TECHNICAL SPECIFICATION

ISO/TS 17251

First edition

Health informatics — Business requirements for a syntax to exchange structured dose information for medicinal products

Informatique de santé — Exigences d'affaire pour une syntaxe d'échange d'informations de dose structurée pour les produits médicaux

PROOF/ÉPREUVE

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Foreword

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 215, *Health informatics*.

Introduction

The requirements for the exchange of structured dose instructions is intended to be independent of any technology standard or software platform and has been developed with the aim of specifying the necessary The requirements for the exchange of structured dose instructions are intended to be independent of any technology standard or software platform and have been developed with the aim of specifying the necessary clinical and business requirements precisely and unambiguously. Implementation of the requirements within a suitable medium designed to support communication of healthcare information should provide support to clinicians and their applications in storing, retrieving, using, and above all, communicating dose instructions information to other clinicians, their applications, and most importantly, to the patient.

The primary audiences for this Technical Specification are software developers building clinical IT systems.

Health informatics — Business requirements for a syntax to exchange structured dose information for medicinal products

1 Scope

This Technical Specification specifies the business requirements for the structured content of structured or semi-structured dose instructions for recording dose instructions in the electronic health record (EHR), supporting clinical decision support, and in exchanging medication orders, as applicable to primary, secondary and tertiary care.

NOTE See 2.9, note to entry, regarding the use of “medication order” and “prescription”.

Comprehension of dose instructions by the patient is an overarching consideration for patient safety and the best patient outcomes. Related factors are discussed, but are not part of the primary scope.

This Technical Specification does not define an information model, except to the extent that those information model concepts are necessary to define business requirements.

Outside the scope of this Technical Specification are:

— the functionality of health, clinical and/or pharmacy systems;

— other kinds of content of health, clinical or pharmacy systems that are needed to support the whole process of health care providers, such as:

  — wide range of knowledge about medicines that would be handled in drug knowledge databases and decision support systems;

  — the complete medical record (EHR);

  — a medicinal product dictionary.

2 Terms and definitions

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

2.1
dose instructions
instructions pertaining to the medication, which describe the amount of medication per dose, method of administration, the frequency or interval of dose, associated instructions for dosing or skipped doses, and other associated parameters necessary for appropriate administration of the medication

2.2
dose syntax
structured dose instructions
structured set of data elements which represent the dose instructions in a consistent, computable format

2.3
structured information
information assembled from predefined concepts (vocabulary or code set) using an organizational scheme (information model)

2.4
unstructured information
information assembled from narrative words and word fragments, following either casual conventions or language-specific grammatical rules

2.5
semi-structured information
information containing both structured content and unstructured content

2.6
sig
directions to be written on a package or label for the use of the patient

Note 1 to entry: Sig (sometimes written as SIG) appears to be an acronym, but is an abbreviation of the Latin term "signā".

Note 2 to entry: In the context of this Technical Specification, "sig" had the same meaning as "dose instructions" (see 4.1).

2.7
storage and handling information
information provided to the patient/caregiver regarding the appropriated conditions to maximize the shelf life of the medicinal product

Note 1 to entry: While essential information, this does not directly relate to administration and is not within the scope of this Technical Specification.

2.8
medication order
documented instruction on intended therapy for an individual person with a medicinal product issued by an authorized health professional

Note 1 to entry: There is no inherent limitation on the setting for the medication order (inpatient, ambulatory, etc.).

[SOURCE: ISO/TR 22790:2007]

2.9
prescription
directions created by an authorized health professional to instruct a dispensing agent regarding the preparation and use of a medicinal product or medicinal appliance to be taken or used by a subject of care

Note 1 to entry: In the context of this Technical Specification, "prescription" or "medication order" could be used. We have chosen to use "medication order". In this sense, we imply that "medication order" is inclusive of "prescription."

[SOURCE: ISO/TR 22790:2007]

2.10
message syntax
structured set of data elements which represent the medication order in a consistent computable format

3 Conformance

Systems that create or consume electronic medication orders can claim conformance to this Technical Specification when it fulfils all requirements in Clause 4.

4 Business requirements for structured dose instructions

4.1 General

The business requirements for structured dose information shall focus on the primary goal of ensuring that the patient receives the appropriate medication dose at the appropriate time in a consistent manner. In addition to the patient-centric aspects, certain information is required to achieve this goal. The following requirements address both patient and information aspects.

NOTE The following conformance statements refer to either, or both, the message syntax and the dose syntax. Requirements which are not unique to the dose instructions, or useful in other components of a medication order, are described as part of the “message syntax”. Requirements which are specific to the dose instructions are described as part of the “dose syntax”.

4.2 Use cases

Dose instructions serve the following use cases.

— Indicating the right dosage during prescribing.

— Recording the indicated dosage in the HER:

  — to be used in clinical decision support systems, like dose checking;

  — exchange of information between health care providers.

— Indicating comprehensible dose instructions on the patient label in order to make clear how to use the medicine. Comprehension may not be a component of the dose instructions specifically, but comprehension does influence the presentation of the instructions to the patient. Patient comprehension information shall be present in the medication order in some manner such that the dispenser can create appropriate instructions for the patient or caregiver.

4.3 Elements of a dose instruction

Based on the use cases, the elements of a dose instruction include the following.

— Text representation. The purpose of this Technical Specification is to specify requirements for structured dose instructions. However, some parts of a dose instruction cannot be captured in structured information. To support a human readable text of the whole dose instruction of a certain medicine, a textual representation of the whole dose instructions will remain an important element. This textual representation includes both the structured and the unstructured part of the dose instruction. Also, if a scenario occurs which prevents the structured content from being produced, the textual representation is then necessary for communicating the dose instruction. The structured content and the textual content, if both are present, shall agree, neither omitting nor adding any significant content between the two.

— Amount of medication to be administered at each dose event.

  — This may be comprised of a number of units of presentation (e.g. “1 tablet”) or a number and unit of measure (e.g. “5 ml”, “500 mg”). Calculated amounts (e.g. “50 mg/kg body weight) may be appropriate in some cases, however an explicit amount is generally preferred over an implied amount.

  — The administered amount may vary over time (e.g. tapered dose) or relative to other parameters (e.g. insulin sliding scale).

  — The administered amount may be a range (1 to 2 tablets).

  — The administered amount should be quantified whenever possible. Indeterminate and non-quantifiable amounts (e.g. “apply a thin film”, “use a pea-sized amount”) should be quantified

