinical or care purposes determine the logic to keep data elements together in the context for which they are specified. This is done to prevent wrong interpretations and misleading conclusions.

This is further clarified in the following examples:

a) Atomic CIMs. The CIMs consist of one single data element with a specific purpose. One example is the CIM Body Mass Index. The BMI has one data element, which is the result of a formula. To use this CIM "BMI", both the CIM for length and for weight are required. Another small CIM can be the skull circumference for youth care. Another reason to create an atomic CIM might be the reuse of the data element in various other CIMs, such as body position in the blood pressure CIM and in the body length CIM.

b) Molecular CIMs. Most CIMs consist of multiple data elements. There is no exact nature determined, due to the diversity of clinical practice documentation. For instance, the CIM body length has five data elements. Besides the value of the body length itself and the body position, the device used, potential confounding variables and the origin of the value are also specified. However,

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most implementations will only use the actual measurement. Nevertheless, there are circumstances where all these other data elements would be useful. In the case of the general practitioner providing preventive care to diabetes patients, blood pressure must be measured in a consistent manner only, which the guideline defines as in a sitting position, to ensure reliable comparison over time. In this situation, the body position "sitting" can be used a default value or can be left out. Other examples of CIM can have many data elements. For example, a Dutch risk assessment scale for child abuse (DMO protocol) includes 80 data elements but can still be considered a (larger) molecule.

The reasons for reuse and separation of data elements into separate CIMs include:

— A single standing data element using other existing CIMs that can be used as separate entities themselves (e.g. Body Mass Index, using length and weight).

— A data element that is often reused in other CIMs with (almost) the same purpose; a generic level CIM can refer to a more specific (partial) CIM containing this data element (e.g. body position).

— A data element which, outside the scope of intended use, has a risk for misinterpretation and errors in judgment. Then the CIM serves to appropriately define the content. In contrast, it might be that a specified data element has been validated for secondary and tertiary uses, such as the HbA1c values for patient outcomes for diabetes care.

c) Partial CIMs. These are small, usually atomic sized, CIMs that are not used by themselves, but only as component in molecular CIMs to provide a specific context. Examples of such contexts include body position, anatomic location, laterality and more. These partial CIMs are almost never used as such, but only as part of another concept or CIM. These partial CIMs improve the use of CIMs through consistent modelling of frequently used contextual parts.

d) Compositions of CIMs. Typically, several CIMs can be grouped together in various compositions such as grouping CIM blood pressure, CIM heart rate, CIM body temperature and CIM breathing into a composition of vital signs. Similarly, in the HL7® organization, a DAM typically defines a whole clinical area (diabetes care, pressure ulcer risk prevention and care) in which it is logical to de-compose all data into a series of CIMs, each of which can be maintained separately and reused. Models for clinical context such as specific types of clinical situations and/or specific types of steps in the clinical process are other examples of CIM in compositions. References [8] and [9] describe how the de-composition of clinical artefacts as forms can lead to a collection of clinical information models that are reusable parts that can be composed into various healthcare ICT solutions. There are some differences in approach between various clinical modelling initiatives, but this decomposition and composition approach is common to all. The construction of clinical templates is an important approach to make CIMs useful in relationship to each other. The generic term for such combination of CIMs is composition. The major benefit is the overall standardization of data and its consistency.

4.2 Purpose for Clinical Information Models

The purpose of Health and Care Information models is to provide the basis for precise, semantically consistent data and terminology specifications plus the processing rules which are comparable and sharable between multiple care providers, health enterprises and standards-based HIT. Typically, a set of CIMs serves as building blocks for one or more use cases.

The conceptual context and knowledge expression of CIMs and their logical model of data elements provide a common starting point and resource for Reference Architectures or can be directly converted into machine processable representations. CIMs can also be mapped to different RIM/RM, see 4.4. CIMs can be used by software applications to provide for or contribute to a variety of functional needs. Each function requiring the processing and use of clinical (EHR) data determines the degree of semantic interoperability needed. This is largely determined by the required use of the terminology applied to define various CIMs data elements, attributes and relationships to support each function; what is important is a shared use of terminology by trading partners exchanging information expressed so that specifications on the same concept are consistent for all functions that it tries to achieve.

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The logical specification of a CIM is not restricted for use within one (or a limited number of) software application(s). It can be used for multiple purposes and/or applications including:

— Context and knowledge of health, clinical and care concepts that precisely express the conceptual and logical model of the CIMs to support data collection and management in EHRs, including Storage, Data Processing and User Interfaces.

— Clinical content and knowledge with unambiguous detail which can be used across domains and disciplines, for instance the use of health, clinical or care data communication and exchanges in messages and services, including Medical Devices and Applications.

— Standardization and reusability of data and knowledge to suit multiple functions and purposes, such as Clinical Decision Support Systems, Continuity of Care, reporting of Quality Measures to National Registries, submitting data for Epidemiology and/or Research, Management, Public Health management.

— Lifetime storage and retrieval of health, clinical or care data and metadata, linked to the knowledge applied and the context in which data collection took place.

4.3 Context of Health and Care Information Models

To be relevant and to contribute to healthcare quality, CIMs need to be specifically related to identified health problems and healthcare requirements. Health problems/conditions and clinical processes including healthcare activities are examples of important clinical concepts that need to be defined and explained conceptually as well as contextually. And the clinical concepts are at the heart of the business requirements for many (clinical) information management activities in healthcare.

CIMs can be developed bottom-up: specifying specific clinical concepts and their context, or top down, using a more abstract concept model of healthcare as a business, or a process description. A concept model or process model can be used as a basis for specifying the content and context of CIMs for common and shared understanding and interoperability. This is often specified in use cases using health concepts. ISO 13940 (Contsys) is a system of concepts in health informatics that can fulfil such needs when working top-down. The most relevant clinical concepts included in Contsys as bases for CIMs are clinical process, health condition (problem) and healthcare activity (intervention). CIMs specify and concretize such relevant general clinical concepts.

In many policies, including the European eHealth Framework, the business ecosystem or domain ontology is depicted on several layers. The ICT and infrastructure layers represent how they "integrate into" the health care business. Figure 1 presents an example of how CIMs can be positioned into a Business Framework. A Business Framework functions as a systematic organization of business requirements for the application of healthcare information and communication technology. Figure 1 shows the six aspects, as layers, of the development of an information enabled organizational unit that provides and/or consumes health and care services. Such an organizational unit can be as small as a single patient or health professional, or as large as the health system of a country. For clarity of the concept, the main actors are depicted on each of the layers. The CIMs are exclusively situated in the Information layer. The six layers are further explained below.

— The top layer (1) is the legal framework, guiding clinical work, IT, privacy, and data security requirements among others.

— Layer 2 includes the requirements on the policy level. Stakeholders come to agreements about use cases, architectures, clinical processes, models, IT solutions, infrastructures and many more aspects of implementing IT in healthcare.

— Layer 3 is the clinical process requirements level. Here the use case is described, who are involved, what is the patient journey, how is care arranged. In the ICT world, Contsys represents (parts of) this layer.

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— Layer 4 is then the information requirements layer. This is where the clinical ontologies reside, the terminologies, the CIMs, and more, to ensure the semantics of information in healthcare are useful and properly addressed.

— Layer 5 describes how various requirements for ICT solutions can assist the clinical processes and facilitate the semantics of information.

— The bottom layer (6) describes requirements for infrastructural choices.

For example, the Netherlands based its half a billion Euro policy in health care IT investments on choices made on these 6 layers of the eHealth Framework.

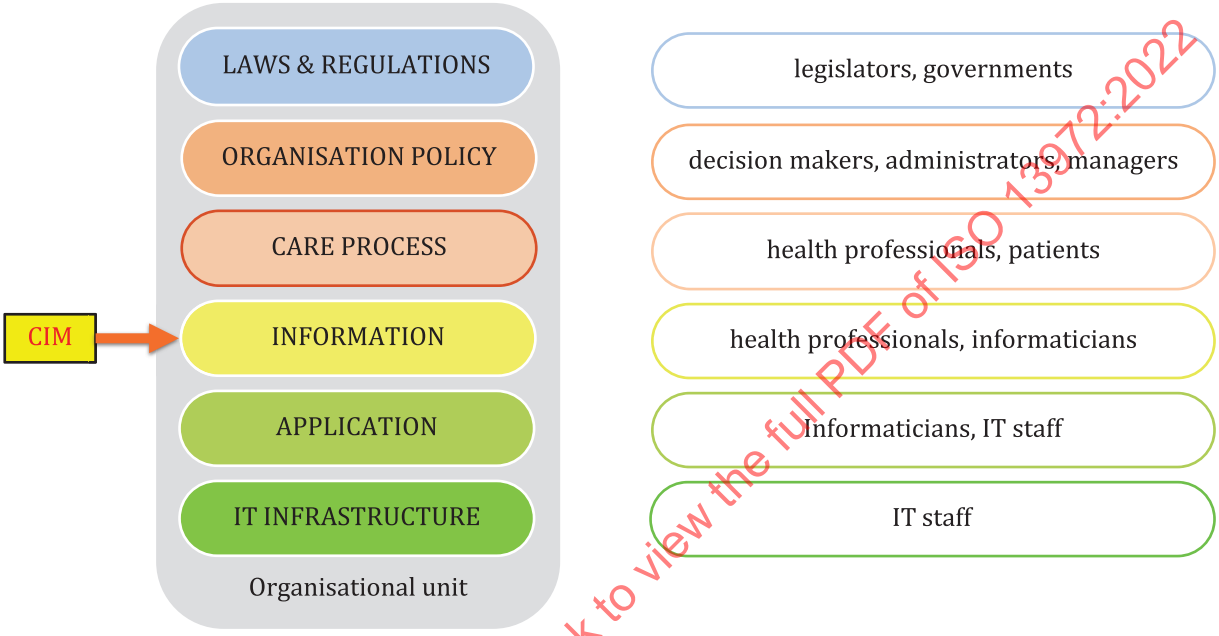

Figure 1 — Compact description of the business requirements essentials of the Refined eHealth European Interoperability Framework (ReEIF)[44]

The design of different logical models containing the same conceptual clinical content is acceptable. This occurs for example when some create CIMs, others create archetypes and a third creates specific HL7® FHIR® resources and profiles for the same clinical concepts. Such situations could introduce risks for errors and patient safety if their content differs due to the specific modelling approaches. Some will argue that this will bring unacceptable risks by potentially reducing the degree of quality of clinical documentation, semantic interoperability and impeding version control and traceability. Others will argue that it can be perfectly acceptable, depending on the clinical contexts and the intent of the CIMs and how they will be used in health, clinical or care settings. Such transformations and design from the conceptual and logical model into other richer logical models need to be carefully handled. The real test would be that the variations are isosemantic, that is, the meaning undergoes no changes. One should not assume a plug and play semantic interoperability at this stage. CIMs cover the data requirements for the continuum of care and multiple purposes for data use. Health, clinical and/or care knowledge is an essential component of any health ICT platform. As such, CIMs represent a key foundational building block for the introduction and use of interoperable person-centric health records and health information infrastructures. Transformations into archetypes based on ISO 13606-2 or ISO 13606-3 and/or FHIR® resources and profiles for implementations should be done with care.

Health IT platforms facilitate information sharing and integration within and between organizations and between subjects of care and their care providers. Both health information users and health software developers rely on the interoperability services provided by the health IT platform and, as such, depend on the reference information model upon which the platform is based.

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However, there is a mixed order of many different systems in the current health ICT environment which do not adhere to all standards relevant in a national platform and do not meet the business requirements. On many occasions a migration strategy is required to achieve seamless semantic interoperability and it is here that CIMs can fill a gap.

4.4 Architectural Considerations for Clinical Information Models

4.4.1 General

To guarantee that the quality of data of the healthcare systems', interoperability, and facilitation of data reuse are maintained, it is necessary to define the stakeholders' business objectives for that system along with its interrelation with (effects on) the environment. In this context, the real-world system must be properly designed, and the underlying concepts properly represented. Therefore, the components of the system, their functions and interrelationships (i.e. the architecture of that system) must be formally modelled through focusing on stakeholders' goals and their perspectives of the system, including naming and structuring the relevant concepts in the domains of interest, thereby ensuring the conceptual integrity of the resulting models.

When designing a new system, its level of need for interoperability can be determined by the functions to be supported and this is useful in positioning CIMs in the health care ICT environment. This forms the basis for choosing the many components that collectively make up the system architecture. It is necessary to understand that the choices made regarding each component must result in the best possible or optimum collective performance.

When working with existing (current) systems, the functions that can be supported are determined by the system's best possible interoperability capacity as determined by decisions made around the systems architecture. The CIMs framework provides a way to leverage the value of much of the health, clinical or care modelling work that has already been conducted. This document provides a level of abstraction that releases the expression of information requirements from the implementation framework in which they were developed. This can simplify the review process and allow wider and safer reuse of the logical model artefacts. The approach using CIMs aims to make sure that a mapping is always possible from the generic CIMs to an implementable specification, whichever technology is going to be deployed[15]. Annex D provides an example of mapping a CIM to ADL. Annex G presents a mapping from CIM to HL7 FHIR. Such mappings between types of models are sometimes called transformations.

To review CIMs initiatives appropriately, it is important to place them in this architecture for health care information.

4.4.2 CIMs in an architectural view

A good CIM shall be based on a real clinical business case or use case and business requirements. Therefore, it should describe the clinical business system architecture as the composition of that business system's components, their function, and their relations, in other words the system's structure and behaviour. The architectural components, operations and (logical) relations are represented by the underlying clinical concepts based on the clinical ontologies addressed. The ISO 12967 series (HISA) describes an open and modular architecture integrating the common data and business logic into a specific architectural layer and does not relate to specific applications. For instance, in the ISO 12967 series (HISA), CIMs would be placed in the information layer. ISO 12967-2 specifies the fundamental characteristics of information models implemented by the information ecosystem. ISO 12967-2 further provides comprehensive and integrated management of the health data and supports the fundamental business processes of the healthcare organization.

CIMs are models in which the relationship between concepts is represented using formal logic. For more information regarding the architectural model of a business case and its representation by a conceptual model based on business domain ontologies, see References [49][50][51][52] For implementing CIMs, the conceptual models of the business domain shall be transferred into ICT domain model representations using ICT ontologies, thereby starting with the business view and then covering the entire suite from the enterprise view through the information view, computational view and the engineering view up to

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the technology view as defined in the RM-ODP of the ISO/IEC 10746 series. Such an approach is defined by ISO 23903. The business view has been added to RM-ODP, preceding the enterprise level.

4.4.3 CIMs placed in the Generic Component Model

Clinical Information Models are not directly implementable. For implementation in running applications, CIMs shall be transformed into ICT models, thereby running the entire development process. The Generic Component Model (GCM) architecture for structurally and behaviourally modelling interoperable healthcare systems characterizes any system by three axes. The GCM is a cube and is represented in Figure 2. It consists of:

— Domains;

— System components;

— System development.

Each axis is discussed and the manner in which each axis fits in an interoperability and systems integration reference architecture according to ISO 23903 is explained. Based on the GCM[49][52], the relative position of CIMs in each of the three axes is further illustrated in Figure 2. The GCM cube's three axes are illustrated:

a) Domain

In the Business view a specific clinical domain is analyzed and modelled, leading to identification of actors, workflow, data, and data structures. The business view is represented on the vertical or y-axis of the GCM. On the bottom level, the required data elements and data structures link to a (collection of) CIMs. In addition, the Electronic Health Record architecture of ISO 18308 links the health care business requirements to logical models for records, addressing the cross-domain aspects of the GCM. Although there is potential to link EHR requirements to specific CIMs, a generic link from business to the detailed specifications would suffice. However, it is different for an EHR system as there is ample opportunity to link the required content to CIMs specifications in the functional model for EHR systems, such as HL7®/ ISO EHR-S FM.

b) System components

CIMs are placeholders for expressed clinical conceptual and logical content in the Business View as in ISO 23903, and in the Reference Model of Open Distributed Processing (RM-ODP) framework ISO/IEC 10746-1; ITU-T X.901. The RM-ODP is a coordinating framework for the standardization of open distributed processing (ODP). RM-ODP uses a five-component analytical model including enterprise, information, computational, engineering and technical viewpoints. The business view extends the RM-ODP. This x-axis is the horizontal base of the GCM in an enterprise architecture framework for the specification of ODP systems. CIMs fits into the business view and to the first parts of RM-ODP, enterprise view and information view. Some CIMs components by exception would fit in some of the computation view. The latter is specifically only for operations on data that are intrinsic to CIMs such as calculation specifications for total scores or the use of formulae or constraints on data, amongst others.

c) System development

Model Driven Architecture (MDA) provides an open, vendor-neutral approach to business and technology change. MDA separates business and application logic from underlying platform technology[53]. MDA is part of the solution that creates an integrated healthcare IT landscape which allows data use and reuse, bridges gaps between systems and facilitates aggregation from clinical data. MDA is dependent upon standards, traceability and on the relationships between components[49][52]. In MDA, CIMs are important as they provide this consistency, traceability, and reusability across domains. That is not only between clinical domains, e.g. between general practice and surgery, but also between the clinical care domain and the aggregate domains of, e.g. epidemiology and/or quality assurance. This is depicted in the z-axis of Figure 2, illustrating the various System Domains.

