# TECHNICAL REPORT



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# Health infomatics — Medication management concepts and definitions

Informatique de santé — Concepts et définitions relatifs à la gestion de la médication

# iTeh STANDARD PREVIEW (standards.iteh.ai)

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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 <a href="https://www.iso.org/directives">www.iso.org/directives</a>).

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This document was prepared by Technical Committee ISO/TC 215, Health informatics.

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### Introduction

The approach of this document is first to explain the logical steps in a medication therapy of a patient and to state which data elements are required at that step and what is done with the data. The best definition that would fit at that stage of medication therapy was identified. It was noticed that where a listing of definitions that the interpretations of the various terms were to be made, this would lead to endless discussion of the meaning of the terms.

IHE pharmacy, HL7 Pharmacy and ISO/TC 215 have been convening frequently and noticed that each individual had a different interpretation of the terms used. As SDOs where communication of medication information is the core purpose of these organizations, it is of course vital to understand what a noun means so that all persons have a common understanding of the words used. Terms that have composite ingredients are to a certain extent arbitrarily defined, but this document contains the definitions that are agreed on by HL7 pharmacy, IHE Pharmacy and ISO/TC 215.

The scope in the first stage will be on the definitions of composite information, such as lists. This will be set against the workflow and process in medication therapy.

Communicating information by means of IT can be separated into four layers:

- The conceptual meaning of terms 1)
- The content and characteristics of terms 2)
- The container of information TANDARD PREVIEW 3)
- 4) The communication of information.

The fourth and bottommost layer is the physical distribution of the information, such as pull or push mechanisms. The logistical aspects are not in the scope of this document, nor is the method or required infrastructure to obtain the information part of this document.

The third layer defines how the content is formatted so that senders and receivers can recognize the elements of the content. Examples are CDA documents, HL7v3 or HL7v2 messages. This document is not intended to go into this matter.

The second layer from the top is also called the syntax layer. It defines the content of a term. Some of these elements in the content will be optional. In the context of this document the term syntax refers to the rules governing the composition of meaningful elements. As an example the geographical coordinates (i.e. 41°24'12.2"N 2°10'26.5"E) could have been chosen as the syntax for a location, but it could as well be a street, number, postal code and city as the preferred notation of a logical address. This document is not intended to dive into the syntax of the medication terms.

The top layer is also called the semantic layer. This document focuses on this layer. The intention is to understand the meaning of a term. The result should be, that when a term as "unreconciled medication list" is used, that all readers should interpret the term in the same manner. The context in which the information is exchanged is also of importance for the concept. As an example a medication list for an intake into a mental ward could put more emphasis on other data than a medication list for discharge at a general hospital.

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### Health infomatics — Medication management concepts and definitions

#### **1** Scope

The purpose of this document is to define the various concepts and terminologies used in the pharmacy domain when applied to the topic of creating medication lists from existing data.

#### 2 Normative references

There are no normative references in this document.

NOTE For future considerations, the terms from ISO 13940 will be considered.

#### **Terms and definitions** 3

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:

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- ISO Online browsing platform: available at <a href="http://www.iso.org/obp">http://www.iso.org/obp</a>
- standards.iten.ai
- IEC Electropedia: available at http://www.electropedia.org/

#### 3.1

contraindication https://standards.iteh.ai/catalog/standards/sist/aefeb0cd-e899-443f-824d-92f59883757f/iso-tr-20831-2017

#### contra-indication

condition or factor that increases the risk involved in using a particular drug, carrying out a medical procedure, or engaging in a particular activity

Note 1 to entry: Pursuing the intention is inadvisable.

[SOURCE: IHE Pharmacy, Standard terminology, modified]

#### 3.2

#### dispensing

process of validation of the electronic prescription, preparation of the medicinal product, labelling, informing and handing the medication to the patient or administering healthcare professional

[SOURCE: ISO 17523:2016, 3.2]

#### 3.3

#### health concern

health-related matter about a patient that is of interest, importance or worry to someone

Note 1 to entry: This someone may be the patient, the patient's family or a patient's healthcare provider.

Note 2 to entry: A health concern is sometimes called a problem concern. A difference is that a problem concern is mostly related to one diagnosis, while a health concern can change overtime as the situation of the patient aggravates, for example from a simple cough, to pneumonia ending in COPD.

[SOURCE: HL7 929, Health Concern Domain Analysis Model v.3, September 2015]

#### 3.4

#### medication administration

application of medicine to a subject of care

Note 1 to entry: In general only the medication administration that is registered in a system is taken into consideration.

[SOURCE: IHE Pharmacy: Standard terminology, modified]

#### 3.5

#### medication

substance that has an intended therapeutic effect on a patient and may influence the medication safety of a patient

Note 1 to entry: This would include prescribed, but also non-prescribed medication such as cough syrups. A placebo has the intent of a therapeutic effect and is thus considered medication. Alcoholic beverages however also influence medication safety, but are not considered to be medication because they do not have the intent of giving therapy.

#### 3.6

#### medication management

act of exercising directives on the medication of a patient

Note 1 to entry: It includes reviewing the medication profile of a patient, providing new medication therapies, adjusting or stopping existing therapies and evaluating its outcome.

#### 3.7

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#### medication statement

declaration given by the subject of care of a third party about the usage or non-usage of medicine by the subject of care

Note 1 to entry: The primary information is about the medication, but it may include supporting information about observations and conclusions, for example reasons for diverging from the intended dosage.

[SOURCE: IHE Pharmacy, Standard Terminology]

#### 3.8

#### prescription

set of values or attributes that is produced as the output of a prescription act

Note 1 to entry: A prescription is a set of instructions written by a prescriber that authorizes a medicinal product or treatment to be given to a patient. It is a) an instruction by an authorized healthcare professional, b) a request to dispense by an authorized healthcare professional and c1) advice to a patient on his/her medication treatment, or c2) an instruction to administer by an authorized healthcare professional.

