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Health informatics — Quality metrics for detailed clinical models

Informatique de santé — Indicateurs de qualité pour modèles cliniques détaillés

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Foreword

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

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

Normalization and formalization of evidence-based clinical data are fundamental requirements towards enabling a high quality and safe healthcare system. Normalized data elements and clinical models can help to ensure data consistency and comparability among users and systems, and formalized data specifications can support the sharing of clinical knowledge among diverse jurisdictions with higher efficiency and lower cost.

The goal of shareable, executable clinical guidelines is both worthwhile and challenging. One of the greatest hurdles is that of representing the clinical information in a precise and shareable manner. The Detailed Clinical Model (DCM) is an information model that is an essential part of the infrastructure supporting the codification and standardization of evidence-based knowledge elements across EHR systems. Each DCM is a logical model that shows the meaning, structure, possible content and relationships between data elements for a given subject of EHR documentation. The coded elements have explicit bindings to allowed coded values. Models are independent of any specific programming language or type of database. DCMs support explicit, unambiguous query statements against data instances. The DCM aids decision making by medical staff, and supports the valid reuse of medical data for example for epidemiology, quality assurance and managerial goals.

The DCM for supporting evidence-based clinical practice is already in common use in the EHR systems of some countries and regions. The Clinical Element Model of Intermountain Healthcare, templates defined by HL7 International, archetypes defined by the openEHR Foundation and ISO 13606, the Clinical Information Model in the Netherlands, and the Clinical Content Model by the Center for Interoperable EHR in South Korea are examples of published DCM formalisms that can be used to organize the clinical content of an EHR interoperability message and an EHR repository, share decision logic, and build a data capture form of a clinical application. Each instance of a DCM defines how a corresponding generic EHR representation is used to represent particular types of clinical information. Example DCMs include representations for allergies, problem lists, laboratory tests, medication and diagnostic orders, medication administration, adverse reaction, physical examination and clinical measurements, signs, symptoms, diagnosis, clinical documents, procedure, family history, medical history and review of symptoms.

According to the open EHR clinical community, medication, problem/diagnosis, adverse reaction, vital signs group, laboratory report, alert, blood group, procedure, admission/episode and clinical synopsis are the top ten priority archetype modelling areas. Examples of DCM instances might include representations for documenting a pain symptom, heart sounds, liver function tests, a prescribed drug, or a chest x-ray report. The standardization of EHR content through DCMs enables consistency and interoperability in many possible application areas within healthcare, quality assurance, and research. DCMs support multiple contexts as in the following:

— EHR data storage;

— message payload and service payload;

— exchanging clinical content;

— querying and analytics over clinical content;

— decision support over clinical content;

— entering clinical content;

— displaying clinical content;

— healthcare quality measures;

— clinical trials data (clinical research);

— normalization of data for secondary use;

— capture of coding output from NLP.

Whereas DCMs have the potential to improve clinical decision support and clinical documentation in EHR systems, the critical challenge is to identify the qualitative and quantitative requirements of DCMs. A few studies have suggested some quality requirements for DCMs (Table A.1). For the flexibility and scalability of DCMs, general requirements for the system in which clinical data models are implemented demand the following:

a) the addition of elements and attributes to the clinical model without the necessity of changing the underlying software or database schema;

b) use of an existing formalism/syntax for the representation of the model;

c) binding of model attributes to standard terminology systems; and

d) the existence of a mechanism for stating 'negation'.

General principles of good modelling include:

1) adoption of standard terminologies for use in the models;

2) representing the models in standard modelling languages;

3) sharing and approving the DCMs with a community of clinical experts;

4) defining data elements for decision support analysis of EHR clinical content.

DCM quality criteria have also been proposed where the following qualities were identified as being important requirements of a good DCM: usefulness, desirability, the degree of use/acceptance in clinical services, reusability, the degree of clinician introduction/validation, the proper use of vocabulary, easy mapping to information models, applicability, application to other technologies, and ease of maintenance.

Principles for the development of DCMs can be classified as principles pertaining to the structure of the DCM, principles for creating the DCM content, and principles for the DCM development process. The principles that pertain to the structure of DCMs contains information about the language formalism, description of binding of attributes to standard terminologies, a strategy for supporting semantic links among DCM instances, the definition of standard data types, and the description of standard units of measure. The principles for DCM content creation emphasize the granularity, reusability, correctness, and comprehensiveness of the models. Principles for the DCM development process emphasize evidence-based model development, the need for proper use cases, use of metadata to track changes, and compliance to the syntax of the modelling language.

There is common knowledge and understanding about the creation and utilization of DCMs. The Clinical Information Modeling Initiative (CIMI) is an international collaboration that is dedicated to providing a common format for DCMs so that semantically interoperable information may be created and shared in health records, messages and documents. The strategic goal of CIMI is to enable sharing of data, applications, reports, alerts, protocols, and decision support modules with anyone in the world. "Plug-n-play" interoperability is the primary goal of CIMI. To accomplish these goals, CIMI is now developing a shared repository of detailed clinical information models. CIMI is committed to making these specifications openly available in a number of formats, beginning with the Archetype Definition Language (ADL) from the openEHR Foundation (ISO 13606-2) and the Unified Modeling Language (UML) from the Object Management Group (OMG), with the intent that the users of these specifications can convert the models into their local formats. These formalisms are based on a common set of base data types with formal bindings of the models to standard coded terminologies. The CIMI repository is open to everyone and models are free for use at no cost.

The CIMI Reference Model Taskforce has established a set of requirements for the CIMI Reference Model (RM) and Clinical Modeling Language respectively. The CIMI RM is the underlying Reference Model on which CIMI's clinical models are defined. The CIMI RM requirements define or recommend the candidate elements that should be in the CIMI RM. The Clinical Modeling Taskforce is working to test the candidate reference model in the development of a set of initial clinical information models. The Clinical Modeling Language document lists the set of known requirements of the Clinical Modeling Language.

Many parties that have been involved in the various clinical modelling activities (13606/OpenEHR/HL7 templates/UML-DCM/CEML/Korean examples) are jointly working in CIMI.

