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Health informatics — Patient healthcard data —

Part 7: Medication data

Informatique de santé — Données relatives aux cartes de santé des patients —
Partie 7: Données de médication

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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

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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).

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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 21549-7:2007), which has been technically revised with the following changes:

— medication notes definition in Clause 1 is modified;

— the list of definitions in Clause 3 is shortened and several definitions are corrected and clarified;

— the list of abbreviation in Clause 4 is shortened;

— an explanation is added in 5.1 why MedicationData is modelled as a direct child of the PatientHealthcardData;

— "healthcare person" in 6.2.3 is replaced by "healthcare professional";

— "factor of the quantity" in 6.2.4 is replaced by "quantity units";

— "medication history" in 6.4 is changed to "medication notes" in the title and an explanation of a major use is modified;

— in Clause 7, all the names of attributes in the tables are harmonized with the class diagrams. The term "data object" is replaced by "class". Additional comments are included in the tables. For implementer's convenience, the fragments of ASN.1 definitions are gathered together in the new Annex A;

— explanation of MedicationNotes in 7.2.1 is modified;

— comments in Table 3 are modified;

— comments in Table 4 are modified;

— comments in Table 5 are modified;

— Example in 7.2.5 is moved to informative Annex B;

— Figures 7 and 8 are merged. Class “Prescriber” is defined as an attribute. The attribute “qualification” is replaced by the attribute “qualifier” having datatype “CodedData”. The attribute “medicinalProduct” is renamed as “prescribedMedicinalProduct”. The class “MedicinalProduct” is renamed as “PrescribedMedicinalProduct”. The class “ManufacturedMedicinalProduct” is renamed as “PrescribedManufacturedMedicinalProduct”. The class “MagistralMedicinalProduct” is renamed as “PrescribedMagistralMedicinalProduct”. Datatype of the attribute “strength” is replaced by “Strength”, the definition of this new datatype is added. Datatype of the attribute “quantityOfMedicinalProduct” is replaced by “Quantity”. Datatype of the attribute “amountOfIngredient” is replaced by “Amount”. The class “AmountOfIngredient” is replaced by the class “Amount”;

— Figures 17 and 18 are merged. Class “Dispenser” is defined as an attribute. The attribute “dispensedMedicinalCode” is replaced by the attribute “dispensedMedicinalProduct” having new datatype “DispensedMedicinalProduct”. This new datatype is a generalization of the classes “DispensedManufacturedMedicinalProduct” and “DispensedMagistralMedicinalProduct”. The attributes “strength”, “form”, manufacturerOfMedicinalProduct” are moved from the class “ActualDispensedItem” to the class “DispensedManufacturedMedicinalProduct”. The attributes “batchIdentifier”, “genericSubstitution” are moved from the class “DispensingInformation” to the class “DispensedManufacturedMedicinalProduct”. Datatype of the attribute “quantityDispensed” is replaced by “QuantityToDispense”, so the class “QuantityDispensed” becomes unused and is deleted. The attributes “magistralMedicinalProductName” and “dispensedQuantity” are added to the class “DispensedMagistralMedicinalProduct”. The attribute “nameOfIngredient” is deleted from the class “DispensedIngredient”. Datatype of the attribute “quantityOfIngredient” is replaced by “Amount”. The attribute “nameOfContainerOrApplicationAid” is deleted from the class “DispensedContainerOrApplicationAid”;

— Figures 26 and 27 are merged;

— new ASN.1 definition is added in Annex A.

A list of all parts in the ISO 21549 series can be found on the ISO website.

Introduction

With a more mobile population, greater healthcare delivery in the community and at patients' homes, together with a growing demand for improved quality of ambulatory care, portable information systems and stores have increasingly been developed and used. Such devices are used for tasks ranging from identification, through portable medical record files, and on to patient-transportable monitoring systems.

The functions of such devices are to carry and to transmit person-identifiable information between themselves and other systems; therefore, during their operational lifetime, they may share information with many technologically different systems which differ greatly in their functions and capabilities.

Healthcare administration increasingly relies upon similar automated identification systems. For instance, prescriptions may be automated and data exchange carried out at a number of sites using patient transportable computer readable devices. Healthcare insurers and providers are increasingly involved in cross-region care, where reimbursement may require automated data exchange between dissimilar healthcare systems.

The advent of remotely accessible databases and support systems has led to the development and use of "Healthcare Professional" identification devices that are also able to perform security functions and transmit digital signatures to remote systems via networks.

