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

EESTI STANDARDIKESKUS EVS
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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 13119:2012 sisaldab Euroopa standardi EN ISO 13119:2012 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 13119:2012 consists of the English text of the European standard EN ISO 13119:2012.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 01.11.2012.	Date of Availability of the European standard is 01.11.2012.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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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)

This European Standard was approved by CEN on 31 October 2012.

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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of an identical text or by endorsement, at the latest by May 2013, and conflicting national standards shall be withdrawn at the latest by May 2013.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.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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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, 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.

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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