Most of these aspects are specified in ISO/TS 13972, which provides characteristics, principles and processes for development of detailed clinical models. With increasing research and implementation of DCMs in international standards organizations and local health information systems as well, it is important to ask how the models' quality can be objectively measured. The last version of the CIMI RM is 99,9 % consistent with ISO/TS 13972 characteristics. The remaining differences deal with archetype specification typicalities which are not relevant to ISO/TS 13972, since the Technical Specification covers multiple technical formalisms.

To illustrate the level of detail for a DCM, one example (Figure 1) is presented for heart rate, using the ISO/TS 13972 format and the HL7 DCM project.

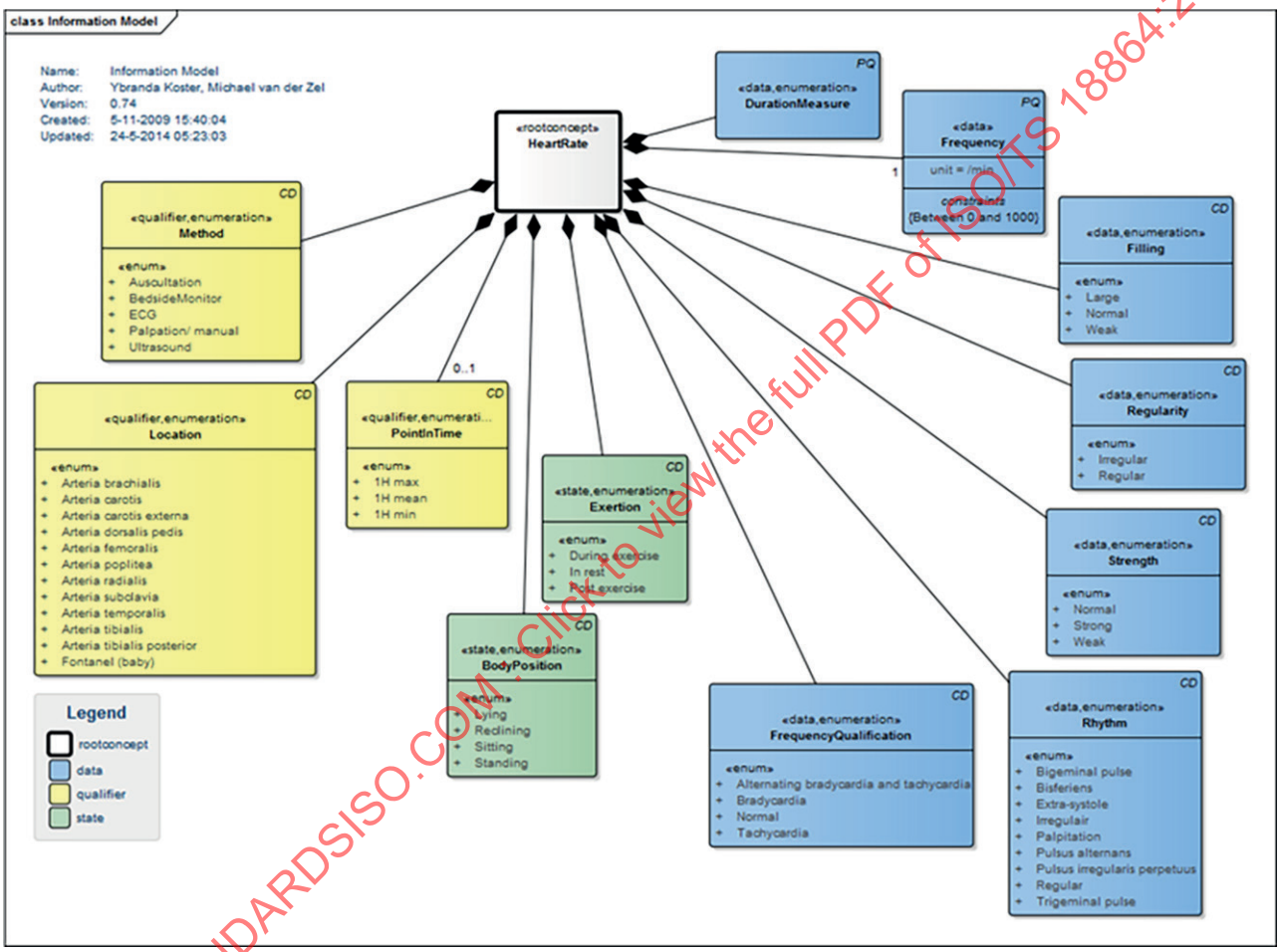

Figure 1 — DCM for heart rate example for the details required

Some quality requirements and criteria (see Table A.1) for DCMs proposed general principles of good modelling, including:

i. adoption of standard terminologies for use in the models;

ii. representing the models in standard modelling languages;

iii. sharing and approving the DCMs with a community of clinical experts;

iv. defining models that can serve as unambiguous references for data used in decision modules;

v. allowing different styles of models that represent the same clinical data (though only one style of model should be selected as the preferred style);

vi. applying the DCM Quality Management system (ISO/TS 13972) for DCM maintenance and governance.

Most of these requirements also include metadata of DCM, design and development process, governance and management as quality aspects of DCMs. Published requirements also specify process, product and provenance-related DCM quality. However, one critical limitation of these attempts is that there is no measurable metric to identify qualified DCMs for intended use.

If DCMs are to adequately support the EHR documentation needs of clinical practice, be endorsed by clinical professional bodies and health services, and be adopted by vendors, these models have to be of good quality, trusted, and in the future, certified. This document defines a set of quality metrics which are required to evaluate the DCMs objectively. Quality metric for DCMs specifies:

— definition;

— evaluation target;

— evaluation method;

— evaluation result to evaluate DCMs.

This set of quality metrics, which constitutes essential qualitative and quantitative quality requirements for DCMs, can be used to support rational decision-making by DCM developers and clinical users.

Health informatics — Quality metrics for detailed clinical models

1 Scope

The purpose of this document is to define objective, reliable and reproducible quality metrics for detailed clinical models (DCM).

This document specifies the principal metrics which are necessary and sufficient to evaluate DCMs.

The intended audiences of this document are:

— DCM developers, all users of information represented using DCMs, and evaluators of DCM quality;

— clinical and IT professionals of healthcare institutions;

— technical staff in the healthcare technology industry;

— experts involved in standards development;

— national and regional healthcare information technology leadership including certification bodies.

