INTERNATIONAL STANDARD

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Health informatics — Clinical knowledge resources — Metadata

Informatique de santé — Ressources des connaissances cliniques — Métadonnées

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Foreword

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

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

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

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

ISO 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.