TECHNICAL SPECIFICATION

ISO/TS 13972

First edition
2015-10-01

Health informatics — Detailed clinical models, characteristics and processes

Informatique de santé — Modèles cliniques détaillés, caractéristiques et processus

Reference number
ISO/TS 13972:2015(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

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

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

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

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.

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]

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]

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]

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]

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]

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]

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]

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.

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).

— 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

— Clinical content for use in Medical, Health Care and Epidemiological Research

— Specification of clinical content and knowledge for use in Healthcare Guidelines and Protocols

— Clinical content for use in Medical Devices and Applications

— Clinical content used for management and policy decisions such as Cost Parameters in Health Care

— Specification of clinical content and knowledge for use in Public Health management

— Use of clinical data for aggregation for other applications

4.3 Reference (Information) Models and Detailed Clinical Models

The adoption of any one of a variety of Reference (Information) Models (RIM or RM) by the computing structure enables system connectivity. Most health system RIMs / RMs include the necessary computing structure, data types and varying degrees of clinical knowledge structures but may also include other models such as services or business or information flow models. In the interests of semantic interoperability, it is fundamental that DCMs be based on the RIM that underlies the EHR system, message structures or health IT platform within which they are to be implemented.

At the conceptual model level, a point of reference can be the description of the system of concepts (ISO 13940), allowing to specify the clinical knowledge, processes, concepts and their relationships. This offers the health care knowledge to the DCM work.

Similarly, at the logical level, the ISO 13606-1 and openEHR foundation's RM for electronic health records have separated the clinical model from its RM; no clinical knowledge is included within the generic Reference Model. All clinical knowledge must be structured in clinical reference models in accordance with domain-specific characteristics of electronic health record entries linked to the RM via data types only to increase its flexibility.

When exchanging information between different EHR and other systems, similar approaches are deployed using the HL7 Reference Information Model, or ISO 13606 RM. In the HL7 v3 RIM, the computing structure is recorded in informational classes and relationships against which clinical knowledge structures are mapped. Thus, it is possible to separate out the information exchange technicalities from the clinical domain concepts.

4.4 Types of Detailed Clinical Models

Information models are commonly derived from high-level abstract models through to concrete technology implementation models. The ISO Health Informatics Profiling Framework (ISO/TR 17119) defines three levels of specificity for information models and other artefacts: conceptual, logical and physical. Conceptual information models specify the meaning of concepts and their relationships. Detailed Clinical Models specify clinical information structures for these concepts to define the WHY: the clinical context for the model content. Hence, the clinical concepts can be specified based on domain knowledge. When this material is to be implemented in information technology, it must be further specified in logical models which allow computation.

Logical models provide detailed specifications for its components (e.g. container, section and link classes in an EHR's UML object model) and the relationships between the components, albeit with some technological constraints. The logical part of the DCM specifies in detail the WHAT and HOW from a clinical perspective. There is a direct relationship between how these logical structures are specified and the Reference Information Model (RIM) or Reference Model (RM) adopted via the RIM's/RM specific set of characteristics, for example data types. This requires a logical model as an intermediate step in moving from conceptual knowledge to the physical model for technical implementation. Currently there are and will continue to be Detailed Clinical Models related to a variety of RIMs or RMs; a logical model is independent of any particular physical implementation technology.

A physical information model on the other hand includes technological constraints to enable the building of a particular implementation of the logical model (e.g. an EHR system built for a particular hardware and software platform).

A conceptual model is insufficiently specific to be patient-safe and require logical and physical models for implementation in information systems. Detailed Clinical Models do represent these logics, such as relationships between data elements, binding to terminology and specification of the data types amongst others. However, the DCM logics are usually insufficiently specified for full implementation. This Technical Specification recommends that any DCM be defined against a generic reference model or reference information model such as the Conceptual Model of healthcare as depicted in ISO 13940 (Contsys). Other possible models are the logical information models outlined in the Health Level 7 Reference Information Model or the OpenEHR Reference Model amongst others. Specific examples of logical models that would allow implementation include the ISO 13606/OpenEHR archetype format and the HL7 v3 R-MIM based templates. Consequently, it is not always a case of one logical artefact fits all although there are many similarities as the generic content on the conceptual level remains the same. Some representational logical forms produce models with greater consistency than do others however all require a standard terminology to enable consistent binding to all the data concepts and data elements included in the Detailed Clinical Model and its representation as logical model.

The benefits of the clinical concept's aligned core characteristics will potentially be preserved between RIM/RM-specific instances. In this respect, a Detailed Clinical Model can be seen as a model, which has explicit core logical modelling features that may be further specified into one or more logical models that either represent the EHR or the information exchange reference model in full. In other words, the logical model part of a DCM will usually need to add characteristics such as the WHO, WHERE and WHEN which are derived from the larger RIM or RM. For example, the DCM will specify the logics of the 'what' of a blood pressure measure, give guidance on exactly 'how' to document it and explain 'why' it clinically makes sense to take a blood pressure measure. However, not each DCM will specify the patient name, date of birth, the location where the measure took place and the date/time of measurement. Such additional characteristics would normally apply to many thousands of DCMs, creating an overload of redundancy. The 'who', 'where', and 'when' is better specified at a higher level in the RIM/RM. Nevertheless, such referring to a higher level must be done in such a manner that each single DCM can still make use of it.

Once the Detailed Clinical Model is further harmonized with, specified against and/or mapped to such rich and complete reference (information) models, implementation specifications can be defined for the variety of physical models seen in current health care information technology. It has been argued that the Detailed Clinical Model would have its own reference model which expresses how data elements are specified, data types are defined, relationships are visualized and terminologies are bound to data elements and value sets. At this stage, such underlying patterns have not been developed. Work is underway in the Clinical Information Modeling Initiative and its results might be considered for inclusion in the 13972 work in future at the time of revision. The design of different logical models containing the same conceptual clinical content could introduce risks for errors and patient safety if their content differs due to the modeling. Some will argue that this will bring unacceptable risks by potentially reducing the degree of semantic interoperability and impeding version control and traceability. Others will argue that it may be perfectly acceptable, depending on the clinical contexts and the intent of the DCMs and how they will be used in clinical settings. Such transformations and design from the conceptual and logical model into other richer logical models need to be carefully handled and not assuming a plug and play semantic interoperability at this stage. Hence, the quality process introduced in this TS is important for assuring patient safety.

4.5 Context of Detailed Clinical Models

Detailed Clinical Models must be able to cover the data requirements for the continuum of care and multiple purposes for data use. Clinical knowledge is an essential component of any health IT platform. As such, DCMs represent a key foundational building block for the introduction and use of interoperable person-centric health records.

Health IT platforms facilitate information sharing and integration 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.

However, we do see a mixed order of many different systems in current health IT environment, which do not adhere to all standards relevant in a national platform. On many occasions a migration strategy is required to achieve seamless semantic interoperability and it is here that DCM can fill a gap. Figure 1 illustrates that when designing a new system its interoperability capacity need can be determined by the functions to be supported and is useful in positioning the Detailed Clinical Model in the health care IT 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 DCM framework provides a way to leverage the value of much of the clinical modelling work that has already been conducted. This Technical Specification provides a level of abstraction that releases the expression of clinical information requirements from the particular implementation framework in which they were developed. This may simplify the review process and also allow wider and safer reuse of the logical model artefacts.

4.6 Architectural approach to healthcare interoperability and Detailed Clinical Models

To guarantee healthcare systems' interoperability, it is necessary to define the relevant stakeholders' business objectives for that system along with its interrelation (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 interests, thereby ensuring the conceptual integrity of the resulting models.

It is very likely that stakeholders will maintain different views on the system in the development process from the problem description through the definition of business objectives, requirements, design, specification, implementation and deployment, leading to different architectural models and their ontological representation. An architectural framework helps to correctly place the different reference and instance models in the discourse space and to evaluate them in order to guarantee that they appropriately enable the interoperability of the analysed or intended real world system. There are different possible approaches which will achieve such a representation. One is the top down approach based on defining an artefact against the characteristics of a whole standard, such as starting with a Reference (Information) Model. Alternatively, it is possible to work inductively, i.e. define the artefact against a phenomenological approach, revealing its characteristics from the real world, specifying the internal logical model and then mapping it to reference materials. In order to review DCM initiatives appropriately, it is important to place them in a relevant architecture for health care information.

A useful approach to this is the Generic Component Model (GCM) originated by the German OMG community in the early 1990s and further matured by Blobel et al. (see a summary in Blobel (2010)). GCM provides a framework for analysing and integrating different approaches towards creation and maintenance of interoperable healthcare information technology that is architecture-centric, model-driven and uses formalized processes. Blobel (2010) argues that all aspects of the design and development process of personalized health care also beyond the pure IT perspective have to be considered from an architectural viewpoint in order to fit the multitude of drivers seamlessly together, thereby stressing the challenge of sharing knowledge, capabilities and skills.

Blobel (2010) emphasizes the formal aspects of modelling and implementing eHealth and personal health interoperability, focusing on multidisciplinary integration in order to develop domain-specific, organizational, and technical paradigms, requirements and solutions for care. He argues that exploiting all interoperability levels from structural through syntactic and semantic up to the pragmatics of service interoperability becomes possible. Further, in the context of this approach, a special focus is put on ontologies and knowledge representation in the different domains.

4.7 Architectural considerations for Detailed Clinical Models based on the GCM

A good Detailed Clinical Model (DCM) must be based on the real clinical business case. Therefore, it should describe the clinical business system architecture as the composition of that business system's components, their function and their relations, or in other words by that 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. So, a DCM is a model, in which the relations of the concepts are represented using formal logics. For more information regarding the architectural model of a business case and its representation by a conceptual model based on business domain ontologies, see "Detailed Clinical Modeling – A Critical Analysis" (Blobel et al., 2013). For implementing DCMs, the conceptual models of the business domain must be transferred into ICT domain model representations using ICT ontologies, thereby covering the entire suite from the enterprise view through the information view, computational view and the engineering view up to the technology view as defined in the RM-ODP of ISO 10746.