Full traceability of CIMs and data allows the identification of which processes and systems are affected when information definitions change. In MDA, a relation from the whole to the CIMs suffices. There

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is no need for duplication and thus no inconsistencies should occur. CIMs address the conceptual and the internal logical level and express links to the larger logical model such as Reference (Information) Models (RIM), illustrating relationships between data elements and constraints. CIMs do not address the physical implementation level. However, in an EHR system or in a HL7® message, there can be a reference to a particular CIM stored in a repository for full description.

4.4.4 The Interoperability and Integration Reference Architecture in ISO 23903

The GCM as explained above has been further developed into ISO 23903. ISO 23903 defines a system-oriented, ontology-based, policy-driven, sustainable model and framework for managing systems integration and advanced interoperability across multiple domains. It enables the analysis and design of multi-domain systems, but also systems integration. It does this by use case specific deployment of existing standards and/or artefacts from different domains, i.e. selection, placement, constraining of the ICT components and their relationships. Contrary to traditional enterprise architectures, ISO 23903 provides a way to easily reconcile different knowledge domains without requiring the alteration of their inherent structures and semantics to fit each other, as well as the ICT domain. This implies the reconciliation of perspectives and requirements of the domains' stakeholders without bothering them with technology. ISO 23903 plays the same role for domain knowledge-based interoperability as the HL7® Communication Standard[34] does it for data and information level interoperability. The ISO/IEC 21838 series supports knowledge representation and management across networks of information systems.

Figure 2 shows the placement of CIMs in the Reference Architecture in ISO 23903 in relation to other architectural approaches and information models. The CIMs are part of the business view, part of the enterprise view and part the information view. This model enables integration of the different standards, specifications and artifacts into a coherent and implementable Reference Architecture.

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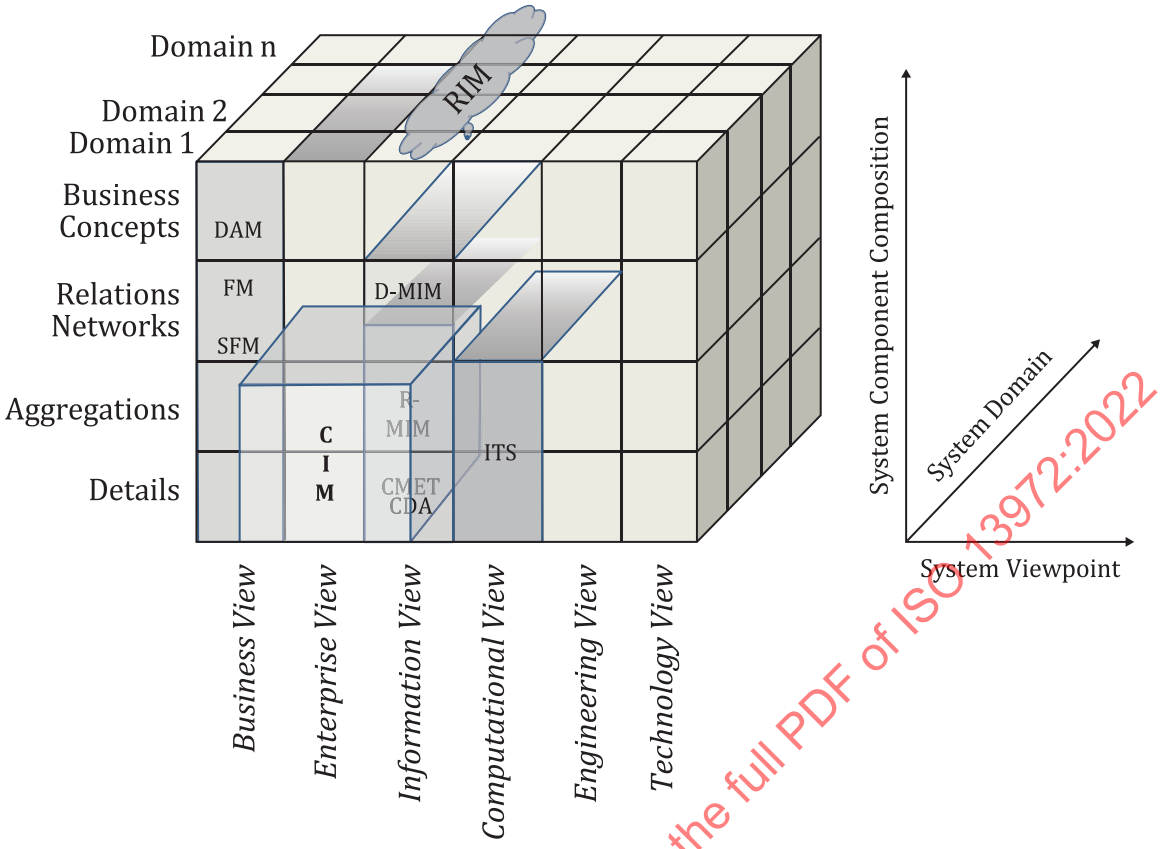

Key

DAM: Domain Analysis Model
FM: Functional Model
SFM: Specialized Functional Model
RIM: Reference Information Model
D-MIM: Domain Message Information Model
CEMT: Common Message Element Type
CDA: Clinical Document Architecture
ITS: Information Technology Specification

Figure 2 — Placement of CIMs in the Interoperability and integration reference architecture in ISO 23903 in relation to other architectural approaches and information models

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Figure 3 illustrates the placement of ISO 13940, ISO 13606-2 archetypes and HL7® FHIR® in the Interoperability and Integration Reference Architecture in ISO 23903 in relation to other architectural approaches and information models. This schema enables integration of the different standards, specifications, and artifacts. This also illustrates the distinctions between for instance CIMs, archetypes and FHIR® specifications. In addition, design models at the physical level will ensure that the instantiation of logical information models respect the CIM defined constraints. This normally is the final step for CIM use in specific systems or products, in Figure 2, it is identified as the engineering view and technology view.

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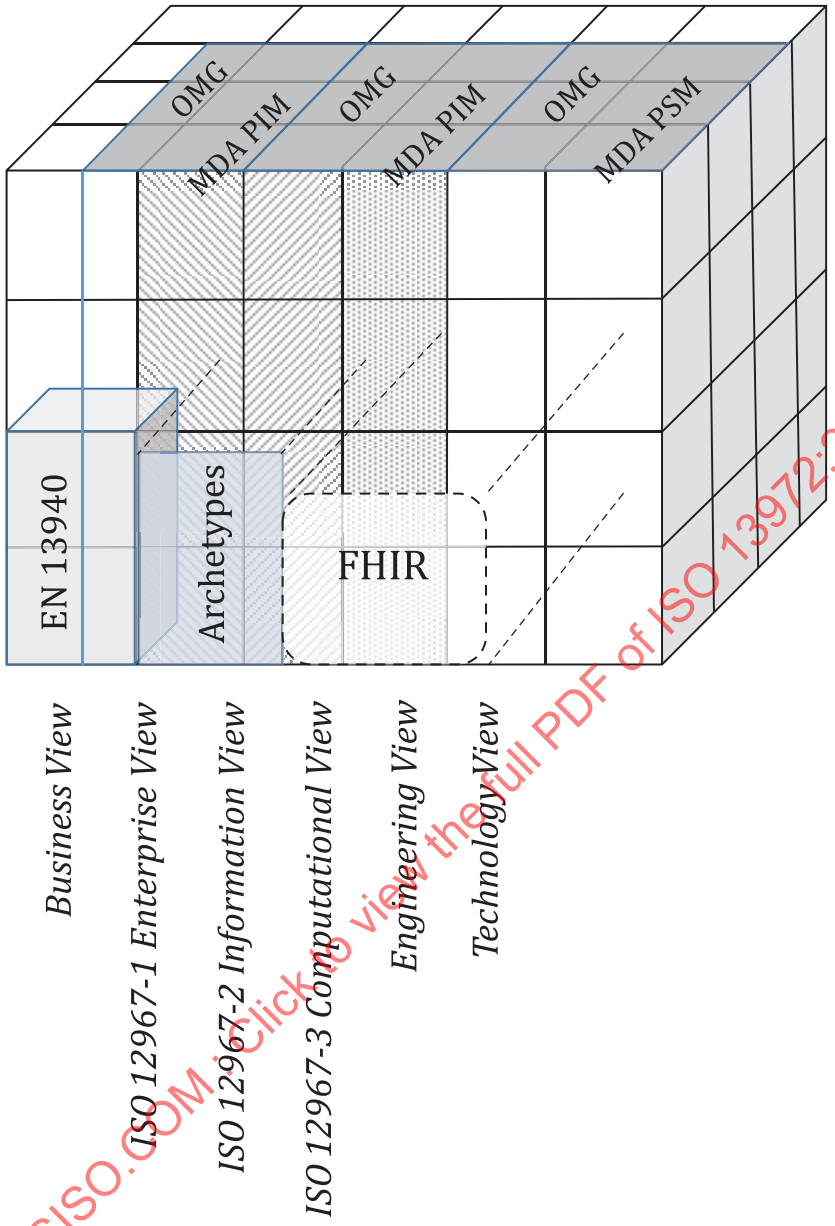

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Key

OMG: Object Management Group
FHIR: Fast Healthcare Interoperability Resources
MDA: Model Driven Architecture
PIM: Platform Independent Model
PSM: Platform Specific Model

Figure 3 — Placement of other modeling approaches as ISO 13940, the ISO 12967 series, the ISO 13606 series and HL7® FHIR® in the Interoperability and integration reference architecture in ISO 23903

4.4.5 Representation of ReEIF through the ISO Interoperability and Integration Reference Architecture Framework

This subclause explores how ISO 23903 can assist the eHealth Framework to meet business requirements. To prevent confusion between the business requirements essentials of the Refined eHealth European Interoperability Framework (ReEIF)[44] and Interoperability and Systems Interoperability Reference Architecture in ISO 23903, an illustration is presented in Figure 4.

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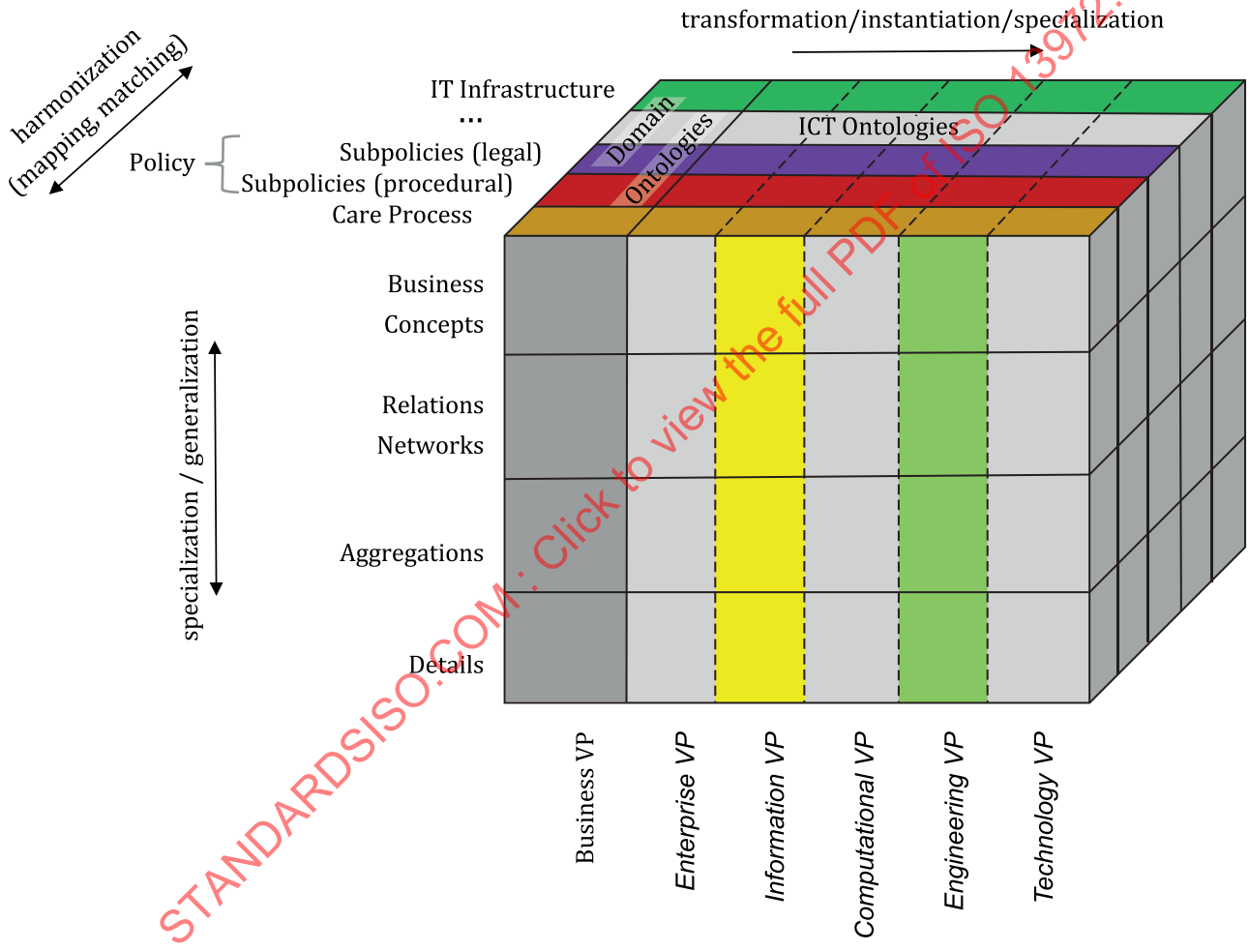
To illustrate how the ReEIF can use architectural approaches, its five layers are plotted in the Cube of the Interoperability and the Integration Reference Architecture Model in ISO 23903 (see Figure 4). The policies are in the domain space on top of the cube (red and purple). This is double coloured because several parts of the ReEIF are sub policies, including collaboration agreement, for example. Privacy and security form a separate domain and are partly bound to the legal domain and also part of another (sub)domain ontology for information security measures. Hence, there are many other domains contributing to one layer in the ReEIF. The care processes (orange) are another layer in the domain space, bridging several of the slices of the RM-ODP. The information layer of ReEIF (yellow) can best be represented in the Information Viewpoint in RM-ODP. The application layer of ReEIF (light green) goes in the Engineering Viewpoint. Finally, the IT infrastructure, again crosses many domains, and is placed on top of the cube as a full separate domain. Transformations between slices or layers shall not lead to simplifications. The intention of placing it on the right slice is to prevent oversimplification and to allow that the inevitable transformations between, e.g. requirements, standards and artifacts take place at the right level in each of the three axes of the cube.



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Key

IT: Information Technology

ICT: Information and Communication Technology

Figure 4 — Representation of the Refined eHealth European Interoperability Framework EIF (see Figure 1) through the Interoperability and Integration Reference Architecture Framework in ISO 23903 (see Figure 2)

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5 Quality Management System for Clinical Information Models

5.1 General

Clause 5 explains several requirements around the creation, use and governance of CIMs in healthcare, clinical and care environments. It describes general processes, including lifecycle management of CIMs, following flexible good practices for a Quality Management System (QMS).

5.2 CIMs quality management system

Clinical Information Models typically undergo a lifecycle via a CIMs quality management system. Figure 5. explains how this CIMs quality management system appears.

From the information perspective, CIMs shall be based on requirements from various stakeholders in healthcare, clinical situations and care. The focus is on the non-ICT perspective to properly represent the health, clinical and care world, and their ontologies.

Requirements for CIMs should be based on systematic analysis of processes, user needs, scientific literature, evidence-based guidelines and many more.

Stakeholders should participate in the CIMs lifecycle to ascertain that their requirements are met.

