BS EN ISO 13119:2012

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Health informatics — Clinical knowledge resources — Metadata (ISO 13119:2012)

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National foreword

This British Standard is the UK implementation of EN ISO 13119:2012. It supersedes DD CEN/TS 15699:2009 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its secretary.

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ISBN 978 0 580 69482 0

ICS 35.240.80

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2012.

Amendments issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13119

November 2012

ICS 35.240.80

Supersedes CEN/TS 15699:2009

English Version

Health informatics - Clinical knowledge resources - Metadata (ISO 13119:2012)

Informatique de santé - Ressources des connaissances cliniques - Métadonnées (ISO 13119:2012)

Medizinische Informatik - Klinische Wissensressourcen - Metadaten (ISO 13119:2012)

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Ref. No. EN ISO 13119:2012: E

Foreword

This document (EN ISO 13119:2012) has been prepared by Technical Committee CEN/TC 251 “Health informatics", the secretariat of which is held by NEN, in collaboration with Technical Committee ISO/TC 215 "Health informatics".

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2013, and conflicting national standards shall be withdrawn at the latest by May 2013.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes CEN/TS 15699:2009.

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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.

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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.

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ISO 13119 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).

This International Standard is a revision of CEN/TS 15699:2009, *Health informatics — Clinical knowledge resources — Metadata*.

Introduction

The internet is rapidly changing the way we access medical knowledge. Health professionals use web-based knowledge sources while digital documents are provided from databases and via e-mail. Also, patients and the general public turn to the internet, particularly in those countries in Europe where more than 50 % of households already have internet access in their homes. The European Commission eEurope action plan 2002 describes the following challenge:

"Health-related information is among the most frequently accessed information on the Internet. Yet at present, the European citizen has very few resources with which to assess the quality and authenticity of this vital information."

The European Commission has in response to this requirement published a set of quality criteria for health-related websites[18].

One way to help navigate the multitude of information of varying quality is to establish a "Trustmark" to label web documents that meet certain criteria. This was proposed in the TEAC-Health project of the 4th framework and was the basis for the start of the MEDCERTAIN project started in September 2000. There are, however, other possible solutions as well that may have advantages and may exist in parallel. A trustmark indicating a "minimum" level of trustworthiness requires the following elements.

a) A set of quality requirements. This might be very difficult to agree on as relevant for all contexts. The agreed criteria may be regarded as too low or too high for certain purposes.

b) Third party control by governmental bodies or professional associations of all possible resources to receive the mark.

c) Reliance on a self-declaration by the issuer in which case the user of the information has no real guarantee that the criteria are met even if the mark is there.

Instead of reviewing the actual content of the medical knowledge resources, we can define the processes behind their development, which may impose requirements on professional education, quality assurance principles in general, scientific reviews, etc.

This whole area requires collaboration of many different parties with different roles. Important work has started in several professional associations and among web publishers of health information. Health authorities in many countries, and in collaboration with the Commission, have considered the possible requirements for legislation and control procedures; generally, the conclusions have been that rather than trying to ban bad quality information, one should facilitate for the citizens as well as for the health professionals to find the type of information they request where quality criteria behind a knowledge resource are easily accessible.

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 researchers' protocols for clinical trials.

Some types of documents may have legal implications; a health professional is obliged to follow them, or they may define the officially recommended treatment. This International Standard aims to make the type of document explicit. 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 International Standard will not only be useful for the assessment of a knowledge resource but also to facilitate search and retrieval of knowledge resources.

This International Standard for metadata is based on the general purpose metadata standardization initiative Dublin Core[1)] which developed the first set of 15 metadata elements, later published as ISO 15836:2003, which has been cancelled and replaced by ISO 15836:2009.

This International Standard 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 rapid development.

The basic structure (taken from Dublin Core), with the extensions provided in this International Standard, 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 laymen and corresponding to the language used in the resource itself. This International Standard does in no way preclude the use of such national metadata vocabularies. However, even when this is the case, this International Standard can serve as an inspiration for defining important metadata.

It should also be emphasized that the extensive set of possible metadata elements defined in this International Standard is usually useful only as a subset for a specific set of resources. The compilation of a possible application profile with a minimum set of metadata elements for various purposes may be the scope of future work.

