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Health informatics - Requirements for medication safety alerts (ISO/TS 22703:2021)

Informatique de santé - Exigences relatives aux alertes de sécurité sur les médicaments (ISO/TS 22703:2021)

Medizinische Informatik - Anforderungen an Arzneimittel-Warnmeldungen (ISO/TS 22703:2021)

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European foreword

This document (CEN ISO/TS 22703:2021) 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 22703:2021 has been approved by CEN as CEN ISO/TS 22703:2021 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.

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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

To improve the quality and safety of patient care in digital work-flow environments, computer assisted clinical decision support systems (CDSSs) have been emphasized and implemented in healthcare organizations and pharmacies, especially focusing on medication safety.

CDSSs for medication safety have been developed and used in many countries as an essential component for decision support for clinicians in prescribing, dispensing and administering medication in connection with an electronic health record (EHR), computerized physician order entry (CPOE) system or pharmacy electronic health record (PEHR) and digitized knowledge bases.

Depending on the availability of knowledge bases and functionalities, CDSS can be classified into four types[12]:

Type 1 CDSS: provides categorized information that requires further processing and analysis by users before a decision can be made. This type of decision support includes direct access to relevant information, such as web-based access to current rules for travel inoculation.

Type 2 CDSS: presents the clinician with trends of a patient's changing clinical status and alerts clinicians to out-of-range assessment results and intervention strategies. Clinicians are prompted to review information related to the alerts before arriving at a clinical decision.

Type 3 CDSS: uses deductive inference engines to operate on a specific knowledge base and automatically generate diagnostic or intervention recommendations based on changing patient clinical condition, with the knowledge and inference engines stored in the knowledge base. These systems include systems that consider the disease and medication of the patient and whether these have contraindications for new medication. These systems require computer-readable rules and an underlying computer EHR system that is also computer processable. They also require computerized terminological representation of clinical concepts.

Type 4 CDSS: uses more complex knowledge management and inference models than the other three decision support types. These systems include case management reasoning, neural networks and statistical discrimination analysis to perform outcome or prognostic predictions. Such systems possess self-learning capabilities and use fuzzy set formalism and similarity measures or confidence level computation as mechanisms to deal intelligently and accurately with uncertainty.

Among the four types of CDSS, type 3 has been focused on developing CDSS for medication safety alerts in the countries where EHRs are in use, though type 4 is available in some countries.

Since the primary purpose of a medication CDSS implementation is the prevention of potential harmful effects of medication or errors, all types of CDSS have been designed to have the functionality of alerting or warning clinicians in a prospectively actionable fashion for all settings.

However, the desired outcome of prevention of harmful drug therapy with the use of CDSS for medication safety has not been clearly defined. This can be attributed to factors such as poor and varied stratification (mainly due to lack of clear consensus on terminology and rules) of safety risk warnings or alerts. In addition, alert fatigue (the result of frequent alerts to clinicians which are not clinically significant or tailored to speciality interests) is known to be one of the major factors contributing to alert overrides, which can result in serious clinical consequences.

Unclear content and verbose language in medication safety alerts can also be barriers to clear communication with clinicians of the clinical significance of potential safety risks.

In addition, since the alerts are linked to the embedded CDSS knowledge base through specifically designed algorithms, the differences between algorithms to produce alerts, even though they are based on the same knowledge base, can be another inhibiting factor in getting uniform and maximal benefit from safety alert systems operating on the same patient population with the same clinical condition or situation.

In the USA, a number of EHR and CPOE vendors, as well as several drug knowledge bases, are in use with wide differences in content, alert types and displays. Medication safety alerts in computerized information systems have typically been developed for pharmacy software, often in connection with pharmacy benefit management, the requirement for a prospective drug utilization review (DUR) programme for outpatients using a prescription filling service in community pharmacies, or both. For prospective DUR programmes, the potential medication problem types for medication safety alerts were defined by federal regulation and have been used for developing CDSS for pharmacy practitioners and CPOE by system vendors.

In the Republic of Korea, a number of drug knowledge bases (in the form of CDSS) with the functionality of safety alerts which are developed by system vendors and pharmacy benefit managers of national health insurance bodies are in use, mostly benchmarking the prospective DUR programme in the USA. However, they are not detailed enough to meet individual use cases and thus healthcare organizations resort to commercial vendors for more in-depth and user-friendly coverage of medication alert content.

In other countries, various types or methods for providing medication safety alerts in connection with digitized knowledge bases have been developed and implemented in digitized health information systems. However, there are no internationally or regionally standardized requirements for improving patient safety by alerting healthcare professionals to potential safety risks.

Given the wide variability of medication safety alert content and implementation approaches across different system vendors and drug knowledge bases, there is a need for medication alert standardization both nationally and internationally.

Stakeholders can use this document for developing common and structured medication safety alert systems to improve patient safety.

The actors included in the scope of this document include, but are not limited to:

— healthcare organisations which deploy EHR or PEHR systems incorporating medication safety alerts;

— vendors and implementors of systems with medication safety alerts or those who provide information for the alerts, such as:

  — CDSSs

  — EHRs

  — pharmacy systems

  — clinical information systems

  — practice management systems (EHR-like systems for individual or small-group settings).

Health informatics — Requirements for medication safety alerts

1 Scope

This document specifies the requirements for medication safety alert systems and the topics which are relevant to alert system vendors. This document applies to clinical decision support systems (CDSSs) whether or not these are medical devices.

This document addresses:

— requirements for terminology used in medication safety alerts;

— requirements for choosing a knowledge base for medication safety alert systems;

— requirements for the proper functionality of CDSSs as related to medication safety alert systems;

— requirements for medication safety alert display;

— requirements for quality measurements to improve the effectiveness of medication safety alerts.

The following are out of the scope of this document:

— the development of content (rule-based knowledge base) for CDSS;

— the development of algorithms for generating medication safety alerts in CDSS;

— the development of alert processors for medication safety alerts in CDSS.

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/TS 22756, *Health informatics — Requirements for a knowledge base for clinical decision support systems to be used in medication related processes*

ISO 27789, *Health informatics — Audit trails for electronic health records*

IEC 82304-1, *Health software — Part 1: General requirements for product safety*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/