TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

CEN ISO/TS 22756

September 2020

ICS 35.240.80

English Version

Health Informatics - Requirements for a knowledge base for clinical decision support systems to be used in medication-related processes (ISO/TS 22756:2020)

Informatique de santé - Exigences relatives aux bases de connaissances pour systèmes d'aide à la décision clinique à utiliser dans le cadre des processus liés aux médicaments (ISO/TS 22756:2020)

Medizinische Informatik - Anforderungen an eine Wissensbasis für medizinische Entscheidungsunterstützungssysteme von medikationsbezogenen Prozessen (ISO/TS 22756:2020)

This Technical Specification (CEN/TS) was approved by CEN on 4 September 2020 for provisional application.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. CEN ISO/TS 22756:2020 E

European foreword

This document (CEN ISO/TS 22756:2020) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

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Endorsement notice

The text of ISO/TS 22756:2020 has been approved by CEN as CEN ISO/TS 22756:2020 without any modification.

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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).

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This document was prepared by Technical Committee ISO/TC 215, *Health Informatics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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

0.1 Safe and effective usage of medicines is important

When a patient gets his/her medicines prescribed and dispensed, it is not only important that the patient gets the correct medicine and that ordering and reimbursement is supported by using a Medicinal Product Dictionary (MPD), but it is also important that the medicine is safe and effective with respect to the specific situation of the patient.

Because an MPD contains just the identification of the medicines, it is important that an MPD is enriched with clinical decision support (CDS). The aim of CDS is to help prescribe and dispense the medicine that fits the patient's personal situation in respect of effectiveness and toxicity of the medicine. Based on a knowledge base combined with the patient's situation such as comedication, comorbidity, age, laboratory values, diet, allergy, a healthcare professional can be warned for likely side effects or ineffectiveness, and change the therapy.

0.2 Need for a standardized knowledge base

To achieve the aim described in Clause 0.1, there are several success factors, in literature, referred to as the 'five rights'[28]:

— The *right information:* the information should be evidence based and give concrete guidance for action.

— To the *right person:* the alerts should be presented to the person who is the most likely one to take action (e.g. the clinician, the pharmacist, the caretakers).

— In the *right CDS intervention format:* such as an alert, a request to measure certain laboratory parameters, or an answer to a clinical question.

— Through the *right channel:* this can be the clinical information system like the pharmacy information system, or a web-browser that makes available the data of the knowledge base.

— At the *right time in workflow:* for example, during prescription or dispensing, or in batch at night to have certain data available the next morning.

To provide the *right information*, a knowledge base is necessary; and also providing the knowledge to the *right person,* the *right format* and at the *right time in the workflow* is part of a knowledge base, as far as it concerns the 'knowledge' of it.

There are clinical decision support systems (CDSSs) that provide this knowledge, but Helmons stated that there are several barriers for implementing a CDSS, one of them being 'content issues' like: 'Typically installed without any validated decision rules, which have to be developed and/or validated in each individual institution (also called 'having to reinvent the wheel')'[26].

Therefore, a (technically) validated, standardized knowledge base is the recommended basis for CDS.

The needs for a standardized knowledge base are as follows:

— There is an overwhelming amount of data in the summary of product characteristics (SPC), guidelines, literature and handbooks. Prescribers, physicians and pharmacists cannot easily find what to do for a certain drug combination or drug-disease combination. The most relevant data and accompanying recommendations are curated from literature and put in rules in a knowledge base.

— Information about the availability, safety and efficacy of medication to be used for the prescription by physicians is often outdated even when the information is available electronically (e.g. in the drug interaction management system in a doctor's office). Linking the information from the Medicinal Product Dictionary to a CDSS that uses a validated, standardized knowledge base makes sure that during prescribing/dispensing up-to-date information is always used.

— While the population is still growing, people become older and have more comorbidity and polypharmacy, the need for smart knowledge base rules that provide the basis for generating alerts with a high specificity and sensitivity, is increasing.