This document defines a set of quality metrics required to evaluate DCMs objectively. These quality metrics can be used to support rational decision making by DCM developers who will have the essential qualitative and quantitative quality requirements to use as guidelines as they create new content. Clinical users can then use the quantitative assessments as they select models for specific use cases and implement them in their clinical systems.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

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

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

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

3.1
archetype
knowledge-related data structure that strongly supports semantic interoperability of EHRs

Note 1 to entry: They help to ensure reliable and easy sharing of meaningful sets of data between different healthcare providers while allowing the re-use of their 'atomic' data components separately or within other clinical models.

3.2
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 electronic health record reference model

[SOURCE: ISO 13606-1:—, 3.14]

3.3
archetype modeling language
formal language for expressing archetypes

Note 1 to entry: It provides a formal, textual syntax for describing constraints on a domain entity whose data are described by an information model.

3.4
attribute
characteristic of an object or entity

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

[SOURCE: ISO/IEC 11179-1:2015, 3.1.1, modified]

3.5
concept definition
description of the attributes of a concept to delineate its meaning

3.6
conceptual model
description of 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, modified]

3.7
content quality
quality of DCM content as determined by a set of international standard-based or evidence-based quality criteria

3.8
data
re-interpretable representation of information in a formalized manner suitable for communication, interpretation or processing

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

3.9
data element
unit of data that is considered, in context, to be indivisible

[SOURCE: ISO/IEC 2382:2015, 2121599, modified]

3.10
data type
set of distinct values, characterized by properties of those values, and by operations on those values

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

3.11
Detailed Clinical Model
DCM
relatively small, standalone information model designed to express a clinical concept in a standardized and reusable manner

[SOURCE: ISO/TS 13972:2015, 2.22, modified]

3.12
logical Model
information model that specifies the structures and relationships between data elements but is independent of any particular technology or implementation environment

3.13
electronic health record
EHR
logical representation of information regarding or relevant to the health of a subject of care

[SOURCE: ISO 18308:2011, 3.20, modified]

3.14
electronic health record architecture
EHRA
logical generic components from which electronic health records are designed, defined in terms of an information model and computational services

[SOURCE: ISO 18308:2011, 3.21, modified]

3.15
entity
concrete or abstract thing of interest, including associations among things

[SOURCE: ISO/IEC 2382:2015, 2121433, modified]

3.16
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 18308:2011, 3.24]

3.17
governance for Detailed Clinical Models
system by which development, distribution, and maintenance of detailed clinical models are directed and controlled

[SOURCE: ISO/TS 13972:2015, 2.28, modified]

3.18
HL7 template
expression of a set of constraints on a Reference Information Model (RIM) or a RIM derived model that is 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

Note 1 to entry: A template is represented by:

— a formal definition in one or more human readable languages or notations;

— [optionally] a formal definition as a static model;

— [optionally] one or more implementation specific representations that can be used to validate instances in a particular context template.

[SOURCE: HL7 Ballot January 2010 Templates Project]

3.19
metadata
data that define and describe other data

[SOURCE: ISO/IEC 11179-1:2015, 3.2.16, modified]

3.20
metric
verifiable measure that captures performance in terms of how something is being done relative to a standard, allows and encourages comparison, supports business strategy

3.21
model
representation of a domain that uses abstraction to express the relevant concepts

3.22
modelling
construction of abstract representations in the course of design, for example to represent the logical structure of software applications before coding

Note 1 to entry: http://www.omg.org/gettingstarted/what_is_uml.htm

3.23
patient safety
prevention of harm caused by errors of commission and omission

[SOURCE: Reference 30]

3.24
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 9000:2015, 3.6.2, modified]

3.25
quality management system
framework described by the ISO 9000 family of standards and comprised of three core elements: quality control, quality assurance and quality improvement

3.26
quality measure
quantitative measure of one or more quality characteristics (two or more quality measures may be required to specify one aspect of quality)

3.27
quality metric
agreed methods and means for measuring the levels of achievement, performance or conformance of a component or its quality characteristics(s)

3.28
safety
freedom from unacceptable risk of harm

[SOURCE: ISO/IEC Guide 51:2014, 3.14, modified]

3.29
semantic interoperability
ability for data shared by systems to be understood at the level of fully defined domain concepts

[SOURCE: ISO 18308:2011, 3.45]

3.30
terminological system
ordered collection of concepts, in which each concept is expressed by terms, words or expressions

[SOURCE: ISO/IEC 11179-1:2015, 3.2.25, modified]

3.31
usage pattern
consistent and recurring use case for a particular detailed clinical model

3.32
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 of the value set

[SOURCE: HL7 Version 3 Core Principles]

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.

4 Abbreviated terms

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

EHR	Electronic Health Record
DCM	Detailed Clinical Model
CIMI	Clinical Information Modeling Initiative
ADL	Archetype Definition Language
AOM	Archetype Object Model
CEM	Clinical Element Model
CDA	Clinical Document Architecture
CCM	Clinical Contents Model
FHIR	Fast Healthcare Interoperability Resources
UML	Unified Modeling Language
OWL	Web Ontology Language
XML	Extensible Markup Language
OID	Object Identifier
QFD	Quality function deployment

5 Relationship with other activities

5.1 ISO/TS 13972

ISO/TS 13972 has been developed in order to leverage ISO 9000-based quality management in the contexts of DCMs. The characteristics of DCMs, which are addressed in ISO/TS 13972, can be transformed into measurable metrics as described in this document. Transformation of characteristics to metrics can be one to many, many to one, or one to one.

5.2 ISO 13606-2

Archetype representation requirements published in ISO 13606-2 focused more on the technological aspects of models. They are divided into requirements for archetype definition, archetype node constraints, and data value constraints. They have been consulted, but not used directly, in developing these quality metrics.

5.3 EuroRec quality criteria for archetypes

EuroRec, an organization that certifies EHRs in the European Union, led a research project funded by the European Commission to develop criteria for the quality classification of EHR systems. The research resulted in a set of archetype quality criteria, which covered administrative, clinical, technological, information management, and repository operation requirements. Furthermore, they emphasized the use of standard terms and modelling language, the construction of repositories for DCM sharing, and the importance of metadata. Among the clinical requirements, the requirement for clinical use suggests that the listing of accurate use patterns of clinical concepts, specification of whether the corresponding archetype is used in a specific workflow, description of subject population groups, as well as expert groups using an archetype, etc. are important to note.