Note 2 to entry: The word "prescription" is sometimes used when referring to the act of prescribing - "prescription process". To avoid confusion with the term "prescription" as an information object, throughout this document the word "prescription" is reserved for the information object. For the act of prescribing, the term "prescribing" is used.

Note 3 to entry: An older definition of prescription can also be found in ENV 13607: "Direction created by an authorized healthcare person, 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". This definition is more appropriate when referring to the act of prescribing.

[SOURCE: ISO 17523:2016, 3.7]

#### 3.9

sex

biological background of a patient

Note 1 to entry: This is as opposed to gender, which is the preference of the patient.

Note 2 to entry: The biological background is considered to be more relevant for the purpose of medication management.

#### 4 Abbreviated terms

ER Emergency room. Unit of a hospital where emergency care takes place. EHR Electronic Health Record. Used as the abbreviation for Care Provider IT systems for health records with data structured and represented in a manner suited to computer calculation and presentation. NOTE: The UK National Health Service (NHS) uses the term Electronic Health Record to describe the concept of a longitudinal record of a patient's health and healthcare from cradle to grave and uses the term EPR to describe the record of the periodic care provided mainly by one institution. GP General Practitioner. Doctor that performs general practice, in some countries also called as family doctor or primary care provider (PCP). International Normalized Ratio. INR Ratio that gives an indication how much longer time the blood of a thrombosis patient would need for coagulation than a normal patient. Integrating Healthcare Enterprises D PREVIEW IHE Standards organization that uses existing communication standards for the healthcare to combine them in a workflow in the care. These workflows such as an ordering process, are called IHE profiles. ISO/TR 20831:2017 Over the counter. https://standards.iteh.ai/catalog/standards/sist/aefeb0cd-e899-443f-824d-OTC Refers to medication that does not require a prescription to procure such as cough syrups. painkillers, sterilizing liquids. PHR Personal Health Record. Health IT system in which a patient can manage their own personal health information by downloading and storing information from a variety of sources.

#### 5 General process



Figure 1 — Cycle of treatment process

The medication process is actually a recurring cycle (symbolized in Figure 1). This is often not recognized by healthcare providers, because the healthcare providers are frequently replaced, or the patient is transferred from one institution to another, but certainly from the point of view of the patient the events of the medication therapy can be seen as a recurring loop.

The loop does not have always have a smooth constant flow. While "gather data" is the logical starting point in the medication management process diagram, it is not uncommon for the process to start at a different step/point in the process. Events could happen all the time that could make intervention necessary. For example admission of patient into hospital triggers review of patient's existing medication list and the medication profile. The condition of the patient changes (deteriorates or improves) or new lab results are published that requires adjustments of the dosage. This all affects the medication management and provides short cuts in the loop.

These steps in the flow of the medication management of the patient result in different kinds of lists, profiles of medication of the patient. The purpose and the status of each type of list must not only be understood by the author, but also by other care professionals who share the information with the original source. The intent of this document is to distinguish the different steps in medication management and which type of document belongs to which process part.

The following sequence of sections is used for the explanation of definitions:

- identify the basic data elements relevant to medication management;
- define the possible process steps and the variations in the processes;
- name the various report types that can be linked to that part of the process.

The emphasis of this document is focused on steps 1 to 5 (gathering data up to determine the medication management and therapy). The actual therapy, such as administering the medication is performed in step 6. Steps 7 and 8 (evaluate outcome and generate new data) of course do have effect on the medication management, but it will be apparent if the process restarts with step 1.

#### 6 Data elements relevant to medication management

#### 6.1 General

Effective medication therapy management requires the inputs of relevant historic and current information including medication and related clinical information. This clause provides an overview of the information important for medication therapy management planning and review processes. Details of the information requirement (including data elements, data types and terminology constraints) for each of these data components are out-of-scope for this document.

The collection of data elements is seen as a list of possible data components. It is evident that it is not possible to make a compulsory list of data elements. The ultimate goal would be to know everything, but there is a cost incurred to put information into systems. That effort might not always be worthwhile. Tradition, but certainly also a level of computerization, accessibility of that information, jurisdictional restrictions and the differences in workflow are factors that influence the availability of data.

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#### 6.2 Prescriptiontdataandards.iteh.ai/catalog/standards/sist/aefeb0cd-e899-443f-824d-

92f59883757fiso-tr-20831-2017 A prescription is a medication request usually authorized by a qualified practitioner such as medical practitioner, dentist, nurse practitioner (and in some jurisdictions, pharmacist). The medication request could be part of larger care plan, including other treatment and therapies such as nutrition requests, procedures (e.g. dialysis, dressing, operations).

Prescribed medications are drugs that can only be made available to patients by a medication request (usually written and signed) of a qualified practitioner.

It is important to recognize that the data of a prescription consists of two distinct components:

- a therapy that the prescriber has agreed with the patient;
- a logistical order to supply a tangible product, most commonly the medication.

In certain settings these elements might be seen as separate entities. An order to stop medication can be seen as an example of a request where there is a therapy instruction to stop using the medication and where the supply is left void.

Depending on the constituency and the type of process the prescriber might leave the level of detail of the order open for others to fill in. In many cases the medication on the prescription would be prescribed on a generic level with the focus on the active ingredient while what is dispensed is most certainly a tangible product.

Prescription (together with dispense and administration) data are key components of a patient's medication list and medication profile. These data are very important for safe and effective management of a patient's medication therapy and are an integral component of the patient's medication management plan.

The most common source for prescription data are the prescribing systems.