CIMs should be developed in a developmental process, based on simple principles useful to guide modelling practice. These principles can include the following: Understandable, Repeatable, Usable, Adequate, Accurate, Current, Consistent and Evidence-based.

The CIMs developmental processes yield the artefacts that ultimately satisfy the stakeholders requirements.

Various stakeholders, should accept, adopt and use CIMs. It is anticipated that CIMs are used in electronic patient records, electronic health records, in health apps and devices, in health data exchange systems, in data warehouses, in datamarts, in national registries and many more.

Use of CIMs should lead to evaluation, review, change requests and other maintenance efforts.

CIMs should undergo a governance process in order to keep them adjusted to the requirements of various stakeholders, which will undergo changes in time, and which leads to a continuous process of acceptance by stakeholders, including health professionals and patients.

Data in health information systems and/or information exchange that are based on CIMs – so called instance data – should require an information governance process. However, this information governance process is not part of this document.

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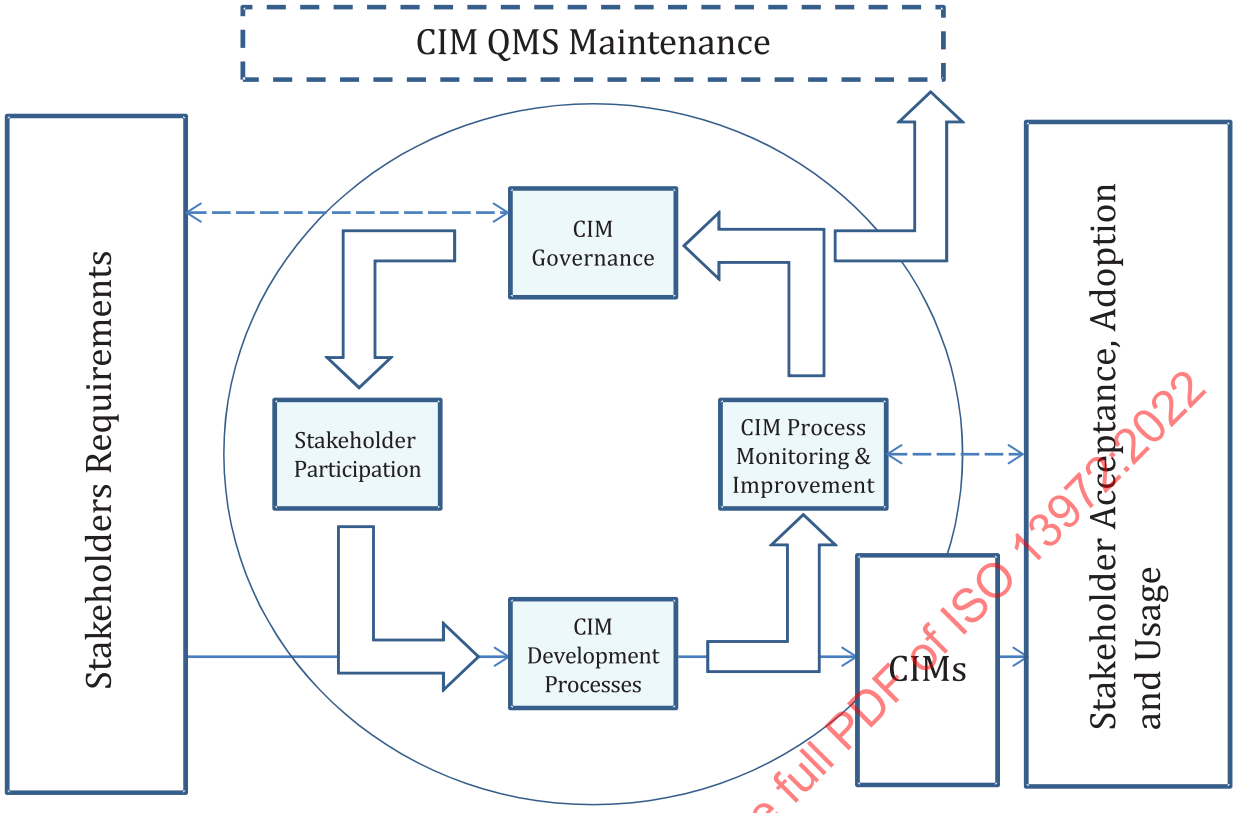

Key
QMS: Quality Management System
CIM: Clinical Information Model

Figure 5 — The Clinical Information Model Quality Management System

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5.3 CIMs Requirements

CIMs development typically starts with identifying the goal, scope and concrete objectives and follows with the identification of stakeholder requirements. Approaches often used include mind mapping of the domain that needs to be modelled or the preparation of a use case specification for one or more purposes.

A domain is deliberately defined vaguely. It could be any healthcare, clinical, or care related area, medical discipline, health care setting, cooperation between professionals, continuity of care, secondary use of data, and so on. A domain could be broad, or small, depending on the scope, goal, use case and budget. Examples include the domains of acute hospital admission, stroke care, perinatology, diabetes care, continuity of care from hospital to home, first line ambulant psychiatric care, insurance of products for specific handicaps, health/ welfare services in the community, using health apps, weaning from a ventilator, development of a nursing record system, application of a monitor for vital signs, content for a personal health record, exchanging data from an Electronic Health Record (EHR) System to a patients Personal Health Record System.

A domain usually requires input from different perspectives such as healthcare at large, specific clinical areas, managerial, scientific, quality improvement, logical, financial, and technical. Given the focus of CIMs on the healthcare, clinical or care data, it is obvious that health care professionals and providers are the main stakeholders, however patients and patient organizations are the customer and their needs and requirements should also be met. This is clearly indicated because patients have become a true stakeholder in their care.

Clinical Information Models shall differentiate between the structure of the data elements and the policy of how and what must be collected/used in a specified practice setting on an implementation or

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computable level, allowing constraints to local settings, or differences between domains or different use cases.

5.4 CIMs acceptance, adoption and use

To ascertain reliability and safety around the acceptance, adoption and use of CIMs, some formal procedure shall be applied in which CIMs can be reviewed, quality tested and endorsed.

Endorsement should preferably be obtained from one to many professional organizations and/or stakeholders.

CIMs shall be expressed such that their use and re-use for multiple purposes is facilitated.

CIMs shall be implementable in EHR, electronic messages and other health information technology systems, however, that requires another model to facilitate the implementation, e.g. HL7® FHIR®, HL7® V3, or ISO 13606-3 archetypes.

CIMs should not specifically address any technical standard or implementation but facilitate various technologies to be deployed.

5.5 Achieving quality CIMs

The business context shall be the base for the modelling of CIMs. CIMs should represent the core of health care information from the care process, which is used for continuity of care, and reused for other purposes such as quality registration, transfer of patients, or patient-related research and public health reporting.

An organization developing CIMs shall have established, documented, implemented, and maintained a Quality Management system for CIMs development, use and governance (QMS-CIM) in accordance with the requirements of this document.

Where an organization has outsourced CIMs development, the organization shall exercise sufficient control over such processes such that conformance to this document can be ensured.

An organization's QMS-CIM shall include documentation regarding its quality policy and quality objectives and governance process.

An organization's QMS-CIM shall maintain a CIMs quality manual and procedures, including modelling guidance, CIMs versioning, and document control management.

Each Clinical Information Model should be subjected to some (risk) assessment mechanism to ensure it is fit-for purpose and meets information (safety) requirements. This can be supported using ISO/TS 18864.

NOTE It can be difficult to consider the risk associated with a CIM without considering the implementation and deployments contexts in which the CIM will be used. Therefore, the risk assessment could be undertaken within the context of expected use.

CIMs and perhaps also CIM collections should facilitate architectural and model flexibility and scalability.

Localizing a CIM for flexibility, scalability or other adaptation shall be achieved without compromising or contradicting its semantics. In other words, it shall not deviate from its intended meaning.

The CIMs governing organization should have appropriate mechanisms in place by which quality CIMs can be extended and maintained to fully support the requirements of the health care community.

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5.6 Governance of CIMs

The management framework, which governs CIMs development and maintenance decision-making practices, shall address the direction and control for the development and maintenance of CIMs. The framework for CIMs governance shall comprise of the following three critical components:

a) Structure of a governance committee (examples include a program board, a technical committee, a content committee).

b) Membership and accountability (expertise required to populate the structure, roles, and responsibilities of each membership category) of the governance committee.

c) Processes (i.e. the decision-making processes, decision rules that govern the decision processes, disagreement/conflict resolution, processes ensuring separation of project management from decision making).

It is assumed that that these principles are kept when governance moves from a project to a continuous maintenance organization, albeit adjusted to the change in organization.

5.7 Repositories of CIMs

A repository is a place in which CIMs can be stored, quality tested, maintained, presented, and distributed. It is important for the governance of the CIMs that verification, publication, maintenance and the distribution environment shall be identified and established in order to facilitate the health care community's ability to create, use and share the Clinical Information Models.

A repository for CIMs can be constructed in such a manner that its knowledge base, data elements, relationships, keywords, and meta-data can be searched.

A CIMs governing organization shall facilitate stakeholders, including patients, health professionals, researchers, project leaders, technicians and other target groups in finding the appropriate Clinical Information Models via multimodal approaches, such as keywords, versions, categories, and metadata.

A CIMs developing and or maintaining organization shall provide the versioning control mechanism.

A CIMs developing and/or maintaining organization shall support changing status of CIMs versions.

Clinical Information Model repositories shall provide different certification levels to the CIMs to indicate the levels of review and approval CIMs have received (e.g. under development, in testing phase, or tested and approved for use).

CIMs repositories should ideally provide a notification mechanism to notify/alert users, e.g. alert users with changes to the existing models, notify users with new models. Annual releases with clear version indicators prove to be a proper mechanism.

5.8 CIMs Development Processes

Data exchange using technical representation(s) of CIMs carries specific hazards concerning data loss, unauthorized access, and data corruption. Therefore, the definition and implementation of CIMs should be subject to rigorous multidisciplinary safety risk management, privacy risk management and security risk management covering healthcare, clinical, modelling, terminological and technical aspects.

A formal hazard analysis and mitigation for data exchange should be undertaken as part of a systematic and comprehensive hazard analysis of CIMs content and structure and CIMs transformations.

In CIMs creation there should be a balance between the maximal data set (how much to include), simplicity (not too much to include) and flexibility (allowing selection of subsets from the maximum data set). This is an intricate process in which users of the CIMs need determine what data set fits their purposes. The data set can be determined to meet all use cases for the CIM, or the use case that requires the most data elements. In the latter situation, it is best to have the extensive set optional so that not every user has to implement the complete set. Maximal data set means as big as possible while being

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realistically manageable. Most CIMs will never be finished and continue to move towards the maximum data set so that more users can benefit from it.

There is always an option to create separate CIMs for specific use cases or domains, to stay safe and keep the CIMs precise. There is a risk that the "standardization" with the CIM diverges if any party can create their own extensions to a CIM. Then two parties can come up with similar concepts, assigning different codes and hence, creating inconsistency. So, if extensions on a CIM are required, for example to add highly specialized data elements to a basic CIM, this shall be done in a controlled process. One example can explain this. For pregnancy, many professionals only need to know if a woman is pregnant, for how long and perhaps if it is the first pregnancy. This can be a simple CIM. However, for the midwife and obstetrician, many additional data elements on a pregnancy are needed to deliver quality maternal care. The basic elements should remain consistent and the additions shall be placed into the CIM in a controlled manner to avoid inconsistencies, duplicates, and errors. So, it is possible that different clinical communities have different needs, but instead of creating many variations of the same CIM, one consistent CIM that includes all details is the preferred option. This should be done via allowing different parties to only use the data elements in the CIM that are required for their use case rather than all of them.

Hence, CIMs shall express the concept within a manageable and relevant set of content and data elements that safely define its purpose with the potential for multiple usages in various domains.

As with many consensus-based processes, there is the potential for stakeholders themselves to impede or obstruct the realization of CIMs, simply due to differences in their interests. Hence, a well-functioning quality management process and governance for CIMs requires establishment of a strong governance framework (see 5.6) and well-controlled development process (see 5.8) that includes transparent decision-making.

Annex A presents an example on how the Netherlands has established a strong development and governance framework for CIMs. It is reproduced with permission from Reference [54].

6 Clinical Information Model content, structure and requirements

6.1 Clinical Information Model content and context

Clinical Information Models organize the structural modelling content of healthcare, clinical and other relevant information for the purpose of quality documentation with a focus on continuity of care and semantic interoperability. A careful development which does not allow ambiguity is more important than giving care professionals maximum freedom to express the smallest nuance. A CIM needs to be relevant for the patient, health professional, and healthcare organizations. Likewise, CIMs need to be useful for electronic health record systems and personal health record systems. CIMs further should facilitate electronic data communication and should be suitable for supporting the reuse of health care data for multiple purposes.

There are constraints to which level or what kind of models this document applies. Workflow is not included. However, some dynamic modelling can be part of a CIM, for instance where a repetition in time is required, for example when measuring the Apgar score at 1 min, 5 min, and 10 min. Complex models are not included. This document acknowledges that constructs or compositions based on multiple Clinical Information Models are relevant but how to combine and compose is not specified here. The model's requirements are based on best practices in the communities of Health Level 7, OpenEHR, the ISO 13606 series, Clinical Information Modelling Initiative (CIMI) and Nictiz/ NFU HCIM work since 2011.

It is important that the concept of the CIM be placed in the context of its clinical use. This can be twofold: firstly, the generic use case for the CIM can be defined and secondly through the relationship of the CIM to other clinical concepts. Since each Clinical Information Model specifies one coherent and precise concept or set of related concepts, describing the overall picture can be important for a proper understanding. Context includes patient category. For example, the clinical concept of body position can be related to the concept of blood pressure measurement, which again can be related to the concept of

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vital signs. Mind mapping has been identified as a valid method for domain and concept analysis and identifying such relationships. DAMs can serve as the reservoir of clinical concepts from where CIMs can be derived. Another context is the different formats for reuse of concepts, for instance a quality indicator, or a whole set of quality indicators can be the context.

CIMs are created purposefully. However, there can be situations in which CIMs are used in a context other than the original context. On many occasions, that additional use can be possible and can add value to the CIMs. However, there can be situations where it could be dangerous for patients. If such situations are known, a statement with respect to misuse should be added to the CIMs.

— The Clinical Information Model in question can be placed in context of use in clinical domains and in the context of other related CIMs or models within the specification of their relationships.

— The use of the Clinical Information Model in contexts other than the original clinical purpose shall be made explicit.

Use of a CIM in a non-approved (or non-intended) context should be made explicit including safety risks to patients. CIM content must adhere to several criteria as described in the following sections.

6.2 Concept specification of a Clinical Information Model

A CIM starts with explaining what the concept is about and what the clinical relevance of the concept is. The intent of a CIM shall be clear and the topic understandable to all its users. Defining clinical concepts can be complex when addressing abstract concepts and systems of interrelated concepts. A proper concept analysis, clarification, and definition can be necessary in some cases.

— The topic or subject of the Clinical Information Model in question shall be expressed on the level of the clinical concept and a clinical concept definition or description.

6.3 Purpose of the Concept

Clinical Information Models usually describe clinical concepts such as observations, problems, interventions or actions, assessment scales, instruments, questions, to allow the health care professional to document desired information about the patient and his/her care in an EHR, and to exchange this with the patient and the care team. It shall be clear in the CIM why these data are relevant for clinical practice and what health care professionals try to achieve. Often there is a reference to (local, nationwide, or international) guidelines, laws or good practices.

— The Clinical Information Model shall describe the purpose of the concept in clinical practice.

— The Clinical Information Model shall describe why the concept is used in quality healthcare delivery.

6.4 Patient Population for which the Clinical Information Model is intended

Some concepts pertain to a specific patient category, e.g. adults, children, elderly. It can be important to explain this since using a concept for patients it is not intended for can lead to misuse. On the other hand, several concepts can apply to all patients. In that case, it is also important to know that there are no restrictions.

— The patient category shall be specified in a CIM.

6.5 Evidence Base for the Clinical Information Model topic

Scientific or legal support for the concept modelled in the CIM is important. In order to obtain content specification of the highest quality, the CIM specifies the evidence base or scientific or legal support for the clinical concept described. The description of the (scientific) support can be based on assessment criteria such as used by the Cochrane Collaboration[55]. Cochrane tools such as AGREE (Appraisal of Guidelines for Research and Evaluation) are particularly useful to determine the relevance and quality of clinical concepts that can be expressed in Clinical Information Models. Of interest are the

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criteria for successful and effective usage of the concept in clinical practice and potential other uses. Legal obligations can also be a proper evidence for a CIM. In several CIMs there will not be evidence as suggested above, however, there could be other sources such as best practice, consensus, or simply common sense[56]. It is important to include statements about the source for the CIM content.