5.4 Delphi study

Published criteria (see Table A.1) were used as the input criteria for a Delphi study that established a core subset of criteria that were capable of more objective and formal assessment, published in Reference.[12] ISO/TS 13972, ISO 13606-2 and EuroRec quality have acted as the primary initial source of the quality metrics presented in this document.

6 The purpose and importance of DCM quality

Why are we measuring the quality of DCMs? The role of DCMs is to minimize, and hopefully eliminate much of the ambiguity in the clinical information shared across an eHealth infrastructure. Therefore, the data represented in a DCM shall be accurate. The data shall accurately convey the concepts they are intended to convey. To succeed in this role, DCMs shall, themselves, be fit for purpose. Good quality clinical care relies on good quality information. A poor quality DCM is a potential exogenous source of clinical error. To ensure quality, we employ both quality assurance and quality control. Quality assurance is the adoption and measurable use of standardized processes intended to yield a good quality work product; it is proactive. Quality control is the standardized measurement of the attributes of a work product as compared to the established attributes of a good quality product; it is intended to identify (and rectify) defects and is, therefore, reactive. Systemic quality control issues often uncover underlying quality assurance issues and are therefore necessary for supporting kaizen (continuous quality improvement).

See also ISO/TS 13972:2015, 5.1. This handles how DCM processes can be managed through a Quality Management system (QMS). ISO/TS 13972 addresses the areas of analyses of clinical content and context, involvement of clinicians and other stakeholders to verify DCM, acceptance, adoption and usage of DCMs, use of a generic format for the conceptual and logical levels of DCM specifications for their development, the deployment of a DCM QMS for maintenance, governance, and repositories, and finally a DCM process monitoring and improvement approach. ISO/TS 13972 adapted this into a cyclical process derived from ISO 9001/EN 15224.

7 Quality aspect of DCMs

According to some published quality criteria (see Table A.1) for the flexibility and scalability of DCMs, general requirements for the system in which clinical data models are implemented demand the following:

a) addition of elements and attributes to the clinical model without the necessity of changing the underlying model, software or data base schema;

b) use of an existing formalism/syntax for the representation of the model;

c) binding of model attributes to standard terminology systems;

d) existence of a mechanism for stating 'negation'. In this context, flexibility means that DCM designs can adapt when external changes occur.

DCM metrics check to see if each DCM's data elements and DCM metadata describe 'required' and 'optional' items. Scalability of DCMs refers to ability to enhance each DCM by adding new data elements with minimal effort.

General principles of good modelling include:

1) adoption of standard terminologies for use in the models;

2) representing the models in standard modelling languages;

3) sharing and approving the DCMs with a community of clinical experts;

4) defining models that can serve as unambiguous references for data used in decision modules;

5) allowing different styles of models that represent the same clinical data (though only one style of model should be selected as the preferred style);

6) applying the DCM Quality Management System (ISO/TS 13972) for DCM maintenance and governance.

These published quality criteria describe the requirements to ensure the quality of DCMs. Most of these requirements include metadata of DCM, design and development process, governance and management as quality aspects of DCMs. Published requirements also specify process, product, and provenance-related DCM quality. The published quality criteria focus on the appropriate expression of the content and metadata.

8 DCM quality framework

8.1 DCM quality framework component

A consistent approach to representing DCM quality improvement activities will allow the integration and indexing of target domains, characteristics, metrics, and expected benefits. This over-arching framework identifies suitable metrics by which to assess and assure the quality aspects of DCMs. For example, the purpose of 'Per Data element' target domain is to measure each DCM unit's comprehensiveness and coverage.

It is the intention that the quality framework will cover all quality aspects of DCMs:

— target domains;

— DCM quality characteristics;

— DCM quality metrics;

— expected benefits of high quality DCMs;

— use of the DCM quality management system for long term maintenance and governance of DCMs.