1) The Dublin Core Metadata Initiative (www.dublincore.org).

Health informatics — Clinical knowledge resources — Metadata

1 Scope

This International Standard specifies a number of metadata elements that describe resources containing medical knowledge. It is primarily applicable to 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 medical literature.

The metadata elements:

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

b) are applicable to different kinds of digital resources e.g. recommendations resulting from the 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;

c) can be presented to human readers including health professionals, as well as citizens/patients;

d) 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 International Standard 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);

— prescribe criteria for the quality of the resource content.

2 Terms and definitions

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

2.1
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 This does not only refer to physicians; all health professionals have medical knowledge according to this definition.

2.2
clinical knowledge
part of medical knowledge pertaining to the promotion of good health and the management and prevention of ill health

NOTE This is used to diagnose, treat and alleviate disease/dysfunction.

2.3
knowledge resource
collection of knowledge about a subject area collected for a purpose and made available to a user through some means

2.4
metadata
data that defines and describes other data

2.5
lifecycle
⟨information resource⟩ sequence of events that mark the development and use of an information resource

NOTE Adapted from ISO 15836:2009, definition 3.1.2.

EXAMPLE Conception of an invention, creation of a draft, revision of an article, publication of a book, acquisition by a library, transcription to magnetic disk, migration to optical storage, translation into English and derivation of a new work (e.g. a film).

3 Introduction to metadata

3.1 Purpose and format

Metadata for a knowledge resource conveys information that is non-essential for the purpose of the document but important for other purposes, such as:

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

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

3.2 Sources of generally useful metadata elements

General metadata have been developed by an initiative from library science known as the Dublin Core Metadata, adopted and published as ISO 15836:2009.

3.3 Sources of medical metadata

In the development of this International Standard, several sets of metadata particularly relevant for clinical knowledge were used as input and/or inspiration, including Arden syntax and ISO 13606-3.

3.4 Characteristics of the metadata element set

In the element descriptions in 4.2 to 4.6, 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, recommended practice is to always adhere to the case conventions in the element names given to avoid conflicts in the event that the metadata are subsequently extracted or converted to a case-sensitive environment, such as XML (Extensible Markup Language).

Each element is optional and repeatable. Metadata elements may appear in any order. The ordering of multiple occurrences of the same element (e.g. Creator) may 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 Dublin Core metadata element set and adds other metadata elements as required by the domain. This International Standard is a specialization for the medical knowledge domain.

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

4 Metadata element structure for medical knowledge resources

4.1 Introduction to the medical metadata elements

This clause establishes a categorisation 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 International Standard. Most of these come from the Dublin Core, indicated by (DC). In these cases, additional information may be found in ISO 15836:2009. In a few cases, this structure also proposes a substructure of specialization of the metadata elements. Where elements or sub-elements are defined in this health care International Standard, it is indicated by (HC). The syntax for representing metadata may vary, depending on the format of the metadata expression e.g. XML.

NOTE This International Standard 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 of individual metadata properties in the Resource Description Framework (RDF) of the World Wide Web consortium.

For the purpose of navigation among the many metadata elements of this International Standard, they are presented under a set of group headings. These are not to be implemented as metadata tags in resources.

4.2 Resource form

4.2.1 Group description

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

4.2.2 Type

4.2.2.1 General

Element name: Type (DC)

Definition: nature or genre of the content of the resource (DC).

Health care specific specialization: the following terms may be used to describe Type:

— Text

— Database for human reading

— Interactive resource

— Moving image

— Still image

— Sound

— Dataset

— Software

— Hardware device

It is recommended that these terms are complemented by a type specifier as given below.

4.2.2.2 Text

Element name: Type.Text (DC)

Definition: a resource consisting primarily of words for reading.

NOTE A resource (often called document) which contains still images in addition to the words shall be designated type Text.