For example

The Clinical Information Model provides a short description of the kind of research carried out for a particular assessment scale, including a justification as to why the scale is valid and reliable for certain patient populations.

Careful consideration should be given to what is / is not included in the CIM. Criteria include conciseness, generality, contextuality and tenability to avoid constant amendments with each new development in healthcare.

— A Clinical Information Model should describe or refer to the evidence base for the concept, e.g. published knowledge, and/or clinical experience of the clinical concept where it has informed the development of the CIM.

— If the full evidence base itself is publicly available on a sustainable online website, or a current textbook, a link to that website should be used as substitute for a summary of the evidence.

6.6 Description of the information model and its data elements in CIMs

6.6.1 General requirements for the information model

6.6.1.1 The core of CIMs is the explicit and structured listing of one or more data elements that represent the clinical concept. CIMs should express the clinical content and data elements in a conceptual and logical manner such that they become useful in various Health Information Technologies. The information model maps the concepts from the CIMs clinical content to data elements, their attributes, and their relationships.

The information model represents the domain usually as a hierarchy, or tree, of concepts and/or nested concepts connected via relationships. The leaves of the tree are the “atomic” concepts or data elements, while the root of the tree will normally be the concept that is the focus of the Clinical Information Model. Figure 6 illustrates this with a root concept and different data elements.

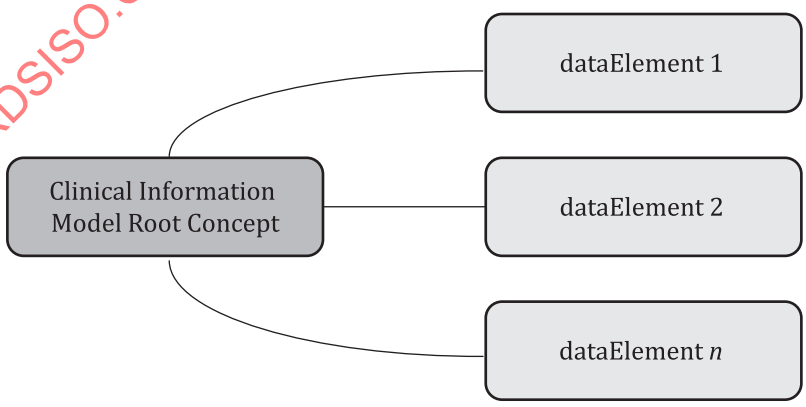

Figure 6 — Clinical Information Model representing a root concept and underlying data elements in a tree structure

6.6.1.2 CIMs documentation shall contain one or more information models specified in a formal methodology.

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6.6.1.3 The CIM's data element specification should be consistent with the order, composition, arrangement, scores, and/or name giving used in guidelines or scientific literature.

6.6.1.4 If necessary, scientific or professional organizations can be asked to give a definitive answer to questions as what the national standard or guideline needs to be used.

6.6.1.5 CIMs shall include the metadata, concepts involved, data elements, (mandatory) attributes, constraints, and relationships between concepts.

6.6.1.6 The relationships between data elements and their occurrence shall be identified within the composition represented in a conceptual information model from which a logical model can be derived.

6.6.1.7 The CIM shall list all concepts and data elements represented in the information model. Conversely, the concept list shall not contain concepts or data elements not represented in the information model.

6.6.1.8 Concepts can be "kinds of" other concepts, which means that these are considered a more specific occurrence of another more general concept. Using this relationship between two concepts, the definition of a more specific concept can be based on the specification of the more generic concept.

6.6.1.9 The CIM may include another CIM or a data element from another CIM through nesting. Such inclusion should be specified through a data element that refers to an existing CIM.

6.6.1.10 The description of the information model shall contain enough detail for a CIM implementation to be interchangeable and unambiguously interpretable within the EHR.

A possible modelling approach to Clinical Information Model is described in Annex C.

In some cases, there is a difference in versions of CIMs that are translated into other languages. Careful consideration shall be given as to whether there are potential consequences for semantic interoperability. If this is the case, the different versions should be specified in separate Clinical Information Models.

For example, the Dutch and English versions of the Barthel index have local variations such as different naming of the data elements, different scores per answer category and hence a significant different total score, and a different interpretation of what score is normal and what score is an abnormal, care is required in this situation. See 6.8.

6.6.2 Data elements

6.6.2.1 Data element, data, variable, clinical elements are considered synonyms in a CIM; "data element" will be used here.

The CIM information model represents concepts either as data elements or as terms. Data elements will generally be presented using classes or records in communication and storage. On the other hand, terms often become converted to codes from coding systems. This way, the CIM information model separates the clinical concepts cleanly into those present in the information model and those represented using terminology.

Experience shows that for a given concept "one to many" data elements are specified. The scope of a single Clinical Information Model is intended to be an optimal data set and specifying the data set allows flexible albeit standardized implementations. Allowing a selection of relevant data elements only, can enhance the broader use of the same standard. The next sections delineate each possible characteristic of a CIM data element (see Figure 7).

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6.6.2.2 A CIM shall be composed of one or more data elements which together represent the clinical concept.

6.6.2.3 Each concept should be split up into simpler concepts until a concept is "atomic" and there is no need to consider and represent its properties as attributes. Based on experience, this lowest representation level is the data element, including its characteristics.

6.6.2.4 A CIM shall represent concepts from the clinical content sections as data elements and assign unique names.

6.6.2.5 One of the concepts present in the information model shall represent the main subject or focal concept of the CIM. This should be called a "root concept".

6.6.2.6 A specified data element in a CIM shall consist of name, definition, datatype, terminology binding and unique coding.

6.6.2.7 CIMs shall reveal default values, value sets, reference values, observations in scores, nesting of subscales or items and flavours of null, cardinality and optionality when they are part of the concepts and their application in practice.

6.6.2.8 If a CIM expresses an assessment scale, score, index, or other scientifically developed instrument for which a total score is calculated, the total score itself shall be added as a separate data element with appropriate coding and datatype specification.

6.6.2.9 If a CIM expresses the outcome of a calculation, the outcome shall be added to the CIM as a separate data element.

6.6.2.10 The applied calculations, algorithms or heuristics shall be fully expressed in the Clinical Information Model, either expressed in the meta-data or appropriately referenced such that a user is able to confirm instantaneous verification.

6.6.2.11 Relationships between data elements in a CIM shall be expressed.

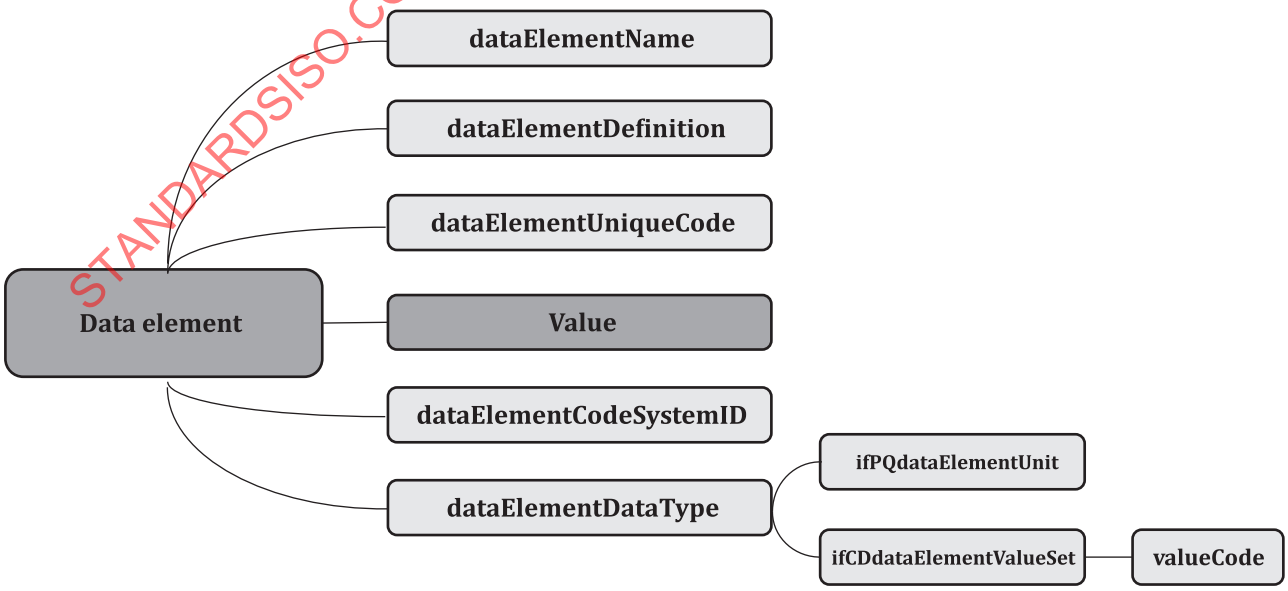

Figure 7 — A data element representing one atomic concept as single data element with its atomic attributes that specify the characteristics required for its use in information systems

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For example, Figure 8 illustrates the details of the CIM for an Apgar Score[57] in a logical model using UML. For an example of a Table format of a CIM, refer to Annex F.

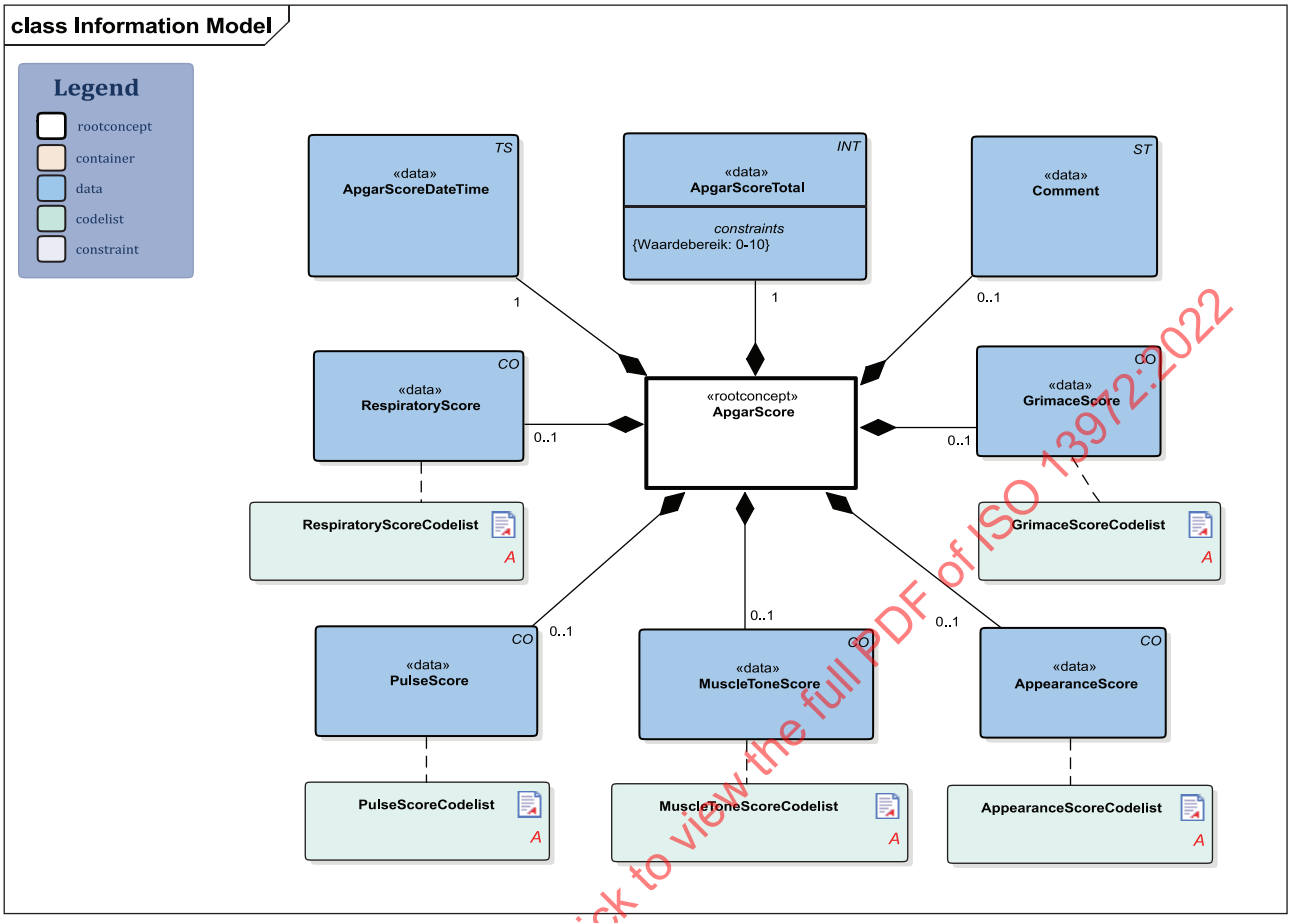

Figure 8 — Logical Model of the Apgar Score illustrating data elements as classes and references to value sets

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6.6.3 Data Element Name and Identifier

6.6.3.1 To document care consistently, the data elements shall be recognizable by health professionals, patients, and other users, via logical and sensible terms, but for the use of data for computation these shall have unique identifiers.

6.6.3.2 Each data element in a CIM shall have a unique name for identification purposes. This unique name can be based on the combination of two or more terms. For example, “observable value” and “related value” can refer to the same base concept but a distinct data element.

6.6.3.3 Each data element should be capable of being mapped to additional terms which offer an equivalent meaning to its name (synonym, alternative name).

6.6.3.4 Each data element in a CIM shall have a unique identifier to allow technical applications to operate with it. Although the naming of data elements in the Clinical Information Model is unique, it is possible for similar names in different CIMs to exist. The identifier differentiates the multiple data elements which could have the same/ a similar name.

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6.6.4 Data Element descriptions

6.6.4.1 The description or definition of each data element clarifies its meaning.

6.6.4.2 The CIMs shall include definitions or descriptions that specify the meaning of each data element.

6.6.5 Semantic coding of data elements

6.6.5.1 To ensure lifelong data storage in records, semantic interoperability and data reuse, each data element's meaning shall be defined through the application of clinical vocabularies, terminologies or classifications that uniquely code the terms used and concepts represented. Unique coding is particularly important in large data sets, complex EHR systems, messaging, and the reuse of data for decision support, querying, quality indicators, epidemiological data and so on.

Normally, the Object Identifier (OID), or equivalent solutions as persistent URLs/URIs, identifies the vocabularies or terminologies applied in a CIM. An alternative method is to use 'display text' to describe the vocabulary. The vocabulary, classification, or terminology specifies the specific unique code for the data element and uses the display text to describe the data element.

A data element can be assigned multiple synonyms as there is no preference for a specific clinical vocabulary or terminology. An important issue is that precise codes shall be selected, not some related concepts that would create imprecision. This particularly pertains to clinical data elements but can be less necessary for time stamps or person identifiers that apply other formats. Since vocabularies constantly evolve to meet changing needs, it can be possible that there is no current code available in a chosen vocabulary for some data elements and therefore a process to request codes for missing concepts will be required. If no code is available in standardized terminologies, it is possible to create a local terminology with unique codes. Sometimes a distinction is made between an interface terminology and a reference terminology. CIMs accept any kind of controlled terminology, but national or local choices can be made.

6.6.5.2 To ensure correct interpretation, the meaning of the concepts / data elements used in the CIM shall be defined.

6.6.5.3 Every data element in the CIM carrying semantic meaning shall be labelled using terminologies.

6.6.5.4 Each data element in a CIM shall have a minimum of one unique code assigned from one or multiple coding systems from a recognized or locally defined vocabulary, terminology, or classification system.

6.6.5.5 Coding of data elements in the CIM shall be unambiguously expressed.

6.6.5.6 Each data element can have equivalent codes from alternative coding systems assigned as synonyms.

6.6.5.7 Each coded data element shall have an associated description which clearly identifies the terminological or classification system by name and/or the identity and version.

6.6.5.8 Each unique code and description for each data element should be derived from a formal standardized terminology.

6.6.5.9 Coding of different data elements in one CIM may be taken from different terminologies, if the terminologies are properly identified with both name and identity to prevent confusion.

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6.6.5.10 The CIM information model shall express clearly which data elements and concept specifications are handled in the information model space and what is handled in the terminology model space in those cases where ambiguity exists.