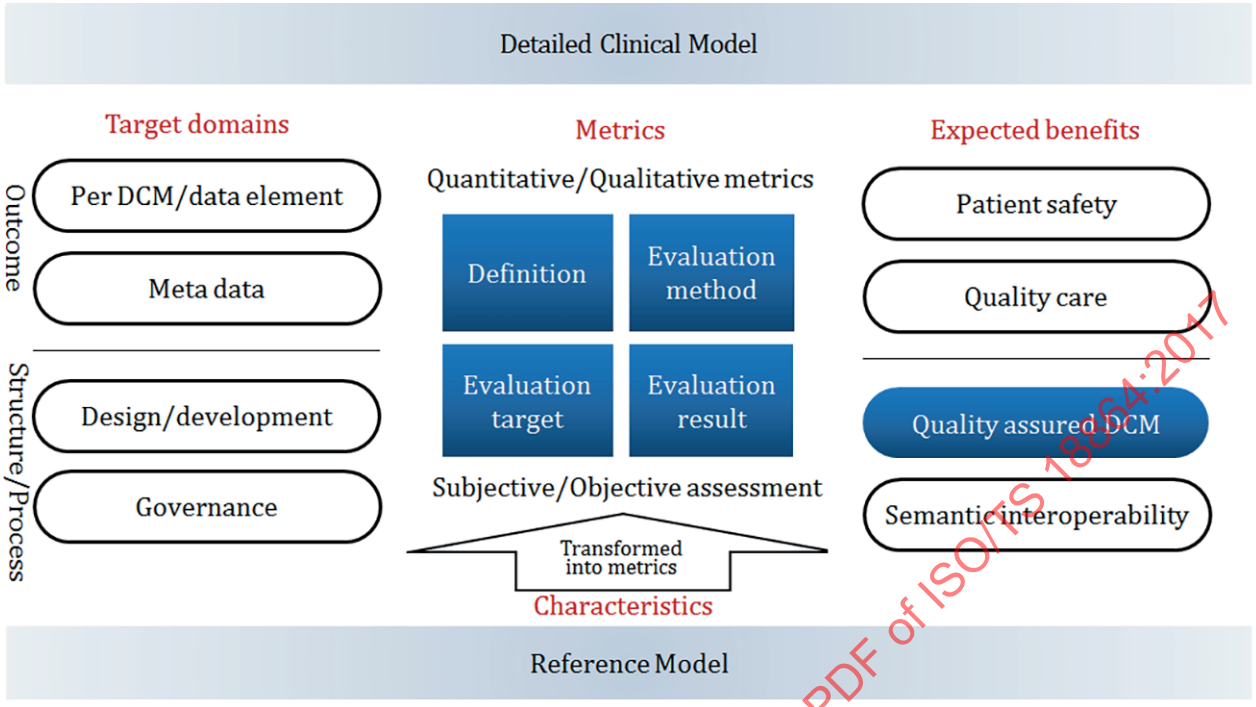

Figure 2 — Framework for the quality criteria for DCMs

8.2 DCM Quality characteristics

There are agreed attributes of a DCM by which its quality is assessed or measured. Most quality characteristics are agreed quality aspects and component in ISO/TS 13972. Not all characteristics will match evaluation target and measurement methods. Agreeing optimal metrics development approaches shall be balanced with what is achievable within known resources.

8.3 DCM Quality metrics

— Definition

Definitions are offered to describe an evaluation target. It describes the evaluation area and associated artifacts. All definitions consist of diverse depths regarding clinical, technical outcomes and governing structure and process.

— Evaluation target

Evaluation target includes DCM metadata, DCM content, language, DCM processes, administrative documents that are the subject of the evaluation.

— Evaluation method

Evaluation methods are of two types. In general, the primary users, such as clinicians and researchers, review DCM contents and manually and subjectively determine whether they are fit for purpose. Determining the correctness, specificity and the level of granularity is a clinical aspect of the assessment of the contents of a DCM. Other metrics can be measured in an automatic and objective way using technical functionalities.

— Evaluation result

The default evaluation result options presented in the metrics are divided into 4 categories:

1) meets the requirement (conforms);

2) does not meet the requirement (does not conform);

3) partially meets the requirement (partially conformant) and includes recommendation or direction as to what is missing or deficient;

4) NA, NR (not relevant).

8.4 Expected benefits of high quality DCMs

— Patient safety

DCMs bring useful clinical contents to the delivery of healthcare, and it is making health care systems safer and more efficient. There are specific patient safety risks that can be mitigated by deploying standards-based DCMs within EHRs. However, patient safety risks can be introduced by DCMs themselves unless there is a robust and relevant quality measure framework and related quality measure activities. Good quality DCMs reduce ambiguity, and minimize any errors of omission and errors of commission.

— Quality care

An important goal is that good information that supports high quality care is accurately stored or conveyed in the EHR. The challenge that most modellers face is to appropriately structure the clinical knowledge and data element specification without losing the meaning of clinical data in the system. Evidence-based clinical guidelines and protocols shall be defined by reference to DCMs to achieve high quality healthcare. Therefore, information which is properly defined in DCMs guides and supports clinicians and other stakeholders in providing evidence-based good care. Based on the metrics, the design, development, and management of DCM quality can be improved.

— Semantic interoperability

Representation of clinical semantics with standard structure supports patient safety and semantic interoperability. Health service delivered using standards for the consistent and clear representation of clinical data is essential. When quality of DCMs has been assured using the specified metrics, it ensures that the meaning of information is preserved over time, between heterogeneous systems and actors and care providers. Semantic interoperability is one of the key benefits of quality assured DCMs. It enables the integration and safe use of computerized protocols and alerts and ensures the meaningful and reliable use of clinical data for research and public health.

9 Quality metrics for DCMs

9.1 Design and development

9.1.1 General

There may be varying degrees of partial conformance to quality metrics, and the same holds true for (full) conformance. It is thus deemed necessary to provide a range between greater or equal to (≥) 1 point, but less than (<) 2 points for partial conformance; and greater or equal to (≥) 2 points, but less than (<) 4 points for (full) conformance. If a quality metric deals with a yes/no, or true/false question, the score for the quality metric is 1 point for partial conformance, and 2 points for (full) conformance. Otherwise, if partial or full conformance deals with an amount, number, or quality, the user should use his/her own expert judgment in assigning a proper score, even a non-integer value for its score. It is, however, reasonable to suggest that a value should be limited to the first digit after the decimal point.

Annex B provides an overview about typical detailed clinical modelling approaches.

9.1.2 Stakeholders participated in the development (or design) of DCM

1) Definition: The development or design of the DCM shall have participating stakeholder(s) [non-technical clinicians, clinical informaticians, technical modellers, and information/data architects in the discipline of the DCM content (such as physician, surgeon, pharmacist) from public and private healthcare providers, medical schools (academia) and government health authorities], who helped incorporate data users. The involvement Were there of any extent to the development or design of the DCM by any non-technical clinicians, clinical informaticians, technical modellers, and information/data architects in the discipline of the DCM content (such as physician, surgeon, pharmacist) from public and private health care providers, medical schools (academia) and government health authorities involved in the development or design of the DCM, who helped incorporate data user. Were there any non-technical clinicians involved in the development or design of the DCM, who helped incorporate data user requirements?

2) Evaluation target: DCM content, metadata.

3) Evaluation method: Check to see if any clinicians from stakeholders' organizations have participated in the DCM development/design. Check to see if any clinicians have participated in the DCM development/design.

4) Evaluation result:

   — meets the requirement (conforms): ≥2 points, but <4 points;

   — does not meet the requirement (does not conform): 0 point;

   — partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: ≥1 point, but <2 points;

   — NA, NR (not relevant): 0 point.

9.1.3 Stakeholders participated in the verification/approval of DCM

1) Definition: The verification/approval of the DCM shall denote the number of clinicians, clinical informaticians, technical modellers, and information/data architects involved in the verification, and/or approval of the appropriateness of usage pattern definitions (within organization/without organization).

2) Evaluation target: DCM metadata (contributor, reviewer), DCM content and administrative documents.

3) Evaluation method: The number of clinicians involved in the verification (and/or approval) of DCM content.

4) Evaluation result:

   — meets the requirement (conforms): ≥2 points, but <4 points;

   — does not meet the requirement (does not conform): 0 point;

   — partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: ≥1 point, but <2 points;

   — NA, NR (not relevant): 0 point.