Hence, a good DCM must focus on the business domain and its representation using business domain ontologies. This is the only way to harmonize between different ICT models based on ICT ontologies, as they can be easily mapped using the architectural representation of good DCMs as well as the architectural representations of those different approaches by deploying the Generic Component Model as a systematic, neutral representation of any kind of systems (Blobel, 2010). So, Detailed Clinical Models are not directly implementable. For implementation in running applications, DCMs must be transformed into ICT models, thereby running the entire development process. The Generic Component Model framework for structurally and behaviourally modelling interoperable healthcare systems characterizes any system by three axes is represented by Figure 1 and consists of:

— Domains

— System components

— System development

Based on Blobel's GCM (2010), the relative position of DCM in each of the three axes is further explored and explained.

a Domain

In Domain Analysis Models (DAM), a specific clinical domain is analysed and modelled, leading to identification of actors, workflow, data and data structures. DAM deals with the ***vertical*** axis of GCM. On the bottom level, the required data elements and data structures link to a (collection of) DCM. 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 Generic Component Model for the top level of health care. Although there is potential to link EHR requirements to specific DCM(s), only 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 DCM specifications in the functional model for EHR systems, such as the HL7 / ISO EHR-S FM.

b System components

DCM is a placeholder for expressed clinical conceptual and logical content 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. It is the ***horizontal*** base of the GCM in an enterprise architecture framework for the specification of ODP systems. DCM fits into the first three parts: enterprise, information and (some) computation, the latter specifically for operations on data intrinsic to DCM such as total scores or 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 (OMG, 2010). 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 in particular on the relationships between components (Blobel, 2010). In MDA, DCMs are important as they provide this consistency, traceability and reusability across domains. Full traceability allows the identification of which processes and systems are affected when a single information definition changes. In MDA a relation from the whole to the DCM suffices, there is no need for duplications and thus no inconsistencies. The DCM addresses the conceptual and the internal logical level and expresses links to the larger logical model such as a RIM, illustrating relationships between data elements and constraints. DCMs do not address the physical implementation level. However, in an EHR system or HL7 message, there might be a reference to a particular DCM stored in a repository for full description. This is depicted in the Z axis of Figure 1, illustrating the various System Domains.

This architectural framework and the position of DCM is illustrated in Figure 1 with the information view of RM/RIM on top.

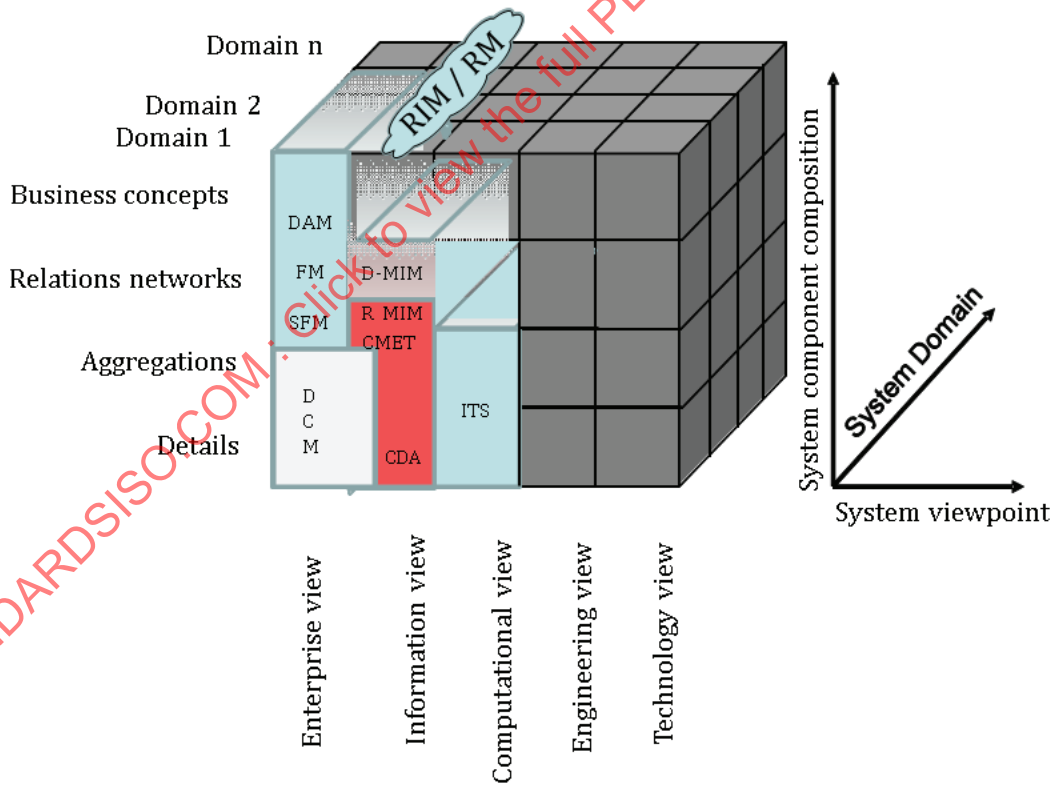

Figure 1 — Position of DCM in architectural framework

5 Requirements and Methodology for Detailed Clinical Models

5.1 DCM application, structure and management

Detailed Clinical Models define clinical content and clinical context. The aims for use are several: clinical developments of health care IT, analyses, improvement and follow up. From the information perspective, DCMs clarify the requirements on structured information to be included in electronic health records, making them useful in clinical management as well as in clinical documentation. Clinical information based on DCMs is created and used in clinical processes. The structure and content of DCMs are (preferably) the result of systematic analyses of different types of clinical processes.

Determination of clinical processes, analyses, determination of indicators, improvements and follow up of clinical data are all integrated requirements of a Quality Management system (QMS) (e.g. ISO 9001 and EN 15224). This Technical Specification for Detailed Clinical Models addresses the following different but strongly related areas:

a Analyses of clinical content and clinical context in different types of clinical processes related to the QMS

b Clinical involvement with and verification of Detailed Clinical Model content by stakeholders, leading to a set of clinical requirements for the DCM

c Aspects of acceptance, adoption and usage of DCM

d DCM Quality Management system for DCM Maintenance

e DCM governance, including repositories for Detailed Clinical Models storage, retrieval and maintenance

f Stakeholder participation

g DCM Development Processes

h A generic format for the conceptual level of DCM, including clinical use, evidence base, data expression including terminology bindings, metadata and versioning and information modelling guidance on the logical level that specifies data elements, their characteristics and relationships, facilitating a reference model based expression

i DCM Process Monitoring and Improvement, with a focus on clinician acceptance, adoption and use

Management of these aspects of Detailed Clinical Modelling must be controlled in order to maintain consistency and facilitate semantic interoperability; informative material on the background and normative material for quality and methodology for Detailed Clinical Models for each area is described within this Technical Specification.

The motivation for a quality-centric DCM development approach is the same as the motivation for DCMs generally: to help ensure clinical quality and patient safety by improving the specificity and interoperability of the clinical information based on DCMs. Misunderstandings between care providers present a risk to human safety and wellbeing. Indeed, recent studies have reported that communications issues are the leading cause of hospital deaths and have been associated with 50 % of detected adverse events in general practice (Walker and Pascal, 2009). Referencing ISO 31000 *Risk Management*, a quantification of risk may be calculated as the product of the LIKELIHOOD of harm and the IMPACT of harm (probability and consequence).

$$\text{RISK} = \text{LIKELIHOOD} * \text{IMPACT}$$

The primary role of standardized DCMs is to help achieve semantic interoperability. This mitigates the potential for ambiguity or incompleteness of clinical information communicated electronically between caregivers. It reduces the LIKELIHOOD of harm and mitigates patient safety risks.

However, the ability of DCMs to mitigate patient safety risk relies on the tacit assumption that the DCMs themselves are "fit for purpose". The role of the present Technical Specification is to describe quality requirements for DCM development and the attributes of high-quality DCM artefacts and is intended to ensure the development of DCMs that are fit for purpose.

The processes described in this section generally follow the QMS framework described by the ISO 9000 family of standards. The use of DCMs may be regarded as a specialization of that framework specifically focused on developing high-quality specification of clinical content and context for patient-safe DCMs and quality in care. The QMS for DCM development will be comprised of the three core elements: quality control, quality assurance and quality improvement. For cross-referencing and illustrative purposes, the corresponding ISO 9001 QMS section numbers as referenced in Figure 2, will be noted in each relevant section of this document.