6.6.6 Datatype

6.6.6.1 Different data formats are used in clinical care such as text, numbers, pictures, graphs, date and times, true-false statements, enumerations of lists of observations (concept descriptors) and sets of predetermined answers to questions. Health Information Technology has learned how to properly process such formats. Different standards developing organizations have created lists of datatypes which have been harmonized into ISO 21090. This is recommended for CIMs, although any equivalent system would be acceptable.

Experience has shown that despite the numerous variations in datatypes, only a limited set is frequently used in the majority of CIMs.

6.6.6.2 The datatype for each data element shall be unambiguously expressed from a fixed set.

6.6.6.3 The formalism to express a CIM shall allow the use of the minimum of the datatypes expressed in Table 1.

6.6.6.4 The datatypes should be consistent with ISO 21090 or an equivalent datatype specification.

Table 1 — Minimum set of datatypes for CIMs

Code	Name	Description	Type
ANY	Any datatype	Data representing any datatype.	
CD	Concept Descriptor	Data representing a uniquely coded concept from a terminology defining a precise meaning.	Complex
CO	Coded Ordinal	Data representing coded ordinal concepts, representing both a meaning and a numeric value for calculations.	Complex
PQ	Physical Quantity	Data representing quantities with both a scalar value and unit, including ratio data.	Complex
INT	Integer	Data representing numerical values of type integer, that is without decimals.	Primitive
ST	String	Data representing text.	Primitive
BL	Boolean	Data representing Boolean values representing true or false.	Primitive
TS	Time Stamp	Data representing a moment in time.	Primitive
II	Instance Identifier	Data elements that uniquely identify a thing or an object. (including OID, URI and URL).	Complex
ED	Encapsulated Data	Data representing sampled data, images, sound and multimedia.	Complex

6.6.6.5 The formalism may support other simple types, provided they are specializations of the types listed above.

6.6.6.6 A CIM may include datatypes representing an interval of time, an interval of a quantity and/or an interval of a numerical value.

Annex E presents a specific Datatype profile for the logical model part of a CIM.

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6.6.7 Value

6.6.7.1 A data element always has a value. Data elements can have common or different characteristics. An example of a common characteristic is that it can be carried out at a particular date, time and location.

For example

If the patient is observed, questioned, or measured, it normally results in a value which must be documented, resulting in the actual patient instance data.

In several examples of clinical knowledge particularly for measures, clinical observations, diagnosis and assessment scales, the result of clinical work reveals a specific rate, assessment score or descriptor. In some examples, the value can be derived from a predefined list of options; this kind of representation is called a value set. From a value set, one or more values can be selected, representing what the clinician finds appropriate to document. For an intervention planned or carried out, the data can simply be a statement of its clinical status 'done' or 'not done'.

6.6.7.2 A description of the value shall be part of the CIM specification.

6.6.7.3 Where applicable, for values with Concept Descriptor (CD) or Coded Ordinal (CO) according to ISO 21090, the data element shall specify the value set and its unique identifier (Persistent URI/URL or OID) or equivalent specification.

6.6.7.4 For data elements representing a quantity, the value shall specify the unit expressed in Unified Code for Units of Measure (UCUM)[59] or equivalent standard units of measurement.

Example data element value: An example value should be added to each data element expression. For instance, if the data element is body temperature, the example value can be 37 °C.

6.6.7.5 A data element can have a minimum of one example of the value described.

6.6.7.6 A CIM shall indicate how many times the data element shall be present in an instance via the cardinality.

6.6.7.7 The CIM shall specify whether a data element is optional (allowed to not be present in an instance) or required (should be present in each instance if the data is available).

6.6.7.8 The CIM should specify an upper boundary to the number of occurrences, which may be "unlimited".

6.6.7.9 If the CIM does not specify upper boundaries to occurrences, this implies that the data element can occur once at most.

6.6.7.10 The CIM shall specify whether the data element can contain no data.

6.6.7.11 If a data element is required and data is not available, the CIM should express a requirement for the data element to indicate the reason why it contains no data.

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6.6.8 Value set expression

6.6.8.1 A value set can be described as a micro vocabulary of allowed answers to questions or a limited subset of observation findings; most often these are Concept Descriptors (CD) or Coded Ordinals (CO).

A Concept Domain expresses the options within a value set that needs to be encoded but is not tied to a specific terminology; this coding within a value set is known as value domain coding. Alternatives are to create subsets of values from existing coding systems, such as from SNOMED CT®[3)][60] and LOINC®[4)][61], Further, examples are known where specific clinical instruments have been precisely coded within a controlled terminology.

6.6.8.2 A value set is a micro vocabulary and shall have a name and a separate identification (Persistent URL, URI or OID).

6.6.8.3 All clinical terms in value sets shall be associated with at least one code from any (specified) coding system.

6.6.8.4 For data elements in CIMs that have the CD (Concept Descriptor), or CO (Coded Ordinal) datatype, each enumerated value in the value set shall be uniquely coded. A reference to an external value set is acceptable.

6.6.8.5 The CIM shall be able to associate one or more codes from any coding system to any term specified in a value set for a data element.

6.6.8.6 The value set specification for a data element should be based on a standardized terminology such as SNOMED CT ®, LOINC®, IDMP, or similar, or on more local standardized terminologies.

6.6.8.7 Coding of different values within one value set may be taken from different terminologies, if the terminologies are properly identified with both terminological system name and unique identifier (Persistent URI/URL or OID) to prevent confusion.

NOTE In several CIMs, the value set identifies options within the observation findings and adds a specific numeric value; the latter is known as the Coded Ordinal (CO) datatype and is generally used in measurement scales or assessment instruments. This CO allows mathematical operations to be carried out, thereby deriving a total or sum score on an instrument. At the same time, a meaning can be given because the number for each individual score represents an observation in the real world. The meaning of the observation can be added to the CO numeric value in the form of a display text.

See ISO 21090 for more details on datatypes.

6.6.9 Relationships in CIMs

The following relationships will frequently be applied in CIMs.

The formalism used to model CIMs should support the following types of relationships between data elements / classes:

— **Association;**

— **Aggregation;**

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3) SNOMED CT is the registered trademark of the International Health Terminology Standards Development Organization (IHTSDO). This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

4) LOINC is the registered trademark of Regenstrief Institute. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

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— **Composition;**

— **Generalization;**

— **Specialization.**

6.6.10 Localization of CIMs

6.6.10.1 The CIMs describe the optimal representation of the clinical concept and its data elements and associated characteristics. Nevertheless, not everybody will use the CIM in the same manner. Depending on the context of use of a CIM, some or all of its data elements should have default values, or alternatively, need adjustments. Localization is adjusting a CIM to another jurisdiction, for example another country, another clinical domain (for example from general practitioner to mental health), using it for another patient category (from adult to children), or another use (storage in an electronic health record versus electronic data exchange).

6.6.10.2 The CIMs should allow localization through not using some of its data elements or not using some of the associated values in a value set.

6.6.10.3 Not using some data elements shall only be possible for CIMs content which does not affect proper clinical practice.

6.7 Example instances

Clinical information modelling is still abstract work, often difficult to understand by stakeholders. It can be seen best practice to add one full expressed example of a CIM. That means that all the parts are represented both via all data elements, and that for each data element a relevant value is added to illustrate the use of the CIM. Typical examples include draft forms, screen mock-ups, user interface designs and more, which are filled with instance data that are example data.

— The Clinical Information Model can be expressed in one or more example formats to illustrate the clinical concept and its use(s).

6.8 Interpretation

In several CIMs, the combination of data elements, for example for an assessment scale, or lab results, can lead to specific interpretations of what is a normal score or value, what is too low, too high, etc. If relevant, this subclause can be used to specify clinical knowledge on normal, low, high scores. Clinical guidelines usually provide the clinical content and knowledge that can be summarized via a short description of how the results of the scale, or the collection of data should be interpreted as well as the resulting consequences for patients and their care.

— A short description of the interpretation of results of scales, indexes, scores can be present in the CIM.

— When interpretation of values of total scores, or similar, is bound to certain limits or boundaries, these can be expressed in this section.

— This section can also be used to explain the consequences of results for patient and care.

— If an interpretation varies per specific target group or patient category, this can be expressed in this section.

— If a clinical decision during care delivery is based directly on a particular score or value, this can be described here.

— If guidance applies for the interpretation of the CIM outcome, score, or results, these should be expressed as point of reference or a reference to an authoritative source should be included.

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— The CIM should describe specific consequences of a result or score for a patient.

For example

A pressure sore risk assessment scale, such as the Braden Scale[62], is often used to calculate the potential for developing pressure ulcers. The sum scores indicate nursing actions to be taken to prevent pressure ulcers in that patient.

There is an increased risk at a score of >8 which increases again after 12, stated as:

<8 no increased risk, 8-12 increased risk and >12 extra increased risk.

Instructions for clinical care:

If a sum score is <8, then actions 1, 2 and 3 are indicated.

If a sum score is between 8 and 12, then actions 3, 4 and 5 are indicated.

If a sum score is >12, then actions 5, 6 and 7 are indicated.

6.9 Constraints or Limitations for use

In some situations, it might be necessary to limit or narrow down the usage possibilities of a CIM. Constraints currently identified are presented in this subclause. A text section in a CIM would normally be enough to outline the limitations or constraints.

— Each CIM should clearly express – when applicable – any identified limitations of use of the model in practice or in systems.

— Constraints in the model or its technical representations shall be clearly expressed.

Specifically, limitations might be necessary for CIM data elements, occurrences, relations, value set, or value set bindings.

— Context-specific constraints on data elements should be clearly expressed.

For example

— A data element in a Clinical Information Model might only be applicable for a male and not for a female or vice versa.

— Constraints on value set expressions and their code bindings should be expressed.

For example,

— The dedicated codes for each of the values in the value set for each of the data elements of the Braden Scale[62] that are created in the Logical Observation Identifiers Names and Codes (LOINC®) code system.

— Constraints on relationships between data elements should be expressed

Types of relationships between data elements can be classed as hierarchical (arranged according to importance), nesting (e.g. a combination of data elements which is a subset of a larger CIM) and use of style patterns (e.g. data elements that are defined in a specific manner). They can be expressed as data element A 'has a' relationship to data element B or an 'is a' relationship.

— Constraints on types of relationships between data elements should be expressed.

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Cardinality specifies the multiplicity or wide range of a relationship. For example, a total score can be derived from underlying data elements; the multiplicity for a total score is 1 total score consisting of '*' (many) sub scores.

— Constraints on cardinality of relationship between data elements should be expressed in the Clinical Information Model.

There can also be a range or minimum/maximum value limit for an Integer value (INT).

— Constraints on values, such as minimum or maximum values should be expressed in the Clinical Information Model.

Some data elements within a CIM require or are the result of a derivation mechanism, such as sum score calculation, use of algorithms, among others.

— The derivation of value limits should be identified to ensure that consistent measures are taken.

— Algorithms used or derivation methods applied on data element values should be clearly expressed to support appropriate interpretation of data.

For example,

— Body Mass Index (BMI) is calculated based on the formula body weight (in kilograms) divided by the square of body length (in meters).

It can be considered best practice to implement only some selections or subsets from the usual core data set in a CIM. This approach allows constraints and/or selections of some data elements of the Clinical Information Model's data set. These constraints are not part of the CIM specifications but can go in additional separate implementation specifications.

For example,

— Only three of the data elements out of a set of 15 may be implemented in a particular EHR and included in a HL7® v3 message. For example, for a report on blood pressure for a national diabetes quality registry, only systolic and diastolic value and the body position sitting would be reported, not the circumstances of the patient and not the time of the day it was measured, not the cuff size etc.

6.10 Instructions for use of CIMs

To obtain correct, safe and meaningful data in the EHR, data communication and use for identified purposes, it is assumed that data based on the Clinical Information Model are recorded in a valid and reliable way. If CIMs are deployed in medical devices, proof of valid and reliable recording of data shall be present to rely upon the output of the device. Of course, for medical devices more reliable methods exist to determine the validity and reliability including calibrations and validation measurements by trusted national organizations and/or biomedical engineering departments.

Such principles of recording semantically valid and reliable information such as observations, administration of assessment scales, carrying out of activities or conducting measurements with devices applies to any type of CIM (see Reference [63]). Provenance prevents unwanted variability in the documentation per data element and the CIMs concepts.

The consequences of clinical findings based on the data elements for patient care should be guidance for a valid and reliable interpretation of the CIMs concepts. It can also be used to derive minimum or maximum values in medical devices, EHRs or messages.

— The Clinical Information Model should contain a reference to identified usage guidelines and/or instructions for appropriate use of the clinical model for various use cases, care processes, or clinical systems, where appropriate.

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— A CIM should express any differences in the variation of results of a score, assessment, or index per patient target population.

6.11 Care process / dependence

Clinical Information Model content can be relevant in specific phases of the care process, assessment, treatment plan or care path. If constraints are placed on the CIMs, these are explained in this subclause.

If necessary, provide a description of the place of the CIMs in the care process including any dependencies of its use and implementation in relation to other activities in the care process as well as criteria, decisions that need to be taken in advance and who needs to do what. This is still use case independent since all patients some way or the other receive care via a care process.

For example, two types of Clinical Information Models can be identified in the care process as depicted in ISO 13940 (Contsys). One type of CIM covers the health-related condition (e.g. observed, evaluated or stated in SNOMEDCT® as the Observable Entity or Clinical Finding Hierarchy) and the other type of CIM is activity related (e.g. contains method description, how and who). One Activity CIM would be to "take the blood pressure" and the Health-related Condition CIM would be the result of the activity of taking the blood pressure, in this case an observation with an actual blood pressure value.

Both CIM types could be used in different steps in a care process, whether generic or specific. The Activity CIM only says what kind of information is needed, information about the indications/contraindications, current condition, goal condition, activities, patient view of the activity is still required.

This can then be applied to specific care processes such as for 'congestive heart failure, adult' where the activities and conditions relevant in this specific case are populated. However, that is use case specific, and will not be part of the CIM.

There should be reference to both the CIMs which provide the structure for the type of information that a health-related condition could contain and the kind of information an activity CIM will contain within the different steps of a care process. This allows the application of different CIMs. Alternative care process representations where CIMs can be placed include care or clinical pathways and patient journeys.

— CIMs should be developed independent of any use case, specific care process, context, or clinical system when possible.

— Clinical Information Models, when developed for a specific use case, or care process or context, should clearly express the identified clinical care processes and or compositions it has been designated to support.

6.12 Issues

The issue section provides guidelines for Clinical Information Model content. It can explain the relationships with terminologies and classifications and whether they are used, if there are missing codes or whether a set of codes has been requested.

Remarks can be made about the quality of the material along with suggestions for future adaptations. Possible inclusions are a notation that evidence or other literature is missing along with suggested approaches for obtaining the evidence along with local changes / variations in CIM content.

Modelling issues, choices or difficulties can be explained as well, preferably including the options and choices made. In general, it is similar to the discussion section in a research paper.

For example, The CIM for the Barthel Index notes that its information model and CIM description is based upon the Dutch version, which differs in scores from the original English version.

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Alternatively: often codes are not available for each data element in a CIM. Data elements for which codes are missing can be listed here.

— A CIM could contain specific information on modelling choices, e.g. when these lead to a specific representation of the concept, which could have alternatives.

— Each Clinical Information Model should identify unresolved, controversial, or contentious issues that require further discussion in future revisions of the model and that model users should be aware of before applying the CIM.

6.13 Example of the use of a CIM

An example can be included for clarification purposes such as the use of a scanned paper document or picture of the instrument as it is used in practice in a paper-based record, preferably a good and readable quality of JPEG / BMP / PNG / TIFF or another common format. Another option is a screenshot from an existing EHR system.

It is also possible to create a User Interface mock-up with real data values for illustration though permission needs to be granted from the developers of that example and explicitly stated within the CIM.

— A Clinical Information Model may have a section allowing inclusion of examples from clinical practice, screenshots or User Interface mock-ups of the clinical concept and its data elements and example values.

6.14 References

This section provides references that are relevant to the content of the CIM including projects, literature, world wide web pages and vocabulary to properly acknowledge prior work. Also note the projects from which source material for the CIM has been developed, if in the form of artefacts such as an archetype, HL7® R-MIM, template or XML component.

Identify vocabularies including the release and/or version.

For example, two vocabularies are referenced with their matching OIDs: SNOMEDCT® with OID: 2.16.840.1.113883.6.96, LOINC® with OID: 2.16.840.113883.6.1.

For example, use of SNOMEDCT in a care setting and/or an application requires a license. More information can be found on the website of SNOMED International https://www.snomed.org/snomed-ct/get-snomed or the websites of national member bodies.