9.1.4 Translations, only if applicable

1) Definition: There may exist one or more recorded translations for values of each data element (e.g. between international and realm-specific reference terms or between semantically equivalent terms in different coding systems).

2) Evaluation target: DCM content.

3) Evaluation method: Check to see if the clinical model has one or more translations recorded.

4) Evaluation result:

   — meets the requirement (conforms): 2 points;

   — does not meet the requirement (does not conform): 0 point;

   — partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: 1 point;

   — NA, NR (not relevant): 0 point.

9.1.5 Relationships

1) Definition: There may be representation of structural and/or semantic relationships (or links) between different information components within one or more clinical information models.

2) Evaluation target: Document, DCM content or language (ADL, XML, UML, OWL, etc.).

3) Evaluation method: Allowed relationships, semantic links exist.

4) Evaluation result:

   — meets the requirement (conforms): ≥2 points, but <4 points;

   — does not meet the requirement (does not conform): 0 point;

   — partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: ≥1 point, but <2 points;

   — NA, NR (not relevant): 0 point.

9.2 Per detailed clinical model

9.2.1 Compliance to standard

9.2.1.1 Formal syntax

1) Definition: A formal syntax shall be used.

2) Evaluation target: Language (codes of data elements written in ADL, XML, UML, OWL, etc.).

3) Evaluation method: Check to see if DCM content is represented unambiguously in formal syntax

4) Evaluation result:

   — meets the requirement (conforms): 2 points;

   — does not meet the requirement (does not conform): 0 point;

   — partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: 1 point;

   — NA, NR (not relevant): 0 point.

9.2.1.2 Data element specification at logical level

1) Definition: Unambiguous representation and definition of all required data elements and their relationships should be specified.

2) Evaluation target: Listing of data elements with1-n and their relationships among them.

3) Evaluation mMethod: Check to see if DCM specifies relationships among data elements (1:1 or 1:M), required to represent the concept and to store data.

4) Evaluation result:

   — meets the requirement (conforms): ≥2 points, but <4 points;

   — does not meet the requirement (does not conform): 0 point;

   — partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: ≥1 point, but <2 points;

   — NA, NR (not relevant): 0 point.

9.2.1.3 Use of standard terminology

1) Definition: The DCM shall include, or map to, standard terminology, but only when and if applicable.

2) Evaluation target: DCM content terminology bindings, Language (codes of data elements written in ADL or XML).

3) Evaluation method: Check to see if terminology bindings in DCM instances include, or map to, terms from standard terminology.

4) Evaluation result:

   — meets the requirement (conforms): ≥2 points, but <4 points;

   — does not meet the requirement (does not conform): 0 point;

   — partially meets the requirement (partially conformant) ± include recommendation or direction as to what is missing or deficient: ≥1 point, but <2 points;

   — NA, NR (not relevant): 0 point.

9.2.1.4 Use of standard data types

1) Definition: The data types of DCM content shall use, or map to, such standard data types as ISO 21090 or HL7 V3 XML data types.

2) Evaluation target: DCM instance datatype references.

3) Evaluation method: Check to see if any standard data types are used in DCM content.

4) Evaluation result:

   — meets the requirement (conforms): ≥2 points, but <4 points;

   — does not meet the requirement (does not conform): 0 point;

   — partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: ≥1 point, but <2 points;

   — NA, NR (not relevant): 0 point.

9.2.1.5 Identification of the terminological or classification system by name and/or the OID or URI

1) Definition: There shall be identification of each coded data element with an associated code description from the terminological or classification system by name and/or the OID or URI.

2) Evaluation target: Each coded data element has name and/or the OID or URI.

3) Evaluation method: Check to see if each coded data element has name and/or the OID or URI.

4) Evaluation result:

   — meets the requirement (conforms): ≥2 points, but <4 points;

   — does not meet the requirement (does not conform): 0 point;

   — partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: ≥1 point, but <2 points;

   — NA, NR (not relevant): 0 point.

9.2.1.6 Use of standard units of measures

1) Definition: There shall be standard units of measures, such as UCUM and SNOMED CT, used in the DCM, and the DCM content shall use units of measures that are mapped to such standard units of measures.

2) Evaluation target: DCM instance unit of measure bindings.

3) Evaluation method: Check to see if there exists a code for each appropriate data element.

4) Evaluation result:

   — meets the requirement (conforms): ≥2 points, but <4 points;

   — does not meet the requirement (does not conform): 0 point;

   — partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: ≥1 point, but <2 points;

   — NA, NR (not relevant): 0 point.

9.3 Metadata

9.3.1 DCM Version

1) Definition: There should be version(s) for the DCM content.

2) Evaluation target: DCM metadata, and/or language (ADL, XML, UML, OWL, etc.).

3) Evaluation method: Presence of version information and its actual meaning (ex: published, draft).

4) Evaluation result:

   — meets the requirement (conforms): 2 points;

   — does not meet the requirement (does not conform): 0 point;

   — partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: 1 point;

   — NA, NR (not relevant): 0 point.

9.3.2 Purpose of DCM

1) Definition: There shall be description of the purpose(s) for the development and use of DCM content.

2) Evaluation target: DCM metadata.

3) Evaluation method: Whether there exists such description of purposes.

4) Evaluation result:

   — meets the requirement (conforms): 2 points;

   — does not meet the requirement (does not conform): 0 point;

   — partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: 1 point;

   — NA, NR (not relevant): 0 point.

9.3.3 Appropriate description of application target patient or population of DCM

1) Definition: There should be description of target patient communities or populations to whom DCM content are applicable.

2) Evaluation target: DCM metadata.

3) Evaluation method: Whether there exists such descriptive information about the target patient communities or populations.

4) Evaluation result:

   — meets the requirement (conforms): 2 points;

   — does not meet the requirement (does not conform): 0 point;

   — partially meets the requirement (partially conformant) ± include recommendation or direction as to what is missing or deficient: 1 point;

   — NA, NR (not relevant): 0 point.

9.3.4 Description of multiple uses

1) Definition: There may be description of multiple uses of the DCM such as

   — exchanging clinical content;

   — querying, analytics and research over clinical content;

   — decision support over clinical content;

   — entering clinical content (e.g. using a form-based user interface);

   — displaying clinical content;

   — storing clinical content in EHR systems.

