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Health informatics — Detailed clinical models, characteristics and processes

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Medizinische Informatik - Detaillierte klinische Modelle, Charakteristika und Prozesse (ISO/TS 13972:2015)

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Contents

Page

European foreword **3**

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European foreword

This document (CEN ISO/TS 13972:2015) has been prepared by Technical Committee ISO/TC 215 "Health Informatics" in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

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Full document details: PD CEN ISO/TS 13972:2015

Contents

Page

Foreword ..... **v**

Introduction ..... **vi**

1 Scope **1**

2 Terms and definition **1**

3 Abbreviated terms **8**

4 Definition, purpose, contexts and position of Detailed Clinical Models **8**
4.1 Definition of Detailed Clinical Models 8
4.2 Purpose for Detailed Clinical Models 10
4.3 Reference (Information) Models and Detailed Clinical Models 11
4.4 Types of Detailed Clinical Models 11
4.5 Context of Detailed Clinical Models 12
4.6 Architectural approach to healthcare interoperability and Detailed Clinical Models 13
4.7 Architectural considerations for Detailed Clinical Models based on the GCM 14

5 Requirements and Methodology for Detailed Clinical Models **16**
5.1 DCM application, structure and management 16
5.2 Clinical Requirements 19
5.2.1 General 19
5.2.2 Clinician/user requirements, involvement, and verification for Detailed Clinical Models 20
5.3 Clinical acceptance, adoption, and use 20
5.4 DCM QMS Processes for the systematic approach for quality of DCMs 21
5.4.1 General 21
5.4.2 General requirements 21
5.4.3 General DCM documentation requirements 21
5.5 DCM Governance 22
5.5.1 General 22
5.5.2 Governance and Management responsibility for Detailed Clinical Models 22
5.5.3 Organizing Detailed Clinical Model governance 22
5.5.4 Submission criteria for Detailed Clinical Models 22
5.5.5 Search/access criteria for Detailed Clinical Models 23
5.5.6 Contributors and key competence 23
5.5.7 Clear Accountability 23
5.5.8 Quality 23
5.6 Stakeholder Participation 23
5.7 DCM Development Processes 24
5.7.1 General 24
5.7.2 Hazards in data exchange between clinical information systems 24
5.7.3 Include data exchange specifically in Detailed Clinical Model hazard analysis 25
5.7.4 Keep the Detailed Clinical Model as simple as possible 25
5.8 Detailed Clinical Model content and artefacts 25
5.8.1 General 25
5.8.2 Clinical concept specification of a particular Detailed Clinical Model 26
5.8.3 Context of clinical concept in a Detailed Clinical Model 26
5.8.4 Purpose of the Detailed Clinical Model at instance level 26
5.8.5 Evidence Base for the Detailed Clinical Model topic 27
5.8.6 Description of data elements in the Detailed Clinical Model 28
5.8.7 Instructions for documentation of DCM content 33
5.8.8 Care process / dependence 34
5.8.9 Issues 34
5.8.10 Example of the DCM 35
5.8.11 References 35

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Documents
Document Sharing Hub
Full document details: PD CEN ISO/TS 13972:2015

5.8.12 Copyrights of source materials, Disclaimer, Terms of use and Copyrights for Detailed Clinical Model ... 36
5.8.13 Metadata ... 37
5.8.14 Version management ... 41
5.8.15 Guidelines and principles for Detailed Clinical Modelling ... 42
5.8.16 Inclusion of other Detailed Clinical Models ... 48
5.8.17 Use of terminology ... 48
5.9 Measurement, analysis and improvement ... 48
5.9.1 General ... 48
5.9.2 Detailed Clinical Model maintenance ... 49
5.9.3 Monitoring and measurement ... 49

Annex A (informative) **Data type profile used for the logical model parts for Detailed Clinical Models** ... **50**

Annex B (informative) **Example Detailed Clinical Model in UML and Table format** ... **51**

Bibliography ... **54**

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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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The committee responsible for this document is ISO/TC 215, *Health informatics*.