— Each Clinical Information Model shall include identified references to all published and unpublished literature, guidelines, knowledge, specifications, terminologies, and all other materials that have informed its content.

— Representation of each reference should adhere to common citation formats used in scientific literature.

NOTE The APA, Harvard, NLM or Vancouver formats for referring to literature, or any other formal guidance can be used to list references (see Reference [64]).

6.15 Intellectual property issues around Clinical Information Models

There are four areas of concern around issues in CIMs content, use and intellectual property (IP). These include copyrights of source materials, disclaimers, terms of use and copyrights for the models themselves. The first issue is the use of existing clinical materials to describe the concept and medical background, which could include copyright and or licensed materials.

— A Clinical Information Model should include a clear statement of any copyright or licensing restrictions that apply to the content of the CIMs to respect the intellectual property.

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— Permission to use specifications from other sources than the CIMs shall be included.

The second is the potential use of a disclaimer which can be relevant to the development and use of the Clinical Information Model or after it has been declared obsolete.

— A Clinical Information Model can include a disclaimer that applies to the content of the CIM to prevent liability issues.

A third area of concern is terms of use of the models.

— A CIM can contain a specification of terms of use under which any stakeholder can apply the CIM, e.g. in guidelines, care processes, information standards, EHR systems, electronic messaging or as data definitions for secondary purposes.

The fourth concern is the copyright of the CIMs themselves. Clinical Information Models have authors and responsible parties and they have intellectual property rights. These can be waived, e.g. through creative commons policies or similar.

— Authorship, IP holders and/or governing authorities of Clinical Information Models, including means of obtaining permissions for obtaining licenses for use, should be made explicit in the meta data.

— The author of each Clinical Information Model should be clearly identified to ascertain trustworthiness.

NOTE The author can also be an organization, such as a clinical organization.

— The copyright holder and/or governing authority for each Clinical Information Model should be clearly expressed.

The idea behind the CIMs is the provision of high-quality sharable specifications of clinical concepts for use in health care IT. This implies sharing and contributing. It also implies that the CIM shall be traceable to authors and responsible parties. Also, a quality label can be given. The following bullets refer to normative statements that highlight certain aspects of legal issues around CIMs.

— Certain rules should apply for proper deployment of CIMs.

— Changes in content, data, and codes of CIMs could be viewed as an infringement of copyright and potentially damaging to patients because it jeopardizes the realization of semantic interoperability.

— Changes can be suggested to the author or responsible party of a CIM and, if accepted, they can lead to:

  — A revised CIM

  — Variations adapted to a local situation, without changing the original CIM, which could be done via extensions.

— A Clinical Information Model, or its repository should include information for (potential) users on how to conduct change requests.

There should be online information for users of any CIMs from a source organization regarding change requests and patient safety and quality of care implications of changing a CIM without permission. Including this information in every CIM would be burdensome but a link to the main discussion site for change requests could easily be included in every CIM. How this is operationalized will vary. The minimum, however, would be to include it as a separate statement in an individual CIM if there is no reference available.

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7 Metadata for clinical information models

7.1 General

Several metadata elements are required for Clinical Information Models. It is necessary to identify responsibility for a particular CIM in order to allow an assessment of the integrity of the work. This area would include any unique identifiers, author details and endorsing organization.

Metadata conveys information that is non-essential for the purpose of the clinical concept being described but that is important for other purposes such as:

— Locating a specific Clinical Information Model based upon e.g. subject, area of applicability, form of presentation.

— Assessing quality of the Clinical Information Model, e.g. its age, author integrity, certification status and by whom its use in clinical practice has been endorsed.

CIMs will be available in an accessible repository and/or a registry with metadata, supporting their easy retrieval.

— The metadata should support unambiguous and international understanding of important aspects to describe a Clinical Information Model, e.g. author, version, validity.

— The metadata should be applicable to all Clinical Information Models, e.g. observations, scales, procedures.

— Metadata should be presented in a manner capable of being correctly interpreted by both technological and human stakeholders, whether a health professional or a patient.

— The metadata should be potentially usable for automatic processing, e.g. support search engines to restrict matches to Clinical Information Models of a certain type or quality level.

— Governing authorities for a CIM should enable any reference to published knowledge or policy to include a date when the knowledge is due to be reviewed (and therefore when the CIM itself might be reviewed).

The metadata here described is not intended to:

— Describe documents or electronic records about a single patient, such as medical records.

— Describe details of the medical content of the document or record (though some idea of the content can be ascertained via keywords or codes).

— Prescribe the criteria for the quality of the document or record content.

7.2 The metadata elements of the Clinical Information Models

Relevant metadata elements are presented in Table 2 along with their description. The cardinality expresses whether the element is mandatory or optional and the terms in the use column expresses the normative strength.

This CIMs metadata list is based on an analysis of ISO 13606-2 (on archetypes), ISO/IEC 11179 (on metadata), ISO 13119, CEN/TS 15699 (on metadata), Eurorec documents[66], HL7® templates specification[67], and HITSP/TN903[68]. In the list, “mandatory” and “recommended” are included. Mandatory means that it shall always be present without exception. Recommended means that if these metadata are available, they should be included. For example, the expiration date of a CIM should be included if it is known.

1. A Clinical Information Model should include meta-information as specified in Table 2.

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Table 2 — Clinical Information Models Metadata elements, descriptions, datatypes, mandatory or recommended uses

Metadata element	Description	Datatype	Cardinality	Use
1. Name	The name of the Clinical Information Model as given by its creator. It is a free text natural language name identifying the Clinical Information Model concept. Reference: HITSP/TN903, HL7® Template project, ISO/IEC 11179-1:2015, 3.2.21, Eurorec	ST	1..1	mandatory
2. Type	There is an assumption that different types of Clinical Information Models can be identified, such as observation, procedure and evaluation. At this stage however, it is unclear which types will exist. If ISO 13940 (Contsys) is used, then the type of Clinical Information Model will be identified from the business process as defined in that standard.	CD	0..1	recommended
3. Identification	A globally unique, non-semantic identifier for the Clinical Information Model assigned by "the owner". This can be a persistent URI/URL or an OID but equally could be another identification system. Reference: ISO 13606-2, HITSP/TN903, HL7® Template project, ISO/IEC 11179	II	1..1	mandatory
4. Keywords	A set of terms from a controlled reference terminology which can assist with indexing and searching for a Clinical Information Model. A keyword can be a synonym, derivative term or a generic (such as the Braden Scale with a keyword Pressure Ulcer Risk). In all cases the display text and the code are used in order to allow clinical verification at all times. Reference: ISO 13606-2, HL7® Template project	ST and/or CD	1..*	mandatory
5. Author(s)	A uniquely identified person and/or organization and / or governing organization, it would also contain names of those who contributed to the development of the Clinical Information Model. A distinction is between the author of the clinical content, the author of the information model, the person who provided the coding and the person who reviewed the end product. The organization for which these individuals work is also mentioned. The position/role of the author can also be stated. Reference: ISO 13606-2, HITSP/TN903, HL7® Template project	PN	1..*	mandatory

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Table 2 *(continued)*

Metadata element	Description	Datatype	Cardinality	Use
6. Endorsing authority	The authoritative organization which has reviewed the Clinical Information Model for clinical accuracy and relevance, endorsing it for publication and/or use. Reference: HL7® Template project, ISO/IEC 11179	EN AD TEL	1..*	mandatory
7. Identification of the endorsing authority	Formal identification of the above organization. Reference: HL7® Template project	II	1..*	mandatory
8. Version number	Version identifier for the Clinical Information Model; the ability to determine the correct version is essential to its identification. The version number shall be raised in every change. NOTE If the creator identifies no version number, the registry or repository will assign a version number using the publication date associated with the Clinical Information Model expressed in the format YYYYMMDD. Reference: Eurorec, HITSP/TN903, HL7® Template project, ISO/IEC 11179	INT	1..1	mandatory
9. Creation date	The date this Clinical Information Model was created in YYYYMMDD format. Reference: HITSP/TN903, HL7® Template project, ISO/IEC 11179	TS	1..1	mandatory
10. Publication date	The date on which the Clinical Information Model came/will come into use expressed in YYYYMMDD format. Use of the CIM prior to this date would be considered invalid usage. Reference: ISO 13606-2, HITSP/TN903, HL7® Template project, ISO/IEC 11179	TS	1..1	mandatory
11. Expiration date	The date on which the Clinical Information Model expires expressed in YYYYMMDD format. It can be used as point of reference for data analysis based on historical data but after this date it should no longer be employed. Reference: HITSP/TN903, HL7® Template project	TS	0..1	recommended
12. Superseded by	The Clinical Information Model that has superseded this CIM and which should be used instead. This field can only be created if the publication status of the former CIM is set to 'Superseded'. Reference: ISO 13606-2, HL7® Template project	II	0..1	recommended
13. Revision date	The date this Clinical Information Model was revised when applicable in YYYYMMDD format. Reference: HITSP/TN903, HL7® Template project	TS	0..1	recommended

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Table 2 *(continued)*

Metadata element	Description	Datatype	Cardinality	Use
14. Next revision date	The anticipated date of review for the current Clinical Information Model to confirm it remains clinically valid in YYYYMMDD order. ISO 13606-2	TS	0..1	recommended
15. Development status	Status of the Clinical Information Model during its development: Author Draft(s); Committee Draft(s); Organization draft(s); Submitted; Withdrawn. Reference: ISO 13606-2, HITSP/TN903, HL7® Template project, ISO/IEC 11179	CS	1..1	mandatory
16. Lifecycle status	The status of the Clinical Information Model during system implementation. Reference: Eurorec	CS	0..1	recommended
17. Publication status	The status of the Clinical Information Model in relation to its publication in the registry or repository. Several options are possible for shared publication status, e.g. complex distributed governance structures for example: Not for Use (i.e. teaching); Approved for testing; Approved for Production Use; Withdrawn; Superseded; Rejected; Obsolete. Reference: ISO 13606-2, HITSP/TN903, HL7® Template project, ISO/IEC 11179	CS	1..1	mandatory
18. Publisher	The party responsible for submitting this Clinical Information Model to the registry or repository. Reference: ISO 13606-2, HL7® Template project	EN AD TEL	1..1	mandatory
19. Language	The natural language(s) in which the Clinical Information Model is represented using the ISO 639 series code (two, three, or four letter language identifiers). Metadata will be expressed in this language. Reference: ISO 13606-2, HL7® Template project, ISO/IEC 11179	CS	1..*	mandatory
20. Quality label or certification	Formal quality validation of the Clinical Information Model; specify the type of test performed. Reference: ISO 13606-2	ED	0..*	recommended
21. Format	As there are different formalisms possible to define a Clinical Information Model such as textual description in a word file, table lay out in Excel, XML expression, ADL version 1.4, ADL version 1.5. UML, OWL, HL7® template, HL7® version 3 R-MIM model, among others, it is helpful to identify in which format the CIM is available. Reference: HL7® Template project	ST	1..*	mandatory

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Table 2 *(continued)*

Metadata element	Description	Datatype	Cardinality	Use
22. Additional formats	If the Clinical Information Model has been transformed into other formats; currently CIMs have been presented in UML, XML, HL7® v3 clinical statement, ADL version 1.4, Excel tables and Word document. Reference: HL7® Template project.	ST	0..*	recommended

8 Version management of clinical information models

New versions of Clinical Information Models are often built on previous versions so the governing authority should apply some sort of mechanism to track and trace modifications over time. Information about its current version needs to be present and providing historical references allows users to identify the changes between different issues.

NOTE All versions of a Clinical Information Model would normally be backwards compatible with prior versions. Any change to the semantic meaning that is not backward compatible requires the creation of a new CIM with a different identifier. A change is not backwards compatible if it could result in an instance data processor which is unaware of the more recent definition of the CIM and therefore interprets conformant data incorrectly. Generally, removing or changing the meaning of existing data elements or their associated vocabularies is not backwards compatible (HL7® Template project[67]).

a) The responsible formative organization shall apply a strict version control to CIMs.

b) Each Clinical Information Model shall be versioned by the formative organization.

c) Any material change to a CIM shall result in a revised version that references the former version.

d) The last CIM change should specify the person and/or organization and/or governing authority responsible for the latest change, the date of the change, a description of what has been changed and the reasons for the change.

e) A CIM should specify if its draft versions have been developed through an open consultation or social computing form of peer review (e.g. undergone a ballot cycle or published for public comment).

The proposed version features in this Clause are presented as a 'minimal' approach. A more comprehensive (and machine-readable) mechanism to track model component changes could be required for actual use in practice.

See Annex B for further guidance.

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Annex A
(informative)

Release and maintenance process example in the Netherlands

Several countries have other models, in particular Spain and Australia, which ISO 13606-2 based archetypes. Sweden has also started the creation of clinical information models in 2020. This document includes agnostic examples that apply the UML based approach. Since the Netherlands is deploying this approach, this document the Dutch model as an example[54][69].

In 2011, the Netherlands created CIMs for use in EHR systems, data exchange and data reuse. It started in eight University Hospitals. Since then, hospitals, mental health, general practitioners, and nursing homes and home care have adopted this approach. Several professional organizations also have input, such as medical specialists, nurses, general practitioners and, recently, physiotherapists.

The Dutch CIMs (zibs) currently form a key component of several projects whose focus is to achieve a sustainable national information framework for healthcare[69]. This Dutch development is largely based on the Refined European eHealth Framework[44] (Figure 1) and governed through NEN 7522.

Since CIMs are used nationally, a strong governance process has been laid out[71] in which a CIM development team – consulting stakeholders – creates draft CIMs or summarizes proposed changes in existing CIMs. Next, via a public consultation for all interested parties, change requests are solicited and handled. The pre-final CIMs are then submitted to the CIM authorization body, represented by expert policy officers from stakeholder organizations. This authorization body will not redo the content development, but it mainly focuses on the correct procedures, on the fact that all comments are handled correctly and that the overall set of CIMs remains adequate for purpose.

After approval, the finalized CIMs are published on the CIM wiki, for which the operational management is carried out by Nictiz. The wiki contains information about the three most recent publications of the CIMs[69]. Publications appear on average once every year or two years and each contains a set of CIMs that are finalized and consistent. To implement CIMs in accordance with a publication, all relevant CIMs in the version as mentioned in the relevant publication summary should be used. However, this does depend on the kind of government implementation projects ongoing for each health care domain.

Each of these projects defines a specified set of CIMs ,e.g. for use in EHR, data exchange, or national quality registries. During such projects, and ongoing use, limitations of CIMs will be experienced and to handle change requests, an online software tool is deployed. Anyone with an interest, e.g. vendors implementing CIMs in their applications, professional organizations not represented in the authorization body, or individuals, can submit change requests on CIMs, or CIM components as depicted in Clause 6.

To meet the demand for flexibility for early adopters without undermining the desired and necessary stability, current developments are released in between one and four pre-publications per year. These pre-publications are consistent sets of CIMs and include the accepted change requests to existing CIMs, and the newly approved CIMs. However, there is no guarantee that these CIMs will not be changed in the period until the next actual publication. Pre-publication users should realize this risk. Unlike publications, pre-publications will not remain available on the Dutch wiki[69] but will be replaced by the following (pre-) publication.

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Annex B
(informative)

Version management backwards compatibility

In the case of new versions, there can exist implementation questions about backwards compatibility. If the models are backwards compatible, there is usually no issue. However, when there is no backwards compatibility, usually changes are required in the systems. And then it is important to have more information. That is quite different per jurisdiction and per type of system and even per vendor.

— A new version or revision number of a CIM should be assigned if backwards compatibility is guaranteed.

— A new version of a CIM should be created if there is no backwards compatibility. This new CIM shall be assigned a separate unique identifier.

— A new version of a CIM should be created if there is no backwards compatibility. Assigning this new CIM a different CIM name could be considered.

— A previous CIM shall be assigned a status of Superseded when a new version of a Clinical Information Model is created due to lack of backwards compatibility of the former version.

— If there is no backwards compatibility, the newly created CIM should be linked somehow to the Superseded CIM so that users of the new CIM can trace the history of both the new and the previous related CIMs.

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Annex C
(informative)

Guidelines and principles for Clinical Information Modelling

C.1 General

The data model section maps the concepts identified in the Clinical Information Model's clinical content to data elements and their relationships. An information model contains classes, attributes of these classes and constraints on these attributes. In addition, this annex specifies the rules used to assert validity of the data contained in the attributes. It also specifies the relationships between data elements in the (class) model. A principle applied is that one single data element is represented by one single class.