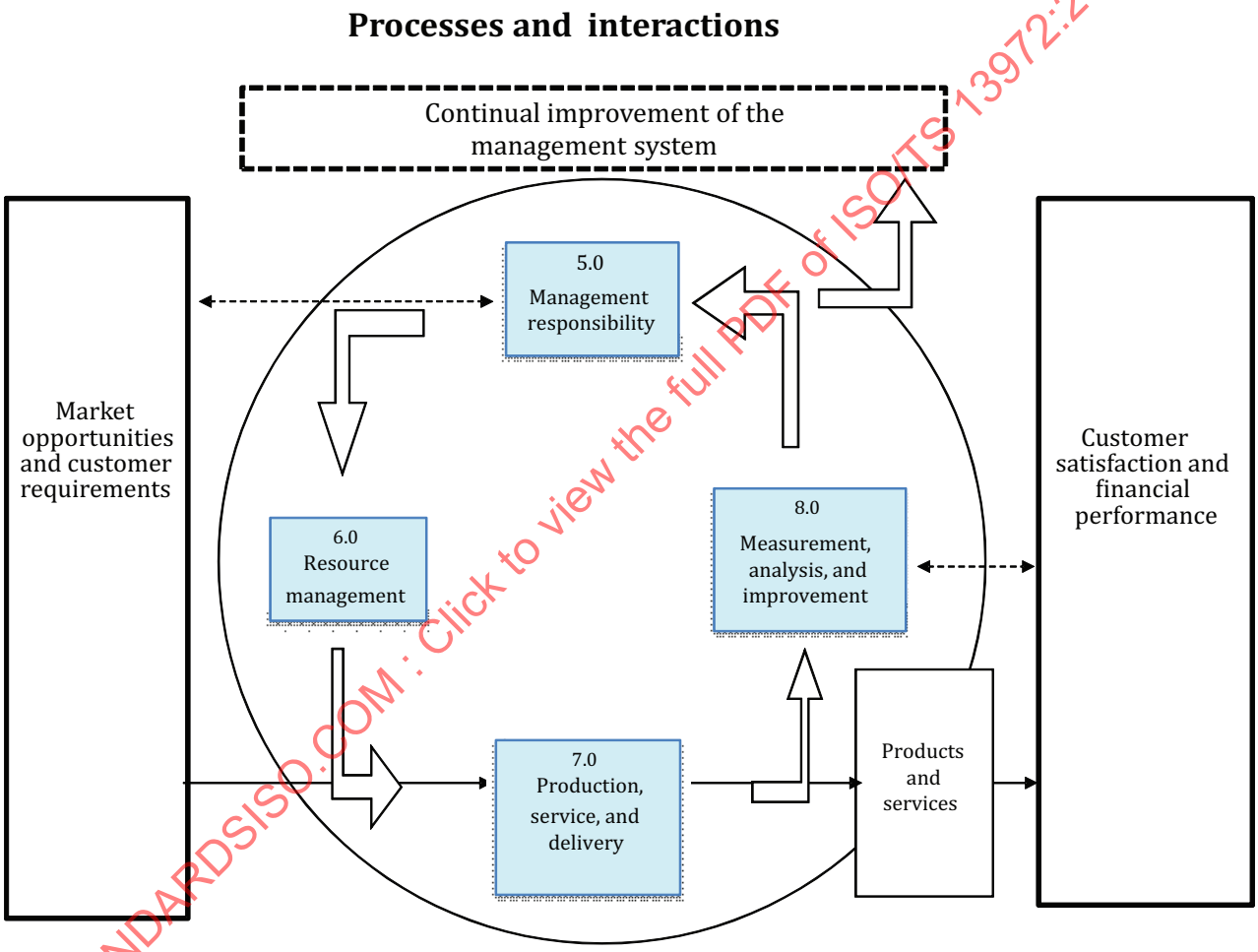

Figure 2 — ISO 9001 Quality Management system Model as example

In order to illustrate how a QMS framework can be used in DCM development, the generic QMS processes described in ISO 9001 have been mapped to the DCM processes described in this Technical Specification. This mapping is illustrated by Figure 3.

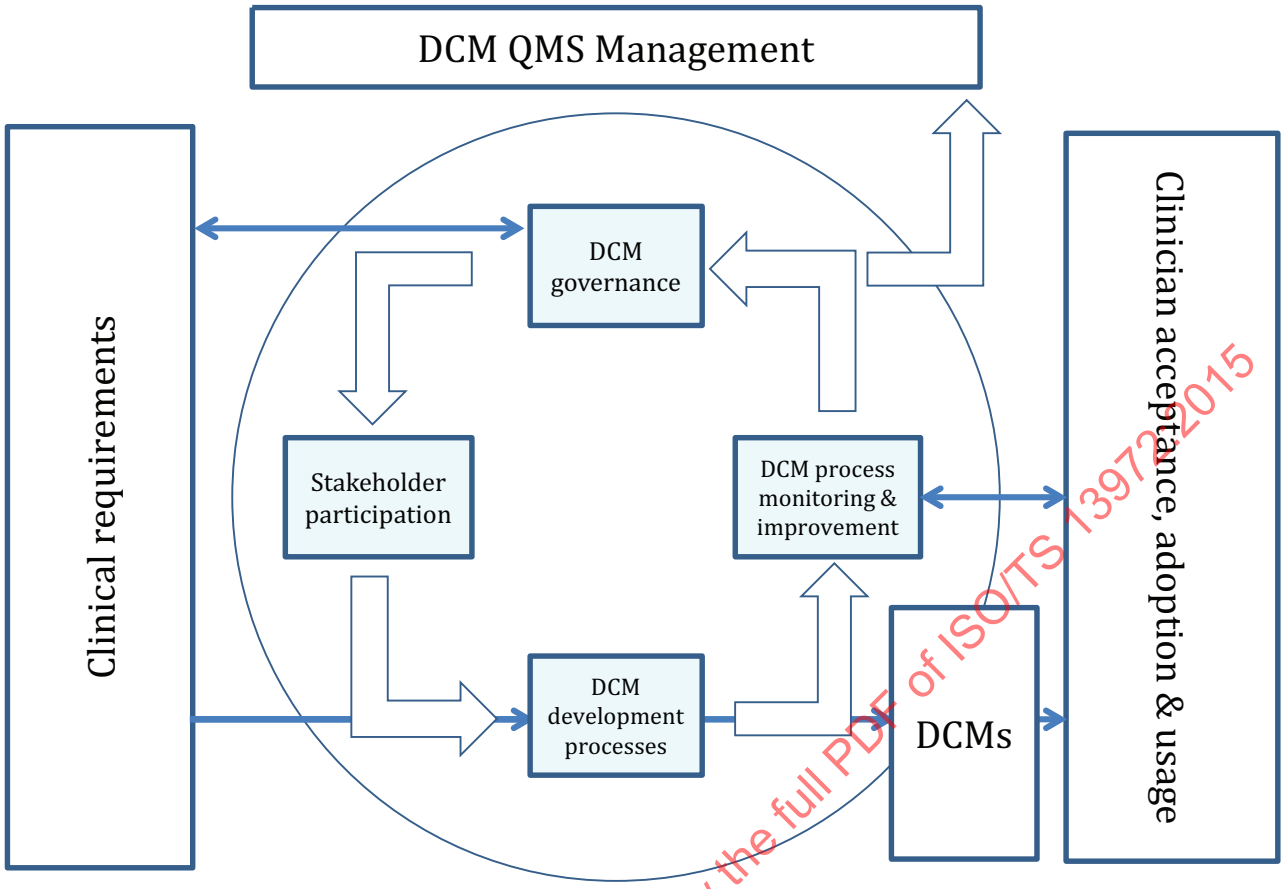

Figure 3 — QMS for DCM development and implementation

The following table describes the mapping between the QMS and how it relates to the Detailed Clinical Model development (QMS-DCM).

Table 1 — Mapping between the QMS and how it relates to the DCM development

QMS (based on ISO-9001/EN 15224**)**	**QMS-DCM**	**Clause**
Quality characteristics and quality requirements	Clinical Requirements	6.2
Customer Satisfaction and Financial Performance	Clinical Acceptance, Adoption and Usage	6.3
4. General requirements	Processes for the systematic approach for quality of DCMs	6.4
5. Management responsibility	DCM Governance and leadership	6.5
6. Resource management	Stakeholder Participation	6.6
7. Production, Service and Delivery	DCM Development Processes	6.7
Products and Services	Detailed Clinical Model artefacts (DCMs)	6.8
8. Measurement, Analysis and Improvement	DCM Process Monitoring and Improvement	6.9

Using a QMS system assists in maintaining patient safety in the Detailed Clinical Model specifications (conceptual content and logical model) and processes around DCM.

Following is a top-level discussion of the QMS-DCM. The QMS framework is itself framed by the clinical requirements for DCMs and the adoption, acceptance and usage of DCM artefacts. These represent at the highest level the “demand” for DCMs and the measure of how well the resultant DCM artefacts are

satisfying that demand. Overarching the overall DCM framework is the DCM QMS management process itself. This crucial process represents the mechanism through which ongoing process improvements in DCM development are operationalized and indeed may become reflected in subsequent revisions of this Technical Specification.

The QMS-DCM core processes themselves give effect to the core mandates of quality control, quality assurance and quality improvement. The DCM Governance process is a consumer of input from the ongoing monitoring and improvement activities and the arbiter of which are to be embraced as modifications to the standard operating procedures and ultimately which will be promoted as updates to this DCM Technical Specification. The governance process is also tasked with the vetting and distilling of clinical requirements and the prioritizing of those as an input to the DCM stakeholder community who will be responsible for developing DCM artefacts. The governance processes deploy a framework comprised of goals, objectives and scope for the DCMs and their specific uses. Beside the DCM artefacts, the requirements management and decision principles are part of this process. In order to allow such governance to be set up, the structure, accountability and working processes need to be made explicit.

DCM processes are undertaken by a community that must be representative of both clinical and technical excellence to which relevant additional stakeholder expertise is added in order to ensure a high-quality, patient-safe work product. Elements of this Technical Specification speak to the make-up and competencies of this stakeholder group.

The DCM development processes yield the artefacts that ultimately satisfy the clinical requirements and are adopted and used. These DCM development processes must exhibit certain engineering principles regarding process repeatability and consistency of practice for it is these principles that give effect to DCM quality control. The DCM development practices section of this Technical Specification describes normative quality process controls. Simple principles useful to guide modelling practice may include the following: Understandable, Repeatable, Usable, Adequate, Accurate, Current, Consistent and Evidence-based.

Quality assurance is achieved by establishing process control feedback. The section in this Technical Specification regarding the monitoring and evaluation of resultant DCM artefacts operationalizes the quality assurance function of the QMS-DCM. As illustrated by Figure 3, this process is connected to the consumers of DCM artefacts and employs in its quality assurance analyses the acceptance, adoption and usage of DCMs resulting from the development efforts. It is also from this activity that candidate process improvements are provided as inputs to the DCM Governance process. Resource management should also include those individuals/organizations responsible for DCM quality and maintenance, for instance governance entities and quality managers.

Refer to ISO/IEC 9126 or ISO 25010 for a set of modelling practice guiding principles.

5.2 Clinical Requirements

5.2.1 General

Any DCM development starts with identifying the goal, scope and concrete objectives and follows with the identification of stakeholder requirements. One approach often used is mind mapping of the domain that needs to be modelled. A domain is deliberately vaguely defined. It can be any clinical relevant area, medical discipline, health care setting, cooperation between professionals, and continuity of care and so on. It can be broad, or small, depending on the scope, goals and budget. Examples include the domain 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, weaning from a ventilator, development of a nursing record system, application of a monitor for vital signs, content for a personal health record.

A domain usually requires input from different perspectives such as clinical, managerial, logical, financial and technical. Given the focus of DCM on the clinical data, it is obvious that clinicians are the main stakeholders, however patients and patient organizations are the “customer” and their needs and requirements must also be met.

ISO/TC 251 has accepted technical report ISO/TR 11487 about clinician involvement. It is therefore relevant to describe how that can be made practical. This first section of Detailed Clinical Model work describes guidelines for determining the desired, useful and feasible clinical data content that clinicians want to document and use in electronic health records, electronic message communications and other uses of Healthcare Information Technologies in order to obtain clinically meaningful information that requires a focus on semantic interoperability within HIT. This is largely based on exemplary international projects that informed this Technical Specification. All involve content specified by clinicians, determining the normative part of the DCM Technical Specification on clinician involvement.