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Introduction

In current healthcare information technology, there is an identified need for clinical information recorded by one professional or in one information system and transferred electronically to another professional or information system to retain enough of its intended and precise meaning to be safe and useful [HL7, ISO 13606, EC Recommendation COM (2008) 3282 final]. In particular, clinical safety requires that the receiving system and user of all data elements contributing to clinical knowledge makes the exact same interpretation of their meaning as applied in the source system. Semantic interoperability enables actors in a clinical process to cooperate by ensuring they share a common understanding of information and activities pertinent to the clinical process. When actors in a clinical process use a combined system containing two (or more) information systems, semantic interoperability occurs as an emergent (whole system) characteristic of those data exchanges that constitute meaningful communications between actors using different information systems. As is typical for engineering properties of systems, semantic interoperability is not absolute. It enables sufficiently unambiguous understanding of stored, used, and communicated data so that patients, health care professionals, and others including automated systems can interpret and act upon data in health care information systems (health IT systems) consistently and accurately.

Semantic interoperability is defined as "ensuring that the precise meaning of exchanged information is understandable by any other system or application not initially developed for this purpose" [EC Recommendation, COM (2008) 3282 final]. Semantic interoperability addresses issues of how to best facilitate seamless computer mediated processes of coding, transmission, and use of meaning across health services, between providers, patients, citizens and authorities, research, and training (modified from Semantic Health, 2009). A key requirement to achieve this is the standardization of clinical concept representation within health data, including content, structure, context, and transmission processes. This represents the core development need for future electronic health records (EHR) and other health IT systems and for communication between these systems. In addition, standardization of clinical concept representation is a desirable and cost effective way to aggregate data from multiple health IT systems and operate as a cohesive whole, for example for clinical audit and research. Exchanging information using standardized clinical concept representations thereby takes its place as one of the specific kinds of semantic interoperability, with well-defined benefits and limitations.

The ability to exchange information between clinical information systems without loss of clinical meaning is also essential to enable safe and effective implementation of automated decision support. Whether a decision support system requests specific information from an EHR system or an EHR system requests specific computations from a decision support system (and both of these patterns of interaction are used), it is essential that the clinical information exchanged is understood accurately and consistently by both systems.

This Technical Specification provides guidance on representation format and processes to improve the quality of modular data specifications for clinical information, here called Detailed Clinical Models (DCM). The modelling approach described in ISO/TR 17119 as the ISO Health Informatics Profiling Framework (HIPF) is followed. ISO/TR 17119 defines three levels of specificity for artefacts which are CONCEPTUAL, LOGICAL, and PHYSICAL and describes six perspectives for an artefact, the WHO, WHAT, HOW, WHERE, WHY, and WHEN perspectives.

With respect to the processes for DCM, 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 DCM artefacts. In terms of the HIPF, this provides WHO, HOW, and WHEN perspectives at the LOGICAL level of specificity.

The scope of this Technical Specification is the conceptual and logical aspects of a DCM and quality management processes for DCM artefacts. Although the DCM is modelling a clinical concept, we are defining these concepts at the logical level. Therefore, these are **logical** constructs. There is ongoing debate in the Health Informatics community about the exact nature and role of modular data specifications for clinical information. This Technical Specification reflects a pragmatic consensus based on experience, in particular regarding the level of detail in the breakdown and representation

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of a DCM and how instances of a DCM are likely to be used within an actual Healthcare Information Architecture.

The following organizers and participants contributed to the Technical Specification:

— Health Level 7 International (HL7) (USA)

— National ICT Institute in Health Care (NICTIZ, Netherlands)

— National Health Service (NHS) (England)

— Canada Infoway (Canada)

— National E-Health Transition Authority (NEHTA),(Australia)

— OpenEHR (International)

— EN 13606 association (Europe)

— Intermountain Healthcare (USA)

— Center for Interoperable EHR (CiEHR) (South Korea)

— Parelsnoer Initiative (Netherlands)

— Netherlands Normalization Institute, Detailed Clinical Model Quality Center (Netherlands)

— Portavita (Netherlands)

— Clinical Information Modelling Initiative (CIMI) (International)

— Results 4 Care BV (Netherlands)

— And the many other individuals and organizations that contributed.