EXAMPLES Books, letters, dissertations, poems, newspapers, articles and archives of mailing lists. Note that 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 This is information directed towards a patient/subject of care about a particular health issue. This includes medication inserts in medicinal products.

g) FAQ

NOTE FAQ stands for Frequently Asked Questions.

h) Algorithm

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

i) Clinical_guideline

NOTE This is defined in EN 13940 as “set of systematically developed statements to assist the decision of health care parties about health care activities to be provided with regard to a health issue in specified clinical circumstances”.

j) Policy_strategy

NOTE A document that is a policy or a strategy for the operation of health care services.

k) Information_standard

NOTE A standard relating to health information and health informatics.

l) Teaching_material

NOTE This includes learning/self-learning materials.

m) Computable_clinical_information_model

NOTE This includes, for example, the special form of constrained information model used to describe a part of an Electronic Health Record as described by ISO 13606-2 or OpenEHR (see http://www.openehr.org/home.html). Also, HL7-based templates could be tagged with this.

n) Terminological_resource

o) Metainformation

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

p) Case_report

q) Proposal

NOTE This term should be used to label a plan for a project.

r) Event

NOTE This term may 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 described the outcome of an event.

s) Service_description

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

t) Product_information

u) Critically_appraised_topic

NOTE 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. It includes all topics produced by question-answering services.

v) Known_uncertainty

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

w) Observational_study

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

x) Qualitative_study

NOTE Studies which research social, emotional and experiential phenomena in health care.

y) Randomized_controlled-trial

NOTE 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 Research studies not included in any of the other publication types. This is used for case study and case series. This is not to be used unless all other publication types have been excluded.

aa) Review

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

bb) Systematic_review

NOTE 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) may or may not 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, Review should be used.

cc) Structured_abstract

NOTE An abstract of a single journal article with headings that conform 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

4.2.2.3 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

4.2.2.4 Interactive resource

Element name: Type.InteractiveResource (DC)

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

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

4.2.2.5 Moving image

Element name: Type.MovingImage (DC)

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

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

4.2.2.6 Still image

Element name: Type.StillImage (DC)

Definition: a static visual representation.

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

4.2.2.7 Sound

Element name: Type.Sound (DC)

Definition: a resource primarily intended to be heard.

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

4.2.2.8 Dataset

Element name: Type.Dataset (DC)

Definition: data encoded in a defined structure.

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

4.2.2.9 Software

Element name: Type.Software (DC)

Definition: type of knowledge resource with embedded knowledge information to be executed on an external system.

4.2.2.10 Hardware device

Element name: Type.Device (HC)

Definition: type of knowledge resource with embedded software and knowledge.

NOTE The content of this may consider using ISO/IEEE 11073-10101:2004, *Health informatics - Point-of-care medical device communication - Part 10101: Nomenclature*.

4.2.2.11 Format

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 http://www.isi.edu/in-notes/iana/assignments/media-types). Below is a list of commonly used media-types:

a) Text/ISO-8859-1

b) Text/plain

c) Text/html

d) Text/xml

e) Application/pdf

f) Application/msword

g) Application/rdf

h) Application/postscript

4.2.2.12 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”.*

4.2.2.13 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.

4.2.3 Language

Element name: Language (DC)

Definition: language of the intellectual content of the resource (DC).

Specification of content: recommended practice is to use RFC 3066, which, in conjunction with ISO 639, defines two- and three-letter primary language tags with optional subtags. Examples include “en” or “eng” for English, “akk” for Akkadian and “en-GB” for English used in the United Kingdom.

NOTE Language codes are available at: http://www.ietf.org/rfc/rfc4646.txt.

4.3 Intended use

4.3.1 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.

4.3.2 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 may be used to indicate the content of this metadata element:

a) Reduced_Understanding

NOTE 1 This term is applied in cases where the knowledge is expressed in such a way as to be easier for children or persons with reduced cognitive function to read/understand.

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

b) General_Population

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

c) Student

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

d) Health_Professional

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

e) Health_Specialist

NOTE This term is used when the audience is a health professional with a certain specialist knowledge and role. In this case, it is recommended that the Health_Specialist term can be complemented with a description of the specialist knowledge needed.

f) Researcher

NOTE The audience is a research person with specialist knowledge; it only has indirect clinical use.

g) Manager

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

4.3.3 Situation

Element name: Situation (HC)

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

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

Specification of content: the following terms may be used:

a) Clinical_guidance

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

b) Self_guidance

NOTE Guidance for patients for self-treatment/assessment.

c) Supporting_software

NOTE 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 1 This implies knowledge that is not directly intended for directing patient decisions, including research.

