INTERNATIONAL STANDARD

ISO 13119

Second edition
2022-10

Health informatics — Clinical knowledge resources — Metadata

Informatique de santé — Ressources des connaissances cliniques — Métadonnées

Reference number
ISO 13119:2022(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword

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

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

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

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

For an explanation 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.

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.

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.

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.

Although some environments, such as HTML, are not case-sensitive, it is recommended to always adhere to the case conventions in the element names given to avoid conflicts in the event that the metadata is subsequently extracted or converted to a case-sensitive environment, such as XML (Extensible Markup Language).

Each element is optional and repeatable. Metadata elements can appear in any order. The ordering of multiple occurrences of the same element (e.g. Creator) can have a significance intended by the provider, but ordering is not guaranteed to be preserved in every system.

To promote global interoperability, a number of the element descriptions suggest a controlled vocabulary for the respective element values. The Dublin Core set assumes that different domains develop where necessary controlled vocabularies as specifiers of the content of the general purpose metadata element set and adding other metadata elements as required.

The Dublin Core metadata initiative is providing valuable informative material concerning the use of metadata and system implementation advice.

5 Metadata element structure for clinical knowledge resources

5.1 Clinical metadata elements

This clause establishes a categorization of clinical knowledge resources that is intended to facilitate finding appropriate metadata elements. These metadata element groups are not intended to be represented as actual metadata for the knowledge resources.

For each Metadata Element Name, there is a proposed way of expressing the content of that metadata, often by using a controlled vocabulary presented or referenced in this document. Most of these come from the Dublin Core indicated by (DC), in these cases, additional information can be found in ISO 15836-1. In a few cases, this structure also proposes a substructure of specialisation of the metadata elements. Where elements or sub-elements are defined in this document specifically intended for Health Care, it is indicated by (HC). The syntax for representing metadata can vary dependent on the format of the metadata expression, e.g. XML.

NOTE This document is based on the original expression of metadata elements with qualifiers expressed using the dot-notation (e.g. Type.Text). The Dublin Core Metadata Initiative has also provided an alternative expression based on an abstract model and provisions in RDF of individual metadata properties.

For the purpose of navigation among the many metadata elements of this document, they are presented under a set of Group Headings. These shall not be implemented as metadata tags in resources.

A list of all metadata elements is provided in Annex A and a diagram of all classes in Annex B.

5.2 Resource form

5.2.1 Group description

The resource form group of metadata describes the form of delivery of knowledge from the resource.

5.2.2 Type

5.2.2.1 General

Element name: Type (DC)

Definition: Nature or genre of the content of the resource (DC)

Healthcare specific specialisation: The following terms can be used to describe Type:

— Text

— Database for human reading

— Interactive resource

— Moving image

— Still image

— Sound

— Dataset

— Software

— Hardware device

These terms should be complemented by a type specifier as given below.

5.2.2.2 Text

Element name: Type.Text (DC)

Definition: A resource consisting primarily of words for reading

NOTE 1 A resource (often called document) that contains still images in addition to the words is designated type Text.

EXAMPLE Books, letters, dissertations, poems, newspapers, articles, archives of mailing lists. Facsimiles or images of texts are still of the genre Text.

Specifiers of Type.Text health care specific (HC):

a) Journal_article

b) Book_chapter

c) Book

d) Report

e) Abstract

f) Patient_education_handout

NOTE 2 Information directed towards a patient/subject of care about a particular health issue. This includes medication inserts in medicinal products.

g) FAQ

NOTE 3 Frequently Asked Questions.

h) Algorithm

NOTE 4 Formal description of a procedure, e.g. a calculation method.

i) Clinical_guideline

j) Policy_strategy

NOTE 5 A document that is a policy or a strategy for the operation of healthcare services.

k) Information_standard

NOTE 6 A standard regarding health information and health informatics.

l) Teaching_material

NOTE 7 This includes learning / self-learning materials.

m) Computable_clinical_information_model

NOTE 8 This includes, for example, the special form of constrained information model to describe a part of an Electronic Health Record as described by ISO 13606-2 or OpenEHR. Also HL7 based Templates could be tagged with this.

n) Terminological_resource

NOTE 9 Collection of terminological entries.

o) Metainformation

NOTE 10 Information about other resources (bibliography, catalogue, reviews, gateway, search engine).

p) Case_report

q) Proposal

NOTE 11 This term is used to label a plan for a project.

r) Event

NOTE 12 This term can be used to label properties of an event such as invitations, descriptions and schedules of meetings and other events where people meet. It is not used to describe the outcome of an event.

s) Service_description

NOTE 13 Service in this context can include health care services as well as other services, e.g. IT-related.

t) Product_information

u) Critically_appraised_topic

NOTE 14 An answer to a clinically focused/structured question, which has been produced from a search and appraisal of the evidence, within a short timeframe. The answer cannot be considered to be a systematic review due to the rapid nature of production. Include all topics produced by question-answering services.

v) Known_uncertainty

NOTE 15 Therapeutic uncertainties identified through systematic reviews, clinical guidelines, and other formal mechanisms.

w) Observational_study

NOTE 16 Studies in which patient or health professional preference determines whether a patient receives treatment or control. Use for cohort studies and case-controlled studies.

x) Qualitative_study

NOTE 17 Studies that research social, emotional, and experiental phenomena in health care.

y) Randomised_controlled-trial

NOTE 18 Experiment in which individuals are randomly allocated to receive or not to receive an experimental preventative, therapeutic or diagnostic procedure and then followed to determine the effect of the intervention.

z) Research_study

NOTE 19 Research studies not included in any of the other publication types, e.g. use for case study and case series.

aa) Review

NOTE 20 A non-systematic literature review, topic overview or descriptive article.

bb) Systematic_review

NOTE 21 A review of a clearly formulated question that uses systematic and explicit methods to identify, select and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review. Statistical methods (meta-analysis) can be used to analyse and summarize the results of the included studies. If the review does not state it is systematic, or no details of the searching methods are given, use Review.

cc) Structured_abstract

NOTE 22 An abstract of a single journal article with headings that conforms to one of the agreed protocols for reporting research results (e.g., sample, data collection, data analysis, results, discussion) that also contains a commentary on or appraisal of the article.

dd) Care_pathway

ee) Health_Technology_Assessment

NOTE 23 The systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies. HTA is conducted by interdisciplinary groups that use explicit analytical frameworks drawing on a variety of methods.[22]

5.2.2.3 Database for human reading

Element name: Type.DatabaseforHumans (HC)

Definition: Type of knowledge resource with structured data and established retrieval functions for human reading

Specifiers of Type.DatabaseforHumans:

a) Journal

b) Metainformation

c) Terminology

d) Guideline_collection

5.2.2.4 Interactive resource

Element name: Type.InteractiveResource (DC)

Definition: A resource requiring interaction from the user to be understood, executed, or experienced

EXAMPLE Forms on Web pages, applets, multimedia learning objects, chat services, discussion lists or virtual reality environments.

5.2.2.5 Moving image

Element name: Type.MovingImage (DC)

Definition: A series of visual representations imparting an impression of motion when shown in succession

EXAMPLE Animations, movies, television programs, videos, zoetropes, or visual output from a simulation. Instances of the type Moving Image can also be describable as instances of the broader type Image.

