
**Health informatics — Clinical
knowledge resources — Metadata**

*Informatique de santé — Ressources des connaissances cliniques —
Métadonnées*

STANDARDSISO.COM : Click to view the full PDF of ISO 13119:2022



STANDARDSISO.COM : Click to view the full PDF of ISO 13119:2022



COPYRIGHT PROTECTED DOCUMENT

© ISO 2022

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Introduction to metadata	2
4.1 Purpose and format.....	2
4.2 Sources of medical metadata.....	2
4.3 Characteristics of the metadata element set.....	2
5 Metadata element structure for clinical knowledge resources	3
5.1 Clinical metadata elements.....	3
5.2 Resource form.....	3
5.2.1 Group description.....	3
5.2.2 Type.....	3
5.2.3 Format.....	7
5.2.4 Language.....	8
5.3 Intended use.....	8
5.3.1 Group description.....	8
5.3.2 Audience.....	8
5.3.3 Situation.....	9
5.3.4 Clinical process stage.....	10
5.4 Subject and scope.....	10
5.4.1 Group description.....	10
5.4.2 Subject.....	10
5.4.3 Description.....	10
5.4.4 Coverage.....	11
5.4.5 Inclusion criteria.....	11
5.4.6 Exclusion criteria.....	11
5.4.7 Relation.....	11
5.5 Identification and source.....	11
5.5.1 Group description.....	11
5.5.2 Identifier.....	12
5.5.3 Title.....	12
5.5.4 Creator.....	12
5.5.5 Creator contact information.....	12
5.5.6 Date created.....	12
5.5.7 Date available.....	13
5.5.8 Date issued.....	13
5.5.9 Status.....	13
5.5.10 Rights management.....	13
5.5.11 Publisher.....	14
5.5.12 Publisher type.....	14
5.5.13 Publisher contact information.....	14
5.5.14 Contributor.....	14
5.5.15 Citation.....	15
5.5.16 Source.....	15
5.6 Quality control.....	15
5.6.1 Group description.....	15
5.6.2 Evidence Grade.....	15
5.6.3 Recommendation Strength.....	15
5.6.4 Risk consequence class.....	16
Annex A (informative) List of metadata elements	18

Annex B (informative) Class diagram	23
Bibliography	24

STANDARDSISO.COM : Click to view the full PDF of ISO 13119:2022

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 15836:2009¹⁾, 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 experiential 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.

5.2.2.6 Still image

Element name: Type.StillImage (DC)

Definition: A static visual representation

EXAMPLE Paintings, drawings, graphic designs, plans and maps. A best practice is to assign the type Text to images of textual materials. Instances of the type Still Image can also be describable as instances of the broader type Image.

5.2.2.7 Sound

Element name: Type.Sound (DC)

Definition: A resource primarily intended to be heard

EXAMPLE A music playback file format, an audio compact disc, and recorded speech or sounds, an audio instruction for a procedure.

5.2.2.8 Dataset

Element name: Type.Dataset (DC)

Definition: Data encoded in a defined structure

NOTE A dataset can be useful for direct machine processing. This includes also settings of a hardware device which can be stored on, e.g. a ROM memory.

5.2.2.9 Software

Element name: Type.Software (DC)

Definition: Type of knowledge resource with embedded knowledge information to be executed on external system

5.2.2.10 Hardware device

Element name: Type.Device (HC)

Definition: Type of knowledge resource with embedded software and knowledge

NOTE The content of this can use ISO/IEEE 11073-10101.

5.2.3 Format

5.2.3.1 General

Element name: Format (DC)

Definition: Physical or digital manifestation of the resource (DC)

Specifiers for Format: For electronic resources, use the MIME media types (for more information, see Reference [15]). Below is a list of commonly used media-types:

- a) Text/ISO/IEC-8859-1
- b) Text/plain
- c) Text/html
- d) Text/xml

- e) Application/pdf
- f) Application/msword
- g) Application/rdf
- h) Application/postscript

5.2.3.2 Extent

Element name: Format.Extent (DC)

Definition: The size or duration of the resource.

Specification of content: Because the refinement Extent is used in a variety of situations, it generally consists of both a numeric value and a caption that is needed to interpret the numeric value. Best practice is to separate the numeric value and the caption with a space, whether the caption appears before or after the value, e.g. "899 Kb", "97 pages", "21 minutes".

5.2.3.3 Medium

Element name: Format.Medium (DC)

Definition: The material or physical carrier of the resource (DC)

Specification of content: Medium is generally used when the resource is of a physical nature, for instance a painting or model, where the physical carrier or material used is relevant to the user. For instance, if the resource is a movie on DVD, and is only available as a physical object, it should be described as such.