Clinical concepts as core of EHR and message content

Detailed Clinical Models are highly specialized logical models of clinical concepts. Their development and management require common and more generic definitions/descriptions of clinical concepts. ISO 13940 is suitable as a common base for development of DCMs.

To support communication between actors in clinical processes as described above and also to enable design review by both clinical domain experts and technical modellers, an artefact describing a DCM must contain considerable detail concerning the values and types of attributes and how they fit together to convey the clinical reality being communicated. In this way, Detailed Clinical Models define representations of clinical concepts independent of implementation, enabling safe translation from one technological implementation of a Detailed Clinical Model into another of the same DCM.

Data specifications similar to the DCM described in this Technical Specification have been found to be useful in a wide range of health care information and communication technologies, including but not limited to EHR systems, telehealth applications, messaging integration, medical devices, computer algorithms, and deductive reasoning for decision support (e.g. Huff et al., 2004, Hoy et al., 2007, 2009, Kalra et al., 2008, Rector, Qamar, Marley, 2008, Goossen et al., 2010, Shafarman and Gilliam, 2010, among others).

Standardized Detailed Clinical Models underpin the coherence of Electronic Health Records (EHR, ISO 18308), where data needs to be accepted from multiple sources and stored in a consistent deterministic fashion. In addition, for a functional EHR system (EHR System Functional Model, ISO/HL7 10781), queries must be constructed based on clinical knowledge and tied to clinical context and workflow; services need to be automated based on known values of patient parameters linked to agreed protocols; data display and data entry needs to reference clinical guidelines while safety and quality issues for clinicians moving from system to system can be minimized through consistent information representation. In this way, standardized Detailed Clinical Models become the lingua

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franca of reuse and reusability in and across clinical systems. They promote safety and quality, enable decision support; are a pre-requisite for effective and reliable analysis and aggregation for research and they underpin safe and effective exchange of clinical information. A final important aspect of Detailed Clinical Models is that in any given implementation context, they will need to be combined into larger interlinked structures, sometimes with changing levels of detail as might occur for specifying a hospital discharge summary. A consequence of such requirements is that mechanisms such as specialization are needed to enable DCM to be safely represented at different levels of detail. *A hospital discharge summary consists of many elements, many of which might be seen as DCM, however the data specification of a discharge summary is a separate artefact making use of a number of DCMs and is* ***not*** *a DCM in itself*. How these combinations of DCM can be achieved is not part of this Technical Specification. For example, the HL7 version 2 and version 3 standards both provide means whereby composite message models can be constructed from previously defined parts. Often such combinations are defined in a Domain Analysis Model. In the ISO 13606 environment it is usually called templating.

There is widespread acceptance that models need to be developed and standardized by clinicians on the one hand and also be technology 'neutral' yet usable in real systems on the other. To be patient-safe, a DCM must be defined in terms of an underlying information model (RM, RIM). This Technical Specification is about meeting this challenge by detailing clinical model quality requirements, principles, development methodology, and governance, addressing the conceptual content for the logical levels of modelling, but not intervening in the physical implementation. This means we are modelling clinical concepts at the logical level, but we are not doing conceptual modelling and are not doing physical implementations.

The electronic health record (EHR, ISO 18308) is the core requirement intended to achieve safe, efficient semantic interoperability. EHRs are based on a logical structure whereby data can be entered in a structured format that represents systematic meaning and where the clinical concepts captured are represented in a manner that ensures consistent semantics of what is managed and stored. This ideally requires semantic interoperability between all EHRs, whether organizational, personal, or national and the clinical systems which contribute to, and make use of, that data. The achievement of that vision will be a long journey however Detailed Clinical Models will accelerate progress by determining clearly what we need to exchange for specific purposes such as clinical record keeping, continuity of care or for aggregation purposes.

