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European foreword

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

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Health informatics — Detailed clinical models, characteristics and processes

Informatique de santé — Modèles cliniques détaillés, caractéristiques et processus

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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).

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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.

