SLOVENSKI STANDARD
oSIST prEN ISO 13119:2021

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Zdravstvena informatika - Viri kliničnega znanja - Metapodatki (ISO/DIS 13119:2021)

Health informatics - Clinical knowledge resources - Metadata (ISO/DIS 13119:2021)

Medizinische Informatik - Klinische Wissensresourcen - Metadaten (ISO/DIS 13119:2021)

Informatique de santé - Ressources des connaissances cliniques - Métadonnées (ISO/DIS 13119:2021)

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Foreword

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

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

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

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, Health informatics.

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

The main changes compared to the previous edition 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 we access medical knowledge. Health professionals use web-based knowledge sources and databases and also the patients/citizens 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, we assist citizens, health professionals and software developers to find the type of information they request by making quality criteria behind a knowledge resource easily accessible.

This may be achieved by a combination of quality requirements with third party control by governmental bodies or professional associations or reliance on a self-declaration by the issuer.

Instead of reviewing the content of the medical knowledge resources, we can 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 may have legal implications - a health professional is obliged to follow them, or they may define the officially recommended treatment. This 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 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 fifteen metadata elements, later published as ISO 15836:2003, which has been updated as ISO 15836-1:2017.

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 a rapid development.

The basic structure (taken from Dublin Core) and 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 laypersons 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 is also be emphasized that the extensive set of possible metadata elements defined in this International Standard are usually useful only as a subset for a specific set of resources. The compilation of a possible

1) The Dublin Core Metadata Intitiative - www.dublincore.org

application profile with a minimum set of metadata elements for various purposes may be the scope of future work.

Health informatics — Clinical knowledge resources — Metadata

1 Scope

This International Standard 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 citizens/patients*

— 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 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15836-2:2017, *Information and documentation — The Dublin Core metadata element set — Part 2: DCMI properties and classes*

3 Terms and definitions

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

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

3.4
metadata
data that defines and describes other data

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

3.5
lifecycle of information a resource
sequence of events that mark the development and use of a resource

[SOURCE: ISO 15836-1:2017, 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 movie).

4 Introduction to metadata

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

4.2 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 an ISO standard [ISO 15836: parts 1 and 2].

4.3 Sources of medical metadata

In the development of this document several sets of metadata particularly relevant for clinical knowledge were used as input and/or inspiration, including Arden syntax, ISO 13606-3, GEM (Guidelines Element Model), The US National Guidelines Clearinghouse (NGC).

4.4 Characteristics of the metadata element set

In the element descriptions in clauses 5.2 – 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, the best practice recommended is to always adhere to the case conventions in the element names given to avoid conflicts in the event