5.2.4 Language

Element name: Language (DC)

Definition: Language of the intellectual content of the resource (DC)

Specification of content: The recommended practice is to use either a non-literal value representing a language from a controlled vocabulary such as ISO 639-2 or ISO 639-3, or a literal value consisting of an IETF Best Current Practice 47 language tag.

NOTE A link list to updated IETF documents on language tags is given in Reference [25].

5.3 Intended use

5.3.1 Group description

This group of metadata elements contains a description of the primary target group and the clinical setting where the knowledge resource is intended to be used.

5.3.2 Audience

Element name: Audience (HC)

Definition: Description of the primary target group for the knowledge resource considering the level of complexity and coverage as well as prerequisites to be able to use the resource (HC)

Specification of content: The following terms can be used to indicate the content of this metadata element:

- a) Reduced_Understanding

NOTE 1 This term is applied where the knowledge is expressed to be easier to read/understand by children or persons with reduced cognitive function.

NOTE 2 Adaptation for other functional impairments such as reduced hearing, eyesight is described as Format, see 5.2.3.

b) General_Population

NOTE 3 This term can be used for the general adult population, patient or not.

c) Student

NOTE 4 Intended as, e.g. teaching material used in training of future health professionals.

d) Health_Professional

NOTE 5 This term is used when the audience is a health professional with a generalist knowledge - audience with general medical background.

e) Health_Specialist

NOTE 6 This term is used when the audience is a Health Professional with a certain specialist knowledge and role. The Health_Specialist term can be complemented with a description of the speciality knowledge needed.

f) Researcher

NOTE 7 The audience is a research person with specialist knowledge and only indirectly of clinical use.

g) Manager

NOTE 8 This term is used when the intended audience is a person with responsibility for management of a health care organisation or a legislator or other politician steering health care.

5.3.3 Situation

Element name: Situation (HC)

Definition: Description of the situation where the knowledge is intended to be used (HC)

NOTE 1 This can also be understood as the intended role of the knowledge resource.

Specification of content: The following terms can be used:

a) Clinical_guidance

NOTE 2 Guiding a clinician in the care of an individual patient.

b) Self_guidance

NOTE 3 Guidance for patients for self-treatment/assessment.

c) Supporting_software

NOTE 4 Software system used in clinical care. This includes what is traditionally referred to as Decision Support Software but can also include the simple listing of, e.g. available imaging procedures that can be ordered.

d) Research_protocol

e) Background_knowledge

NOTE 5 This implies knowledge that is not directly intended for directing patient decisions, including research.

NOTE 6 This is a non-exhaustive list. Other situations can be added.

5.3.4 Clinical process stage

Element name: Clinical_Stage (HC)

Definition: Stage in the clinical process where knowledge is intended to be applied (HC)

NOTE 1 Multiple values can be relevant.

Specification of content: The following terms can be used:

a) Risk_assessment

NOTE 2 The risk assessment or prognosis is used when knowledge is used in predicting future events/diseases based on current health state, lifestyle and previous events.

b) Exception

NOTE 3 Recognizing clinical situations when to seek assistance, e.g. blood pressure criteria where patient must be referred to specialist.

c) Diagnosis

NOTE 4 Knowledge relevant for diagnostic process, e.g. reference values for a set of measurements in a particular population.

d) Treatment_selection

NOTE 5 Knowledge relevant for selecting the most appropriate treatment for a certain patient in a certain setting.

e) Treatment_delivery

NOTE 6 Knowledge describing how a treatment is performed.

5.4 Subject and scope

5.4.1 Group description

Standardized way of characterizing the subject area and the scope of the knowledge content.

5.4.2 Subject

Element name: Subject (DC)

Definition: topic of the content of the resource (DC)

Specification of content: This shall be indicated with one or several Medical Subject Headings as defined by the US National Library of Medicine including the MeSH codes^[20].

5.4.3 Description

Element name: Description (DC)

Definition: An account of the content of the resource (DC)

Specification of content: Examples of Description include, but are not limited to, an abstract, table of contents, reference to a graphical representation of content or free-text account of the content.