2) Evaluation target: DCM metadata.

3) Evaluation method: Whether there exists such description of multiple uses.

4) Evaluation result:

   — meets the requirement (conforms): ≥2 points, but <4 points;

   — does not meet the requirement (does not conform): 0 point;

   — partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: ≥1 point, but <2 points;

   — NA, NR (not relevant): 0 point.

9.3.5 Appropriate description of discipline of DCM user

1) Definition: There may be a description of the discipline of the DCM user(s) (non-technical clinicians, clinical informaticians, technical modellers, and information/data architects).

2) Evaluation target: DCM metadata.

3) Evaluation method: Whether there exists such description of user(s) and it is a sufficient description.

4) Evaluation result:

   — meets the requirement (conforms): ≥2 points, but <4 points;

   — does not meet the requirement (does not conform): 0 point;

   — partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: ≥1 point, but <2 points;

   — NA, NR (not relevant): 0 point.

9.3.6 DCM author(s)

1) Definition: There shall be description of the author(s) or organization(s) of the DCM content.

2) Evaluation target: DCM metadata, or language (ADL, XML, UML, OWL, etc.).

3) Evaluation method: Whether there exists such description of author(s) or organization(s).

4) Evaluation result:

   — meets the requirement (conforms): 2 points;

   — does not meet the requirement (does not conform): 0 point;

   — partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: 1 point;

   — NA, NR (not relevant): 0 point.

9.3.7 Authoring date

1) Definition: There should be description of date of authoring of the DCM content.

2) Evaluation target: DCM metadata.

3) Evaluation method: Whether there exists such description of date of authoring.

4) Evaluation result:

   — meets the requirement (conforms): 2 points;

   — does not meet the requirement (does not conform): 0 point;

   — partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: 1 point;

   — NA, NR (not relevant): 0 point.

9.3.8 Modification date

1) Definition: There should be description of date of modification of the DCM content.

2) Evaluation target: DCM metadata.

3) Evaluation method: Whether there exists such description of date of modification.

4) Evaluation result:

— meets the requirement (conforms): 2 points;

— does not meet the requirement (does not conform): 0 point;

— partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: 1 point;

— NA, NR (not relevant): 0 point.

9.3.9 Initial review round date

1) Definition: There may be description of initial review round date of each DCM.

2) Evaluation target: DCM metadata.

3) Evaluation method: Whether there exists such description of date of initial review.

4) Evaluation result:

— meets the requirement (conforms): 2 points;

— does not meet the requirement (does not conform): 0 point;

— partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: 1 point;

— NA, NR (not relevant): 0 point.

9.3.10 Number of review rounds

1) Definition: There may be description of the number of review rounds for each DCM.

2) Evaluation target: DCM metadata.

3) Evaluation method: Whether there exists such description of the number of review rounds.

4) Evaluation result:

— meets the requirement (conforms): ≥2 points, but <4 points;

— does not meet the requirement (does not conform): 0 point;

— partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: ≥1 point, but <2 points;

— NA, NR (not relevant): 0 point.

9.3.11 Last review round date

1) Definition: There may be description of the last review round date for each DCM.

2) Evaluation target: DCM metadata.

3) Evaluation method: Whether there exists such description of the date of the last review.

4) Evaluation result:

— meets the requirement (conforms): 2 points;

— does not meet the requirement (does not conform): 0 point;

— partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: 1 point;

— NA, NR (not relevant): 0 point.

9.3.12 Status of content publication

1) Definition: There shall be description of the status of content publication for each DCM.

2) Evaluation target: DCM metadata.

3) Evaluation method: Whether there exists such description of the status of content publication (draft/review/paused/published/reassess, etc.).

4) Evaluation result:

— meets the requirement (conforms): ≥2 points, but <4 points;

— does not meet the requirement (does not conform): 0 point;

— partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: ≥1 point, but <2 points;

— NA, NR (not relevant): 0 point.

9.3.13 Mention of reference(s) used in DCM development, only if applicable

1) Definition: There may be mention of what clinical sources were used to gather the data. It may be clinical sources, not just formal journal references, and include clinical evidence guideline(s).

2) Evaluation target: DCM metadata.

3) Evaluation method: Evaluation of the contents in the "Reference" part (example: clinical practice guidelines, medical textbooks, represent common practice, communication with clinical domain experts).

4) Evaluation result:

— meets the requirement (conforms): ≥2 points, but <4 points;

— does not meet the requirement (does not conform): 0 point;

— partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: ≥1 point, but <2 points;

— NA, NR (not relevant): 0 point.

9.4 Per data element

9.4.1 Valid value of DCM

1) Definition: Data elements and their values shall be accurately defined.

2) Evaluation target: Data elements of the DCM content.

3) Evaluation method: Clinician's evaluation on the extent of the embodiment of usage patterns in the data elements of the DCM content.

4) Evaluation result:

— meets the requirement (conforms): ≥2 points, but <4 points;

— does not meet the requirement (does not conform): 0 point;

— partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: ≥1 point, but <2 points;

— NA, NR (not relevant): 0 point.

9.4.2 Terminology binding

1) Definition: Meaning of a data group or data element should be determined by binding it to a coded concept, or a coded concept expression.

2) Evaluation target: DCM content.

3) Evaluation method: Check to see if data elements is bound to coded concepts or concept expressions.

4) Evaluation result:

— meets the requirement (conforms): ≥2 points, but <4 points;

— does not meet the requirement (does not conform): 0 point;

— partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: ≥1 point, but <2 points;

— NA, NR (not relevant): 0 point.

9.5 Governance

9.5.1 Maintenance organization of DCM

1) Definition: The maintenance organization should be publicly accessible.

2) Evaluation target: DCM metadata, administrative documents, homepage.

3) Evaluation method: Whether information on maintenance organization is accessible.

4) Evaluation result:

— meets the requirement (conforms): 2 points;

— does not meet the requirement (does not conform): 0 point;

— partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: 1 point;

— NA, NR (not relevant): 0 point.

9.5.2 Existence of user feedback mechanism for DCM

1) Definition: It should be possible for users to provide feedback such as DCM content evaluation, or requests for addendum of data elements.