NOTE 2 This is a non-exhaustive list. Other situations may be added.

4.3.4 Clinical process stage

Element name: Clinical_Stage (HC)

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

NOTE Multiple values can be relevant.

Specification of content: the following terms may be used:

a) Risk_assessment

NOTE 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 Recognizing clinical situations that require assistance, e.g. blood pressure criteria where the patient should be referred to a specialist.

c) Diagnosis

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

d) Treatment_selection

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

e) Treatment_delivery

NOTE Knowledge describing how a treatment should be performed.

4.4 Subject and scope

4.4.1 Group description

This is a standardised way of characterizing the subject area and the scope of the knowledge content.

4.4.2 Subject

Element name: Subject (DC)

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

Specification of content: this shall be indicated by one or several Medical Subject Headings as defined by the US National Library of Medicine, including the MeSH codes (see www.nlm.org).

4.4.3 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.

4.4.4 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.

4.4.5 Inclusion criteria

Element name: Subject_Criteria_Inclusion (HC)

Definition: criteria for including subjects in a clinical study.

4.4.6 Exclusion criteria

Element name: Subject_Criteria_Exclusion (HC)

Definition: criteria for excluding the subjects in a clinical study.

4.4.7 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

4.5 Identification and source

4.5.1 Group description

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

4.5.2 Identifier

Element name: Identifier (DC)

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

Specification of content: recommended 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).

4.5.3 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.

4.5.4 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.

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

4.5.5 Creator contact information

Element name: Creator.Contact (DC)

Definition: contact details for knowledge creator (DC).

Specification of content: one or several of the following keywords followed by a colon and a string of specific content:

a) Address

b) Mailto

c) Tel

d) Http

e) Fax

4.5.6 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].

4.5.7 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].

4.5.8 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].

4.5.9 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 may be used:

a) Tentative

b) Draft

c) Recommended

d) Former

e) Deprecated

NOTE The Status indicated will be as decided to be conveyed by the publisher of the resource. Possible decisions that may come from other sources on status might of course influence this published status.

4.5.10 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 may be made about any rights held in or over the resource.

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

a) Free

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

b) Charge

NOTE Publicly available at a cost.

c) Private

NOTE Only available to a selected group.

4.5.11 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.

4.5.12 Publisher type

Element name: Publisher.Type (NGC)

Definition: category of publisher.

Specification of content: the following terms may be used:

NOTE Modified from the US National Guideline Centre.

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-Organisation. The actual name, such as WHO or EU, would appear as the Publisher (name).

i) Commercial_publisher

j) Pharmaceutical_company

k) Other_company

4.5.13 Publisher contact information

Element name: Publisher.Contact (DC)

Definition: contact details for publisher.

Specification of content: one or several of the following keywords followed by a colon and a string of specific content:

a) Address

b) Mailto

c) Tel

d) Http

e) Fax

4.5.14 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).

4.5.15 Citation

Element name: Citation (HC)

Definition: bibliographic reference for citation of the resource.

Specification of content: bibliographic reference in Vancouver style format.

4.5.16 Source

Element name: Source (DC)

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

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

4.6 Quality control

4.6.1 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.

4.6.2 Evidence grading

Element name: EvidenceGrade (HC)

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

Specification of content: the terminology developed by GRADE and recently recommended by WHO for guideline development (http://www.health-policy-systems.com/content/4/1/21) is to be used. It is recommended that the source (organization or person) of the recommendation is given within parentheses after the EvidenceGrade category.

a) High

b) Moderate

c) Low

d) Very low

4.6.3 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: the categories developed by GRADE and recently recommended by WHO for guideline development (http://www.health-policy-systems.com/content/4/1/21) are to be used. It is recommended that the source (organization or person) of the recommendation is given within parentheses after the RecommendationStrength category.

a) High

b) Low

4.6.4 Risk consequence class

Element name: Risk (HC)

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

Specification of content: one of the following terms derived from ISO/TS 25238, *Health informatics – Classification of safety risks from health software* is to be used:

a) Catastrophic

b) Major

c) Considerable

d) Significant

e) Minor

NOTE For definitions of these, see ISO/TS 25238:2007, 6.2.