5.2.2 Clinician/user requirements, involvement, and verification for Detailed Clinical Models

Usability of the clinical content is seen as an important aspect. Input must be as broad as possible to ensure that models meet the full scope of the domain under consideration. Additional considerations may include: geographical location, balance of specialities and other domain expertise appropriate to the model, jurisdictions versus organizations versus grassroots, clinicians versus reporting, primary versus secondary/tertiary care, etcetera. The input required may vary depending on the concept being modelled. Therefore, there are several relevant aspects about clinician and other user or stakeholder involvement, verification and validation applicable to Detailed Clinical Models:

a) A Detailed Clinical Model shall be designed with multi-professional, domain experts and other pertinent input

b) A Detailed Clinical Model shall be based on clinical and other relevant evidence as available in scientific literature and/or national and jurisdictional regulatory requirements and/or national or international guidelines according to agreed methodologies in the domain covered

   NOTE The shall applies where such evidence, guidelines exist. Where such evidence does not exist, a DCM shall be based on a consensus-driven expert clinician engagement process.

c) Detailed Clinical Model 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 implementation or computable level, allowing constraint to local settings.

5.3 Clinical acceptance, adoption, and use

Once DCMs are developed or available in a repository, they must be validated, and/or endorsed by the stakeholders, in particular the clinicians who have to work with it. Therefore it is important to set up a formal procedure in which DCMs can be reviewed, quality tested and endorsed. It is envisioned that in upcoming years where use of DCM emerges, many different formats for such endorsement will be created. Some principles here can be set to be normative as ”shall”, others are more optional and have a “should” statement. The acceptance, adoption and use component of the QMS framework is based on the clinical requirements for DCMs, representing “demand”. Measurement of how well the resultant DCM artefacts satisfy that demand is important and will be available in the future through another document.

a) A Detailed Clinical Model shall be verified by all identified stakeholders including author(s), clinicians, users, content reviewers, translators, terminologists and modellers

b) A Detailed Clinical Model shall be validated in a real world clinical setting, for instance a pilot project

c) Detailed Clinical Models shall be expressed such that their use and re-use for multiple purposes is facilitated

d) Detailed Clinical Models should be endorsed by one or more relevant professional bodies in order to allow achieving proper status for its use in implementation

e) Detailed Clinical Models shall be implementable in EHR, electronic messages and other health information technology systems

f) A Detailed Clinical Model should NOT specifically address one technical standard or implementation

5.4 DCM QMS Processes for the systematic approach for quality of DCMs

5.4.1 General

This section speaks to the quality management system and the process documentation required to ensure that repeatable, patient-safe processes are defined and maintained as improvements are made over time. The assumption for all of the statements here is that some sort of designated entity or organization will be undertaking DCM work rather than local activity such as at a local hospital level or local practice level. A small group of clinicians working on some DCMs in a group practice may not be adhering to, or capable of adhering to all of the requirements set out in 5.4.

5.4.2 General requirements

a) An organization developing DCMs shall have established, documented, implemented and currently maintain a Quality Management system for DCM development (QMS-DCM) in accordance with the normative requirements of this Technical Specification

b) Where an organization has outsourced DCM development processes, the organization shall exercise sufficient control over such processes such that conformance to this Technical Specification can be ensured

c) An organization developing DCMs shall define its structure, such as membership, criteria and resources, including human (domain experts and secretariat) and infrastructure

d) An organization developing DCMs shall respect the patient privacy directives regarding the use and disclosure of sensitive information as personal health information

e) An organization managing DCMs shall ensure the privacy of the participants described in DCM work according to existing current regulations and measures

f) An organization managing DCMs shall ensure the security of participants described in DCM work and DCM materials according to existing current regulations and measures

5.4.3 General DCM documentation requirements

a) An organization's QMS-DCM shall include documentation regarding its quality policy and quality objectives

b) An organization's QMS-DCM shall maintain a DCM quality manual

c) An organization's QMS-DCM shall include procedures for document control, records control, internal audit, control of non-conforming DCM artefacts and corrective and preventive actions regarding such artefacts

d) An organization's QMS-DCM shall include effective planning, operation and control of its DCM development processes

e) The DCM Quality Manual shall include the scope of the QMS-DCM

f) The procedures of the QMS-DCM or references to them shall be documented

g) A description of the interactions between the processes of the QMS-DCM and any gating processes requiring oversight, sign-off or other governance shall be included

h) The DCM Quality Manual shall include DCM Document control Management

5.5 DCM Governance

5.5.1 General

This section defines the requirements for stakeholder participation in DCM processes and their "sign-offs" including where they must occur in the development and maintenance management process.

5.5.2 Governance and Management responsibility for Detailed Clinical Models

The management framework, which governs DCM development and maintenance decision-making practices, addresses the direction and control for the development and maintenance of DCM. The framework for DCM governance comprises three critical components:

a) Structure of the 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)

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 remain in place when governance moves from a project to a continuous maintenance organization, albeit adjusted to the change in organization.

This section on governance addresses the DCM quality and maintenance within a repository context. The repository requirements itself are not part of the Technical Specification. A repository is a place in which DCMs can be stored, quality tested, maintained, presented and distributed. It is important for the governance of the DCM that verification, publication, maintenance and the distribution environment are identified and established in order to facilitate the health care community's ability to create, use and share the Detailed Clinical Models. A repository for DCM may be constructed in such a manner that its knowledge base, data elements, relationships, keywords and meta-data can be searched. It is beyond the scope of this Technical Specification to define the full requirements of such a repository though 5.5.4 and 5.9.2 present some criteria for such a repository.

5.5.3 Organizing Detailed Clinical Model governance

In order to be fully user-centric it is crucial to explain how good maintenance and governance of Detailed Clinical Models is to be organized. This section discusses methodologies for governance and maintenance of the DCM and their repositories. Issues to be addressed include creation, approval, distribution, local customization, change control, harmonization on local, national or international levels.

This section describes the quality criteria for governance of Detailed Clinical Models:

a) The DCM governing organization should have appropriate mechanisms in place by which DCMs can be extended and maintained to fully support the requirements of the health care community

b) The author of a Detailed Clinical Model should ensure that appropriate effort has been made to identify relevant evidence, consult relevant stakeholders and examine existing systems and/or specifications in use

5.5.4 Submission criteria for Detailed Clinical Models

A governing organization shall provide transparent processes for submission and inclusion for Detailed Clinical Models.

5.5.5 Search/access criteria for Detailed Clinical Models

A DCM governing organization shall facilitate clinicians, researchers, project leaders, technicians and other target groups/stakeholders in finding the appropriate Detailed Clinical Model via multimodal approaches, such as keywords, versions, categories and metadata.

5.5.6 Contributors and key competence

a) Each Detailed Clinical Model development should be led by an editorial team with domain specific expertise (e.g. immunology) relevant to the DCM in question (e.g. adverse reaction Detailed Clinical Model).

b) A Detailed Clinical Model editor should be supported by a team of contributors with broader but balanced relevant clinical interests (e.g. general practice, internal medicine, respiratory medicine, nursing).

c) Detailed Clinical Model development work shall provide a reviewing mechanism, which will allow the communications between the reviewers and the authors to be captured.

5.5.7 Clear Accountability

a) Each Detailed Clinical Model editorial team shall maintain overall responsibility for managing and if necessary delegating the processes/activities of DCM development including moderating inputs and resolving conflicts in opinion from contributors.

b) A DCM developing and or maintaining organization shall provide the versioning control mechanism.

c) A DCM developing and/or maintaining organization shall support changing status of DCM versions.

5.5.8 Quality

a) Each Detailed Clinical Model should be subjected to clinical risk assessment to ensure it is fit-for-purpose and meets clinical information safety requirements

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

b) Best practice in how to undertake a generic clinical risk assessment of a DCM itself is still an emerging area which will require further research and empirical experience.

c) Architectural/model flexibility and scalability

d) Localizing a DCM 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

5.6 Stakeholder Participation

This section explains how stakeholders can identify their requirements and participate in the DCM processes. A consensus-based approach is usually undertaken for DCM development and governance as all stakeholders can be represented if appropriate for the situation. Consensus methods are well described by Murphy et al (1998). Specific for the DCM work is that the four core components need to be addressed: the medical background knowledge and context, the data elements and their relationships, the code binding between date elements and terminologies, and the meta-information about responsibilities, versioning and such.

a) All interests should be discussed and agreements reached using consensus methods without undue influence or domination by a particular group of members

b) Consensus, dissent and any other comments should be recorded and made available in public record

c) Conflict resolution procedures shall be explicit and publicly available

d) Approval of Detailed Clinical Model development

e) Detailed Clinical Model repository shall provide different certification levels to the DCMs to indicate the levels of review and approval this Detailed Clinical Model has received

f) Detailed Clinical Model repository shall provide a notification mechanism to notify/alert users, e.g. alert users with changes to the existing models, notify users with new models

5.7 DCM Development Processes

5.7.1 General

This section covers management, requirements definition and analysis, modelling processes, quality control processes and (where applicable) controls necessary for DCM development work outsourced to third parties (procurement processes).

It is important to realize that this clause reflects a pragmatic consensus based on experience in several areas, but which has not been deployed in full for DCMs.

5.7.2 Hazards in data exchange between clinical information systems

Industry standard data integration technologies and methods are routinely used to support exchange of clinical information such as between information systems within a hospital or on a larger scale in national EHR initiatives. Transformation of data between different representations (for example, from XML through an "object" in a program into a relational database) is a fundamental part of what data integration technologies do. The hazards arise because such transformations have high complexity in principle[1)] and are also fallible in practice. The hazard is that data on which patient safety depends is "broken" in transit, that is, parts of the data are corrupted or silently lost.

One of the few studies to document the severity and extent of this problem in practice was undertaken by the World Wide Web Consortium[2)]. The specific task that the W3C undertook was to examine the basis for numerous informal reports from the XML implementation community of widespread faulty behaviour in tools that map between XML data instances which conform to an XML schema along with some internal data representation, for example a data structure in a program or a database. W3C went so far as to state that:

"A representative collection of data binding implementations in common use has been used to provide an indication of the "state of the art". State of the art data binding implementations have displayed uneven and inconsistent support of the W3C [XML Schema 1.0] Recommendation resulting in impaired interoperability and a poor user experience of data binding tools:

* rejecting valid [XML Schema 1.0] documents,

* rejecting valid [XML 1.0] instance documents, and

* making the content of valid [XML 1.0] instance documents unavailable in mapped data structures."