With the growing use of data cards for practical everyday healthcare delivery, the need has arisen for a standardized data format for interchange.

The person-related data carried by a data card can be categorized in three broad types: identification (of the device itself and the individual to whom the data it carries relates), administrative and clinical. It is important to realize that a given healthcare data card "de facto" has to contain device data and identification data and may, in addition, contain administrative, clinical, medication and linkage data.

Device data is defined to include

— identification of the device itself, and

— identification of the functions and functioning capabilities of the device.

Identification data may include unique identification of the device holder or of all other persons to whom the data carried by the device are related.

Administrative data may include the following:

— complementary person(s) related data;

— identification of the funding of health care, whether public or private, and their relationships, i.e. insurer(s), contract(s) and policy(ies) or types of benefits;

— other data (distinguishable from clinical data) that are necessary for the purpose of healthcare delivery.

Clinical data may include

— items that provide information about health and health events,

— their appraisal and labelling by a healthcare provider (HCP), and

— related actions planned requested or performed.

Medication data may include

— a record of medications purchased by the patient for self administration,

— copies of prescriptions including the authority to dispense records of dispensed medications,

— records of medications dispensed by a pharmacist to the patient, and

— pointers to other systems that contain information that hold medication data, either medication history or prescribed medicines, (or both) and in the case of prescribed medicines, the authority to dispense.

Because a data card essentially provides specific answers to definite queries while having at the same time a need to optimize the use of memory by avoiding redundancies, “high level” Object Modelling Technique (OMT) has been applied with respect to the definition of healthcare data card data structures.

Patient Data Cards may offer facilities to

— communicate prescription information from one healthcare professional to another healthcare professional such as to a healthcare agent or healthcare organization, and

— provide indexes and/or authority to access prescription information held other than on the patient data card.

Health informatics — Patient healthcard data —

Part 7: Medication data

1 Scope

This document applies to situations in which such data is recorded on or transported by patient healthcards compliant with the physical dimensions of ID-1 cards defined by ISO/IEC 7810.

This document specifies the basic structure of the data contained within the medication data object, but does not specify or mandate particular data sets for storage on devices.

The purpose of this document is for cards to provide information to other health professionals and to the patient or its non-professional caregiver.

It can also be used to carry a new prescription from the prescriber to the dispenser/pharmacy in the design of its sets.

Medication data include the following four components:

— **medication notes**: additional information related to medication and the safe use of medicines by the patient such as medication history, sensitivities and allergies;

— **medication prescriptions**: to carry a new prescription from the prescriber to the dispenser/pharmacy;

— **medication dispensed**: the records of medications dispensed for the patient;

— **medication references**: pointers to other systems that contain information that makes up medication prescription and the authority to dispense.

The following topics are beyond the scope of this document:

— physical or logical solutions for the practical functioning of particular types of data cards;

— how the message is processed further “downstream” of the interface between two systems;

— the form which the data takes for use outside the data card, or the way in which such data is visibly represented on the data card or elsewhere.

NOTE Not only does the definition of “medicinal products” differ from country to country, but also the same name can relate to entirely different products in some countries. Therefore, it is important to consider the safety of the patient when the card is used across borders.

This document describes and defines the Medication data objects used within or referenced by patient-held health data cards using UML, plain text and Abstract Syntax Notation (ASN.1).

This document does not describe nor define the common objects defined within ISO 21549-2, even though they are referenced and utilized within this document.

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 21549-2, *Health informatics — Patient healthcard data — Part 2: Common objects*

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:

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

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

NOTE There are many different terms used to describe the basic concepts in healthcare for different purposes available from ISO, CEN, HL7 and various national organizations. The following definitions are not meant to be universal in ISO work in health informatics, only to facilitate the understanding of this document.

3.1
attribute
characteristic of an object or entity

3.2
batch
amount of material which is uniform in character and quantity as shown by compliance with production and quality assurance test requirements and produced during a defined validated process of manufacture

[SOURCE: EN 375:1992 E, EN 376:1992 E]

3.3
coding scheme
collection of rules that maps the elements of one set onto the elements of a second set

[SOURCE: ISO 21089:2004, 3.25]

3.4
data object
information object
instance of some *information object class* (3.11), being composed of a set of fields which conform to the field specifications of the class

[SOURCE: ISO/IEC 8824-2:2015, 3.4.9]

3.5
dispenser
healthcare professional (3.9) which is a representation of an individual, professionally responsible for filling/dispensing the *prescription* (3.22)

Note 1 to entry: This is usually the pharmacist, but may be other individuals according to local jurisdiction.