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.

Table A.1 — List of metadata elements

Label	Element name	Definition
Type	Type 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*	Nature or genre of the content of the resource (DC).

Table A.1 *(continued)*

Label	Element name	Definition
	Structured_abstract *Care_pathway* Type.MovingImage Type.StillImage Type.Sound Type.DatabaseforHumans *Journal* *Metainformation* *Terminology* *Guideline_collection* Type.Dataset Type.InteractiveResource Type.Software Type.Device	
Format	Format *All media-types e.g.* *Text/ISO-8859-1* *Text/plain* *Text/html* *Text/xml* *Application/pdf* *Application/msword* *Application/rdf* *Application/postscript* Format.Extent (DC) Format.Medium (DC)	Physical or digital manifestation of the resource (DC).
Language	Language	Language of the intellectual content of the resource (DC).
Audience	Audience Specifiers (HC): *Reduced_Understanding* *General_Population* *Student* *Health_Professional* *Health_Specialist* *Researcher* *Manager*	Description of the primary target group for the knowledge resource considering the level of complexity and coverage as well as prerequisites in order to be able to use the resource (HC).

Table A.1 *(continued)*

Label	Element name	Definition
Situation	Situation Specifiers (HC): *Clinical_guidance* *Self_guidance* *Supporting_software* *Research_protocol* *Background_knowledge*	Description of the situation where the knowledge is intended to be used (HC).
Clinical process stage	Clinical_Stage Specifiers (HC): *Risk_assessment* *Exception* *Diagnosis* *Treatment_selection* *Treatment_delivery*	Stage in the clinical process where knowledge is intended to be applied (HC).
Subject	Subject Specifiers: *Coverage* *Subject_Criteria_Inclusion* *Subject_Criteria_Exclusion*	A topic of the content of the resource (DC).
Description	Description	An account of the content of the resource (DC).
Relation	Relation Combined with (HC): *isVersionOf* *hasVersion* *isReplacedBy* *replaces* *isRequiredBy* *requires* *isPartOf* *hasPart* *isReferencedBy*	A reference to a related source.
Evidence Grading	EvidenceGrade	An indication of the guideline developers' assessment of the quality of evidence (HC).
Recommendation Strength	RecommendationStrength	An indication of the guideline developers' overall assessment of the strength of a recommendation (HC).
Risk Class	Risk	Possible consequences of mistakes in applying knowledge, which affect the amount of automatic processing that can be allowed/the amount of manual supervision necessary.
Identifier	Identifier	An unambiguous reference to the resource within a given context (DC).
Title	Title	A name given to the resource (DC).

Table A.1 *(continued)*

Label	Element name	Definition
Creator	Creator	An entity primarily responsible for making the content of the resource (DC).
Creator Contact Information	Creator.Contact Specifiers: *Address* *Mailto* *Tel* *Http* *Fax*	Contact details for knowledge creator (DC).
Date created	Date.Created	Date when knowledge content was created (DC).
Date available	Date.Available	Date when the resource was made available in its present form (DC).
Date issued	Date.Issued	Date of formal issuance (e.g. publication) of the resource (DC).
Status	Status Specifiers: *Tentative* *Draft* *Recommended* *Former* *Deprecated*	Indication of the status of this version of the resource in relation to its intended distribution and use (HC).
Rights management	Rights Specifiers (HC): *Free* *Charge* *Private*	Information about rights held in and over the resource (DC).
Publisher	Publisher	An entity responsible for making the resource available (DC).
Publisher type	*Publisher.Type* *Specifiers (HC):* *National_government* *Local_government* *CareProvider* *University* *Professional_organisation* *Patient_organisation* *Other_non-profit organisation* *Commercial_publisher* *Pharmaceutical_company* *Other_company*	Category of publisher (HC).

