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Entwurf

**Medizinische Informatik –
Klinische Wissensressourcen –
Metadaten (ISO/DIS 13119:2010);
Englische Fassung prEN ISO 13119:2010**

Health informatics –
Clinical knowledge resources –
Metadata (ISO/DIS 13119:2010);
English version prEN ISO 13119:2010

Informatique de santé –
Ressources en matière de connaissances cliniques –
Métadonnées (ISO/DIS 13119:2010);
Version anglaise prEN ISO 13119:2010

Anwendungswarnvermerk

Dieser Norm-Entwurf mit Erscheinungsdatum 2011-01-31 wird der Öffentlichkeit zur Prüfung und Stellungnahme vorgelegt.

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- oder in Papierform an den Normenausschuss Medizin (NAMed) im DIN, 10772 Berlin (Hausanschrift: Burggrafenstr. 6, 10787 Berlin).

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Gesamtumfang 36 Seiten

Normenausschuss Medizin (NAMed) im DIN

Nationales Vorwort

Dieses Dokument (prEN ISO 13119:2010) wurde vom Technischen Komitee CEN/TC 251 „Medizinische Informatik“ (Sekretariat: NEN, Niederlande) in Zusammenarbeit mit dem Technischen Komitee ISO/TC 215 „Health Informatics“ erarbeitet. Der Fachbereich 7 „Medizinische Informatik“ und insbesondere die Mitarbeiter des Arbeitsausschusses NA 063-07-03 AA „Terminologie“ des Normenausschusses Medizin (NAMEd) im DIN haben an der Erarbeitung mitgewirkt. Dieser Norm-Entwurf enthält unter Berücksichtigung des Präsidialbeschlusses 13/1983 den englischen Originaltext der internationalen Norm ISO/DIS 13119, Ausgabe November 2011.

Das Ausgabedatum des Europäischen Norm-Entwurfs stand zum Zeitpunkt der Veröffentlichung dieses DIN-EN-ISO-Entwurfs noch nicht fest; der prEN ISO wird jedoch vom CMC unter der angegebenen prEN-Nummer demnächst zur CEN-Umfrage verteilt. Um der deutschen Öffentlichkeit eine möglichst lange Einspruchsfrist einzuräumen, wurde dieser Norm-Entwurf bereits vorab veröffentlicht.

Dieser Internationale Standard legt eine Anzahl von Metadatenelementen fest, die zur Beschreibung von Dokumenten dienen, die medizinisches Wissen enthalten, in erster Linie sind dies digitale Dokumente wie Web Ressourcen, mit Zugang von Datenbanken oder über File-Transfer, sie können auch verwendet werden für Papierdokumente, z. B. für Artikel in der medizinischen Literatur.

Die Metadaten sollten:

- die eindeutige und internationale Verständigung über wichtige Aspekten zur Beschreibung eines Dokuments unterstützen, z. B. *Zweck, Bearbeiter, beabsichtigter Empfänger, rechtlicher Status und wissenschaftlicher Hintergrund*;
- auf unterschiedliche Arten digitaler Dokumente anwendbar sein, z. B. Anforderungen aus Konsensbildungen von einer professionellen Gruppe, Verordnungen von Regierungsstellen, klinische Versuchsprotokolle von pharmazeutischen Unternehmen, wissenschaftliche Berichte von Forschungsgruppen, Ratschläge von Patienten mit einer bestimmten Erkrankung, Übersichtsartikel;
- die Möglichkeit bieten von Menschen ausgelesen zu werden, sowohl von qualifizierten Personen des Gesundheitswesens als auch von Bürgern/Patienten
- die potentielle Möglichkeiten für eine automatische Weiterverarbeitung bieten, z. B. zur Unterstützung von Suchmaschinen für eingeschränkte Verknüpfungen zu Dokumenten eines bestimmten Typs oder Qualitätslevels.

Die durch diese Norm festgelegten Daten sind nicht dazu bestimmt

- Dokumente eines einzelnen Patienten, wie Behandlungsunterlagen zu beschreiben;
- Details von medizinischen Inhalten von Dokumenten zu beschreiben (aber einige Gedanken zu den Inhalten können über Stichwörter oder Codes beschrieben sein);
- Kriterien für die Qualität des Dokumentinhalts festzulegen.