The need for standardized clinical models has been recognized and endorsed by firstly CEN, and then ISO, who have adopted and incorporated 'archetypes' and an EHR information Reference Model into ISO 13606 where parts 1 to 3 are adapted from early specifications developed by the openEHR Foundation. Finer grained standards for expressing clinical information have been developed as standardized data types (ISO 21090), terminologies (SNOMED CT), and nomenclatures (ISO 11073). This Technical Specification acknowledges that the reference model is underpinned by standardized data types and that Detailed Clinical Models, archetypes and other clinical models need to reference standardized term sets and units of measure. This clinical model approach has also been adopted by HL7 International in developing HL7 v3 templates, reusable components in HL7 v3 message models specifying data types and standardized terminology. Further evidence of shared will and harmonization in this area is that the CEN/ISO and HL7 data types have been harmonized into ISO 21090. DCMs support a migration path towards standards based information systems.

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Health informatics — Detailed clinical models, characteristics and processes

1 Scope

This Technical Specification:

— Describes requirements and recommended methods against which clinicians can gather, analyse and, specify the clinical context, content, and structure of Detailed Clinical Models.

— Defines Detailed Clinical Models (DCMs) in terms of an underlying logical model. They are **logical models** of clinical concepts and can be used to define and to structure clinical information.

— Describes requirements and principles for DCMs, meta-data, versioning, content and context specification, data element specification and data element relationships, and provide guidance and examples.

— Specifies DCM governance principles to ensure conceptual integrity of all DCM attributes and logical model accuracy.

— Describes DCM development and the methodology principles for use that will support the production of quality DCMs to minimize risk and ensure patient safety.

This Technical Specification is not applicable to:

— Details of the content of instances of Detailed Clinical Models. e.g. This Technical Specification will not specify the concrete data elements for the Glasgow Coma Scale, body height, and such (apart from some examples to explain the clauses). It will however give guidance on how to properly specify the clinical knowledge of Glasgow Coma Scale or body height, how to correctly identify, name and model the data elements for these clinical concepts, and how to give unique codes to each data element and, where possible, value set. In other words, it will explain the how to create instances, but not offer the instances themselves.

— Specifications of dynamic modelling, for example workflow.

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

2 Terms and definition

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

2.1
archetype
model of a clinical or other domain-specific concept which defines the structure and business rules of the concept

[SOURCE: ISO/TR 20514:2005]

2.2
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 EHR reference model

[SOURCE: ISO 13606-1:2008]

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2.3
attribute
characteristic of an object or entity

Note 1 to entry: In the context of this Technical Specification: a specific characteristic of a data element.

[SOURCE: ISO/IEC 11179-1:2004]

2.4
care provision
type and scope of responsibility taken-on by the performer of the act for a specific subject of care

Note 1 to entry: The "Act of Care Provision" is the recording of a process that defines the responsibility for supplying support to the target of care. It is a statement of supervision, management, and custody.

[SOURCE: HL7 International]

2.5
clinical
pertaining to healthcare, in particular to characterize activities in which a patient and care professional interact directly or indirectly

2.6
clinical concept
unit of knowledge, expressed by means of characteristics pertinent to its use in health care

2.7
clinical context
the variable situations in healthcare that influence the interpretation of health(care) information

2.8
clinical information
data that is meaningful in a clinical context

[SOURCE: ISO 13940:—]

2.9
clinical knowledge
part of medical knowledge pertaining to promoting good health and the management and prevention of ill health

Note 1 to entry: Used to diagnose, treat, and alleviate disease/dysfunction.

Note 2 to entry: In ISO 13940 (Contys) proposed to be understood clinical information.