3.6
healthcare
activities, services or supplies related to the health of an individual

Note 1 to entry: This includes more than performing procedures for subjects of care. It includes, for example, the management of information about patients, health status and relations within healthcare framework.

Note 2 to entry: In this document, the term “care” is to be understood as a synonym for “healthcare”.

[SOURCE: ISO 13940:2015, 3.1.1, modified]

3.7
healthcare data card
machine-readable card conformant to ISO/IEC 7810 intended for use within the healthcare domain

3.8
healthcare party
organization (3.16) or person involved in the direct or indirect provision of healthcare services to an individual or to a population

[SOURCE: ENV 13607]

3.9
healthcare professional
person entrusted with the direct or indirect provision of defined healthcare services to a *subject of care* (3.25) or a population of subjects of care

EXAMPLE Qualified medical practitioner, pharmacist, nurse, social worker, radiographer, medical secretary or clerk.

[SOURCE: ENV 1613]

3.10
immediate container
container that is in direct contact with the *pharmaceutical product* (3.19)

[SOURCE: ENV 12610]

3.11
information object class
set of fields, forming a template for the definition of a potentially unbounded collection of information objects, the instances of the class

[SOURCE: ISO/IEC 8824-2:2015, 3.4.10]

3.12
ingredient
substance (3.26) included as a component in a product

Note 1 to entry: In this context, product refers to *pharmaceutical product* (3.19).

[SOURCE: ENV 13607]

3.13
magistral medicinal product
extemporaneous medicinal product
medicinal product (3.14) manufactured in a pharmacy or pharmacy department, which is based on a recipe and intended to be used for one and only one *subject of care* (3.25)

Note 1 to entry: A magistral/extemporaneous medicinal product is also a *pharmaceutical product* (3.19).

[SOURCE: ENV 12610, ENV 13607, modified]

3.14
medicinal product
substance (3.26) or combination of substances, which may be administered to human beings or animals for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct or modify physiological functions

Note 1 to entry: A medicinal product may contain one or more manufactured items and one or more *pharmaceutical products* (3.19).

Note 2 to entry: In certain jurisdictions, a medicinal product may also be defined as any substance or combination of substances which may be used to make a medical diagnosis.

[SOURCE: ENV 13607, ENV 12610]

3.15
medicinal product package
delivery unit of a *medicinal product* (3.14) in an *outer container* (3.17)

[SOURCE: ENV 12610]

3.16
organization
unique framework of authority within which a person or persons act, or are designated to act towards some purpose

Note 1 to entry: Groupings or subdivisions of an organization may also be considered as organizations where there is a need to identify them for information interchange.

3.17
outer container
container that serves as an external layer of a package

[SOURCE: ENV 12610]

3.18
payment guarantor
organization (3.16) responsible for the total or partial reimbursement or payment of the price of the *medicinal product* (3.14)

[SOURCE: ENV 13607]

3.19
pharmaceutical product
qualitative and quantitative composition of a *medicinal product* (3.14) in the dose form approved for administration in line with the regulated product information

Note 1 to entry: A medicinal product may contain one or more pharmaceutical products.

Note 2 to entry: In many instances, the pharmaceutical product is equal to the manufactured item. However, there are instances where the manufactured item must undergo a transformation before being administered to the patient (as the pharmaceutical product) and the two are not equal.

[SOURCE: ISO 11616:2012, 3.1.20, modified]

3.20
prescriber
healthcare professional (3.9) authorized to issue *prescriptions* (3.22)

[SOURCE: ENV 13607]

3.21
prescribing
process of creating a *prescription* (3.22)

[SOURCE: ENV 13607]

3.22
prescription
direction created by an authorized *healthcare professional* (3.9), to instruct a dispensing agent regarding the preparation and use of a *medicinal product* (3.14) or medicinal appliance to be taken or used by a *subject of care* (3.25)

[SOURCE: ENV 13607]

3.23
prescription item
specification created by an authorized *healthcare professional* (3.9), to instruct a dispensing agent regarding the preparation and use of single *medicinal product* (3.14)/medicinal appliance or to inform other parties following dispensing regarding the preparation and use of a single dispensed medicinal product/medicinal appliance

Note 1 to entry: A prescription item may contain administrative details needed for dispensing or derived from dispensing, but does not contain information about the *prescriber* (3.20) or the *subject of care* (3.25) for whom the prescription item is prescribed or to whom it has been dispensed.

