TECHNICAL SPECIFICATION

ISO/TS 17251

First edition
2016-07-01

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

Reference number
ISO/TS 17251:2016(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 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 can 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 EHR:

  — 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

wherever possible (e.g. “apply 1 to 2 ml”, “use 1 to 2 gm”) or the non-quantifiable portion included in a text representation element.

— Route of administration.

— Timing of dose event(s). A wide range of dose timing shall be considered. Possibilities include the following.

  — Dosing by frequency (e.g. “twice a day”, “once a month”), dosing by time interval (e.g. “every 6 hours”). Both frequency and interval require a numeric portion and a time portion, frequency being “<number> per <time>” and interval expressing “every <number> <time>”. The numeric portions may involve ranges (e.g. “every 3 to 4 days”).

  — Dosing at specific times (e.g. “at 9 am”), or relative to other events (e.g. meals, sleep, procedures).

  — There may be a start date, and/or time, for dose events. This may be specific (e.g. “begin on 3 October 2015”) or relative (e.g. “the day prior to the procedure”).

  — Dose timing can also be a combination of timing patterns running consecutively (e.g. tapers) or concurrently (e.g. “daily and as needed”).

— Conditional administration. Administration of a dose may be dependent upon other factors. Such factors may be symptoms (e.g. “as needed for cough”), measureable parameters (e.g. “blood glucose > 200 mg/dl”, “temperature > 38 °C”), event or encounter (e.g. “after bee sting”). The use of unspecified or indeterminate conditions (e.g. “as needed” without condition) is not supported in this Technical Specification.

— Ancillary information. As with the textual representation, this information not typically represented in the structured dose instructions and is included here as they are often discussed in relation to dose instructions. Examples include:

  — storage and handling (e.g. keep refrigerated, shake well before use);

  — advise on proper administration (e.g. take with food);

  — reference to dosing information provided elsewhere (e.g. medications following a documented protocol).

Dose instructions do not exist on their own; they are a component of the medication order, and thus the prescriber and dispenser systems. These systems are, in turn, related to other health, clinical, and/or pharmacy information systems. Some aspects of the dose instructions, and the dose syntax model, may be dependent on information in these other systems. Examples of such “other information” include patient weight for weight-based dosing, and procedure schedules for doses administered relative to that event. It is recognized that this Technical Specification includes requirements which are not specifically elements of dose instruction, but may be needed for appropriate interpretation and implementation of the dose instructions. Conformance of a dose syntax model, and dose instructions produced from that model, is not dependent of these “other information” requirements.

4.4 Information requirements

4.4.1 General

The requirements for structured dose information, or the “dose syntax,” are described in this subclause. These requirements build on the elements discussed in 4.2.

Dose syntax can only be assessed for structured (no textual representation present) and semi-structured (textual representation present) dose instructions. For structured, and the structured portion of semi-structured, dose instructions, the following requirements are defined. Some of these “requirements” describe “capabilities” or “features” which will not be used in all structured dose information instances.

Dose instructions can be very complex. Aggregates of sequential and alternating dosing are not uncommon (e.g. “4 tablets once a week (2 in the morning, 2 in the evening)” for methotrexate). Another complex example involves dosing multiple products dispensed as one “kit” [e.g. Didrokit, “once a week 1 tablet (=Didronel) in the morning, 6 times a week 1 tablet (=Cacit) in the evening”]. This specification addresses the information requirements for dose syntax models and derived dose instructions. This Technical Specification does not address all of the possible combinations and permutations of the elements.

4.4.2 Infrastructure

4.4.2.1 Information model

4.4.2.1.1 The dose syntax shall employ an information model.

4.4.2.1.2 The information model shall support the use of standardized vocabularies.

4.4.2.1.3 The dose syntax and the information model may or may not directly produce the patient instructions, but shall always provide a consistent presentation to the pharmacy/dispenser from which patient-friendly dose instructions can be created.

4.4.2.1.4 The information model should use, or be mapped to, the information model(s) used by related health information systems.

4.4.3 Text representation

Text representation of the dose instructions, if present, shall be consistent with any coded representation of the dose instructions.

4.4.4 Administration amount

The dose to administer is typically expressed as a numeric value and a unit of measure (e.g. 15 ml) or unit of presentation (e.g. 1 tablet).

4.4.4.1 The dose syntax model shall support an expression of the numeric value of the dose to be administered at each dosing event.

4.4.4.2 The dose syntax model shall support both a single value (e.g. 1) and a value range (e.g. 1 to 2) for the numeric value of the dose to be administered at each dosing event.