This should not be interpreted as singling out XML as particularly vulnerable to such faults – just that the W3C work has clearly identified how research results on complexity emerge as practical difficulties in implementation.

A particular feature of the reported research is that there is an exponential gap between the complexity of the data structures at each end and the combined complexity of data exchange. This is consistent with the results of the W3C work, where initial results clearly identified the more complex XML

1) There is an established academic literature on this topic, For example http://portal.acm.org/citation.cfm?id=1142357

2) http://www.w3.org/2002/ws/databinding/

schema constructs as most prone to error in implementation, with more extensive analysis and testing gradually finding more and more constructs which cause occasional problems.

5.7.3 Include data exchange specifically in Detailed Clinical Model hazard analysis

Data exchange using technical representation(s) of Detailed Clinical Models carries specific hazards concerning data loss, unauthorized access and data corruption. Therefore, the DCM must be subject to rigorous multidisciplinary safety risk management, privacy risk management and security risk management from 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 Detailed Clinical Model content and structure

It is likely that trade-offs will be necessary between design criteria that address clinical content hazards and design criteria that address data exchange hazards.

5.7.4 Keep the Detailed Clinical Model as simple as possible

Data exchange complexity is exponentially related to the combined complexity of the information models at each end of the exchange. Within health information, the DCM used in modelling a communication can be expected to constitute a significant contribution to its overall complexity. Types of hazards related to data exchange complexity include silent data loss within integration technology and human error by developers of integration software.

There must be a balance between the maximal data set (how much to include), simplicity (not too much to include) and flexibility (allowing to select a subset from the maximum data set). This is an intricate process in which clinicians / users of the Detailed Clinical Model must determine what fits the purpose for them. There is always an option to create separate DCMs for a particular topic.

a) When developing Detailed Clinical Models, simplicity shall govern the design based on the criterion to make explicit how it might or will be affecting system safety.

Current modelling practice tends to accept complex models as inevitable and to regard full expressivity as an ideal. This attitude will need to change.

b) Detailed Clinical Models shall express the concept within a manageable and clinically relevant set of content and data elements that safely defines its purpose with the potential for multiple usages.

It is likely that trade-offs will be necessary between expressivity and simplicity in DCM modelling regardless of which modelling technique or representation is used.

c) Trade-offs between expressivity and simplicity in the Detailed Clinical Model shall be made explicitly with due regard to the hazards involved in complex models.

5.8 Detailed Clinical Model content and artefacts

5.8.1 General

Detailed Clinical Models organize the structural modelling content of health information for the purpose of 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 DCM needs to be relevant for the clinician, be useful for the electronic health record and electronic data communication and must 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 DCM Technical Specification applies. Workflow is definitely not included. However, some dynamic modelling can be part of a DCM, for instance where a repetition in time is required, for example measure the Apgar score at 1 min, 5 min and 10 min. Complex models are also not included. This Technical Specification acknowledges that constructs based on multiple Detailed Clinical Models are relevant but is not specified here. The models requirements are based on best practices in the communities of Health Level 7, OpenEHR, EN 13606

association, Clinical Information Modelling Initiative and Parelsnoer Initiative. A body of evidence needs to be established in the future.

DCM content must adhere to different criteria as described in the following sections.

5.8.2 Clinical concept specification of a particular Detailed Clinical Model

The intent of a DCM must be clear. Determination of clinical concepts can be extremely complex when addressing abstract concepts and ecosystems of interrelated concepts and a proper concept analysis and definition might be necessary in some instances. Involvement of clinicians in this process as described in earlier clauses in this Technical Specification is a requirement.

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

5.8.3 Context of clinical concept in a Detailed Clinical Model

It is important that the concept of the DCM is placed in the context of its clinical use. This can be multifold: firstly the specific use case for the DCM and secondly how the DCM relates to other clinical concepts. Since Detailed Clinical Models specify one coherent and precise concept or set of related concepts, describing the overall picture can be important for a better 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 vital signs. Mind mapping has been identified as a valid method for domain and concept analysis and identifying such relationships. In particular Domains Analysis Models (DAMs) can serve as the reservoir of clinical concepts from where the DCM can be derived. Another context is the different formats for reuse of Detailed Clinical Model concepts. If a quality indicator, the whole set of quality indicators can be the context. The Governance of a Detailed Clinical Model normally ensures that published DCMs such as clinical templates, archetypes or HL7 templates are examined for potential duplication or overlap and with an aim to re-use relevant existing specifications. DCMs are created purposefully. However, there might be situations in which DCMs might be used in a context other than the original intended context. In many occasions that additional use might be possible and add value to the DCMs. However, there might be situations where that can be dangerous for patients. If such situations are known a statement with respect to misuse should be added to the DCMs.

a) The Detailed Clinical Model in question may be placed in context of use in clinical domains and in context of other related DCMs within the specification of their relationships

b) The use of the Detailed Clinical Model in other contexts other than the initial intended clinical purpose shall be made explicit

c) The misuse of a Detailed Clinical Model in specific context should be made explicit

5.8.4 Purpose of the Detailed Clinical Model at instance level

Detailed Clinical Models usually describe clinical concepts such as assessment scales, instruments, questions, observations or actions to allow the health care professional to document desired information about the patient and his/her care. It must be clear why this 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. When something is specifically developed for a specific person or organization, it is to be explicitly mentioned. Purpose, importance and patient category must be specified in this section.

For example: The Glasgow Coma Scale (GCS) is used to measure and determine the level of consciousness in patients who have sustained a head injury.

For example: Measurement of consciousness is an important contribution to diagnosing and monitoring the condition of a patient.

For example: There are different use specifications for the GCS in adults and children. This model describes the use of the GCS for adults.

a) The Detailed Clinical Model shall describe the purpose in clinical practice of the concept that is specified where appropriate

b) The Detailed Clinical Model should describe how the concept is to be used in quality healthcare delivery

5.8.5 Evidence Base for the Detailed Clinical Model topic

In order to obtain content specification of the highest quality, the DCM specifies the evidence base or scientific support for the concept described. The description of the (scientific) support is based on assessment criteria such as used by the Cochrane Collaboration (http://www.cochrane.nl). 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 a Detailed Clinical Model; there are further journals for evidence based practice which often use assessment score systems based upon the criteria of the Cochrane Collaboration and publications on methods and methodological quality.

Of particular interest are the criteria for successful and effective usage of the concept in clinical practice and potential other uses. If possible, describe the type of professionals who may use it. In several instances there will not be evidence as suggested above however there could be other sources such as best practice or simply common sense. It is important to include statements about the source for the DCM content.

For example

The evidence for this DCM is based on direct communications with clinical domain experts from XYZ project.

The Detailed Clinical Model provides a short description of the kind of research carried out for a particular assessment scale including justification why that scale is valid and reliable for certain patient populations. The description may be based upon a nationwide guideline based on consensus between experts and/or on evidence founded through research. It can also be based on (nationwide) developments where materials such as manuals or checklists emerge as well as scales, observations and measuring devices used in national epidemiological research and in the context of performance indicators. Additional examples of relevant knowledge include care pathways, standard data sets, professional policies, and reporting templates. A link made to these applications or sources increases the supporting evidence.

Further, a proper literature search e.g. including Medline, Invert, Cochrane Library, DIMDI, CINAHL and others should normally be part of the content of a Detailed Clinical Model.

— National Library of Medicine: http://www.ncbi.nlm.nih.gov/pubmed PubMed contains 17 million publications of MEDLINE and other scientific medical articles which date back to 1950. Pubmed contains links to full text articles and other sources.

— http://scholar.google.nl/ when the author is known.

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

a) A Detailed Clinical Model shall describe the evidence base, e.g. published knowledge and/or clinical experience of the clinical concept where it has informed the development of the DCM

b) A Detailed Clinical Model should include information about *de facto* specifications (such as existing clinical information systems, EHRs or electronic messages) that have been part of its design basis

c) Detailed Clinical Models may specify the method of analysis and appraisal on which the evidence base is built

Only if the full evidence base itself is publicly available on a sustainable online website may a link to that website be used as substitute for a summary of the evidence base for the clinical concept described in the model.

5.8.6 Description of data elements in the Detailed Clinical Model

5.8.6.1 General

Data element, data item, variable, clinical element and parameter are considered synonyms; "data element" will be used for the remainder of this Technical Specification.

The core of a DCM is the explicit and structured listing of data elements for the clinical concept. DCMs should express the clinical content and data elements characteristics in a conceptual and logical manner such that they become useful in RIM based logical models. A specified data element in a Detailed Clinical Model consists of name, definition, data type, terminology binding and unique coding and where applicable the unit, value set and Object Identifier (OID) specification. Experience shows that for one concept "one to many" data elements must be specified. The scope of a Detailed Clinical Model is intended to be an optimal data set and where no safety issues arise, specifying a maximum data set allows flexible implementation.

The DCM's data element specification must be consistent with the exact same order, composition, arrangement, scores, and name giving used in the guidelines or the scientific literature. The relationships between data elements and their occurrence are to be identified as well with the composition represented in a conceptual information model from which a logical model can be derived. The modelling approach to Detailed Clinical Model is described in 5.3. In some cases there is a difference in versions translated into other languages and there must be careful consideration as to whether there are potential consequences for semantic interoperability. If the case, the different versions should be specified in separate Detailed Clinical Models.

For example The Dutch and English versions of the Barthel index have different local variations such as the naming of the data elements, the score per answer category and the total score.

If necessary, scientific or professional organizations can be asked to give a definitive answer what will become or is the national standard or preferred wording.

a) A Detailed Clinical Model shall be composed of one or more data elements which together represent the clinical concept.

b) Each data element of a DCM should be described in a detailed, accurate and comprehensive manner.

c) If a Detailed Clinical Model expresses an assessment scale, score, index or other scientifically developed instrument for which a total score is calculated, the total score itself should be added as a separate data element with appropriate coding and data type specification.

d) If a Detailed Clinical Model expresses the outcome of a calculation, the outcome shall be added to the DCM as a separate data element.

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

f) Relationships between data elements in a DCM shall be expressed.

The next sections delineate each possible characteristic of a DCM data element.