5.4.4 Coverage

Element name: Coverage (HC)

Definition: Extent, scope of knowledge content of the resource

Specification of content: Examples of specification include:

Spatial, e.g. country

Temporal, e.g. dates

Age, e.g. only elderly

Sex, e.g. only females

5.4.5 Inclusion criteria

Element name: Subject_Criteria_Inclusion (HC)

Definition: Criteria for including subjects in a clinical study

5.4.6 Exclusion criteria

Element name: Subject_Criteria_Exclusion (HC)

Definition: Criteria for excluding the subjects in a clinical study

5.4.7 Relation

Element name: Relation (DC)

Definition: A reference to related source

Specification of content: This shall be a reference using, e.g. a URI or a bibliographic reference in Vancouver style. For medical knowledge resources, it can be combined with a relationship operator from the following list:

- a) isVersionOf
- b) hasVersion
- c) isReplacedBy
- d) replaces
- e) isRequiredBy
- f) requires
- g) isPartOf
- h) hasPart
- i) isReferencedBy

5.5 Identification and source

5.5.1 Group description

This metadata element group is identifying the knowledge resource, its originator(s) and conditions for accessing it.

5.5.2 Identifier

Element name: Identifier (DC)

Definition: An unambiguous reference to the resource within a given context (DC)

Specification of content: Recommended best practice is to identify the resource by means of a string or number conforming to a formal identification system. Formal identification systems include but are not limited to the Uniform Resource Identifier (URI), including the Uniform Resource Locator (URL) or the Digital Object Identifier (DOI), and the International Standard Book Number (ISBN).

5.5.3 Title

Element name: Title (DC)

Definition: A name given to the resource (DC)

Specification of content: A text string with the name by which the resource is formally known.

5.5.4 Creator

Element name: Creator (DC)

Definition: An entity primarily responsible for making the content of the resource (DC)

Specification of content: Examples of Creator include a person, an organization, or a service. Typically, the name of a Creator should be used to indicate the entity. If several levels of specificity are required it is recommended that they are ordered from most specific to least specific, e.g. Dept of Health, Division of Patient Security, Head.

If several creators exist, it is recommended to repeat the metadata element.

5.5.5 Creator contact information

Element name: Creator.Contact (DC)

Definition: Contact details for knowledge creator (DC)

Specification of content: One or several of the following key words followed by colon and a string of specific content

- a) Address
- b) Mailto
- c) Tel
- d) Http
- e) Fax

5.5.6 Date created

Element name: Date.Created (DC)

Definition: Date when knowledge content was created (DC)

NOTE The date when the current version of the resource was created.

Specification of content: YYYY-MM-DD [ISO 8601-1]

5.5.7 Date available

Element name: Date.Available (DC)

Definition: Date when the resource was made available in its present form (DC)

Specification of content: YYYY-MM-DD [ISO 8601-1]

5.5.8 Date issued

Element name: Date.Issued (DC)

Definition: Date of formal issuance (e.g., publication) of the resource (DC)

Specification of content: YYYY-MM-DD [ISO 8601-1]

5.5.9 Status

Element name: Status (HC)

Definition: Indication of the status of this version of the resource in relation to its intended distribution and use (HC)

Specification of content: One of the following terms can be used:

- a) Tentative
- b) Draft
- c) Recommended
- d) Former
- e) Deprecated

NOTE The Status indicated will be as the publisher of the resource decides to convey it. Possible decisions that can come from other sources on status can influence this published status.

5.5.10 Rights management

Element name: Rights (DC)

Definition: Information about rights held in and over the resource (DC)

Specification of content: Typically, Rights will contain a rights management statement for the resource, or reference a service providing such information. Rights information often encompasses Intellectual Property Rights (IPR), Copyright, and various Property Rights. If the Rights element is absent, no assumptions can be made about any rights held in or over the resource.

For health care use the following minimum terminology can be used to specify rights:

- a) Free

NOTE 1 Publicly available at no cost but IPR and copyright can apply.

- b) Charge

NOTE 2 Publicly available but at a cost.

- c) Private

NOTE 3 Only available to a selected group.

5.5.11 Publisher

Element name: Publisher (DC)

Definition: An entity responsible for making the resource available (DC)

Specification of content: Examples of Publisher include a person, an organization, or a service. Typically, the name of a Publisher should be used to indicate the entity.

5.5.12 Publisher type

Element name: Publisher.Type

Definition: Category of publisher

Specification of content: The following terms can be used.

- a) Individual
- b) National_government
- c) Local_government
- d) Care_provider
- e) University
- f) Professional_organisation
- g) Patient_organisation
- h) Other_non-profit_organisation

NOTE Entities such as WHO or various other groups of states can be classified as Other Non-profit-Organization. The actual name such as WHO or EU, etc. would appear as the Publisher (name).

- i) Commercial_publisher
- j) Pharmaceutical_company
- k) Other_company

5.5.13 Publisher contact information

Element name: Publisher.Contact (DC)

Definition: Contact details for publisher

Specification of content: One or several of the following key words followed by colon and a string of specific content

- a) Address
- b) Mailto
- c) Tel
- d) Http
- e) Fax

5.5.14 Contributor

Element name: Contributor

Definition: Person(s) or organization(s) in addition to those specified in the Creator element who have made significant intellectual contributions to the resource, but whose contribution is secondary to the individuals or entities specified in the Creator element.