4.4.4.3 The dose syntax model shall support the expression of the dose unit/unit of presentation for each dosing event (e.g. tablet, ml, puff, mg/kg).

4.4.4.4 The dose syntax model should support the expression of the dose unit/unit of presentation for each dosing event (e.g. tablet, ml) based upon a standardized vocabulary.

4.4.4.5 The dose syntax model may support the expressions of calculated administration amounts (e.g. 50 mg/kg of body weight).

4.4.5 Route/site of administration

4.4.5.1 The dose syntax model shall support the expression of the route of administration for each dosing event (e.g. “oral”, “topical”, “ocular”).

4.4.5.2 The dose syntax model should support the expression of the route of administration for each dosing event (e.g. “oral”, “topical”, “ocular”) based upon a standardized vocabulary.

4.4.5.3 The dose syntax model shall support the expression of the site of administration for each dosing event (e.g. “left deltoid”, “right eye”).

4.4.5.4 The dose syntax model should support the expression of the site of administration for each dosing event (e.g. “left deltoid”, “right eye”) based upon a standardized vocabulary.

4.4.6 Timing of dose event(s)

4.4.6.1 Timing

4.4.6.1.1 The dose syntax model shall support expressing the timing of dosing events as a number of events per period of time (frequency) (e.g. “3 times a day”, “once a week”), as a numeric value and a value to express the unit of time.

4.4.6.1.2 The dose syntax model shall support expressing the timing of dosing events as spaced at equal intervals of time (interval) (e.g. “every 8 hours”).

4.4.6.1.3 The dose syntax model shall support expressing the timing of dosing events as a range of events per interval of time (e.g. “3 to 4 times a day “).

4.4.6.1.4 The dose syntax model shall support expressing the timing of dosing events as spaced at a range of intervals of time (e.g. every 6 to 8 weeks).

4.4.6.1.5 The dose syntax model shall support expressing the timing of dosing event as specific points of time (e.g. “9 am”, “10 am and 6 pm”).

4.4.6.1.6 The dose syntax model shall support expressing the timing of dosing events related to activities of daily living (e.g. “morning”, “at bedtime”).

4.4.6.1.7 The dose syntax model shall support expressing the timing of dosing events as offsets to activities of daily living (e.g. “take 30 min prior to breakfast”, “take 30 minutes prior to appointment”).

4.4.6.1.8 The dose syntax model shall support expressing the timing of dosing events as days within a week (e.g. “every Monday”).

4.4.6.1.9 The dose syntax model shall support expressing the timing of dosing event as days within a month (e.g. “on the first of every month”).

4.4.6.1.10 The dose syntax model should support the expression of the timing (e.g. ‘per day’, ‘per week’) and time (e.g. “hour”, “day”) based upon a standardized vocabulary.

4.4.6.2 Sequential and alternating dosing

4.4.6.2.1 The dose syntax model should support sequential sets of dosing instructions (e.g. “2 now, then 1 every day”, “3 tablets on first day, 2 tablets on second day, 1 tablet on third day”).

4.4.6.2.2 The dose syntax model should support alternating set of dosing instructions (e.g. “1 tablet every Monday, and 2 tablets every Thursday”, or “1 tablet on Monday, Wednesday, Friday, 2 tablets on Tuesday, Thursday, and Saturday, no dose on Sunday”).

4.4.6.3 Start/duration

4.4.6.3.1 The dose syntax model shall support the date/time on which administration should start.

4.4.6.3.2 The dose syntax model should support the date/time on which the administration should end.

4.4.6.3.3 The dose syntax model should support administration start and end as relative to other events (e.g. “begin 1 day prior to procedure”).

4.4.6.3.4 The dose syntax model shall support termination of dosing events (e.g. “until gone”, “then stop”).

4.4.6.3.5 The dose syntax model should support dosing event duration (e.g. “apply for 10 minutes”, “infuse over 30 minutes”, “continuous”).

4.4.6.3.6 The dose syntax model should support dosing rate for parenteral products (e.g. “250 mg/hr”, “125 ml/hr”, “continuous”).

4.4.6.3.7 The dose syntax model should support therapy duration (e.g. “for 10 days”, “during 6 months”).

This is the intended duration of the therapy, not the calculated date on which the supplied medication should be used up.

4.4.6.3.8 The dose syntax model should support maximum therapy durations (e.g. not longer than 7 days).

4.4.7 Conditional administration

4.4.7.1 The dose syntax model shall support the expression of conditions for administration (e.g. “as needed for pain”, “for temperature above 100 °F”).