[SOURCE: ISO 13119:2012]

2.10
clinical statement
expression of a discrete item of clinical, clinically related, or public health information recorded because of its relevance to the care of a patient or other entities

[SOURCE: HL7 International]

2.11
clinical template
clinical information model that structures information round 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

[SOURCE: Hoy et al., 2007, 2009]

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2.12
concept
unit of knowledge created by a unique combination of characteristics

[SOURCE: ISO 1087-1:2000]

2.13
concept analysis
formal linguistic strategy that allows the defining attributes or characteristics of a concept to be examined

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

2.14
concept definition
description of the attributes of a concept to delineate the meaning

2.15
conceptual model
describes common concepts and their relationships particularly in order to facilitate exchange of information between parties within a specific domain of healthcare

[SOURCE: ENV 1613 CR 12587]

2.16
continuity of care
component of patient care quality consisting of the degree to which the care needed by a patient is coordinated among practitioners and across organizations and time

[SOURCE: ISO/TR 18307:2001]

2.17
context
related conditions and situations that provide a useful understanding and meaning of a subject

[SOURCE: ISO/TR 17119:2005]

2.18
data
reinterpretable representation of information in a formalized manner suitable for communication, interpretation or processing

[SOURCE: ISO/IEC 2382-1:1993]

2.19
data element
unit of data that is considered, in context, to be indivisible

[SOURCE: ISO/IEC 14957:2010]

2.20
data item
expression of a single data element or a composite data element represented in a specific format and identified by the preceding field tag

[SOURCE: ISO 15022-1:1999]

2.21
data type
set of distinct values, characterized by properties of those values and by operations on those values

[SOURCE: ISO/IEC 11404:2007]

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2.22
Detailed Clinical Model
DCM
logical model designed to express one or more clinical concepts and their context in a standardized and reusable manner, specifying the requirements for clinical information as a discrete set of logical clinical data elements

2.23
Domain Information Model
DIM
information model describing concepts and relationships relevant to a specific problem area

2.24
Electronic Health Record
EHR
logical representation of information regarding or relevant to the health of a subject of care

[SOURCE: ISO 18308:2011, modified]

2.25
electronic health record architecture
logical generic components from which electronic health records are designed, defined in terms of an information model and computational services

[SOURCE: ISO 18308:2011, modified]

2.26
entity
concrete or abstract thing of interest, including associations among things

[SOURCE: ISO/IEC 2382:—]

2.27
entry
documentation of a discrete item of health information

Note 1 to entry: An entry may for example represent the documentation of a clinical observation, an inference, an intention, a plan or an action.

[SOURCE: ISO 18308]

2.28
governance for Detailed Clinical Models
system by which development, distribution, responsibility, accountability, delegation of authoritative powers, including legal and ethical aspects and maintenance of Detailed Clinical Models are directed and controlled

Note 1 to entry: The management framework which governs DCM development and maintenance decision making

[SOURCE: ISO/IEC 38500:2015, modified]

2.29
harmonization
process whereby a DCM is designed and presented in such a way as to fulfill a range of criteria originally expressed as distinct requirements and possibly originally put forward as distinct DCMs

2.30
Health(care) information
information about a person, relevant to his or her health or health care

[SOURCE: ISO 13606-1:2008]

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2.31
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 27799:2008]

2.32
information
knowledge concerning such things as facts, concepts, objects, events, ideas

[SOURCE: ISO 1087-2:2000]

2.33
lifecycle [of information resource]
sequence of events that mark the development and use of an information resource

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 15836:2003]

2.34
logical information model
information model that specifies the structures and relationships between data elements but is independent of any particular technology or implementation environment

[SOURCE: ISO/TR 17119:2005]

2.35
medical knowledge
field pertaining to the structure, function, or dysfunction of the human body and how it 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.

[SOURCE: ISO 656:1980]

2.36
metadata
data that defines and describes other data

[SOURCE: ISO/IEC 11179-1:2004]

2.37
model
representation of a domain that uses abstraction to express the relevant concepts

2.38
modeling
construction of abstract representations in the course of design, for example to represent the logical structure of software applications before coding

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

2.39
OpenEHR template
directly, locally usable data creation/validation artifact that is semantically a constraint/choice of archetypes and which will often correspond to a whole form or screen

[SOURCE: ISO/TR 20514:2005]

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2.40
OSI reference model
model that divides and defines the functions of communication equipment, such as computers, into a seven layer structure based on the design policy of Open Systems Interconnection (OSI) established by ISO for network structuring, in order to facilitate heterogeneous network data transfer

2.41
parameter
synonym for data item, in particular when used to adapt a computation, or the operation or appearance of a software application for a particular purpose

2.42
patient safety
prevention of harm caused by errors of commission and omission

[SOURCE: Aspden, Corrigan, Wolcott, et al., 2004]

2.43
persistent data
data stored on a permanent basis

[SOURCE: ISO/IEC 11179-1:2004]

2.44
physical model or design model
instantiation of a logical model that respects specific technological constraints, normally for use in building a specific system or product.