Specification of content: Typically a text string with the name(s) of the contributor(s)

5.5.15 Citation

Element name: Citation (HC)

Definition: Bibliographic reference for citation of the resource

Specification of content: Bibliographic reference in Vancouver style format

5.5.16 Source

Element name: Source (DC)

Definition: A reference to a resource from which the present resource is derived

Specification of content: The present resource can be derived from the Source resource in whole or in part. Recommended best practice is to identify the referenced resource by means of a string or number conforming to a formal identification system.

5.6 Quality control

5.6.1 Group description

This group of metadata elements that are particularly important for clinical knowledge shall describe the quality management system behind a knowledge resource to allow use based on some judgement of reliability.

5.6.2 Evidence Grade

Element name: EvidenceGrade (HC)

Definition: An indication of the guideline developers' assessment of the quality of evidence (HC)

Specification of content: Use the terminology developed by GRADE and recently recommended by WHO for guideline development^[21]. It is recommended that the source (organization or person) of the recommendation is given within parenthesis after the EvidenceGrade category.

- a) High
- b) Moderate
- c) Low
- d) Very low

5.6.3 Recommendation Strength

Element name: RecommendationStrength (HC)

Definition: An Indication of the guideline developers' overall assessment of the strength of a recommendation (HC)

Specification of content: Use the categories developed by GRADE and recently recommended by WHO for guideline development^[21]. It is recommended that the source (organization or person) of the recommendation is given within parenthesis after the RecommendationStrength category.

- a) High
- b) Low

5.6.4 Risk consequence class

Element name: Risk (HC)

Definition: Possible consequences of mistakes in applying knowledge, which affects the amount of automatic processing that can be allowed / the amount of manual supervision necessary

Specification of content: Use one of the following terms. The interpretation of these terms in this context is described in [Table 1](#).

- a) Catastrophic
- b) Major
- c) Considerable
- d) Significant
- e) Minor

STANDARDSISO.COM : Click to view the full PDF of ISO 13119:2022

Table 1 — Interpretation of the Consequence categories

Consequence Category	Consequence	Number of patients affected
Catastrophic	Deaths.	Multiple
	Permanent life-changing incapacity and any condition for which the prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term.	Multiple
Major	Death.	Single
	Permanent life-changing incapacity and any condition for which the prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term.	Single
	Severe injury or severe incapacity from which recovery is expected in the short term.	Multiple
	Severe psychological trauma.	Multiple
Considerable	Severe injury or severe incapacity from which recovery is expected in the short term.	Single
	Severe psychological trauma.	Single
	Minor injury or injuries from which recovery is not expected in the short term.	Multiple
	Significant psychological trauma.	Multiple
Significant	Minor injury or injuries from which recovery is not expected in the short term.	Single
	Significant psychological trauma.	Single
	Minor injury from which recovery is expected in the short term. Minor psychological upset; inconvenience.	Multiple
Minor	Minor injury from which recovery is expected in the short term; minor psychological upset; inconvenience; any negligible consequence.	Multiple
		Single

Annex A (informative)

List of metadata elements

[Table A.1](#) is a summary of all element names and definitions. For further specification of content, see [Clause 5](#).

STANDARDSISO.COM : Click to view the full PDF of ISO 13119:2022

Table A.1 — List of metadata elements

Label	Element name	Definition
Type	Type	Nature or genre of the content of the resource (DC).
	Type.Text (DC)	
	Specifiers (HC):	
	Journal_article	
	Book_chapter	
	Book	
	Report	
	Abstract	
	Patient_education_handout	
	FAQ	
	Algorithm	
	Clinical_guideline	
	Policy_strategy	
	Information_standard	
	Teaching_material	
	Computable_clinical_information_model	
	Terminological_resource	
	Metainformation	
	Case_report	
	Proposal	
	Event	
	Service_description	
	Product_information	
	Critically_appraised_topic	
	Known_uncertainty	
	Observational_study	
	Qualitative_study	
	Randomised_controlled-trial	
	Research_study	
	Review	
	Systematic_review	
	Structured_abstract	
	Care_pathway	
	Health_Technology_Assessment	
	Type.MovingImage	
	Type.StillImage	
	Type.Sound	
	Type.DatabaseforHumans	
	Journal	
	Metainformation	
	Terminology	
	Guideline_collection	
	Type.Dataset	
	Type.InteractiveResource	
	Type.Software	
	Type.Device	