Table A.1 *(continued)*

Label	Element name	Definition
Publisher contact	Publisher.contact Specifiers (HC): *Address* *Mailto* *Tel* *Http* *Fax*	Contact details for publisher (DC).
Contributor	Contributor	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 (DC).
Citation	Citation	Bibliographic reference for citation of the resource (HC).
Source	Source	A reference to a resource from which the present resource is derived (DC).
Evidence grading	EvidenceGrade Specifiers: *High* *Moderate* *Low* *Very low*	An indication of the guideline developers' assessment of the quality of evidence (HC).
Recommendation Strength	RecommendationStrength Specifiers (HC): *High* *Low*	An indication of the guideline developers' overall assessment of the strength of a recommendation (HC).
Risk class	Risk Specifiers (HC): *Catastrophic* *Major* *Considerable* *Significant* *Minor*	Possible consequences of mistakes in applying knowledge, which affect the amount of automatic processing that can be allowed/the amount of manual supervision necessary (HC).

Annex B
(informative)

Class diagram

Figure B.1 shows a class diagram of metadata elements indicating as abstract classes the names of the groups of elements.

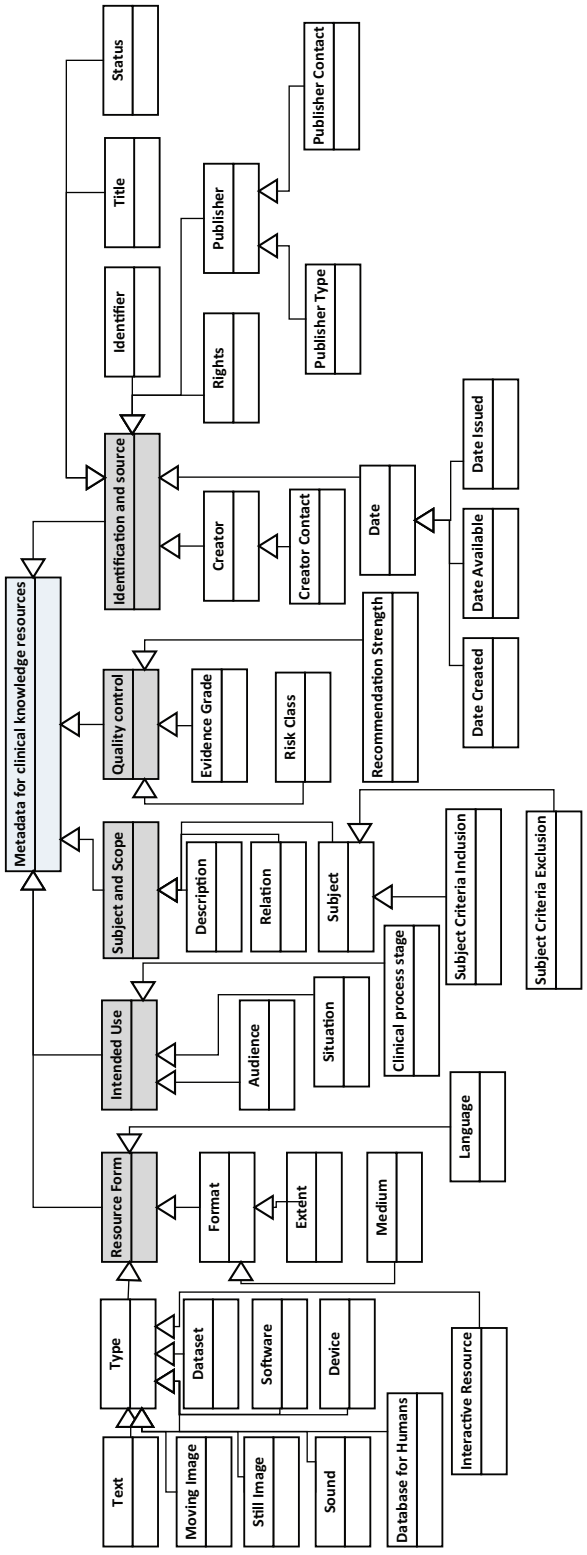

Figure B.1 — Class diagram of metadata elements indicating as abstract classes the names of the groups of elements

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