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Health informatics — Categorial structure for terminological systems of surgical procedures

Informatique de santé — Structure catégorielle pour les systèmes terminologiques des interventions chirurgicales

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 1828 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics*, in collaboration with ISO Technical Committee ISO/TC 215, *Health informatics*, in accordance with the agreement on technical cooperation between ISO and CEN (Vienna Agreement).

The preparation of this International Standard brought to light an urgent need to review the family of terminological standards ISO 704, ISO 1087, ISO 17115 and EN 12264 in order to clarify the relations between concept, generic concept, specific concept, object, class, instance, designation and formal representation. This also applies to the forthcoming edition of ISO/TR 24156 (all parts).

Introduction

The driving factor behind this International Standard is the fact that terminological systems for surgical procedures are used for a wide range of purposes. Some of the main applications include, for instance, being incorporated as an integral part of a computerized health care record for use in discharge summary information, for clinical research, peer review, quality assurance, reimbursement, workload assessment, resource management, utilization comparisons, public health management and epidemiological surveys. Unlike diagnoses, for which the International Classification of Diseases (ICD) is an accepted *de facto* standard, there are at least as many coding systems for surgical procedures as there are developed countries and, very often, several such coding systems for different usages or for different surgical disciplines in each country. On the other hand, most of the countries are unable to satisfy such applications for they lack such terminological systems or use terminological systems from other countries. This hampers the exchange of meaningful health information, for instance for international statistical comparisons.

Five types of health care terminological systems are defined in ISO 17115: classifications, coding scheme, coding systems, reference terminologies and clinical terminologies.

Defining a surgical procedure is considered difficult because there are neither specific criteria to define it nor specific criteria to define the limit between what a surgical procedure is and what it is not.

Within this International Standard, terminological systems of surgical procedures are defined in the following way:

— In this International Standard, a terminological system of surgical procedures is considered to have been defined as such by its owner/developer in order to cover surgical procedures. The owner/developer decides what can be considered a surgical procedure and then defines the content of the terminological system.

Terminological systems for surgical procedures group the different types of terminological systems including terminological systems defined by ISO 17115:2007, 2.7: classifications, coding scheme, coding systems, reference terminology and clinical terminology.

ENV 1828:1995 started by identifying the categories of terms in existing procedure classifications within and outside Europe and also the natural language used in surgical reports. It defined the categorial structure which contains the definition of a set of categories of terms and the internal relations that combine them into a conceptual system.

EN 1828:2002 has been widely tested and/or applied in national and European projects (The Nordic NCSP, the French CCAM, for the revision of UK OPCS and by three German-speaking countries (Austria, Germany and Switzerland) as well as outside Europe in Australia (ACHI and ICHI) and Canada (CCI).

EN 1828:2002 was based on the assessment of different existing health care terminological systems. They are made available in the bibliography as the material on which the standard was based. The main terminological systems of surgical procedures developed since that edition of the standard have been added as well.

WHO-FIC (World Health Organization Family of International Classification) are currently implementing a project called ICHI (International Classification of Health Intervention) which is intended to be based on a concept system that is conformant to this International Standard. SNOMED CT IHTSDO has planned to align the surgical procedures within SNOMED CT with this International Standard.

International standardization efforts by CEN and ISO related to electronic health records and semantic interoperability have resulted in a number of categorial structures which are a step towards supporting health care terminological systems with a full concept system or ontology that in turn will support multiple uses and safe communication. In the present categorial structure standard, several of the definitions of basic terms related to categorial structures have been updated to comply with the most recent edition of ISO 17115. This is the first revision of a categorial structure standard developed by CEN or ISO since 1995, and one of several that are to be reviewed in the next five years. These revisions are being processed in collaboration between CEN/TC 251 and ISO/TC 215.

Health informatics — Categorial structure for terminological systems of surgical procedures

1 Scope

This International Standard specifies the minimal characteristics of a categorial structure for terminological systems of surgical procedures and the minimal domain constraints to support interoperability, comparability and the exchange of meaningful information on surgical procedures, independently of the language, insofar as the significant differences are specified by the system.

NOTE 1 Further characteristics or more detailed value sets can be used for specific purposes.

NOTE 2 Categorial structures support interoperability by providing common frameworks within which to develop terminological systems that can be related to each other, and to analyse the properties of different terminological systems in order to derive relationships between them.

This International Standard is applicable to terminological systems of surgical procedures in all surgical disciplines. It covers only the terminology part, as defined in ISO 1087-1:2000, of the terminological systems of surgical procedures.

It is intended to be used by:

— organizations involved with the development or maintenance of terminological systems for surgical procedures, namely for multipurpose terminological systems on a national or international level;

— organizations developing and maintaining software tools that allow natural clinical language expressions analysis, generation and mapping to the main existing terminological systems of surgical procedures.

This International Standard is intended to be used as an integrated part of computer-based applications and for electronic health care records. It is of limited value for manual use.