[SOURCE: ENV 13607]

3.24
prescription set
collection of one or more *prescription item(s)* (3.23) prescribed and/or dispensed as a unit

[SOURCE: ENV 13607]

3.25
subject of care
person or defined group of persons receiving or registered as eligible to receive healthcare services or having received healthcare services

[SOURCE: ENV 12443]

3.26
substance
matter of defined composition that has discrete existence, whose origin may be biological, mineral or chemical

Note 1 to entry: Substances can be either single substances mixture substances or one of a group of specified substances. Single substances shall be defined using a minimally sufficient set of data elements divided into five types: chemical, protein, nucleic acid, polymer and structurally diverse. Substances may be salts, solvates, free acids, free bases, mixtures of related compounds that are either isolated or synthesized together. Pharmacopoeial terminology and defining characteristics will be used when available and appropriate. Defining elements are dependent on the type of substance.

Note 2 to entry: Discrete existence refers to the ability of a substance to exist independently of any other substance. Substances can either be well-defined entities containing definite chemical structures, synthetic (i.e. isomeric mixtures) or naturally-occurring (i.e. conjugated oestrogens) mixtures of chemicals containing definite molecular structures or materials derived from plants, animals, microorganisms or inorganic matrices for which the chemical structure may be unknown or difficult to define. Substances may be salts, solvates, free acids, free bases, mixtures of related compounds that are either isolated or synthesised together.

[SOURCE: ISO 11238:2012, 2.1.58]

4 Abbreviated terms

ATC	Anatomical Therapeutic Chemical Classification System
DEA	Drug Enforcement Administration Registration Number
ENV	European Prestandard
NCDCP	National Council for Prescription Drug Programs
UML	Unified Modelling Language

5 Basic data object model for a healthcare data card

5.1 Patient healthcard data object structure

A set of basic data objects have been designed to facilitate the storage of clinical data in a flexible structure, allowing for future application specific enhancements. These tools should help the implementation of common accessory characteristics of stored data in a way that allows efficient use of memory, an important feature for many types of data cards.

The tools consist of a generic data structure based on an object-oriented model represented as an UML class diagram as shown in Figure 1.

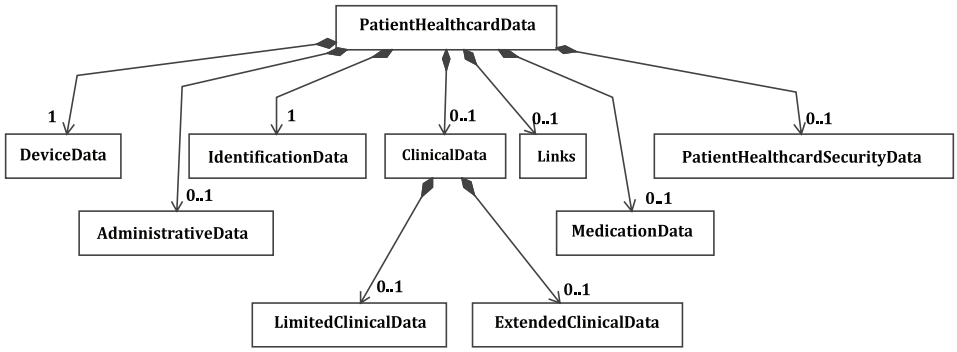

Figure 1 — Patient healthcard data — Overall structure

The content of this object-oriented structure is described both below and intrinsically will also require the use of data objects not defined within this document.

It is recognized that medication data is semantically a type of "clinical data". However, to enable more flexible implementation approaches, it is modelled as a direct child of the PatientHealthcardData object allowing a simpler and reduced model implementation where the full clinical data is not required.

NOTE It is possible to take the data objects and recombine them while preserving their context specific tags, and to define new objects, while still preserving interoperability.

In addition to the capability of building complex aggregate data objects from simpler building blocks, this document allows for associations between certain objects, so that information can be shared. This feature is mainly used to allow, for example, a set of accessory attributes to be used as services to several stored information objects.

5.2 Basic data objects for referencing

5.2.1 Overview

A series of generally useful data type definitions have been made that have no underlying meaning in themselves, but which are used to define other objects within this document. Operations may be performed with these objects in association with other information objects to add usability or business purpose. These objects have formal definitions within ISO 21549-2.

5.2.2 Coded data

Coded values are understood by reference to the coding system to which they apply. The general principle in this document is that it is not mandatory to use a particular coding system, unless specified within this document, when such codes act as parameters. One example is the use of ISO 3166 for country codes.