The description of the data model shall contain enough detail for a CIM implementation to be interchangeable and unambiguously interpretable within the EHR. These criteria are not guidelines about how an author should map concepts in the CIM to a data model, but rather minimum criteria for the contents of the section and the formal methodology used by the author. Since these are minimum criteria, the formalism can support more features than the required set given below.

— Clinical Information Models shall include the metadata, the concepts involved, data elements, mandatory attributes and constraints and relations between concepts.

— CIM documentation shall contain one or more data models specified in a formal methodology, from here on referred to as "the formalism".

NOTE This document uses Unified Modelling Language (UML) as an example formalism.

— The formalism may be used to express aspects of the data model beyond those required by the criteria specified in this document.

— A concept in the domain can be present in the data model section.

— CIM documentation should contain a list of concepts present in the data models, expressed as data elements, accompanied by text to clarify its meaning and its relationships to other concepts in the diagram.

— This list of concepts will from here on be referred to as "the concept list".

— The concept list shall contain all concepts and hence all data elements represented in the data models. Conversely, the concept list shall not contain concepts not represented in the data models.

— CIMs shall reveal default values, value sets, reference values, observations in scores, nesting of subscales or items and flavors of null, cardinality and optionality when they are part of the concepts and their application in practice.

— CIMs should apply reusable components from comparable instruments or observations.

— The CIM information model shall express clearly which data elements and concept specifications are handled in the information model space and what is handled in the terminology model space.

C.2 Specification of concepts in Clinical Information Models

The CIM data model represents concepts either as classes or as terms. Classes will generally be presented using entities or records in communication and storage. On the other hand, terms will

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become converted to codes from coding systems. This way, the data model will separate the concepts cleanly into those present in the information model and those represented using terminology.

— The formalism shall be able to represent concepts from the clinical content sections as data elements in classes and to assign unique names.

— The data models can contain data elements which do not represent concepts from the domain.

— One of the concepts present in the data model section shall represent the main subject or focal concept of the Clinical Information Model. This should be called a 'root concept'.

C.3 Specification of properties of concepts

An information model will not only contain concepts but also the properties of those concepts, modelled as attributes. These properties are regarded as being concepts themselves so they can again have properties that can also be of interest to our model. Continuing this way, each concept will be split up into simpler concepts until, for the purpose of our domain, a concept is "atomic" and there is no need to consider and represent its properties. Based on experience, this lowest representation level is the data element, including its characteristics. This implies that the class representation of one data element is also on the lowest atomic level possible, with attributes further specifying this.

As each data element is itself a concept, it will be associated with a class. In the data model, the data elements at the leaves will be expressed using elementary structures like quantities, numbers and codes, a datatype. These elementary structures are called simple classes. Conversely, a class representing a "non-atomic" concept is called a complex class. Figure 7 illustrates the breakdown of the atomic data element into attributes. The attributes of complex classes can be divided into two categories based on the kind of data they contain:

— Data that was measured, observed or otherwise determined and which is considered as the result of the clinical acts described in the Clinical Information Model, referred to as results.

— Data which is captured during the clinical act described in the CIM but only serves to aid interpretation of the results or which influence the results. These are called qualifiers.

  — The formalism shall be able to specify the properties of concepts as attributes of data elements.

  — The formalism can provide more specific classification of model qualifiers or results. For example, either representing aspects of the state of the patient or the protocol relevant to the interpretation of data gathered in the CIM.

  — The formalism should be able to identify data elements which contain data derived from other attributes present elsewhere in the information model. For instance, a total score class derived from other classes.

  — The formalism should support specification of the way data in a derived attribute is computed from other classes.

  — Every data element, either complex or simple, shall specify the attributes.

  — If an attribute has a complex class, this data element shall be defined in one of the information models of the Clinical Information Model.

C.4 Specification of atomic attributes

A list of criteria shall be met for the specification of atomic attributes.

— The simple class of every atomic data element shall be selected from a fixed set of class types predefined by the formalism.

— This fixed set of predefined class types shall contain a class for each of the following kinds of data:

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— Data representing a coded concept. Attributes of this type shall contain a single expression from a terminology which defines a precise meaning for that term. Attributes of this class shall contain a unique code which identifies this specific concept.

— Data representing coded ordinal concepts. Attributes of this class shall contain a value set expression from a terminology that defines the precise meaning for those terms. Attributes of this class shall also contain a set of unique codes which identify these specific concepts, and the codes shall be of a format that allows calculations, e.g. numbers.

— Data representing quantities. Attributes of this class shall contain both a scalar value and the unit in which the quantity is expressed.

— Data representing numerical values. These values can be integer, fractional or real.

— Data representing text.

— Data representing Boolean values.

— Data representing a moment in time.

— Data representing an interval of time.

— Data representing an interval of a quantity.

— Data representing a ratio value.

— Data representing an interval of a numerical value.

— Data representing images, sound and multimedia.

— Data representing an instance identifier

— Data representing a URI / URL.

  — The formalism can support other simple classes, as long as they are specializations of the types listed above, for instance from datatype ANY.

  — The datatypes should be consistent with ISO 21090 or an equivalent datatype specification

Table C.1 lists the most common datatypes.

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Table C.1 — Common datatypes for CIMs

Code	Name	Description	Type
ANY	Any datatype	Data representing any datatype.	Not applicable
CD	Concept Descriptor	Data representing a uniquely coded concept from a terminology defining a precise meaning.	Complex
CO	Coded Ordinal	Data representing coded ordinal concepts, representing both a meaning and a numeric value for calculations.	Complex
PQ	Physical Quantity	Data representing quantities with both a scalar value and unit.	Complex
INT	Integer	Data representing numerical values of type integer, that is without decimals.	Primitive
ST	String	Data representing text.	Primitive
BL	Boolean	Data representing Boolean values representing true or false.	Primitive
TS	Time Stamp	Data representing a moment in time.	Primitive
II	Instance Identifier	Data elements that uniquely identify a thing or an object.	Complex
ED	Encapsulated Data	Data representing sampled data.	Complex

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C.5 Constraints on the contents of attributes

Using these criteria, it is possible to specify an information model reflecting the hierarchical or other relational structure of the concepts and the data elements or classes used to represent the concepts. Based on these specifications, it is possible to construct a collection of data which adheres to the structure specified in the information model. In this collection of data, each class in the model is instantiated to contain some actual data collected in accordance with the class specification.

In addition to the criteria for specifying the structure of the data, the formalism used to specify the data model will also be required to support the constraint of the allowed range of data within instances.

— The formalism shall be able to specify the occurrence of a data element in an instance of a class: it indicates how many times the data element can be present in an instance of a class. Occurrence shall be specified for all data elements.

— The formalism shall be able to specify whether a data element is optional (allowed not to be present in an instance) or mandatory if available (shall be present at least once in each instance when available).

— The formalism should be able to specify an upper boundary to the number of occurrences, which may be “unlimited”. If the formalism does not support the specification of upper boundaries to occurrences, this implies that the data element can occur once at most.

Normative criteria for the specification of constraints on the content of atomic data elements will be discussed hereafter.

— The formalism shall be able to specify whether the data element can contain no data.

— If an atomic data element can contain no data, the formalism should be able to express a requirement for the data element to indicate the reason why it contains no data.

— The formalism should be able to specify a default value for data elements that are allowed to contain no data. Whenever a data element contains no data in an instance, it is considered to contain this default value.

— For data elements containing a coded concept, the formalism shall be able to specify a set of allowed terms called a value set. If the coded attribute contains a term, it shall be one of the terms from this value set. The formalism should be able to depict the definition of a value set by marking it as abstract, which means further specializations of the class containing such data element shall provide the full definition of the value set.

— For data elements containing a quantity, the formalism shall be able to specify the allowed range of the scalar value of the quantity in combination with a set of allowed units in which the quantity is expressed.

— For data elements containing a numerical value, the formalism shall be able to specify the allowed range of values.

— For data element containing a moment in time, the formalism shall be able to express the element using

— a year only,

— a year and month,

— a year, month, and day,

— a year, month, day, and hour,

— a year, month, day, hour, and minute,

— an hour only, or

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— an hour and minutes.

— For data elements containing an interval, the formalism shall be able to specify whether the interval is closed or open and whether the interval has a lower or upper limit. Since limits are themselves moments in time, quantities or numerical values, the formalism shall be able to constrain the allowed values for these limits. It should use the same mechanism for constraining attributes to restrict the limits of intervals.

— The formalism can express these and further constraints using a constraint formalism like OCL (Object Constraint Language)[72] or GELLO[73].

C.6 Representing specialization hierarchies

Concepts can be "kinds of" other concepts, which means that these are considered a more specific occurrence of another more general concept. Using this relationship between two concepts, the definition of a more specific concept can be based on the specification of the more generic concept. Since concepts are represented in our information model using data elements or classes, this means that the definitions of new data elements can be based on the definitions of existing data elements. These new data elements are then called specializations of the existing data elements and inherit all the data elements and constraints of the original (called the base class); it is also possible that the base class will be extended through the addition or restriction of new data elements or constraints. Classes that serve only as base class for specializations and which are never used for the identification of data properties are called abstract classes.

— The formalism shall be able to specify that some data element or class is a specialization of another data element.

— The formalism shall allow the specialized class to override the constraints specified on the attributes in the base class.

— Overridden occurrence constraints on data elements and relationships shall be stricter than constraints specified in the base class. This means that

  — data elements that are declared optional can be made required,

  — data elements with a minimum occurrence of X can narrow the occurrence to some value higher than or equal to X, and

  — data elements with a maximum occurrence of Y can narrow the occurrence to some value lower than or equal to Y.

— Overridden constraints on the content of a data element shall be stricter than constraints specified in the base class. This means that the set of allowed values for the data element in the derived type is a subset of the set of values of allowed values for the same data element in the base class.

— The formalism should allow a specialized class to constrain coded data elements by disallowing terms from the value set of a coded data element in the base class. It should allow a specialized class to list the terms for an abstract value set specified in a coded data element in the base class

— The formalism should allow a specialized class to constrain any data element of the base class by defining a default value for the data element.

— The formalism shall enable the specialized class to specify data elements in addition to those present in the base class.

— The formalism should be able to mark classes as abstract class. If the formalism supports the notion of abstract classes, the model shall mark them as being abstract.

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C.7 Localization of Clinical Information Models

Depending on the context of use of a Clinical Information Model, some or all its data can have reasonable default values. A desirable feature of the formalism is therefore support for localization, which means constraining the definition of the classes, concept identifying codes and value sets of an existing CIM to generate a subset or new model which is more applicable to its context of use. Examples of such localization are geographical changes, adaptation for a specific care facility or adjustment for a specific clinical domain, e.g. pediatrics.

— The formalism should allow localization of a Clinical Information Model through not using some of its data elements.

— Not using some data elements shall only be possible for CIM content which does not affect proper clinical practice.

For example, it is acceptable to skip concepts on body position in a Clinical Information Model on Heart Rate but is not proper clinical practice to eliminate variables from most assessment scales that summarize into a total score as they will be invalid and unreliable.

— The Clinical Information Model content should specify what is not allowed in localization.

— The formalism should allow the data elements in a localized Clinical Information Model to use specialized data elements instead of their base types in the localized CIM.

— The formalism should allow extensions to the localized model.

C.8 Inclusion of other Clinical Information Models

Although the criteria state that all complex classes used by data elements or as a base for specialization should be present in one of the information models of the section, it is possible to include a complex class on an information model defined in the information model of another Clinical Information Model. Inclusion implies reuse of the definition of another existing CIM, not that one instance of data from one CIM is referring to an instance of data from another. The latter is sometimes referred to as “linking” to or creating a “semantic link” between instance data.

For example, the Body Mass index CIM references but does not repeat all the specifications from length and weight. In blood pressure, body position (lying, sitting, standing) is identified, which can also be reused in other CIMs. Therefore, a means of referring to other CIMs should be included in order to both make it useful and prevent the duplication of data elements.

Including definitions from another Clinical Information Model in a CIM works as follows:

— A data element can refer to the “full definition” of another CIM(s), including the information in the clinical sections such as interpretation or protocols. This kind of reuse will be called Clinical Information Model inclusion.

— The formalism should allow a Clinical Information Model to include another CIM through nesting. Such inclusion should be specified on a data element by ensuring that the data element refers to an existing CIM. The data element’s class will be the referenced CIM’s focal class or root concept.

C.9 Use of terminology

To ensure correct interpretation, it is necessary to define the meaning of the concepts used in the Clinical Information Model. The human-readable name of the elements does not guarantee unambiguous interpretation and does not suffice for automated systems; every element carrying semantic meaning shall be labelled using terminologies.

— The formalism shall be able to associate one or more codes from any coding system to any term specified in a value set for a coded attribute (data element).

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— All clinical terms in value sets shall be associated with at least one code from any coding system.

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Annex D
(informative)

Example mapping a CIM to ADL specification: Glasgow Coma Scale

D.1 Core parts of a CIM

To facilitate the mapping from CIM into any technical representation, reference points are needed at both the level of the CIM and on the level of the representation it is mapped to. See below summary of the key elements of any CIM.

— A CIM has one root concept.

— A CIM has a minimum of one data element.

— A CIM can have one to many data elements.

— A data element has one code binding to external terminologies.

— A data element can have one to many bindings to different terminologies (although at implementation level a choice shall be made).

— A data element has a datatype.

— A data element has a value.

— A data element can have a value set.

— A data element can have a unit.

— Data elements can be grouped into containers for clarity or better organization.

— CIMs can refer to other CIMs for reference.

— CIMs can be grouped together into compositions.

D.2 Mapping a CIM to ADL

To illustrate the implementation of a CIM into an implementable representation, the Glasgow Coma Scale (GCS) is taken[74]. The CIM representation in ADL is presented here for illustration of the mapping according the Interoperability and Integration Reference Architecture. Representations are possible in other technologies as well, but that is not part of this illustration.

The source for the CIM is https://zibs.nl/wiki/GlasgowComaScale-v3.1(2017EN)

The source for the ADL is https://www.openehr.org/ckm/archetypes/1013.1.137

Core components of the CIM include the root concept, data elements, and value sets. In D.3.5, the GCS is presented in UML model, the data elements are listed in a table and for various items the corresponding value sets are expressed in tables. To illustrate the conversion from a CIM into a technical representation the GCS is illustrated as an OpenEHR archetype, including a mindmap and Archetype Definition Language. Before showing the details, the mapping between both CIM and ADL are presented in Table D.1. This mapping between components facilitates the implementation from CIM into ADL. For other technologies, such as HL7® v3 or HL7® FHIR®, a similar mapping exercise is necessary. For purpose of brevity, the variations for infants and children have been removed from the CIM. Another reason is that the ADL example specify different archetypes for adults and for young children.

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Table D.1 — Mapping between CIM and Archetype

CIM	**ADL**	**Example** (these are taken from both CIM and ADL, there is and must be overlap).
Root concepts	Entries (of type) OBSERVATION	Glasgow Coma Scale
Table with data elements	ITEM_TREE	This represents the list of all variables
Containers	Clusters	Not present in GCS
Data elements	Elements	Eyes, Motor, Verbal, Total, Date/Time Condition Comments
Concept	Concept Description	Fifteen-point scale used to assess impairment of consciousness in response to defined stimuli. More correctly known as the Modified Glasgow coma scale (from ADL).
Purpose	Purpose	The GCS score provides the opportunity to document a clinical observation of a patient's conscious state with a validated instrument which makes use of a patient's responses to stimuli. (from CIM)
Evidence base	Use and misuse	See websites
References	References	Teasdale & Jennett (1974)[74]
Meta information	Attributes	One example from CIM: DCM::Id: 2.16.840.1.113883.2.4.3.11.60.40.3.12.8

D.3 The CIM example

D.3.1 General

The next subclauses present excerpts from the CIM for GCS.

D.3.2 Concept

Fifteen-point scale for expressing a person's level of consciousness, from fully awake to deep unconsciousness, in a number: the EMV (Eye-Motor-Verbal) score.

The GCS score or EMV score is a scale to measure the extent of consciousness, based on eye, verbal and motor responses to specific prescribed sound and pain stimuli.

D.3.3 Purpose

The GCS score provides the opportunity to document a clinical observation of a patient's conscious state with a validated instrument which makes use of a patient's responses to stimuli.

D.3.4 Evidence Base

The GCS is used to evaluate a patient's consciousness by means of three elements:

— opening eyes (eye response);

— answering questions (verbal response);

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— motor response.

The three response values are looked at individually and as a whole. The minimum total score is 3 and the maximum is 15. A slightly altered scale is used for infants (age 0 to 2) and toddlers (age 2 to 5).