[SOURCE: ISO/TR 20514:2005 and ISO/TR 17119:2005]

2.45
quality
degree to which all the properties and characteristics of a product, process, or service satisfy the requirements which ensue from the purpose for which that product, process, or service is to be used

[SOURCE: ISO 9001:2008]

2.46
Quality Management System (QMS)
Framework described by the ISO 9000 family of standards and comprised of the three core elements: quality control, quality assurance and quality improvement

2.47
Reference Model for Open Distributed Processing (RM-ODP)
standardized approach to design and governance of information systems, in particular systems involving data communications between organizations that have different computing platforms.

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

2.48
safety
freedom from unacceptable risk of harm

[SOURCE: ISO/IEC Guide 51:2014]

2.49
semantic interoperability
ability for data shared by systems to be understood at the level of fully defined domain concepts

[SOURCE: ISO/TS 18308:2011]

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2.50
template
expression of a set of constraints on the RIM/RM or derived model used to apply additional constraints to a portion of an instance of data which is expressed in terms of some other Static Model, to further define and refine these existing models to specify a narrower and more focused scope

[SOURCE: HL7 V3 Templates. HL7 Version 3 Standard: Specification and Use of Reusable Constraint Templates, Release 2 February 2008]

2.51
term
designation of a defined concept in a special language by a linguistic expression

[SOURCE: ISO 1087-1:2000]

2.52
terminological system
ordered collection of concepts, in which each concept is expressed by terms, words or expressions

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

2.53
value set
uniquely identifiable set of valid concept representations, where any concept representation can be tested to determine whether or not 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: Adapted from TN903 HITSP specified metadata: element, description, HITSP Template Metadata and the HL7 Templates DSTU Property name, MIF mapping. Adapted from HL7 Version 3 Core Principals]

2.54
variable
symbolic name associated with a data element or data item, often a data element or data item whose content or value may change over time

2.55
view
alternate presentation of data for a different user or purpose

[SOURCE: ISO 13606-1:2008]

2.56
workflow
depiction of the actual sequence of the operations or actions taken in a process

Note 1 to entry: A workflow reflects the successive decisions and activities in the performance of a process.

[SOURCE: ISO 18308:2011]

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3 Abbreviated terms

For the purposes of this document, the following abbreviations apply.

CEN	Comité Européen de Normalisation
DAM	Domain Analysis Model
DCM	Detailed Clinical Model
DIM	Domain Information Model
EHR	Electronic Health Record
EHR-S FM	Electronic Health Record System Functional Model
GCM	Generic Component Model
HIT	Healthcare Information Technologies
HL7	Health Level Seven
HL7 CIM	Constrained Information Models
HL7 CMET	Common Message Element Type
HL7 LIM	Local Information Model
ISO	International Organization for Standardization
RIM	Reference Information Model
RM	Reference Model
OCL	Object Constraint Language
OSI reference model	Open Systems Interconnection
UML	Unified Modeling Language
URI	Uniform Resource Identifier
URL	Uniform Resource Locator
W3C	World Wide Web Consortium

4 Definition, purpose, contexts and position of Detailed Clinical Models

4.1 Definition of Detailed Clinical Models

A Detailed Clinical Model is a logical model designed to express one or more clinical concepts and their context in a standardized and reusable manner, specifying the requirements for clinical information as a discrete set of logical clinical data elements.