2) Evaluation target: DCM homepage or repository.

3) Evaluation method: Check to see if it is possible to provide feedback through a DCM homepage or repository.

4) Evaluation result:

— meets the requirement (conforms): 2 points;

— does not meet the requirement (does not conform): 0 point;

— partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: 1 point;

— NA, NR (not relevant): 0 point.

9.5.3 Realm-specific specializations and extensions

1) Definition: The clinical models shall support the ability to be specialized for realm-specific requirements, and to be extended with realm-specific information that does not need to be interoperable between realms.

2) Evaluation target: DCM homepage, DCM management policy or repository.

3) Evaluation method: Check to see if it is possible to provide this policy with constraint on extension through a DCM homepage, related document or repository.

4) Evaluation result:

— meets the requirement (conforms): ≥2 points, but <4 points;

— does not meet the requirement (does not conform): 0 point;

— partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: ≥1 point, but <2 points;

— NA, NR (not relevant): 0 point.

9.5.4 Multiple outputs

1) Definition: There should be provision of automated generation of multiple different artifacts, with no change to the meaning (wherever possible), including:

— computable exchange format specifications (e.g. CDA, HL7 v3, XML Schema);

— clinical models defined in other formalisms (e.g. UML 2.0);

— human-readable visualizations of the models (e.g. HTML and default user interfaces).

2) Evaluation target: Formalism, Language, and computable exchange format specifications.

3) Evaluation method: Check to see if the DCM provides for multiple outputs.

4) Evaluation result:

— meets the requirement (conforms): ≥2 points, but <4 points;

— does not meet the requirement (does not conform): 0 point;

— partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: ≥1 point, but <2 points;

— NA, NR (not relevant): 0 point.

9.5.5 Clinicians participated in the verification/validation of DCM for determining customer satisfaction

1) Definition: Clinicians in the discipline of DCM content (such as physician, surgeon, pharmacist from public and private health care providers, medical schools (academia) and government health authorities) may participate in the verification, and/or validation of the effectiveness of DCM through the process by which to determine customer satisfaction.

2) Evaluation target: DCM metadata, DCM content, administrative documents.

3) Evaluation method: Check to see if the DCM content was verified or validated with the participation of such clinicians.

4) Evaluation result:

   — meets the requirement (conforms): ≥2 points, but <4 points;

   — does not meet the requirement (does not conform): 0 point;

   — partially meets the requirement (partially conformant) and/or includes recommendation or direction as to what is missing or deficient: ≥1 point, but <2 points;

   — NA, NR (not relevant): 0 point.

Annex A
(informative)

Some published quality requirements and criteria for DCMs

DCM quality criteria have been proposed where the following qualities were identified as being important requirements of a good DCM: usefulness, desirability, the degree of use/acceptance in clinical services, reusability, the quality of clinical contents, the degree of clinician introduction/validation, the use of vocabulary, mapping to information models, applicability, application to other technologies, and maintenance.

Principles for the development of DCMs can be classified as principles pertaining to the structure of the DCM, principles for creating the DCM content, and principles for the DCM development and government processes. The principles that pertain to the structure of DCMs contain information about the language formalism, description of binding of attributes to standard terminologies, a strategy for supporting semantic links among DCM instances, the definition of standard data types, and the description of standard units of measure. The principles for DCM content creation emphasize the granularity, reusability, correctness, and comprehensiveness of the models. Principles for the DCM development process emphasize evidence-based model development, the need for proper use cases, use of metadata to track changes, and compliance with the syntax of the modelling language. Most of these aspects are specified in ISO/TS 13972.

Archetype representation requirements published in ISO 13606-2 focus more on the technological aspects of models. They are divided into requirements for archetype definition, archetype node constraints, and data value constraints. EuroRec (see 5.3) led an EC-funded research project to develop criteria for the quality classification of EHR systems. The research resulted in a set of archetype quality criteria, which covered administrative, clinical, technological, information management, and repository operation requirements. Furthermore, they emphasized the use of standard terms and modelling language, the construction of repositories for DCM sharing, and the importance of metadata. Among the clinical requirements, the requirement for clinical use suggests the listing of accurate use patterns of clinical concepts, specification of whether the corresponding archetype is used in a specific workflow, description of subject population groups, as well as expert groups using an archetype, etc.

These attempts describe the requirements to ensure the quality of DCM. Most of these requirements include metadata of DCM, per DCM, pre-DCM data elements (value), governance and management as quality aspects of DCM. Published requirements also specify process, product, and provenance related DCM quality. It focuses on the appropriate expression of the content and metadata.

Table A.1 — Comparison of quality requirements and criteria for DCMs

Type[a]	General requirement for clinical data model	Requirement for DCM	DCM quality criteria	EuroRec Archetype quality criteria	Archetype representation requirements	Requirement for Clinical Information Model
	Coyle et al. ('03)	Huff ('07)	Goossen ('07)	Kalra et al. ('08)	ISO 13606-2 ('08)	Ahn ('10)
Scope and Purpose	—	—	—	An archetype shall specify any particular clinical scenarios or workflows for which it is particularly intended.	A formal statement defining the scope and clinical purpose of this archetype, expressed as a coded term or as free text in a given natural language.	Scope and usage of the model
Accuracy	—	Accurate	Clinical Content Quality	An archetype shall specify the precise nature of the clinical entity (or set of entities) for which it defines a use pattern.	—	Accuracy
Comprehensiveness	The model must be comprehensive- it must accommodate representation of anything that can be stated about a patient.	—	-	An archetype's use pattern should be inclusive of all of the minor variations in clinical entity representation across its use cases, users and scenarios.	—	Comprehensiveness
Vocabulary/ Terminologies	There must be a tight linkage to standard terminologies.	The modelling language must have a mechanism of linking to standard coded terminologies.	Vocabulary use/mapping to coded terminology.	The clinical label for each node shall be drawn from a published controlled vocabulary.	Any node of an archetype may be mapped to any number of additional concepts, terms and synonyms from terminology systems.	Mapping to standard terminologies (SNOMED CT, LOINC, etc.)
Compliance with standards	Standard terminologies	Standard coded terminologies	—	—	—	Compliance with international standards (ISO Data type, UCUM, etc.)