This International Standard is not suitable for, nor intended for use by, individual clinicians or hospital administrators. It is not the purpose of this International Standard to standardize the end user terminological system or to conflict with the concept systems embedded in national practice and languages.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 12264, *Health informatics — Categorial structures for systems of concepts*

3 Terms and definitions

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

3.1
categorial structure
minimal set of domain constraints for representing health care terminological systems entities in a precise subject field to achieve a precise goal

NOTE Adapted from ISO 17115.

3.2
domain constraint
rule prescribing the set of representations of relations that are valid to specialize a category in a certain domain

NOTE Adapted from ISO 17115.

3.3
category
type of entity shared by all the individual instances in existence in the present, past and future

EXAMPLE The category “liver” is instantiated by this liver and all individual livers in existence in the present, past and future.

NOTE 1 Categories may be more or less general. Where one category is subsumed by another, the *is_a* relation is asserted to obtain a hierarchy between the more specific or subsumed category and the more general or subsuming category.

NOTE 2 Each entity instantiates some category.

NOTE 3 Category is a synonym of generic concept as it is in ISO 17115.

3.4
representation of relation
semantic link
formal relation between two or more categories derived from corresponding relations between instances of the respective categories

EXAMPLE hasLocation (with inverse isLocationOf):isCauseOf (with inverse hasCause).

NOTE 1 This includes all relations except Is_a, has_part relation.

NOTE 2 The definition is authorized by a domain constraint.

NOTE 3 Adapted from ISO 17115.

3.5
health care terminological system
set of designations within the domain of health care with, when appropriate, any associated rules, relationships and definitions.

EXAMPLE Annex A details the five types of terminological systems given in ISO 17115:2007, 2.7.

NOTE Adapted from ISO 1087-1:2000 which defines terminology as a set of designations belonging to one language used in a subject field for a special purpose.

3.6
subject field
domain
field of special knowledge

[ISO 1087-1:2000, definition 3.1.2]

NOTE The borderlines of a subject field are defined from a purpose-related point of view.

3.7
goal
statement on situations and applications for which the categorial structure is intended and its limits of use

3.8 Categories of health care entities for terminological systems of surgical procedures

3.8.1
surgical deed
deed which can be done by a medical practitioner to the patient’s body during the surgical procedure

EXAMPLES Excising, destroying, dividing, puncturing.

NOTE 1 For the purposes of this International Standard, the surgical deed shall be described without reference to any specific human anatomy (3.8.2) or interventional equipment (3.8.4).

NOTE 2 Surgical deed terms are presented by the neutral inflection of a verb as a present participle (e.g. removing).

NOTE 3 Surgical deed categories do not include reason and outcome (e.g revascularization).

NOTE 4 A surgical deed is part of a surgical procedure; major surgery is composed of a series of surgical deeds. A surgical deed in case of minor surgery can be considered itself as the essential component of a surgical procedure.

3.8.2
human anatomy
biological science that concerns the discovery, analysis and representation of the structural organization of the human body

[EN 15521:2007]

NOTE The categories of human anatomy are given in Annex C. The definition and names of categories of human anatomy should conform to EN 15521:2007. They are listed in Annex B.

3.8.3
lesion
abnormal morphologic structure

EXAMPLES Cyst, foreign body, exostosis, polyp.

NOTE 1 A lesion shall be described without reference to **human anatomy** (4.8.2) or any specific diagnosis such as embolism, hypertension, priapism, myocarditis.

NOTE 2 A lesion may be the result of inheritance, disease, trauma, or previous surgical procedures.

NOTE 3 The Oxford English Dictionary provides another similar definition: region in an organ or tissue which has suffered damage through injury or disease.

3.8.4
interventional equipment
medical device for use in surgical procedures

EXAMPLES

— surgical prostheses (hip implant, pacemaker, prosthetic valve)

— surgical instruments (drill, needle, scissors, clamp)

— fixation devices (nail, screw, plate, rod, pin)

— tubular devices (catheter, drain, tube)

— connecting material (suture, clip)

— imaging devices (endoscope, microscope, X-ray, ultrasound equipment)

— surgical agents (electricity, liquid nitrogen, laser)

— substance (air, ionizing ray)

— chemical (drug, anaesthetic agents)

— animal organs and tissues

NOTE Most terms concerning interventional equipment can be found in the application field of the definitions of Council Directive 93/42/EEC concerning medical devices or in the International Classification of Clinical Services (ICCS) section “Medical and surgical supplies”.

3.9 List of authorized representations of relations

3.9.1
hasObject
representation of relations between the category “surgical deed” and the categories on which the surgical deed is carried out

EXAMPLE 1 In the terminological phrase “removing colon”, the surgical deed “removing” hasObject “Colon”.

EXAMPLE 2 In the terminological phrase “removing polyp from colon”, “removing” hasObject “Polyp”.

EXAMPLE 3 In the terminological phrase “inserting two pins into left femur”, “inserting” hasObject “two pins”.

NOTE 1 The categories which can have this representation of relation with the surgical deed belong to the categories human **anatomy** (3.8.2), **lesion** (3.8.3) and **interventional equipment** (3.8.4).

NOTE 2 Every surgical procedure terminological phrase complying with this International Standard has this semantic link.