They are models constructed to bridge/link the intersection between the enterprise and information perspectives. Traceability to an underlying clinical process- (regarding clinical context) and/or a clinical concept reference model (regarding clinical content) is required for DCMs. A Detailed Clinical Model must further be expressed against underlying logical reference models (RMs) or reference information models (RIM) however this TS does not specify which RM or RIM.

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Structurally, a DCM provides the data elements and attributes of a clinical concept, including the possible values and types of attributes and the relationships needed to convey the clinical requirements to domain experts, data users, modellers and implementers.

Ideally all Detailed Clinical Models make use of a pragmatic and/or where possible, a purposeful defined maximal data set for a universal use case. For safety, we should favour simplicity which favours "for purpose" DCMs that utilize only the required data elements from the maximal data set, needed to suit the purpose of the DCM. DCMs which represent the clinical concepts at the logical model level are to be implemented and therefore must refer to an appropriate selection from the list described below or equivalent models:

— An agreed conceptual model of health care, such as ISO 13940 (Contsys).

— Agreed clinical reference models based on process and concept descriptions in a standard such as ISO 13940 (Contsys).

— An agreed standard Electronic Health Record (EHR) reference (information) model, such as ISO 13606 and/or openEHR. 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 Detailed Clinical Model.

— An agreed standard information exchange reference information model such as the HL7 v3 RIM or ISO 13606-1.

— Requirements for EHR architectures, such as ISO 18308 or HL7 EHR-S-FM.

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

This is further clarified in the following examples:

a **Atomic DCM**. The DCM consists of one single data element only. This data element has a specific purpose and therefore is specified. One example is the DCM Body Mass Index. The BMI has one data element, which is the result of a formula. To use this DCM BMI, both the DCM for length and for weight are required. Another small DCM is for the HbA1c value for diabetes care. Although normally part of a DCM for laboratory values, the HbA1c does have a special role in continuity of care and as an outcome indicator. Because of this separate role, it is useful to create a single element DCM. Another reason to create an atomic DCM might be the reuse of the data element in various other DCMs, such as body position in the blood pressure DCM and body length DCM.

b **Molecular DCM**. Most DCMs consist of multiple data elements. There is no exact nature determined, due to the diversity of clinical practice documentation. For instance, the DCM body length has five (5) 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, 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 of diabetes patients, blood pressure must be measured in a consistent manner which the guideline defines as in a sitting position only to ensure a reliable comparison over time. Conversely, a Dutch risk assessment scale for child abuse (DMO protocol) includes 80 data elements.

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

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

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

— A data element that, outside the scope of intended use, has a risk for misinterpretation and errors in judgment. Then the DCM 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 **Compositions.** Typically, several DCMs can be grouped together in various compositions such as grouping DCM blood pressure, DCM heart rate, DCM body temperature and DCM breathing into a composition of vital signs. Similarly, in the Health Level 7 (HL7) organization, a Domain Analysis Model (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 DCMs which each 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 Detailed Clinical Models in compositions. There are some differences in approach between various clinical modelling initiatives.

4.2 Purpose for Detailed Clinical Models

The purpose of Detailed Clinical 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 Healthcare Information Technologies (HIT).

The conceptual context and knowledge expression of DCMs and their logical model of data elements provide a common starting point and resource for RIM/RM-based model creation or may be directly converted into machine process able representations. DCMs based on a reference information model / reference model 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 Detailed Clinical Model 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, such as described hereafter.

The logical specification of a DCM 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 clinical concepts which precisely expresses the conceptual and logical model of the DCM to support data collection in EHRs

— Clinical content with unambiguous detail which can be used across domains and disciplines, for instance the use of clinical data communication and exchanges in messages and services

— Support of the logical modelling of the DCM for implementation based on the selected reference model or reference information model

— Standardization and reusability to suit multiple functions and purposes

— Specification of clinical content for User Interfaces

— Clinical data use in (health) care provision

— Support of continuity of care

— Lifetime storage and retrieval of clinical data, linked to the context in which data collection took place

— Specification of clinical content for use in (Clinical) Decision Support Systems

— Clinical content for use as Quality Measures and National Registries

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