The EMV score can be expressed as a combination of each of the three individual scores, such as: E3M2V4 (opens eyes when spoken to, arms stretch in response to pain and patient produces incomprehensible sounds).

If one of the EMV elements cannot be evaluated - such as might be the case if a patient is intubated and incapable of verbally responding or is paralyzed/weak and incapable of fulfilling the motor request, then the individual score is included (score 1), but with an extra comment.

V1T is used for an intubated patient, in which t = 'tube'.

Clinical decisions are based on each of the specific data of the eyes, motor, and verbal responses and, if evaluation is not possible, an explicit explanation.

The CIM for the GCS is depicted in Figure D.1 and Table D.2. Tables D.3, D.4 and D.5 specify the values for each individual element of this scale. Table D.6 shows the metadata of the Dutch example.

D.3.5 CIM example Information model for Glasgow Coma Scale

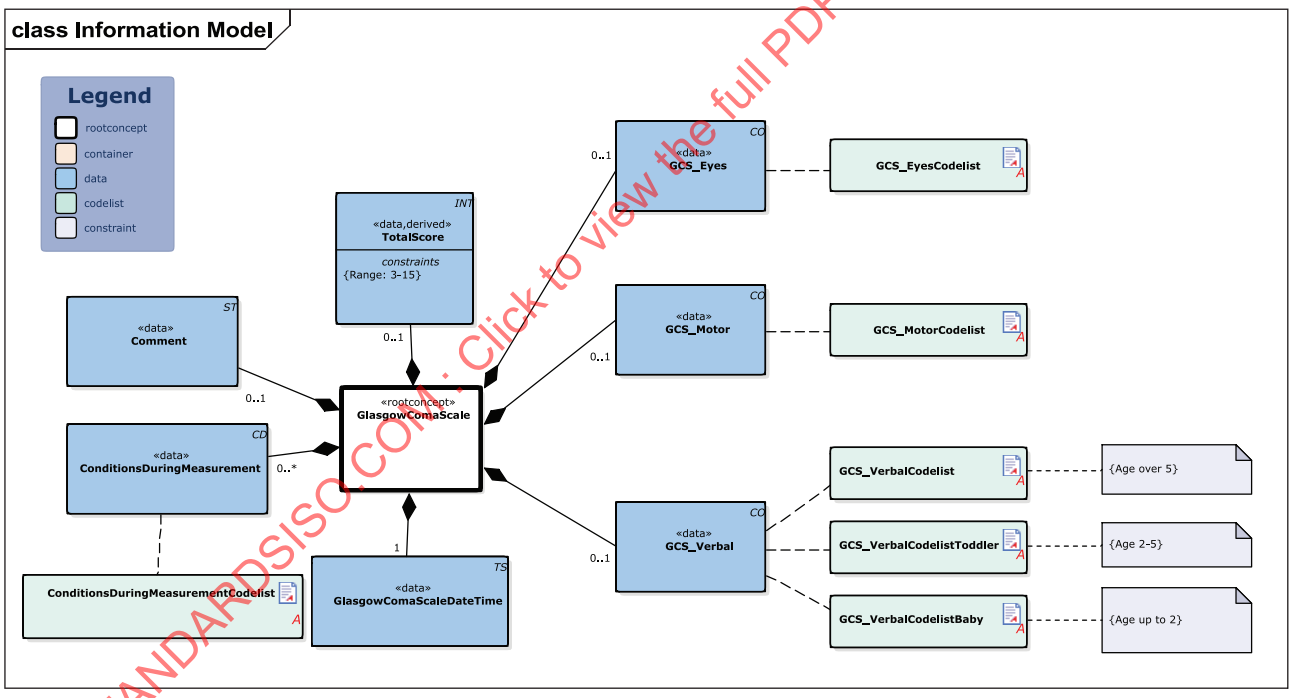

Figure D.1 — UML representation of the Glasgow Coma Scale[69][74]

Table D.2 — Data element specification of the Glasgow Coma Scale

Type	Id	Concept	Card	Definition	Definition Code	Reference
	NL-CM:12.8.1	GlasgowComaScale		Root concept of the Glasgow-ComaScale information model. This root concept contains all data elements of the Glasgow-ComaScale information model.	LOINC®:35088-4 Glasgow coma scale	The scale as an instrument
TS	NL-CM:12.8.8	GlasgowComaScale-DateTime	1	Time at which the EMV score was determined.		

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Table D.2 *(continued)*

Type	Id	Concept	Card	Definition	Definition Code	Reference
CO	NL-CM:12.8.2	GCS_Eyes	0..1	Best eye response to a stimulus. The element is mandatory but does not require a numerical value. If no value is given, the reason for this is to be provided in the ConditionsDuringMeasurement concept.	281395000 Glasgow coma score eye opening subscore (observable entity)	GCS_EyesCodelist
CO	NL-CM:12.8.4	GCS_Motor	0..1	Best motor response to a stimulus. The element is mandatory but does not require a numerical value. If no value is given, the reason for this is to be provided in the ConditionsDuringMeasurement concept.	281396004 Glasgow Coma Score motor response subscore	GCS_MotorCodelist
CO	NL-CM:12.8.6	GCS_Verbal	0..1	Best verbal response to a stimulus. The element is mandatory but does not require a numerical value. If no value is given, the reason for this is to be provided in the ConditionsDuringMeasurement concept.	281397008 Glasgow coma score verbal response subscore (observable entity)	GCS_VerbalCodelist GCS_VerbalCodelist-Baby GCS_VerbalCodelist Toddler
INT	NL-CM:12.8.10	TotalScore	0..1	The sum of the EMV scores, expressed as a number on a scale from 3 to 15. The value does not have to be recorded, as it can always be calculated based on the individual scores, and as recording the total is not common for a difficult to determine individual score.	LOINC®: 9269-2 Glasgow Score Total	The score result
CD	NL-CM:12.8.11	ConditionsDuring-Measurement	0..*	Conditions during the measurement that prevent one or more of the subscores from being determined (non testable), e.g. intubation during testing of GCS_Verbal.		ConditionsDuring Measurement Codelist
ST	NL-CM:12.8.9	Comment	0..1	Comment on (the context of) the EMV score measurement, such as any problems or factors that may influence interpretation.	48767-8 Annotation comment	

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Table D.3 — GCS_EyesCodelist Valueset OID: 2.16.840.1.113883.2.4.3.11.60.40.2.12.8.1

Conceptname	Conceptcode	Conceptvalue	Codesystem name	Codesystem OID
Spontaneous	E4	4	GCS_Eyes	2.16.840.1.113883.2.4.3.11.60.40.4.2.1
To verbal stimuli, command, speech	E3	3	GCS_Eyes	2.16.840.1.113883.2.4.3.11.60.40.4.2.1
To pain only	E2	2	GCS_Eyes	2.16.840.1.113883.2.4.3.11.60.40.4.2.1
No response	E1	1	GCS_Eyes	2.16.840.1.113883.2.4.3.11.60.40.4.2.1

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Table D.4 — GCS_MotorCodelist Valueset OID: 2.16.840.1.113883.2.4.3.11.60.40.2.12.8.2

Conceptname	Conceptcode	Conceptvalue	Codesystem name	Codesystem OID
Obeys	M6	6	GCS_Motor	2.16.840.1.113883.2.4.3.11.60.40.4.2.2
Localises pain	M5	5	GCS_Motor	2.16.840.1.113883.2.4.3.11.60.40.4.2.2
Withdrawal response	M4	4	GCS_Motor	2.16.840.1.113883.2.4.3.11.60.40.4.2.2
Flexor response	M3	3	GCS_Motor	2.16.840.1.113883.2.4.3.11.60.40.4.2.2
Extensor response	M2	2	GCS_Motor	2.16.840.1.113883.2.4.3.11.60.40.4.2.2
No response	M1	1	GCS_Motor	2.16.840.1.113883.2.4.3.11.60.40.4.2.2

Table D.5 — GCS_VerbalCodelist Valueset OID: 2.16.840.1.113883.2.4.3.11.60.40.2.12.8.3

Conceptname	Conceptcode	Conceptvalue	Codesystem name	Codesystem OID
Oriented	V5	5	GCS_Verbal	2.16.840.1.113883.2.4.3.11.60.40.4.2.3
Confused	V4	4	GCS_Verbal	2.16.840.1.113883.2.4.3.11.60.40.4.2.3
Inappropriate speech	V3	3	GCS_Verbal	2.16.840.1.113883.2.4.3.11.60.40.4.2.3
Incomprehensible sounds	V2	2	GCS_Verbal	2.16.840.1.113883.2.4.3.11.60.40.4.2.3
No response	V1	1	GCS_Verbal	2.16.840.1.113883.2.4.3.11.60.40.4.2.3

Table D.6 — CIM Metadata

DCM::CoderList	Kerngroep Registratie aan de Bron
DCM::ContactInformation.Address	*
DCM::ContactInformation.Name	*
DCM::ContactInformation.Telecom	*
DCM::ContentAuthorList	Projectgroep Generieke Overdrachtsgegevens & Kerngroep Registratie aan de Bron
DCM::CreationDate	29-11-2012
DCM::DeprecatedDate	
DCM::DescriptionLanguage	nl
DCM::EndorsingAuthority.Address	
DCM::EndorsingAuthority.Name	PM
DCM::EndorsingAuthority.Telecom	
DCM::Id	2.16.840.1.113883.2.4.3.11.60.40.3.12.8
DCM::KeywordList	Glascow coma schaal
DCM::LifecycleStatus	Final
DCM::ModelerList	Kerngroep Registratie aan de Bron
DCM::Name	nl.zorg.GlasgowComaScale
DCM::PublicationDate	31-12-2017
DCM::PublicationStatus	Published
DCM::ReviewerList	Projectgroep Generieke Overdrachtsgegevens & Kerngroep Registratie aan de Bron
DCM::RevisionDate	31-12-2017
DCM::Supersedes	GlasgowComaScale-v3.0

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Table D.6 *(continued)*

DCM::Version	3.1
DCM::PublicationLanguage	EN

D.3.6 ADL Glasgow Coma Scale mindmap

Figure D.2 shows the mindmap for GCS as archetype.

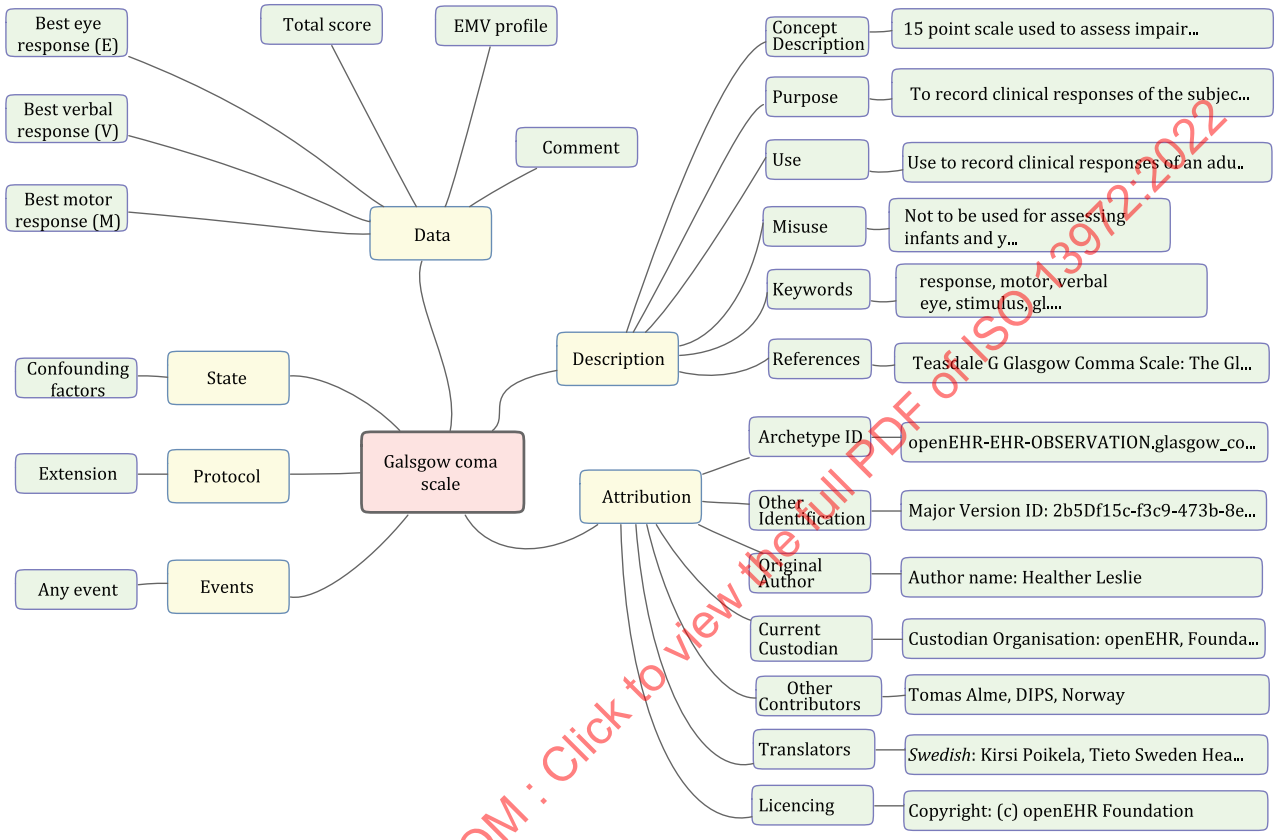

Figure D.2 — Mindmap of the Glasgow Coma Scale

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D.3.7 ADL representation for GCS

The next section (as excerpt) presents the ADL representation for GCS as archetype.

```
definition
OBSERVATION[at0000] matches {  -- Glasgow coma scale
data matches {
    HISTORY[at0001] matches {  -- Event Series
    events cardinality matches {1..*; unordered} matches {
    EVENT[at0002] occurrences matches {0..*} matches {-- Any event
      data matches {
      ITEM_TREE[at0003] matches {-- Tree
    items cardinality matches {3..*; unordered} matches {
      ELEMENT[at0009] matches {   -- Best eye response (E)
    value matches {
    1|[local::at0010],   -- None
    2|[local::at0011],   -- To pressure
    3|[local::at0012],   -- To sound
    4|[local::at0013]    -- Spontaneous
    }
    null_flavour existence matches {0..1} matches {
      DV_CODED_TEXT matches {
    defining_code matches {[openehr::273]}
    }
```


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```
    }
    }
    ELEMENT[at0007] matches { -- Best verbal response (V)
    value matches {
    1|[local::at0014],  -- None
    2|[local::at0015],  -- Sounds
    3|[local::at0016],  -- Words
    4|[local::at0017],  -- Confused
    5|[local::at0018]   -- Orientated
    }
    null_flavour existence matches {0..1} matches {
    DV_CODED_TEXT matches {
    defining_code matches {[openehr::273]}
    }
    }
    }
    ELEMENT[at0008] matches { -- Best motor response (M)
    value matches {
    1|[local::at0019],  -- None
    2|[local::at0020],  -- Extension
    3|[local::at0021],  -- Abnormal flexion
    4|[local::at0022],  -- Normal flexion
    5|[local::at0023],  -- Localising
    6|[local::at0024]   -- Obeys commands
    }
    null_flavour existence matches {0..1} matches {
    DV_CODED_TEXT matches {
    defining_code matches {[openehr::273]}
    }
    }
    }
    ELEMENT[at0026] occurrences matches {0..1} matches {  -- Total score
    value matches {
    DV_COUNT matches {
    magnitude matches {|3..15|}
    }
    }
    }
    ELEMENT[at0030] occurrences matches {0..1} matches {  -- EVM profile
    value matches {
    DV_TEXT matches {*}
    }
    }
    ELEMENT[at0037] occurrences matches {0..*} matches { -- Comment
    value matches {
    DV_TEXT matches {*}
    }
    }
    }
    }
    }
    state matches {
    ITEM_TREE[at0040] matches {   -- Tree
    items cardinality matches {0..*; unordered} matches {
    ELEMENT[at0041] occurrences matches {0..*} matches { -- Confounding factors
    value matches {
    DV_TEXT matches {*}
    }
    }
    }
      }
      }
      }
}
}
}
protocol matches {
    ITEM_TREE[at0038] matches {   -- Tree
    items cardinality matches {0..*; unordered} matches {
    allow_archetype CLUSTER[at0039] occurrences matches {0..*} matches { -- Extension
    include
```

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```
    archetype_id/value matches {/.*/}
    }
    }
      }
}
}
```

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