— Besides assuring that the most precise and current information is to be used in the knowledge base for the benefits of the patient, this specification will also provide a basis or 'handles' how to map the information to the MPD, the IDMP vocabulary and their own local data in EHR and pharmaceutical domains.

0.3 Focus — A knowledge base for drug-related problems that cohere with the intended drug use

This document is about a standardized knowledge base to be used in medication-related processes. In the context of this document, this means a knowledge base that has its focus to enhance decisions and actions in drug-related problems that cohere with the intended drug use, namely once a drug has been chosen, in any domain of prescribing, dispensing, administering of the drug and monitoring the patient.

Aspects like choosing the right drug according to guidelines and patient coaching for the correct usage are not included in the scope of this document (which does not mean that the requirements that are described in this document are not useful for knowledge bases with such kind of scopes).

0.4 Why this document: general principles versus medication specific aspects for developing a knowledge base

Describing how a structured, standardized knowledge base should be developed, what are the criteria to take into account, is a rather general process. As such it is not specific for medication processes. Assessing literature and developing rules is also applicable for other domains.

In this respect, this document contains two sorts of requirements. First, there is the overarching level, not specific for medication processes. This includes, for example, the requirements for selecting and assessing literature, updating the knowledge base. Secondly, there is a medication-specific level in this document. This includes the area to which the requirements are applied: if the requirement is to determine which kind of people will assess the rules, the document mentions the disciplines in healthcare: such as pharmacists, physicians.

0.5 Use cases

The use cases for a knowledge database for drug-related problems are primarily decision support based on validated, standardised rules to enhance decisions in the process of:

— prescribing

— dispensing

— administering

— monitoring the therapy of the patient.

Besides that, decision support based on a standardised knowledge base can also be useful for (not exhaustive):

— travel medicines

— health counselling.

0.6 Target users of this document

The target users of this document for a knowledge base in medication-related processes include:

— Academic organisations in the field of pharmaceutical healthcare, that develop knowledge bases for medicines;

— Vendors and other parties developing CDSSs (based on knowledge bases as described in this document), like (not exhaustive):
  — clinical or pharmacy information systems
  — hospital ward information system
  — doctor‘s office information systems
  — decision aids for patients.

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1 Scope

This document specifies the requirements for developing a knowledge base for drug-related problems that cohere with the intended drug use, to be used in rule-based clinical decision support systems (CDSS), such as the criteria for selecting a raw data source and the quality criteria for the development and maintenance for the rules or clinical rules for drug safety. It also describes the process of how to develop a knowledge base, the topics to be considered by the developers of a knowledge base, and it gives guidance on how to do this.

This document gives guidelines for the development of a knowledge base:

— with rules to enhance decisions and actions in drug-related problems that cohere with the intended drug use;

— which can be used by all kinds of healthcare professionals, such as those who prescribe, dispense, administer or monitor medicines;

— which can be used in every care setting, including chronic and acute care, primary and specialized care;

— which is a repository of evidence/practice bases rules, assessed by experts;

— which is meant to be used in conjunction with a medicinal product dictionary;

— whose knowledge is structured in rules and therefore to be used in the type of rule-based CDSS.

This document does not:

— describe the exact content of a knowledge base i.e. the outcome of the process of developing rules.

— provide the requirements for a clinical decision support system, the software that uses the knowledge base combined with the patient's data, and presents the outcome of the rules to the healthcare professional. These requirements are described in ISO/DTS 22703[1)].

— give the requirements for non-medication knowledge bases. Some aspects of the requirements in this document are general in nature and applicable to other kinds of knowledge bases, but this document does not address all of the requirements of non-medication knowledge bases.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11615, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*

ISO/TS 19256, *Health informatics — Requirements for Medicinal Product Dictionary Systems for Healthcare*

1) Under preparation. Stage at the time of publication: ISO/DTS 22703.