Für die Anwendung dieses Dokuments gelten die folgenden Begriffe:

Begriff	Definition	Term	Definition
medizinisches Wissen	Wissensgebiet betreffend die Struktur, Funktion oder Funktionsstörung eines menschlichen Körpers und wie diese von internen und externen Faktoren und Interventionen beeinflusst werden können Anmerkung Medizinisch bedeutet nicht unbedingt "Mediziner", sondern alle qualifizierten Personen des Gesundheitswesens haben ein medizinisches Wissen in Übereinstimmung mit dieser Definition	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 Medical does not imply "physician" – all health professionals have medical knowledge according to this definition.
klinisches Wissen	Teil des medizinischen Wissens betreffend die Unterstützung einer guten Gesundheit und das Management und die Vorbeugung von Krankheiten Anmerkung Verwendet für Diagnose, Behandlung und Schmerzlinderung von Krankheiten/Fehlfunktionen	clinical knowledge	part of medical knowledge pertaining promoting good health and the management and prevention of ill health NOTE Used to diagnose, treat and alleviate disease/dysfunction.
Wissensressourcen	Wissenssammlung über ein Fachgebiet für einen Zweck und in einer bestimmten Erscheinungsform dem Anwender verfügbar gemacht	knowledge resource	collection of knowledge about a subject area collected for a purpose and made available to a user as some manifestation
Metadaten	Daten, die andere Daten definieren oder beschreiben [ISO 1087-1:2000]	metadata	data that defines and describes other data [ISO 1087-1:2000]
Lebenszyklus [für Informationsressourcen]	Folge von Ereignissen die die Entwicklung und Verwendung einer Informationsressource ausmachen [ISO 15836:2009] BEISPIEL Konzept für eine Erfindung, Entwicklung eines Entwurfs, Revision eines Artikels, Publizierung eines Buches, Beschaffung durch eine Bibliothek, Abschrift auf einer Magnetplatte, Migration auf eine optische Speicherung, Übersetzung ins Englische und Herkunft einer neuen Arbeit (z. B. eines Films)	lifecycle [of information resource]	sequence of events that mark the development and use of an information resource [ISO 15836:2009] 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).

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Medizinische Informatik — Klinische Wissensressourcen — Metadaten (ISO/DIS 13119:2010)

*Informatique de santé — Ressources en matière de connaissances cliniques — Métadonnées
(ISO/DIS 13119:2010)*

Health informatics — Clinical knowledge resources — Metadata (ISO/DIS 13119:2010)

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Foreword

This document (prEN ISO 13119:2010) has been prepared by Technical Committee CEN/TC 251 "Health informatics" the secretariat of which is held by NEN in collaboration with the Technical Committee ISO/TC 215 "Health informatics".

This document is currently submitted to the parallel Formal Vote.

Introduction

The internet is rapidly changing the way we access medical knowledge. Health professionals use web based knowledge sources and digital documents are provided from databases and via e-mail. Also the patients/citizens 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 amongst 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 websites¹.

One way to help navigate in the multitude of information of various 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:

- 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 documents 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 processes behind their development, which may put 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 requirement for legislation and control procedures, but 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 researcher's protocols for clinical trials.

In some cases, document type may have legal implications - a health professional is obliged to follow them, or they may define the officially recommended treatment. Some guidelines are based on extensive high quality scientific review/meta quality systems involving scientific reviews and can be influenced also by other

¹ COM(2002) 667, eEurope 2002: Quality Criteria for Health related Websites.

(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 Core² which developed the first set of fifteen metadata elements later approved by ISO and published first in 2003 and recently in a revised version as ISO 15386:2009.

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 has now 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 standard shall be regarded as 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 easy 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 herein will usually be 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.

² The Dublin Core Metadata Initiative - www.dublincore.org

1 Scope

This International Standard defines a number of metadata elements that describe documents 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 should:

- support unambiguous and international understanding of important aspects to describe a document e.g. *purpose, issuer, intended audience, legal status and scientific background*;
- be applicable to different kinds of digital documents
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;
- be possible to present to human readers
including health professionals as well as citizens/patients
- be 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 here described is not intended to:

- describe documents about a single patient, such as medical records;
- describe details of the medical content of the document (but some idea of the content can be described via keywords or codes);
- prescribe criteria for the quality of the document content.

2 Normative references

Not applicable.

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 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 Used to diagnose, treat and alleviate disease/dysfunction.