4.4.7.2 The dose syntax model should support the expression of conditions for administration in controlled vocabularies; this includes both valued concepts (e.g. “equal to or greater than” and “100” and “° F”) and unvalued concepts (e.g. “as needed for pain”).

4.4.7.3 The dose syntax model shall support limitations on the number of doses permitted in a specified period of time (e.g. “not more than 4 doses in 24 hours”).

4.4.7.4 The dose syntax model should support the expression of conditions that result in alteration of administration (e.g. “discontinue if rash develops”, “skip dose when prior to dental appointment”).

4.4.8 Patient-specific information

4.4.8.1 General

This information is not specifically part of the dose instructions. This information may influence the how the dose instructions are prepared or rendered for the patient/caregiver. This information is typically found in other aspects of the medication order, or related to capabilities of the messaging protocols.

Since these elements may not be under the control of the same system containing the dose syntax model, these “requirements” are not binding on the dose syntax model, or dose instructions produced

by that model. The dose syntax model may state conformance to this Technical Specification without addressing this patient-specific information.

4.4.8.2 Language

4.4.8.2.1 The primary language of communication for the patient/caregiver should be present in the message syntax.

4.4.8.2.2 The language should be coded using ISO 639-1 or ISO 639-2.

4.4.8.2.3 Multiple languages may be included for the patient/caregiver.

4.4.8.2.4 If multiple languages are specified for the patient/caregiver, then the patient/caregiver's preferred language shall be indicated.

4.4.8.2.5 The patient/caregiver's ability to understand written instructions in their preferred and alternate languages may be indicated.

4.4.8.2.6 This proficiency may be indicated as a "grade-level" or "good/fair/poor" rating.

4.4.8.3 Functional limitations

Patient functional limitations which may influence the patient's ability to read and act on the dose instructions should be supported by the message syntax.

Examples of functional limitations include, but are not limited to:

— limited visual acuity;

— limited dexterity;

— impaired cognitive function.

4.4.8.4 Patient characteristics

Where clinically appropriate, a prescriber may indicate an amount to administer relative to height, weight, body surface area or other patient characteristics. To support this, the following recommendations apply.

4.4.8.4.1 The message syntax should have the capability to communicate necessary patient characteristics (e.g. patient height, weight, body surface area).

4.4.8.4.2 If the dosage is supplied as a calculated value, then the medication order message syntax should include the patient characteristics required for the indicated calculation.

4.4.9 Ancillary information

Examples include storage and handling (e.g. keep refrigerated, shake well before use), advise on appropriate administration (e.g. take with food), or reference to dosing information provided elsewhere (e.g. medications following a documented protocol). As with the textual representation, this information is not typically represented in the structured dose instructions and is included here only as they are often discussed in relation to dose instructions.

Bibliography

[1] ISO 639-1, *Codes for the representation of names of languages — Part 1: Alpha-2 code*

[2] ISO 639-2, *Codes for the representation of names of languages — Part 2: Alpha-3 code*

[3] ISO 11239:2012, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging*

[4] ISO 11615:2012, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*

[5] ISO 11616:2012, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*

[6] ISO 11240:2012, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement*

[7] ISO/TR 22790, *Health informatics – Functional characteristics of prescriber support systems*[1)]

[8] HL7 Version 2.7 Chapter 4A: Order Entry: Pharmacy/Treatment, Vaccination 2011. Health Level 7 International, www.hl7.org

[9] HL7 Version 3 Standard: Pharmacy; Medication Order, Release 2 5/12/ 2014, Health Level 7 International, www.hl7.org

[10] Connecting For Health Dose Syntax Abstract Model N.H.S. v0.8 (2008) (Health and Social Care Information Centre, HSCIC, UK)

[11] Doseerinstructies. Geïntegreerde aanpak voor eerste en tweede lijn. KNMP/NHG/Z-Index, version 0.8 24 december 2014

[12] NCPDP Structured and Codified Sig Implementation Guide v2.0, National Council for Prescription Drug Programs, www.ncpdp.org

[13] NCPDP SCRIPT Standard v10.6, National Council for Prescription Drug Programs, www.ncpdp.org

[14] SKMT. Standards Knowledge Management Tool, Joint Initiative for Global Standards Harmonization – Health Informatics Document Registry and Glossary, www.skmtglossary.org

1) Withdrawn.

ICS 35.240.80

Price based on 9 pages