1) Name of the data element: Each data element is given 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. However there may be exceptions where this is not possible resulting in the should option for this statement, but with strong emphasis on attempting to describe in practice as a shall option.

2) Each data element within a Detailed Clinical Model shall have a unique name

3) Each data element should be capable of being mapped to additional terms which offer an equivalent meaning to its name

4) Identification of the Data Element

5) Each data element is given a unique identifier in order to allow technical applications. Although the naming of data elements in the Detailed Clinical Model is unique, it is possible for similar names in different DCMs to exist. The identifier differentiates the multiple data elements which could have the same / similar name.

6) Each data element within a Detailed Clinical Model shall have a unique identifier

5.8.6.2 Data Element descriptions

The description or definition of each data element clarifies its meaning with the clinical vocabularies of terminologies, classifications and coding systems applied. SNOMED CT refers to each concept using the fully specified name.

a) The Detailed Clinical Model shall include a definition or description that specifies the semantics of each data element. Example data element value: An example value will be added to each data element expression. For instance if the data element is body temperature, the example value can be 37 °C.

b) A data element may have a minimum of one example of the value described

5.8.6.3 Data type

Different data formats are used in clinical care such as text, numbers, pictures, graphs, observations and sets of predetermined answers to questions. Health Information Technology has learned to how to properly process such formats. Different standards organizations have created lists of data types which have been harmonized into ISO 21090 though any equivalent system would be acceptable.

Experience has shown that despite the numerous variations in data types, only a limited set is used in the majority of instances. Usability of this particular set for different purposes needs to be tested.

a) The data type for each data element shall be unambiguously expressed.

b) Coding of data elements in the Detailed Clinical Model shall be unambiguously expressed.

To ensure semantic interoperability, each data element's meaning must be defined at all times through the application of clinical vocabularies. Unique coding is particularly important in messaging and the reuse of data for decision support, query, quality indicators, epidemiological data and so on. Normally the Object Identifier identifies the vocabulary. An alternate method is to use display text to describe the vocabulary. Next, the vocabulary specifies the specific unique code for the data element and uses the display text to describe the data element.

A data element may be assigned multiple synonyms so reference to the source of the fully specified concept must be provided as there is no preference for a specific clinical vocabulary. An important issue is that precise codes must be selected, not related concepts. This particularly pertains to clinical data elements but is usually not necessary for time stamps or person identifiers which apply other formats. Since vocabularies constantly evolve to meet changing needs, it may 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.

c) Each clinical data element shall have one unique code assigned from multiple coding systems from a recognized or locally defined terminological or classification system

NOTE As described above the terminology can be derived from any controlled terminology or vocabulary. Sometimes a distinction is made between an interface terminology and a reference terminology. This Technical Specification accepts any kind of controlled terminology to support this statement.

d) Each data element may have more equivalent codes assigned as synonyms.

e) The Detailed Clinical Model shall include the requisite terminology for each clinical data element, thus facilitating the application of multiple terminologies, coding systems and synonym codes in a DCM.

f) Each coded data element shall have an associated code description which clearly identifies the terminological or classification system by name and/or the OID and version for that vocabulary.

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

5.8.6.4 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. A different characteristic includes the use of a value which is not necessary for all data elements. Frequently used values include numeric, text, date and times, enumerations of lists and formats such as pictures which is to be recorded in the DCM according to ISO 21090 data type specification or equivalent.

For example If the patient is observed, questioned or measured, it normally results in a value which must be documented. It must be known whether some data elements are carried out or not, which can be dealt with via a Boolean indicator recording “Carried out, true or false”.

When the data element contains two or more values, all value options must be enumerated and uniquely coded. Frequently used values include numeric, text, date and times, enumerations of lists and formats such as pictures. These will be handled in detailed clinical model according to the ISO 21090 data type specification, or equivalent.

In several instances of clinical knowledge particularly for measures, clinical observations, diagnosis and assessment scale, the result of clinical work reveals a specific rate, assessment 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.

a) Where a value is part of the characteristics of a data element, a description of the value shall be part of the DCM specification.

b) For data elements representing a quantity, the value shall be expressed in UCUM or equivalent standard units of measurement.

5.8.6.5 Value set expression

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).

A Concept Domain expresses the options that must be encoded within a value set, but is not tied to a specific terminology; this coding within a value set is known as value domain coding. In several instances, the value set identifies options within the observation findings and adds a specific numeric value; the latter is known as the Coded Ordinal (CO) data type 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 may be added to the CO value in the form of a display text. See the ISO 21090 for more details on data types.

a) Internal value sets for data elements should be individually represented and defined or described or be part of logic that reveals intensional values.

b) External value sets for data elements should be referenced in the DCM.

c) The value set specification should be based on a standardized terminology such as SNOMED-CT, LOINC or other local terminologies.

d) For data elements in Detailed Clinical Model that have the CD (Concept Descriptor) data type, each value in the value set shall be uniquely coded or a reference to an external value set enumeration must be included.

e) When defined in the DCM itself, a value set shall link each value to a (standardized) terminology.

f) A value set shall identify which terminologies can be used for the values.

g) A value set is a micro vocabulary and should have a separate identification.

Figure 4 details the DCM for an Apgar Score in a logical model using UML.

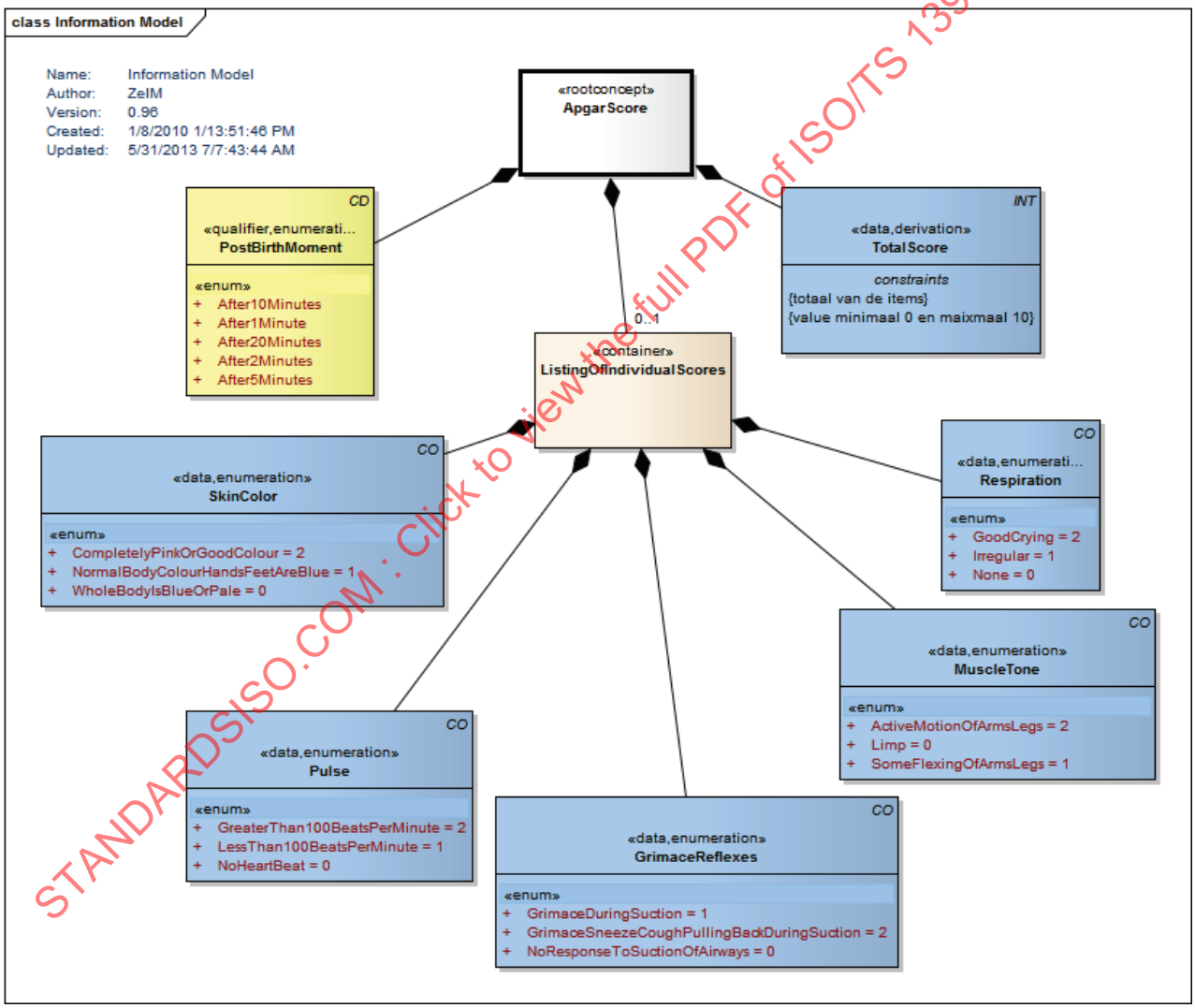

Figure 4 — Logical Model of the Apgar Score

5.8.6.6 Limitations for use

In some instances it is necessary to limit or narrow down the usage possibilities of a Detailed Clinical Model; those currently identified would be presented in this section. A text section would be sufficient to outline the limitations.

a) Each Detailed Clinical Model should clearly express when applicable any identified limitations of use of the model in systems.

b) Constraints in the Technical Specifications shall be clearly expressed.

In some instances it is necessary to limit or narrow down the characteristics of a DCM, its data elements, occurrences, relations, or value set or value set bindings. Identified limitations are presented in this section; several instances of constraints in the modelling of the structural components will apply in several instances.

It may be considered best practice to implement only some selections or subsets from the usual core data set. This allows in particular constraints and/or selections of some data elements of the detailed clinical model's maximum data set. These constraints are not identified at DCM level but in additional separate implementation specifications.

For example Only three of the data elements out of a set of 15 will be implemented in a particular EHR and included in a HL7 v3 message. E.g. 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.

c) Context-specific constraints on data elements should be clearly expressed

For Example:

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

d) Constraints on value set expressions and their code bindings should be expressed

For instance, the dedicated codes for each of the values in the value set for each of the data elements of the Braden Scale that are created in the Logical Observation Identifiers Names and Codes (LOINC) code system.

e) 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 DCM) and use of style patterns (e.g. data elements that are defined in a specific manner). They may be expressed as data element A 'has a' relationship to data element B or an 'is a' relationship.

f) Constraints on types of relationships between data elements should be expressed

Cardinality specifies the multiplicity or wide range of a relationship. For instance, 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.

g) Constraints on cardinality of relationship between data elements should be expressed in the Detailed Clinical Model itself

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

h) Constraints on values should be expressed in the Detailed Clinical Model itself

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

i) 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).