NOTE 3 When the object is a physiologic or function entity, an additional **category** (3.3) function can be used but the category human **anatomy** (3.8.2) is mentioned.

3.9.2
hasSite
representation of relations referring to that site to which, from which or in which the surgical deed is carried out

EXAMPLE 1 In the terminological phrase “removing cyst from left kidney”, “removing” hasObject “cyst” which hasSite “left kidney”.

EXAMPLE 2 In the terminological phrase “removing fluid from cyst in left kidney”, “removing” hasObject “fluid” which hasSite “cyst” which hasSite “leftkidney”.

EXAMPLE 3 In the terminological phrase “replacing battery in pacemaker in chest wall”, “replacing” hasObject “battery” whic hasSite “pacemaker” which hasSite “chest wall”.

NOTE 1 The categories which can have this representation of relation with the categories **lesion** (3.8.3) and **interventional equipment** (3.8.4) belong to the categories **human anatomy** (3.8.2), or **lesion** (3.8.3) or **interventional equipment** (3.8.4).

NOTE 2 This representation of relation can be used several times in the same terminological phrase allowing the different parts of a complex interventional equipment, such as the battery of a pace maker or the different parts of a stent, to be represented.

3.9.3
hasMeans
representation of relations referring to the means by which the surgical deed is carried out

EXAMPLE 1 In the terminological phrase “bypass coronary artery using mammary artery”, “bypass” hasObject “coronary artery” and hasMeans “mammary artery”.

EXAMPLE 2 In the terminological phrase “removing polyp from colon by means of endoscope”, “removing” hasObject “polyp” which hasSite “colon” and hasMeans “endoscope”.

NOTE The categories that can have this representation of relations with the surgical deed belong to the categories **human anatomy** (3.8.2) and **interventional equipment** (3.8.4).

3.9.4
hasSubsurgicaldeed
representation of relations referring to the subprocess by which the main surgical deed is carried out

EXAMPLE 1 In the terminological phrase “straightening penis by plicating and excising of the corpus cavernosum”, “straightening” hasObject “penis” and hasSubsurgicaldeed “plicating”, which hasObject ”corpus cavernosum” and hasSubsurgicaldeed “excising” which hasObject “corpus cavernosum”.

EXAMPLE 2 In the terminological phrase “endarteriectomy of the carotid bifurcation by everting”, “excising” hasObject “endarterium” of “carotid bifurcation” and hasSubsurgicaldeed “everting” which hasObject “carotid bifurcation”.

NOTE 1 The category that can have this semantic relation with the category **surgical deed** (3.8.1) belongs to the category **surgical deed** (3.8.1).

NOTE 2 This representation of relation is a hasPart type relation.

4 Description of categorial structure for terminological systems of surgical procedures

4.1 General

A **categorial structure** for a terminological system of surgical procedures (3.1) claiming conformance to this International Standard shall provide the information described in 3.8, 3.9 and 4.2 and shall comply with the five minimal domain constraint requirements specified in Clause 5.

The categorial structures for terminological systems of surgical procedures shall be in accordance with the categorial structure specified in EN 12264 and in ISO 17115 (see 3.1).

To describe a **categorial structure** for terminological systems of surgical procedures, the following information shall be provided:

— **categories** that organize the health care entities for this terminological system of surgical procedures and subdivide their representation in the domain;

— list of the **representations of relations** authorized by **domain constraints**;

— **goal** of the terminological system of surgical procedures for which the **categorial structure** is set.

4.2 Goal of the terminological system for which the categorial structure is set

The goal of each terminological system for surgical procedures shall be defined by the users and make statement on situations and applications for which the categorial structure is intended and the limits of use.

EXAMPLE Controlled vocabulary, production for clinicians or comparison with another terminological system for coding centres.

To be conformant with this International Standard, each terminological system for surgical procedures shall state its goal. To be conformant with EN 12264, each terminological system of health care and biomedical science shall also state that it is conformant to the categorial structure standard EN 12264 outside the limits of use in the subject field of surgical procedures.

4.3 Categories

Categories organize the health care entities for this terminological system of surgical procedures and subdivide their representation in the domain as defined in 3.8.

4.4 List of the representations of relations

The list of the representations of relations is authorized by domain constraints as defined in 3.9.

5 Domain constraint requirements

The list of minimal **domain constraints required** by the goal of the categorial structure shall contain among the different authorized **representations of relations** (3.9) and the different related authorized **categories** (3.8) the ones which are valid and necessary for the precise **goal** (4.2) of **a categorial structure** (3.1) for a terminological system of surgical procedures.

5.1 Each surgical procedure terminological phrase shall, as a minimum, consist of a **surgical deed** (3.8.1) and have the semantic link **hasObject** (3.9.1).

5.2 Each surgical procedure terminological phrase shall contain the **category human anatomy** (3.8.2), in relation to the semantic link **hasObject** (3.9.1) or **hasSite** (3.9.2) when the object does not belong to the category human anatomy but to the **category lesion** (3.8.3) or to the **category interventional equipment**