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Health informatics — Clinical knowledge resources — Metadata

Informatique de santé — Ressources des connaissances cliniques — Métadonnées

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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).

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

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

For an explanation of 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 www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 13119:2012), which has been technically revised.

The main changes are as follows:

— a new Document Type has been added – Health Technology Assessment.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

The internet is rapidly changing the way people access medical knowledge. Health professionals use web-based knowledge sources and databases, and patients/ individuals turn to the web to search for knowledge. There is a need for mechanisms to assess and clearly describe the quality and authenticity of such knowledge sources. Rather than trying to ban bad quality information, it is preferable to assist individuals, health professionals and software developers to find the type of information they request by making quality criteria behind a knowledge resource easily accessible.

Instead of reviewing the content of the medical knowledge resources, it is possible to define structures and processes behind their development, including quality assurance principles in general, peer review, professional education, etc. This area requires collaboration among many types of actors such as professional associations, publishers and health authorities.

One feasible and important approach is to establish a set of metadata to describe the content and procedures behind its production.

Many different types of documents are produced with the broad intent of providing "clinical knowledge", e.g. advice to patients for certain clinical problems, reports of research in the medical literature, guidelines issued by governmental authorities and researcher's protocols for clinical trials.

Some types of documents can have legal implications. Some guidelines are based on extensive high-quality scientific review/meta quality systems involving scientific reviews and can be influenced also by other (e.g. financial) considerations. In many areas of clinical care, the patients and professionals use advice of lesser status produced by one or a group of qualified experts. Such clinical guidelines are increasingly available on the internet and it is very important to provide information to assist in judgment about the nature, status and scientific background of such documents.

This document will not only be useful for the assessment of a knowledge resource but also to facilitate search and retrieval of knowledge resources.

This document for metadata is based on the general purpose Dublin Core Metadata Initiative which developed the first set of fifteen metadata elements, later published as ISO 15836:2009[1)], which has been revised as the ISO 15836 series.

This document provides an international set of health care specific extensions to this set. Some of the issues covered by health specific metadata tags in the CEN/TS 15699 have been replaced by corresponding Dublin Core qualifiers now available. This area is in a rapid development.

The basic structure (taken from Dublin Core) and the extensions provided in this document constitutes a source for possible use for a specific use case. An international set is certainly preferable when there is an audience for the knowledge resource outside of the country of origin. This is common for clinical knowledge resources in languages with users in many countries such as English, Spanish, French and Arabic.

However, for many use cases of metadata, it is important to provide a vocabulary that is easily understood perhaps also by laypersons and corresponding to the language used in the resource itself. This document can serve as an example for defining such national metadata vocabularies.

It is also emphasized that the extensive set of possible metadata elements defined in this document can be useful as a subset for a specific set of resources.

1) Withdrawn.

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Health informatics — Clinical knowledge resources — Metadata

1 Scope

This document specifies a number of metadata elements that describe resources containing medical knowledge, primarily digital documents provided as web resources, accessible from databases or via file transfer, but can be applicable also to paper documents, e.g. articles in the medical literature.

The metadata elements

— support unambiguous and international understanding of important aspects to describe a resource, e.g. purpose, issuer, intended audience, legal status and scientific background,

— are applicable to different kinds of digital resources, e.g. recommendation from consensus of a professional group, regulation by a governmental authority, clinical trial protocol from a pharmaceutical company, scientific manuscript from a research group, advice to patients with a specific disease, review article,

— are possible to present to human readers including health professionals as well as individuals/patients, and

— are potentially usable for automatic processing, e.g. to support search engines to restrict matches to documents of a certain type or quality level.

The metadata elements defined in this document are not intended to

— describe documents about a single patient, such as medical records,

— describe details of the medical content of the resource (but some idea of the content can be described via keywords or codes), or

— prescribe criteria for the quality of the resource content.

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 terminology databases for use in standardization at the following addresses:

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

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

3.1
medical knowledge
field of knowledge pertaining to the structure, function or dysfunction of the human body and how these can be influenced by external or internal factors and interventions

Note 1 to entry: Medical does not imply “physician” – all health professionals have medical knowledge according to this definition.

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3.2
clinical knowledge
part of medical knowledge pertaining promoting good health and the management and prevention of ill health

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

3.3
knowledge resource
collection of knowledge about a subject area collected for a purpose and made available to a user as some manifestation in a resource form

3.4
metadata
data that defines and describes other data

[SOURCE: ISO/IEC 11179-3:2013, 3.2.74]

3.5
metadata element
resource property name that can be used in metadata and that can be given a value

[SOURCE: ISO 24622-1:2015, 2.12, modified — Example and Note to entry deleted.]

3.6
term
designation that represents a general concept by linguistic means

EXAMPLE "Patient", "doctor", "body temperature", "pacemaker", "Covid-19".

[SOURCE: ISO 1087:2019, 3.4.2, modified — Example modified and Note to entry deleted.]

3.7
clinical guideline
set of systematically developed statements to assist the decision of health care parties about health care activities provided with regard to a health issue in specified clinical circumstances

Note 1 to entry: See ISO 13940:2015.

4 Introduction to metadata

4.1 Purpose and format

Metadata for a knowledge resource conveys information that is important for such purposes as:

— locating a knowledge resource depending on, e.g. subject, area of applicability, form of presentation;

— assessing quality of the knowledge, e.g. how old it is, how trustworthy the author is.

4.2 Sources of medical metadata

This document relies on several sets of metadata particularly relevant for clinical knowledge, including Arden syntax, ISO 13606-3 and GEM (Guidelines Element Model).

4.3 Characteristics of the metadata element set

In the element descriptions in 5.2 to 5.6, each element has a descriptive label intended to convey a common understanding of the element, as well as a unique, machine-understandable, single-word name intended to make the syntactic specification of elements simpler for encoding schemes.

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