5.8.7 Instructions for documentation of DCM content

In order to obtain correct, safe and meaningful data in the EHR, communicate and use for identified purposes, it is assumed that data elements based on the Detailed Clinical Model are recorded in a valid and reliable way. In particular, if DCMs are deployed in medical devices, proof of valid and reliable recording of data must be present in order 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 DCM[3)].

Provenance prevents unwanted variability in the documentation per data element and the DCM concept as a whole. A description of when the scale, instrument, observation or action is not applied or when it is incorrect to do so supports the valid and reliable data recording of such assessment instruments. Sometimes a clear protocol with extended instructions and interpretation guidelines already exists. In such cases a short abstract can be given in the DCM with reference to a protocol.

a) The Detailed Clinical Model should contain a reference to identified usage guidelines and/or inclusion of instructions for appropriate use of the clinical model within a clinical system where appropriate.

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

Guidelines usually provide the clinical content that can be summarized 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 patient and care. If appropriate, distinguish the information by target groups. Also describe how a score is used in the process of the caregiving. If a decision is based directly on the score, add here.

b) Express any differences in the variation of results of a score, assessment or index per patient target population in the DCM.

c) If particular guidance applies for the interpretation of the Detailed Clinical Model outcome / results, these should be expressed as point of reference

d) A short description of the interpretation of results of scales, indexes, scores should be present in the Detailed Clinical Model

e) A description of specific consequences of a results or score for a patient of his care should be expressed in the Detailed Clinical Model as point of reference

For example A pressure sore risk assessment scale, such as the Braden Scale, 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.

3) The reader is referred to the text by White and Hauan on scale representation in health care information technology (White and Hauan, 2002).

Instructions for clinical care:

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

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

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

For example Decisions based on a cluster of data can be described as:

If a cluster of data A, B and C, then action 1 is indicated.

If a cluster of data K, L and M, then action 23 is indicated.

If a combination of A, K and P are found then data Z is created.

5.8.8 Care process / dependence

Detailed Clinical Model content might be relevant in particular phases of the care process, assessment, treatment plan or care path. If constraints are placed on the DCM, explain in this section.

If necessary provide a description of the place of the DCM 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 to be taken in advance and who needs to do what.

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

Both DCM types would be used in different steps in a care process, whether generic or specific. The Activity DCM 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 is then applied to specific care processes such as for *congestive heart failure, adult* where the activities and conditions relevant in this specific case are populated.

Reference both the DCM which provides the structure for the type of information that a health-related condition could contain and the kind of information an Activity DCM will contain within the different steps of a care process. This allows the application of different DCMs with interpretation guidelines.

a) Each Detailed Clinical Model should clearly express the identified clinical care processes and or compositions it has been designed to support within the metadata

5.8.9 Issues

The issue section provides guidelines to Detailed Clinical 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 along with local changes / variations in DCM content. Modelling issues or difficulties can be explained as well, preferably including the options and choices made. In general, it can be seen as similar to the discussion section in a research paper.

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

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

a) Each Detailed Clinical Model should identify unresolved, controversial or contentious issues that require further discussion in future revisions of the model

5.8.10 Example of the DCM

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 other 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 must be granted from the developers of that example and explicitly stated within the DCM.

a) A Detailed Clinical Model may have a section allowing inclusion of examples from clinical practice, screenshot or User Interface mock up of the clinical concept and its data elements and example values

5.8.11 References

5.8.11.1 General

As with other scientific publications, provide all references relevant to the content of the Detailed Clinical Model including projects, literature, world wide web pages and vocabulary in order to properly acknowledge of prior work. All literature is to be collected and saved so it can be consulted at any time. Note the projects from which source material for the DCM has been developed, in particular 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 matching OIDs: SNOMED CT with OID: 2.16.840.1.113883.6.96, LOINC with OID: 2.16.840.113883.6.1.

For example Use of SNOMED CT in a care setting and/or an application requires a license. More information can be found on the website of IHTSDO www.ihtsdo.org, or the national member bodies such as Nictiz (Dutch Institute for ICT in healthcare), www.nictiz.nl.

The APA, Harvard, NLM or Vancouver formats or any other formal guidance is to be used to list references[4].

5.8.11.2 Requirements and recommendations

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

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

c) Permission to use specifications from other sources than the Detailed Clinical Model shall be included in the list of references.

4) The reader is referenced to http://www.ncbi.nlm.nih.gov/books/NBK7262/ for further information

5.8.12 Copyrights of source materials, Disclaimer, Terms of use and Copyrights for Detailed Clinical Model

There are four areas of concern around issues in DCM content, use and intellectual property (IP). The first is the use of existing clinical materials to describe the concept and medical background, which could include copyright and or licensed materials.

a) A Detailed Clinical Model shall include a clear statement of any copyright or licensing restrictions which apply to the content of the DCM.

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

A sample disclaimer follows where information contained within < < < > > > is amended to provide the relevant details for the given DCM.

< < < Insert name ordering costumer here > > > as ordering customer and < < DCM developer > > give utmost care to the validity, reliability and timeliness of data in this Detailed Clinical Model. < < < The ordering costumer > > > and < < < DCM developer > > > are not responsible for damages resulting from errors or inaccuracies in the information, nor for damages arising from problems caused by or inherent within the spreading of information via the Internet as failures or interruptions from either errors or delays in the distribution of information or services by < < < The ordering costumer > > > or < < < DCM developer > > > or from you to < < < DCM developer > > > by means of a website from < < < The ordering costumer > > > or < < < DCM developer > > > by e-mail or other electronic means.

< < < The ordering costumer > > > and < < < DCM developer > > > do not accept responsibility for possible damage suffered as a result of the use of data, advice or ideas provided by or in name of < < < The ordering costumer > > > by way of this Detailed Clinical Model. < < < The ordering costumer > > > does not accept responsibility for the content of information in this Detailed Clinical Model to which or from which a hyperlink or otherwise is referred.

In case of contradictions in the afore-mentioned Detailed Clinical Model documents and files, reference is made to the most recent and highest version mentioned in the revision.

In case information included in the electronic version of a Detailed Clinical Model is also provided in writing, the written version takes precedence where textual differences occur if the version description and date of both are equal.

Include an explanation about versioning.

A third area of concern is DCM copyright. Detailed Clinical Models do have authors and responsible parties.

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

c) The original author of each Detailed Clinical Model should be clearly identified.

d) The copyright holder and/or governing authority for each Detailed Clinical Model should be clearly expressed.

The DCM is open source, so free to use and not to be changed. The idea behind the DCM 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 DCM must be traced to authors and responsible parties, governance is planned and implemented and that a quality label can be given. Further, it implies that certain rules apply for its proper deployment. Changes in content and codes in particular are viewed as an infringement of copyright and damage the realization of semantic interoperability.

Changes may be suggested to the author; if accepted, they may lead to:

— A revised DCM and results

— Variations adapted to a local situation

This is all based upon: a “common ownership” but not a “special stewardship”.

e) A Detailed Clinical Model should include information for (potential) users on how to conduct change requests.

NOTE There should be online “up front” information for users of any DCMs from a source organization - regarding change requests and patient safety and quality of care implications of changing a DCM without permission. Including this information in every DCM would be burdensome but a link to the main discussion site for change requests could easily be included in every DCM. So it depends per situation how this is operationalized. The minimum however would be to include it as a separate statement in an individual DCM if there is no reference available.

5.8.13 Metadata

5.8.13.1 General

A number of metadata elements are required for Detailed Clinical Models. It is necessary to identify responsibility for a particular DCM 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 is important for other purposes such as:

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

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

DCMs will be available in a web based repository and/or a registry and metadata supports their retrieval.

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

b) The metadata should be applicable to different kinds of Detailed Clinical Models e.g. observations, procedures.

c) 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.

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

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.

5.8.13.2 The metadata elements of the Detailed Clinical Model

Relevant metadata elements are presented in Table 2 along with a description of each. Whether the element is mandatory or optional is expressed in the cardinality.

The DCM metadata list is based on an analysis of ISO standards, Eurorec documents, CEN archetypes and HL7 templates specification. In the list the shall, should or may statements are included. should

means that if this metadata are available it must be included. For instance, the expiration date of a DCM should be included if it is known.

a) Governing authorities for a Detailed Clinical Model 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 DCM itself might be reviewed).

b) A Detailed Clinical Model should include meta-information as specified in Table 2.

Table 2 — Detailed Clinical Model Metadata elements, descriptions, data types, mandatory or optional uses

Metadata element	Description	Data type	Cardinality	Use
Name	The name of the Detailed Clinical Model as given by its creator. It is a free text natural language name identifying the Detailed Clinical Model concept. Reference: HITSP/TN903, HL7 Template project, ISO/IEC 11179-5:2005, Eurorec	ST	1..1	shall
Type	There is an assumption that different types of Detailed Clinical 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 as standard, then the type of Detailed Clinical Model will be identified from the business process as defined in that standard.	CD	0..1	should
Identification	A globally unique, non-semantic identifier for the Detailed Clinical Model assigned by the "owner". This can be an OID but equally could be another identification system. Reference: ISO 13606-2, HITSP/TN903, HL7 Template project, ISO/IEC 11179	II	1..1	shall
Identification of the Repository	If the Detailed Clinical Model is located in a repository then this repository must be identified. A globally unique, non-semantic identifier for the primary repository must be provided. It can be an OID but equally could be another identification system. It is assumed that several repositories will exist, e.g. on national level in different countries. Reference: HITSP/TN903, HL7 Template project, ISO/IEC 11179	II	0..*	should
URL	If the Detailed Clinical Model is located in a repository then the URL for this repository must be provided. Reference: HITSP/TN903, HL7 Template project, ISO/IEC 11179	URL	0..1	should

Table 2 *(continued)*

Metadata element	Description	Data type	Cardinality	Use
Keywords	A set of terms from a controlled reference terminology which may assist with indexing and searching for a Detailed Clinical 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 is used in order to allow clinical verification at all times. Reference: ISO 13606-2, HL7 Template project	ST and/or CD	1..*	shall
Care Process and/or Composition	The identified clinical care processes and/or compositions this DCM has been designed to support.	II	0..*	should
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 Detailed Clinical 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: Reference: ISO 13606-2, HITSP/TN903, HL7 Template project	PN	1..*	shall
Contact information	Details for the creator, registrar, stewardship and submission contacts which can be an organization (name and address) or a person (name). Reference: ISO/IEC 11179	EN AD TEL	0..*	may
Endorsing authority	The authoritative organization which has reviewed the Detailed Clinical Model for clinical accuracy and relevance, endorsing it for publication and/or use. Reference: HL7 Template project, ISO/IEC 11179	EN AD TEL	0..*	should
Identification of the endorsing authority	Formal identification of the above organization. Reference: HL7 Template project	II	0..1	should
Supporting organization	Organizations that have implemented the Detailed Clinical Model. Once they have adopted a particular DCM, they can notify the repository.		0..*	may

Table 2 *(continued)*

Metadata element	Description	Data type	Cardinality	Use
Version number	Version identifier for the Detailed Clinical 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 Detailed Clinical Model expressed in the format YYYYMMDD. Reference: Eurorec, HITSP/TN903, HL7 Template project, ISO/IEC 11179	INT	1..1	shall
Creation date	The date this Detailed Clinical Model was created in YYYYMMDD format. Reference: HITSP/TN903, HL7 Template project, ISO/IEC 11179	TS	1..1	shall
Publication date	The date on which the Detailed Clinical Model came/will come into use expressed in YYYYMMDD format. Use of the DCM prior to this date would be considered invalid usage. Reference: ISO 13606-2, HITSP/TN903, HL7 Template project, ISO/IEC 11179	TS	1..1	shall
Expiration date	The date on which the Detailed Clinical 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	should
Superseded by	The Detailed Clinical Model that has superseded this DCM and which should be used instead. This field can only be created if the publication status of the former DCM is set to 'Superseded'. Reference: ISO 13606-2, HL7 Template project	II	0..1	should
Revision date	The date this Detailed Clinical Model was revised when applicable in YYYYMMDD format. Reference: HITSP/TN903, HL7 Template project	TS	0..1	should
Next revision date	The anticipated date of review for the current Detailed Clinical Model to confirm it remains clinically valid in YYYYMMDD order. ISO 13606-2	TS	0..1	should
Development status	Status of the Detailed Clinical 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	shall

Table 2 *(continued)*

Metadata element	Description	Data type	Cardinality	Use
Lifecycle status	The status of the Detailed Clinical Model during system implementation. Reference: Eurorec	CS	0..1	should
Publication status	The status of the Detailed Clinical 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	shall
Publisher	The party responsible for submitting this Detailed Clinical Model to the registry or repository. Reference: ISO 13606-2, HL7 Template project	EN AD TEL	1..1	shall
Language	The natural language(s) in which the Detailed Clinical Model is represented using the ISO 639 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..*	shall
Quality label or certification	Formal quality validation of the Detailed Clinical Model, specify the type of test performed. Reference: ISO 13606-2	ED	0..*	should
Format	As there are different formalisms possible to define a Detailed Clinical 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 DCM is available. Reference: HL7 Template project	ST	1..*	shall
Additional formats	If the Detailed Clinical Model has been transformed into other formats; currently DCMs 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..*	should

5.8.14 Version management

New versions of Detailed Clinical Models are built on previous versions so the governing authority must apply some sort of mechanism to track and trace such 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 Detailed Clinical Model would normally be backwards compatible with prior versions. Any change to the semantic meaning which is not will require the creation of a new DCM with a different identifier. A change is not backwards compatible if it could result in an instance processor which is unaware of the more recent definition of the DCM 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).

a) Each Detailed Clinical Model shall be versioned.

b) The last DCM 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.

c) A new version or revision number of a Detailed Clinical Model should be assigned IF backwards compatibility is guaranteed.

d) A new version of a Detailed Clinical Model should be created IF there is no backwards compatibility. This new DCM shall be assigned a separate unique identifier and shall have a different DCM name.

e) A previous DCM shall be assigned a status of Superseded when a new version of a Detailed Clinical Model is created due to lack of backwards compatibility of the former version.

f) Any material change to a Detailed Clinical Model shall result in a revised version that references the former version.

g) A Detailed Clinical Model 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 may be required for actual use in practice.

5.8.15 Guidelines and principles for Detailed Clinical Modelling

5.8.15.1 General

The data model section maps the concepts identified in the Detailed Clinical Model's clinical content to data elements and their relationships. In the context of this Technical Specification, a data model contains classes (also called types), attributes of these classes and constraints on these attributes. In addition, this section can specify the rules used to assert validity of the data contained in the attributes. Moreover, this section specifies the relationships between data elements in the model.

The description of the data model must contain sufficient detail for a DCM implementation to be interchangeable and unambiguously interpretable within the EHR. These criteria are not guidelines about how an author should map concepts in the DCM 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 may support more features than the required set given below.

a) Detailed Clinical Models shall include the metadata, the concepts involved, data elements, mandatory attributes and constraints and relations between concepts.

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

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

d) A concept in the domain may be present in the data model section.

e) Detailed Clinical Model documentation should contain a list of concepts present in the data models, 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”.

f) The concept list shall contain all concepts represented in the data models. Conversely, the concept list shall NOT contain concepts not represented in the data models.

g) Detailed Clinical Models 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.

h) Detailed Clinical Models should apply reusable components from comparable instruments or observations.

i) The Detailed Clinical Model 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. Use of a slot-based compositional grammar can support this.

5.8.15.2 Specification of concepts in Detailed Clinical Models

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

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

b) The data models may contain data elements which do not represent concepts from the domain

c) One of the concepts present in the data model section shall represent the main subject or focal concept of the Detailed Clinical Model

5.8.15.3 Specification of properties of concepts

A data model will not only contain concepts but also the properties of those concepts, modelled as *attributes*. We will regard these properties as being concepts themselves so they may again have properties that may 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. As a consequence, the model will represent the domain as a hierarchy, or tree, of concepts and nested concepts connected via attributes. The leaves of the tree are the “atomic” concepts, while the root of the tree will normally be the concept that is the focus of the Detailed Clinical Model. Figure 5 illustrates this with a root concept and different data elements.

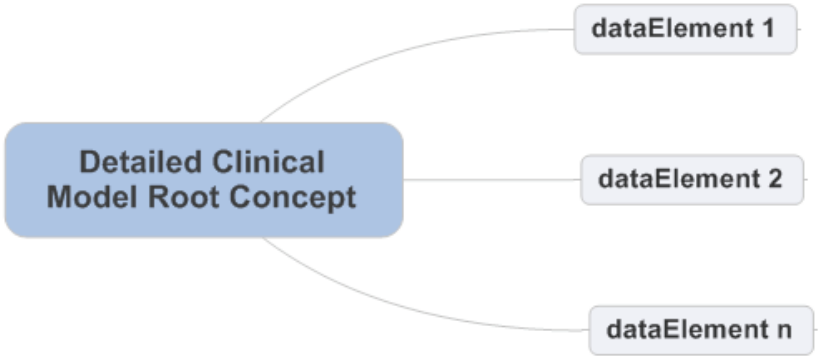

Figure 5 — Detailed Clinical Model representing a concept and underlying data elements in a tree structure.

As each attribute is itself a concept, it will be associated with a type. In the data model, the attributes at the leaves will be expressed using elementary structures like quantities, numbers and codes. These elementary structures are called *simple types*. The attributes at the leaves are called *atomic attributes*. Conversely, a type representing a "non-atomic" concept is called a *complex type*. Figure 6 illustrates the breakdown of the atomic data element into attributes.

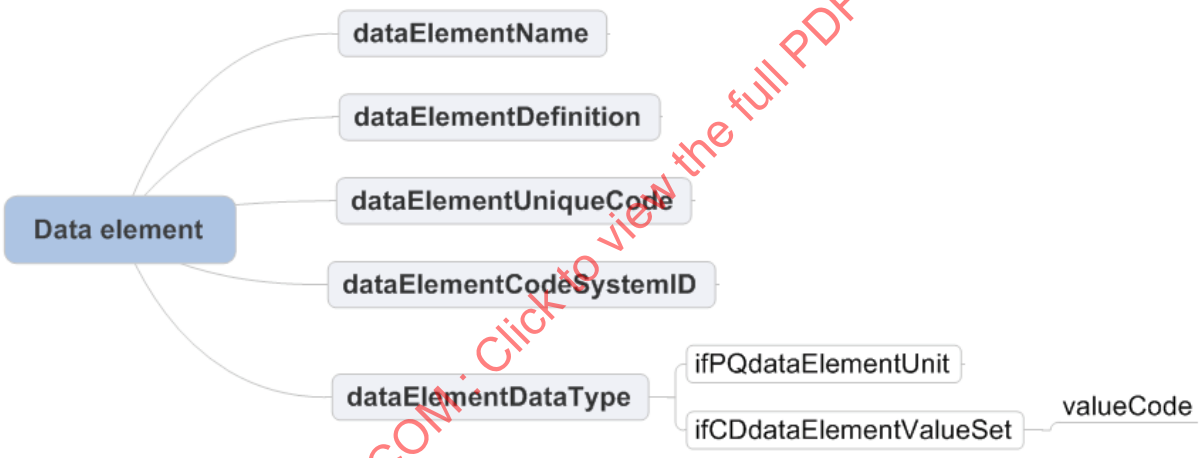

Figure 6 — A data element representing one atomic concept, as single data element, with its atomic attributes that specify the characteristics required for its use in information systems.

We can divide the attributes of complex types 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 Detailed Clinical Model, referred to as *result attributes*.

— Data which is captured during the clinical act described in the DCM but only serves to aid interpretation of the results or which influence the results. We will call these attributes *model qualifiers*.

a) The formalism shall be able to specify the properties of concepts as attributes of data elements

b) The formalism may provide more specific classification of model qualifiers or result attributes, for example either representing aspects of the state of the patient or the protocol relevant to the interpretation of data gathered in the DCM

c) The formalism should be able to identify attributes which contain data derived from other attributes present elsewhere in the data model

d) The formalism should support specification of the way data in a derived attributed is computed from other attributes